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AN EVIDENCE-BASED CLASSIFICATION FRAMEWORK FOR HALLUX RIGIDUS

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Paul Beeson

DISCLAIMER

This thesis describes original work by Paul Beeson which was completed during the period of registration as a post-graduate/PhD student of the University of Northampton, except where reference is made to the work of others. No part of this work has been previously submitted for a higher degree at this or any other University.

ABSTRACT

Hallux rigidus (HR) is the second most common pathology affecting the first metatarsophalangeal joint and a primary cause of morbidity and disability. Classification of this condition helps to inform management. Over the years a number of formal HR classification systems have been devised but despite this collective experience there is no consensus on classification design, construction, application or parameters' validity. The aim of this research was to develop an evidence-based classification framework for HR and establish its validation and reproducibility. This was achieved through four studies.

An initial study of 110 patients was used to determine the clinical parameters of HR. In addition to other pertinent findings this showed a positive relationship between second toe length and first metatarsophalangeal joint pain ($P<0.001$). Correlations were found between first metatarsophalangeal joint pain and pes planus ($r=0.84$, $P=0.05$) and between reduced first metatarsophalangeal joint range of motion and hallux abductus interphalangeus ($r=0.92$, $P=0.05$).

A second study examined the radiological parameters of HR (in the same population). Amongst other relevant findings comparison of joint space narrowing with either hallux abductus interphalangeus ($P<0.005$) or osteophyte severity ($P<0.002$) was established.

Intra and inter-rater reliability studies were undertaken for all parameters. Overall, inter-rater reliability was poor. Only 28% of angular inter-rater measurements fell within a 5° range.

A fourth study was used to determine 'expert' opinion on HR classification using semi-structured interviews. The results revealed the need for consensus agreement among clinicians and patient involvement in creation and substantiation of classification content.

This research has provided a new understanding of HR classification and informed the development of a HR classification framework based on history, clinical and radiological domains. The established framework provides more than just a measure of severity and includes other dimensions such as contributory factors and functionality. Depending on its context, other applications include use as a diagnostic tool, establishing HR prevalence, monitoring progress, and surgical decision making. An algorithmic approach can enable the classification framework to be applied in different contexts proving clinical relevance and meaning to a range of professions.

This research also highlights that classification parameters should be validated, reliable, sensitive, quantifiable and few in numbers and that there is a requirement to provide a 'gold standard' against which future HR research can be compared.

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LIST OF ABBREVIATIONS

BMI – Body Mass Index
CI – Confidence Interval
DJC – Degerative Joint Changes
DJD – Degenerative Joint Disease
DP – Dorsal Plantar
EHL – Extensor Hallucis Longus
FDL – Flexor Digitorum Longus
FF - Forefoot
FH – Family History
FHB – Flexor Hallucis Brevis
FHL – Flexor Hallucis Longus
FHLim – Functional Hallux Limitus
FPI – Foot Posture Index
FHSQ – Foot Heath Status Questionnaire
HAI – Hallux Abductus Interphalangeus
HL – Hallux Limitus
HR – Hallux Rigidus
HV – Hallux Valgus
ICC – Intraclass Correlation Coefficients
IPJ – Interphalangeal Joint
ISD – Intersesamoidal distance
JSA – Joint Space Asymmetry
JSN – Joint Space Narrowing
MA – Metatarsus Adductus
MCJ – Metatarsal Cuneiform Joint
MOFQ – Manchester Oxford Foot Questionnaire
MPE – Metatarsus Primus Elevatus
MRI – Magnetic Resonance Imaging
MTPJ – Metatarsal Phalangeal Joint
NCJ – Navicular Cuneiform Joint
OA – Osteoarthritis
PACS – Picture Archiving Communication System
PCA – Principle Component Analysis
PVD – Peripheral Vascular Disease
RCSP – Relaxed Calcaneal Stance Position
ROM – Range of Motion
SIA – Sagittal Intermetatarsal Angle
SS – Subchondral Sclerosis
SD – Standard Deviation
TNJ – Talo-Navicular Joint
TP – Tibialis Posterior
VAS – Visual Analogue Scale

CHAPTER 1

INTRODUCTION

The term *hallux rigidus* (HR) describes a painful malady of the first metatarsophalangeal joint (MTPJ) characterized by stiffness, progressive loss of dorsiflexion and degenerative joint changes. Symptoms associated with this condition were initially reported by Davies-Colley (1887), although Cotterill (1887) is credited with proposing the term *hallux rigidus* and Nicoladoni (1881) its first clinical description.

No known study validates a clinical or diagnostic threshold separating the terms hallux limitus and rigidus. These arbitrary divisions are most likely to be part of a continuum. Contemporary definitions utilize hallux limitus and hallux rigidus interchangeably. For ease of discussion the later definition was chosen for the present research.

Hallux rigidus is a frequently seen foot condition. It is the most common osteoarthritis (OA) of the foot with a prevalence of 1:40 adults over 50 years of age (Hamilton et al, 1997; Coughlin, 1999). It is the second most common disorder of the first MTPJ after hallux valgus (Calvo et al, 2009) and a primary cause of morbidity and disability (Haddad, 2000). Great amounts of time and resources are spent in managing this condition by a variety of professional groups.

The abundance of research stimulated by HR reflects the importance of this condition. The conflicting notions on its aetiology and the variety of surgical procedures used for its management reflect the complexity and incomplete understanding of HR. Numerous studies have examined various facets of HR including, its estimated incidence (Gould et al, 1980; Coughlin, 1999), aetiology (Camasta, 1996) and management (Beeson, 2004). Prevalence of first MTPJ pain has also been evaluated (Garrow et al, 2004; Wilder et al, 2005). However, despite much being written on the subject of HR, a great deal of uncertainty remains. Some authors disagree on concepts such as HR age of onset (Mann et al, 1979; MacKay et al, 1997), presentation (Bonney & MacNab, 1952; Gold et al, 1981) gender predilection (Hattrup & Johnson, 1988; Hamilton et al, 1997) and clinical data associated with HR e.g. pes planus (Viegas et al, 1998; Shurnas, 2009). The only consensus generated is that HR is multifactorial and progressive (Chang, 1996; Camasta, 1996; Napolitano & Zmuda, 2001; Curran, 2003a; Coughlin & Shurnas, 2003a).

Since 1930 a number of HR classification systems have been devised but despite this collective experience there is no consensus on classification design, construction, application or parameters' validity. Criteria used to justify inclusion of chosen parameters have been based mainly on clinical experience rather than evaluative research (Beeson et al, 2008). Many of the devised classification systems lack standardisation of assessment criteria. The different methods and parameters used between studies make comparison difficult and have been directly implicated as impeding research.

To date there is no research which validates development of HR classification construction or which examines the measurement development of the parameters used. Application of the methodology principles of validity, reproducibility and responsiveness are lacking.

Given the prevalence of HR and the personal and economic costs of treatment, a validated classification would be of value and would aid future management and research (Beeson et al, 2008). The recognition that first MTPJ OA (HR) may not be a single disease, but a group of diseases, supports the development of an evidence-based multiple parameter classification (Wilder et al, 2005). Comprehensive evaluation of clinical and radiological parameters associated with HR is required. A need to examine their validity, reliability, clinical utility and application in a classification framework is indicated.

The aims of this research were to develop a classification framework for assessment and grading of HR based upon clinical and radiological findings, and secondly to establish validation and reliability of the devised classification framework.
This research seeks to address the following key objectives:

1) To determine face validity for HR by undertaking a cross-sectional clinical study (Study 1).

2) To determine face validity for HR by undertaking a cross-sectional radiological study (Study 2).

3) To determine intra- and inter-rater reliability of HR parameters by undertaking reliability studies (Study 3).

4) To provide a further form of validation using expert opinion by undertaking semi-structured interviews (Study 4).

In this research a mixed methods model is applied in a sequential strategy; starting with a quantitative approach, followed by a qualitative approach to supplement and elaborate on findings (Appendix 1).

In order to achieve the research objectives, chapter two begins with a review of the literature in relation to clinical and radiological parameters of HR and existing classifications systems used for this condition.

Based on the findings of the literature review, clinical (Study 1) and radiological (Study 2) studies were undertaken respectively to examine the HR parameters and determine which would be of use for inclusion in a classification framework. The methods used for each study, their findings and interpretation are discussed in their respective chapters and compared with results obtained for similar studies reported in the literature.

Before such measurement techniques can be considered reliable their reproducibility is investigated and discussed in chapter five (Study 3).

The choice and selection of statistical tests used for analysis of data and results obtained for studies 1, 2 and 3 is presented and discussed in their respective chapters (chapters three to five).

The rationale for the semi-structured interviews, its methodology, results, analysis and interpretation are discussed in Chapter six (Study 4). Expert opinion is used to evaluate face validity (clinical credibility) and relevance of the classification framework content. It is difficult, perhaps impossible, to prove formally that the parameters chosen represent all relevant HR parameters. Face validity therefore examines whether the classification appears to be measuring what it intended to measure, whereas content validity examines the extent to which the domain of interest is comprehensively sampled (Suk et al, 2005).

The final chapter (Chapter seven) draws the findings of the studies together, and applies these to the clinical context. The clinical implications of the research are identified and discussed. In addition, recommendations and direction for further study are presented which build upon the work conducted in this research.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1: CLINICAL PARAMETERS

2.1.1: Impact of patient history on HR

A number of historical factors have been implicated in the development of HR. The research findings associated with these factors have been disputed and there is conflicting demographic information.

2.1.1.1: Age

Age distribution has been shown to vary widely between studies. Only a handful of studies reported on HR in childhood or adolescence (Table 2.1).

Author	No. of cases	Age range (yrs)	Mean age (yrs)
Collier (1894)	9	11-30	15
Jack (1940)	15	11-44	18.7
Bingold & Collins (1952)	33	18 cases <25yrs 15 cases >25yrs	no mean
Kessel & Bonney (1958)	9	9-18	12.4
Goodfellow (1966)	3	13-18	15
McMaster (1978)	7	12-33	21

Table 2.1: Age range of HR in early studies (1894-1978)

Some authors (Nilsonne, 1930; Bingold & Collins, 1950) categorize HR as either primary (adolescent) or secondary (adult). Pathological specimens from both age groups with HR were consistent with degenerative arthritis (Bingold & Collins, 1950). It may be hypothesized that there is no distinction between the two age groups but that one is merely a continuation of the other. One study considered that it was unnecessary to split them into two groups given the small number of adolescent patients (Coughlin & Shurnas, 2003a). Others stated that the greater mean age in their patients would seem to support the notion that HR is a manifestation of OA; therefore its incidence might increase with age (Zgonis et al, 2005). Recent studies consistently present higher proportions of older patients with HR (Table 2.2). It is concluded that age is a potential confounding factor.

Study	**No. of patients**	**Age range (yrs)**	**Mean age**
Mann et al (1979)	20	35-77	56.8
Drago et al (1984)	42	17-80	45
Geldwert et al (1992)	47	26-69	52
Mackay et al (1997)	39	18-79	56
Hamilton et al (1997)	34	None given	56.2
Thomas & Smith (1999)	19	20-69	46
Kurtz et al (1999)	33	35-75	50.6
Easley et al (1999)	57	36-70	51
Feltham et al (2001)	67	23-80	54
Bryant et al (2001)	30	28-67	52.8
Coughlin & Shurnas (2003a)	114 5% < 20yrs	13-70	43

Table 2.2: Age range of HR in recent studies (1979-2003)

2.1.1.2: Gender predilection

A higher incidence of HR in male adolescents (7/9 patients) was first reported by Collier (1894). Studies by Gould (1981) and Hattrup & Johnson (1988) both found a male predilection to HR (Table 2.3).

Study	**Female** No. (%)	**Male** No. (%)
Gould (1981)	15 (36)	27 (64)
Hattrup & Johnson (1988)	19 (35.8)	34 (64.2)

Table 2.3: Higher number of male to female patients

Gould (1981) reported that 64% of HR patients were males. Interpretation of these findings should be treated with caution in view of the small sample size (42 patients). In an earlier epidemiological study by Gould et al (1980) gender predilection was found to depend upon age (Table 2.4). Caution is advised on interpretation of these results as they were based on 15,000 out of 45,000 returned questionnaires sent to shoe shops, where briefed shoe fitters asked and marked questions. No clinical examination was undertaken. The findings were then projected into the total United States population (186 million) at the time. Also the ratio of ethnicity (Caucasians to Blacks) between age groups was different.

Age Range (years)	**Male to Female ratio**
Under 14	1:1
15-30	1.4:1
31-60	8:1
60+	2:1

Table 2.4: Age range and male / female ratio (Gould et al, 1980)

In complete contrast, virtually all recent HR studies (mainly surgical) show a higher female to male ratio. A sample of studies illustrates this (Table 2.5).

Study	**Female** No. (%)	**Male** No. (%)
Hardy & Clapham (1951)	11 (58)	8 (42)
Bonney & MacNab (1952)	30 (68)	14 (32)
McMaster (1978)	5 (71)	2 (29)
Mann et al (1979)	13 (65)	7 (35)
Drago et al (1984)	24 (57)	18 (43)
Hamilton et al (1997)	26 (87)	4 (13)
Kurtz et al (1999)	20 (61)	13 (39)
Thomas & Smith (1999)	10 (59)	7 (41)
Muliër et al (1999)	12 (55)	10 (45)
Coughlin & Shurnas (2003a)	69 (63)	41 (37)

Table: 2.5: Female/ male HR patients in recent studies

A self-selected review of 18 post-surgery HR studies by Coughlin & Shurnas (2003a) found that 62% of females were affected by HR, a finding similar to their own results (63%) and concluded there was an association between HR and female gender. They found females were more commonly affected in all age groups. It has been concluded therefore that gender is a potential confounding factor.

2.1.1.3: Bilateral versus unilateral HR

Despite the limitations of demographic analysis in studies, the relative incidence of bilateral or unilateral joint involvement has been reported. Unilateral involvement is considered the most common presentation with reports indicating a range of 37-95% (Table 2.6). Patient numbers and mean age were relatively low which may have influenced findings. Although the study by Grady et al (2002) had high patient numbers of which 95% had unilateral HR, a lack of methodological explanation and insufficiently explicit exclusion criteria may have affected their findings.

Author/s	No. patients	Mean age	% unilateral
Nilsonne (1930)	30	None given	37
Jack (1940)	15	19	53
Bonney & MacNab (1952)	44	None given	70
McMaster (1978)	7	21	71
Kessel & Bonney (1958)	9	12	89
Drago et al (1984)	42	45	69
Citron & Neil (1987)	8	33	75
Mann et al (1979)	20	56	70
Saxena (1995)	11	46	91
Horton et al (1999)	81	52	76
Muliër et al (1999)	20	31	90
Thomas & Smith (1999)	19	46	63
Grady et al (2002)	772	46	95
Roukis et al (2003)	12	52	75

Table 2.6: Reported unilateral involvement in HR

Other studies reported bilateral HR or bilateral presentation with unilateral symptoms (Gould, 1981; Shereff & Baumhauer, 1998). One study found mainly bilateral HR and unilateral HR related to trauma (Coughlin & Shurnas, 2003a). Caution is required in analyzing surgical studies because patients may have bilateral involvement, but only present with unilateral symptoms. Patient age is important to note because a higher percentage of patients will exhibit bilateral disease with time.

2.1.1.4: Footwear

Poor footwear has been implicated in the development of HR for many decades; a link was first proposed by Davis-Colley (1887). Footwear that is too short (Bingold & Collins, 1950; DuVries, 1959), too loosely fitting (Boyd et al, 1993) or that causes hyperextension of the great toe such as high heeled shoes or boots (Cracchiolo et al, 1998) have been proposed as a cause of HR. Other authors report that patients with HR are intolerant to footwear due to dorsal osteophytes rubbing the toe box or difficulty bending the joint to don footwear (Camasta, 1996; Coughlin, 1999). Unfortunately, the vast majority of "evidence" has been anecdotal and therefore of poor quality. The few studies that addressed the issue found that the association between footwear and HR was not statistically significant. One study examined 118 shod and 107 unshod Chinese subjects (Sim-Fook & Hodgson, 1958); only 17% of those wearing footwear and 10.3% not wearing footwear, were affected by HR. However, a marked gender bias was evident i.e. 84% of unshod were female and 67% of shod were male. Also the unshod subjects were chosen from a fishing population who lived on boats and used the hallux to hold fishing lines taught. This may have had some bearing on findings. Another study found that 16% of 114 patients considered their footwear to be a contributory cause of their HR (Coughlin & Shurnas, 2003a) but found no statistically significant correlation between footwear and HR to confirm this (r =0.08, p >0.1). The role of footwear appears to be an aggravating factor rather than a primary cause.

2.1.1.5: Family history

The link between family history and hallux valgus (HV) has been established (Piqué-Vidal et al, 2007) but to date no family studies have been undertaken to examine consanguineous blood relatives in HR.

2.1.2: Impact of clinical features on HR

2.1.2.1: Pes Planus

Pes planus (flat foot) as a cause of HR has been implicated by a number of authors (Cotterill, 1887; Cochrane, 1927; Nilsonne, 1930; Lloyd, 1935; Jack, 1940; Bingold & Collins, 1950; Giannestras, 1973; Cavolo et al, 1979; Feldman et al, 1983; Cohen & Kanat, 1984; Drago et al, 1984; Meyer et al, 1987; Saxena, 1995, Viegas, 1998). No demographic data were reported in any of these studies to substantiate this notion.

Assessment of foot posture by observing the weight-bearing arch of the foot has been used to assess pes planus (Jack, 1940) but no criteria used to quantify this. Jack considered an association between pes planus and HR but was unclear which comes first or whether the two develop *pari passu*. Foot posture using a Harris Beath mat to measure arch height or excess heel valgus has also been used (Coughlin & Shurnas, 2003a) but only 11% of 114 patients had pes planus. These results were similar to those of Harris & Beath (1948) who reported 15% of 3619 normal military recruits examined with the condition. The Harris Beath mat has not been tested for validity and reliability and it was considered that the results of Coughlin & Shurnas (2003a) which were based on previous studies should be treated with caution.

It is suggested that calcaneal eversion can theoretically limit first MTPJ motion (Scherer, 1991; Harradine & Bevan, 2000). Researchers have examined the effect of static rearfoot eversion (using 3º, 5º and 8º valgus wedges in a standard shoe) on first MTPJ range of motion (ROM). A reduced joint ROM with increasing calcaneal eversion was found (Harradine & Bevan, 2000). This study artificially replicated three magnitudes of pronation but findings may not be representative of the full continuum of foot pronation seen in the general population.

The relationship between rearfoot valgus and the first MTPJ has been examined and it was found that 23% of 1,592 patients developed first MTPJ OA with rearfoot valgus (Mahiquez et al, 2006). Patients with first MTPJ OA were also found to demonstrate higher medial forefoot pressures and more pronated foot postures (Halstead et al, 2005). In a retrospective analysis of 772 HR patients 5.53% had aetiologies of both trauma and excessive pronation while 21.7% had excess pronation alone (Grady et al, 2002).

Blockade of first MTPJ sagittal plane motion produces compensation within other planes. It is contended that compensatory subtalar and mid-tarsal joint pronation (frontal plane) with forefoot abduction (transverse plane) can ensue, producing flatfoot in some HR patients (Payne & Dananberg, 1997).

A study which examined the relationship between navicular drop (a component of foot pronation) with passive first MTPJ motion found a negative correlation (r = -0.474; p = 0.02); as navicular drop increases, the angle of hallux dorsiflexion decreases (Paton, 2006). These findings concur with several other studies (Jack, 1953; Roukis et al, 1996; Harradine & Bevan, 2000) as all agree that lowering of navicular height or, conversely, dorsiflexion of the first ray decreases passive first MTPJ ROM in stance. Perceived limitations of Paton's study included a small patient group, 4:1 ratio of women to men, reliability of navicular drop measurement being dependant on the examiner's ability to reproduce subtalar joint neutral as the zero measuring position and the end position of hallux dorsiflexion being subjectively determined.

Whilst the above studies provide interesting theories linking pes planus with HR, none use a validated tool to quantify foot posture. The six component Foot Posture Index (FPI) quantifies foot posture (degree of pronation or supination) in a relaxed stance position and require no manipulation of the foot or measurement with instrumentation. It is a valid, reliable and objective measure of foot function (Redmond et al, 2005). Internal reliability and construct validity (subjective versus objective correlation) using Cronbach's alpha reliability coefficient has been investigated, examining planar and segmental aspects of the 8-component FPI (Redmond et al, 2001). This was high (0.84) and all FPI components proved to be good or excellent predictors for total FPI score. Some have attempted to verify FPI validity and found that it was a useful tool to broadly classify foot postures, but not sensitive to small movements (Scharfbillig et al, 2004).

2.1.2.2: Functional hallux limitus

Functional hallux limitus (FHLim) is defined as reduced first MTPJ dorsiflexion on simulated loading of the foot compared to passive first MTPJ dorsiflexion non-weight bearing and has been proposed as a cause of HR (Dananberg, 1993a & 1993b; DiNapoli, 1993; Payne et al, 2002). The associated prevalence and incidence of FHLim has not been identified because FHLim is often an unrecognized entity due to lack of symptoms (Curran, 2003a).

The concept of FHLim has been questioned by some to be theoretical conjecture and a subjective diagnosis (Coughlin & Shurnas, 2003b; Clough, 2005). Others feel it has been conceived to explain abnormalities seen on in-shoe pressure readings and visual gait assessments (Harradine et al, 2003). It is hypothesized that FHLim may represent residual elevatus occasionally noted on dorsiflexion stress X-rays of patients with severe HR (Coughlin & Shurnas, 2003a) or it may be a consequence of flexor hallucis longus (FHL) tenosynovitis which limits its excursion and subsequently that of first MTPJ dorsiflexion on foot loading (Michelson & Dunn, 2005).

2.1.2.3: First ray hypermobility

First-ray hypermobility has been implicated as a cause of HR (Jack, 1940; Bingold & Collins, 1950; Drago et al, 1984; Camasta, 1994; Kurtz et al, 1999), although objective data was not presented in any of these reports. In contrast first ray rigidity was reported by Cosentino (1995) and Viegas (1998) but no objective data was presented in support of these findings. Recent studies have found no association between first ray hypermobility and HR (Coughlin & Shurnas, 2003a; Grebing & Coughlin, 2004). An external caliper (Klaue's device) validated by Jones et al (2005) was used to quantify first ray mobility. Using Klaue's criteria for hypermobility (Klaue et al 1994), only 1/127 feet were considered hypermobile (Coughlin & Shurnas, 2003a). Based on such clear cut findings first ray hypermobility in HR does not warrant further evaluation.

2.1.2.4: Soft tissues

Muscle imbalance and soft tissue contracture has been implicated in HR development by early researchers. Hallucal plantar flexion contracture (Nicoladoni, 1881), relative shortening of flexor hallucis brevis (FHB) (Schede, 1924) or shortening of flexor hallucis longus (FHL) have been proposed (Bartsch, 1927). Early studies were anecdotal, lacked clinical evidence, varied in quality and their measurement criteria proved inconsistent. Demographic data was limited, no control groups were used and no statistical data published.

Later studies have re-examined the role of soft tissue contracture and muscle imbalance in HR development (Gerbert, 1991; Fuller, 2000). One author concluded that a weak extensor hallucis longus, over-pull of tibialis anterior and contracture/ spasticity of FHL/ FHB was implicated (Gould, 1981). Increased tension within the plantar fascia may prevent distal movement of the sesamoids thus preventing hallux dorsiflexion (Durrant & Siepert, 1993). It has also been suggested that first ray elevatus may be due to peroneus longus insufficiency (Lichniak, 1997). Such beliefs challenge existing theories of mechanical and structural anomalies but were based on concepts and conjecture rather than the outcome of controlled clinical studies. It may well be that there is a reciprocal relationship between both mechanical and soft tissue theories.

An association between Achilles tendon contracture and HR has been suggested (Bingold & Collins, 1950). Isolated gastrocnemius tightness (equinus) has been reported in up to 24% of “normal” patients (defined as $<5^{\circ}$ ankle joint dorsiflexion with knee extended) but the condition is implicated in the pathogenesis of forefoot pathology (DiGiovanni et al, 2002). A randomly selected control group of 34 patients with no foot pathology and 34 patients with various forefoot/ mid-foot problems (unclear how many had HR) had similar patient demographics. Although a higher rate of equinus was evident in the patient group, nearly a quarter of the control group also had equinus (DiGiovanni et al, 2002). One study found no association between Achilles tendon tightness (defined as <0º dorsiflexion with knee extended and foot in neutral) and HR (Coughlin & Shurnas, 2003a). Only 3.5% of their patients had 5º or less of dorsiflexion but there was no control group with which to correlate the results. Recent research concludes that gastrocnemius contracture plays a vital biomechanical role in chronic foot problems (Grebing & Coughlin, 2004).

2.1.2.5: Lesser toes

It has been noted that medial deviation of the lesser toes in HR can result from compensation during gait (Coughlin, 1993; Roukis et al, 2002). Also a correlation between HR and a longer second toe has been found in ballet dancers (Ogilvie-Harris et al, 1995). One clinician examined 59 dancers (34 female & 25 male) comparing them to a randomly selected control group of 60 patients (30 female, 30 male). The authors defined any difference in length of <2mm as not significant recording it as normal. No radiographic evidence was used and the lack of this may have influenced the outcome of results. They reported that 40% male and 27% female ballet dancers had a long second toe compared to the hallux. In the control group (in which there was no HR), 60% of males and 43% of females had a longer second toe. The authors concluded that 44% of ballet dancers, with a long second toe, had bilateral HR but failed to elicit the related pathomechanics.

The interest of clinically assessing lesser toe position and second toe length may relate to metatarsal/ proximal phalanx length and may need to be combined with radiological assessment.

2.1.2.6: Hallucal interphalangeal joint (IPJ)

Hyperextension of the hallucal IPJ has been reported in HR (Camasta, 1996; Roukis et al, 2002). Three mechanisms are proposed for its development:

1) Altered loading (low-gear push-off theory) in which the hallux, lateral forefoot and toes take increased load due to reduced first MTPJ ROM. Foot pressure studies support this theory (Zammit et al, 2008).

2) An os trigonum or steida's process may interfere with FHL function. Increased pull of extensor hallucis longus (EHL) is enabled producing IPJ hyperextension (Roukis et al, 2002).
3) FHB spasm due to first MTPJ pain provokes proximal phalanx plantar flexion resulting in secondary distal phalanx dorsiflexion (Camasta, 1996).

Early presentation of this finding may suggest that IPJ hyperextension is another causal factor increasing susceptibility to HR (Lynn, 2004) rather than being secondary to reduced MTPJ dorsiflexion (Shurnas, 2009). Further investigation of this feature may be of value.

2.1.2.7: First MTP joint size, pain and restricted motion

Some studies have documented increased joint bulk in HR related to joint changes (Giannestras, 1973; Mann et al, 1979) and soft tissue swelling (Mann et al, 1979; Mackay et al, 1997). These may provide indirect clinical measures of joint damage.

First MTPJ pain during dorsiflexion has been widely documented (Regnauld, 1986; Mann & Clanton, 1988; Shereff & Baumhauser, 1998; Easley et al, 1999; Coughlin & Shurnas, 2003b; Vanore et al, 2003; Michelson & Dunn, 2005). The timing of pain during joint motion and its association with joint changes may prove useful.

The minimum range of first MTPJ dorsiflexion necessary for normal gait ranges from 65-75° (Gerbert, 1991; Shereff & Baumhauer, 1998). If this minimum range is not achieved, toe jamming and articular damage may result. Numerous studies have documented restricted joint motion in HR (Nilsonne, 1930; Bingold & Collins, 1952; Smith et al, 2000; Coughlin & Shurnas, 2003a). Quantifying this feature may provide a useful measure of patient functionality.

2.1.2.8: Altered gait and lesser metatarsal overload

Pain and joint restriction in HR can modify gait. The results of some studies concur that gait in HR is everted (Kessell & Bonney, 1958; Mann et al, 1979; Mann & Clanton, 1988; Easley et al, 1999; Mulier et al, 1999) or supinated (Jack, 1940; Payne & Dananberg, 1997; Coughlin & Shurnas, 2003a). The sagittal plane facilitation theory (Dananberg, 1993b; Payne & Dananberg, 1997) supports this and describes five forms of compensation in HR (described further in Chapter 3, Section 3.4.3.3.10). A supinated gait can cause lesser metatarsal head overload and pain (Clough, 2005).

2.2: RADIOLOGICAL PARAMETERS

2.2.1: Impact of radiological features on first MTPJ

Initially radiological findings of HR are subtle while clinical findings may prompt a closer evaluation of the joint. The main radiological feature of HR is joint space narrowing which represents cartilage loss and predicts pain (Sorto et al, 1992; Hamilton et al, 1997; Hart & Spector, 1998). Subchondral sclerosis is a feature of subchondral bone repair following joint damage, and is described in some HR studies (Mann et al, 1979; Gould, 1981; Camasta, 1996). Subchondral cysts represent articular damage but have not been described in any HR studies. Osteophytes (Figures 2.1a & 2.1b) are bony growth originating at tendon insertions and capsular attachments. They represent attempted intra-capsular repair to changes in subchondral and marginal bone (McMaster, 1978; Camasta, 1996; Mulier et al, 1999).

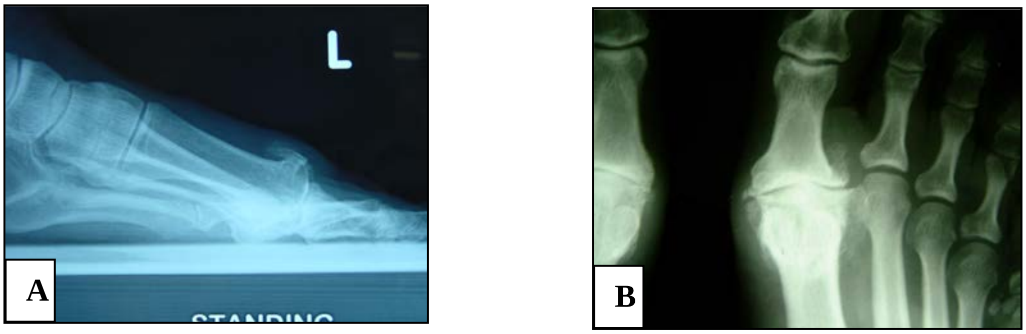


Figure 2.1a: Dorsal osteophyte **2.1b: Peripheral osteophytes**

Intra-capsular loose bodies (Figure 2.2) may influence joint function/ pain and have been described in some HR studies (Cosentino, 1995; Camasta, 1996; Schweitzer et al 1999).

Figure 2.2: Loose body

2.2.2: Specific radiological features of HR

Radiological assessment of HR focuses on first MTPJ changes (Regnauld, 1986; Camasta, 1996) and other radiological foot parameters.

2.2.2.1: Proximal hallucal phalanx

Proximal phalanx length may influence foot type. A long proximal phalanx may result in an Egyptian foot: hallux longer than the second toe (Kravitz et al, 1994; Vanore et al, 2003). A short proximal phalanx may result in a Morton's or Greek foot: hallux shorter than the second toe and; a square foot is where the hallux and second toe are equal length (Magee, 2006). Some authors propose that proximal hallucal phalanx length contribute to

HR development (Cochrane, 1927; Monberg, 1935; Camasta, 1996) but to-date measurement methods are inconsistent and no reputable statistical correlation has been established.

Some consider changes in proximal hallucal epiphyseal density, shape and fragmentation (Glissan, 1946; Brailsford, 1948) a precursor to OA. Others contend that these changes are seen in normal feet and that, cone-shaped epiphysis, are rare in the hallux (Hughes, 1948; Bingold & Collins, 1950). Lyritis (1983) examined 1,500 (8-17 yrs) children and found 3.5% with abnormal hallucal epiphysis. Upon clinical follow-up, 25% of these patients demonstrated HR.

2.2.2.2: Metatarsal head shape

It has been suggested that metatarsal head morphology could contribute to HR (Derner et al, 2005). The association of a flat (square) or chevron (square with ridge) shaped (Figure 2.3) metatarsal head with HR has been hypothesized (DuVries, 1959; Mann et al, 1979; Gerbert, 1991; Mann & Coughlin, 1986; Mann & Clanton, 1988; Barca, 1997; Kurtz et al, 1999), although the incidence in the general population is not known.

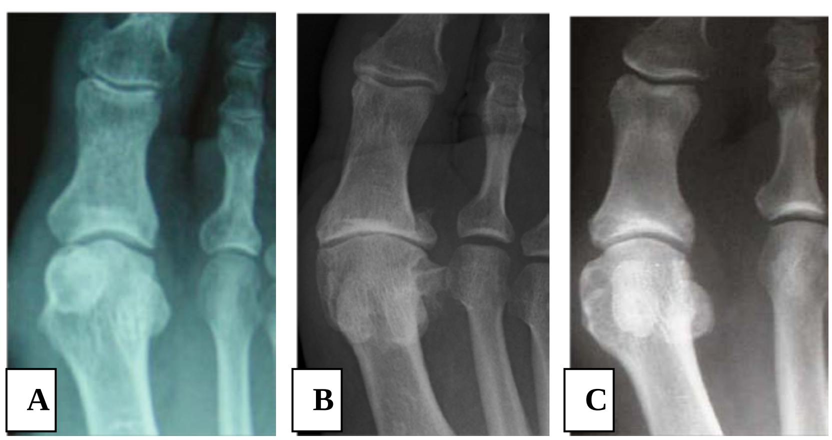


Figure 2.3: Metatarsal head shapes - a: Chevron, b: Flat, c: Oval

Hardy & Clapham (1951) blamed an apparent flattening of the first metatarsal head based on observations of 450 radiographs that correlated with clinical observation of HR. Such findings corroborate the results of

Harris & Joseph (1949) who observed an association between a flat first metacarpal head and limited first metacarpo-phalangeal joint motion. Joseph (1954) cast doubt on the observations made by Hardy & Clapham (1951) as further investigation identified an associated flattening from side to side and not from the plantar to dorsal aspect. It was further commented by Joseph (1954) that no associated flattening was observed on the lateral radiograph. It is perplexing why side-to-side joint flattening (dorsal/ plantar view) with no flattening on the lateral view could be associated with reduced sagittal plane motion.

A study using magnetic resonance imaging (MRI) observed no difference in metatarsal head shape between patients with HR and HV (Schweitzer et al, 1999) but only 24 patients were included (4 with HR, 11 with HV and 9 with both HR and HV). A large cohort study (100 X-rays) found associations between an oval metatarsal head shape (Figure 2.3c) and HV (Ferrari & Malone-Lee, 2002).

Although an association between the development of HR and a flat or chevron shaped metatarsal head has been alluded to (Mancuso et al, 2003) few studies have substantiated this. Most published data is from surgical studies, where it is only mentioned in passing, with a consequent lack of supporting statistical information. A four-year retrospective study by Brahm (1988) investigated first metatarsal head shape. Patient demographics were poorly balanced (25 male and 3 female) and by the authors' own admission, the study was derived from an aged population (female: 60-70 yrs, male: 35-78 yrs). This poor sample balance alone represents a methodological weakness. Only 19 weight-bearing X-rays were examined. No control group was used and all examinations carried out after patients had had joint implant surgery. Brahm found a 'positive correlation' citing a causal link (no figures given) between abnormal foot mechanics/ metatarsal head shape and HR and HV. The correlation between different shaped metatarsal heads and HR was not investigated. In view of the methodological shortcomings of this study, findings should be interpreted with caution.

It has been hypothesized that a flat shaped metatarsal head, was more prone in HR due to its increased stability (DuVries, 1959). Dorsal metatarsal head squaring/ enlargement were reported on pre-operative X-rays in a study of 28 cheilectomy patients (Mann & Clanton, 1988). Radiographic evidence of metatarsal head flattening and widening was reported in a post-cheilectomy study involving 40 females and 7 males (Geldwert et al, 1992). Unfortunately, this was not substantiated with any statistical data and it is therefore unknown how many of the study group was affected. One study found a correlation between a flat and chevron-shaped first metatarsal head and HR in 74% of patients: 50.9% flat, 22.7% chevron (Coughlin & Shurnas, 2003a). It is suggested that such joint shapes resist transverse plane deformity and predispose to HR (Ferrari & Malone-Lee, 2002).

A pathological process leading to a flat metatarsal head has been hypothesized (Goodfellow, 1966). This theory is supported by others who argue that the flat head produces relative restriction to first MTPJ transverse plane motion, creating increased sagittal plane stress and accelerating joint damage (Mann & Coughlin, 1981; Karasick & Wapner, 1991). With time and increasing severity of HR, flattening and widening of the joint surface has been reported (Drago et al, 1984; Hanft et al 1993; Saxena, 1995) and attributed to periarticular osteophytes (McMaster, 1978; Mann et al, 1979; Mann & Clanton 1988; Mackay et al, 1997).

Despite such reports, it is debatable whether a definite causal relationship between metatarsal head shape and HR exists. There is no doubt these observations are of radiological value, however such assessment could indicate joint changes of the condition and not an underlying predisposition to HR. Joint incongruence may be acquired through abnormal kinetics resulting in a chevron-like articular surface (due to long-term repetitive erosion) or a tight medial plantar fascial band rather than being congenital (Flavin et al, 2008). Metatarsal head shape would still be of value to a classification as it needs to reflect differences in HR severity and joint changes over time.

2.2.2.3: Associated hallux valgus (HV)

Nilsonne (1930) proposed that the development of HV precluded the development of HR. Some authors found no association between HV and HR (Giannestras, 1973; Geldwert et al, 1992) whereas others found an association (Shereff & Baumhauser, 1998; Lundeen & Rose, 2000). One study reported that the incidence of concurrent HV and HR was 12% of 114 patients (Coughlin & Shurnas, 2003a). They stated that the incidence varied from 15% to 100% in other studies but failed to support this with referenced work.

2.2.2.4: First metatarsal length

Three types of forefoot are based on first metatarsal length (Jahss, 1982):

- *Index minus* – Second metatarsal longer than first and third metatarsals.
- *Index plus* – First metatarsal longer than second metatarsal.
- *Index plus-minus* - First metatarsal equal in length to second metatarsal.

Different radiographic techniques have been studied to quantify metatarsal protrusion (Morton, 1930; Harris & Beath, 1947; Stokes et al, 1979). The method described by Hardy & Clapham (1951) is the most accepted by the scientific community and was recommended by the Research Committee of the American Orthopaedic Foot and Ankle Society (Smith et al, 1984). Since then Reese and Scofield (1987) and Valley and Reese (1991) have described three different systems to evaluate metatarsal protrusion of the second, third, and fourth metatarsals but these have not been proven for reliability.

<u>2.2.2.4.1: Short first metatarsal</u>

Some authors have proposed that a short first metatarsal was associated with HR (Camasta, 1996; Chang, 1996; Kurtz et al, 1999; Zgonis et al, 2005). Jack (1940) reported a 15% incidence of short first metatarsal length in a study of 15 patients. Harris & Beath (1949) examined 7,167 feet of 3,619 Canadian army recruits and, reported an incidence of 21.3% with a first metatarsal < 2mm or more shorter than the second metatarsal. Mann et al (1979) who studied 20 patients (13 female, 7 male) found 30% had a short first metatarsal. Drago et al (1984) examined 32 patients (18 male, 24 female) and found 21.9% affected by a short first metatarsal. Rzonca et al (1984) examined 25 patients (31 feet), 20% demonstrated a short first metatarsal. These studies were weakened by small sample size (with the exception of Harris & Beath) and the absence of control groups, resulting in a lack of good clinical evidence. Additionally there were no common measurement criteria between them. One study using 44 patients (47 feet), found that 17% had a short first metatarsal (Roukis, 2002) defining a 2mm difference between the first and second metatarsals as pathological. A recent study (Coughlin & Shurnas, 2003b) assessed 127 feet preoperatively reporting 32% of first metatarsals as shorter by ≥1mm (compared to second metatarsal) but failed to conclude on its relevance. The percentage of "normal" patients with a short first metatarsal is unknown.

2.2.2.4.2: Long first metatarsal

An aetiological link between a long first metatarsal (Figure 2.4) and the incidence of HR has been suggested (Nilsonne, 1930; Bonney & MacNab, 1952; Kessel & Bonney, 1958). Nilsonne (1930) developed a new standard referred to as the 'metatarsal index'. It was observed that an index-plus first metatarsal predisposed to excessive first MTPJ stresses (Mancuso et al 2003). Other authors have cited a similar association (Bingold & Collins, 1950; Root et al, 1977; Saxena, 1995; Lichniak, 1997).

Figure 2.4: Long first metatarsal

Although a long first metatarsal has been implicated in the development of HR (Smith, 1952; Villadot, 1973; Durrant & Siepert, 1993; Chang, 1996; Ronconi et al, 2000), only a few studies have reported data on the comparative length of the first and second metatarsals (Jack, 1940; Bonney & MacNab, 1952; Drago et al, 1984; Schweitzer et al, 1999; Bryant et al, 2000; Pinney et al, 2002; Roukis et al, 2002). Calvo et al (2009) conducted a retrospective study comparing 132 cases of HR with a control group. They measured first metatarsal length on lateral weight bearing X-rays using a method described by Perry et al (1992) and found a longer first metatarsal in the HR group. They stated that this was a relative length when in fact an absolute length was measured; also reliability of this method was not proven.

Mann et al (1979) examined 20 patients (13 female, 7 male) and found no incidence of metatarsal protrusion. In 70% of patients the first and second metatarsals were equal length; the remaining 30% had a short first metatarsal. Drago et al (1984) examined 42 patients (18 male, 24 female) and found 12% had a long first metatarsal, 17% a short metatarsal and the remaining were of normal length. Rzonca et al (1984) examined 25 patients and 12% had a longer first metatarsal. In these studies patient cohorts were small, no control groups were used and measurement criteria not stated.

Vilaseca & Ribes (1980) located a true distal epiphysis of the first metatarsal head after reviewing 420 children's foot X-rays. They concluded that growth proceeding from two epiphyseal centres and, prolonged presence of the distal epiphysis was responsible for a long first metatarsal.

Another study reviewed a series of 49 pairs of cadaveric metatarsals and their respective proximal phalanges. The grade of cartilage degeneration of the proximal phalanx was shown to have a significant relationship to the length of the first metatarsal ($p<0.005$) rather than the cartilage degeneration of the metatarsal head (Unger et al, 2000).

Bryant et al (2000) undertook a radiographic comparison of normal, HV and HR feet in 90 patients (30 controls, 30 HV and 30 HR). Age range was broadly similar in all groups, but the female to male ratio was unequal (control: 12 male/18 female; HV: 3 male/27 female; HR: 9 male/21 female). Different clinicians were used to collect data. No correlation between first metatarsal length and HR was found. A retrospective study examined 44 patients (47 feet) and found 17% had a longer (>+2mm) first metatarsal, compared to 66% with a 'normal' metatarsal length (Roukis et al, 2002). Another study which examined 127 feet reported that 28.3% had a long first metatarsal (>1mm) (Coughlin & Shurnas, 2003a). Due to the lack of a control group, the authors correlated their results with an older study (Harris and Beath, 1949) that had similar results to their own. They concluded that there was no significant difference in metatarsal length between sub-groups with HR and that there was no correlation between first metatarsal length and development of HR.

The general consensus is that there is a weak case for an association between a long first metatarsal and HR. It is noticeable, that apart from poor methodology (small samples, no control groups) there were variations in how first metatarsal length had been measured (which may influence results) making comparisons between studies difficult.

2.2.2.5: Metatarsus primus elevatus (MPE)

MPE is suspected if the superior first metatarsal cortex is positioned above the second metatarsal (Figure 2.5). With unopposed contracture of FHB the dorsal rim of the proximal phalanx is driven into the metatarsal head (Meyer et al, 1987).

Figure 2.5: Metatarsus primus elevatus

The concept of MPE as a cause of HR has been endorsed by a number of authors on the basis of little or no objective data (Collier, 1894; Lambrinudi, 1938; Jack, 1940; Cavolo et al, 1979; Drago et al, 1984; Cohn & Kanat, 1984; Citron & Neil, 1987; Pontell & Gudas, 1988; Geldwert et al, 1992; Durrant & Siepert, 1993; Dananberg, 1993a; Cosentino, 1995; Camasta, 1996; Roukis et al, 1996; Lundeen & Rose, 2000; Ronconi et al, 2000; Lombardi et al, 2001) whereas radiographic evidence to the contrary has also been reported (Mann et al, 1979; Meyer et al, 1987; Horton et al, 1999; Bryant et al, 2000).

In Bryant et al's (2000) study patients were not selected according to specified parameters such as measurable limited ROM or pain and radiographic technique was not specified. Furthermore all patients were X-rayed in a "standardised fashion" but X-ray tube angles and positioning were not precisely described. Thus any variance may greatly affect the radiographic angles, the very subject of this study.

Horton et al (1999) reported that first metatarsal elevation during midstance was a normal radiographic finding and was reported as $\leq$ 8 mm in patients with and without HR (Horton et al, 1999). Meyer et al (1987) reported similar findings and discouraged the common practice of evaluating radiographic elevatus as a criterion in predicting the possible development of HR. Horton et al (1999) could not find any direct linear relationship between the amount of first metatarsal elevation and grade of HR. They concluded that higher elevations were more likely to be seen in patients with advanced HR as a secondary phenomenon, not a primary cause. Bonney & Macnab (1952) noted MPE in two thirds of patients with HR, but questioned whether the elevatus was a consequence or effect. Other authors concur (Kessel & Bonney, 1958; Kilmartin, 2000). One author reported a mean preoperative elevatus of 5.5mm (well within normal limits) and a mean first metatarsal declination angle within normal limits both pre and post-operatively (Coughlin & Shurnas, 2003b). They observed an increasing first metatarsal elevatus in association with increasing HR severity proposing it to be analogous to metatarsus primus varus in HV; as the bunion deformity progresses so does the first/ second intermetatarsal angle, and similarly as HR progresses so does the first ray elevation. It is hypothesized that MPE is uncommon and largely secondary to a plantar flexed proximal phalanx.

Clearly MPE does have a role in the development of HR and its quantification is useful when classifying HR (whether or not it is perceived to be a cause or consequence). Several techniques have been described:

<u>First metatarsal declination angle</u>: Several authors concur that this measurement is useful for evaluating MPE (Youngswick, 1982; Camasta, 1996; Gentili et al, 1996; Bryant et al 2000; Bryant, 2001). Normal values are reported to be between 19º and 25º (Meyer et al, 1987; Horton et al, 1999). One author found no significant relationship between first metatarsal declination angle and HR (Coughlin & Shurnas, 2003a).

Sagittal intermetatarsal angle (SIA): Bryant et al (2001) and Roukis (2005) have used this angle to measure MPE. Roukis (2005) found a direct correlation (linear relationship) between the SIA and Seiberg index (Seiberg et al, 1994). Seiberg's technique (Figure 2.6) used two reference points whereas Horton's used one (Horton et al, 1999).

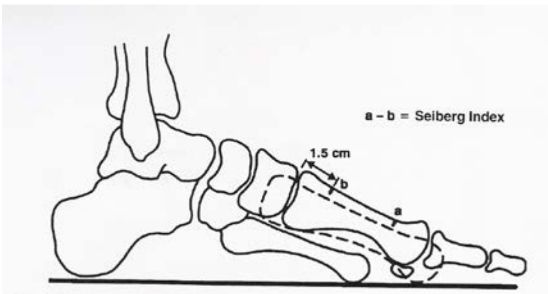


Figure 2.6: Seiberg index

Coughlin & Shurnas (2003a) found Horton's technique provided a reliable estimation of first metatarsal elevatus and reported a correlation between first metatarsal declination angle and MPE ($r = 0.6$, $p = 0.03$).

Talar declination angle: Seiberg et al (1994) and Bryant et al (2000) used this angle to measure MPE.

2.2.2.6: Hallux abductus interphalangeus (HAI)

HAI (Figures 2.7a & 2.7b) presents as a lateral (transverse plane) distal twist in the proximal phalanx. Some consider HAI to be a predictor for HR development (Duke et al, 1982; Bryant et al, 2000). A normal hallux interphalangeal angle (HIPA) was reported to be 5° (Bryant, 2000) whereas in subjects with HR a mean HIPA of 15° was reported (Sorto et al, 1992; Bryant, 2000). An association between HR and HAI exists and it is hypothesized that as the MTPJ becomes more resistant to transverse plane deformity, this predisposes it to an increased HAI (Coughlin & Shurnas, 2003a).

Figure 2.7a: Radiological HAI

Figure 2.7b: Clinical HAI

2.2.2.7: Distance between sesamoids and metatarsal head

A considerable variation in sesamoid position related to the first metatarsal head (dorsal plantar view) has been found but no relationship between posterior sesamoid displacement and forefoot pathology (Harris & Beath, 1949). The distal tip of the tibial sesamoid does not normally extend proximally to the anatomical neck or distally to the first MTPJ (Jahss, 1981). Proximal sesamoid displacement in HR may be due to FHB spasm (guarding response to pain) resulting in proximal phalanx plantarflexion or fibrosis secondary to reduced movement (Camasta, 1996). Various authors have measured the distance of the sesamoids from the first metatarsal head (Yoshioka et al, 1988; Hetherington et al, 1989; Prieskorn et al, 1993; Roukis et al, 2002; Munuera et al, 2008). Comparison of findings is difficult due to different methods used and variation in first metatarsal length.

2.2.2.8: Sesamoid-metatarsal joint

Sesamoid degeneration and immobility is a potential causative factor in HR (Collier, 1894). Although periodically mentioned, there is little relevant clinical data available and most published literature is descriptive with no substantiating evidence. McMaster (1978) reported that one of his seven study participants (a female) had a loose body under the metatarsal head, but it is unclear if this was related to the sesamoid apparatus. Sussman & Picora (1985) documented a case where the tibial sesamoid had fused to the metatarsal head. They believed that insufficient flexor plate and sesamoid mobility precluded first MTPJ dorsiflexion. Karasick & Wapner (1991) reported degenerative changes to the ‘hallux-sesamoid’ articulation but failed to mention patient demographics. Sesamoid-metatarsal joint degeneration can cause restricted first MTPJ ROM (Camasta, 1996). Sesamoid immobility can result from chronic FHB spasm (Jack, 1940) and lead to constant repetitive traction producing reactive bone proliferation and subsequent sesamoid hypertrophy (Hanft et al, 1993). Diffuse osteopenia of sesamoids may reflect sesamoid immobility. This is progressive in nature and secondary to disuse where the first MTPJ is “locked” and there is restricted sesamoid motion or the sesamoids fuse to the metatarsal head (Camasta, 1996). A direct correlation between the degree of first MTPJ OA, sesamoid hypertrophy, and sesamoid osteopenia therefore exists.

2.2.2.9: Metatarsus adductus

Metatarsus adductus (MA) is a newly reported aetiology in HR and therefore little has been published. It is speculated that forefoot adduction may possibly increase transverse plane pressure on the medial aspect of the first MTP joint increasing the risk of HR. Drago et al (1984) studied 42 cases of HR following surgery (24 female, 18 male) and based on radiographic evidence reported that 45% of patients had either; metatarsus primus adductus, MA or forefoot adductus. Coughlin & Shurnas (2003a) examined 114 patients (127 feet) reporting a mean MA angle of 13.2º (range 5º-25º). They found no statistically significant association between MA and HR although patients in their series had a far greater incidence than the general population. As their study lacked a control group it is unclear, to which ‘general population’ they correlated their results.

2.2.2.10: Transverse plane deviation of the second MTPJ

Medial column instability (flat foot) can promote second MTPJ synovitis with resultant lateral collateral ligament attenuation (Coughlin, 1993) and medial deviation of the second MTPJ. This radiological feature may provide a measure of severity of HR.

2.2.2.11: First metatarsal cuneiform joint (MCJ) morphology/ angle

Kravitz (1994) concluded that a horizontally orientated first MCJ was associated with HR while an increased angle is associated with hallux valgus (Hyer et al, 2004). A lack of standardized radiographic assessment has produced conflicting opinions on first MCJ morphology. Some authors concluded that the position of the first ray on the dorsal plantar view could falsely create the appearance of an increased obliquity angle (Brage et al, 1994; Sanicola et al, 2002).

Further evaluation of HR parameters using standardized techniques may help in classification development.

2.3: HR CLASSIFICATION SYSTEMS

Since 1930 (Nilsonne, 1930) a number of formal classification systems have been reported for HR which grade severity (Appendix 2). These have been varied in their design and application. The purpose of these classification systems is to aid decision-making on management and to allow meaningful comparisons to be made between pre- and post-surgery states and between different treatment strategies.

2.3.1: Classification methodology

A number of pertinent issues require consideration when constructing a classification; these include the psychometric properties of validity, reliability, responsiveness and clinical utility.

2.3.1.1: Validity

Validity relates to the concepts of content, construct and criterion validity (Suk et al, 2009).

Content validity is concerned with how comprehensively the system evaluates the problem it is assessing (Wassertheil-Smoller, 1995). Though it can be, content validity is rarely formally tested. Instead *face validity* or clinical credibility of an instrument is commonly inferred from a panel of experts who evaluate the relevance of the content (Suk et al, 2009).

Construct validity is a means of quantitatively assessing the validity of an individual component of the system (Fitzpatrick et al, 1998). For instance, for HR, patients with greater joint damage would be expected to have more pain and require greater amounts of analgesia. Construct validity would compare these two measures and assess whether there was a positive relationship (a convergent validity) or a negative relationship (a divergent validity).

Criterion validity examines whether a selected measure correlates with an already established “gold standard” measure (Fitzpatrick et al, 1998). The system should be able to accurately predict the patient’s disease status, preferably by correlating it to an already validated measure (concurrent validity). In addition, a measure should be able to predict future status, e.g. if a certain radiological joint appearance is strongly correlated with a patient’s inability to respond to conservative treatment it is said to have predictive validity.

2.3.1.2: Reliability

This is defined as the extent to which a measurement yields the same result on independently repeated trials under the same conditions (Suk et al, 2005). Any chosen measure should be reliable, which is an assessment of potential error within the system. The reliability of a system is assessed by both its reproducibility and internal consistency. The system should have both inter-rater and intra-rater reproducibility. Internal consistency measures how consistent the questions/ observations are in the scale at measuring the same concept (Cox et al, 1992).

2.3.1.3: Responsiveness

This measures the ability of a component to predict change in the status of the patient (Suk et al, 2005). For instance, does a designated radiological feature, e.g. degree of joint space narrowing correlate with the degree of pain exhibited by a patient?

2.3.1.4: Clinical utility

Clinical utility relates to whether the chosen classification system has been tested for its ability to be used in the clinical setting. The measurements used should be acceptable to patients to minimize their burden in terms of time and effort and be easy (feasible) for the clinician to administer and analyze (Suk et al, 2009).

This review has used the criteria of validity, reliability, responsiveness and clinical utility to assess each of the 18 identified (formal) HR classification systems. Not all studies devised a formal classification system (Appendix 3). Despite the limitations of early scientific enquiry (pre 1950), knowledge of HR would be lacking without them and they still remain fundamental to understanding this condition.

A critical appraisal tool applying concepts proposed by Buchbinder et al (1996) and Suk et al (2005) was formulated to help review these classification systems (Appendix 4).

2.3.2: HR classification systems

2.3.2.1: 'Grading' the progression of HR

Despite clinical and radiographic features of HR being well documented in the literature, there are no longitudinal studies reporting its progression (Zgonis et al, 2005). It is recognised that the degree to which HR develops depends on many factors (Kravitz et al, 1994). On the basis of empirical observations of the aetiology of HR (Appendix 5), authors have proposed several systems to stratify the severity of HR including two grades (Nilsonne, 1930; Kelikian, 1965; Giannestras, 1973), three grades (Mann et al, 1979; Ronza et al, 1984; Regnauld, 1986; Hattrup & Johnson, 1988; Karasick & Wapner, 1991; Geldwert et al, 1992; Hanft et al, 1993; Barca, 1997; Easley et al, 1999; Coughlin, 1999), four grades (Drago et al, 1984; Kravitz et al, 1994; Selner et al, 1997; Viegus, 1998; Lombardi et al, 2001 & 2002; Roukis et al, 2002; Giannini et al, 2004; Vanore et al, 2003) and five grades (Kellgren & Lawrence, 1957; Coughlin & Shurnas, 2003b). These have been based predominantly on radiological and/ or clinical features combined to grade the degree of first MTP joint OA (Ronconi et al, 2000). Only four systems were predominantly radiological (Kellgren & Lawrence, 1957; Regnauld, 1986; Karasick & Wapner, 1991; Hanft et al, 1993).

Several classification systems add modifications to an existing scheme (Pontell & Gudas, 1988; Geldwert et al, 1992; Keogh et al, 1992; Mackay et al, 1997; Muliër et al, 1999; Feltham et al, 2001) while others developed a hybrid radiological classification (Roukis et al, 2002) combining the work of three authors (Drago et al, 1984; Hanft et al, 1993; Kravitz et al, 1994). Combined classifications may have stemmed from concerns about the reliability or validity of each system. However, this may have further compounded these problems.

Some studies have based their grades on concepts such as functional hallux limitus or metatarsus primus elevatus (Drago et al, 1984; Hanft et al, 1993; Saxena, 1995; Lombardi et al, 2001) which are not underpinned by sufficient research. Coughlin & Shurnas (2003b) dismissed classification systems devised by both Drago et al (1984) and Hanft et al (1993) as “being based on hypothetical concepts or notions”. The inclusion of metatarsus primus elevatus (MPE) is considered a divisive factor in joint-specific grading systems, and is an example of *content irrelevance* in light of more recent research which emphasizes that it is a secondary rather than primary problem (Coughlin & Shurnas, 2003b).

Regnauld (1986) is the only system to have been translated into English from another language (French). Variation in its reproduction may be attributed to translation variations. Barca (1997) studied a surgical procedure involving tendon arthroplasty, and graded participants with a system referenced as Regnauld (1986). However, the system reproduced bears so little similarity to the English-language version that Coughlin & Shurnas (2003a) described this system as original.

The number of grades in a system was often not explained nor why a grade was subdivided into *two* and *two-B* (Hanft et al, 1993), *three-A* and *three-B* (Kravitz et al, 1994), *two-A* (Muliër, 1999), *two-B* (Feltham, 2001), instead of merely adding another numerical grade. Grading systems that subdivide one or more of the grades might suggest the authors' decided that the grades used in previous systems, were too broad to ensure comparability. However, alterations in the structure of a grading system by researchers using the system might reflect upon the validity of the respective system. Presumably these additions were made to improve construct, content and face validity.

Insufficient published information on a grading system may explain why inconsistencies in the use of that grading system occur. Confusion over the actual use of grading systems is best demonstrated by Gonzalez et al (2005) who reported the study by Drago et al (1984) who used a four grade classification but reported that the patients were not formally classified.

A lack of consistency in the construction of classification systems makes comparisons between them difficult. The content and type of grading used within studies where HR classification has been developed is variable and validity (content, construct and criterion) is not demonstrated (Appendix 2). Despite the continued publication of new systems, no one single classification system is universally accepted.

2.3.3: Critique of HR classification systems

The following discussion compares the methods used and evaluates the strengths and weaknesses of these classification systems.

2.3.3.1: Methods used

Various methods have been used and in some cases sample size was small thus limiting findings (Table 2.7). Most appear to be based on the author's opinion, experience or anecdotal sources (Nilsonne, 1930; Lapidus, 1940; Kelikian, 1965; Giannestras, 1973). Several author's reported deriving their classification criteria from a sample of subjects but gave little indication of how this was actually achieved (Drago et al, 1984; Rzonca et al, 1984). Later studies were based on the author's opinion but derived from earlier work (Cohen & Kanat, 1984; Regnauld, 1986; Karasick and Wapner, 1991, Giannini et al, 2000; Vanore, 2003).

Single case	**Case controlled**	**Quantitative / qualitative**	**Cohort study**	**Clinical control trial**
Lambrinudi **R**	Goodfellow **R** 3	Mann et al **R *Q*** 20	Hanft et al **R** 110	Bingold & Collins **P** 33
		Drago et al **R *Q*** 42 (53)	Hattrup & Johnson **P** 58	
		Coughlin & Shurnas **R *Q*** 110 (114)	Easley et al **P** 57	
		Roukis et al **P *Q*** 44 (47)	Kellgren & Lawrence **P** 85	
		Rzonza et al **R *Q*** & **q** 25 (31)	Bonney & MacNab **P** 44	
		Lombardi et al **R *Q*** 17 (19)	Jack **P** 15	
			Kessell & Bonney **P** 9	
			McMaster **P** 7	
			Schweitzer et al **P** 4	

Table 2.7: Methods used and sample size for HR classifications

R = Retrospective, **P** = Prospective, ***Q*** = Quantitative, ***q*** = Qualitative, numbers = patients, numbers in parentheses = feet.

Studies have mainly been used for testing interventions but none (to date) has been devised for measurement development alone.

The inclusion and exclusion criteria used by studies presented to date are not always clearly specified, and neither are the definitions of criteria used.

When designing a classification system the validity (face and construct) and reliability (inter-rater and intra-rater) of the components of that system are important to establish. In the HR classifications examined, no independent attempt to establish validity or reliability of their components could be found. There is sparse information provided within many papers containing 'new' grading systems, and the studies that subsequently use these systems. This could invalidate the results of investigations that have relied upon these classifications, and has therefore limited attempts at methodological evaluation of HR joint grading systems.

Comparability between studies using similar or different classification systems cannot be assumed. Several problems are apparent:

1) Studies may use selected parts of, or implement, a 'modified' system (McMaster, 1978; Pontell & Gudas, 1988; Geldwert et al, 1992; Keogh et al, 1992; Mackay et al, 1997; Muliër et al, 1999). The scope of modification varies between studies (Keogh et al, 1992; Selner et al, 1997; Coughlin & Shurnas, 2003b).
2) Number of grades in classification or their subdivision was not always explained (Hanft et al, 1993; Kravitz et al, 1994; Muliër et al, 1999; Feltham et al, 2001).
3) Inconsistent or inaccurate interpretation of (Barca, 1997) or combination of two or more systems (Roukis et al, 2002).
4) Systems not referenced (Geldwert et al, 1992) or where no standardized protocol is used (Lambrinudi, 1938; Jack, 1940; Lapidus, 1940; Bingold, & Collins, 1950; Bonney & MacNab, 1952; Kessell & Bonney, 1958; Goodfellow, 1966; McMaster, 1978; Mann et al, 1979; Cohen & Kanat, 1984; Schweitzer et al, 1999).
5) Special skills/ training by clinicians required (Vanore et al, 2003).

6) Systems feasibility i.e. not simple to understand and analyse, easy to administer, time taken to complete, reliance on radiological examination alone in some cases.
7) Comparing MRI with plain X-rays (Schweitzer et al, 1999).

These identified problems are comparable with upper limb studies of classification systems (Buchbinder et al, 1996).

2.3.3.2: Strengths and weaknesses of HR classification systems

Early studies introduced a number of concepts. Although these are not perceived to be strengths and no formal HR classification was derived, they were used by later studies in the development of classification systems (Appendix 3). The significance of the relationship between hallux flexus and MPE (Lambrinudi, 1938) and contracture of tibialis anterior and MPE (Lapidus, 1940) were introduced. Jack (1940) initiated the concept that inter-cuneiform diastasis was related to HR while Nilsonne (1930) introduced the concept of primary and secondary forms of HR with differentiation between ages of onset. Nilsonne also proposed a long first metatarsal or trauma/ degenerative joint disease as a cause of HR. The strengths and weaknesses of studies after 1940 are outlined in Table 2.8.

Studies	Strengths	Weaknesses
Kellgren & Lawrence (1957)	Large sample size. Ordinal radiological criteria of OA. Independent testing & evaluation.	Foot joints not included. IPJ's of hand applied to MTPJ of foot. No clinical criteria. Too much emphasis on osteophytes to classify OA (Menz et al, 2009). Lack of sensitivity to change.
Giannestras (1973)	Concept - radiological features not always comparable to intra-operative findings.	Brief information.
Drago et al (1984)	Fourth grade indicates total joint obliteration + loose bodies in joint/ capsule. First to present 'functional' grade HL.	Brief method. Compilation of classification not described. Applied system retrospectively to same sample used to develop it.
Hattrup & Johnson (1988)	Combined appraisal of JSN, osteophytes & subchondral degeneration.	Only radiological criteria used based on fundamental changes to first MTPJ.
Karasick & Wapner (1991)	Used MO view to demonstrate joint changes not seen on other views.	Insufficiently detailed radiological criteria used.
Hanft et al (1993)	Progressive accumulation of radiological features. Grades two and three sub-categorized to include subchondral cysts.	No clinical information.
Schweitzer et al (1999)	MRI findings correlate well with plain X-rays.	No direct comparison of X-ray findings with MRI. Small sample
Roukis et al (2002)	First grading system applied prospectively and to include second MC joint OA. 'Trumpeting' used to describe MTPJ shape.	Incorrect terminology describing osteophytes as exostosis. Biased selection of systems all with MPE.

Coughlin & Shurnas (2003b)	Timing of joint pain during ROM. Includes best elements of prior systems. Subjective & objective clinical data + X-ray data to determine grade. Grade zero for asymptomatic patients, early loss of ROM.	Grades applied retrospectively to sample at final follow-up.
McMaster (1978)	Mechanism of osteochondral defect.	Brief radiological/ clinical criteria. Only adolescence. Small sample.
Ronza et al (1984)	Table outlining HR clinical features.	Applied system retrospectively to same sample used to develop it.
Felson & Anderson (1995)	Recommended applying devised system to separate sample.	Not specific to HR.
Regnauld (1986)	Clear radiological parameters first MTPJ.	Fails to include many aspects of HR easily assessed clinically. Only fundamental radiological changes to first MTPJ.
Vanore et al (2003)	Succinct management algorithm.	MPE in stage one, but MPE is a secondary characteristic? Some criteria described only seen intra-operatively. Few clinical features.

Table 2.8: Strengths and weaknesses of HR classification systems

MO = Medial oblique, HL = hallux limitus, JSN = Joint space narrowing, MC = Metatarsocuneiform.

Early studies provide a brief and incomplete description of clinical signs and fail to provide formal grading using defined criteria (Nilsonne, 1930; Lambinudi; 1938; Jack, 1940). Their feasibility and fitness for purpose are questionable and their failure to be comprehensive is a primary weakness. Although Lapidus (1940) provided a crude clinical description of HR no radiological features were included.

Later studies continue basing their classifications solely on radiological criteria (Kellgren & Lawrence, 1957; Easley et al, 1999; Roukis et al, 2002; Giannini et al, 2004). The criteria used concentrate purely on the first MTPJ with limited use of other radiological parameters. Such systems are relatively insensitive to change (Guermazi et al, 2009).

Overlap of categories in some systems is confusing making comparison difficult. In the studies examined the criteria for determining inclusion of specific clinical parameters into each grade were not always clearly specified.

Despite Roukis et al (2002) referencing the two most frequently cited systems (Regnauld, 1986; Hattrup & Johnson, 1988) to support determination of grade, no further mention, or use, of these systems is reported.

Coughlin & Shurnas (2003a) disregarded systems including concepts they disputed which could be considered a source of bias. Their radiological criteria lacked detail and no patient history was included. Their HR classification was reported as reliable due to the "correct prediction of a successful outcome in 108/110 patients". This assertion must be queried because grades were applied retrospectively to the sample, at final follow-up. This means that a pre-operative grade, decided by a combined radiographic and clinical evaluation, was allocated to a patient up to 20 years after they had presented for surgery; it is unclear whether this was done by reviewing patient notes or asking the patient to recall symptoms.

In this instance the dual purpose of the study of grading and long-term results of operative treatment seem to require conflicting methodology. A prospective allocation of grading may have provided a better measure of reliability.

The selection of subjects in some studies (Bingold & Collins, 1950; Bonney & MacNab, 1952; Kessell & Bonney, 1958; Kelikian, 1965; Gianestras, 1973; Mann et al, 1979; Cohen & Kanat, 1984) in terms of inclusion/ exclusion criteria was not robust and introduced variables that may have influenced results. Variability in age range and gender profile between studies also influenced results.

The only way to ensure that subjective opinion has not bias selection of included criteria would be to use a standard methodological approach. This has not been reported in any classification system to date. Despite such variations in application and use, it is surprising how little comment about classification systems is made within the above studies.

The main problem encountered when attempting to evaluate classification systems was the lack of any longitudinal study into the progression of HR and the absence of any ‘gold standard’ against which systems could be compared.

2.3.4: Value of classification systems

Despite reports that severity of pre-operative HR may contribute to differences in post-operative outcome (Lau & Daniels, 2001), some evidence exists that HR (radiological) grade does not correlate with overall surgical results (Feltham, 2001). Mann & Clanton (1988) found little correlation between clinical rating of results and radiological appearance of affected joints. Therefore it is recognised that the use of classification systems is only one possible cause of conflicting results.

Different approaches to measurement, in this case different classification systems, have been directly implicated as impeding clinical research, with significant problems in generalizing one set of findings with another (Beeson, 2004; Becher et al, 2005).

2.3.5: Use of HR classification systems

Conflicting evidence between studies is complicated by inconsistent use of grading systems for example in analyzing the outcome of first MTPJ cheilectomy procedures (Table 2.9).

Author	**Grade/s**	**Classification type used**
Pontell & Gudas (1988)	1	Regnauld (1986)
Mackay et al (1997)	1 & 2	Regnauld (1986)
Lombardi et al (2001)	2	Modified Regnauld (1986)
Giannini et al (2004)	2	Modified Coughlin & Shurnas (2003b)
Becher et al (2005)	2	Hattrup & Johnson (1988)
Coughlin & Shurnas (2003a)	1, 2, +/- 3	Coughlin & Shurnas (2003a)

Table 2.9: Grades used for Cheilectomy

This problem has echoes in studies examining classifications used for other joints. Hirsch (1998) assessing hip OA found that differing classification systems do not always give the same result when applied to the same case. If classification system reliability has not been demonstrated, it is unclear whether even studies using the same system can be directly compared. None of the studies in this review have tested their systems for reliability (inter- and intra-rater) and validity. Aster et al (2004) stated that surgical algorithms are only reliable if measures of severity are reliable. Thus, assessing the reliability and validity of HR classification systems is important.

2.3.6: Reliability of classification systems

A widely accepted grading system may be used as an international standard to evaluate disease response or to evaluate sub-groups with the condition. However, there is no standard approach to how these systems are developed. Although methodological guidelines have been published for OA based on the Zoetemeer (Van Saase et al, 1989) and Clearwater studies (Wilder et al, 2005) these focused on a limited number of foot joints based on dorsal plantar X-rays only (Menz et al, 2009). Also there are concerns regarding their reliability and validity (Felson & Anderson, 1995; Aster et al, 2004; Suk et al, 2005). No studies testing reproducibility or internal consistency of HR classifications could be found in the literature.

2.3.7: Validity of classification systems

There are several types of validity (Section 2.3.1.1) but *content, criterion* and *construct* validity are regarded as most important for a disease assessment index (Suk et al, 2005). Studies validating HR classification systems for content and construct validity are lacking. There is no current 'gold standard' for diagnosing OA (Felson & Anderson, 1995) which means that caution must be displayed when evaluating criterion validity (Reijman et al, 2004). Many common examination findings are incorporated into classification criteria. The value of these is influenced by agreement of their presence and relevance, or their validity. No research has been published which establishes the validity of any of the HR classifications systems described. Furthermore, it has not been shown that the criteria for inclusion into the categories are valid and reliable. Clinical utility of HR classifications has not been tested in any studies.

2.3.8: Conclusion

Any system constructed for the classification of HR should consider using a combination of clinical and radiological variables. These should be validated for content and construct and its components tested for reliability. In the absence of any ‘gold standard’ the devised classification should be validated against ‘expert opinion’ to determine criterion validation.

CHAPTER 3

A study to evaluate clinical parameters of hallux rigidus

3.1: Introduction

Since Davies-Colley's description of HR in 1887 numerous authors have reported on the clinical parameters of HR (Appendices 5 & 6; Beeson et al 2009b). Symptoms and objective information from HR history and physical examination are well documented (Appendix 6). There is, however, conflicting information on demographics (Tables 2.1 & 2.2), proposed aetiologies (Appendix 5) and clinical evaluation, as well as widespread disagreement on certain clinical parameters (Appendix 7).

Patients complaints associated with HR include generalized foot pain, first MTPJ or metatarsosesamoid joint pain, first MTPJ stiffness, locking and spasm/ cramp (Beeson et al, 2009b). In some cases, significant synovitis may accompany these complaints. Variability of severity and location of first MTPJ pain may be dependent upon numerous factors including lifestyle and activity levels (Beeson et al, 2009b). In the early stages, discomfort predominates at the dorsal aspect of the joint and becomes more diffuse with the progression of the condition. Other complaints include metatarsalgia, inability to rise up on toes and altered gait (Appendix 6).

This study aimed to identify the demographics and clinical parameters associated with a group of patients with HR which may be valid and reasonable to include in a classification framework.

3.2: Methodology

An observational, cross-sectional study was undertaken involving a quantification of specific clinical parameters applied to a sample of patients with varying degrees of HR severity.

3.2.1: Patient sampling and recruitment

One hundred and ten HR patients (180 feet) aged between 18 to 70 years were used in this study. This age range was chosen because HR mainly presents in adults (Section 2.1.1.1) and those greater than 70 years have an increased chance of developing criteria of exclusion.

The sample size of 110 was chosen so that collection of multiple parameters was feasible. Initially systematic random sampling was considered. However, it was realized that an insufficient sample size would be obtained because a lower frequency of HR exists compared with hallux valgus and co-morbidity may exclude patients. Subsequently a convenience sample (nonrandom) was chosen.

All patients were accessed from two orthopaedic foot and ankle clinics and one podiatric surgery clinic.

3.2.2: Inclusion / exclusion criteria

HR patients with restricted first MTPJ dorsiflexion (<65°) with either pain, deformity or both were included in the study. Careful preliminary examination of patients' clinical notes was undertaken to remove those possessing criteria of exclusion (Table 3.1). Detailed exclusion criteria were reviewed at time of data collection. Justification for chosen exclusion criteria are outlined (Appendix 8). An upper age limit of 70 years was based on the fact that more pathology in the exclusion criteria may present above this age.

Hallux valgus-rigidus (intermetatarsal angle $\geq$12°)
Hallux flexus (checkrein deformity) or hallux extensus
Severe multiple forefoot deformities
Significant trauma sustained to foot/ leg in previous 12 months
Neuropathy
First-ray/ forefoot surgery (including digital/ excluding soft tissue)
Morton's neuroma affecting any inter-metatarsal space
Septic arthritis first MTP joint
Inflammatory arthritides
Neuromuscular disorders
Insulin-dependent Diabetes Mellitus
Hypermobility syndromes
Long-term steroid use
History of severe peripheral vascular disease
Metabolic bone disease

Table 3.1: Exclusion criteria

An invitation letter (Appendix 9) and study information sheet (Appendix 10) was sent to suitable patients giving them time for consideration (> 24 hours) prior to inclusion in the study.

3.2.3: Ethics

The use of human subjects necessitated the need for ethical consideration. Approval was granted by Leicestershire Northants and Rutland Ethics Committee (Appendix 11), Three Shires Hospital Medical Advisory Committee (Appendix 12) and Research and Development offices of the Northampton Acute & Primary Care Trusts (Appendix 13).

Patients gave informed consent and data collection sheets were coded for confidentiality. Copies of the signed consent form (Appendix 14) were given to patients and added to their hospital notes to confirm their involvement in the study and the patient's GP was informed of their involvement (Appendix 15). All data derived from patients' clinical notes was classed confidential and stored under lock and key at The University of Northampton (to be kept for four years following study publication).

3.2.4: Pilot study

A pilot study using five patients and two examiners was undertaken. The method was found to be practicable and data produced in line with study aims and objectives. Data collection sheet layout was unclear in parts and extra HR parameters were suggested. Therefore data collection sheets were further refined to improve utility (Appendix 16) and additional parameters added to ensure comprehensive analysis of HR:

- Aggravating factors for HR.
- Proximal phalanx pain.
- Timing of first MTPJ pain.
- Hallux abductus interphalangeus measurement.
- Gait compensations at propulsion.

3.2.5: Clinical evaluation

This was undertaken by one examiner to eliminate inter-examiner error and split into three parts: history, physical examination and completion of Foot Health Status Questionnaire.

3.2.5.1: History

Patients were asked about the history of their HR using standardized questions. These included: family history of great toe problems, age of onset (denoted by first MTPJ deformity or restriction/ pain), duration of pain or symptoms (including stiffness, locking, spasm/ cramp), variability of pain, factors aggravating symptoms, factors relieving symptoms, effect on activity levels and types of activities restricted, contribution of occupation to HR and footwear restrictions. Body mass index (BMI) was documented to determine its effect on the clinical parameters. Repetitive first MTP joint trauma can result in joint damage precipitating HR; the patient’s type and frequency of sporting activities was documented. The association of first MTPJ OA (HR) and OA at other sites was documented.

3.2.5.2: Physical examination

A standardized inspection of both feet (exclusion criteria permitting) non-weight bearing and weight-bearing was undertaken. The following clinical data was obtained: Foot in relaxed calcaneal stance position (RCSP) using the Foot Posture Index (Redmond et al, 2001 & 2005). The Foot Posture Index (FPI) quantified the degree of foot pronation or supination. Six foot parameters were evaluated and graded (Appendix 17 & 18). Final aggregate scores were applied to categorize type of foot posture. Location, magnitude and timing of first MTPJ pain were assessed. Passive first MTPJ ROM was measured using a modification of the method described by Greene & Heckman (1994). A standard plastic full-circle goniometer, calibrated to 2º increments was used (Figure 3.1).

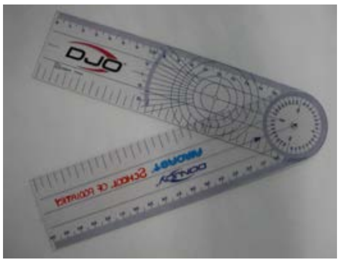


Figure 3.1: Goniometer

The proximal phalanx and first ray (medial mid-line axis) were used as reference points. The goniometer arms were placed in the zero-position prior to making each reading. Both passive dorsiflexion and plantarflexion were measured (Figures 3.2a & 3.2b) and total ROM calculated. This was compared with normal values and used to calculate reduction in joint motion (Green & Heckman, 1994).

Figure 3.2a: Dorsiflexion

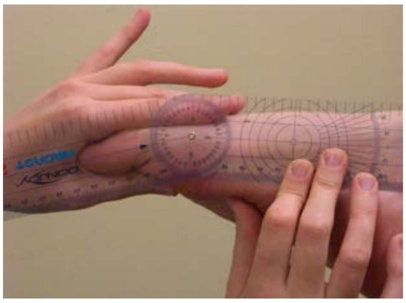


Figure 3.2b: Plantarflexion

Active first MTPJ dorsiflexion was measured in a static weight bearing position using a goniometer. Patients were asked to push forward onto the ball of the foot (avoiding supinating) to obtain maximum dorsiflexion. Patients' ability to rise up on toes without supinating was also observed.

Frontal plane hallucal position was determined by comparing the angle of the hallucal nail plate with the ground. Hallucal IPJ hyperextension was measured in a weight bearing position with a goniometer using the medial mid-axial line of the proximal and distal phalanges as reference points. Transverse plane hallucal IPJ deformity (hallux abductus interphalangeus) was measured with a goniometer using the dorsal mid-axial line of proximal and distal phalanges as reference points (Figure 3.3). Hallucal IPJ pain was also documented.

Figure 3.3: Hallux abductus interphalangeus

Hallucal flexor power was quantified by assessing the ability of the hallux to prevent a piece of paper being pulled away from under it in RCSP (Ashford et al, 2000; DeWin et al, 2002; Menz et al, 2006; Menz, 2008) .
The location of plantar callosities, lesser toe deformities and lesser MTPJ pain were also documented.

Comparison of hallux with second toe length was documented using the method described by Davidson et al (2007). With the foot in RCSP a carpenter's square was placed up against the end of the hallux and aligned with a line of graph paper to ensure the end of the toe was straight. The edge of a paint spatula tool was then stamped on a black ink stamp pad and slide down between the toe and edge of the square, making a black line.

This was repeated for the second toe. The distance between the two lines was recorded in millimeters.

Ankle joint dorsiflexion was measured with a goniometer using the technique described by Silfverskiold (1924) (knee extended and flexed position). The foot was held at right angle to the leg with the talonavicular joint reduced to eliminate transverse tarsal or subtalar motion (Beeson, 2002; Grebing & Coughlin, 2004). The fibula and plantar-lateral border of the foot were used as landmarks (Figure 3.4). A right angle was considered to be the neutral position. The goniometer arms were always placed in the 90° position prior to making each reading.

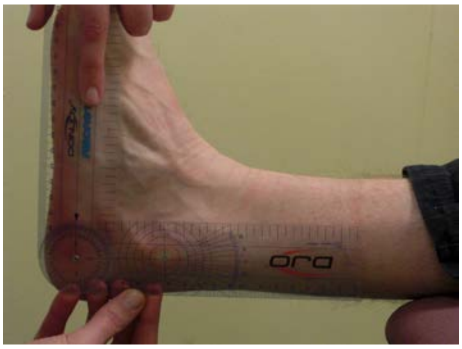


Figure 3.4: Measurement of ankle joint dorsiflexion

A brief subjective assessment of the patients' gait at propulsion was undertaken; the observed parameters are outlined in Table 3.2.

The measurement scales for the other clinical parameters are presented in Table 3.2.

Magnitude first MTPJ pain	None	Mild	Moderate	Severe			
Timing of pain during active ROM	None	Beginning	Midway	End	All of		
Location first MTPJ pain	None	Dorsal bump	Joint	Sesamoids	DC/ EHL	PP	Combination
Hallucal rotation	None	Valgus	Varus				
Hallucal IPJ hyperextension	Absent	Mild >5°	Moderate >10°	Severe >15°			
Hallux abductus interphalangeus	Absent	Mild >5°	Moderate >10°	Severe >15°			
Hallucal flexor power	Weak (easy)	Medium (resistant)	Strong (not moveable)				
Hallucal IPJ pain	Absent	Mild	Moderate	Severe			
Callosity location	None	PMHIPJ	Second MTPJ	Third MTPJ	Fifth MTPJ	LB	
Second toe length compared to hallux	Longer	Equal	Shorter				
Lesser MTPJ pain	Never	Rarely	Some days	Most days	Everyday		
Gait at propulsion	Normal	MTJP	Supination	DHL	VTO	AOAT	Knee flexion

Table 3.2: Measurement scales for clinical parameters

DC/ EHL = Dorsal capsule/ Extensor Hallucis Longus, PP = Proximal phalanx, PMHIPJ = Plantar medial hallucal interphalangeal joint, LB = Lateral border, MTJP = Midtarsal joint pronation, DHL = Delayed heel lift, VTO = Vertical toe-off, AOAT = Abductory or adductory twist.

3.2.5.3: Foot Health Status Questionnaire (FHSQ)

The FHSQ, a validated questionnaire (Bennett et al, 1998a) was completed by each patient and used to measure health-related quality-of-life dimensions (Appendices 19 & 20). The FHSQ was chosen because it is easy to administer, detects changes over time that matter to patients and has been validated for content, construct and criterion (Bennett el al, 1998a, 1998b, & 2001; Suk et al, 2005) and has high test-retest reliability (intra-class correlation coefficients 0.74-0.92) and internal consistency (Cronbach's Alpha 0.85-0.88). The FHSQ was chosen over the Manchester Oxford Foot Questionnaire (MOFQ) (Dawson et al, 2006) because a greater number of publications validate its use. Retrospectively collected data has less impact for FHSQ (as it rates symptoms within the last week) than the MOFQ which rates them within the last month.

3.2.6: Data analysis

Descriptive and comparative statistical analyses were performed using SPSS for Windows version 15.0 (SPSS Inc., 233 S. Wacker Drive, Chicago, IL 60606, USA). Standard chi-square analysis (x^2) was performed on categorical data. Pearson and binary correlation coefficients were used to evaluate the non-continuous data. Differences were considered to be significant when the P value was ≤ 0.05.

3.2.6.1: Justification for using paired data

One of the fundamental requirements of statistics is that each data point must represent an independent observation to justify being considered a unit (Altman & Bland, 1997). Menz (2004) and Bryant et al (2006) stated that if data is recorded from both feet during a study, a major problem arises. They queried whether the unit of measurement is a subject or a foot: if it is accepted that the unit of analysis is a subject, then it follows that by analyzing both feet of a subject the sample size is doubled. However, by doing so the independence assumption of statistical analysis has been violated, and it is likely that many of the significant "differences" are in fact spurious i.e. Type I errors (Altman & Bland, 1997; Menz, 2004). In this study each foot (exclusion criteria permitting) was treated as an independent observation. It is plausible that structural characteristics particular to one foot may affect the progress or severity of HR in a way specific to that side. The aim of this study was to correlate clinical data but not to make inferences regarding individual patients.

3.3: Results

3.3.1: Demographic data

The findings of this study demonstrate that HR was associated with increased female prevalence, bilateral involvement, and older age of patients at onset (Figures 3.5, 3.6, 3.7). Few patients in the present study had adolescent onset. It is recognised that this may be influenced by the minimum age of patients (18 years) used and the fact that patients were only taken from an adult orthopaedic clinic.

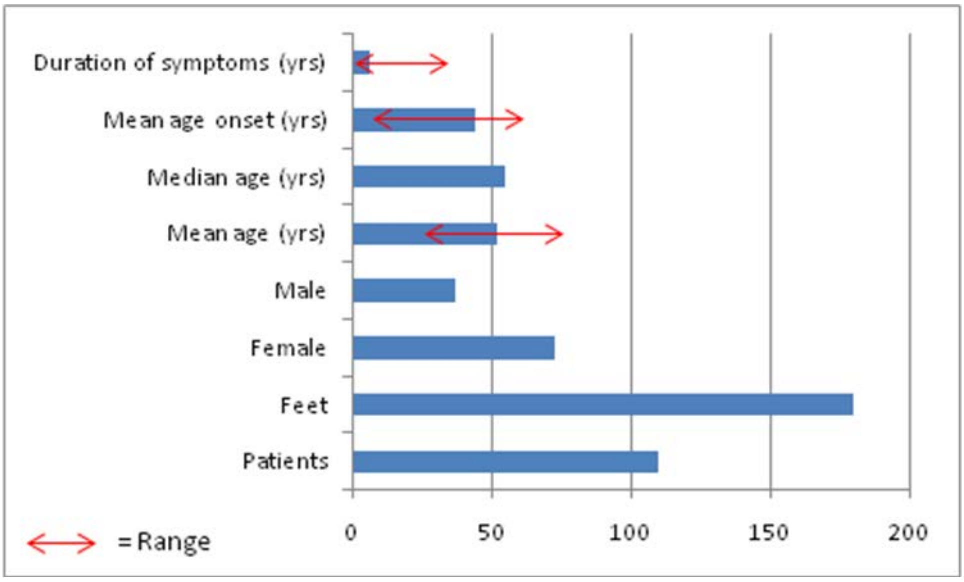


Figure 3.5: Sample characteristics

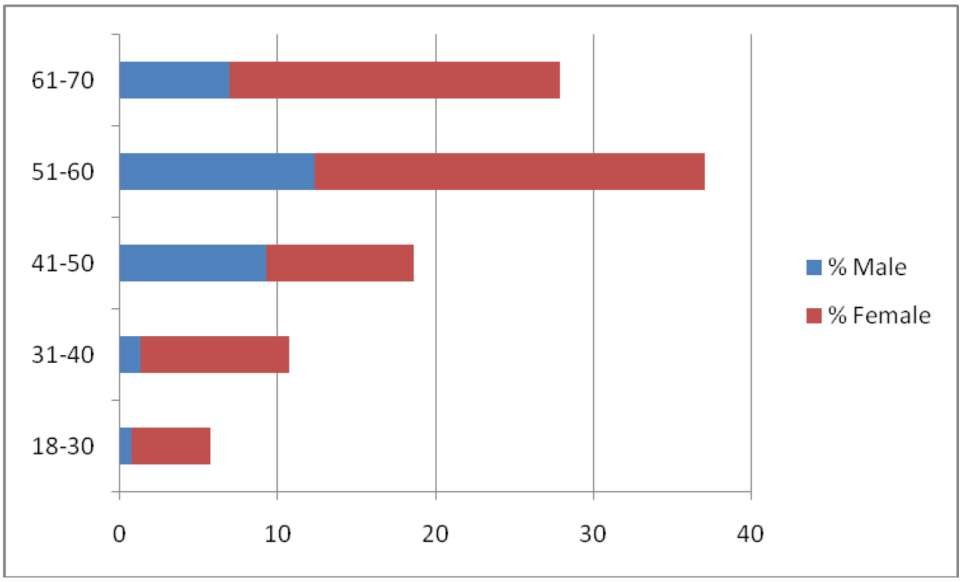


Figure 3.6: Age groups

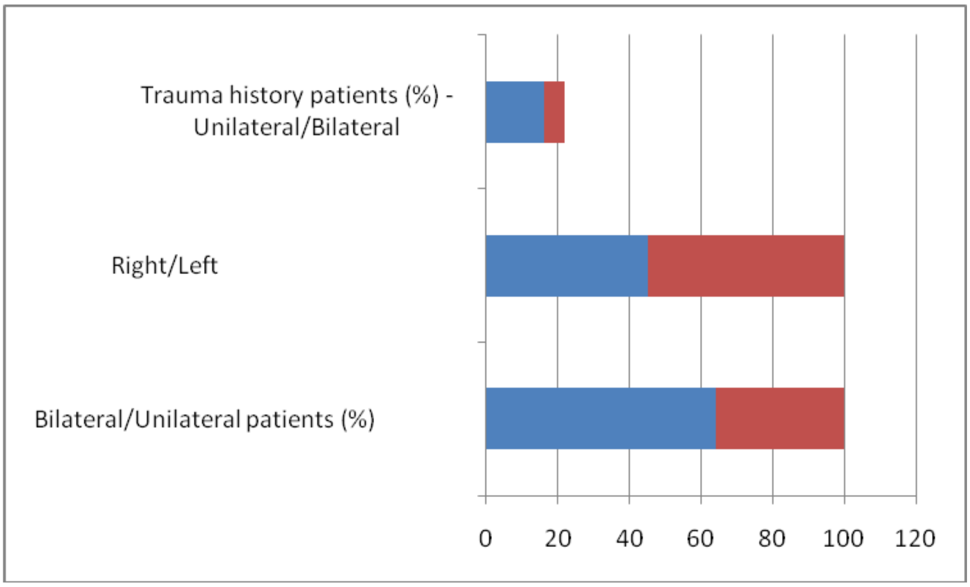


Figure 3.7: Foot involvement

The mean patient age was provided so that comparison with other studies was possible. In this study the median age is emphasized as the distribution of age was not symmetrical (non-parametric).

The mean age of onset of symptoms (first MTPJ deformity or restriction/ pain) was 44 years. This is eleven years prior to the median age of presentation at a foot and ankle clinic (55 yrs) and supports the concept that this condition may be one of insidious development. Overall patients were marginally overweight (>25 Kg/m^2), indicated by a mean BMI of 25.93 Kg/m^2 (19.53-37.26) but with no gender difference for this variable (male: 26.48, female: 25.70).

In the present study there was a pronounced difference between genders. More females presented with HR (Figure 3.5), the mean age of HR onset was less in females (43 years) than males (51 years) and the ratio of females to males was greater in the younger age groups (Figure 3.6).

The mean age of HR onset in the bilateral group was 50 years and unilateral group 53 years. Bilateral foot involvement was similar between genders (62% females, 68% males).

3.3.2: History data

No statistically significant association was found between HR and a history of trauma ($p<0.1$). Trauma history was only found in a small proportion of patients and was more common in those with unilateral HR (Figure 3.7). A statistically significant association between unilateral HR and trauma was found ($p<0.05$)

Onset of HR was reported to be insidious in 86 (78%) of patients and acute in 24 (22%) patients. First MTPJ pain (within the last 6 months) was reported to be severe in 26 (23.6%) patients, moderate in 42 (38.2%), mild in 22 (20%) and not present in 20 (18.2%) of the patients. Categorical history findings are presented in Tables 3.3A and 3.3B.

Parameters *Count (%)*	Never	Rarely	Some days	Most days	Everyday
Activity levels restricted by HR	8 *(7)*	16 *(14.5)*	17 *(15.5)*	35 *(31.8)*	33 *(30)*
Footwear contributing to first MTPJ pain	4 *(3.6)*	20 *(18.1)*	25 *(22.7)*	40 *(36.3)*	21 *(19.3)*
Variability first MTPJ pain	6 *(5.4)*	8 *(7.2)*	37 *(33.6)*	42 *(38.3)*	17 *(15.4)*
First MTPJ pain on movement	9 *(8.1)*	2 *(1.8)*	24 *(21.8)*	35 *(31.8)*	40 *(36.3)*
First MTPJ pain at rest	42 *(38.1)*	14 *(12.7)*	32 *(29)*	16 *(14.5)*	6 *(5.4)*
First MTPJ stiffness	15 *(13.6)*	10 *(9)*	26 *(23.6)*	36 *(32.7)*	23 *(20.9)*
First MTPJ stiffness a.m. only	38 *(34.5)*	7 *(6.3)*	15 *(13.7)*	29 *(26.4)*	21 *(19.1)*
First MTPJ stiffness p.m. only	31 *(28.1)*	14 *(12.2)*	24 *(21.8)*	28 *(25.4)*	13 *(11.8)*
First MTPJ stiffness all day	39 *(35.4)*	11 *(10)*	23 *(20.9)*	21 *(19)*	16 *(14.5)*
First MTPJ spasm/ cramp	50 *(45.4)*	18 *(16.3)*	32 *(29)*	9 *(8.3)*	1 *(0.9)*
Locking of first MTPJ	70 *(63.6)*	13 *(11.8)*	23 *(20.9)*	3 *(2.7)*	1 *(0.9)*
Ability to rise up on toes	23 *(20.9)*	24 *(21.8)*	20 *(18.1)*	21 *(19)*	22 *(20)*
Lesser MTPJ pain	111 *(61.6)*	16 *(8.8)*	33 *(18.3)*	12 *(6.6)*	8 *(4.4)*
Change in walking pattern	11 *(10)*	13 *(11.8)*	29 *(26.1)*	21 *(19)*	36 *(32.7)*
Able to push off through ground	21 *(11.6)*	36 *(20)*	50 *(27.7)*	22 *(12.2)*	51 *(28.3)*
Roll out during propulsion	45 *(25)*	24 *(13.3)*	38 *(21.1)*	31 *(17.2)*	42 *(23.3)*

Table 3.3A: Categorical history findings (Based on 110 patients)

Parameters	None	Cod liver oil	Glucosamine Sulphate	Glucosamine Sulphate + Chondroitin	Topical non-steroidal Gels	Paracetamol	Brufen	Voltarol	Co-dydramol	Co-codamol
Count (%)	51 *(46)*	7 *(6)*	13 *(12)*	12 *(11)*	1 *(1)*	4 *(3.5)*	11 *(10)*	7 *(6.3)*	2 *(1.8)*	2 *(1.8)*

Table 3.3B: Categorical history findings – Drugs used for first MTP joint pain (Based on 110 subjects)

The correlations for history parameters are outlined in Table 3.4.

Correlation	**Result**
Use of painkillers and symptoms	$N = 110$, $r = 0.82$, $p = 0.05$
HR and occupation	$N = 110$, $r = 0.08$, $p = 0.1$
First MTPJ pain and stiffness	$N = 110$, $r = 0.79$, $p = 0.01$

Table 3.4: Correlations for history parameters

Patients stated that footwear contributed to the development of HR in 25 (23%) cases, however, pain in the first MTPJ was found to be associated with footwear on most days in 40 (36%) patients. Short, tight, loose fitting, high-heeled and new footwear was found to aggravate symptoms of HR. The most common types of footwear restrictions are outlined in Table 3.5. No footwear restrictions were reported in a quarter of patients 18 (72%) of which were males.

Footwear type	**Number of patients *(%)***
Women's high heels	34 *(31)*
Slip-on shoes	18 *(16)*
Dress shoes	15 *(14)*
Flat shoes	5 *(5)*
Wellington boots	3 *(3)*
Shoes with seam over 1st MTPJ	3 *(3)*
Walking boots	2 *(2)*
New shoes	1 *(1)*

Table 3.5: Common footwear restrictions

Occupation contributed to HR in 32 (29%) patients. Specific details of occupations were not collected. There was no statistically significant correlation between HR and footwear or occupation ($p>0.1$).

Factors found to aggravate (Table 3.6) and relieve (Table 3.7) the symptoms of HR were reported by patients.

Aggravating factors	**Number of patients *(%)***
Footwear	25 *(23)*
Cold/ damp weather	12 *(11)*
Walking on even terrain	11 *(10)*
Walking long distances	11 *(10)*
Normal walking	9 *(8.2)*
Running	7 *(6.4)*
Descending stairs	7 *(6.4)*
Stubbing first MTPJ	*5 (4.5)*
Not wearing insoles	5 *(4.5)*
Kneeling	*5 (4.5)*
Driving for long periods	*4 (3.4)*
Standing for long periods	3 *(2.7)*
Weight of bed covers	3 (2.7)
Increased body weight	1 *(0.9)*
None	2 (1.8)

Table 3.6: Factors aggravating symptoms of HR

Relieving factors	**Number of patients *(%)***
Sitting	26 *(23.6)*
Removal of footwear	26 *(23)*
Wearing of insoles with trainers	10 *(9)*
Use of painkillers	6 *(5.7)*
First MTPJ distraction	5 *(5)*
Immersing joint in warm water	4 *(4.3)*
Use of flat stiff soled shoes	3 *(3.5)*
Modifying gait	3 *(3.4)*
Foot exercises	3 *(3)*
Massaging joint	3 *(2.9)*
Walking on flat surfaces	3 *(2.6)*
Use of non-steroidal gel	1 *(1)*
None	14 *(13)*

Table 3.7: Factors relieving symptoms of HR

A positive family history of HR was found in 26 (24%) of patients (86% of which had bilateral HR).

3.3.3: Clinical data

Table 3.8 shows the clinical findings and confidence intervals.

Parameters *(counts*)*	**Mean**	**± SD**	**95% CI** Lower	Upper	**Range**
Passive first MTPJ ROM					
- Dorsiflexion	41°	19°	37°	43°	0-82°
- Plantar flexion	15°	5°	11°	17°	0-25°
Active first MTPJ ROM					
- Dorsiflexion	58°	19°	53°	60°	0-90°
Ankle joint equinus					
- Knee extended	10°	2°	8°	10°	5°-17°
- Knee flexed	13°	3°	12°	15°	8°-25°

Table 3.8: Mean clinical findings (Based on 180 feet)

*= nominal data, SD= Standard deviation, CI = confidence intervals.

The hallucal position (frontal plane) was rectus in 91 (50.5%) feet, valgus in 75 (41.6%) feet and varus in 13 (7.2%) feet. Hallucal flexor power was weak in 10 (5.5%) feet, medium in 20 (11.1%) feet and strong in 150 (83.3%) feet. The length of the second toe compared with the hallux was found to be longer in 54 (30%) feet, the same length as the hallux in 111 (61.6%) feet and shorter than the hallux in 15 (8.3%). During passive first MTPJ dorsiflexion pain occurred at the end-of-range in 29 (26.3%) patients, mid-range in 41 (37.2%) patients, beginning in 35 (31.8%) patients and, all-of-range in 5 (4.5%) patients.

Osteoarthritis was present in joints other than the first MTPJ in 32 (29.1%) patients; hips were affected in 14 (12.7%) patients, knees in 40 (36.3%) patients and finger joints in 56 (50.9%) patients.

Table 3.9 outlines the correlations for clinical parameters and Table 3.10 details Chi-square analyses.

Correlation	Result
Pronated (pes planus) foot and first MTPJ pain	$N = 84$, $r = 0.84$, $p = 0.05$
Increased first MTPJ range of motion and pronated feet	$N = 75$, $r = 0.72$, $p = 0.01$
First MTPJ pain and increased first MTPJ range of motion at propulsion	$N = 64$, $r = 0.84$, $p = 0.01$
Hallux Abductus interphalangeus and first MTPJ pain	$N = 120$, $r = 0.82$, $p = 0.03$
Hallux Abductus interphalangeus and reduced first MTPJ range of motion	$N = 129$, $r = 0.92$, $p = 0.05$
First MTPJ pain and ability to rise up on toes	$N = 38$, $r = 0.40$, $p = 0.03$
Valgus hallucal rotation and limited first MTPJ ROM	$N = 75$, $r = 0.59$, $p = 0.01$
Valgus hallucal rotation and first MTPJ pain	$N = 141$, $r = 0.78$, $p = 0.05$
Hallucal interphalangeal joint hyperextension and first MTPJ pain	$N = 68$, $r = 0.78$, $p = 0.01$
Lesser MTPJ pain and change in walking pattern	$N = 69$, $r = 0.80$, $p = 0.05$

Table 3.9: Correlations for clinical parameters

Variables	Result
Second toe length and first MTPJ pain	$X^2 = 18.47$, $df = 4$, $p < 0.001$
Hallucal interphalangeal joint pain & first MTPJ pain	$X^2 = 8.56$, $df = 6$, $p < 0.24$
Lesser MTPJ pain and supination at propulsion	$X^2 = 22.46$, $df = 6$, $p < 0.001$

Table 3.10: Chi-square analyses

Tables 3.11A and 3.11B show categorical clinical findings for HR.

Parameters Count *(%)*	Normal	Delayed heel lift	Supination	Vertical toe-off	Abductory twist	Knee flexion
Gait at propulsion	37 *(20.5)*	50 *(27.7)*	68 *(37.7)*	11 *(6.1)*	12 *(6.6)*	2 *(1.1)*
	None	Hallux IPJ	Second MTPJ	Third MTPJ	Fifth MTPJ	First MH
Location of callosities*	58 *(32.2)*	67 *(37.2)*	18 *(10)*	10 *(5.5)*	18 *(10)*	9 *(5)*
	Severely supinated	Supinated	Neutral	Pronated	Severely pronated	
Foot Posture Index*	6 *(3.3)*	12 *(6.6)*	78 *(43.3)*	64 *(35.5)*	20 *(11.1)*	
	None	Hammer	Claw	Mallet	AV	
Lesser toe deformities*	9 *(5)*	13 *(7.2)*	77 *(42.7)*	18 *(10)*	63 *(35)*	
	$\leq$ 20° DF	$\leq$ 15° DF	$\leq$ 10° DF	$\leq$ 5° DF	$\leq$ 0° DF	
Ankle joint equinus*	5 *(2.7)*	58 *(32.2)*	107 *(59.4)*	10 *(5.5)*	0 *(0)*	
	Absent	Mild > 5°	Moderate > 10°	Severe > 15°		
Hallucal IPJ hyperextension*	60 *(33.3)*	66 *(36.6)*	46 *(25.5)*	8 *(4.4)*		
HAI° *	51 *(28.3)*	50 *(27.7)*	57 *(31.6)*	22 *(12.2)*		
Hallucal IPJ pain*	144 *(80)*	18 *(10)*	16 *(8.8)*	2 *(1.2)*		

Table 3.11A: Categorical clinical findings (Based on 110 subjects or 180 feet*****)

HAI°= Hallux abductus interphalangeus angle, DF= dorsiflexion, MT= metatarsal head, AV= adducto-varus.

Parameters	**Count**	**Percentage**
Location of HR pain:		
Dorsal bump (DB)	75	41.6
First MTPJ	21	11.6
Sesamoids	10	5.5
Proximal phalanx (PP)	4	2.2
PP+ DC/ EHL	3	1.6
DB + first MTPJ	12	6.6
DB + PP	9	5
DB + DC/ EHL	2	1.1
DB + sesamoids	13	7.2
DB + joint + sesamoids	7	3.8
DB + DC/ EHL + sesamoids	11	6.1
Joint + DC/ EHL	11	6.1
Joint + PP	2	1.1

Table 3.11B: Categorical clinical findings (Based on 180 feet)

EHL= Extensor hallucis longus, DC= Dorsal capsule.

3.3.4: Foot Health Status Questionnaire

Questions on foot pain and physical function related to the previous week whereas perceptions of foot health related to the last month. A number of general concepts were examined by the FHSQ (Table 3.12).

FOOT PAIN Count *(%)*	Never	Occasionally	Often	Very often	Always
Frequency of foot pain	6 *(5)*	9 *(10)*	30 *(27)*	57 *(52)*	7 *(6)*
Frequency of aching feet	6 *(5)*	18 *(16)*	25 *(23)*	51 *(46)*	10 *(9)*
Frequency of sharp pains	25 *(23)*	53 *(48)*	22 *(20)*	6 *(5)*	4 *(4)*
PHYSICAL FUNCTION	Not at all	Slightly	Moderately	Quite a bit	Extremely
Feet limit work activity	15 *(14)*	22 *(20)*	33 *(30)*	25 *(22)*	15 *(14)*
Feet limit type of work	65 *(59)*	25 *(23)*	6 *(5)*	2 *(2)*	2 *(2)*
Foot health limits walking	13 *(12)*	22 *(20)*	35 *(32)*	25 *(22)*	15 *(14)*
Feet limit climbing stairs	9 *(10)*	22 *(20)*	37 *(34)*	21 *(19)*	19 *(17)*
FOOTWEAR	Strongly agree	Agree (A)	Neither A or D	Disagree (D)	Strongly disagree
Hard to find comfy shoes	9 *(8)*	11 *(10)*	27 *(25)*	50 *(45)*	13 *(12)*
Hard to find shoes to fit	11 *(10)*	9 *(8)*	27 *(25)*	50 *(45)*	13 *(12)*
Limited in shoes worn	13 *(12)*	50 *(45)*	27 *(25)*	9 *(8)*	11 *(10)*
PERCEPTIONS FOOT HEALTH	All the time	Most of the time	Some of the time	Little of the time	None of the time
Did foot problems tire	10 *(9)*	25 *(23)*	53 *(48)*	17 *(15)*	5 *(5)*
Did you have lots of energy	5 *(5)*	18 *(16)*	52 *(47)*	26 *(24)*	9 *(8)*

Did you feel worn out	9 *(8)*	25 *(23)*	51 *(46)*	17 *(16)*	8 *(7)*
Did you feel full of life	5 *(5)*	18 *(16)*	52 *(47)*	26 *(24)*	9 *(8)*
	Very good	Fair	Poor		
GENERAL HEALTH	90 *(88)*	18 *(16)*	2 *(2)*		
	Severe	Moderate	Mild	Very mild	None
FOOT PAIN	41 *(37)*	22 *(20)*	20 *(18)*	9 *(10)*	17 *(15)*
	Excellent	Very good	Good	Fair	Poor
CONDITION OF FEET	4 *(4)*	18 *(16)*	58 *(53)*	20 *(18)*	10 *(9)*
OVERALL FOOT HEALTH	5 *(5)*	17 *(15)*	58 *(53)*	20 *(18)*	10 *(9)*
TIME FOOT PAIN AFFECTED PATIENT EMOTIONALLY	No time at all 10 *(9)*	Small amount 25 *(23)*	Moderate amount 53 *(48)*	Quite a bit of 17 *(15)*	All of time 5 *(5)*

Table 3.12: Foot Health Status Questionnaire (110 questionnaires)

Ninety (88%) of patients reported their general health as very good but 41 (37%) of patients reported their foot pain as severe and 57 (52%) reported the frequency of their foot pain as very often (Table 3.12). Foot pain was reported to affect 53 (48%) of patients emotionally a moderate amount of time (Table 3.12).

3.4: Discussion

A number of findings are commonly reported in patients with HR (Appendices 5 and 6) and were verified in this study.

3.4.1: Demographics and history findings

3.4.1.1 Family history

Bonney and MacNab (1952) reported that patients with a positive family history (FH) of great toe arthritis had an earlier onset of disease and Coughlin & Shurnas (2003a) found an association between HR and a positive FH of great toe problems in almost two-thirds of patients (95% had bilateral HR). Although a positive FH provides strong support to the genetic hypothesis for the basis of HR, there may be an important effect of shared environment. The findings of the present study do not concur with Bonney and MacNab (1952) or Coughlin & Shurnas (2003a). Only 26 (24%) patients reported a positive FH (86% had bilateral HR) and they could not differentiate between HR and hallux valgus (HV). The method used to obtain a FH is highly relevant. Asking patients to recall from memory if a FH of HR exists may be inaccurate. Patients may confuse HV with HR and if a patient was adopted they will have no recollection of birth parents/ siblings. The results of the present study should be considered with caution. Future HR studies may need to consider a properly controlled and correctly designed family study before a positive FH is concluded.

3.4.1.2: Age of onset

Much has been written about the age of HR onset but not all authors are in agreement (Section 2.1.1.1). In reviewing studies that report on age

(Tables 2.1 & 2.2) the mean age at onset was 38 years. The mean age at onset in the current study was 44 (14-68) years; only 3 (2.7%) of patients developed symptoms at an age of less than 18 years. Given the small number of adolescent patients with HR reported by this study and others (Tables 2.1 & 2.2) and the fact that pathological specimens from both adults and adolescent patients with HR were found to be consistent with degenerative arthritis (Bingold & Collins, 1950) it is concluded that artificially dividing patients into primary and secondary categories is unnecessary.

<u>3.4.1.3: Gender predilection</u>

Early studies found a male predilection to HR (Table 2.3). In complete contrast, virtually all recent HR studies (Table 2.5), show a higher female predilection (62%), a percentage comparable to the present study (66%). This female predilection to HR may not be due to biological differences but to social and cultural factors that result in women wearing footwear that aggravate a predisposition to develop HR or aggravate pain in deformities of similar magnitude. The present study found females more commonly affected in most age groups except the 41-50 year-old group (Figure 3.6), a finding comparable with that of Coughlin et al (2003a). However, this finding may only reflect the higher number of females receiving surgical treatment for HR, but not the true male/ female incidence in the general population who have the condition but have not as yet, had surgical intervention. Intolerance to certain types of footwear and general cosmetic appearance of the foot are thought to play a prominent role for this higher incidence of surgical intervention in female patients (Horton, 2000). The present study shows a much higher ratio of females in the younger age groups (Figure 3.6), which raises the question: Is this because 18-40 year-old females are more likely to wear inappropriate footwear?

<u>3.4.1.4: Body mass index (BMI)</u>

It was considered that an increased BMI may predispose patients towards HR and contribute towards levels of pain experienced. In the present study no abnormal BMI or gender difference was found (Section 3.3.1). BMI was considered not to be a predisposing factor for HR in these patients.

3.4.1.5: Bilateral involvement

Unilateral HR has been reported (Figure 3.7); some found increased involvement in females, but presented no demographic data to support this (Drago et al, 1984). In the present study unilateral involvement presented in 40 (36%) patients (equal numbers of left or right feet) (Figure 3.7); 38% were female. Other studies report bilateral HR (Section 2.1.1.3) or bilateral presentation with unilateral symptoms. In the present study bilateral involvement presented in 70 (64%) patients (Figure 3.7), which may reflect the predominance of older patients (Figure 3.6) rather than the true incidence as, with the passage of time, a higher percentage of patients are likely to exhibit bilateral disease. This finding concurs with Coughlin & Shurnas (2003a) who found bilateral HR at final follow-up (79%) compared to 19% at initial examination. This may reflect the type of clinic (surgical) from which patients were taken. In the present study analysis was undertaken at the point of referral.

In the present study a history of trauma was common in patients who developed unilateral HR. A positive trauma history was found in 24 (22%) of the study sample; 74% of whom had unilateral involvement (Figure 3.7). No association between HR as a whole and a history of trauma (p = 0.1) was found. A statistically significant association between unilateral HR and trauma ($p < 0.05$) was found agreeing with the findings of Coughlin & Shurnas (2003a).

A small proportion of unilateral HR patients had the asymptomatic foot examined. In these cases it was apparent that structural differences between the feet existed (e.g. HV in other foot) and that this may result in different biomechanical function of the first MTPJ. Although these findings suggest a trend the numbers of patients where such a comparison was possible was too small to enable definitive conclusions to be drawn.

3.4.1.6: Footwear

Poor footwear has been implicated in the development of HR for many decades (Section 2.1.1.5). In the present study only 25 (23%) of patients considered their footwear a contributory cause of their HR. Nineteen (76%)

of these were women and only 6 (24%) were men. However, the frequency of first MTPJ pain in HR associated with footwear was found to affect 36% of patients on most days (Table 3.3A). The most common types of footwear restrictions reported by females were high heeled shoes possibly because the first MTPJ is held in extension during gait. Other footwear restrictions are outlined in Table 3.5. It is suggested that slip-on shoes and Wellington boots may cause FHB overuse to maintain stability and subsequent sesamoid pain. Dress shoes compress the forefoot, this may alter first MTPJ biomechanics and flat shoes may increase the requirement for first MTPJ dorsiflexion at propulsion. Anecdotal evidence suggests shoes with a seam over the first MTPJ can rub the joint especially if dorsal osteophytes present and can compress the dorsomedial cutaneous nerve resulting in dysesthesia or numbness along the medial hallucal border. No footwear restrictions were reported in a quarter of patients (76% of which were males).

3.4.1.7: Factors aggravating HR

In the present study patients reported a number of factors responsible for aggravating the symptoms of HR. Although footwear was the most common other factors were also reported (Table 3.6). Some of these were of mechanical origin where increased first MTPJ movement was required (e.g. walking on uneven terrain, running). Others were due to altered foot pressures (i.e. not wearing insoles) or joint trauma (e.g. stubbing first MTPJ, weight of bed covers). These findings agree with other studies (Bingold & Collins, 1950; Roukis et al, 2002). The severity of HR was reflected by the type of activity aggravating the condition. Some patients reported that prolonged activity while barefoot or in soft-soled shoes was often difficult. Only 1.8% of patients reported that no factors aggravated their HR. This suggests that factors aggravating HR are likely to be idiosyncratic, influenced by lifestyle and general health.

3.4.1.8: Relief of HR symptoms

Patients reported strategies responsible for immediate relief of HR symptoms; sitting and removal of footwear were the most common (Table 3.7). It is interesting that so few patients opted to use painkillers (Table 3.3B) although this is reflected in that only 26 (23.6%) of patients reported severe first MTP joint pain. A strong correlation between the use of painkillers and symptoms in these particular patients was found ($r = 0.82$, $p = 0.05$). The other strategies reported for obtaining relief of symptoms were varied and particular to certain patients. Some obtained instant relief of symptoms i.e. first MTPJ distraction, immersing joint in warm water and massaging joint. Others were used to aid symptoms when walking i.e. use of flat stiff soled shoes, modified gait (walking on outer border of foot) or walking on flat surfaces. In 14 (13%) of patients with well advanced disease no measure would obtain immediate pain relief.

Patients presented with a range of HR pathology. Most experienced symptoms everyday (Table 3.3A) which were severe (Table 3.12) but the majority took either no pain medication or over the counter drugs (Table 3.3B). As HR has a mainly insidious onset, patients may perceive their pain as an expected consequence of aging. The patient's or GP's perception of the importance of HR in relation to others conditions they may suffer may influence their decision (prioritizing health). The negative press about non-steroidal anti-inflammatory drugs (NSAID's) may also be influential (Page & Henry, 2000). Only 18 (16.3%) of patients took NSAID's.

3.4.1.9: Restriction of activity levels

First MTPJ pain in HR was found to restrict activity levels in 35 (31.8%) of patients on most days (Table 3.3A) and 33 (30%) of patients were affected in their activities everyday (Table 3.3A). The types of activities restricted by HR included: running, long walks (particularly hill walking), walking on uneven surfaces, dancing, multidirectional sports and aerobic exercise. Predominantly activities requiring a forced excursion of the first MTPJ in the sagittal and/or frontal plane may precipitate pain. Transverse plane movement however, is resisted because of increased transverse plane stability promoted by bony changes in HR.

3.4.1.10: Occupation

In the present study 46 (42%) of patients lead an active occupation but only 32 (29%) of patients considered that their occupation contributed to HR. This concurs with the FHSQ data (30% of patients reported being affected at work by their HR) and another study who found no statistically significant correlation between HR and occupation (*r*= 0.08, *p*>0.1) (Coughlin & Shurnas, 2003a).

In the present study 30 (27%) of patients were retired, which may influence activity levels and subsequent HR pain. In retirement some patients are more active while others less active because of ill health (Disney et al, 2006). Differences in reported self-assessed health are large (Baker et al, 2004). Individuals who are inactive often have an incentive (for self-esteem) to report worse-than-actual health (Bound, 1991). This factor has not been considered in other HR studies.

3.4.1.11: First MTPJ symptoms

In the present study patients reported moderate (38.2%) and severe (23.6%) first MTPJ pain within the last 6 months (Section 3.3.2). Only 9 (8.1%) of patients reported no pain (Table 3.3A). First MTPJ pain presented in 75 (67%) of patients during waking hours (on movement) and was variable on most days for 42 (38%) of patients; some patients 32 (29%) presented with pain at rest on some days (Table 3.3A).

Patients were asked to grade and indicate the timing of their first MTPJ stiffness. This was graded on a continuum between zero and ten (0= no stiffness, 10 = unable to move). In the present study 95 (86%) of patients reported first MTPJ stiffness (Table 3.3A) and if variable, at its worst, 45% were graded as 5 out of 10. Only 15 (13.6%) of patients reported no first MTPJ stiffness. There was a strong correlation between first MTPJ pain and stiffness (*r*= 0.79, *p*= 0.01) which was statistically significant. The timing of first MTPJ stiffness during the day was also reported and found to be worse in the evening (Table 3.3A).

First MTPJ locking was reported in 40 (36%) of patients but was variable and short lasting in nature (Table 3.3A). More commonly 60 (55%) of patients experienced first MTPJ and hallux cramp/ spasm (Table 3.3A) a consequence of capsulitis and FHL/ FHB tenosynovitis. Patients reported first MTPJ symptoms to be worse during the heel-rise and propulsion phases of gait.

3.4.1.12: Patients perception of their gait

In the current study 99 (90%) of patients considered that their walking pattern had changed during development of their HR, of which 36 (33%) considered that this change affected them everyday (Table 3.3A). Only 51 (28%) of feet were able to push through the ground at propulsion everyday, the remainder were affected to varying degrees of severity (Table 3.3A) and 135 feet (75%) rolled outwards during propulsion. The differences in frequency for each of the gait variables are outlined in Table 3.3A.

3.4.1.13: Presence of OA in other joints

An association between radiological foot OA and radiological OA at other sites has been reported (Wilder et al, 2005). In the present study 32 (29%) of patients (76% female) reported OA in other joints; mainly fingers (51%). Whilst this indicates a relationship this is not necessarily causal.

3.4.1.14: Sport

Sports can produce first MTPJ trauma and may precipitate HR development whilst their frequency may exacerbate symptoms (Kubitz, 2003). In the present study 69% of patients reported undertaking sport (e.g. football, rugby, tennis, golf, badminton, rock climbing, running, walking, horse riding, aerobics) of variable frequency (one to five times per week) prior to HR onset but their relative influence is unclear.

The history questions were based on findings from previous research (Appendices 5 & 6). It is unclear whether they reflect the needs of patients or those perceived by clinicians to be relevant. Patient-generated questions based on prior patient-based questionnaires (i.e. what patients' perceive important in HR), may have been useful.

3.4.2: Foot Health Status Questionnaire (FHSQ)

The FHSQ findings (Table 3.12) broadly concur with the history and physical results of the current study (Tables 3.3A, 3.8, 3.11A, 3.11B). The severity (37% severe) and frequency (42% very often) of foot pain documented was greater than that verbally reported (Table 3.3A). This may be because the FHSQ data related to foot pain within the previous week rather than the last six months. Interestingly the frequency of foot pain was found to vary (52% very often) more in the short term (one week) than over a longer period of six months (38% most days). Some patients reported that their first MTPJ pain made them feel tired and worn out; thus affecting them physically and emotionally (Table 3.12).

The restrictions of physical function documented by patients were related to similar activities as those found in the clinical component of the study (aggravating factors). Patients reported that although it was possible to find footwear which does not hurt their feet the number and type of footwear was limited (Table 3.12). Female patients particularly, were not happy with the appearance of their enlarged first MTPJ's and, considered that this together with joint pain, limited them in their choice of footwear. Existing co-morbidities e.g. heart disease (two patients) may influence mobility and function and subsequently FHSQ results. This finding is consistent with a previous study by Gilheany et al (2008). Although the patients' perception of their general foot health was good (apart from first MTPJ) many felt that their HR limited them in vigorous physical and social activities and were concerned about its impact on their long term general health.

The FHSQ has certain limitations. It was originally validated on a relatively small sample (111 participants) and is lacking in some areas of theoretical development and validation (Budiman-Mak et al, 2006). It is not a 'patient-generated questionnaire' (i.e. developed out of patient interviews) but generated from focus groups with podiatric surgeons - whose concerns (priorities and breadth) may differ from those of surgical patients. This potentially threatens the instrument's 'content validity' (as far as patient's perspective might be concerned). Generally questionnaires should be validated within the context in which they are to be used. Lack of expectation as to how responses were to be interpreted may have given patients difficulties in answering or resulted in lack of precision of the scale and raises concerns about the level of expertise in questionnaire development (Dawson, 2007). No other measure, clinical or independent, has been compared with the FHSQ in the paper presenting its measurement properties. This limits the extent to which claims about validation can be made. The study by Bennett et al (1998a) was cross-sectional, so it is unclear how responsive the FHSQ is to change in patients' clinical status. No data exists on the amount of change required for the FHSQ that is considered important (i.e. minimally important difference) to patients (Landorf & Burns, 2009). These were the main misgivings; they do not mean that the FHSQ is inadequate but insufficient evidence has been presented to allow for that judgment to be made.

3.4.3: Clinical findings

3.4.3.1: Factors thought to contribute to development of HR

3.4.3.1.1: Pes Planus

Pes planus as a cause of HR has been implicated by a number of authors (Section 2.1.2.1) with the understanding that excessive pronation results in increased plantar fascia tension, increasing forces under the first metatarsal head and reducing hallux dorsiflexion.

In the present study, the Foot Posture Index (FPI) was used. It is a valid, reliable and objective measure of foot function (Redmond et al, 2005). The FPI quantifies the degree of pronation or supination in a relaxed stance position. It requires no manipulation of the foot, marking of lines or measurement with instrumentation. Thus the controversial issues relating to goniometer assessment and validity of neutral subtalar joint positioning are avoided (McPoil & Cornwall, 1994).

In the present study 84 (47%) feet had pes planus; 11% of which were severely pronated (Table 3.11A). A strong correlation between a pronated (pes planus) foot and first MTPJ pain was found ($r = 0.84$, $p = 0.05$) which was statistically significant. It is theorized that in a pes planus foot forefoot hypermobility at propulsion may promote first MTPJ instability, increasing ROM and pain. A statistically significant correlation between increased first MTPJ ROM and pronated feet ($r = 0.72$, $p = 0.01$) support this concept. Whilst these findings indicate a relationship between the parameters this is not necessarily causal.

3.4.3.1.2: Functional hallux limitus

Functional hallux limitus (FHLim) has been proposed as a cause of HR (Section 2.1.2.2). Although the findings of the present study concur with earlier research (Harradine & Bevan, 2000; Coughlin & Shurnas, 2003b), it proposes that in early stage HR, FHLim may be a consequence of tenosynovitis of the FHL tendon which limits the tendons excursion and subsequently that of first MTPJ dorsiflexion on foot loading (Michelson & Dunn, 2005). Standardization of ankle joint position is important when assessing for FHLim (a factor not mentioned by previous authors). If the ankle is plantar flexed when passive first MTPJ dorsiflexion is tested, then hallux dorsiflexion is likely to increase as the flexor hallucis longus (FHL) is taken off stretch.

3.4.3.1.3: Second toe length

Three forefoot types can influence second toe length compared to the hallux (Section 2.2.2.4). Ogilvie-Harris et al (1995) assessed second toe length in ballet dancers and found a correlation between HR and a longer second toe. The present study does not concur with that of Olgilvie-Harris et al (1995); 54 feet (30%) had a long second toe while 111 feet (62%) had a second toe the same length as the hallux (Section 3.3.3). Chi-square analysis of second toe length and first MTPJ pain revealed a statistically significant finding (p<0.001). In a radiographic study of the same patients the proximal phalanx was longer than the distal phalanx (Beeson et al, 2009a). The overall length of the hallux may be a factor contributing to HR. This finding concurs with Munuera et al (2007) who compared HR with non-HR patients and found a longer hallux in the HR group. Whilst these findings indicate a relationship between the parameters this is not necessarily causal.

3.4.3.2: Factors used as markers of severity

3.4.3.2.1: Increased joint size and soft tissue swelling

Increased first MTPJ size in HR (Section 2.1.2.7) is related to the presence of osteophytes, joint distension secondary to synovitis and may provide an indirect clinical measure of joint damage. Soft-tissue swelling has also been reported (Appendix 6) and may be related to a dorsal prominence that becomes painful from constant rubbing against footwear. Capsulitis and EHL tenosynovitis can result from stretching of soft tissues over dorsal osteophytes (Camasta, 1996). This may be responsible for HR patients complaining of pain on hallucal plantarflexion. In the present study it was observed that the magnitude of joint size increased with severity and duration of HR.

3.4.3.2.2: Pain with first MTPJ motion

Some studies describe pain during first MTPJ motion (Section 2.1.2.7). The present study reported first MTPJ pain during passive ROM. The timing of pain during joint movement was documented in an attempt to quantify the severity of HR (joint damage). Twenty-nine (26%) of patients reported end-of-range pain suggestive of minimal joint damage, 76 (69%) of patients reported pain at the beginning or mid-range pain accounting for mild to moderate joint damage and 5 (4.5%) reported all-of-range joint pain representing severe joint damage. This reflected the range of severity of HR within the patients. Interestingly a strong correlation between first MTPJ pain and increased first MTPJ ROM at propulsion was found ($r = 0.84$, $p = 0.01$) which was statistically significant. This may explain why in a damaged first MTPJ where there is still free and unrestricted joint motion, pain is often likely whereas, in an ankylosed first MTPJ where movement is restricted pain is less likely. Feet with restricted first MTPJ ROM may present pain in other areas (i.e. lateral forefoot) due to compensation imposed by the restricted joint motion. During active ROM patients reported pain primarily during heel lift and propulsion where first MTPJ dorsiflexion was required. In the present study patients reported that they could modify the severity and timing of symptoms by altering their gait pattern.

3.4.3.2.3: Variability of first MTPJ pain

The natural history and symptoms of HR can vary from day-to-day and are influenced by numerous aggravating or relieving factors. In some cases, the condition takes a relatively benign course and in others symptoms are more persistent (Yee & Lau, 2008). In the present study 96 (87%) of patients reported daily variability of joint pain (Table 3.3A). It is concluded that this variability is multifactorial and may include factors such as lifestyle, health, footwear and others (Section 3.4.1.7). Whilst occupation does not appear to play a role in the development of HR it may be responsible for its variability.

3.4.3.2.4: Location of HR pain

Patients presented HR pain in a number of locations around the first MTPJ (Table 3.11B). Dorsal bump pain was the most common seen in 75 (42%) of patients and was an early finding in HR. Sesamoid pain was more common in established HR. The location of HR pain is likely to be idiosyncratic, influenced by severity, lifestyle and general health.

3.4.3.2.5: Restricted joint motion

Studies have documented restricted first MTPJ motion in HR, especially dorsiflexion (Section 2.1.2.7). The present study concur with these findings (Table 3.8) suggesting that soft tissue restriction (FHB, FHL, medial band plantar aponeurosis and sesamoid immobility) may be involved, but this was not analysed. Similar findings were reported by Flavin et al (2008) who proposed congenital or acquired (inflammation/ contracture) aetiology. This concept is supported by Michelson & Dunn (2005) and Kirane et al (2008), who demonstrated a causal relationship between flexor hallucis longus (FHL) stenosing tenosynovitis and HR. They speculated that the proximally restricted FHL tendon may limit normal gliding motion of the proximal phalanx over the metatarsal head during dorsiflexion and contribute to restricting joint movement. Such findings may influence HR progression and management. Additional clinical and histopathological investigations are indicated.

3.4.3.2.6: Passive versus active first MTPJ ROM

Overall, passive first MTPJ ROM was reduced; mean dorsiflexion 41° (0-82°) was below the normal range 65°-90° (Camasta, 1996) and, plantarflexion was also reduced, mean 15° range 0-25° (Table 3.8).

Active first MTPJ dorsiflexion increased with weight-bearing. Mean active dorsiflexion 58° range 0-90° (Table 3.8) was greater than mean passive dorsiflexion, this may be a result of body weight and forward momentum increasing available joint dorsiflexion however, this was still well below the normal range (65°-90°). Because of joint pain, some patients supinated their foot during gait reducing the need for as much dorsiflexion. These findings concur with the radiological study (Chapter four) in which a mean hallux equinus angle of 11° was found during stance, this is outside the normal range 16°-18° (Beeson et al, 2009a).

Both bone, including joint, and soft tissue changes associated with HR are responsible for a reduced joint ROM (particularly dorsiflexion). The dorsal capsule and EHL can become stretched and inflamed by dorsal osteophytes causing pain and may contribute to limited plantarflexion.

3.4.3.2.7: Hallux abductus interphalangeus (HAI)

In the present study 129 feet (72%) presented with HAI (Table 3.11A). A moderate degree (> 10°) of HAI (transverse plane) was present in 57 feet (32%). In 79 feet (44%) the HAI angle was greater than normal (where normal $\leq$ 10°). Strong correlations were found between HAI and first MTPJ pain (r = 0.82, p = 0.03) and HAI and reduced first MTPJ ROM (r = 0.92, p = 0.05) which were statistically significant. It is hypothesized that the presence of HAI indicates a more progressive HR process and that with increased first MTPJ damage the first metatarsal head becomes flatter and more resistant to transverse plane movement, thus predisposing to an increased HAI. These findings agree with those of Coughlin & Shurnas (2003a).

3.4.3.3: Factors associated with or secondary to HR

3.4.3.3.1: Ability to rise up on toes

In HR if first MTPJ dorsiflexion is restricted or painful then patients may avoid forced dorsiflexion of the joint imparted by rising up on their toes. In the present study 21% of patients were unable to undertake this manoeuvre; the remainder could perform the task to varying degrees (Table 3.3A). A weak correlation between first MTPJ pain and ability to rise up on toes was found (r= 0.40, p= 0.03). Most patients can still perform this manoeuvre by supinating their foot.

3.4.3.3.2: Hallucal position (frontal plane)

Medial first ray deviation, increased first/ second intermetatarsal angle and lateral deviation of the hallux may alter the pull of abductor hallucis causing it to rotate the hallux and medial sesamoid into valgus. Valgus hallucal rotation is normally associated with hallux valgus (Coughlin & Mann, 1999) but can present in HR (Figure 3.8) where it may influence first MTPJ sagittal plane motion and sesamoid tracking. The findings of this research support these changes in HR.

Figure 3.8: Valgus hallucal rotation

In the present study 75 feet (42%) presented with valgus hallucal rotation (Section 3.3.2). A moderate correlation between valgus hallucal rotation and limited first MTPJ ROM (r= 0.59, p= 0.01) was found. A correlation between valgus hallucal rotation and first MTPJ pain was found (r= 0.78, p= 0.05) which was statistically significant. It was concluded that hallucal valgus rotation may biomechanically alter first MTPJ function in HR. It is unclear whether this feature progresses with time, however, in the small number of hallux valgus-rigidus patients excluded from this study a more severe and late stage HR was seen.

3.4.3.3.3: Hallucal interphalangeal joint (IPJ) hyperextension

This can be seen during early stages of HR when MTPJ motion is still good. Lynn (2004) considered that IPJ hyperextension is another causal factor which increases susceptibility to HR rather than being secondary to reduced MTPJ motion. In the present study varying degrees of severity of hyperextended hallucal IPJ were found and 30% of these were greater than 10° (Table 3.11A). A correlation was found between hallucal IPJ hyperextension and first MTPJ pain (r = 0.78, p = 0.01). This relationship is not necessarily causal. In the present study the degree of hallucal IPJ hyperextension did not appear to increase with increasing severity of HR.

3.4.3.3.4: Hallucal interphalangeal joint pain

As sagittal plane restriction of the first MTPJ can result in compensatory transverse and/or sagittal plane deformity of the hallucal IPJ it was assumed that hallucal IPJ pain may develop. In the present study a painful IPJ was reported in 36 patients (20%) and only 18 (10%) of these had moderate to severe pain (Table 3.11A). Chi-square analysis of hallucal IPJ pain and first MTPJ pain revealed no significant finding ($p < 0.24$). In this group of patient's hallucal IPJ pain was not considered to be a feature associated with HR.

3.4.3.3.5: Hallucal flexor function

Tenosynovitis of the hallucal flexor tendons in HR may influence hallucal purchase power. The ability of the hallux to prevent a piece of paper from being pulled away from under it during static stance was not found to be impaired in HR where 150 feet (83%) had a strong, but not moveable, response. Evaluation of the magnitude of pressure applied to a force-plate may have provided a more scientific measure of flexor function power.

3.4.3.3.6: Location of plantar callosities

Callosities may be related to abnormal function. Increasing severity of first MTPJ pain results in more supinatory compensation and subsequently more laterally placed callosities. In 67 feet (37%) callus presented over the plantar medial hallucal IPJ. This may be related to 47% of patients who presented with a pronated gait in which there is likely to be increased hallucal IPJ propulsion. Of the remaining feet callus was predominantly located under the lateral metatarsal heads (Table 3.11A). These findings are supported by Vernon (1999) who demonstrated predominant locations of plantar shoe wear patterns in HR. Callosity formation in HR may be influenced by lifestyle, activity levels and footwear type. The reliability of callosity location as a marker of HR severity can only be relied upon with caution as callus patterns may increase following altered foot function but equally decrease due to reduced mobility.

3.4.3.3.7: Lesser toe position

Roukis et al (2002) noted that medial angulation of the second toe can result from compensation during gait. In an attempt to provide medial column stability the flexor digitorum longus (FDL) muscle contracts. A "windswept" (medial deviation) appearance to the entire forefoot, rather than just the second toe may result. In the present study lesser toe clawing and medialisation (adducto-varus) of third to fifth toes predominated (Table 3.11A).

3.4.3.3.8: Ankle equinus

Various studies have suggested an association between Achilles tendon contracture and HR (Section 2.1.2.4).

In the present study 10 (5.5%) feet had 5° or less dorsiflexion with the knee fully extended and foot held in neutral, to eliminate subtalar and mid-tarsal joint involvement (Table 3.11A). No patient had an Achilles tendon contracture <0°. The mean ankle dorsiflexion with the knee extended was 9° (5°-17°) this increased to 13° (8°-25°) with the knee flexed (Table 3.8). It is concluded that ankle equinus secondary to Achilles tendon tightness is not associated with HR.

3.4.3.3.9: Lesser metatarsal overload

Supinated gait in response to restricted first MTPJ motion can cause overload and pain in the lesser MTPJ's (Clough, 2005). In the present study lesser MTPJ pain (transfer metatarsalgia) was reported in 69 (38%) feet with varying degrees of frequency (Table 3.3A). A strong correlation between lesser MTPJ pain and a change in walking pattern ($r = 0.80$, $p = 0.05$) was found which was statistically significant. Chi-square analysis of lesser MTPJ pain and supination at propulsion revealed a statistically significant finding ($p < 0.001$). This study concludes that first MTPJ restriction/ pain may be responsible for altered forefoot loading and subsequent metatarsalgia (Table 3.3A). This is supported by gait modifications found within the same proportion of patients where 68 (37%)

of feet were held in supination at propulsion (Table 3.11A). As different gait modifications are associated with HR not all patients will complain of forefoot pain.

3.4.3.3.10: Altered gait

It is reported that gait in HR may become increasingly antalgic as the MTPJ stiffens resulting in an everted (Kessell & Bonney, 1958; Mann et al, 1979; Mann & Clanton, 1988; Easley et al, 1999; Muliër et al, 1999) or supinated foot position (Jack, 1940; Payne & Dananberg, 1997; Coughlin & Shurnas, 2003a). The sagittal plane facilitation theory (Payne & Dananberg, 1997) describes five forms of compensation for sagittal plane blockade in HR (Appendix 21); all of which were observed in this study (Table 3.11A).

This cross-sectional study has documented the key clinical parameters associated with HR and the discussion has highlighted a number of difficulties and limiting factors associated with their clinical evaluation. Only certain clinical parameters were useful to evaluate HR. Some features were either too time-consuming, too difficult to measure, or the reliability of their measurement (particularly angular measurements) was in doubt (Coughlin & Freund, 2001; Beeson et al, 2008).

3.6: Conclusion

The findings of this research are based on the defined study population. HR was associated with female gender, bilateral involvement, older age groups (a condition developing over time), increased HAI angle, FHL tenosynovitis, a second toe of similar length to the hallux and restricted and/or painful first MTPJ dorsiflexion. HR was also associated with dorsal bump pain (particularly early stages), hallucal IPJ hyperextension, lesser MTPJ pain (when supinating at propulsion), medial deviation of the second toe, flat foot and various specific gait alterations. Unilateral involvement was less common, and mostly associated with trauma. In bilateral cases, a positive family history could not be concluded, however a properly constructed family study may prove such an association. OA at other sites (finger joints) particularly in women was found in this study. Further research to determine if a relationship between HR (OA) and OA at other sites may be helpful. Future epidemiological studies would be useful to determine whether a systemic aetiology is involved in HR and clarify the respective influences of mechanical and systemic factors in the conditions development.

HR was not associated with Achilles tendon tightness. Footwear was not found to be a contributory cause but was reported to be an aggravating factor (particularly in women). Few patients had adolescent onset HR.

For clinical parameters to be considered valid for inclusion in a classification of HR their content validity needs to be firstly established by formal research (Beeson et al, 2008). The purpose of this study was to establish such validity.

CHAPTER 4

A study to evaluate radiological parameters of hallux rigidus

4.1: Introduction

Objective measurements form the basis of the scientific process and are critical to the understanding of a pathological change (Roukis et al, 2002). The most common objective evaluation of HR has been by radiological measurement (Roukis et al, 2002). The magnitude and configuration of radiological change in HR differs from HV due to different kinematic patterns and overall biomechanical properties (Bock et al, 2004).

This study aimed to define a set of radiological parameters which represent a underlying dimension of HR and which are valid and reasonable to include in a classification framework. In addition to the first MTPJ a variety of other radiological foot parameters linked to HR were examined.

4.2: Method

An observational, cross-sectional study was undertaken. This involved quantification of specific radiological parameters applied to a sample of patients with varying degrees of HR severity.

4.2.1: Patient sampling and recruitment

One hundred and ten HR patients aged between 18 to 70 years were used in this study (the same patients as Study 1). The rationale for the chosen age range was similar to that given in Study 1 (Section 3.2.1).

Initially systematic random sampling was considered to eliminate bias. However, it was realized that an insufficient sample size would be obtained because a lower frequency of HR exists compared with HV. Subsequently a convenience sample (nonrandom) was chosen.

All patients were accessed from two orthopaedic foot and ankle clinics and one podiatric surgery clinic.

4.2.2: Inclusion / exclusion criteria

HR patients with restricted first MTPJ dorsiflexion (<65°) with either pain, deformity or both were included in the study. Careful preliminary examination of patients' clinical notes was undertaken to remove those possessing criteria of exclusion (Table 3.1). Detailed exclusion criteria were reviewed at time of data collection.

An invitation letter (Appendix 9) and study information sheet (Appendix 10) was sent to patients from the previous study giving them time for consideration (> 24 hours) prior to inclusion in the study.
From the 110 patients entered into the study 180 (94 plain, 86 digital) standard pre-operative weight-bearing X-rays were selected. This was based on the fact that not all patients had bilateral HR.

4.2.3: Ethics

X-rays of human subjects were required, thus ethical consideration was needed. Approval was granted by Leicestershire Northants and Rutland Ethics Committee, Three Shires Hospital Medical Advisory Committee and Research and Development offices of the Northampton Acute & Primary Care Trusts (Appendices 11, 12, 13).
Patients gave informed consent and data collection sheets were coded for confidentiality. Copies of the signed consent form (Appendix 14) were given to patients and added to their hospital notes to confirm their involvement in the study and the patient's GP was informed of their involvement (Appendix 15). All data derived from patients' clinical notes and X-rays was classed

confidential and stored under lock and key at The University of Northampton (to be kept for four years following study publication).

4.2.4: Pilot study

A pilot study using 10 X-rays and two examiners was undertaken. The method was found to be practicable and data produced in line with study aims and objectives. As a result of the pilot study data collection sheets were further refined (Appendix 22) and the following measurements excluded due to perceived methodological problems:

- Non weight-bearing (oblique and axial) views were not included as standardisation and therefore reliability could not be guaranteed.
- Evaluation of first metatarsal frontal plane rotation (Eustace et al, 1993) 1993) was not easy in practice and no standardized protocol exists.
- Evaluation of frontal plane sesamoid rotation (axial view) (Talbot & Saltzman, 1998) was not easy to interpret raising reservations about its reliability. A specially designed tangential position device has been described (Kuwano et al, 2002), but its reliability is not proven and it would not be available in a standard radiology department and requires specialist training.
- Measuring the distance between the metatarsal head and sesamoids (lateral view) was difficult due to superimposition of bones. The axial sesamoid view is better for demonstrating this parameter but is subject to variation (i.e. non-weight bearing view).
- The method for measuring metatarsus adductus angle (MA°) described by Coughlin & Shurnas (2003a) (Figure 4.1) was unreliable. The four tarsal reference points could not be consistently identified on all X-rays; however, the intermediate cuneiform base was easier to recognize. The angle formed between a perpendicular to this line with a longitudinal bisection of the second metatarsal was used instead to represent the MA° (see Figure 4.14). This is a modification of the method applied by Engel et al (1983).

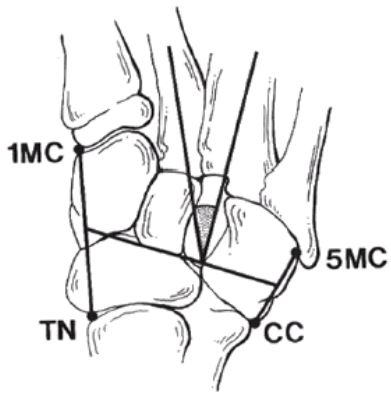


Figure 4.1: Metatarsus adductus angle

- Evaluation of first metatarsal cuneiform joint (MCJ) OA using a modified version (lateral view) of the method (Appendix 23) described by Coughlin et al (2005) (who used a dorsal oblique view) was difficult due to superimposition and shadowing of tarsal bones and reliability could not be guaranteed.

Both Morton's method (Morton, 1928) and the arc technique (Hardy & Clapham, 1951) were compared to derive relative first metatarsal length and enable the comparison of protocol results with those in previous studies. A greater percentage of patients were found to have a short first metatarsal using Morton's method; these findings concur with Grebing & Coughlin (2004). Morton's technique does not allow for measurement changes in the length of the first metatarsal due to angular deviation of the first metatarsal. The arc technique allows for variation in the angle of the first metatarsal (intermetatarsal angle) without influencing the relative lengths of the metatarsals. Angular malalignment in HR is not as common as HV but can occasionally present so Hardy and Clapham's method was chosen.

Patients presented with navicular cuneiform joint (NCJ) sagging (lateral view) and first MCJ angulation. The NCJ sag angle was difficult to quantify due to problems in defining bones and resulted in significant variation. Only observation of this parameter was included.

Body mass index (BMI) was calculated in order to determine its effect on the radiological parameters.

4.2.5: Radiological technique

To ensure the best possible comparability of X-rays, standard weight-bearing views were taken and rigid protocol adherence was followed (Smith et al, 1984).

Dorsal plantar (DP) and lateral views of both feet (exclusion criteria permitting) were used. Positioning of the feet and tube-head angle were the same for individual and bilateral X-rays (standard radiological protocol used). The only parameter that differed was where the X-ray beam was centered in the tarsus. For DP views the X-ray beam was craniocaudal angled (directed 15º from vertical) and aimed centrally between the feet, centred on the navicular. On individual feet it was centered on the intermediate cuneiform (Prieskorn et al, 1993). In each case the feet were parallel, and in line. Angle and base of gait was not used. It was considered that this may vary between patients and it was thought that these different positions may introduce unwanted variables between patients making comparisons between feet difficult. Film focus distance was 100cm; the kilovoltage and milliamperage were set at 55 and 6.3 respectively (Christman, 2003; Weijers et al, 2005). For lateral views a horizontal tube-head angulation of 90º, mediolateral directed beam, centered on lateral cuneiform with the film vertically placed, parallel to the second metatarsal (Christman, 2003).

4.2.6: Radiological evaluation

X-rays were evaluated/ interpreted using one of two standardized methods:

1. A film marker and standard full-circle plastic goniometer (calibrated to 2º increments for angles, 1mm increments for length) on plain film with a clear acetate sheet to protect it.

2. A digital workstation with high-resolution monitor computer picture archiving communication system (PACS) using a web image browser (Visage, version 4.0 SR1-SP1) to display lossless JPEG images.

Computerized X-ray measurement was undertaken in two centres whilst hand measured X-rays were evaluated in one other. The use of two methods enabled evaluation and comparison of techniques.

4.2.7: Radiological parameters

These were evaluated (Table 4.1) by one examiner to eliminate inter-observer error.

Area assessed	**Radiological criteria**
First MTPJ	Narrowing, symmetry, presence & severity of osteophytes, subchondral sclerosis, subchondral cysts, loose bodies.
Hallux	Proximal/distal phalanx length ratio, HAI°, IPJ OA, equinus angle.
Sesamoids	Type & shape. Distance between metatarsal head & proximal edge of sesamoids. Inter-sesamoid distance.
First metatarsal	Head shape. Length compared to 2nd & 3rd metatarsals. First metatarsal/ proximal phalanx length ratio. Sagittal plane position, first MCJ angle/ joint sag.
General features	MA°, lateral talus-first metatarsal angle. Transverse plane angulation second MTPJ, NCJ sag, medial/ intermediate cuneiform diastasis & gross alterations in tarsal morphology.

Table 4.1: Radiological measurements

HAI° = hallux abductus interphalangeus angle, MCJ = metatarsal cuneiform joint, MA° = metatarsus adductus angle, NCJ = navicular cuneiform joint.

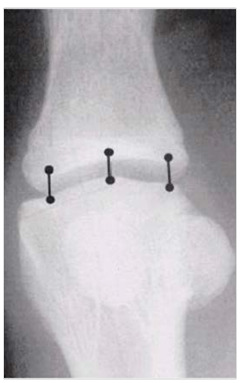
4.2.8: Radiological protocol

4.2.8.1: First MTPJ width

Two methods were used:

1) Joint space narrowing between bone end plates (not osteophyte bridging) was objectively graded as: none, definitely narrowed, severely narrowed or joint fusion at one point at least.

2) Summation method using six separate measurements. Three points were placed along corresponding joint surfaces of each view (Figure 4.2a & 4.2b). A perpendicular line connecting each pair of corresponding points was used to measure joint width in millimeters. Average joint width was calculated.



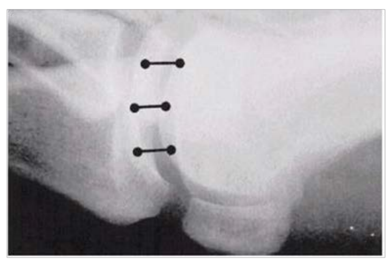


Figure 4.2a: DP view **4.2b: Lateral view**

First MTPJ symmetry (symmetrical, medial or lateral narrowing), periarticular subchondral sclerosis (none, minimal, moderate or severe); osteophyte location and severity (minimal, moderate or severe) were documented. Presence of loose bodies and bone cysts was also documented.

4.2.8.2: Hallux

The longitudinal axis of the proximal and distal phalanges was charted. Two metaphyseal-diaphyseal reference points were used. Next the length was measured in millimeters using the method described by Munuera et al (2007a), Figure 4.3.

Figure 4.3: Method of measuring hallucal phalanx

The hallucal length ratio was calculated by dividing proximal by distal phalanx length. The hallux abductus interphalangeus (HAI) angle was formed by intersection of the longitudinal bisections of the hallucal phalanges and graded as: absent, mild (>5º), moderate (>10º), severe (>15º). The hallux equinus angle was measured using lateral longitudinal bisections of the proximal phalanx and first metatarsal (Figure 4.4). Hallux equinus is defined as <15º.

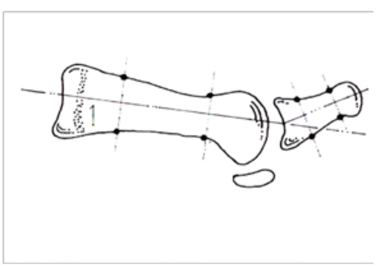


Figure 4.4: Hallux equinus angle

4.2.8.3: Sesamoids

Sesamoid morphology was documented as: normal, irregular/ hypertrophic, cystic, osteopaenic or bi/ tri/ quadripartite. The distance between the sesamoids (distal end) and metatarsal head (dorsal plantar view) was calculated. A line tangential to the distal articular surface of the first metatarsal head and perpendicular to its longitudinal axis was drawn. A line was drawn at the articular surface of the first metatarsal head perpendicular to its longitudinal axis. The distance from this line to the distal end of each sesamoid was measured in millimeters and the inter-sesamoidal distance (ISD) was calculated as the shortest distance between the sesamoids, to the closest 0.5mm (Figure 4.5).

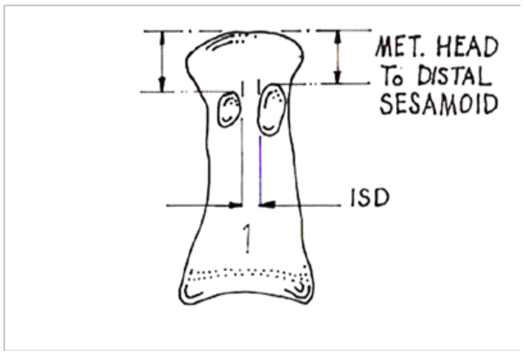


Figure 4.5: Sesamoid distance from metatarsal head and ISD

4.2.8.4: First metatarsal head morphology

This was documented as: oval, chevron or flat (Figures 4.6a – 4.6c). If flat, the degree of flatness was graded as: minimal, moderate or severe.

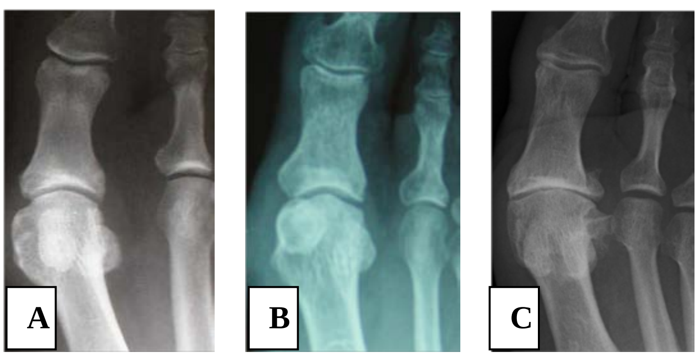


Figure 4.6: Metatarsal head shapes - a: Oval, b: Chevron, c: Flat

4.2.8.5: First metatarsal length

The longitudinal bisection line was measured in millimeters using the method described by Munuera et al (2007a) (Figure 4.7). The first metatarsal/ proximal phalanx length ratio was calculated by dividing first metatarsal by proximal phalanx length.

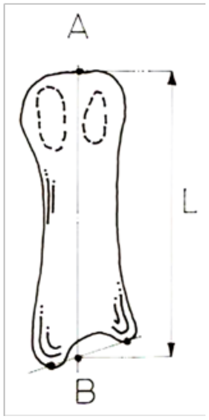


Figure 4.7: Method for measuring first metatarsal length

4.2.8.6: First metatarsal length compared to 2nd & 3rd metatarsals

Relative metatarsal measurement (protrusion distance) is a comparative measurement where the lengths of the metatarsals are compared with a specified point in the tarsus. The method was used as it is not influenced by increased 1-2 intermetatarsal angle or metatarsus adductus. The same method cannot be reproduced by computer software so an absolute (complete) metatarsal measurement was required for digitized X-rays.

Plain X-rays (relative measurement): A modified Hardy & Clapham (1951) method was used. A transverse tarsal line was made by bisecting the lateral base calcaneocuboid joint and medial base talonavicular joint. The second metatarsal longitudinal axis was marked using two metaphyseal-diaphyseal reference points. The point where the second metatarsal axis intersected with the transverse tarsal line acted as the center of rotation for the axis. The axis line was rotated (using a compass) and three arcs drawn, at the most distal extent of the first, second and third metatarsal heads. This enabled the protrusion distance (relative measurement) between first and second, and first and third metatarsals to be measured in millimeters using a perpendicular line drawn between the three arcs (Figure 4.8). A positive value indicates a longer first metatarsal relative to second and third metatarsals and a negative value indicates a shorter first metatarsal. Measurements within 1mm of each other were considered equal.

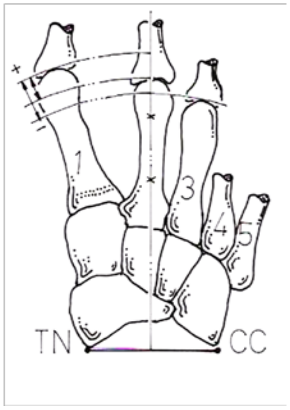


Figure 4.8: Relative metatarsal protrusion measurement

Digitized X-rays (absolute measurement): The method described by Munuera et al (2007a) was used (Figure 4.9). A perpendicular line was drawn between the respective horizontal lines and measured in millimeters to calculate the difference in lengths between first and second and first and third metatarsals. A positive value indicates a longer first metatarsal and a negative value indicates a shorter first metatarsal. Measurements within 1mm of each other were considered equal.

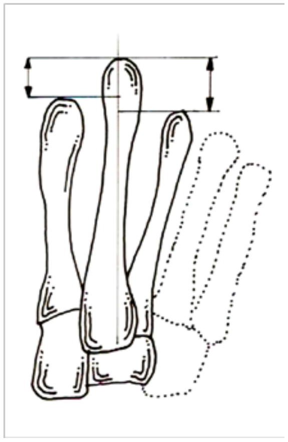


Figure 4.9: Measurement of absolute metatarsal length

4.2.8.7: First metatarsal sagittal plane position

The sagittal plane position of first metatarsal relative to the second metatarsal was made. The difference between the distal dorsal metaphyseal cortex (head-neck junction) of the first and second metatarsals (lateral X-ray) was measured. A perpendicular line was drawn between the two dorsal cortices, and the difference measured in millimeters (Figure 4.10). A positive value indicated a more elevated first metatarsal.

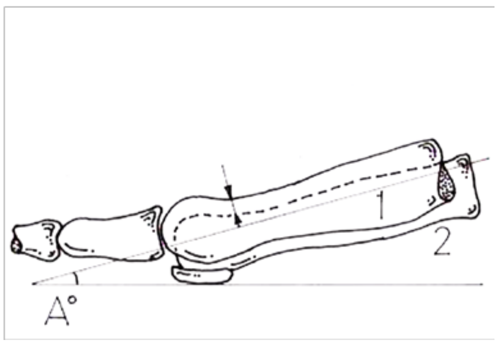


Figure 4.10: First metatarsal sagittal plane position

4.2.8.8: First metatarsal declination angle

The lateral longitudinal axis of the first metatarsal (using mid-metaphyseal-diaphyseal reference points) relative to the plantar surface of the foot was used (Figure 4.10, Angle A). The line representing the plantar surface of the foot (on supporting surface) used intersecting reference points on the plantar calcaneus and medial sesamoid. Normal range = 19º-25º.

4.2.8.9: Talar declination angle

The lateral talus-first metatarsal (talar declination) angle formed between bisections of the talus and first metatarsal was measured (Figure 4.11). Normal = 0º (midline axis of talus and first metatarsal are in line).

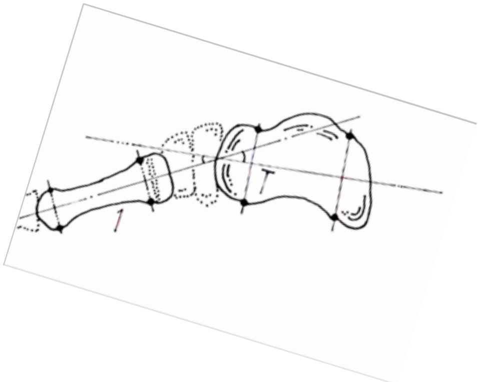


Figure: 4.11: Talar declination angle

4.2.8.10: First metatarsal cuneiform joint (MCJ)

First MCJ morphology and angle were documented. The angle was represented by intersection of the first metatarsal longitudinal bisection with a line perpendicular to the medial cuneiform distal articular surface (Figure 4.12).

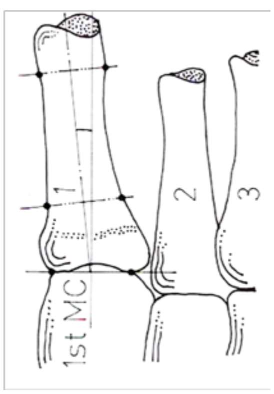


Figure 4.12: First MCJ angle

4.2.8.11: First MCJ and navicular cuneiform joint (NCJ) sagging

This was documented (observed not measured) using the lateral view. Normal joint positions were denoted by parallel dorsal cortices of bones on either side of the joints. A difference in height between the two bones dorsally with plantar joint gapping represented sagging.

4.2.8.12: General features

Metatarsus adductus (MA) was measured. A line parallel to the articular surface of the intermediate cuneiform base (Figure 4.13) represented the forefoot (FF) reference line (Engel et al, 1983). A line perpendicular to the forefoot reference line was drawn. The angle formed between the intersections of this perpendicular line and a longitudinal bisection of the second metatarsal represented the degree of MA (Figure 4.14), and graded: absent, mild (16º–19º), moderate (20º-25º), severe (>25º).

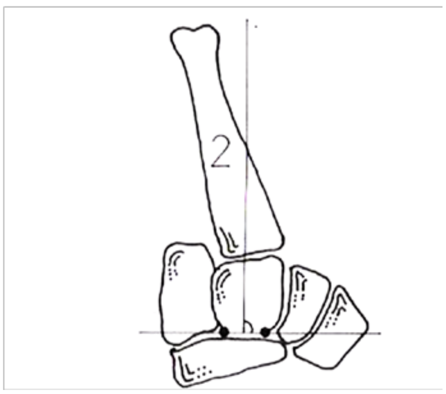


Figure 4.13: FF reference line

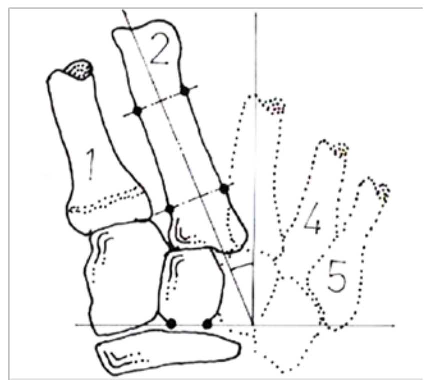


Figure 4.14: MA angle

Transverse plane angle deviation of the second MTP joint was measured. The angle formed between the bisection (proximal and distal metaphyseal–diaphyseal junctions) of the proximal phalanx second toe and the longitudinal bisection of the second metatarsal shaft (Figure 4.15). Lateral deviation of the second toe was denoted as negative, medial deviation positive. Normal value = 7º lateral (Roukis et al, 2002).

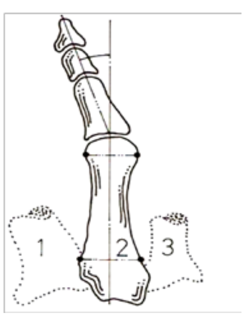


Figure 4.15: Transverse plane angle deviation second MTPJ

The presence of medial/ intermediate cuneiform diastasis and gross alterations in tarsal morphology were also documented.

4.3: Data analysis

Descriptive and comparative statistical analyses were performed using SPSS for Windows version 15.0 (SPSS Inc., 233 S. Wacker Drive, Chicago, IL 60606, USA). Standard chi-square analysis (x^2) was performed on categorical data. Pearson and binary correlation coefficients were used to evaluate the non-continuous data. Differences were considered to be significant when the *P* value was $\leq$0.05. As HR can affect one or both feet each foot (exclusion criteria permitting) was treated as an independent observation (separate case). The aim of this study was to correlate radiological data but not to make inferences regarding individual patients.

4.4: Results

4.4.1: Demographic findings

The findings of the current study demonstrate that HR was associated with increased female prevalence, bilateral involvement and older age of patients (Tables 4.2 and 4.3), agreeing with the findings of previous research (Coughlin & Shurnas, 2003a). Few patients in this study had adolescent onset. Overall patients were marginally overweight, indicated by a mean body mass index (BMI) of 25.93 Kg/m^2 (19.53-37.26) but with no gender difference for this variable (Table 4.2).

Patients (feet)	110 (180)
Gender	
Female	73 66%
Male	37 34%
Age (years)	
Mean (range)	52 (23-70)
Median	55
Age of onset, mean (range)	44 (14-68)
Mean duration of symptoms years (range)	6 (1-33)
BMI (kg/m^2), mean (range)	25.93 (19.53-37.26)
Male	26.48
Female	25.70
Trauma history (feet) %	(39) 22%
Unilateral	74%
Bilateral	26%

Table 4.2: Sample characteristics

Years	**18-30**	**31-40**	**41-50**	**51-60**	**61-70**
%	5.7	10.7	18.6	37.1	27.9
F:M ratio	7:1	7:1	1:1	2:1	3:1

Table 4.3: Age groups

The mean age of onset of symptoms (first MTPJ deformity or restriction/ pain) was 44 years. This is eleven years prior to the median age of presentation at a foot and ankle clinic (55 years) and supports the concept that this condition may be one of insidious development. Foot biomechanics, footwear type and activity levels may have some bearing on the development of symptoms and subsequent progression of disease. Epidemiological studies show that the pathological process of OA takes place several years before radiological detection is possible (Van Saase et al, 1989), so the prevalence of first MTPJ radiological change presented here is an underestimate of the actual prevalence of cartilage degeneration.

4.4.2: Radiographic

Table 4.4 shows general radiographic findings and Tables 4.5 and 4.6 data specific to each radiological parameter. The confidence interval (CI) illustrates the range of measures drawn from the study sample.

Mode of evaluation		Bilateral (patients) %	Unilateral (patients) %
Analog	Digitized	(70) 64%	(40) 36%
94 (52%)	86 (48%)		L (18) 45%, R (22) 55%

Table 4.4: X-ray data

Radiological parameters *(counts*)*	**Mean**	**± SD**	**95% CI**		**Range**
			Lower	**Upper**	
First MTPJ width	1.1 mm	0.79	0.93	1.41	0-3
Hallucal length ratio	1.20	0.16	1.16	1.26	1-1.80
Hallux abductus interphalangeus	18.2°	2.00	14.6	22.8	5°-30°
Hallux equinus angle	11.10°	3.68°	10.01	12.20	2-18°
Sesamoid distance: Tibial	7.2 mm	2.75	6.41	8.05	1-15
Fibular	8.7 mm	2.97	7.97	9.74	1-17
Inter-sesamoidal distance	1.36 mm	0.86	1.10	1.62	0-4
First metatarsal length	60.3 mm	6.0	58.54	62.02	50-76
First metatarsal length ratio	2.09	0.19	2.03	2.15	1.61-2.8
First met length compared to second: *Shorter (69), Equal (45), Longer (66)*	0.08 mm	3.01	-0.22	0.97	-5 to 10
First met length compared to third: *Shorter (26), Equal (23), Longer (131)*	4.73 mm	3.90	3.57	5.88	-4 to 15
Metatarsus primus elevatus	4.96 mm	2.02	4.35	5.56	0-11
First metatarsal declination angle	21.14°	2.14	20.5	21.78	16°-26°
Lateral talus-first metatarsal angle	1.30°	2.08	0.67	1.89	0-9°
First Metatarso-cuneiform joint angle:	9.68°	6.93	7.58	11.74	0-26°
Male	9.7°	____	_____	_____	_____
Female	9.1°	____	_____	_____	_____
Transverse plane angle second MTPJ (104)	3.93°	4.09	2.72	5.15	0-21°

Table 4.5: Mean Radiographic findings (Based on 180 feet)

* = nominal data, SD = Standard deviation.

Radiological parameters	**Count**	**Percentage**
First MTPJ space:		
None	39	22%
Definitely narrowed	40	22%
Severely narrowed	63	35%
Joint fusion one point	38	21%
First MTPJ symmetry:		
Symmetrical	102	57%
Medial narrowing	32	18%
Lateral narrowing	46	25%
Subchondral sclerosis:		
None	22	12%
Minimal	62	34%
Moderate	67	37%
Severe	29	16%
First MTPJ osteophtyes:		
None	30	17%
Lateral only	22	12%
Dorsal only	7	4%
Lateral + dorsal	70	39%
Medial + dorsal	7	4%
Lateral + medial	27	15%
Lateral + medial + dorsal	17	9%
Osteophyte severity:		
Minimal	56	31%
Moderate	84	47%
Severe	40	22%
Metatarsal head shape:		
Oval	49	27%
Flat	61	34%
Chevron	70	39%

Severity of flatness where flat:		
Mild	51	29%
Moderate	79	43%
Severe	50	28%
Sesamoid changes:		
Normal	63	35%
Irregular/ hypertrophic	54	30%
Cystic	28	15%
Bi/tri/quadripartite	23	13%
Atrophic	12	7%
First MCJ position:		
Flat	57	32%
Angled	123	68%
First metatarso-cuneiform joint sag	7	5%
Navicular-cuneiform joint sag	55	31%
Second metatarsal-intermediate cuneiform joint OA	22	12%
Metatarsus adductus:		
Absent	97	54%
Mild (16°-19°)	42	23%
Moderate (20°-25°)	25	14%
Severe (>25°)	16	9%
Medial-intermediate cuneiform diastasis	101	56%

Table 4.6: Categorical & nominal radiological findings (Based on 180 feet)

Loose bodies were found in 23 (13%) first MTPJ's, subchondral bone cysts in 45 (25%) metatarsal heads and 38 (21%) proximal phalanx bases. Hallucal IPJ OA was rarely associated with HR and present in 19 (11%) feet.

Differences in tarsal morphology (Table 4.7) are presented in 32 feet (18%).

Radiological feature	Count	Percentage
Enlarged medial cuneiform	2	1.1%
Accessory navicular:		
Type I	1	0.5%
Type II	4	2.2%
Type III	10	5.5%
Os supra naviculare	3	1.7%
Os peroneum	2	1.1%
Hallucal IPJ accessory ossicle	3	1.7%
Talonavicular OA	4	2.2%
Spurred facet first metatarsal lateral base	3	1.7%
TOTAL	32	17.7%

Table 4.7: Differences in tarsal morphology

Correlation	Result
First MTPJ space narrowing DP & lateral view	$N = 141, r = 0.98, p = 0.01$
Subchondral sclerosis & loss of 1st MTPJ space	$N = 158, r = 0.76, p = 0.01$
Subchondral sclerosis & MPE	$N = 158, r = 0.29, p = 0.01$
Severity of 1st MTPJ osteophytes & loss of joint space	$N = 124, r = 0.50, p = 0.01$
Increased HAI° & 1st MTPJ space reduction	$N = 133, r = 0.84, p = 0.05$
MPE & severity of 1st MTPJ narrowing lateral view	$N = 20, r = -0.29, p = 0.05$
MPE & severity of 1st MTPJ narrowing DP view	$N = 20, r = -0.28, p = 0.05$
First metatarsal declination angle & MPE	$N = 124, r = 0.59, p = 0.01$
Second MTPJ transverse plane angle & direction	$N = 104, r = 0.72, p = 0.01$
Increased metatarsus adductus & increased second MTPJ transverse plane angle	$N = 83, r = 0.42, p = 0.01$

Table 4.8: Correlations for radiological parameters

Variables	**Result**
First MTPJ space narrowing and HAI	$X^2 = 10.59$, $df = 2$, $p < 0.005$
Severity of osteophytes and HAI	$X^2 = 5.59$, $df = 4$, $p = 0.234$
Severity of osteophytes and JSN	$X^2 = 22.04$, $df = 7$, $p < 0.002$
Joint space symmetry and HAI	$X^2 = 2.36$, $df = 3$, $p = 0.40$

Table 4.9: Chi-square analyses

4.5: Discussion

4.5.1: Radiographic findings

In the present study analysis was undertaken at the point of referral. Bilateral involvement presented in 70 (64%) patients (Table 4.4), which may reflect the predominance of older patients (Table 4.3) rather than the true incidence as, with the passage of time, a higher percentage of patients are likely to exhibit bilateral disease. It may also reflect the type of clinic (surgical) from which patients were taken. Conservative management may delay attendance for a surgical opinion by which time, although only one side is severe enough to warrant surgery, bilateral involvement may present.

4.5.1.1: First MTPJ

All patients were clinically diagnosed with HR and presented with varying degrees of severity. A loss of first MTPJ width (Table 4.5) was found in 78% of feet (Table 4.6) with a mean of 1.1mm (0-3mm) with 35% severely narrowed. The remaining 22% of patients with no loss of joint space represent early clinical stage HR in which no radiological joint changes were present. As pathological process precedes radiological detection (Van Saase et al, 1989) (subchondral bone changes precede loss of joint space) a stage in clinical HR may exist which precedes radiological joint space loss. A strong correlation was found between first MTPJ space narrowing on the dorsal plantar (DP) and lateral views (r = 0.98, p = 0.01) which was statistically significant. This was an interesting observation bearing in mind that the first MTPJ is not a ball and socket joint and that joint space may differ between views because of variations in metatarsal head shape between the transverse plane (DP view) and frontal plane (lateral view).

Normal joint space symmetry was found in 102 (57%) feet. It was expected that asymmetrical joint changes would be more commonly associated with more severe HR or hallux valgus rigidus. In this study concurrent presentation of HV and HR was not common.

Chi-square analysis of joint space narrowing and hallux abductus interphalangeus (HAI) revealed a significant finding ($p<0.005$) whereas for joint space narrowing and joint space symmetry there was no statistical significance. Whilst these findings indicate a relationship between the parameters this is not necessarily a causal relationship.

Assessment of periarticular subchondral sclerosis was subjective and difficult to quantify. The severity of first MTPJ sclerosis increased with loss of MTPJ space (Table 4.6) with 67 (37%) of feet having moderate sclerosis. There was a correlation between sclerosis and loss of joint space ($r= 0.76$, $p= 0.01$). A weak correlation between sclerosis and MPE ($r= 0.29$, $p= 0.01$) was found, this concurs with Coughlin & Shurnas (2003a) who also found a weak correlation ($r= 0.5$, $p= 0.01$). In some cases sclerosis of the proximal phalanx base was an artifact i.e. due to superimposition of bones (plantar flexed proximal phalanx) or osteophytosis.

Osteophytes were predominantly found on the lateral and dorsal aspects of the first MTP joint in 70 (39%) feet and were moderately severe in 84 (47%) feet (Table 4.6). The severity of first MTPJ osteophytes were correlated with a loss of joint space ($r=0.50$, $p=0.01$). Chi-square analysis of severity of osteophytes and HAI revealed no significant finding ($p=0.234$) but there was a significant relationship between severity of osteophytes and joint space narrowing ($p<0.002$). This relationship is not necessarily causal. Joint pain has been strongly associated with the presence and size of osteophytes in knee OA studies (Creamer et al, 1999).

Loose bodies were only found in 23 (13%) first MTPJ's. This is comparable with other researchers' results 17% (Roukis et al, 2002; Coughlin & Shurnas, 2003a).

In this study the incidence of subchondral cysts was low: 36 feet (25%) metatarsal head and 30 feet (21%) proximal phalanx. This was lower than expected considering the profile of patients but may suggest a different process of subchondral bone change in HR compared to other forms of OA.

4.5.1.2: Hallux and IPJ

In this study the proximal phalanx was found to be longer than the distal phalanx (mean hallucal length ratio of 1.20). Another study has found similar results when comparing HR with non-HR patients (Munuera et al, 2007b). Five patients presented with a radiologically short proximal phalanx. This was considered to be an artifact due to proximal phalanx plantar flexion secondary to FHB spasm in patients with early joint changes or elevation of the first metatarsal in those with more advanced joint changes. Both resulted in the metatarsal head overlying the base of the proximal phalanx giving the impression that the proximal phalanx was short. The hallucal length ratio may differ in patients with HAI due to a lateral twist in the proximal phalanx shaft. Overall hallucal length may be a factor contributing to HR. This is supported by others who compared HR with non-HR patients and found a longer hallux in the HR group (Munuera et al, 2007b). It was concluded that where there is increased length a proportional increase in girth (squaring) of the proximal phalanx base is likely. This, combined with flat metatarsal head morphology, may play some part in restricting first MTPJ dorsiflexion in HR (Munuera et al, 2007b).

The hallux abductus interphalangeus angle (HAI°) averaged 18.2°. In 133 feet (74%) the HAI° was greater than normal (where normal $\leq$10°). There was a strong correlation between an increased HAI° and first MTPJ space reduction (r= 0.84, p= 0.05). It is hypothesized that the presence of HAI indicates a more progressive HR process and that with increased first MTPJ damage the first metatarsal head becomes flatter and more resistant to transverse plane movement, thus predisposing to an increased HAI°.

As 131 (73%) of feet had a flat or chevron shaped metatarsal head this may also contribute to resistance to transverse plane movement. A correlation between an increased HAI° and diminished HV or intermetatarsal angle was found by one author (Coughlin & Shurnas, 2003a) who used the theory of transverse plane resistance to explain this. Chi-square analysis of joint space symmetry and HAI revealed no significant finding (p=0.40).

The mean hallux equinus angle 11° (2-18°) was well below the normal range 16°-18° Rzona et al (1984) found. This is a useful radiological measure of HR as it may represent the amount of proximal hallucal plantar flexion generated by soft tissue spasm (capsular and FHB) or joint changes. The reliability of this measure is unclear and would therefore need to be tested.

4.5.1.3: Sesamoids

Sesamoid morphology was found to be abnormal in 117 (65%) feet with 54 (30%) presenting as irregular or hypertrophic. These sesamoid changes contribute to the pathological process in HR but are not a cause of it. Increased sesamoid length in HR was found, this finding concurs with other researchers (Durrant & Siepert, 1993; Camasta, 1996; Munuera et al, 2008). Abnormal sesamoid morphology and increased length is attributed to excessive traction exerted by the retracted FHB and is likely to restrict first metatarsal plantarflexion contributing to reduced first MTPJ extension, quality of motion and pain. It may also be attributed to the increased pressure a longer first metatarsal exerts on the sesamoids. Increased sesamoid length may be an artifact in MPE where sesamoids can show a ground projected image larger than a normal first metatarsal position as they are more parallel to the ground (Munuera et al, 2008). As MPE is a secondary change seen in advancing grades of HR this is likely to be a factor associated with more severe cases.

The findings of this study suggest that proximal sesamoid displacement in HR may be due to FHB spasm (guarding response to pain) or contracture secondary to joint stiffness. Logically this may be more prevalent in the later phase of HR i.e. in older patients where the condition has developed over time and is more advanced. This sample was more likely to be influenced by such findings as the older age range predominated. The tibial and fibular sesamoid distance from the metatarsal head was used to measure proximal sesamoid displacement. Yoshioka et al (1988) (without giving specific values) and Munuera et al (2008) found that the tibial sesamoid is closer to the metatarsal head than the fibular sesamoid. Yoshioka et al (1988) proposed that this is because the tibial sesamoid is usually larger, more elongated and has a shorter sesamophalangeal ligament (Yoshioka et al, 1988). The findings of this study concur, in that, the mean tibial sesamoid distance was 7.2mm ± 2.75 (1-15) and fibular 8.7mm ± 2.97 (1-17). This is greater than that found by Prieskorn et al (1993) who evaluated 100 paired feet without foot pathology (tibial sesamoid distance 4.9 ± 1.8mm, fibular sesamoid distance 7.6 ± 1.9mm). The findings of the present study are comparable with those of Roukis et al (2002) who found a mean tibial sesamoid distance 5.8 ± 1.8mm (range 2-9mm) and mean fibular sesamoid distance 8.0 ± 1.8mm (range 0-12mm) and Munuera et al (2008) who found a mean tibial distance 4.7mm ± 1.8 and mean fibular distance 6.2mm ± 1.7. The difficulty in comparing the findings of the present study with studies examining normal feet is that the methodology used was not comparable. It is not possible to draw firm conclusions as measurement of sesamoid distance from the first metatarsal head is influenced by the first metatarsal length. For example, a sesamoid located 10mm from the joint space in a metatarsal measuring 60mm would not have the same significance as in one that measures 50mm. By expressing the measurement as a percentage of first metatarsal length this factor could be taken into account. The findings of the present study do not concur with those of Munuera et al (2008), this may be due to the different age profile between the studies with much younger patients (mean age 23 yrs) used by Munuera et al (2008). Proximal sesamoid displacement appears to be a late effect. The value of this radiological parameter needs further investigation. Evaluating sesamoid position in early-stage HR and monitoring its evolution in the same patients over time to observe how sesamoid distance increases with severity.

Inter-sesamoidal distance was found to be difficult to measure due to merging of the inner edge of the sesamoids with the first metatarsal head trabeculae or in sesamoid osteopaenia (due to immobility or fusion with metatarsal head). The reliability of this measurement could not be guaranteed.

4.5.1.4: Metatarsal head shape

Of the 180 feet 49 (27%) had an oval metatarsal head shape, 70 (39%) chevron and in 61 (34%) it was flat. For individual patients with bilateral HR, joint shapes were the same on both feet and thus 140 (78%) had a flat or chevron-shaped metatarsal head. In this study an association between a flat or chevron-shaped metatarsal head and HR presented. Of those with a flat metatarsal head, 79 feet (43%) had moderate severity of flatness with the remainder being equally distributed between minimally and severely flat. Whilst these findings concur with other researchers (Coughlin & Shurnas, 2003a), and the general hypothesized assumption that an association exists between HR and a flat or chevron-shaped metatarsal head (Mann & Clanton, 1988; Kurtz et al, 1999) firm conclusions cannot be made as the incidence of occurrence in the general population is unknown. Obviously with time and increasing severity of HR, joint flattening and widening (attributed to osteophytes formation) will occur (McMaster, 1978; Smith et al, 1984; Mann & Clanton, 1988; Kurtz et al, 1999; Mann et al, 1979). It is suggested that such joint shapes resist transverse plane deformity, predisposing to sagittal plane deformity and HR. Flat metatarsal head morphology can be seen in a healthy joint but such a joint shape can predispose to HR (Camasta, 1996). A strong correlation between an increased HAI° and first MTPJ space reduction ($r = 0.84$, $p = 0.05$) was found. With increased first MTPJ damage the metatarsal head becomes flatter, leading to a lack of sagittal plane movement, which may result in increased transverse plane IPJ movement and subsequent HAI deformity.

A small proportion of the unilateral HR patients had X-rays of the asymptomatic foot. In these cases it was apparent that first metatarsal head shape differed between the HR and non-HR foot. The metatarsal head shape was predominantly oval in the non-HR foot. Consequently different first metatarsal head shape may result in different biomechanical joint function. Although these findings suggest a trend the numbers of patients where such a comparison was possible was too small to enable definitive conclusions to be drawn.

Changes in metatarsal/ proximal phalanx girth and head trabecular pattern were observed but not measured and may reveal valuable information about function. A long first metatarsal may constrain first metatarsal plantarflexion at propulsion promoting changes in first metatarsal head pressure. In addition if the joint is stable in the transverse plane (flat or chevron morphology) excessive joint compression may be generated at propulsion. These pathological changes in bone pressure during function may modify first metatarsal/ proximal phalanx girth and head trabecular pattern.

4.5.1.5: Absolute or relative first metatarsal length and comparative length to second metatarsal

The mean first metatarsal length ratio of 2.09 demonstrates that, in most cases, the first metatarsal is about twice the length of the proximal phalanx. The relevance of first metatarsal length in HR is unclear. Multiple pathologies of the foot caused by metatarsal parabola malalignment (excessive shortness or length) of one or more metatarsals have been previously reported (Morton, 1935; Besse et al, 2002; Beeson, 2002; Maestro et al, 2003; Barouk, 2005; Dominguez et al, 2006). A long first metatarsal has been implicated in the development of HR (Villadot, 1973;

Chang, 1996; Ronconi et al, 2000), with the incidence varying between 0 and 60% (Jack, 1940; Bingold & Collins, 1950; Mann & Coughlin, 1979; Drago et al, 1984; Munuera et al, 2007a). The method of measurement appears to influence the reported incidence of a long first metatarsal (Munuera et al, 2007a; Coughlin & Shurnas, 2003a). Some authors express first metatarsal length as a percentage of the total length of the second metatarsal (Tanaka et al, 1995 & 1997; Munuera et al, 2007a). An in vitro study speculated that the lateral view provides better accuracy than the DP view for measuring absolute first metatarsal length and found that changing the tarso-metatarsal angle shortened the DP length by 19% (Perry et al, 1992). A modified version of the method described by Hardy & Clapham (1951) was used in this study (Section 4.2.8.6) as it was not found to be influenced by metatarsus adductus or an increased 1-2 intermetatarsal angle. Some studies have actually reported on the comparative length of the first and second metatarsals (Jack, 1940; Bonney & MacNab, 1952; Drago et al, 1984; Schweitzer et al, 1999; Bryant et al, 2000; Coughlin & Shurnas, 2003a; Munuera et al, 2007a) but no studies have reported on the comparative length of the first and third metatarsals.

This study demonstrated a shorter first metatarsal (38%), equal metatarsal length (25%) and longer first metatarsal (37%) when compared to the second metatarsal. The incidence of a long first metatarsal in HR was no more common than that found by Harris & Beath (1948) who examined 7167 asymptomatic military recruits. Coughlin & Shurnas (2003a) found a smaller proportion of feet (28%) with a long first metatarsal. In the present study there was no significant difference in the relative metatarsal length of HR patients unlike that found by other studies (Jack, 1940; Bingold & Collins, 1950; Mann et al, 1979; Drago et al, 1984; Munuera et al, 2007a) nor was there any correlation between increased first metatarsal length and severity of HR. This concurs with the findings of other researchers (Byant et al, 2000; Munuera, 2007a) but differs from a study where non-HR feet were measured (using Hardy & Claphams method) where it was found that the first metatarsal relative to the second metatarsal had a mean protrusion of +1.88mm (Dominguez et al, 2006). The sample characteristics of Dominguez's study i.e. non-HR and mean age (22 years) may have been responsible for this. A later study (Munuera et al, 2007a) which examined early hallux limitus (mean age 23 years) suggested that increased first metatarsal length presents in younger subjects and, that in older subjects with more advanced HR, the metatarsal length could be altered (shortened) by degenerative first MTP joint changes and metatarsal head flattening (Munuera et al, 2007a). A different pathogenesis between young HR and old HR may also be responsible.

One disadvantage of using digitized X-rays was that the available computer software was not able to measure relative metatarsal lengths. An alternative method was adopted where absolute values were measured. Although measurement of individual absolute metatarsal length has been shown to be reliable (Munuera et al, 2007a) it does not allow for the effects of metatarsus adductus or increased 1-2 intermetatarsal angle.

4.5.1.6: Biomechanical considerations of first metatarsal relative to third metatarsal length

It is hypothesized that in a normal metatarsal parabola, the first metatarsal is equal in length to the third metatarsal with the second metatarsal longer than both (Bøjsen-Moller, 1979a). In the present study, the comparative lengths of the first and third metatarsals revealed that the first metatarsal was longer in 131 (73%) feet (mean 4.73mm). It is hypothesized that the relative length differential between the first and third metatarsals may predispose to HR due to altered forefoot biomechanical function. It is determined that the second metatarsal acts as a fulcrum with weight transferring from the lateral to medial forefoot around the second metatarsal fulcrum (Bøjsen-Moller, 1979a). For this to occur efficiently the first metatarsal should be the same length as the third with the second longer than both. It is postulated that an abnormal metatarsal parabola may result in disruption of weight-bearing through the forefoot with jamming of the first MTPJ. The mechanism for this pathology may be explained by the work of Bøjsen-Moller (1979b) who described two axes within the foot. The oblique axis (low gear) represented by a line passing through the second to fifth MTPJ and the transverse axis (high gear) represented by a line passing through the first and second MTPJ.

During propulsion through first and second MTPJ's (high gear); the plantar fascia tightens and first MTPJ dorsiflexes. This supports the windlass mechanism of Hicks (1954) who, like Bøjsen-Moller (1979a) and Kappell-Bargas et al (1998), found that when the plantar fascia tightened, the first metatarsal would plantarflex against the ground under the stabilizing influence of the peroneus longus tendon. During propulsion through second to fifth MTPJ's (low gear), the plantar fascia fails to become taught medially and the first metatarsal dorsiflexes as the stabilizing effect of the windlass mechanism and peroneus longus is lost. The hallux plantar flexes to provide some stability at final propulsion to the medial side of the foot. This concurs with aspects of the sagittal plane facilitation and centre of pressure theories (Payne & Dananberg, 1997; Fuller, 2000). Where the first metatarsal is long, high gear toe-off is impossible to achieve because there is only one axis extending from the first MTPJ through to the fifth. Moreover, the first metatarsal cannot plantarflex because its length means it cannot rotate over the ground but instead is jammed into dorsiflexion. In this study only 38% of feet had a second metatarsal longer than the first, while 131 (73%) feet had a first metatarsal that was longer than the third metatarsal, thus modifying the low gear axis and subsequent forefoot function. The implication is that the relative length differential between the first and third metatarsals may be of considerable aetiological significance in HR however, firm conclusions cannot be made as the incidence of occurrence in the general population is not known.

Various anatomical differences have been described between the male and female foot skeleton (Smith, 1997; Ferrari et al, 2004; Dominguez, 2009). The present study demonstrated differences in relative metatarsal length between genders which concur with these studies. These may have possible repercussions on the biomechanical patterns by gender.

4.5.1.7: Metatarsus primus elevatus (MPE)

The importance of MPE in HR was first proposed by Lambrinudi in 1938 and later endorsed by others (Jack, 1940; Bingold & Collins, 1950; Kessell & Bonney, 1958; Cavolo et al, 1979; Cohen & Kanat, 1984; Drago et al, 1984; Chang, 1996; Ronconi et al, 2000; Geldwert et al, 1992; Lundeen & Rose, 2000), however, more recently radiographic evidence to the contrary has been reported (Meyer et al, 1987; Horton et al, 1999; Bryant et al, 2000). In this study MPE, first metatarsal declination angle and lateral talus-first metatarsal angle were used as measures of first metatarsal sagittal plane position. It was found that 89% of patients had radiographic measurements for MPE that were within a normal range ($\leq$8 mm) (Horton et al, 1999) with a mean MPE 4.96mm ± 2.02 (0-11). There were only 10 cases of up to 11mm of MPE identified. The findings of this study concur with those of other authors (Di Napoli, 1993; Horton et al, 1999; Coughlin & Shurnas, 2003a) and suggest that MPE is a secondary change resulting from an arthritic MTPJ and that as HR progresses so does first ray elevation (analogous with the increased intermetatarsal angle associated with increasing severity of hallux valgus) (Coughlin & Shurnas, 2003b). Surprisingly a weak correlation was found between MPE and severity of first MTPJ narrowing lateral view (r = -0.29, p= 0.05) and DP view (r = -0.28, p= 0.05) unlike others (Coughlin & Shurnas, 2003a) who found a stronger correlation (r = 0.5, p = 0.01). The mean first metatarsal declination angle was 21.14° ± 2.14 (16°-26°) which falls within the normal range 19°-25° (Bryant et al, 2000). This finding concurs with several researchers (Meyer et al, 1987; Horton et al, 1999; Bryant et al, 2000). The mean lateral talus-first metatarsal angle was 1.3° ± 2.08 (0-9°) also within the normal range

(0-4°). A good correlation was found between first metatarsal declination angle and MPE ($r = 0.59$, $p = 0.01$), similar to the findings of Coughlin & Shurnas (2003a) ($r = 0.60$, $p = 0.03$). No correlation between MPE and metatarsus adductus was found. Again this concurs with other findings of researchers (Roukis et al, 2002, Coughlin & Shurnas, 2003a).

The theory of functional hallux limitus has been proposed as a cause of HR (Di Napoli, 1993; Dananberg, 1993; Payne & Dananberg, 1997). In this study and that of Coughlin and Shurnas (2003a) the mean MPE and mean first metatarsal declination angles fall within normal limits. These findings therefore question the concept of functional hallux limitus.

4.5.1.8: Tarso-metatarsal and inter-tarsal joints

The first MCJ position was found to be angled in 131 feet (73%) with a mean joint angle of 9.68° (±6.93). The mean angle was possibly not a good representation of the data as the standard deviation was found to be large. This angle increased with age from a mean of 6.9° in the youngest age group (18-30 yrs) to 10.57° in the oldest (61-70 yrs). Hyer et al (2004) found a similar trend with increasing age. In the current study the mean angle in males (9.7°) was marginally greater than females (9.1°). Hyer et al (2004) found a greater mean angle in females but their method was not comparable as it consisted of measurements from (77) dry bone samples.

The first MCJ angle was difficult to interpret due to overlapping contours on the DP view, a finding also reported by Dykyj et al (2001). The position of the first ray on this view may have created the appearance of an increased angle of obliquity, a finding supported by other researchers (Brage et al, 1994; Sanicola et al, 2002). It is anticipated that bigger first MCJ angles would be associated with hallux valgus. First MCJ OA was seen in 11 (8%) feet and first MCJ sag only found in a few feet 7 (5%). This concurs with Jack (1940) who describes the first MCJ as a flat stable joint with a limited range of motion.

Using lateral weight-bearing X-rays, Jack (1953) described three anatomical types of flat foot based on the level of the joint break within the medial column (talar-navicular, navicular-cuneiform or both). The navicular cuneiform joint (NCJ) sag was the commonest seen (Jack, 1953). In this study 55 (31%) feet presented with NCJ sag. The significance of this finding in HR is supported by recent research linking hindfoot valgus with first MTPJ OA (Mahiquez et al, 2006).

Second metatarsal cuneiform joint OA was found in 22 (12%) patients in this study. It has been suggested that patients with a functionally short first ray (or functionally long second) have radiographic evidence of overload stresses on the second metatarsal segment consisting of cortical and/ or shaft thickening or a gap between the first and second cuneiforms (Morton, 1930). These stresses may accumulate over time and result in arthrosis. In this study 69 (38%) of feet were found to have a second metatarsal longer than the first metatarsal. Davitt et al (2005) suggested a clear association between midfoot arthrosis and a long second metatarsal and suggests a possible mechanical aetiology.

Metatarsus adductus was absent in 97 (54%) of feet but 42 (23%) had a mild metatarsus adductus angle (MA°) of 16°-19° (normal = 15°). In 25 (14%) of feet the MA was between 20°-25° and only 16 (9%) feet had a severe MA (>25°). There was no statistically significant association between HR and MA, however the overall percentage of patients with metatarsus adductus 83 (46%) was greater than that seen in the general population (0.1%) (Wynne-Davies, 1964).

It is speculated that metatarsus adductus may increase medial transverse plane pressure at the first MTPJ increasing the risk of HR.

4.5.1.9: Transverse plane angle second MTPJ

This was present in 104 (58%) of feet (mean 3.93°) and a strong correlation found between second MTPJ transverse plane angle and direction (r = 0.72, p = 0.01). Medially deviated second MTPJ's were seen in 44 (31%) with 38 (27%) laterally deviated and the remaining 61 (43%) rectus. Transverse plane drift of the second MTPJ is considered a subtle indicator of first ray hypermobility and can be promoted by flatfoot or medial column instability (NCJ sag). This can lead to second MTPJ synovitis with attenuation of the lateral collateral ligament, allowing unopposed pull of the first lumbricale, thereby creating medial angulation of the second toe. In subjects presenting with an asymptomatic second MTPJ, the second toe angulation may result from forceful contraction of flexor digitorum longus (FDL) in an attempt to provide medial column stability. Roukis et al (2002) found similar findings with increasing HR severity. In the current study a moderate correlation was found between patients with increased metatarsus adductus and increased second MTPJ transverse plane angle (r = 0.42, p= 0.01).

4.5.1.10: Medial intermediate cuneiform diastasis (MICD)

MICD was first reported by Jack (1940) as a common feature in HR. It may be a result of increased transverse plane movement in compensation for reduced first MTPJ sagittal plane motion. In this study it presented in 101 (56%) of feet (Table 4.6). It has also been associated with a functionally short first ray (Morton, 1930). It is a difficult feature to assess and its presence is influenced by foot position. Medial cuneiform rotation may present its lateral angled surface giving the impression of a diastasis. Reduced bone density or metatarsus adductus may magnify this effect. Without normal values for comparison there is a temptation to consider any gap as being abnormally wide.

Gross alterations in tarsal morphology presented in 32 (18%) of patients (Table 4.7) but these differences were not found to be significant.

4.5.2: Which radiological parameters?

This study supports the inclusion of the following radiological parameters in a classification of HR to aid surgical decision-making (Table 4.10).

Radiological parameter	Statistical relevance in this study
First MTPJ	
Joint space narrowing (JSN)	JSN in 78% feet
Joint space symmetry	Asymmetrical joint space 43%
Sclerosis	JSN & sclerosis (r= 0.76, p= 0.01)
Osteophtyes	Severity & JSN (p=0.002)
Hallux	
Proximal phalanx (PP) length	78% long PP & increased base size.
HAI°	74% HAI° >10°. Chi-square JSN & HAI (p=0.005).
Equinus°	Mean angle 11° (normal 16-18°).
Sesamoid	
Morphology	65% abnormal (30% hypertrophic).
Displacement	Proximal > non-HR. Mean tibial 7.2mm ± 2.75; fibular 8.7mm ± 2.97mm.
Metatarsal head morphology	73% flat or chevron shaped.
First metatarsal length	73% longer than third metatarsal (mean 4.73mm).
Navicular cuneiform joint (NCJ) sag	31% NCJ sag.
Metatarsus adductus	46%: more common in HR than general population but no significant correlation with HR severity.
Second MTPJ deviation (transverse plane)	58% (mean 3.93). Correlation between second MTPJ angle and medial direction (r = 0.72, p= 0.01)

Table 4.10: Useful radiological parameters to consider

4.5.3: General radiological limitations

Difficulties associated with radiological evaluation of the foot may have influenced findings (Resch et al, 1995; Aster, 2004; Beeson et al, 2009c). Sources of error are related to the relationship of the roentgen tube, the object, and the film, such as tube-head angulation (Camasta, 1994), focus film distance (Venning & Hardy, 1951), where the X-ray beam is centred in the tarsus (Christman et al, 2001), distortion (Weijers et al, 2005) and foot position. Variation in first metatarsal sagittal plane position and declination angle can result from foot pronation or supination (Hlavac, 1967; Weijers et al, 2005). Previous publications may have unwittingly introduced unwanted variables by using angle and base of gait rather than a standardized foot position. Comparison with these studies has taken such factors into account.

The radiological measurement techniques used, though convenient, were far from refined and this study may have been constrained by their accuracy and reliability.

4.6: Conclusion

The purpose of this cross-sectional study was to document the key radiological parameters associated with HR. In doing this a number of limiting factors associated with radiological evaluation and, assessment of the foot was highlighted (Beeson et al, 2009c). Digitized X-rays provide an easier format for evaluation and for interpretation of the radiological features of HR.

Only certain radiological parameters were useful to evaluate HR. The incidence of some features was low (first MCJ OA) and therefore represented no significant association with HR, while others were either too time-consuming, too difficult to measure, or the reliability of their measurement (Coughlin & Freund, 2001; Beeson et al, 2008) (particularly angular) were in doubt (Hyer et al, 2004). Frontal plane sesamoid rotation may have a bearing on sesamoid tracking. Future assessment of this feature using a weight-bearing axial sesamoid view may provide a more reliable method (Lipscombe & Hennessy, 2007).

The findings of this research are based on the defined study population. HR was associated with female gender, bilateral involvement, older age groups, flat or chevron-shaped metatarsal head, longer proximal phalanx (with increased sized base), increased HAI angle and a first metatarsal longer than the third metatarsal. Unilateral involvement was more commonly associated with trauma. In bilateral cases a positive family history could not be concluded however, a properly constructed family study may prove such an association. Metatarsus adductus was more common in HR than the general population but a significant correlation was not found with HR severity. HR was not associated with MPE, increased first metatarsal length relative to second metatarsal and there were few patients with adolescent onset.

For radiological parameters of the foot to be considered valid for inclusion in a classification of HR their content validity needs to be firstly established by formal research (Beeson et al, 2008). The purpose of this research study was to establish such validity.

CHAPTER 5

RELIABILITY STUDY

5.1: Introduction

The surgical management of HR is predominantly based upon assessment of its clinical and radiological parameters. Measurements of such parameters are used to assess severity, monitor progress and direct management. The widespread use of these quantitative measurements hinges on an unstated belief in the reliability of such variables. One factor in determining which measurements to use, how they are used and the value of their inclusion in any classification system is their reliability. Angular measurements of radiographic and clinical parameters are influenced by measurement technique, including placement of reference points and the examiners' experience and ability. Studies have evaluated intra- and inter-rater measurement errors in hallux valgus (Salzman et al, 1994; Resch et al, 1995; Bryant et al, 2000; Coughlin & Freund, 2001; Chi et al, 2002; Condon et al, 2002; Schneider et al, 2003; Aster et al, 2004; Piqué-Vidal, 2006) but none have examined such errors in HR.

This study aimed to identify the reliability of clinical and radiological measurements and observations used to assess HR and establish the value of incorporating them into a HR classification framework.

5.1.1: Reliability

Reliability in clinical medicine is defined as the extent to which a measurement yields the same result on independently repeated trials, on the same subject, under the same conditions (Mathieson & Upton, 2008). It is an assessment of potential error within the system, and any chosen measure should be reliable (Suk et al, 2005). A measure with poor reliability contains a large amount of measurement error, is inconsistent, not dependable, and should not be used in clinical decision-making (Elveru et al, 1988).

5.1.2: Why is reliability important?

Reliability is an essential property of any classification system. If it is not reliable, then changes observed in patients used to classify the condition may be attributed to a problem inherent to the component measures of that classification system instead (Suk et al, 2005). The reliability of a system is assessed by both its reproducibility and internal consistency (Steiner & Norman, 1995).

5.1.2.1: Reproducibility

There are two forms of reproducibility: Inter-rater and intra-rater (test-retest). Inter-rater measures how closely examiner #1 agrees with examiner #2 using the same instrument and the same patient (Suk et al, 2005). Intra-rater measures the reproducibility when the same instrument is administered to the same patient by the same examiner on two different occasions (Polger & Thomas, 1995). When measuring the same thing twice the correlation between the two examinations will depend in part by how much time elapses between the two measurement occasions (Beaton, 2000). The shorter the time gap, the higher the correlation (Suk et al, 2005). The rater’s memory of the previous measure may also be influential.

5.1.2.2: Internal consistency

Internal consistency measures how consistent the questions/ observations are in the scale at measuring the same element (Bowling & Ebrahim, 2005).

5.2: Background / literature review

Comparisons of reliability coefficients in the foot are difficult because few investigators have used the same study design and a variety of statistical tests have been reported. Early investigations appear to overuse comparisons of mean values, which do not take into account compensatory errors (Stratford et al, 1984). Exclusive use of correlation coefficients should also be avoided because they do not take into account systematic variation of grading by different raters or in different measurements (Field, 2005).

5.2.1: Sources of measurement error

Reliability error estimates depend on many factors, including the person performing the test (examiner), the population being tested (examined) and the equipment (examination) (Allison, 2007).

5.2.1.1: The examiner

Experience in use of goniometers, consistent foot position and procedure can influence measurements (Elveru et al, 1988). Maintaining the desired joint position whilst identifying bony landmarks and manipulating the goniometer can be difficult. Angular measurements are reliant on the correct placement of points on bones for clinical and radiological assessment. Skin can move over bony prominences distorting readings and incorrect positioning can result in parallax error (Boone et al, 1978). Failure to use a zero-starting-position when recording angles, difficulty reading the scale or improper reading of the scale due to its inversion (likely to occur between 70° and 110° than at extremes of range) can result in error (Stratford et al, 1984). End-digit preference can be a potential error where the rater reads values that end with a particular digit (Ekstrand et al, 1982). When undertaking repeated measures, raters' expectation and anticipation of the next reading may influence error.

5.2.1.2: The examined

Mode or site of measurement and, differences in motivation, may account for measurement error on the part of the patient (Stratford et al, 1984). Reliability of ROM may vary with the type and severity of clinical problem and may differ from that of healthy patients (Gajdosic & Bohannon, 1987).

5.2.1.3: The examination

Error of the measuring device (goniometer) may be related to its calibration (2° or 5°), excessive wear resulting in loose pivot joints and worn incremental markings making them difficult to use and read. Use of different goniometers between readings can result in measurement error (Elveru et al, 1988). The environment can influence the measurement process i.e. inappropriate lighting (too little light or too much reflection) or a noisy disrupted setting.

5.2.2: Problems of goniometric reliability

Goniometric reliability is affected by measurement procedure and in the lower limb intra-rater measurement (over short period of time) is more reliable than inter-rater (Low, 1976; Boone et al, 1978; Rothstein et al, 1983; Elveru et al, 1988; Menz, 1995; Sun et al, 1997; Taranto et al, 2005).

There are considerable variations in established values and methods of determining first MTPJ ROM (Joseph, 1954; Kelikian, 1965; Giannestras, 1973; Low, 1976; Root et al, 1977; Mann, 1979; Sarrafian, 1983; Buell et al, 1988; Kilmartin, 1988; Greene & Hecknam, 1994; Norkin & White, 1995; Menz, 1995; Coughlin & Mann, 1999). Several studies found that inter-tester reliability improved when all examiners used consistent, well-defined testing positions, anatomical landmarks to align the goniometer and measurement methods (Watkins et al, 1991; Hart & Spector, 1995; Coughlin & Mann, 1999). Some researchers use the average (mean) of repeated measures to reduce the effect of individual fluctuations on variability of measurement (Low, 1976; Gajdosic & Bohannon, 1987; Riddle et al, 1987) whereas others considered one measurement to be sufficiently reliable (Elveru et al, 1988; Hart & Spector, 1995; Mantha et al, 2000).

Goniometer arm length may influence reliability. Short arm goniometers are recommended for small joints whereas longer arm goniometers reduce the effects of error in placement of the goniometer axis. Riddle et al (1987) reported no difference in reliability between large and small goniometers, however, this only referred to measuring shoulder joint ROM.

In practice measures of HR parameters may be made serially over time and often by more than one clinician. Therefore, both intra-rater and inter-rater reliability of these measurements must be known if they are to be used in clinical decision making.

5.3: Method

Intra-rater and inter-rater studies were undertaken to evaluate the reliability of clinical and radiological parameters in HR patients. These methods were chosen as they provide a quantitative means to determine measurements and observations within and between clinicians.

5.3.1: Participants

Two types of participants were used i.e. patients and raters:

Patients

Twenty patients aged 18-70 years with varying degrees of HR were used; both feet (exclusion criteria permitting). Patients were randomly selected (using computer-generated random number tables) from a podiatric surgery outpatient clinic. An invitation letter (Appendix 9) and study information sheet (Appendix 24) were sent to suitable patients giving time for consideration (> 24 hours) prior to inclusion in the study. Patients gave informed consent for access to their medical notes/ X-rays (Appendix 25).

Raters

A total of four raters were use in the studies (Table 5.1). The disciplines were chosen as they represent the key groups who manage HR and regularly use X-rays. One rater (Orthopaedic surgeon) fell ill and could not participate and was replaced with Podiatrist B.

Rater	**Intra-rater study:** ***Clinical & Radiological***	**Inter-rater study:** ***Radiological***	**Inter-rater study: Clinical**
Podiatric Surgeon	√	√ (Plain X-rays)	√
Podiatrist A	√	√ (Plain X-rays)	√
Rheumatologist		√ (Digitised X-rays)	
Podiatrist B		√ (Digitised X-rays)	

Table 5.1: Raters used for reliability studies

All raters had more than 10 years clinical experience in managing foot problems and were invited as they represent groups who regularly evaluate and manage HR. An invitation letter (Appendix 26) and study information sheet (Appendix 10) was sent to raters giving them time for consideration (>24 hours) prior to inclusion in the study. Raters gave informed consent (Appendix 27). All raters were given the same guidelines (Appendix 28) for taking measurements and making observations to ensure consistency when collecting data. Clarification on measurement techniques was given and raters allowed to practice until they felt confident. By using different professional groups it was felt that the reliability of the raters selected would be representative of the reliability that could be expected generally.

All raters were experienced in using both radiological measurement techniques, but for the purposes of time constraint, it was decided to allocate measurement of digitised X-rays to the Rheumatologist and Podiatrist B.

5.3.2: Inclusion / exclusion criteria

HR patients with restricted first MTPJ dorsiflexion (<65°) with either pain, deformity or both were included in the study. Careful preliminary examination of patients' clinical notes was undertaken to remove those possessing criteria of exclusion (Table 3.3). Detailed exclusion criteria were reviewed at the time of data collection.

5.3.3: Ethics

Studies involved human participants and their X-rays, thus ethical consideration was required and, granted by Leicestershire Northants Rutland Ethics Committee (Appendix 11) and Leicestershire Primary Care Research Alliance (Appendix 29). Copies of the signed consent form (Appendix 25) were given to patients and added to their hospital notes to confirm their involvement in the study and the patient's GP was informed of their involvement (Appendix 30).

5.3.4: Pilot study

A pilot study using two raters and two patients was undertaken. The methodology was found to be practicable and data produced in line with study aims and objectives. The rater guidelines were further refined to aid standardization of measurements and the data collection sheets layout improved (Appendix 31 and 32).
Accuracy of the goniometers was tested before the study by using each goniometer to measure 10 randomly chosen, computer-generated angles between 0 and 180 degrees drawn by a graphics plotter.

5.3.5: Instrumentation

Two standard full-circle plastic goniometers (Figure 3.1) were used for the measurement of joint angles and lengths (calibrated to 2º increments for angles and 1mm increments for length). Measurement to the nearest degree was made by interpolation when the cursor fell between two interval marks. There is, however, some latitude for end digit preference because the values are taken from a continuous scale and the observer must make a judgement when reading the cursor on the scale. Assessment to error of less than 1° would be suspect with this instrument (Statford et al, 1984).

5.3.6: Procedure

Clinics were arranged in the morning to avoid the influence of diurnal effects on data collection and the same rooms with the same level of lighting. No other clinics were running, so noise levels and disruption were kept to a minimum.

Measurement protocol was standardised for clinical (Section 3.2.5.2) and radiological (Sections 4.2.5, 4.2.8) data collection and represented a method of testing which could be found in a normal clinical setting. All parameters were measured independently by clinicians, and measurements repeated on two separate occasions (intra-rater). A time interval of more than 24 hours but less than four weeks was used between readings (without reference to previous ratings) to determine intra-rater reliability. The patient and X-ray order used for measuring HR parameters was changed between data collection sessions to avoid learning bias. For intra-rater sessions the raters were blinded to the results of the first session before the second testing session. The readings were compiled and reviewed only after all measurements were taken.

5.3.6.1: Clinical Protocol

Clinical parameters validated by an earlier study (Beeson et al, 2009b) were measured (Table 5.2) and observations made (Table 5.3).

- Passive first MTPJ ROM (dorsiflexion/ plantarflexion)
- Active first MTPJ dorsiflexion
- Hallucal interphalangeal joint hyperextension
- Hallux abductus interphalangeus
- Ankle joint dorsiflexion

Table 5.2: Clinical goniometric measures

- Magnitude & timing first MTPJ pain during active ROM
- Location of first MTPJ pain
- Hallucal frontal plane rotation
- Location of plantar callosities
- Second toe length compared to hallux
- Lesser MTPJ pain
- Gait at propulsion

Table 5.3: Clinical observations

Measurement scales for observed clinical parameters are presented in Table 5.4.

Magnitude first MTPJ pain	None	Mild	Moderate	Severe			
Timing of pain during active ROM	None	Beginning	Midway	End	All of		
Location first MTPJ pain	None	DB	Joint	Sesamoids	DC/ EHL	PP	Combination
Hallucal rotation	None	Valgus	Varus				
Callosity location	None	PMHIPJ	Second MTPJ	Third MTPJ	Fifth MTPJ	LB	
Second toe length compared to hallux	Longer	Equal	Shorter				
Lesser MTPJ pain	Never	Rarely	Some days	Most days	Everyday		
Gait at propulsion	Normal	MTJP	Supination	DHL	VTO	AOAT	Knee flexion

Table 5.4: Measurement scales for observed clinical parameters

DB = Dorsal bump, DC/EHL = Dorsal capsule/ Extensor Hallucis Longus, PP = Proximal Phalanx, PMHIPJ = Plantar medial hallucal interphalangeal joint, LB = Lateral border, MTJP = Midtarsal joint pronation, DHL = Delayed heel lift, VTO = Vertical toe-off, AOAT = Abductory or adductory twist.

A standardized protocol was used to collect clinical data using methods described in Section 3.2.5.2. Patients feet were not marked to aid consistent goniometer location for joint ROM measures because:

- It is not common practice.
- Skin marks require erasing between measurements so as not to influence inter-rater readings.
- The position of lines could be influenced by skin movement.
- Consistency of skin markings and goniometric readings compound error.

Passive first MTPJ range-of-motion (ROM) was measured using a modification of the method described by Greene & Heckman (1994).The proximal phalanx (medial mid-axis) and first metatarsal were used as reference points. The goniometer arms were placed in the zero-position prior to making each reading. Both dorsiflexion and plantarflexion (Figures 3.1a & 3.1b) were measured and total ROM calculated.

Active first MTPJ dorsiflexion was measured in stance using a goniometer. Subjects were asked to push forward onto the ball of the foot (avoiding supinating) to obtain maximum dorsiflexion. Sagittal and transverse plane position of the hallucal IPJ was measured using a goniometer. Ankle joint dorsiflexion was measured using the method described in Section 3.2.5.2, Figure 3.4.

5.3.6.2: Radiological Protocol

To ensure the best possible comparability of X-rays, standard weight-bearing views were taken and rigid protocol adherence was followed (Smith et al, 1984; Aslam et al, 2004). The radiological technique used was the same as that described in Section 4.2.5.

The order of the X-rays was randomised (using computer-generated random number tables with each reading to avoid bias).

Radiological measures of HR were collected using one of two methods:

1. A film marker and plastic goniometer on plain film with a clear acetate sheet to protect it.

2. A digital workstation with high-resolution monitor computer picture archiving communication system (PACS) using a web image browser (Visage®) to display lossless JPEG images for diagnostic interpretation.

X-rays were compiled in hard copy and electronic folders and identifying information removed.

The procedures used for measuring the radiological parameters were those described in Section 4.2.8 and validated by an earlier study (Beeson et al, 2009a). Measured (Table 5.5) and observed radiological parameters plus their measurement scales (Table 5.6) are detailed.

- First MTPJ space
- Joint space symmetry
- Length ratio – proximal/ distal hallucal phalanges
- Hallux abductus interphalangeus angle
- Hallux equinus angle
- Tibial/ fibular sesamoid distance from first MTPJ
- Intersesamoidal distance
- First metatarsal length
- First metatarsal/ proximal phalangeal length ratio
- Length first metatarsal compared to 2nd & 3rd metatarsals
- First metatarsal sagittal plane position
- First metatarsal declination angle
- First metatarsocuneiform joint angle
- Metatarsus adductus angle
- Lateral talus/ first metatarsal angle
- Transverse plane angulation second MTPJ

Table 5.5: Radiological goniometric measures in HR

First MTPJ space narrowing	None	Minimal	Moderate	Severe		
First MTPJ symmetry	Symmetrical	Medial Narrowing	Lateral narrowing			
Subchondral sclerosis	Present	Absent				
First MTPJ osteophyte position	None	Lateral	Medial	Dorsal		
First MTPJ osteophyte severity	None	Minimal	Moderate	Severe		
First MTPJ loose body	None	Lateral	Medial	Dorsal	Central	
Sesamoid morphology	Normal	Cystic	Hypertrophic	Irregular	Osteopaenic	BTQP
Met head shape	Oval	Chevron	Flat			
Severity of first met head flatness	Minimal	Moderate	Severe			
Medial-intermediate cuneiform diastasis	Present	Absent				

Table 5.6: Measurement scales for observed radiological parameters

BTQP = Bi/ Tri/ Quadripartite.

5.3.7: Data Analysis

Descriptive and comparative statistical analyses were performed using SPSS for Windows version 15.0. Means and confidence intervals (CI's) were used to report magnitude of error in clinically relevant units. The level of error was compared with what is considered clinically important. Limits of agreement bias: ±2 Standard Deviations (SD) and statistical significance was set at $p \leq 0.05$.

HR can affect one or both feet. Each foot (exclusion criteria permitting) was therefore treated as an independent observation. The data was used to test intra- and inter-rater reliability. Data distribution for measured parameters was tested for normality using the Kolmogorov-Smirnov test and Q-Q plots (Field, 2005). Tests were found to be non-significant ($p > 0.05$) and Q-Q plots demonstrated near straight line fit (nearer normality) indicating the sample distribution was not significantly different from a normal distribution.

For nominal and ordinal categorical (>2 categories) data, a weighted kappa (k) statistic was used to assess levels of agreement between raters (Field, 2005). A non-weighted k was used for a single rater's assessment. Kappa coefficient is an observed agreement above and beyond that due to chance (Field, 2005). In contrast to the standard k, the weighted k also takes into account that the relative importance of disagreement between categories may not be the same for adjacent categories as it is for distant categories (Malek et al, 2006). For example, if one rater scored an osteophyte as a three (severe) while the other scored it as a two (moderate), the weighted k approach would consider this to be less of an error compared to one rater scoring a zero and the other scoring a three. The quadratic assignment of weights described by Fleiss (1981) was used:

$$w = 1 - \frac{(i-j)^2}{(k-1)^2}$$

Where *w* represents weighting, *i* row number, *j* column number, and *k* total number of categories (in this case, four). Resultant weightings are shown (Table 5.7) but only used for joint space narrowing and osteophyte grading as each used four categories.

	None (0)	Minimal (1)	Moderate (2)	Severe (3)
None (0)	1.00	0.89	0.56	0
Minimal (1)	0.89	1.00	0.89	0.56
Moderate (2)	0.56	0.89	1.00	0.89
Severe (3)	0	0.56	0.89	1.00

Table 5.7: Quadratic weighting of the *k* statistic

Low *k* scores can result from high-agreement-low *k* paradox where some scores are under-represented within sample despite high levels of absolute agreement (Feinstein & Cicchetti, 1990; Menz et al, 2007).

Bland-Altman plots were chosen to analyse reliability of a single measurement method, to compare intra-rater measurements and for measurement method comparison - plain and digital X-rays (Bland & Altman, 1986). They provide graphical representation of the key reliability findings and calculate the range within which the difference between the two occasions will lie with a probability of 95% (Mantha et al, 2000; Bland & Altman, 2003), less than two SD's.

Correlation coefficients were only used to calculate intra-rater variation but not between different methods of measurement. To determine reliability of overall radiological findings (all observations and views combined), intraclass correlation coefficients (ICC's) and corresponding 95% CI's were calculated for both intra- and inter-rater comparisons. ICC quantifies the proportion of variance of ratings that is due to between-raters variability. Values vary from 0 to 1.0, the nearer to 1.0 the stronger the reliability of the rater (Portney & Watkins, 1993). The level of reliability for the ICC was classified using the characterization reported by Landis & Koch (1977). As with other reliability coefficients, there is no standard acceptable level of reliability using ICC (Bruton et al, 2000) but any measure should have an ICC of at least 0.6 to be useful (Rankin & Stokes, 1998).

5.4: Results

Measurements from 20 patients (12 female, 8 male) were used with a mean age of 56 ± 7.22 years (36-65). Each foot with HR was treated as an independent observation (nine left, 13 right) so analysis of reliability was conducted on 22 feet.

5.4.1: Intra-rater reliability

Mean and SD of difference between readings were calculated for intra-rater reliability for measured clinical and radiological parameters (Tables 5.8a and 5.8b). These signified a wide spread of values around the mean and typically only 36% of angular measurements fell within a 5° range (good reproducibility). Wider confidence interval (CI) limits for clinical parameters indicates that measurements can vary between testing sessions. For some parameters these wide intervals indicate measurement error associated with the technique used and may therefore not be considered sufficiently reliable for use in the clinical setting. This lack of precision is unacceptable considering that small differences are important.

Pearson's correlation coefficient (*r*) was only used to calculate intra-rater variation for the same method of clinical measurement using a goniometer. Correlations ranged from weak to strong and only considered significant when $p \leq 0.05$ (Tables 5.8a and 5.8b). For angular radiological measures the level of concordance between the manual technique (goniometer) and Visage ® software program was examined. The null hypothesis for angular radiological assessment was that the distribution of measurements by any one rater is the same using a computer as it is using plain film. Variability in radiological measurements between two measuring techniques may not be the same for all raters. Bland-Altman plots failed to demonstrate poor agreement between the two methods. There was no overall evidence of an increase in intra-rater reliability with use of the computer compared with plain X-rays ($p = 0.12$), although investigation of results specific to each rater suggested that raters may differ in their responses to the alternative measuring techniques.

	Rater 1				
Clinical	**MoD**	**± SDoD**	**95% CI** Lower	Upper	***r***
Passive first MTPJ ROM:					
Dorsiflexion	6°	6.28	2	14	0.83
Plantarflexion	4°	4.44	1	10	0.78
Total ROM	7°	7.69	3	19	0.82
Active first MTPJ dorsiflexion	8°	8.46	3	20	0.70
Hallucal IPJ hyperextension	1°	2.05	0.4	1.9	0.91
HAI°	1°	2.25	0.3	2.1	0.90
Ankle joint dorsiflexion	9°	9.69	4	22	0.38
Radiological	**Plain X-rays**		**Digital X-rays**		
	MoD	**± SDoD**	**MoD**	**± SDoD**	
First MTPJ space					
- Dorsal plantar view	0.18mm	0.25	0.13mm	0.20	
- Lateral view	0.20mm	0.28	0.18mm	0.25	
Length ratio: hallucal phalanges	0.04	0.07	0.06	0.90	
HAI°	3°	3.50	2°	2.50	
Hallux equinus angle	4°	3.35	2°	1.35	
Sesamoid distance from 1st MTPJ					

- Tibial	3mm	3.5	0.5mm	1.1
- Fibula	2.5mm	3.0	0.3mm	0.19
Shortest intersesamoid distance	0.4mm	0.75	0.7mm	0.86
First metatarsal length	0.95mm	1.50	1mm	2.05
First metatarsal/ PP length ratio	0.04	0.06	0.60	0.76
Length first met compared to 2^{nd}	0.65mm	0.87	2mm	1.40
Length first met compared to 3^{rd}	0.70mm	0.86	1.4	4.6
First met sagittal plane position	0.45mm	0.75	0.7mm	0.86
First metatarsal declination angle	1.60°	1.66	2.5	3.0
First MCJ angle	3.7°	3.24	5.7°	6.28
Metatarsus adductus angle	1.4°	4.6	7.1°	7.69
Lateral talus/ first met angle	2.05°	1.57	3.5°	3.20
TPA second MTPJ	1.55°	2.35	2.5°	3.00

Table 5.8a: Intra-rater reliability: Measured HR parameters

MoD = Mean of Difference, SDoD = Standard deviation of difference, CI = Confidence intervals, *r* = Pearson correlation coefficient, HAI° = Hallux abductus interphalangeus angle, IPJ = Interphalangeal joint, PP = Proximal phalangeal, met = metatarsal, MCJ = metatarsal cuneiform joint, TPA = Transverse plane angulation.

	Rater 2				
Clinical	**MoD**	**± SDoD**	**95% CI**		***r***
			Lower	**Upper**	
Passive first MTPJ ROM:					
Dorsiflexion	6°	6.43	2	15	0.81
Plantarflexion	6°	6.27	2	14	0.84
Total ROM	7°	8.20	3	20	0.73
Active first MTPJ dorsiflexion	7°	9.75	3	22	0.70
Hallucal IPJ hyperextension	1°	2.05	0.4	1.9	0.91
HAI°	0	0	0	0	1.00
Ankle joint dorsiflexion	10°	10.97	5	23	0.30

Radiological	**Plain X-rays**		**Digital X-rays**	
	MoD	**± SDoD**	**MoD**	**± SDoD**
First MTPJ space				
- Dorsal plantar view	0.05mm	0.15	0.03mm	0.13
- Lateral view	0.07mm	0.16	0.12mm	0.21
Length ratio: hallucal phalanges	0.05	0.04	0.06	0.90
HAI°	1°	1.83	2°	2.50
Hallux equinus angle	2°	4.32	3°	5.12
Sesamoid distance from 1st MTPJ				

- Tibial	0.35mm	0.58	0.6mm	1.2
- Fibula	0.8mm	0.76	0.6mm	0.59
Shortest intersesamoid distance	0.2mm	0.41	0.6mm	0.56
First metatarsal length	1mm	0.79	1.2mm	2.6
First metatarsal/ PP length ratio	0.07	0.07	0.80	0.86
Length first met compared to 2nd	0.03mm	0.07	1mm	0.78
Length first met compared to 3rd	0.35mm	0.48	1.5	5.3
First met sagittal plane position	0.60mm	0.59	0.7mm	0.86
First metatarsal declination angle	1.20mm	0.61	3.5	3.2
First MCJ angle	1.75°	2.71	6.7°	7.28
Metatarsus adductus angle	0.25°	1.11	9.1°	9.69
Lateral talus/ first met angle	0.95°	1.09	4.5°	4.20
TPA second MTPJ	0.40°	0.50	1.5°	4.3

Table 5.8b: Intra-rater reliability: Measured HR parameters

An example of the Bland-Altman plot graphically demonstrates reliability of passive first MTPJ dorsiflexion (Figure 5.1).

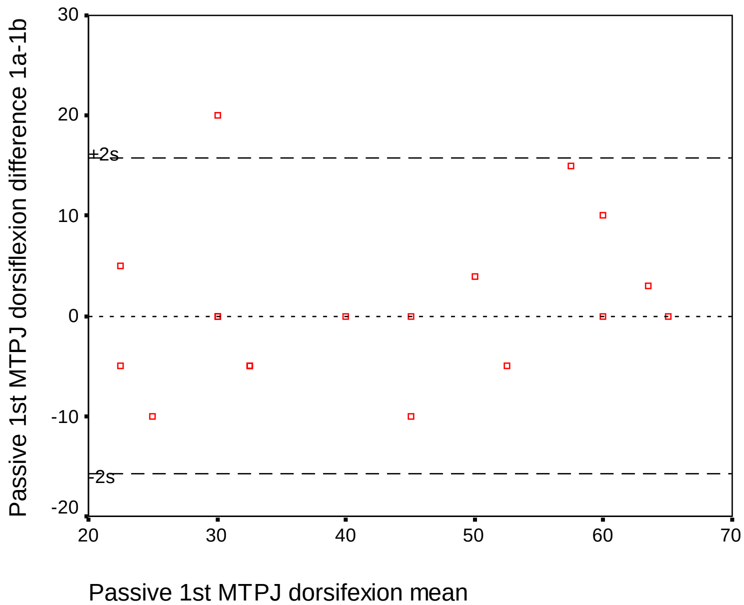


Figure 5.1: Bland-Altman plot

Reliability statistics for intra-rater comparisons of observed clinical parameters are shown in Table 5.9. Percentage agreement ranged from 91% to 99 %. Weighted *k* ranged from 0.33 to 0.95, indicating fair to excellent levels of agreement. There were no notable differences between raters and measurement sessions. Reliability of clinical observations was similar across parameters except for gait at propulsion. It was expected this may differ due to the number of variables involved in gait assessment. Differences were also noted between raters for location of first MTPJ pain. Changes in patient's symptoms between visits may have influenced this.

Reliability statistics for intra-rater comparisons of observed radiological parameters for plain X-rays (Table 5.10a) and digital X-rays (Table 5.10b) are shown. For plain X-rays percentage agreement ranged from 80% to 99% and weighted *k* ranged from 0.20 to 0.95, indicating poor to excellent levels of agreement. For digital X-rays percentage agreement ranged from

80% to 99% and weighted *k* ranged from 0.33 to 0.95, indicating fair to excellent levels of agreement. There were no notable differences between raters and measurement sessions. Reliability of radiological observations was similar across features and between dorsal plantar and lateral first MTPJ views. Digital X-ray measurement was found to be more reliable than plain X-ray. This may be due to improved quality of digital images and ability to manipulate to aid interpretation.

For overall plain X-ray observations, the ICC was 0.69 (95% CI 0.62—0.76) for rater 1 and 0.72 (95% CI 0.64—0.78) for rater 2. For overall digital X-ray observations, the ICC was 0.81 (95% CI 0.74—0.88) for rater 1 and 0.88 (95% CI 0.82—0.91) for rater 2. The mean 95% CI for each observed radiological parameter crossed zero, indicating no significant difference between the test and re-test means and no systematic error between the testing sessions. Narrow CI limits suggest an acceptable degree of agreement between testing sessions.

	Examiner 1			Examiner 2		
Parameter	% Agreement	*k*	Interpretation	% Agreement	*k*	Interpretation
Timing of pain DA ROM	95	0.80	Substantial	97	0.82	Excellent
Location first MTPJ pain	98	0.94	Excellent	94	0.67	Substantial
HIPJH	93	0.55	Moderate	92	0.51	Moderate
Hallucal rotation	94	0.33*	Fair	91	0.32*	Fair
Location of callosities	98	0.92	Excellent	99	0.95	Excellent
Second toe length CT hallux	93	0.66	Substantial	94	0.68	Substantial
Lesser MTPJ pain	91	0.39*	Fair	90	0.41*	Fair
Gait at propulsion	92	0.51	Moderate	98	0.78	Substantial

Table 5.9. Intra-rater reliability: Observed clinical parameters

DA = During active, HIPJH = Hallucal IPJ hyperextension, CT = Compared to.

* = high-agreement-low *k* paradox due to low prevalence of some scores. Poor $k \leq 0.20$; fair $k = 0.21\text{-}0.40$; moderate $k = 0.41\text{-}0.60$; substantial $k = 0.61\text{-}0.80$; excellent $k = \geq 0.80$ (Landis & Koch, 1977).

	Examiner 1			Examiner 2		
Parameter	% agreement	*k*	Interpretation	% agreement	*k*	Interpretation
First MTPJ						
JSN – Dorsal plantar view	96	0.76	Substantial	99	0.90	Excellent
JSN– Lateral view	98	0.78	Substantial	99	0.90	Excellent
Joint space symmetry	95	0.52	Moderate	96	0.81	Substantial
Subchondral sclerosis	81	0.32	Fair	80	0.20	Poor
Osteophytes	95	0.80	Substantial	98	0.90	Excellent
Loose bodies	92	0.45*	Fair	92	0.45*	Fair
Subchondral cysts	81	0.39	Fair	90	0.41*	Fair
Sesamoid morphology	95	0.64	Substantial	95	0.66	Substantial
First met head morphology	99	0.95	Excellent	98	0.92	Excellent
First MCJ						
Sagittal plane sag	96	0.55	Substantial	94	0.58	Moderate
Navicular-Cunieform joint						
Sagittal plane sag	94	0.60	Substantial	95	0.66	Substantial
General features						
M-IC diastasis	95	0.75	Substantial	92	0.55	Moderate
Alteration in gross tarsal morphology	93	0.65	Substantial	95	0.64	Substantial

Table 5.10a: Intra-rater reliability – Observed radiological parameters (plain X-rays)
JSN = Joint space narrowing, met = metatarsal, MCJ = metatarsal cuneiform joint, M-IC = Medial-intermediate cunieform, * = high-agreement-low *k* paradox due to low prevalence of some scores.

	Examiner 1			Examiner 2		
Parameter	% agreement	*k*	Interpretation	% agreement	*k*	Interpretation
First MTPJ						
JSN – Dorsal plantar view	98	0.90	Excellent	99	0.90	Excellent
JSN– Lateral view	95	0.67	Substantial	99	0.78	Substantial
Joint space symmetry	94	0.68	Substantial	96	0.81	Substantial
Subchondral sclerosis	80	0.34	Fair	94	0.33*	Fair
Osteophytes	95	0.80	Substantial	98	0.90	Excellent
Loose bodies	91	0.32*	Fair	93	0.49*	Moderate
Subchondral cysts	93	0.56	Moderate	94	0.55	Moderate
Sesamoid morphology	95	0.76	Substantial	95	0.64	Substantial
First met head morphology	99	0.95	Excellent	98	0.92	Excellent
First MCJ						
Sagittal plane sag	96	0.85	Excellent	98	0.82	Excellent
Navicular-cunieform joint						
Sagittal plane sag	94	0.60	Substantial	95	0.66	Substantial
General features						
M-IC diastasis	96	0.75	Substantial	92	0.55	Moderate
Alterations in gross tarsal morphology	94	0.60	Substantial	95	0.52	Substantial

Table 5.10b: Intra-rater reliability – Observed radiological parameters (digital X-rays)
JSN = Joint space narrowing, met = metatarsal, MCJ = metatarsal cuneiform joint, M-IC = Medial-intermediate cunieform, * = high-agreement-low *k* paradox due to low prevalence of some scores.

5.4.2: Inter-rater reliability

Reliability statistics for inter-rater comparisons for digitised X-ray parameters are shown in Tables 5.11a (measured) and 5.11b (observed). Mean and SD of difference between readings were calculated for inter-rater reliability for measured clinical parameters (Tables 5.8a & 5.8b). These signified a wide spread of values around the mean and typically only 28% of angular measurements fell within a 5° range (good reproducibility). High rates of inter-rater variability were found and overall, inter-rater reliability was less than intra-rater reliability. Inter-rater reliability percentage agreement ranged from 91% to 99% for observed clinical parameters (Table 5.9). Weighted *k* ranged from 0.32 to 0.95, indicating fair to excellent levels of agreement.

For observed digitised radiological parameters (Table 5.10b) percentage agreement ranged from 80% to 99%. Weighted *k* ranged from 0.33 to 0.95, indicating fair to excellent levels of agreement. Observations of subchondral sclerosis and loose bodies demonstrated the lowest levels of agreement. Subchondral cysts had better levels of agreement than that seen in plain X-rays possibly due to the increased quality of digital X-rays. Reliability statistics for inter-rater comparisons for plain X-ray parameters are shown in Tables 5.8a and 5.8b (measured) and Table 5.10a (observed). For measured parameters a greater spread of mean and SD of difference was found than that seen in digital X-rays. For observed plain X-ray parameters percentage agreement ranged from 78% to 99%. Weighted *k* ranged from 0.20 to 0.95, indicating poor to excellent levels of agreement. Observations of subchondral sclerosis and subchondral cysts demonstrated the lowest levels of agreement.

For overall plain X-ray observations, the ICC was 0.56 (95% CI 0.50—0.63). For overall digital X-ray observations, the ICC was 0.61 (95% CI 0.55—0.67). Overall radiological measures correlated poorly with clinical measures ($p < 0.05$, $r = 0.28$).

	Rater 1		Rater 2		Rater 3		Rater 4	
Parameter	MoD	± SDoD	MoD	± SDoD	MoD	± SDoD	MoD	± SDoD
First MTPJ								
JSN – DP JSN- Lateral	0.13mm 0.18mm	0.20 0.25	0.03mm 0.12mm	0.13 0.21	0.24mm 0.26mm	0.28 0.31	0.30mm 0.40mm	0.34 0.47
Hallux								
HPLR	0.06	0.90	0.06	0.90	1.00	1.30	1.3	2.70
HE°	2°	2.50	3°	5.12	4°	6.10	5°	7.12
HAI°	2°	1.35	2°	2.50	2.5°	3.10	3.0°	4.10
Sesamoids								
TSD	0.5mm	1.10	0.6mm	1.20	0.7mm	1.30	1mm	2.05
FSD	0.3mm	0.19	0.6mm	0.59	2.0mm	1.40	3mm	4.20
SISD	0.7mm	0.86	0.6mm	0.56	0.8mm	0.96	0.9mm	1.40
First met								
Length	1mm	2.05	1.2mm	2.60	2.5mm	6.30	3.0mm	7.40
First MPPLR	0.6	0.76	0.8	0.86	1.1mm	3.40	1.4	4.60
Length CT second met	2.0mm	1.40	1mm	0.78	2.5mm	2.05	2.9mm	5.10
Length CT third met	1.4mm	4.60	1.5mm	5.30	1.9mm	6.02	2.0mm	4.20
SP position	0.7mm	0.86	0.7mm	0.86	2.0mm	5.40	2.5mm	6.10
First MDA	2.5°	3.00	3.5°	3.40	4.0mm	4.20	2.9mm	3.10

LT-First Ma	3.5°	3.20	4.5°	4.29	5.3°	5.20	6.1°	7.2
First M-CJ								
Angle	5.7°	6.28	6.7°	7.28	12°	13.60	9°	10.1
General features								
MAA	7.1°	7.69	9.1°	9.69	11°	11.70	8°	8.72
2^{nd} MTPJ TPA	2.5°	3.00	1.5°	4.3	3.5°	5.20	4.5	7.40

Table 5.11a: Inter-rater reliability – Measured radiological parameters (digital)

JSN = Joint space narrowing, DP = Dorsoplantar, HPLR = Hallucal phalanx length ratio, HE° = Hallux equinus angle, HAI° = Hallux abductus interphalangeus angle, TSD = Tibial sesamoid distance, FSD = Fibula sesamoid distance, ISD = Intersesamoid distance, MPPLR = Metatarsal proximal phalanx length ratio, CT = Compared to, SP = Sagittal plane, MDA = Metatarsal declination angle, LT-first Ma = Lateral talus first metatarsal angle, M-CJ = Metatarso-cunieform joint, MAA = Metatarsus adductus angle, TPA = Transverse plane angle.

	Examiner 1			Examiner 2			Examiner 3			Examiner 4		
Parameter	% Agree	*k*	Int	% Agree	*k*	Int	% Agree	*k*	Int	% Agree	*k*	Int
First[t] MTPJ												
JSN – DP	98	0.90	E	99	0.90	E	98	0.78	S	94	0.68	M
JSN- Lateral	95	0.67	S	99	0.78	S	93	0.56	M	92	0.55	M
JSS	94	0.68	S	96	0.81	S	95	0.67	S	93	0.56	M
SS	80	0.34	F	94	0.33*	F	92	0.51	M	78	0.20	P
Osteophytes	95	0.80	S	98	0.90	E	92	0.49	M	94	0.38*	F
LB's	91	0.32*	F	93	0.49*	M	92	0.45*	M	93	0.58*	S
SC	93	0.56	M	94	0.55	M	92	0.55	F	95	0.69	M
SM	95	0.76	S	95	0.64	S	93	0.57	M	91	0.30*	F
First MHM	99	0.95	E	98	0.92	E	92	0.50	M	95	0.72	S
First MCJ												
Position	96	0.85	E	94	0.56	S	91	0.49	M	92	0.52	M
SPS	96	0.85	E	98	0.82	E	78	0.20	P	79	0.29	F
NCJ												
SPS	94	0.60	S	95	0.66	S	80	0.35	F	92	0.52	M
Gen features												
M-ICD	96	0.75	S	92	0.55	M	94	0.61	S	90	0.30*	F
GTMA	94	0.60	S	95	0.52	S	94	0.60	S	92	0.54	M

Table 5.11b: Inter-rater reliability – Observed radiological parameters (digital)

% Agree = percentage agreement, *k* = kappa, Int = Interpretation, P = Poor, F = Fair, M = Moderate, S = Substantial, E = Excellent, JSN = Joint space narrowing, DP = Dorsoplantar, JSS = Joint space symmetry, LB's = Loose bodies, SC = Subchondral cysts, SM = Sesamoid morphology, MHM = Metatarsal head morphology, MCJ = Metatarsal cunieform joint, SPS = Sagittal plane sag, NCJ = Navicular cuneiform joint, M-ICD = Medial-intermediate cunieform diastasis, GTMA = Gross tarsal morphology alterations. ***** = high-agreement-low *k* paradox due to low prevalence of some scores.

5.5: Discussion

5.5.1: Introduction

In this study intra-rater reliability showed a wide spread of values around the mean and typically only 36% of angular measurements fell within a 5° range (good reproducibility). Similarly for inter-rater reliability only 28% of angular measurements fell within a 5° range. The inter-rater reliability for first MTPJ ROM was poor. This lack of precision is clinically unacceptable considering that small differences are important. These findings are similar to the poor levels of reliability other authors have reported for passive ROM measurements for the knee (Rothstein et al, 1983), ankle and subtalar joint (Elveru et al, 1988) and first MTPJ dorsiflexion on lateral stressed dorsiflexion views (Taranto et al, 2005).

In this study the absolute percentage agreement and weighted *k* are similar to previously published reliability studies in other lower limb joints (Sun et al, 1997; Menz et al, 2007). Consistent with all previous studies, inter-rater reliability was lower than intra-rater, despite the level of training for the raters being identical. This suggests that there is some degree of inherent variability in the interpretation of some aspects of the radiological parameters measured. Based on this observation, this study concurs with previous recommendations that, for research purposes, single examiners or consensus grading should be used to document radiological changes where possible (Hart & Spector, 1995).

In the present study raters appeared to be internally consistent in the assessment of first MTP joint space symmetry; however, some X-rays were much more difficult to assess than others. Overall the reliability of joint space measurements showed substantial agreement (k = 0.76) over two occasions, although this did vary by rater. When this agreement was assessed individually, the kappa statistic ranged from moderate (k = 0.55) to excellent (k = 0.90). Therefore there was great variation between raters in their ability to make the same assessment of joint space on two occasions. This concurs with the findings of Aster et al (2004), Coughlin & Freund (2001) and Chi et al (2002) that examined radiological reliability of joint congruency in hallux valgus and found great variation within and between raters. Coughlin & Freund's (2001) study however, was not comparable as photographs of X-rays were used which introduced other sources of measurement error.

Overall the present study found radiological measures correlated poorly with clinical measures ($p < 0.05$, $r = 0.28$). Correlation coefficients should be interpreted with caution as they look at the degree of interdependence but not actual sizes of numbers.

5.5.2: Methodological issues

Due to the wide range of clinical and radiological variables measured in this study it was not feasible to use large numbers of patients/ X-rays. Twenty patients were used. The numbers used may have affected estimates of reliability as small samples can lead to a relatively large standard error of the mean (Rankin & Stokes, 1998).

The present study questioned the value of average (mean) readings. In HR, systematic increases in ROM might result from serial measurements, as the joints' soft tissues become more compliant. Averaged readings may affect reliability as variations in time and pressure applied by different examiners and between readings of the same examiner may introduce other variables. Furthermore the study wished to replicate the normal clinical situation where time constraints restrict multiple readings.

An important design aspect for interpretation of intra-rater reliability is the time interval between repeat readings. The reliability of instruments and procedures is more accurate when short time intervals separate tests because the accuracy of the measurement is increased with few uncontrolled variables (Sun et al, 1997). Ideally a standard time interval between ratings should be used. This needs to be long enough to prevent examiners from remembering previous ratings, but not too long since other factors (including training of examiners) do change over time. In the present study identical time spans were used (>24 hrs but < four weeks) to minimise undue influence on results.

The method used for a particular parameters' assessment may play an important role in its reliability. Osteophytes were assessed using an ordinal four-category system but their size was not measured, unlike joint space narrowing that was measured using an ordinal four-category observational and a six-point measuring system thereby refining its reliability. Efforts to improve measurement standardization, quantification and training of examiners may enhance reliability of other, less reliable radiographic features. These should be representative of the settings in which the scores are to be employed. A wide spectrum of severity of HR was chosen for the present study. This was considered to be important as it needed to reflect the spectrum of patients for which the instrument is to be used.

5.5.3: Goniometric reliability

In the present study the results indicated that goniometric measurements were poorly reliable, however, intra-rater measurements taken over a short period of time were more reliable than those carried out by several different raters. These findings concur with other clinical investigations of goniometric reliability in the lower limb (Low, 1976; Boone et al, 1978; Rothstein et al, 1983; Menz, 1995; Hart & Spector, 1995; Sun et al, 1997; Rankin & Stokes, 1998) and particularly those who examined foot joints (Gajdosic & Bohannon, 1987; Elveru, 1988; Kilmartin, 1988; Taranto et al, 2005).

Reliability is affected by measurement procedure and the current study concurs with other research that inter-rater reliability may be optimised if consistent, well-defined testing positions, anatomical landmarks to align the goniometer arms and measurement methods are used (Watkins et al, 1991; Hart and Spector, 1995; Coughlin & Mann, 1999). Standardizing the amount of manual force applied by the rater or patient to move the joint is one variable which was not easy to control.

Goniometer degree markings are up to one-third of a millimetre wide. The millimetre spaces between increment marks require the rater to estimate when bisection lines fall between the goniometer markings. Reading the goniometer thus provides considerable room for variation. Whether this was a source of greater variation than the actual placing of the goniometer arms was not determined.

5.5.4: Sources of measurement error

The current study found that a number of aspects of the measuring and recording process contributed to measurement error. These findings concur with those already mentioned (Section 5.2.1) by other researchers (Boone et al, 1978; Ekstrand et al, 1982; Gajdosic & Bohannon, 1987; Elveru et al, 1988; Watkins et al, 1991; Norkin & White, 1995; Menz, 1995; Bruton et al, 2000; Taranto et al, 2005; Allison, 2007). *A posteriori* analyses were performed in an attempt to identify other sources of error that may have affected measurement reliability. These are discussed under the headings: examiner, examined, examination and/or radiological sources.

5.5.4.1: The examiner

Although measurement position and procedure were standardised the variable magnitude and length of time the rater applied pressure during passive ROM measurements affects reliability. These were difficult to reproduce, because stretching of soft tissues at the limits of motion depends on the force applied, which must, therefore, be carefully controlled. These findings concur with Gajdosic & Bohannon (1987). Methods to standardise force and time applied during joint measurement could decrease error. A standardised measurement technique was applied to control for variables leading to incorrect reading of the goniometer scale. However, error in reading the wrong side of the scale was encountered i.e. when the pointer was mid-way between 40° and 50°, the rater may read 55° rather than 45°.

Depending on the method used for measuring e.g. metatarsal length (Morton, 1928; Hardy and Clapham, 1951; Besse et al, 2002; Barouk, 2005; Davidson et al, 2007) reliability may vary. First MTPJ dorsiflexion was found to increase if the ankle joint was allowed to plantarflex during measurement. This may be related to a reduced distal excursion (tension) of FHL.

Rater expectation is known to contribute to measurement error (Gajdosic & Bohannon, 1987). If the rater knows the previous measurement he/ she may have an expectation of the next value to be measured. In the present intra-rater study expectation was an unlikely factor due to the time interval between readings, but anticipation was thought to contribute. The rater may anticipate a restricted joint ROM after observing the patients clinical features e.g. extensive dorsal osteophytes. As variations can occur within the subjects' joint (stiffness or swelling) during and between (climatic changes) days anticipation may not always represent findings.

5.5.4.2: The examined

The current study concurs with Elveru et al (1988) in that biological variations were difficult to control and may have accounted for measurement error on the part of the patient. Increased activity levels on the day prior to measurement may have resulted in greater joint pain reducing joint ROM. Errors incurred due to passive exercise could have been reduced by exercising the joint for several days prior to commencing measurements and/or, taking measurements at regularly spaced intervals. Standardizing patient activity levels between intra-rater readings to control for variables is problematic.

It was not known whether the perceived joint restriction was solely attributed to the patient being tense due to pain, anticipating pain, or due to joint stiffness. It was not routine for the rater to exercise the joint to 'warm it up' prior to measurement. Had this process been adopted, it may have increased joint ROM, but in doing so introduced additional unwanted variables.

In the present study the types of measurements used i.e. passive or active ROM, may have influenced accuracy and reliability of measurements. Also the site of measurement may influence measurement error e.g. first metatarsal lateral sagittal plane position may have been influenced by the degree of metatarsal declination.

The extent to which patients were motivated to perform a given movement in the current study may have influenced the size of the angle or ROM measured. Gajdosic & Bohannon (1987) found that the amount of effort and time applied by patients during active ROM measurements influenced measurement error. Also rater approval and enthusiasm have been considered relevant (Stratford et al, 1984). In the current study the patients perceived timing of pain during passive ROM may have been affected by motivation. However, for some the difficulty specifying the exact timing of symptoms may be due to their fluctuation with time.

5.5.4.3: The examination

In this study extraneous movement of goniometer arms during measurement may have contributed to measurement error. Use of a digital goniometer (used for finger joints) had been considered in the pilot study but was found to be too small for male patients. Bony landmarks were difficult for raters to detect in obese patients and their location varied on X-rays contributing to error. The present study agrees with Davidson et al (2007) who contended that foot deformity may be responsible for measurement error and found difficulty comparing hallux and second toe length in patients with a hallux or second toe deformity. Overall Davidson et al (2007) found excellent reliability (ICC=0.98) when measuring this parameter without deformity. The current study concurs: intra-rater percentage agreement ranged from 93% to 94% and *k* (0.66-0.68) indicating substantial agreement.

5.5.4.4: Radiological sources

Technical problems exist when taking foot X-rays and clinicians need to be aware of these difficulties and limiting factors when undertaking reliability studies (Beeson et al, 2009b). Weijers et al (2005) investigated the effect of tube angulation on angular distortion and concluded that the relatively small improvement in angular measurement using different tube angles did not outweigh the adverse effects of changing the standard radiographic protocol. Standardizing foot X-ray position (Weijers et al, 2005) helps maintain the relative position of bony landmarks used for goniometric measurement. Longitudinal rotation of the first metatarsal or proximal phalanx may alter estimates of joint space narrowing and symmetry, and may be difficult to take into consideration when using bony landmarks on standard X-ray views. The computer software used for digital X-rays was not able to measure relative metatarsal lengths using the same method as the plain X-rays. Instead the reliability of measuring absolute lengths was evaluated. The two methodologies were not comparable and it is therefore unclear as to the value of this data. Differentiation between irregular and hypertrophic sesamoids was difficult and more clarity was required. Reference points for first metatarso-cuneiform and navicular joint sag were sometimes difficult to define. Large differences in metatarsus adductus angle (MAA) values were found in the pilot study. The method used by Coughlin & Shurnas (2003a) was applied but found to be inconsistent as the four reference points could not be routinely identified on all X-rays. An additional three reference points and two line axes are required to measure the angle (Figure 5.2), all compound the error. An alternative method has been suggested which reduces the number of variables (Section 4.2.8.12) and may increase reliability.

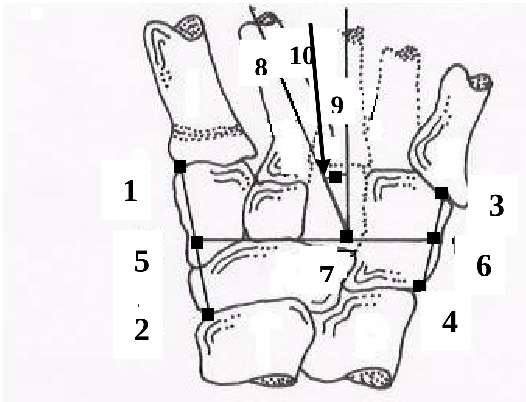


Figure 5.2: Ten errors using Coughlin & Shurnas (2003) method to measure MAA

5.5.5: Digitised X-rays

This study does not compare conventional radiographs with digitised; rather hard-copy radiographs were compared with soft-copy (computer monitor) images obtained digitally. Thus, measurement techniques were compared and not differences in quality between plain film and digital images. However, issues of quality did have a bearing on measurement reliability. The current study concluded that a computer workstation improves consistency by elimination of marking pen and goniometric errors. In addition clarity of the digitised image aids evaluation of subtle joint parameters. Where visualization of structures proves difficult (e.g. trabecular pattern superimposed on inside edge of sesamoid making inter-sesamoid distance difficult to measure) the X-ray contrast can be changed or inverted image used to improve image quality or magnified to increase clarity and enhance accuracy. Large viewing screens also help in evaluation. New methods using software to automatically measure joint space width may prove useful in the future (Klooster et al, 2008).

Computerized angle measurement of foot X-rays has been evaluated for intra- and inter-rater reliability with plain films (Coughlin & Freund, 2001; Chi et al, 2002; Piqué-Vidal et al, 2006) and has been found to be reliable.

The present study concurs with other researchers (Farber et al, 2005; Piqué-Vidal et al, 2006; Munuera et al, 2008) in that a digital work station helps reduce intrinsic sources of measurement error and that inter-rater angular measurements were more reliable than manual measurements. It also agrees with Piqué-Vidal (2006) that manual radiographic measurements may underestimate the true values where smaller angles are measured (e.g. HAI° or first MCJ°) due to higher variability in this technique. For measurement of large angles, such as hallux equinus and first metatarsal declination angle, results obtained with both measurement techniques are similar. It is recognized that human error influences reliability as it is the rater who chooses points that the computer uses for angle and linear calculation. Linear measurements were more reliable than angular measurements as fewer points are required. Observations may be more reliable than measurements because no equipment is required. When radiological variables were categorized by the level of severity (ordinal data), the degree of agreement between the measurement techniques was much lower than for continuous data. Measurements were clearly related to the measurement technique, i.e. for MA angle, the manual technique had a tendency to show higher values.

5.5.6: Statistical observations

In the present study the absolute percentage agreement and weighted *k* are similar to previously published reliability studies in lower limb joints (Sun et al, 1997; Menz et al, 2007). The low *k* scores for clinical observations of hallucal rotation and lesser MTPJ pain and radiological observations of loose bodies and subchondral cysts (plain X-rays) are likely to be a result of the high-agreement-low *k* paradox (Feinstein & Cicchetti, 1990; Menz at al, 2007). This statistical aberration arises when some scores are under-represented within the sample, so despite high levels of absolute agreement, the calculated *k* is low. In these situations, the absolute percentage agreement statistic provides a more accurate indicator of the actual level of concordance between raters. The interpretation of *k* is also controversial. Two common systems are used (Svanholm et al, 1989; Munoz & Banqdiwala, 1997), each with a different weighting. Therefore it is prudent to mention the observed agreement value and *k* coefficient value.

Although ICC is a well accepted measure of reliability, it is difficult to interpret ICC values since they are dependant on variability of the group being assessed and thus, may not transfer to different patient populations (Rothstein et al, 1983). Therefore in addition to ICC the standard error of measurement (SEM) may have been useful to include as another index of reliability and used to calculate the minimal detectable change for measurements (MDC) which reflects the amount of change required for change to be considered “real”, over and above measurement error (Hopkins, 2000).

5.5.7: Value of using strategies to improve reliability?

The main sources of measurement error (as previously discussed) could be emphasized to examiners in advance of undertaking a reliability study. Whilst this would go some way towards controlling for these variables and improving reliability it would not be fool-proof. The use of such rigid protocols may be valid for research purposes but cannot be practical in normal clinical practice. Due to the complexity of joint measurement and human nature it would be difficult to control for all these variables to ensure reliability.

In the present study angular radiological measurements have been shown to vary, even with standardised methodology, due to interpretation of reference points and choice of longitudinal axes. Such methods should be avoided if possible.

5.5.8: Consequences of level of reliability

The moderate intra-rater reliability for clinical and radiological measurements in HR is clinically relevant. These measurements when taken by the same examiner, over a short period of time, may be useful when comparing bilateral HR of the same patient or evaluating the results of first MTPJ mobilization.

The consequences of poor inter-rater reliability for certain radiological and clinical HR parameters (Tables 5.8a to 5.11b) are that communication among clinicians will be impeded. These variables cannot be used in a classification system to grade HR, aid decision-making on its management or allow meaningful comparisons to be made between different treatment strategies. Studies that have used such variables as a point of reference for decision making should be interpreted with caution if their results are based on unreliable measurements.

The construction of a classification system for HR should refrain from relying heavily on the use of goniometric measurements. This would avoid the controversial issues relating to goniometer assessment and its reliability (McPoil & Cornwall, 1994; Redmond et al, 2005; Munuera et al, 2008) and the need for manipulation of the foot, marking of skin lines and measurement with instrumentation. Factors such as location and timing of pain during dorsiflexion rather than the magnitude of dorsiflexion in degrees may be equally useful. The present reliability study supports inclusion of specific clinical and radiological parameters in a HR classification to aid surgical decision-making based on their reliability (Table 5.12).

The statistical significance of passive and active first MTPJ dorsiflexion (intra-rater) was high (Table 5.12) but their clinical significance was low. Tables 5.8a and 5.8b signified a wide spread of values around the mean and wider confidence interval (CI) limits indicating that measurements can vary between testing sessions. These wide intervals indicate measurement error associated with the technique used and may therefore not be considered sufficiently reliable for use in the clinical setting. This lack of precision is unacceptable considering that small differences are important.

HR parameter	**Radiological / Clinical**	**O / M**	**Statistical relevance in this study**
Timing of pain during active ROM	Clinical	O	% Agreement = 95, *k* = 0.80
Location first MTPJ pain	Clinical	O	% Agreement= 98, *k* = 0.94
Second toe length compared to hallux	Clinical	O	% Agreement = 94, *k* = 0.68
Location of callosities	Clinical	O	% Agreement = 98, *k* = 0.92
Joint space narrowing	Radiological	O	% Agreement = 99, *k* = 0.90
Osteophytes	Radiological	O	% Agreement = 98, *k* = 0.90
Sesamoid morphology	Radiological	O	% Agreement = 95, *k* = 0.66
First met head morphology	Radiological	O	% Agreement = 98, *k* = 0.92
NCJ sag	Radiological	O	% Agreement = 95, *k* = 0.66
Hallux abductus interphalangeus angle	Radiological	M	Mean = 2°, SD = 2.5
First metatarsal length	Radiological	M	Mean = 2.0mm, SD = 2.6
*Passive first MTPJ dorsiflexion	Clinical	M	r = 0.81, p = <0.05
*Active first MTPJ dorsiflexion	Clinical	M	r = 0.70, p = <0.05
*First metatarsal-proximal hallucal phalanx length ratio	Radiological	M	Mean = 0.06, SD = 0.76

Table 5.12: Reliable clinical and radiological parameters of HR

O/M = Observed/ Measured, SD = standard deviation, *r* = Pearson correlation coefficient.

* - Reliability of these parameters is only valid for intra-rater.

5.6: Conclusion

It is recognised that quantitative evaluation is more reliable than non-quantitative methods i.e. subjective visual assessment (Munuera et al, 2008). However, due to poor reliability of clinical measures using goniometers their incorporation in a classification system for HR may not be useful. Clinicians using such measures to make decisions regarding patient care and clinical outcome need to keep in mind these potential errors. Because goniometric reliability is dependent on a host of factors, clinicians using goniometers who work in the same clinic should adopt standardized methods of testing. Clinicians should be careful in the interpretation and the reporting of goniometric findings in HR. As a rule, ROM measurements are just that, not measurements of muscle “tightness”, the length of specific structures, or other factors that may affect ROM. In the current studies intra-rater variation was found to be less than inter-rater for the parameters of HR assessed. Based on these studies only specific HR parameters were found to be reliable (Table 5.12) and valid for inclusion in a classification framework, to aid decision-making on its management or allow meaningful comparisons to be made between different treatment strategies. Although the statistical significance of passive and active first MTPJ was high their clinical significance was found to be poor and therefore their inclusion in the classification framework is not advised.

Clinicians who examine HR should be aware of the measurement error of its clinical and radiological parameters, and when possible one clinician should take all repeated measurements. Clinicians who measure first MTPJ ROM should be aware that error exists in this measurement, and clinical decisions based on its use must be seriously reconsidered. The inter-rater variation for certain clinical and radiological measurements of HR is large enough to completely invalidate their use in clinical decision-making. Such parameters should not be compared unless measured by the same examiner. In order for future classification systems of HR to be reliable, the measures of HR severity must also be reliable.

CHAPTER 6

QUALITATIVE STUDY

6.1 Introduction

The aim of this study was to obtain 'expert' opinion on HR classification by interviewing clinicians. This enabled an in-depth qualitative analysis of the issues surrounding HR classification and provided a further form of validation which allowed a different dimension of the classification to be investigated.

6.2 Background

Different interview methods were considered for this study. Some may have enhanced numbers of participants but the quality of data and depth of analysis would have been restricted. A summary of the potential alternative methods and the reasons why they were not used for this study is outlined in Table 6.1.

Interview type	Limitations
Questionnaire	Rigid structure; closed-questions. Depth of questioning limited. Depth of understanding restricted (Drever, 2003).
Telephone interview	Non-verbal information missing. Difficult to sense whether participant understands question. Reduces number of items participants can deal with simultaneously; requires more motivation to keep going (Rudestam & Newton, 2007).
E-mail interview	Responses too colloquial for research - abbreviated or edited. E-mails can be ignored (Rudestam & Newton, 2007).
Unstructured interview	Time consuming; lacks consistency (Gillham, 2005).
Focus group	Practicalities of arranging a clinical expert group meeting to include a wide range of professionals.
Delphi technique	The different rounds of questionnaires required may have precluded certain experts due to their lack of available time.

Table 6.1: Reasons for not using alternative methods

Semi-structured interviews straddle the divide between the *“formal”* structured interview and *“informal”* unstructured interview (Drever, 2003). A semi-structured interview incorporates many of the approaches suggested for more structured questionnaires (Lindlof & Taylor, 2002). It uses a simple schedule with a thematic approach and the main questions form a logical sequence, so that the interview ‘flows’ naturally (Drever, 2003). Question development is from general to specific (Witzel, 2000). It takes time to do and analyse and so requires realistic planning. There is focus on reconstruction of orientation and actions, so participants feel they are taken seriously, responding with trust, self-reflection and opening-up (Suto, 2000).

A semi-structured interview format was chosen in preference to a structured interview/ questionnaire because:

- It establishes participant rapport and allows two-way communication.
- It guides discussion to ensure equivalent coverage (Gillham, 2005).
- It is flexible; not constrained to a particular order of questioning.
- The interviewer is freer to probe interesting areas that arise or answers that may require clarification (Patton, 2002).
- It can follow participant's interests, preferences or concerns.
- It explores participant's experiences, motivations and reasoning.
- It enables explanation of ambiguities and misunderstandings of questions to be corrected (Patton, 2002).
- Complex issues can be discussed.
- It yields rich information and guarantees good coverage (Drever, 2003).

Consideration was given to utilising NVivo, formerly NUD*IST (Non-numerical Unstructured Data Indexing Searching Theorizing) or Hyper-Transcribe; recognised tools for analysing interviews (Rudestam & Newton, 2007). These were not used because they can lead to loss of 'feel' of data (Drever, 2003) limiting interpretive sensitivity (Gillham, 2005). The code-and-retrieve style of organization used can lead to data fragmentation, loss of elements and contextual meaning (Rudestam & Newton, 2007).

6.3: Methodology

6.3.1: Participants

A list of 30 representatives of all the professional groups locally involved with the management of HR was made. Participants were contacted and invited to take part in the study, and given more than 24 hours to decide. Seventeen clinicians agreed to participate (Table 6.2). Large numbers of participants were not required as the aim was not to find universal truths but simply to obtain information about their local context and professional application. Equal numbers of professionals were not required as a comparison of professions was not being undertaken.

Participants were clinical leads in their respective fields (Table 6.2) and selected as they routinely examine and treat HR; have a sound knowledge of the condition and issues relating to its classification and management. To avoid professional bias participants were chosen from a range of professional groups with different experience and clinical scope of practice.

Professional group	***Number***
Orthopaedic Surgeon	1
Podiatric Surgeon	2
Rheumatologist	2
Physiotherapist	2
Podiatrist - Extended Scope Musculoskeletal	5
Podiatrist - Generalist	3
Research Podiatrist	2
TOTAL	17

Table 6.2: Participants interviewed

6.3.2: Ethics

Studies involved human participants, thus ethical consideration was required and, granted by Leicestershire Northants Rutland Ethics Committee (Appendices 11 and 33).

6.3.3: Interview schedule

The findings of the first three studies helped inform development of the semi-structured interview schedule. This schedule (Appendix 34) was developed, to guide rather than dictate the flow of the interview.

6.3.3.1: Themes

Four themes were identified to help construct the interview schedule:

1. Current use of a HR classification.
2. Classification type, scale and interpretation.
3. Construction of HR classification.
4. Clinical ease of use (utility).

These themes were used to elicit each participant's opinions on issues about classification content and design considered important (Suk et al, 2005).

6.3.3.2: Construction of questioning

Open-ended questions were used to help the interviewer appreciate the participant's perspective (Finlay & Ballinger, 2006), encourage the narrative to unfold and, facilitate production of highly descriptive data (Smith, 1995). It offered opportunities for the participant to answer at some length in his/her own words, and the interviewer periodically to respond using prompts, probes and follow-up questions to get the participant to clarify or expand on the answers (Cummings et al, 2001). Prompts and probes were used to help fill in the structure: prompts by encouraging broad coverage, probes by exploring answers in depth (Drever, 2003). If the participant had much to say in response, the prompts were used as a checklist for adequate coverage, without actually being asked. However, if the interviewer felt that the question might have been misunderstood or the participant's interest not engaged, the prompts were given as follow-up questions to trigger more detail. If the participant was judged to be receptive the probe questions were asked to confirm, clarify, or elicit more depth of understanding or consideration of the associated issues. They were also used to connect (show link with something else) or to close down the focus. Probes were low-key and neutral, encouraging participants to expand on what they think but neither leading them nor challenging them.

The structure provided allowed interviewing to be business-like and, the variable control through the use of prompts and probes enabled flexibility. The number of questions was kept deliberately low, each being quite distinctive. The schedule guaranteed consistency of questions across a set of interviews allowing comparison of participant's answers and, permitted some control of areas under discussion, in order to aid subsequent analysis.

6.3.4: Pilot study

Two participants were interviewed by an independent person (not the researcher) to check the methodology was practicable. This resulted in the following changes:

a) Reformatting interview schedule to fit onto two pages of A4.

b) Addition of theme timings to interview schedule to aid time keeping.

c) Enhancement of prompts/ probes for each question to further aid interview flow and encourage broad coverage and depth.

d) Prompts/ probes changed to italic typeface to help interviewer.

6.3.5: Protocol

In advance of the interview each participant was sent:

1. History, clinical/ X-ray photographs of HR patient and asked to grade.
2. The proposed HR classification system (Appendix 35).
3. The four themes to be covered in the interview (Section 6.3.3.1).
4. Participant invitation letter and information sheet (Appendix 36 & 37).
5. Consent form (Appendix 38).

Written consent was obtained from participants prior to interview. Interviews were conducted by an independent person (not the researcher) to limit any influence or bias and restricted to 45 minutes, to minimise inconvenience to participants but to allow for adequate coverage. The interviewer (podiatrist) was chosen because they understood the subject area and had experience in interviewing. Participants were given the option to withdraw their involvement from the study at any time.

6.3.6: Transcription of interviews

Each interview was recorded onto a digital voice recorder (Olympus VN-3100PC™) by prior arrangement and written consent. The recording was transferred to a computer in compressed and WAV file formats and transcribed verbatim by the researcher into Microsoft Word™. As far as was practicable, this process began as soon as possible after each interview had been completed. This was so that should the researcher require any clarification with the interviewer it would ensure that the 'freshness' of each encounter remained.

6.3.7: Analytical approach

The themes and subthemes in the interview schedule served as an initial organizing framework for the data. The analytical process used was that described by Drever (2003) and Gillham (2005). Judgement was exercised in the way that data was summarized without distorting participant's

responses or omitting anything important. Common and specific issues were addressed. In the case of questions about desirability of HR classification parameters '*answers in favour*' versus '*answers against*' were indicated and where necessary supported by narrative. Within each subtheme participant's responses were further grouped based on: their balance of opinion, theories, contentions, judgements, ambiguous statements and conditional approval (Gillham, 2005). Subthemes were extracted from the material by summarizing one of the fuller answers into a list of short points. Individual opinions were included for completion.
Another technique used was to reorganize the material in certain themes to replace a number of unique answers with clusters of equivalent statements in each of a small number of subthemes (Drever, 2003). This enabled a summary of relevant participant's responses to be made using numbers. It seemed reasonable to suppose that participants have taken sides, and so one may expect to count them up as pros or cons. However, when looking at responses it is clear that some are clearly positive or negative, but others give mixed responses. This technique not only enables a judgement about each issue to be made, partly on the number of statements made in each category, but also considers their response as a whole (Drever, 2003; Gillham, 2005). The analysis states clearly whether the evidence supports a conclusion, suggests alternatives, is divided, is insufficient, or rejects a view but does not offer an alternative.

Another technique used was to count the number of statements made (rather than percentages) in each category by presenting a table (Appendix 39) that cross-references the sets of categories (Drever, 2003; Gillham, 2005). The existence of empty categories also provides meaning. It might be considered that counting statements rather than people will 'over-represent' the more talkative participants. However, this study is not conducting a poll in which each participant is entitled to an equal vote. It is an attempt to describe the variety and relative prevalence of views that a group of clinicians hold and express when invited to do so.

A brief analysis of professional group views was provided. Whilst the purpose of this analysis was not to formally compare group findings its aim was to emphasize any interesting profession-specific opinions. Extra caution was applied to this particular analysis because groups are inevitably small and individuals significant. It was recognized that before claiming the group has a distinctive view it was necessary to focus on various members. Therefore it needs to be considered, if this participant had not been interviewed (e.g. only one orthopaedic surgeon), would similar claims about the group be made?

6.4: Results and discussion

The transcribed data from all interviews was collated under the four respective themes from the interview schedule (Appendix 34). These broad areas were used to prioritise and inform the main themes for the discussion. This section interprets and discusses the findings from each theme and explains the emerging issues and sub-themes developing from within them and provided by additional in-depth information. Many of the issues raised are considered in more than one section and are cross referenced between sections. This reveals the significance of the issues raised by the participants and that they should not be considered in isolation. Thus many of the themes discussed overlap and compliment each other.

This section begins with a description of the participant's current use of a HR classification (Section 6.4.1). Next, the classification type and scale used and how these are interpreted are explored (Section 6.4.2). This is followed by examination of the construction of the HR classification (Section 6.4.3). The final section (Section 6.4.4) discusses the clinical ease of use (utility) where the acceptability and feasibility of the HR classification are explored (Section 6.4.4). In the following sections, both the common and divergent opinions (where appropriate) will be reflected in a description of the findings.

6.4.1: Theme 1- Current use of a HR classification

The purpose of this theme was to explore participant's views on HR classifications and examine which and why they currently use these for the management of HR.

Participants were asked what HR classification they currently use, and if so, how it compared with the proposed system. The majority of participants agreed that a number of systems exist. A few concluded from this that:

> *"The fact that a number of systems exist suggests little consensus on their use and volumes about them in that none work particularly well" [Participant 6]*

> *"It is clear from the literature that a number of HR classification systems exist. "Consensus on use is therefore limited" [Participant 7]*

One of the emerging issues was that participants considered that it was important to start with a short list and work towards reducing it to something more manageable. It was concluded that this information is required to separate patients into categories. The medically qualified participants used few parameters. Three of these participants made the same observation:

> *"We use two to three relevant clinical (pain, loss of dorsiflexion, altered function) and radiological (osteophtyes, joint space loss) parameter" [Participant 15]*

> *"Only a few clinical and radiological parameters are of value to me in the clinical setting" [Participant 17]*

> *"Why use lots of parameters when you can just concentrate on the key clinical and radiological components"[Participant 16]*

Two participants used the system devised by Shurnas & Coughlin (2003b) and considered that it compared well with the proposed system. A few others used the purely radiological systems devised by Regnauld (1986) and, Hattrup and Johnson (1988). A minority of participants expressed the opinion that they were not aware of any published classification systems but agreed that one was required.

One of the subthemes to emerge was that participants were varied in their use of classification systems. Most participants revealed that they do not use a formal classification system but instead relied on their clinical experience; often applying degrees of limits of joint ROM using visualisation. A few said they use goniometric measures to compare with the non-HR side (where possible). Some participants reasoned that this was because of clinical time constraints saying they used a simple/ mild/ moderate and severe classification. These participants claimed that they based the classification on a mixture of clinical and radiological features. Two participants stated that:

> *"Because we work in different NHS Trusts we use different systems and therefore we try not to be rigid in their application or interpretation" [Participant 1]*

> *"We work in different NHS Trusts and they expect us to use different systems" [Participant 2]*

For three of the participants, their scope of practice was influential. This issue was revealed by their perceived clinical needs:

> *"I only use clinical criteria as I don't have access to radiology" [Participant 7]*

“It is important that in order to make clear surgical decisions I need foot X-rays” [Participant 16]

“To make management decisions I need to check the radiological changes in the foot” [Musculoskeletal podiatrist]

One issue that most participants felt strongly about was that the length and complexity of the proposed system was greater than they would routinely use. However they did qualify this by confirming that the parameters listed were relevant. Comments made by two participants elaborate on this point:

“It is clear that the complexity and length of the suggested system is more than could currently be used clinically due to time restraints” [Participant 4]

“While it is clear that the proposed HR classification is long all the parameters that have been included are necessary and very relevant” [Participant 8]

A key subtheme to emerge was related to the concept of validity. A clear majority of participants expressed the view that a validated classification would be of value. Three participants made the following comments to support the concept of classification validity:

“A validated tool would help to provide an overview of the condition and how it impacts on lifestyle” [Participant 3]

“The classification system used needs to be proven for validity” [Participant 7]

“If the HR classification is not validated in shape or form it cannot be a valuable clinical tool” [Participant 10]

A lack of consensus on use of HR classifications and consistency of application of clinical parameters between participants was apparent, reflecting confusion over choice of classifications, a lack of understanding of their application (best parameters to use) or a lack of suitable available systems. It was agreed that for classification parameters to be of value they should be few and tested for validity and reliability. Face validity - clinical credibility inferred from experts evaluating content relevance was provided.

Participants were asked to reveal what they were looking for in their ideal HR classification. All participants agreed that a structured approach which was succinct, easy to use, not time consuming and with grading was indicated. An important subtheme emerges here which emphasizes the issue of the participants' role. Five participants expressed their opinion that job role may have an influence on classification requirements:

> *"If you are an academic or clinical researcher then classification systems are useful to allow you to study individuals or conditions because you need a homogenous group of patients"..."It enables you to compare like with like and outcomes" [Participant 9]*

> *"As a clinician I feel that a fairly succinct system is required as the time that I have available for each patient is limited" [Participant 5]*

> *"Most researchers are looking for a system that is reliable, valid with useful clinical indicators" [Participant 14]*

> *"Clinical researchers may have different priorities to academic researchers" [Participant 12]*

> *"Just because I'm a clinician doesn't mean that the issues relevant to a pure researcher don't apply to me, but it is just the issue of time" [Participant 9]*

Most participants expressed the opinion that the classification should include a number of different parameters and that these should include a variety of key history, radiological and clinical parameters to justify grading. Participants expressed the view that parameters should be:

> *"Not too extensive so as not to get bogged down but sufficiently comprehensive to include main indicators, a maximum of ten"*
> *[Participant 1]*

> *"Easy to quantify and score" [Participant 13]*

> *"Able to help apply own clinical reasoning" [Participant 14]*

One emerging subtheme was the importance of the weighting of radiological parameters. Some participants judged that radiological parameters could not be used alone as they may not be valid. This is because a severely damaged joint may not necessarily be painful but could be clinically restricted. One participant stated that:

> *"I don't make clinical decisions based on radiological parameters alone, this is because sometimes a patients clinical features do not always relate to what you see radiologically" [Participant 17]*

Eight participants concluded that radiological features and joint range of motion should not be weighted heavily in an HR classification. Several reasons were given to support this issue:

> *"Some patients compensate for reduced motion and some have less stiffness but more pain while others may have severe radiological findings with no pain" [Participant 5]*

> *"I wouldn't weight radiological parameters heavily as I don't base my treatment on what the X-ray looks like" [Participant 17]*

“Radiological findings do not always to the clinical features that patients present with” [Participant 16]

Clearly there are issues as to whether the objective scale correlates to any clinical significance as some patients can have severe joint pain but no radiological changes.

A majority of participants expressed the importance of the classification system being evidence-based. Clearly this is an important concept. Several participants substantiated their opinion by expressing the following views:

“We are looking for an evidence-based system to demonstrate validity and reliability and link to clinical management” [Participant 2]

“There is a need to determine the consequences of HR over time”. To enable this to be measured the system needs to be evidence-based” [Participant 7]

The need to be realistic about what is included in the HR classification is an important issue emphasized by participants. This is because there maybe redundant information in the proposed system that doesn’t contribute to clinical decision-making but which may be important in terms of classifying the condition. This issue is highlighted by the following remarks:

“I feel that there are some radiological parameters which may indirectly influence clinical function in HR and may be of use in an HR classification system” [Participant 8]

“It is so easy to assume that because a parameter has no clinical relevance it would be redundant in a classification of that condition” [Participant 2]

“Just because a parameter has no obvious relationship to the 1st MTPJ doesn’t mean it might not be of value to classifying HR” [Participant 1]

One of the subthemes to emerge was related to the use of numbers and the subsequent value of goniometers. Most participants expressed the view that the use of numbers to indicate the degree of severity in the classification should be avoided hence goniometric use to measure or monitor HR over time should be avoided. The reasons behind these comments include:

> *"In terms of clinically relevant parameters if we are using how it affects the patient, the degree of joint immobility is only a very gross indicator" [Participant 15]*

> *"A patient may be able to tolerate a level of joint stiffness up to a certain point before developing symptoms but, once they begin to notice limitation the degree is not really important" [It was felt that] "this cut-off will differ between individuals and, so what is important is when the patient brings this to your attention rather than the specific number of degrees" [Participant 16]*

An emerging subtheme was that of the need to evaluate pain. The difficulty in quantifying pain and the constraints of the visual analogue scale (VAS) were raised. Pain severity was considered important but nine participants perceived that timing of pain during function was also relevant. Others stated that specification of pain location was of value. For example:

> *"It is useful to specify the location of pain i.e. bump, joint, sesamoids, FHL, as this differs between patients and has a bearing on management" [Participant 12]*

Another key subtheme which emerged was that of foot position and its effect on function. Ten participants expressed the view that overall foot position or structure was important to include in the HR classification. The magnitude of pronation (flat foot), abnormal metatarsal formula and location of callosities was also considered important as it may reflect the degree of altered foot function. This was exemplified by the following observations:

“Inclusion of foot position is important because in patients with more pronation the HR is often more symptomatic” [Participant 3]

“I find that foot structure has a bearing on HR severity, its inclusion in an HR classification cannot be emphasized enough” [Participant 6]

“The Foot Posture Index should be a necessary inclusion because it quantifies abnormal foot position and its potential influence on abnormal foot function” [Participants 2, 7 & 9]

An important subtheme to emerge was the importance of soft tissue parameters. Nine participants (physiotherapists, rheumatologists and musculoskeletal podiatrists) felt that inclusion of more soft tissue parameters in the HR classification was needed. It was expressed that it may prove useful to add FHL/ FHB tightness, length/ mobility of plantar fascia, sesamoid pain/ mobility and first MTPJ transverse plane slide/ glide rather than pivoting. Comments by several participants exemplify this:

“The reason why the 1st MTPJ may be painful and have limited motion is that the soft tissues could be tight” [Participants 10 & 11]

“The soft tissues play a key role in HR pathology and it would therefore be of value to assess/ measure these structures” [Participant 8]

In addition the physiotherapists contended that inclusion of the following may prove helpful:

“Ankle mobility, tibialis posterior (TP) strength/ ability to stabilise foot may prove useful” [and that]”A short/ tight overworking FHL leads to weak underactive TP” [Physiotherapists]

These participants (physiotherapist) also expressed the view that joint stiffness is difficult to quantify and introduced the concept of measurable stiffness versus perceived stiffness.

A further subtheme to emerge was that related to the importance of history parameters. Ten participants considered the history to be most important and the need to think of the patient as a person rather than a condition. Participants emphasized a number of issues relating to history which they perceived to be important:

> *"The classification needs to mirror the same things you look for in terms of patient history related variables" [Participant 15]*

> *"Certain aspects of the patient history are paramount to include as only they can provide clear evidence of HR disease progression" [Participant 11]*

> *"History parameters can provide valuable information about patient function or lack of it and would be helpful to include in the HR classification" [Participant 9]*

These participants also emphasized the need to document changes in function then link this to clinical and radiological signs. One participant considered that it would be useful to break down the history to specify the level of disability caused by HR during certain activities i.e. work, sport, housework. Whilst it is a useful idea this moves away from a classification and more towards a questionnaire. Another participant held the opinion that there should be more emphasis on self assessment of daily living as this would allow the clinician to be more realistic of patient expectations of you. Again this is a valid point but confuses the classification with an activities-of-daily-living measure.

There is clearly a need to develop patient history (e.g. impact on lifestyle). Soft tissue restrictions and magnitude of pronation are also worthy of inclusion. Compensatory gait mechanisms are consequences of HR and dependant on numerous factors and are therefore not considered reliable. Use of radiological parameters alone or goniometers should be avoided.

Participants were asked to describe the ways the proposed classification might meet their requirements. Of the seventeen participants only four gave outright support to the proposed classification, while three strongly rejected it. Half gave answers in which conditional acceptance predominated over rejection, while two expressed an even balance between these. Most participants revealed that in its current form the classification was not adequate. An example of this is:

> *"In its current form it is too long and complex for patient assessment and decision-making although all relevant areas are covered" [Participant 14]*

The use of the HR classification was a key subtheme to emerge. Some participants found the tick box format useful and clinical prompts helped act as an aide memoire and felt that is was applicable to biomechanical evaluation of HR. This issue was raised by the majority of participants and the following views were expressed to substantiate its value:

> *"Its value may be as an initial screening which you can refer back to on subsequent follow-ups" [Participant 17]*

> *"Its use in planning which management pathway is indicated" [Participant 10]*

> *"It helps clinicians explain to patients how certain parameters influence management and facilitate their compliance" [Participant 5]*

A number of the participants (9) provided additional insight by concluding that if the classification was used for decision-making the clinical and radiological parameters would need moderating with history findings. It was also stated that a measure of the patient's functionality over time and its impact on lifestyle would be valuable and needs emphasis.

It is clear that the complexity and length of the classification need reduction and that the measure of patient functionality may need developing.

Participants were asked to reveal their views as to the most ideal scoring system for HR. All participants expressed the opinion that a scoring system would be necessary to help grade severity and that a validated weighting of different parameters to stratify different stages of HR was indicated. It was generally expressed that the concept of scoring the HR classification was necessary and this was substantiated by various opinions:

> *"The scoring system would need to be simple, and succinct with three (mild, moderate, severe) to four levels of scale with different ranges providing less noise than 0-100" [Participant 16]*

> *" A process of scoring will help to grade severity but in order for this to be meaningful a weighting of different parameters must be provided" [Participant 2]*

> *"It is important that the classification is able to be scored but for this to be of value it must be valiadated" [Participant 7]*

A key issue raised by participants related to the importance of an evidence-based consensus on weighting of classification parameters. A clear majority of participants expressed the opinion that an evidence-based consensus agreement as to the appropriate weighting of parameters was required based on its validity, importance in respect of functionality (i.e. pain) and as an indicator for referral purposes. Participants concluded that the clinical application would need to focus on decision-making for treatment that was useful and evidence based and that the features that are least useful are those for which there is least evidence and which are the hardest to score. Furthermore certain participants (rheumatologists) expressed the view that:

“A scoring system looking at how much of a problem the patient has after an intervention would be useful so you can start gathering an objective way of scoring if your treatment is helpful i.e. the functionality of the patient rather than how much movement the toe has” [Participant 15]

Most participants agreed that more weighting needed to be applied to the history component of the HR classification but a third of these considered that history variables may prove difficult to score as they are subjective.

The majority of participants expressed concerns regarding the difficulty of scoring gait. They explained that scoring may require breaking gait down into what the changes are and whether joints proximal to the foot are responsible for these changes.

A few participants voiced concerns about accumulative scoring over this range of parameters saying that this may complicate matters because big numbers would be involved unless sections are scored individually.
Five participants contended that the method used to score parameters had implications for assessment of severity and that multiplying parameters provides a more useful score of severity than adding them together. It was explained by a few participants that:

“An exponential curve (multiplying scores) better describes progression of HR and difference between grades than linear (adding scores) i.e. less difference between 5 + 5 = 10, than 5 x 5 = 25” [Participant 5]

“Two components – grade and severity are required to weight the score to give it more meaning” [Participant 7]

Ten of the participants contended that the weighting needs to be loaded towards the direct effects on the joint rather than associated factors as these can be seen in non-HR patients. Activity levels restricted by HR need to be quantified so their impact on daily life is weighted and also patients' age and expectations.

Clearly there is a need for a validated scoring system with evidence-based consensus agreement on weighting of parameters. This needs careful consideration and further research is warranted.

6.4.2: Theme 2 - Classification type, scale and interpretation

The purpose of this theme was to examine the participant's rationale for the type of classification they used and explore issues relating to its scale and interpretation.

Participants were asked their opinion on the purpose of classifying HR. The majority expressed the view that communication between professional groups was valuable from an educational point of view explaining that if a surgeon refers a patient back to the GP it may help to give a rationale for the treatment approach at that point in time. Participants expressed a number of views:

> *"It would aid clinical decision-making and longitudinal evaluation of treatment using a build-up of criteria" [Participant 11]*

> *"It provides an estimate of when to refer on for surgery" [Participants 5 & 6]*

> *"It should not be used in isolation as other factors need consideration such as patient preference" [Participant 2]*

The concept of how certain radiological parameters change following surgery was raised by participants. Five participants questioned the value of some radiological parameters post surgery which may change depending on the surgical procedure chosen. Comments made by these participants fell into two broad groups (surgeons and rheumatologists). The following are examples of the views presented:

> *"The parameter of joint space changes following a fusion" [Surgeons]*

> *"Treatment evaluation may centre on improvement of symptoms rather than joint motion" [Rheumatologists]*

Furthermore its role in surgical procedure selection only plays a part as other factors are required to make this decision e.g. patient motivation, proximal joint involvement.

One of the subthemes to emerge was whether radiological features could always be applied to clinical features. Twelve participants contended that there was not always a difference between levels of HR morbidity and radiological features. This response overlaps with a similar subtheme in Section 6.4.1 where participants agreed that use of radiological parameters alone is insufficient. A number of participants concur on this point. Two participants in particular held strong views on this:

> *"There is not always a correlation between the level of HR morbidity (pain and functional limitation) and radiological features presenting" [Participant 16]*

> *"Certainly my experience is that the radiological findings of the joint do not always represent its clinical signs and symptoms" [Participant 17]*

The issue that classifying HR may differ between clinicians and researcher's was expressed by participants and seen to be an emerging issue. This overlaps with a similar issue raised in Section 6.4.1. This point was emphasized again by some participants who explained that inclusion criteria for clinical research can be rigorous. One Participant explained that:

> *"Inclusion criteria for clinical research can be strict because you are trying to obtain a homogenous group of individuals" [but] "in clinical practice classification systems become less important because, you are more concerned with patient centred variables rather than the stage of HR i.e. trying to relate anatomical problems to the patient rather than a literal classification" [Participant 16]*

Clearly the HR classification has a number of potential uses. These may differ depending on the context of application and combination of parameters used. Also its purpose may differ between clinicians and researchers.

Participants were asked to share their views as to the most important parameters for constructing a HR classification. These parameters were raised by earlier studies (Beeson et al, 2009a & 2009b). The level of acceptance for each parameter is summarized (Appendix 39). Participants expressed a variety of opinions about parameters:

> *"Patient history is key particularly activity levels, change in walking pattern and difficulty wearing footwear as it clearly illustrates the problem" [Participant 6]*

> *"Gross assessment of joint movement defined as (unrestricted, restricted, very restricted, completely restricted) may be more relevant than measuring angles when assessing function" [Participant 13]*

> *"I don't feel measurement adds a lot" [Participant 8]*

Participants shared different views on the inclusion of joint pain. Some felt that the frequency of joint pain is relevant (similar point raised in Section 6.4.1) whereas others perceived that pain scales only become relevant pre and post-intervention as the patient can tell if their symptoms are better i.e. not better, a bit better, better, a lot better. Others (rheumatologists) felt that they didn't need to numerate pain for clinical practice but that it was relevant for research.

Ten participants felt that secondary features associated with HR such as metatarsalgia and lesser toe deformity were not relevant as these can be found in non-HR patients.

A few participants expressed the opinion that although certain parameters (hallucal and 2nd toe length) may be relevant to epidemiological research of HR they may not be of value to clinical management.

The lack of importance of certain radiological parameters was an issue which was seen to emerge. Some participants questioned the relevance of joint space asymmetry and subchondral sclerosis when managing HR. They stated:

> *"Joint space asymmetry is more of a problem in hallux valgus than in HR" [Participant 2]*
>
> *"Subchondral sclerosis is difficult to quantify" [Participant 14]*
>
> *"It is irrelevant to quantify subchondral sclerosis because it is a consequence of what is going on" [Participant 15]*

Measurement of joint angles was not always considered important. Navicular-cuneiform sag, second MTPJ, sesamoid distance and medial-intermediate cuneiform diastasis were not routinely mentioned.

Some participants gave a mixed response whilst others provided conditional approval (Appendix 39). A clear majority reiterated that any parameters chosen for inclusion should be evidence-based and subjected to appropriate validity and reliability testing.

Criteria and evidence for making judgements clearly varied between participants. Appendix 39 clearly illustrates which parameters participants consider most important. However, after subsequent analysis (Chapters 3 and 4) some (*) are rejected. It is concluded that use of few key parameters is more manageable and indicated for classifying and managing. Some professionals expressed the view that:

> *"The functional side (walking distance before pain) may prove useful to surgeons pre-operatively but the history and function may prove more helpful than clinical parameters following surgery, especially if the patient has had a fusion" [Rheumatologist]*

Participants were asked to reflect on what they considered to be the optimal mode of interpretation of the proposed HR classification. This was considered by participants to be an important area and a new subtheme was seen to emerge. Seven participants suggested that the classification parameters could be applied in a structured manner such as an algorithm and a scoring system may enable it to be used as a diagnostic tool. Eleven participants expressed the view that scoring and weighting of parameters was important. This agrees with similar comments made in Section 6.4.1. Participants revealed a number of opinions regarding interpretation:

> *"Each section needs to be scored and weighted based on its importance" [Participant 1]*

> *"The history of pain and effect on function is important" [Participant 16]*

”Radiological features would be weighted less for me as a physiotherapist, I consider them more relevant to a surgeon” [Participant 9]

Nine participants judged that it may be possible to grade severity of HR and its impact on function using an accumulation of parameters where a higher score indicates greater severity. Loading of pain was considered important. In contrast eight participants were concerned about how the parameters combine to provide an overall picture. Just under one-third of participants considered that a number should be applied to each question and that these add up to provide an overall score used to grade HR.

Clearly weighting of parameters should be based on their importance, immediate affect on the patient and give sufficient range for grey areas.

6.4.3: Theme 3 - Construction of HR classification

The purpose of this theme was to explore participant’s views related to the content and construct validity of a selected HR classification.

Participants were asked how well they perceived the proposed HR classification measures what it was supposed to measure (content validity). Again an overlap with Section 6.4.2 is provided where the concept of expanding the patient history is expressed. Some participants concluded that there was a need to expand the history section:

“Its use in clinical decision-making may be optimised if the history was expanded so as to capture individual requirements and expectations” [Participant 14]

“More emphasis on patient history would enable a better judgment of the patient’s lower limb functionality to be made and enable comparisons over time to be made” [Participant 15]

Twelve participants judged that gross assessment of first MTPJ movement was warranted as goniometric measurement was not helpful.

The majority of participants felt that quantification of joint pain frequency was necessary but that pain levels should be replaced with categorical measures of pain and that VAS only becomes relevant pre and post-intervention. Again this overlaps with comments made in Sections 6.4.1 and 6.4.2.

Fourteen participants judged that the magnitude of joint space narrowing and osteophytes may be a useful measure of first MTPJ change, and that radiological content is sufficient for surgical decision-making.

Participants revealed differing opinions on the proposed content of the HR classification. Thirteen participants felt that it contained too many parameters and that it might be difficult to gain immediate familiarity whereas eight participants judged the proposed content as comprehensive, clearly outlined, relevant and a useful checklist.

One of the subthemes to emerge was that patient participation in construction of the HR classification may be of value. Some participants supported this and reasoned that:

> *"It may be helpful if patients participate in creating and substantiating content so that their concerns are reflected" [Participant 1]*

> *"The patient will have particular worries and concerns and these may be useful to include in the HR classification" [Participant 10]*

Patients' responses to history questions in Study 1 were helpful, but these were not involved in creating the classification. Clinician-based outcomes focusing on surrogate measures (e.g. joint ROM) has historically been emphasized and patient input has customarily been considered too subjective. Little is known about the actual relationship between these surrogate measures and a patients' foot health status. Therefore clinicians and researchers need to be careful when interpreting changes in these surrogate outcomes as being relevant and meaningful to the patient (Landorf & Burns, 2009). Whether clinician-generated outcome measures were, indeed, important to patients is an area of great conjecture. Further research on the concept of what is important to the patient in HR may be useful.

Participants emphasized that parameters would only be relevant in measuring aspects of HR if their inclusion was justified based on evidence-based research in which their content validity is established. Studies 1, 2 and 3 attempted to validate the usefulness of such parameters. Categorical measures of pain (i.e. not better, a bit better, better, a lot better) may be more appropriate for clinical practice and numeration of pain for research.

Participants' views on whether the proposed classification was adequate in its quantitative assessment (construct validity) were sought. Most participants reasoned that use of present/ absent was unacceptable and that weighting of parameters for severity and scoring was indicated.

The VAS has good validity (Duncan et al, 1989) and reliability (Reville et al, 1976) but five participants reported its limitation is its unidimensionality i.e. it does not evaluate broader quality-of-life issues. Participants agreed that pain frequency needs quantification and weighting i.e. daily, weekly. One participant expressed the view that it should be correlated to activity:

"It should be linked and scored to activity levels" [Participant 14]

Some participants judged that changes in pain level are important to patients. Meaningful change is a highly complex and contentious issue. The change in pain which is important to the HR patient "minimal important difference" (Schunemann & Guyatt, 2005) may require further investigation.

Five participants expressed the view that numerical values of joint ROM are necessary for grading HR while others preferred to use clinical experience. The concept of placing measurements within a range or band was raised by a third of participants. Six participants emphasized the use of banding for measurements, rather than relying on precise numbers it may be better to indicate that the value falls within a broad range of values. Two of these participants expressed the following opinion:

> *"The fact an angle is more than or less than a given value may be sufficient instead of being 11° rather than 10°" [Participant 15]*

> *"Placing measurements within broad bands may be of more clinical relevance in an HR classification than trying to provide exact values as we already know that specific goniometric values cannot be relied upon" [Participant 6]*

A few participants expressed the view that limits should not be used to determine an arbitrary cut-off between normal and abnormal first MTPJ ROM, but were unable to offer an alternative.

One of the main subthemes that emerged was associated with difficulties in goniometric joint measurements. The problems associated with angular goniometric measures were raised by a clear majority. A variety of comments were expressed:

> *"I find goniometric use time consuming" [Participant 12]*

> *"Goniometric use is only valuable if training is applied and specific criteria used" [Participant 2]*

“Measuring joint ROM is open to error as its value at subsequent visits may be reduced if further error is compounded due to poor reliability of goniometers” [Participant 7]

Two participants concluded that the concept of pain quantification during passive joint motion may be a more useful marker of HR severity than measuring joint ROM due to poor goniometric reliability.

Participants were asked how well the proposed HR classification correlates with a “gold standard” (criterion validity) or next best measure. Participants discussed the importance of this concept at length. Fourteen participants described that there is no consensus on HR, let alone a clear “gold standard” for clinical use. Five participants were aware that different HR classifications exist and one participant stated that these classifications are well documented and that they provide useful background reading, but that he did not find them clinically useful. Two participants considered the next best measure was that described by Shurnas & Coughlin (2003b). During further discussion a subtheme begins to emerge which questions the definition of a “gold standard”. This is exemplified by the following comments:

“We used this because, it is one of the most cited in the literature but this doesn’t mean it is a gold standard” [and] “it may not encompass all relevant parameters” [Participant 13]

Five participants considered that the proposed classification compared well with existing HR classifications because it uses a variety of clinician based and patient reported parameters, is well structured and easy to apply. A few participants also concluded that:

“Based on my understanding of other measurement systems I suspect there will not be a perfect correlation between clinical and radiological parameters” [Participant 16]

“History and clinical parameters are likely to vary as they will be dependant on a number of factors and for each patient these will not depend on the same things” [and that] “there may be a correlation between JSN, pain and restricted dorsiflexion but it will not be as close as you think” [Participant 17]

Clearly no ‘gold standard’ currently exits, but there is a need for a coherent and widely used standard to become adopted as a baseline for future research to be compared with.

Participants were asked to comment on the consistency of the proposed HR classification in measuring the same outcome. Five participants questioned the consistency of certain parameters i.e. sesamoid morphology/ position, and medial/ intermediate cuneiform diastasis. The concept of whether the way in which parameters were documented could influence classification consistency was raised. Some participants substantiated their opinion that consistency of the classification could be influenced by how parameters were documented by saying:

“If parameter recognition is based on measurements then I would question reliability due to measurement error” [Participant 9]

“Parameters based on functionality rather than joint measurement may be more reliable as they do not require angular measurement using a goniometer” [Participant 1]

Eight participants judged that the use of rigid measurement criteria, more suited to research, may aid consistency but preclude clinical use. Nine participants expressed the opinion that the context for the classification needs to be made clear.

In conclusion measurement error (particularly goniometric) may compromise consistency limiting the value of certain classification criteria.

Gait evaluation is subjective and unlikely to be consistent because it is influenced by numerous variables including the effect of more proximal joints.

Participants were asked how reproducible the results of the proposed HR classification would be for the same or different raters. Eight participants said that clinicians need to be aware of likely clinical and radiological measurement error and differences in pattern recognition between clinicians and different professional groups due to a different emphasis. Five participants expressed the view that reproducibility could be optimized as long as specific measurement guidelines were followed and that intra-rater measures should be fairly reliable but more reliable than inter-rater. The main issues raised by participants were related to familiarity, training and misinterpretation. The following comments exemplify these:

> *"Would inter-rater reliability be adequate because some angles and measures may be outside certain clinician's routine practice"*
> *[Participant 6]*

> *"The lack of familiarity with measurements has implications for training and the fact that misinterpretation may occur" [Participant 10]*

> *"Without training, elements may be missed or misinterpreted"*
> *[Participant 3]*

Some participants judged that if the classification included pictures directing the method the computer will do the rest thus reducing that aspect of reproducibility.

Inter-rater reliability was considered inadequate but intra-rater reliability was thought to be satisfactory as long as strict measurement criteria were used. Observations with defined criteria were considered more reproducible than measurements and their inclusion in a classification may aid its reproducibility.

Participants were asked whether they thought the proposed classification was sensitive to change. Nine participants judged that history parameters such as function, walking pattern and pain would be sensitive to change. Eight participants judged that developing the history section may enable a means to reveal lifestyle change over time and demonstrate clinical value to the patient. Four participants said that specifying gait changes by using force plate or in-shoe analysis may improve sensitivity. Subtle changes in plantar pressures, force-time patterns or centre of pressure line deviation may provide an adjunct to the classification that may aid sensitivity.

Two participants felt that presence/ absence of parameters are a useful guide to approaching management but, because it is difficult to score then sensitivity to change becomes a contentious issue. It was judged that use of quantitative measures may help demonstrate sensitivity to change. A few participants considered that sensitivity to change may also depend on the clinician's experience and training and to get a scale that is sensitive and not intuitive may be difficult. It may be argued that a validated classification with clearly defined parameters tested for reliability and using a validated scoring system is likely to be more sensitive and less intuitive.

6.4.4: Theme 4 - Clinical ease of use (utility)

The purpose of this theme was to explore participant's views on patient acceptability and clinician feasibility of a particular HR classification.

Participants were asked in what ways they thought the proposed HR classification was patient friendly (acceptable). Six participants expressed the view that it was accurate, clear and concise. Five participants said that it helps you give patients a clear explanation about their HR. One participant illustrated this by expressing the view that:

> *"Because it clearly breaks down all the key features of HR in a logical manner it may be helpful to use when discussing with patients about their HR condition" [Participant 8]*

An emerging concept was that by adding additional history parameters relating to functionality patient acceptability may be improved. Ten participants developed this idea when expressing the view that inclusion of more history that is pertinent to the needs and expectations of the patient may aid patient utility. This is illustrated by the following comments:

> *"Patients will have particular functional needs that may be affected by HR". The inclusion of these factors as parameters in a classification may provide a more meaningful and useful expression of the condition and the level of disability or morbidity that it causes. "They may be more pertinent to the needs of the patient providing greater patient utility. "Their impact on patient expectations of treatment may be more meaningful". [Participant 6]*

> *"How important are clinician generated questions to patients? "Maybe patient-generated questions relating to their functionality would be more meaningful for patients" [Participant 10]*

One issue which emerged was related to the value of patients completing a validated questionnaire before their assessment for HR. Some participants suggested that prior to assessment patients could complete a validated functional assessment questionnaire. This could feed into the history variables and be applied to the classification. Making it patient driven would reduce the amount of time on the clinician. All participants agreed that the remainder of the classification should be completed by the clinician. A common theme appeared among participants, for example:

“Additional valuable information may be obtained by getting the patient to complete a questionnaire before they are assessed for their HR. “This may provide information that could not be obtained through standard assessment and may add to the classification of their HR” [Participant 3]

Clearly the classification format needs to be short, simple and provide clarity. An area of conjecture among participants was whether clinician-generated questions were, indeed, important to patients.

Participants were asked in what ways they thought the HR classification was clinician friendly (feasible). A number of issues were raised which focused on the use of recognizable terminology which reminded the clinician of the key features of HR and where additional training was not indicated. The following opinions were expressed:

“Normal clinical parameters using familiar self explanatory terminology are used” [Participant 12]

“It provides a useful aid memoire” [Participant 4]

“No additional training is required” [Participant 7]

One of the subthemes to emerge related to the structure of the proposed HR classification. Almost two-thirds of participants judged that the HR classification presents a clear structured format and scalable framework to build a picture rather than picking random elements. This is eloquently expressed by one of these participants:

“The advantage of the proposed HR classification is the way in which it is put together is not only clear and includes parameters that are relevant but that it constructs a representation of an individual patients HR” [Participant 5]

An additional issue that was raised by participants was related to the extent of the proposed HR classification. Although most participants were happy with the structure of the HR classification most (12) felt that in its present form it was too lengthy and would be too time consuming for clinical use. Two participants said that:

> *"It's level of complexity and subtly may be more suited to research and education" [Participant 16]*

> *"Its intricacy certainly reveals how complicated this condition is but in its current form would be more appropriate for research than clinical application" [Participant 8]*

One concept that was perceived to be important among almost half of the participants was related to the need to be able to quantify function. It was judged by these participants that the absent/ present format reads like a list and although it is easy to answer, from a clinical and research perspective you may wish to quantify i.e. how much has function reduced. This was clearly expressed by two of these participants:

> *"If I was able to determine that a patient had a painful 1st MTPJ it would be helpful for me to be able to quantify this so that I could evaluate its potential influence on their function" [Participant 17]*

> *"To obtain the fact that a patients' HR had become more restricted over time is useful but it would be more helpful if this could be quantified to give a real reflection on its impact on their functionality and how quickly the condition was deteriorating" [Participant 1]*

An additional subtheme to emerge was related to a perceived need for precision as to the rationale for the HR classification. Some participants felt that there was a need for clarity as to the purpose of the classification.

What do you want to measure; in what context and what time constraints? Should it be an assessment tool to determine management or evaluate treatment? Some participants proposed:

> *"It could be used to teach students and that such training would ensure correct use and interpretation of findings" [Participant 10]*

> *"If the classification was used to inform management of HR it could be applied as an algorithm" [Participant 12]*

> *"Depending on its context of use, it could be used as a pre-assessment tool" [Participant 1]*

This subtheme was further subdivided when the concept of 'which professional group' was suggested as this may have implications on how the HR classification was applied. Twelve participants felt that this was an important point because depending on which professional group used the HR classification its emphasis may change. The following comments exemplify this:

> *"Physiotherapists may be more likely to place a greater emphasis on soft tissue pathology parameters than radiological parameters" [Participant 6]*

> *"As a surgeon whilst I am interested in both the clinical aspects of HR and its radiological parameters but for decisions on which surgical procedure to undertake I would tend to emphasize these parameters" [Participant 14]*

> *"I find it helpful to have an overview of both clinical and radiological parameters for clinical decision-making because it helps me to decide*

whether to perceiver with conservative treatments or refer on" [Participant 2]

The issue of training to use the HR classification was raised by a few of the participants. The following comments were made:

"Some professionals are more familiar than others with the proposed parameters". There may be a requirement for training among certain disciplines" [Participant 13]

"My feeling is that 'clarification' rather than 'training' is required" [Participant 7]

The issue of whether the classification framework was in fact an outcome measure was strongly articulated by one participant. This participant raised the contention by saying:

"It (the HR classification) is hierarchical (provides a measure of severity) and has implied issues of validity, reliability and sensitivity". Surely this must indicate that it is an outcome measure" [Participant 15]

Outcome measures generally demonstrate the impact of therapy and some wider issues in service delivery (Suk et al, 2009). A classification is probably a subgroup of an outcome measure.

The reduction of a classification to key parameters makes it easier to use. These findings suggest that an algorithmic format where parameters are quantified then scored and an overall grade applied may be more clinically meaningful and relevant. They also suggest that the application between clinicians and researchers should be similar as health outcome assessment spans both areas and is an important issue about which both need a clear understanding.

One of the subthemes to emerge was that the value of different disciplines using an HR classification are quite complex. Participants were asked if the proposed system would be acceptable to different disciplines managing HR. Participants judged that:

> *"It would be of value to those treating feet" [Participant 3]*

> *"It would be of value in research-based clinics" [Participant 17]*

> *"It is less useful in general practice and general rheumatology clinics" [Participant 16]*

> *"Different disciplines would apply a different emphasis to the HR classification dependant upon their speciality and experience" [Participant 9]*

This question raises a number of additional issues. Some participants expressed the opinion that it would aid knowledge transfer and sharing between disciplines and that on-line access to the information may enable this. Nine participants concluded that classification construction should be similar for all disciplines to ensure we all talk the same language giving it clinical value and application and to enable the patient to be followed from pre-op to post-op rehabilitation. A few participants said a generic classification is unlikely to be useful for different disciplines as each have specific needs but the majority judged that it was only the accumulation of scores and subsequent domain weightings that may change emphasizing different interests. However, it may prove difficult to highlight such subtle difference by providing an overall score.

Profession specific issues are considered relevant but caution should be applied to any interpretation because groups are small. Surgeons emphasized the need for a short, simple, quick classification including radiological features. Physiotherapists judged that emphasis of soft tissue (but fewer radiological) parameters was warranted. Rheumatologists felt that greater emphasis on patient history (particularly functionality) with less radiological parameters was indicated.

6.5: Limitations

The findings of this study were based on participants' personal opinions and judgements (influenced by experience, scope of practice and preferred treatment strategy). The composition and number of participants interviewed may have influenced findings. Questions were generated from earlier studies in this research; use of focus groups was not considered. This may have limited the type and construction of questions applied.

6.6: Discussion

This study found that a lack of consensus exists on use of classifications and consistency of application of parameters. This is supported by the literature where different HR classification systems and parameters are used (Section 2.3.2.1). This may reflect confusion over choice, a lack of understanding of their application or a lack of suitable classification systems. It may also influence the subsequent findings of research using such classifications. Participants were clear that classification parameters must be validated, reliable, sensitive, quantifiable, and few in numbers to be of clinical value and suitable utility. These findings agree with the research of others (Clancy & Eisenberg, 1998; Simmons et al, 1999; Suk et al, 2009). Radiological parameters alone were judged insufficient as radiological joint change does not always signify increased pain and reduced function (Bedson & Croft, 2008). It is suggested that pain quantification during passive joint movement may be a more useful marker of HR severity than measuring joint ROM due to poor goniometric reliability. This study emphasized the need for scoring of parameters and that these need to be validated, flexible, objective, based on functionality (rather than ROM) and weighting loaded towards the direct affect on the joint. This is supported by the work of Steiner & Norman (1995) and Beaton (2000). Participants suggested that quantification of pronation and soft tissue tightness (FHB/ FHL, plantar aponeurosis) may help determine HR severity. Such findings agree with those of Gould (1981) and Durrant & Siepert (1993). Whilst compensatory gait mechanisms are a feature of HR (Payne & Danaberg, 1997) participants considered that they are difficult to score; their inclusion is not advised. Participants considered associated factors to HR were not relevant as these are seen in non-HR patients. Appendix 40 outlines the parameters remaining following this study.

The findings of this study agree that a common classification for all professions is required and may help advance clinical practice. However, its application is dependant on the context of its use. Different professions may emphasis different domains. To date this point has not been raised in the literature. Potential applications include use as a diagnostic tool, establishing HR prevalence, a means to measure progress, to determine factors important to patients, monitor severity and contribute towards rehabilitation. These applications agree with those proposed in the literature (Section 2.3.2.1). It may also aid surgical decision-making (Beeson et al, 2008), but certain radiological parameters cannot be used post-operatively. An algorithmic approach may enable the classification framework to be applied in different contexts and provide clinical meaning. Redundant information that doesn't contribute to clinical decision-making is included, because it is important in terms of classifying HR and for evaluating its on-going consequences over time. The need to develop the history domain was expressed to help reveal lifestyle changes over time and is supported by the findings of Bodenheimer et al (2002). Also the contention that clinician-generated questions may not be important to patients revealed the need for further study to investigate parameters perceived important among patients. Patient involvement in creation and substantiation of content may be of value.

6.7: Conclusion

This study has provided insight into additional concepts of a HR classification. Together with earlier findings (Chapters three, four and five) it emphasizes the requirement for a system based on validated research and consensus agreement and, the need to provide a 'gold standard' against which future HR research is compared.

CHAPTER 7

DISCUSSION

This research aimed to develop an evidence-based classification framework for HR and establish validation of the devised system. Findings of each of the studies have been discussed in the relevant chapters, and this section provides an analysis and conclusion.

7.1: Inconsistencies and weaknesses in HR research

When reviewing the literature on HR numerous themes emerged. Previous reported studies were mainly retrospective therefore relying on patients' memory about their history (Coughlin & Shurnas, 2003a). Longitudinal studies on HR progression were lacking and there was an absence of any 'gold standard' against which HR classification systems could be compared. To date no studies have been devised solely for the development of measurement parameters for HR. Small sample sizes were used in some studies and power calculations not always considered (McMaster, 1978; Hamilton et al, 1997). Definitions of inclusion/ exclusion criteria were not always sufficiently explicit (Nilsonne, 1930). No independent attempt to establish validity or reliability of classification parameters could be found. A lack of standardization of measurement parameters and X-ray views used were apparent (Danaberg, 1993; Saxena, 1995). Methods for randomization were not always provided and some studies were randomized by patient but presented results in terms of numbers of feet. This is misleading due to correlation between feet of the same patient. Overall statistical analysis was of inconsistent quality. A need for further research on HR classification was therefore indicated and subsequently undertaken by the present research study so as to add to the knowledge base.

7.2: Interpretation of previous studies on HR classifications

The discrepancy of methodology between previous studies into HR classification produced conflicting results (Section 2.3.3.1). Such diversity has not furthered the understanding of HR and prevented data pooling for meta-analysis. It must be recognized that many HR classification systems were devised a long time ago (from 1930) and the scientific process used to construct them was not as sophisticated and stringent as nowadays. Also the purpose of such studies may differ from present day studies in that they mainly sought to describe the condition. Certainly, well constructed non-randomized studies (observational, cohort studies and case series studies) are likely to be better than evidence based on simply the clinician's experience (Audigé et al, 2004). However, the fact that these classifications were devised before current methodological understanding developed is not a justification for their continued use if they do not stand up to modern scrutiny. Although most HR systems fall short of what is required for a robust classification, at the outset of the research reported in this thesis there were three that come close to what is methodologically acceptable: Roukis et al (2002), Coughlin & Shurnas (2003a) and Vanore et al (2003).

7.3: What makes any classification framework scientifically robust?

The findings reported in this thesis suggest that any classification used in evaluating medical conditions should be developed as the result of carefully planned evaluative research rather than hypothetical concepts. It is also important that the criteria selected are those that most clearly delineate between different stages of the disease process, are most easily and reproducibly assessed, and, for guiding management, most accurately predict future behaviour and the likely outcome of different procedures for a specific stage of the condition.

7.4: Construction of the classification framework

A framework derived from data is more likely to resemble ‘reality’ than is theory derived by constructing a series of concepts based on experience or speculation (Audigé et al, 2004). Such an approach is more likely to offer insight, enhance understanding, and provide a meaningful guide to action. The HR classifications devised by Drago et al (1984) and Hanft et al (1993) offer limited insight as they are based on hypothetical concepts.

Before the present research methodology was established alternative approaches were considered. A meta-analysis of HR classification systems as a form of validation was excluded due to methodological weaknesses already mentioned (Section 7.1). A prospective outcome study to obtain construct validity needs large numbers of patients over many years and validating in a surgical cohort may have been complicated by perioperative variables and variations in surgical procedures used. Measuring responsiveness, the ability of HR grading to change as the status of HR changes over time requires a longitudinal study to show change. The classification is likely to be more than just a severity score; some parameters, e.g. metatarsal length, will not change.

In retrospect, it could be argued that undertaking sections one and two of the semi-structured interviews (Study 4) at the start of the research may have helped inform Study 1 design. However, it was considered that information used to develop and construct Study 1 should be based entirely on existing peer reviewed evidence-based research. Although ‘clinician-generated’ semi-structured interviews may have added to this, they do not replace it. This is because expert opinion remains opinion only (Aveyard, 2007), may be anecdotal and not necessarily based on research findings. Content determined by “experts” alone is arguably not sufficient for assessing face validity i.e. whether the instrument measures what it is intended to measure (Suk et al, 2009). Interviewing HR patients prior to the clinical study may have enabled issues of history, perceived important among these patients, to be included. Following Study 1, use of Principle Component Analysis (PCA) to reduce the number of parameters to determine a set of principle factors was an option. The number of patients obtained was insufficient to enable PCA to be applied as large patient numbers and high patient to variable ratios (15:1) is required (Osborne and Costello, 2004).

7.5: Summary of findings

7.5.1: Clinical parameters (Study 1: Chapter 3)

Some clinical parameters were examined but could not be retained for the classification framework as they required additional research (Table 7.1).

Parameter	**Relevance in present study**	**Best way to assess**
Family history (FH)	24% patients reported positive FH (86% had bilateral HR). Genetic contribution?	Properly constructed family study.
Unilateral or bilateral HR	Greater bilateral involvement. Does it increase over time?	Longitudinal study.
OA at other sites	Relative influence of mechanical & systemic factors in HR?	Epidemiological study.

Table 7.1: Clinical parameters requiring further study

7.5.1.1: Different dimensions of classification framework

Clinical parameters were grouped into broad categories to reflect their emphasis within the classification framework.

7.5.1.1.1: Aetiological/ contributory markers

In this study 47% of HR feet had pes planus. However, this finding is not necessarily causal. The two may develop *pari passu* and the evolving foot position may reflect the need for frontal plane compensation for a sagittal plane deformity (Payne & Danaberg, 1997). Payne (1999) and Curran (2003a & 2003b) expressed concerns that whilst consideration of increased pronation as a cause of pathology is based upon conceivable and conceptual hypotheses, no evidence can be found to either refute or support the notion of increased pronation as an important aetiological factor in foot function. The results from Study 1 (Chapter 3) agree, but, what may be paramount to pronation as a risk factor for HR is the timing and not the magnitude of this anomaly. The key to such analysis is likely to involve the three components of gait analysis: kinetics, kinematics and electromyography.

Study 1 found more patients with a second toe equal in length to the hallux (Beeson et al, 2009b) and the results suggest that overall length of the hallux may be a factor contributing to HR. These findings concur with those of Munuera et al (2007a) who found that the size of the first metatarso-digital segment could be implicated in the development of HR.

7.5.1.1.2: Markers of severity

Location and timing of symptoms were useful measures of HR pathology. First metatarsosesamoid joint pain was more common in established HR where altered sesamoid morphology presented. The results of Study 1 demonstrated a correlation between hallux abductus interphalangeus (HAI) and first MTPJ pain and reduced ROM and concluded that HAI is seen in more progressive HR. These findings concur with those of Study 2 (Section 4.5.1.1) where Chi-square analysis of first MTPJ space narrowing and HAI revealed a significant finding ($p < 0.005$).

7.5.2: Radiological parameters (Study 2: Chapter 4)

Overall radiological measures correlated poorly with clinical measures ($r = 0.28$, $p < 0.05$). The results of studies 1 and 4 support this; confirming that pain levels do not always reflect radiological changes (i.e. severe pain and no radiological change and vice versa). Expansion of early stage HR (clinical symptoms but no radiological changes) was considered useful to include in the classification; only Coughlin & Shurnas (2003b) agree with this concept.

The sesamoids may play a key role in HR. Abnormal sesamoid morphology and increased length was found to be associated with HR; this concurs with the results of other studies (Durrant & Siepert, 1993; Camasta, 1996; Munuera et al 2008). Proximal sesamoid displacement appears to be a late effect in HR; the findings of the present study are comparable with those of Roukis et al (2002) but not Munuera et al (2008), as the former used younger patients.

The results of Study 2 (Chapter 4) suggest that an association exists between a flat or chevron shaped metatarsal head and HR which corresponds with the results of other studies (Roukis et al, 2002; Coughlin & Shurnas, 2003a). A lack of sagittal plane MTPJ motion may result in increased transverse plane IPJ movement and subsequent HAI deformity. Clearly, the value of this parameter can only be judged when the incidence in the non-HR population is known.

In this study, the first metatarsal was longer than the third metatarsal in 73% of feet which may influence foot biomechanics. Again, the incidence of this in the general population is unknown. Radiological and dynamic in-shoe pressure studies comparing HR with non-HR patients would resolve this issue.

7.5.3: Reliability (Study 3: Chapter 5)

Intra-rater variation is smaller than inter-rater variation (Section 5.5.1) agreeing with the results of other clinical and radiological investigations (Elveru et al, 1988; Kilmartin et al, 1992; Aster et al, 2004; Chi et al 2002; Menz et al, 2007). Numerous sources of measurement error were found relating to the examiner, examined, examination and/or radiological criteria (Section 5.5.4). Clinicians using such measurements to make management decisions need to bear these in mind. Goniometric reliability was found to be poor, as it depends on a host of factors. Its use in the classification framework is not advised; thus the controversial issues relating to measurement with instrumentation can be avoided (McPoil & Cornwall, 1994). In clinical and scientific studies, standard methods of assessment need to be adopted and comparison should only be made by the same rater (Suk et al, 2009).

7.5.4: Qualitative parameters (Study 4: Chapter 6)

Qualitative views relevant to the classification framework were established by undertaking semi-structured interviews of a mix of professions with varied experience and scope of practice. Participants concluded that the existence of numerous HR classification systems suggests that little consensus exist on their use and implies that none work particularly well. They agreed that few systems were constructed as a result of carefully planned evaluative research providing evidence of comprehensive use of parameters independently tested for validity, reliability and responsiveness. Participants emphasized clinical utility, sensitivity to change, ease of scoring and patient-centered history parameters as relevant. Some parameters may be changed by surgery thus limiting their application post-operatively. It was concluded that classification construction should be similar for all professions but that domain weighting may differ emphasizing the interests of that professional group. The need to develop the patient history was articulated and to take into account issues perceived important among patients regarding functionality (Dawson et al, 2006).

7.6: Musculo-skeletal classifications

Currently, 170 musculo-skeletal lower limb classifications exist (Suk et al, 2009). Forty are foot classifications; using clinician-based or patient-reported observations or a combination. Seventeen achieve a score less than five out of ten based on methodological evaluation and clinical utility

(Suk et al, 2009) and ten of these do not demonstrate any form of validation. The findings of the present research highlight a number of points seen to be lacking in the above classifications and, which may aid their future development. These include the following:

- The need for a formal process of content development including use of ‘experts’ – clinicians and researchers.
- The need to specify the purpose aims and context of the classification.
- Identifying activities and symptoms important to patients.
- The balance between clinician-based and patient-reported observations needs to be taken into account.
- The concepts of clinical utility need consideration.
- More time is required for question development.
- The need to perform a pilot study and to review/ revise the classification framework.
- Weighting and scoring of parameters need validation.
- The classification field tested with a larger patient sample.

The semi-structured interviews revealed that involving patients in the creation of content was important and that qualitative data may add an additional dimension to the classification framework. It is suggested that further development of patient functionality would be beneficial providing meaning for both the clinician and patient revealing lifestyle changes over time. This finding agrees with those of Dawson et al (2006) who demonstrated the value of patient involvement in creation and substantiation of content in the Manchester-Oxford foot questionnaire. An additional benefit to developing the history domain is that certain radiological parameters change following surgery and therefore cannot be applied post-operatively but history parameters could replace these as a means to assess progress.

Unlike previous HR studies, the present research combines quantitative and qualitative designs and emphasizes measurement development of a comprehensive range of HR parameters. The clinical value and research application of these parameters has been found to be justified. The findings reported in this thesis suggest that there is a need for validity (content, construct and criterion) and reliability testing once content is determined and weighting, scoring and interpretation of parameters are a necessary component of classification construction. These findings agree with those of Steiner & Norman (1995), Fitzpatrick et al (1998) and Suk et al (2009). Further revisions and refinements once the classification is developed would ensure a robust framework.

Current musculoskeletal guidelines recommend that practitioners who wish to improve patient care should assess patient outcomes using a validated condition-specific instrument and focus on functional aspects of the disease secondarily (Barei et al, 2007). There is also a need for the classification to be accurately named to describe its content (rather than author's name) and a manual developed to provide a full description of its application to help communicate between professions.

7.7: Application of classification framework

The results of the present research reflect the need for a common classification for all professions although each profession, because of its particular interests, may emphasize different domains. The classification framework is more than just a severity score and includes other dimensions such as functionality and aetiological/ contributory factors (known to lead to pathology) i.e. first metatarsal length and head morphology. Depending on its context other applications could include: use as a diagnostic tool, establishing HR prevalence, a means to monitor progress, contributing towards rehabilitation and surgical decision-making. It is envisaged that an algorithmic approach may enable the classification framework to be applied in different contexts providing clinical relevance and meaning. However, the purpose was not to predict outcome as the prediction of final outcome is dependant on other factors such as surgical technique, experience and patient motivation.

The clinical implications of this research are that any parameter used in an HR classification needs to be validated and reliable to be of clinical or research value. Some parameters which were initially thought to be important have been shown to be irrelevant or unreliable. The classification should demonstrate simplicity, good clinical utility, scalability, comparability and extendibility to advanced applications requiring more morphological detail i.e. magnetic resonance imaging (MRI). The disadvantage in using plain X-rays for radiological parameters is that it limits sensitivity. MRI would provide greater detail of chondral, sub-chondral regions and demonstrate more subtle changes not apparent with plain X-rays. Technological advances in radiological interpretation of digital images may help to further validate measures of joint space narrowing. In addition to the above recommendations the HR classification should be constructed so that it requires no manipulation of the foot, marking of skin lines or goniometric measurement. Thus controversial issues relating to goniometric reliability (Section 5.5.3) and validity of first MTPJ positioning (McPoil & Cornwall, 1994; Menz, 1995) are avoided. Modification of parameter grading (i.e. HAI) to avoid angular measurement is necessary.

The HR classification must reflect differences of severity (grade) and extent (stage) between patients and is linear over the range from mild to advanced disease. It should identify differences within mild (early) phases of HR more precisely. An expanded scale for early HR may assist management but in younger patients certain markers of severity may be less important.

Appendix 40 outlines the HR parameters examined in this research and those discarded following each study. Only few parameters were found to be valid and reliable due to issues of measurement error. Angular measures were not reliable and first MTPJ dorsiflexion mattered more to the clinician than the patient. Table 7.2 shows the final parameters suggested for inclusion in the classification framework. Validated methods already exist for grading pes planus - Foot Posture Index (Redmond et al, 2005) and osteophytes - radiographic foot atlas (Menz et al 2007). The remaining parameters require further research to validate their grading method.

Domain	**Parameter**
HISTORY	
Markers of severity	Pain magnitude
	Pain frequency
Changes in function	Functional limitation
	Effects on lifestyle
CLINICAL	
Contributory factors	Hallucal length compared to 2nd toe
	Magnitude of pes planus
Markers of severity	Pain location (bump, joint, S, FHL)
	Timing of pain during AD
	Hallux abductus interphalangeus
RADIOLOGICAL	
Markers of severity	Joint space narrowing
	Osteophytes
Contributory factors	First met head morphology
	Sesamoid morphology
	First metatarsal length compared to third metatarsal

Table 7.2: HR classification framework

AD = active dorsiflexion, S = sesamoids, FHL = Flexor hallucis longus.

It is envisaged that the classification framework may require a different construction for different purposes. This could influence interpretation and may require further research to validate its application. Foot pressure studies could be used to supplement classification findings.

7.8: Influencing/ informing practice

Previous classification systems have not always been comprehensive and none have been constructed and designed using a formalized research process. As the use of such systems is open to error, the development of another HR classification may be justified.

As compared with Roukis et al (2002), Vanore et al (2003) and Coughlin & Shurnas (2003b), the proposed classification framework is comprehensive in its content. It offers a tool in which the concepts of measurement development and construction have been considered and in some instances applied i.e. validation (content, construct), reliability, sensitivity (responsiveness) and tested on experts. Furthermore its specificity helps it to be a more responsive measure forming a suitable baseline from which further development may proceed. This research also provides an evidence base to justify the inclusion or exclusion of specific criteria in a HR classification framework. The process of adding or removing parameters has been clarified by the present research and may help with treatment choice or act as an outcome moderator. Whether this can be reliably measured, assessed or recounted is an area for further exploration. The range of radiological parameters tested in Study 2 (Chapter 4) is broader than that of previous studies (Section 2.3.2.1) providing a more in-depth radiological picture of HR.

The classification framework informs clinical practice from various perspectives depending on its context of use:

The value for clinicians is that its clinical utility will enable quick and easy use in busy clinics, thus optimizing clinician and patient compliance. This will maintain short patient waiting times and promote increased patient throughput allowing clinicians to control waiting list time and ensure best use of resources. These concepts support the NHS philosophy of "best practice" and "evidence-based practice" (Darzi, 2008).

The parameters used are those normally examined during clinical assessment, therefore there are no resource implications. This supports the requirement to control NHS costs (BBC News Channel, 2009). Depending on the clinician's needs and circumstances there is flexibility to use different components of the classification to emphasize different aspects of the condition i.e. markers of severity, aetiological/ contributory factors and functionality. This enables the needs of different professional groups to be reflected i.e. it can be seen as a 'package' framework. Its application as an algorithm may help inform treatment providing evidence based practice (Schoenbaum & Gottlieb, 1990) and help follow patients from pre- to post-operative rehabilitation. It could also support the measurement of outcome (Cairns, 1996; Landorf & Burns, 2009).

It may inform development of patient "expectations" (anticipation of certain events) that can occur during or as a result of medical care for HR; as opposed to patient "desires" (patient's wishes that a given event occur). These can be compared with future expectations following treatment. This approach may give clinical researchers a means of defining "success" after surgery (Mahomed et al, 2002; Suk et al, 2009). Clinician and patient expectation can differ. The magnitude and direction of these differences could be dependant on HR severity and vary with time (Montgomery & Fahey, 2001).

It is envisaged that the classification framework will help improve clinicians understanding of the key parameters to apply and why systems which solely use radiological parameters i.e. Regnauld (1986); Hattrup and Johnson (1988); Hanft et al (1993) may have limited value. It could also help clinicians explain to patients how certain parameters influence management and facilitate their compliance (Section 6.4.1.3). This is supported by research which examines the importance of patient understanding (Eraker et al, 1984; Ross et al, 1993) and choice (Ryan & Farrar, 2000; Say & Thomson, 2003).

The results of this research has highlighted the relevance of patients participating in the creation and substantiation of classification content (so their concerns are reflected), the need to consider a balance of clinician-generated and patient-generated questions in classification construction and the need to account for patient expectations. This is supported by recent policy changes in health promoting the value of these concepts (Wilson, 2001; Baggott, 2005).

The classification framework provides a format which helps patients to better understand their HR condition and promote the value of service user involvement in service development, as promoted by the NHS (NHS Evidence, 2009).

The classification framework will enable podiatrists to practice evidence-based medicine and challenge previously held anecdotal beliefs. It will empower them to be effective and ethical in their management of HR. It will also promote good use of resources and help maintain professional standards. By enabling practitioners to contribute to providing an objective basis for collection of HR data it will aid construction of HR treatment strategies. It could also enable the development of HR care pathways for specific patient categories (e.g. elderly, sports) and generally help inform practice. This supports recent guidelines which set out standards of care for foot health services for people with musculo-skeletal conditions (Podiatry

Rheumatic Care Association, 2008). It might also help in epidemiological research of HR and in developing new procedures, techniques or protocols.

Although the classification framework is condition-specific it is envisaged that it could also have applications to other first MTPJ conditions or disease-specific (OA) in other foot joints. It may encourage alternative thinking about first-ray conditions promoting further research. It will also play a part in advancing podiatry students education and for professional development of extended scope practitioners as it provides the latest research-based understanding of HR.

The classification framework can be used by other professions who commonly manage foot problems such as orthopaedic surgeons, physiotherapists and rheumatologists. It can aid communication, knowledge transfer/ sharing and collaboration between professions through clinical practice and research. This complies with the NHS Musculoskeletal Services Framework which recommends methods to improve service delivery and multidisciplinary working (Department of Health, 2008). Its construction may enable different application and emphasis of different domains depending on the needs of that professional group.

It is envisaged that it will have implications for wider issues of service delivery and the drivers for “best practice” and “best use of resources” as promoted by the NHS Agenda for Change. Its application in orthopaedic triage clinics could help to reduce patient waiting lists and waiting time thus enabling clinical priorities, targets and indicators to be met (Department of Health, 2008). It may help time management and fulfils the tenets of the NHS Knowledge and Skills Framework (Department of Health, 2004). Its use can be applied across disciplines (primary care polyclinics) and impact on ambulatory practice influencing development of care pathways as promoted by the National Institute for Clinical Excellence (NICE) guidelines for OA (Royal College of Physicians, 2008).

7.9: Conclusions

Underlying the many difficulties with HR classification is a lack of understanding of what is perceived to be important in terms of classification construction. Consequently it is concluded that none of the existing HR classifications can claim to be valid measures of this condition, as there has been no research uncovering the need for appropriate HR classification construction. In addition, the validity and reliability of its parameters have been largely ignored to date. Patients and surgeons may differ in their concerns and priorities, and it is increasingly recognized that methods are required to elicit these qualities for classification systems to be of value (Suk et al, 2009). The principle findings of this research have answered questions about the development of a HR classification framework. The need for a properly constructed prospective study was highlighted. Inclusion of scientifically validated, reliable and sensitive parameters based on evaluative research to help stratify different stages of HR and aid clinical and scientific communication was important. Few quantifiable parameters optimise clinical utility; some may need to be patient-centred. Radiological parameters alone were judged insufficient as radiological change does not necessarily signify increased pain and reduced function. It also suggests that functionality is a better measure of responsiveness.

When establishing classification criteria for OA of the knee, hip and hand, no attempt has been made to define the cause of symptoms (Altman et al, 1991); similarly disagreement over the causes of HR should not affect attempts to classify and quantify this condition. HR by nature is progressive; as it advances it may evolve into more than an isolated condition of the first MTPJ. When devising a framework all aspects of HR need to be considered. However, factors secondary to HR were not felt to be relevant as these can be seen in non-HR patients.

Clinicians should be aware of measurement error of clinical and radiological parameters as they can influence reliability and, when possible one clinician should take all repeated measurements. Inter-rater variation for certain clinical and radiological measurements (particularly angular) is large enough to completely invalidate their use in clinical decision-making. Goniometric measurements have poor reliability and their use in an HR classification framework should be avoided.

Expert opinion concluded that future scoring of parameters would need to be flexible, objective, based on functionality and weighting loaded towards the direct effect on the first MTPJ. Compensatory gait mechanisms are difficult to score; their inclusion is not advised.

7.10: Recommendations for future research

Epidemiological studies would be helpful to establish assumptions of normality i.e. prevalence and incidence of HR and compare parameters from the HR classification framework (e.g. first metatarsal head and sesamoid morphology) with non-HR patients. Epidemiological studies to examine any association between HR and OA at other sites may be valuable, as would those seeking to clarify the respective influences of mechanical and systemic factors in the condition's development. Macro radiography may also provide new insights into the changes in first metatarsal/ proximal phalanx girth and head trabecular pattern.

Dynamic joint analysis (kinetics and kinematics) and plantar foot pressure studies comparing HR and non-HR patients may provide useful information on how metatarsal length and metatarsus adductus influences function.

Many classification systems have ordinal scales, these scales have limitations. The numerical value assigned to each grade mean that it is common to view them as continuous variables with ratio or interval characteristics. However, with ordinal scales, the difference between one grade and the next cannot be assumed to be equal i.e. grade four cannot be assumed to be twice as bad as grade two. Also parameters may not progress in a standard fashion, the rates of change may differ. This has implications for how the classification could be scored. Further research is indicated to validate a method of scoring and decide how best to weight each domain and grade each parameter.

In the future, any system which is constructed for classification of a musculskeletal foot problem such as HR needs to consider certain generic principles (Section 7.6). These should be based on evaluative research. Such an approach will help further knowledge and management of foot problems.

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Appendix 1: Summary of methodological process

Study 1 (Clinical study)

Derivation of clinical HR parameters for classification framework

Clinical data collected from 110 HR patients + completion of Foot Health Status Questionnaire.

↓

Study 2 (Radiological study)

Derivation of radiological parameters for classification framework

Radiological data collected from 110 HR patients (180 feet)

↓

Study 3 (Reliability study)

Determination of reliability of clinical/radiological parameters

Intra & inter-observer reliability tested on 20 patients/ X-rays by 4 raters

↓

Study 4 (Qualitative study)

Further validation using expert opinion

Semi-structured interviews of 17 participants

Appendix 2: Formal HR classification evidence table

Author/s Year	Classification type	Radiological criteria	Clinical criteria
Nilsonne (1930)	Primary & secondary HR	None	Primary HR - Adolescent onset (12-15yrs) - Long first metatarsal (due to secondary epiphysis at met head) - Narrow feet. - Marked flat metatarsal arch. Secondary HR - Local trauma to hallux or DJD in elderly patients.
Bonney & MacNab (1952)	Radiological features mentioned. No formal classification.	- Relative lengths of first & second metatarsals. - Degree of degenerative joint changes. - Evidence of MPE.	Functional criteria applied only as it was considered that anatomical abnormality alone is not the common presenting symptom of HR.
Kellgren & Lawrence (1957)	5 Grade radiological system.	Grade 0 - Normal Grade 1 - Mild osteophytes. - No sclerosis. - No JSN. Grade 2 - Moderate osteophytes. - +/- sclerosis. - Possible JSN. Grade 3 - Definite JSN. - Multiple osteophytes. - Some sclerosis. - Possible deformity of bone contour. Grade 4 - Severe JSN. - Severe osteophytes. - Severe sclerosis. - Severe deformity of bone contour.	None

Kelikian (1965)	No formal classification presented. Categorized into: 1. Primary – adolescents. 2. Secondary – associated with degenerative joint changes.	Brief description of radiological features.	Brief description of clinical features.
Giannestras (1973)	Primary & Secondary HR. Radiological & clinical features mentioned only. No formal classification presented.	- Narrowing or total obliteration of joint space. - Spur formation slight or quite extensive with occasional intra-articular loose body.	<u>Primary HR</u> - Post-traumatic localized OA, unilateral in origin. Trauma can be acute or gradual. <u>Secondary HR</u> - Attributed to various Arthritides. <u>Clinical features</u> - First metatarsal head dorsal/ dorsolateral exostosis. - First MTPJ enlarged circumferentially. - Valgus deviation of toe beyond normal limits found occasionally. - Osteophytic ridging base proximal phalanx & articular edge first metatarsal head. - First MTPJ Passive & active ROM limited & painful in both flexion & extension. - In most patients passive extension is lost.
Mann Coughlin DuVries (1979)	<u>Classified into 3 types:</u> - Congenital. - Acquired secondary to post-traumatic arthritis. - Acquired secondary to general arthritides.	Brief description of radiological features.	Brief description of clinical features.

	No formal grading presented.		
Rzona et al (1984)	Classified hallux equinus into 3 stages: - Hallux limitus Pre-school children to pre-teens. - Hallux limitus early teens to geriatric. - Hallux rigidus age variable.	No osseous pathology seen on X-ray in stage 1. Osseous pathology seen but not described. Osseous pathology – joint fusion.	Brief description of clinical features.
Drago, Oloff, Jacobs (1984)	Combined four grade clinical + some radiological.	Grade 1: - Pre-hallux limitus. - Metatarsus primus elevatus. - Plantar subluxation of proximal phalanx on met head. - Pronatory component to the rearfoot. - Minimal adaptive changes. Grade 2: - Some flattening of first met head. - Possible osteochondral defect. - Degeneration of dorsal cartilage. - Small dorsal exostosis. Grade3: - Severe flattening of first met head. - Osteophytes especially on dorsal lateral aspect of proximal phalanx & first met head. - Large dorsal exostosis. - Asymmetric narrowing of first MTPJ. Grade 4: - Total obliteration of first MTPJ. - Loose bodies within joint or capsule.	Grade 1: - Pain end ROM. - Deformity functional with minimal adaptive changes. Grade 2: - Pain end ROM. - Passive ROM limited, most pronounced with FF loaded. - Viable cartilage presents plantarly intra-op & degeneration of dorsal cartilage. Grade 3: - Crepitus & pain on full ROM. - Degeneration of articular cartilage intra-op with loss of ROM. Grade4: < 10º of total MTPJ motion. Associated with inflammatory arthritis. Pt's asymptomatic if total ankylosis.

Regnauld (1986)	Combined 3 stage classification radiological + some clinical.	Stage 1: - Development of arthrosis - Condensation of bone around joint resulting in joint enlargement. - Slight narrowing of joint space - sesamoids regular but slightly enlarged Stage 2: - Hypertrophy of joint space - Narrowing of joint space - Flattening of first met head & base of phalanx. - Elongation - Hypertrophy & irregularity of sesamoids Stage 3: - Ankylosis - Articular hypertrophy - Bony bases - Complete absence joint space. - Hypertrophy of met, phalanx & sesamoids. - Osteophytes bridge met/sesamoid joint.	Stage 1: - Acute/ sub acute pain - limitation of movement $< 40°$ dorsiflexion & $< 20°$ plantarflexion Stage 2: - Intermittent pain & tingling at rest - Limitation first MTPJ motion ¾ - Metatarsalgia Stage 3: - Very little first MTPJ motion - FHL contracture
Hattrup & Johnson (1988)	3 Grade Radiological.	Grade 1 - Mild to moderate osteophyte formation. - Good joint space preservation. Grade2 - Moderate osteophytes. - JSN. - Subchondral sclerosis. Grade 3 - Marked osteophytes. - Loss of visible joint space. - +/- subchondral cysts.	None
Karasick &	3 Grade	Grade 1: (mild)	None.

Wapner (1991)	Radiological.	- Minimal or no JSN. - Minimal dorsal & lateral spurring. <u>Grade 2: (moderate)</u> - Progressive JSN. - Larger spurs. -Subchondral sclerosis +/- cysts. <u>Grade 3: (severe)</u> - Marked JSN. - Advanced subchondral sclerosis. - +/- large circumferential spurs (especially dorsally). -DJC metatarsal-sesamoid joint. - Ossicles or dorsal intra-articular bone fragments resulting from repetitive micro trauma or synovial chrondrometaplasia.	
Hanft et al (1993)	Radiological	<u>Grade 1</u>: - MPE - Mild spurring & dorsal hypertrophy of first met head/ phalangeal base. - Junctional sclerosis first MTPJ. <u>Grade 2:</u> Elements of grade 1 plus: - Broadening & flattening of met head + proximal phalanx. - JSN. - Sesamoid hypertrophy. - Lateral spur first met head. <u>Grade 2b</u>: Elements of grade 2 plus: - Evidence of osteochondral defects. - Subchondral cysts. - Fractured subchondral bone plate. - Loose bodies. <u>Grade 3</u>: Elements of grade 2b plus: - Severe flattening of met head &	None

		proximal phalanx. - Minimal first MTPJ space. - Severe dorsal & lateral osteophytes. - Extensive sesamoid hypertrophy. Grade 3b: Elements of grade 3 plus: - Large osteochondral defects. - Loose bodies. - Subchondral cysts.	
Easley et al (1999)	3 grade radiological system.	Grade 1: - Mild to moderate osteophytes. - Well preserved joint space. Grade 2: - Moderate osteophytes. - JSN. - Subchondral sclerosis. Grade 3: - Marked osteophytes. - Loss of visible joint space.	None
Lombardi et al (2001)	4 grade radiological & some clinical. Modified Regnauld (1986) classification.	Stage I: - No DJC. - MPE Stage II: Joint adaptation Flattening first met head Small dorsal exostosis with periarticular lipping. Osteochondral fibrillation/ erosion. Subchondral eburnation. Stage III: Joint deterioration Non-uniform JSN, subchondral cysts Osteophytes, increased first met head flattening, cartilage degeneration Stage IV: Obliteration of joint space Exuberant osteophytes Loose bodies in joint & joint capsule	Stage I: Functional Hallux Limitus Limited dorsiflexion weight-bearing, normal non-weight-bearing. Hyperextension of IPJ. No pain at end range motion. Pronatory foot type Hallux equinus/ flexus Stage II: Pain end of range motion Stage III: Crepitus on ROM Pain through entire ROM Acute inflammatory episodes Stage IV: Joint ROM minimal to none Total ankylosis may occur
Roukis et al (2002)	4 grade radiological	Grade 1 - Apparent MPE with hallux equinus.	None

	system. Hybrid of: Drago et al (1984), Hanft et al (1993) and Kravitz et al (1994) proposed systems.	- Periarticular subchondral sclerosis. - Minimal dorsal exostosis (first met head/ base proximal phalanx). - Minimal flattening first met head. <u>Grade 2</u> - Moderate dorsal exostosis (first met head/ base proximal phalanx). - Moderate flattening first met head. - Minimal JSN. - Lateral first metatarsal head erosion and/or joint flare/ exostosis. - Sesamoid hypertrophy. +/- Subchondral cysts/ loose bodies. <u>Grade 3</u> - Severe dorsal exostosis (first met head/ base proximal phalanx). - Irregular JSN. - Traction enthesiopathic sesamoid hypertrophy with immobilization-induced osteopaenia. +/- Subchondral cysts/ loose bodies. <u>Grade 4</u> - Excessive exostosis proliferation with trumpeting of first met head, base proximal phalanx/ sesamoids. - Minimal/ absent joint space. - Sesamoid fusion. - Hallucal IPJ and/or first MCJ/or second MCJ OA.	
Coughlin & Shurnas (2003b, 2004)	5 grade combined radiological & clinical system.	<u>Grade 0</u> - Normal <u>Grade 1</u> - Dorsal osteophyte is main finding. - Minor narrowing of MTPJ space. - Minimal periarticular sclerosis. - Minimal flattening of metatarsal head. <u>Grade 2</u>	<u>Grade 0</u> - No pain. - Stiffness or slight loss of MTPJ motion. <u>*Dorsiflexion*</u> 40-60º and/or 10-20% loss compared with normal side <u>Grade 1</u> - Intermittent joint pain/ stiffness. - Mild restriction of MTPJ motion. - Pain at extremes of dorsiflexion and/or plantar flexion.

		- Dorsal, lateral and possibly medial osteophytes giving flattened appearance to metatarsal head. - Mild to moderate joint space narrowing and sclerosis. - No more than ¼ of dorsal joint space involved on lateral radiograph. - Sesamoids not usually involved. <u>Grade 3</u> - Same as Grade 2 BUT: - Extensive osteophyte formation. - Severe joint space narrowing. - Possible periarticular cystic changes. - More than ¼ of dorsal joint space involved on lateral radiograph. - Sesamoids enlarged and/or cystic and/or irregular. <u>Grade 4</u> - Identical findings to Grade 3.	<u>*Dorsiflexion*</u> 30-40º and/or 20-50% loss compared with normal side <u>Grade 2</u> - Moderate to severe, constant joint pain/ stiffness. - Moderate restriction of MTPJ motion. - Joint pain just before maximum dorsiflexion & maximum plantar flexion. <u>*Dorsiflexion*</u> 10-30º and/or 50-75% loss compared with normal side <u>Grade 3</u> - Constant joint pain & substantial stiffness at extremes of ROM. - No pain at mid-range passive MTPJ motion. - Moderately severe restriction of MTPJ motion (<20º total motion). <u>*Dorsiflexion*</u> $\leq$ 10º and/or 75-100% loss compared with normal side. There is notable loss of MTPJ plantarflexion as well (often $\leq$ 10º of plantar flexion). <u>Grade 4</u> - Same criteria as Grade 3 BUT Pain mid-range passive MTPJ motion. <u>*Dorsiflexion*</u> Same as in Grade 3.
Vanore et al (2003)	4 stage radiological/ clinical system.	<u>Stage 1 – Functional Limitus:</u> - Plantar subluxation proximal phalanx. - MPE. - No DJC noted - Pronatory architecture. <u>Stage II – Joint Adaptation:</u> - Flattening of met head. - Osteochondral defect/ lesion. - Cartilage fibrillation & erosion. - Small dorsal exostosis. - Subchondral eburnation. - Periarticular lipping of proximal phalanx, first met head & sesamoids. <u>Stage III – Established Arthrosis:</u>	<u>Stage 1:</u> - Hallux equinus/ flexus. - Joint dorsiflexion may be normal with non-weight bearing, but ground reactive forces elevate first met and yield limitation. -Hyperextension of hallucal IPJ. <u>Stage II:</u> - Pain end of joint ROM. - Passive ROM limited. <u>Stage III:</u> - Pain on full ROM. - Crepitus. - Associated inflammatory joint flares. <u>Stage IV:</u> - < 10º ROM. - Deformity or malalignment.

		- Severe flattening of met head. - Osteophytosis dorsally. - Asymmetric joint space narrowing. - Degeneration of articular cartilage. - Erosions, excoriations. - Subchondral cysts. <u>Stage IV- Ankylosis:</u> - Obliteration of joint space. - Exuberant osteophytosis with loose bodies within joint space or capsule.	- Total Ankylosis. - Inflammatory joint flares. - Local pain secondary to skin irritation, bursitis caused by underlying osteophytes.
Giannini et al (2004)	4 grade radiological system.	<u>Grade 0:</u> - Normal or minimal JSN, no osteophytes. <u>Grade 1:</u> - Dorsal/ lateral osteophyte, minimal JSN, sclerosis & metatarsal head flattening with a lateral spur. <u>Grade 2:</u> - Dorsal, lateral +/- medial osteophytes, flattened met head. - No more than ¼ of dorsal joint space involved on the lateral X-ray. - Mild to moderate JSN & sclerosis. - Sesamoids not involved. <u>Grade 3</u>: - Same as grade 2 BUT, severe JSN, cystic changes, > ¼ dorsal joint space involved lateral view. - Sesamoids enlarged and/or cystic and/or irregular.	None

JSN = Joint space narrowing, DJC = Degenerative joint changes, IPJ = Interphalangeal joint, MCJ = Metatarsal cuneiform joint

Appendix 3: Non-formal HR classification evidence table

HR studies with useful findings but without formal classification system		
Authors	**Radiological criteria**	**Clinical criteria**
Lambrinudi (1938)	None	MPE & hallux flexus introduced.
Jack (1940)	JSN, osteophytes, met/ hallucal length, MPE, sesamoid size/ position.	Briefly mentioned but not linked to radiological criteria.
Lapidus (1940)	None	Associated deformity: HR, Flaccid paralyses, congenital clubfoot, congenital talipes plano-valgus.
Bingold & Collins (1950)	Brief description.	Brief description.
Bonney & MacNab (1952)	Relative lengths 1st/ 2nd met, DJD, MPE.	Functional criteria applied.
Kessel & Bonney (1958)	Very brief description.	Very brief description.
Goodfellow (1966)	First metatarsal head osteochondritis dessicans.	None
McMaster (1978)	JSN, subchondral defect, osteophytes, flattened met head.	Brief description.
Cohen & Kanat (1984)	Brief description.	Brief description.
Schweitzer et al (1999)	MRI findings: JSN, geodes, osteophytes (lat & dorsal). Length first met length, met head shape, marrow oedema, sclerosis.	None

Appendix 4: Critical appraisal tool

Purpose: Is the purpose, setting and population clearly specified?
Content validity (extent to which domain is comprehensively sampled): Is the domain and all the exclusions from the domain clearly specified? Are all relevant categories included? Is the breakdown of categories appropriate, considering the purpose? Are the categories mutually exclusive? Was the method of development appropriate? What and how many measures (parameters) contribute to the system? Are the criteria of content validity satisfied for each category? Is a team of clinicians and patients required to develop content?
Face validity (does it measure what it is intended to measure): What is the classification trying to measure; is it relevant to HR? Is the nomenclature used to label the categories satisfactory? Are the terms used based upon empirical (i.e. directly observed) evidence? Are the criteria for determining inclusion into each category clearly specified? If yes, do these criteria appear reasonable? Are the definitions of criteria clearly specific? Are criteria of face validity satisfied for each category?
Construct validity: Does it discriminate between entities that are thought to be different in a way appropriate for the purpose?
Criterion validity: Does it correlate with a ‘gold standard measure of the same theme? In the absence of any ‘gold standard’ what is it validated against?
Reliability (internal consistency & reproducibility): How consistent are measures in measuring the same outcome? Does the classification system provide consistent results when classifying the same condition (test-retest)?

Is inter-observer reliability satisfactory?
Scoring: How has the instrument been interpreted and each parameter weighted and scored? Has the process been validated? How is classification constructed and evaluated?
Sensitivity: Does the instrument detect changes over time that matter to patients? How responsive is each component of classification to predict change?
Clinical utility (acceptable & feasible) Acceptability (patient friendly) Is it clear, concise, quick, easy to understand and comfortable for patient? Feasibility (clinician friendly) Is the classification simple to understand and administer? Is the classification easy to perform? Does it rely on clinical examination alone? Are special skills, tools and/or training required? How long does it take to perform?
Generalisability: Has it been used in other studies or other settings?

Adapted from Buchbinder et al (1996) & Suk et al (2005)

Appendix 5: Aetiological factors for HR

1) Spontaneous onset (Jack, 1940).
2) Hypermobile first metatarsal (Morton, 1928; Jack, 1940; Bingold & Collins, 1950; Root et al, 1977; Saxena, 1995; Kurtz et al, 1999).
3) No correlation between first ray hypermobility and HR (Coughlin & Shurnas, 2003a; Grebing & Coughlin, 2004).
4) Family history (Bonney & MacNab, 1952; Coughlin & Shurnas, 2003a).
5) Age (Nilsonne, 1930).
6) Gender (Gould, 1981; Shurnas, 2009).
7) Flat or chevron shaped metatarsal head (DuVries, 1959; Gerbert, 1981; Mann & Coughlin, 1981; Mann & Coughlin, 1986; Brahm, 1988).
8) First metatarsal longer or same length as the second (Nilsonne, 1930; Bonney & MacNab, 1952; Vilaseca & Ribes, 1980; Vanore et al, 2003; Cavolo et al, 2009).
9) First metatarsal longer than the third (Kilmartin, 2000).
10) Short first metatarsal (Wilson, 1958).
11) Long proximal hallucal phalanx (Monberg, 1935; Kravitz et al, 1994; Vanore et al, 2003).
12) Metatarsus primus elevatus (Lambrinudi, 1938; Jack, 1940, Gudas, 1971).
13) Hallux abductus interphalangeus (Coughlin & Shurnas, 2003a).
14) Congenital proximal sesamoid displacement (Miller & Arendt, 1940).
15) Ankylosis between sesamoids and first metatarsal head secondary to sesamoid degeneration and immobility (Collier, 1894; Karasick & Wapner, 1991).
16) Gout, psoriatic arthritis, rheumatoid arthritis (Karasick & Wapner, 1991).
17) Trauma (Mann et al, 1979; Gould, 1981; Bryant, 2000). Secondary changes in articular physiology together with increased intra-articular pressure and synovial intrusion caused by trauma is believed to result

in subchondral bone cysts and subsequent OA (Rhaney & Lamb, 1955; Freund, 1977; Resnick et al, 1977; Hanft et al, 1993).

18) Intra-articular first MTPJ fracture (Vanore et al, 2003).
19) Osteochondral fractures (Chang & Camasta, 2001).
20) Hallucal sesamoid fracture (Vanore et al, 2003).
21) Foot eversion during propulsion resulting from abnormal pronation (Jansen, 1921; Mau, 1928; Vanore et al, 2003; Bevans, 2003).
22) Extrinsic and/ or intrinsic muscle imbalance affecting first ray (Vanore et al, 2003).
23) Intrinsic musculature contracture or taught medial slip of the plantar fascia (Durrant & Seipert, 1993; Chang, 1996; Fuller, 2000).
24) Osteochondritis dissecans (Goodfellow, 1960; McMaster, 1978; Vilascera & Ribers, 1980).
25) Neuromuscular disorders (Mann et al, 1979).
26) Iatrogenic – metatarsus primus elevatus secondary to base wedge osteotomy (Bonney & Macnab, 1952; Cicchinelli et al, 1997) or plantar joint adhesions following distal metatarsal osteotomy (Banks & McGlamry, 1992, Chang & Camasta, 2001).
27) Diastasis between the first and second cuneiforms (Jack, 1940).
28) Horizontally orientated first metatarso-cuneiform joint (Kravitz et al, 1994).
29) Poorly fitting footwear (Davies-Colley, 1887; Cotterill, 1887; Bingold & Collins, 1950; DuVries, 1959).
30) Tight Achilles tendon (Bingold & Collins, 1950; Grebing & Coughlin, 2004).
31) Long and narrow foot (Bingold & Collins, 1950).
32) Obesity (Bingold & Collins, 1950).
33) Gait abnormality (Bingold & Collins, 1950; Payne & Dananberg, 1997).

Appendix 6: Documented HR findings

HISTORY	EXAMINATION
Pain with first MTPJ motion Shereff & Baumhauer (1988); Easley et al (1999); Coughlin & Shurnas (2003a); Michelson & Dunn (2005).	**Restricted first MTPJ motion** Nilsonne (1930); Bingold & Collins (1950); Smith et al (2000); Kilmartin (2000); Coughlin & Shurnas (2003a).
Intolerance of footwear Camasta, (1996); Coughlin (1999); Coughlin & Shurnas (2003a).	**Increased joint size (bony)** Giannestras (1973), Mann et al (1979); Coughlin & Shurnas (2003a). **Soft tissue swelling** Kessell & Bonney (1958); Mann et al (1979); MacKay et al (1997).
Inability to go up on tip toes Kessell & Bonney (1958); Mann et al (1979); Shereff & Baumhauer (1988); Easley et al (1999); Mulier et al (1999).	**Everted or supinated gait** Kessell & Bonney (1958); Mann et al (1979); Shereff & Baumhauer (1988); Payne & Dananberg (1997); Mulier et al (1999); Easley et al (1999); Roukis et al (2002); Coughlin & Shurnas (2003a); Vanore et al (2003).

Appendix 7: Disputed HR findings

DEMOGRAPHIC DATA	CLINICAL DATA
Family history ***Early onset of disease:*** Bonney & MacNab (1952). Great toe problems: Coughlin & Shurnas (2003a). ***Age of onset*** ***Adult:*** Mann et al (1979); Geldwert et al (1992); Dananberg (1993a, 1993b); MacKay et al (1997); Kurtz et al (1999); Thomas & Smith (1999); Feltham et al (2001); Coughlin & Shurnas (2003a). ***Adolescent:*** Nilsonne (1930); Bingold & Collins (1950); Kessell & Bonney (1958); McMaster (1978). ***Presentation*** ***Unilateral:*** Bonney & MacNab (1952); Mann et al (1979); Bryant et al (2000). ***Bilateral:*** Gould (1981); Shereff & Baumhauer (1988); Coughlin & Shurnas (2003a). ***Gender predilection*** ***Male:*** Gould (1981); Hattrup & Johnson (1988). ***Female:*** McMaster (1978); Mann et al (1979); Drago et al (1984); Geldwert et al (1992); Hamilton et al, 1997; Mulier et al, 1999; Thomas & Smith (1999); Kurtz et al (1999); Coughlin & Shurnas (2003a); .	***Functional hallux limitus*** ***Supports concept:*** Dananberg (1993a, 1993b); DiNapoli (1993); Payne et al (2002). ***Questions concept:*** Coughlin & Shurnas (2003a); Clough (2005). ***Arch*** ***Pes planus:*** Cotterill (1887); Nilsonne (1930); Bingold & Collins (1950); Cavolo et al (1979); Drago et al (1984); Cohen & Kanat (1984); Meyer et al (1987); Dananberg (1993a, 1993b), Saxena (1995); Viegas (1998). ***Normal:*** Jack (1940), Shurnas (2009). ***Achilles tendon*** ***Contracture:*** Bingold & Collins (1950), DiGiovanni et al (2002). ***Normal:*** Roukis et al (2002); Coughlin & Shurnas (2003a).

Appendix 8: Justification for chosen exclusion criteria

Hallux valgus-rigidus

Concurrent signs of hallux valgus (HV) and HR can occasionally co-exist. In these cases the intermetatarsal angle $\geq$ 12º and HV angle $\geq$ 15º. The radiological, clinical and biomechanical findings are not typical of HR.

Severe multiple forefoot deformities

Midtarsal, Lisfranc, MTPJ and IPJ deformities can present with unusual radiological and clinical features which impact on first MTPJ function.

Significant trauma to foot / leg

Trauma (i.e. fracture, dislocation or crush injury) resulting in deformity and altered radiological parameters may influence first MTPJ function.

Checkrein deformity of hallux (hallux flexus)

Distal tibia fracture resulting in tethering of FHL in midfoot may influence first MTPJ function (Lee et al, 2008). Hallux extensus may also alter first MTPJ function.

Neuropathy

Diabetes, alcoholism or neurological pathologies affecting the sensory and motor nerves of the lower limb can result in unrecognized trauma to the first MTPJ. Bizarre radiological and clinical findings can develop.

Previous First ray / forefoot surgery

Foot surgery and its complications can alter first MTPJ function (McGlamry et al, 1992) and its radiological parameters.

Morton's neuroma affecting any inter-metatarsal space

Pain arising from a nerve entrapment in the foot can alter the patients foot function, plantar pressure distribution and gait.

Infectious arthritis

This can influence first MTPJ radiological and clinical parameters.

Arthritides

The association between arthritides and HR is well documented (Nilsonne, 1930; Kashuk, 1975; Caselli & George, 2003; Vanore et al, 2003) and citied as a causative factor. Karasick & Wapner (1991) reported HR as a secondary feature to gout, RA or psoriatic arthritis. Horton (2000) described them as separate disease entities from HR.

Neuromuscular disorders

Upper and lower motor neurone disorders affect first MTPJ form and function and cause HR (Mann et al, 1979). Tibialis anterior spasticity or peroneus longus weakness can decrease 1st MTPJ ROM (Lapidus, 1940).

Insulin dependent diabetes mellitus

Diabetes can affect collagen increasing joint mobility and ROM.

Severe ligamentous laxity

Marfan's and Ehlers-Danlos syndromes result in increased joint ROM.

Long-term steroid use

Steroid use can result in obscure radiological and clinical changes.

Severe peripheral vascular disease (PVD)

PVD can produce radiological and clinical changes.

Metabolic bone disease

The following metabolic bone diseases result in bone changes that may influence the interpretation of radiological parameters: Osteoporosis, Osteomalacia, Pagets, Primary Hyperparathyroidism and renal Osteodystrophy.

Appendix 9: Patient invitation letter (Studies 1, 2 and 3)

THE UNIVERSITY OF NORTHAMPTON
School of Health

Dear ……..,

Study Title: *Development and validation of a classification system to aid surgical decision-making in hallux rigidus.*

You are being invited to take part in the above research study. You are being asked to take part because you have a foot condition called hallux rigidus affecting your big toe.

A study information sheet is enclosed. It includes information on the purpose of the study and provides answers to questions that participants may typically ask.

Taking part in this study is entirely voluntary. Please take time to decide whether or not you wish to take part.

Please ask us if there is anything that is not clear or if you would like more information.

Thank you for your help,

Yours sincerely,

Paul Beeson

(Chief researcher)

Appendix 10:

STUDY INFORMATION SHEET (Studies 1 and 2)

CONFIDENTIAL

Study Title: *Development and validation of a classification system to aid surgical decision-making in hallux rigidus.*

You are being invited to take part in the above research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of the research is to develop and validate a classification system to help surgical decision making in treating hallux rigidus. This part of the study will last for two years. Hallux rigidus is a common condition of the big toe joint which can cause pain and restriction of movement. It can be caused by structural or mechanical problems associated with the joint.

Why have I been chosen?

You have been asked to take part in the study because you have a hallux rigidus deformity. A minimum of 100 patients with this condition will be used in the study.

Do I have to take part?

Taking part in this research is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will receive a copy of the signed consent form. You are free to withdraw from the study at any time and without giving a reason. It will not affect the type/ standard of care you receive.

What will happen to me if I take part?

We will ask you to complete one questionnaire in order to establish how your toe joint problem affects you. Clinical tests of your feet will also be undertaken. These will not be over and above those involved in standard diagnosis and treatment.
You will only need to be seen **once** for 20 minutes. Overall the study will last 4 years.

What do I have to do?

No lifestyle restrictions or special requirements are necessary. You will be asked to complete one questionnaire. You will need to remove your shoes/ socks so the clinician can undertake some clinical tests on your feet.

What is being tested?

Weight bearing and non-weight bearing tests will be undertaken on your foot joints.

What are the possible disadvantages and risks of taking part?
There are no risks associated with this study. The clinical tests will not be over and above those involved in standard diagnosis and treatment. If as a result of the clinical tests a condition is found that you are unaware of we will inform your GP.

What are the possible benefits of taking part?
The information gained from this study will be used to develop a classification system for hallux rigidus. It will also be used to help surgeons gain a greater insight into the surgical management of this condition and aid in surgical decision making.

What if new information becomes available?
Sometimes during the course of research, new information becomes available about the treatment of the condition that is being studied. If this happens, your research clinician will tell you about it immediately. This will not affect your involvement in the study as the study is not making decisions about your management.

What happens when the research study stops?
The research findings will be written-up as a PhD.

What if something goes wrong?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS or Three Shires Hospital complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?
All clinical information which is collected about you during the course of the research will be reviewed by other health professionals but kept strictly confidential. Your GP will be notified of your participation in the study.

What will happen to the results of the research study?
The research findings will be written-up and published in a professional Journal.

Who is organising and funding the research? The University of Northampton.

Who has reviewed the study?
- Leicestershire, Northamptonshire & Rutland Research Ethics Committee.
- Medical Advisory Committee Three Shires Hospital

Chief Researcher/ Senior Lecturer- Mr Paul Beeson MSc, BSc(Hons), MChS
The University of Northampton

Thank you for reading this

Version 3 (20/10/05)

Appendix 11: Local Research Ethics Committee

Leicestershire Local Research
Ethics Committee One
Lakeside House
4 Smith Way
Grove Park
Enderby
Leicester
LE19 1SS

22 October 2004

Mr Paul Beeson
University College Northampton Senior
Lecturer
University College Northampton,
Park Campus,
Boughton Green Road,
Northampton
Northants
NN2 7AL

Dear Mr Beeson,

Full title of study: Development and validation of a classification system to aid surgical decision making in hallux limitus/ rigidus.
REC reference number: 04/Q2501/93
Protocol number: 5

Thank you for your letter of 09 October 2004, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chairman.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation.
I confirm that this is a 'No Local Investigator' study, therefore no site specific assessment need be sought from other RECs.

Conditions of approval
The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document Type: Application
Version: 2
Dated:
Date Received: 18/10/2004

Document Type: Investigator CV
Version: 1, Paul Beeson
Dated: 16/08/2004
Date Received: 18/08/2004

Document Type: Investigator CV
Version: 1, Carol A. Phillips
Dated: 16/08/2004
Date Received: 18/08/2004

Document Type: Protocol
Version: 5
Dated: 16/08/2004
Date Received: 18/08/2004

Document Type: Summary/Synopsis
Version: 1, Project Proposal
Dated: 16/08/2004
Date Received: 18/08/2004

Document Type: Copy of Questionnaire
Version: The Foot Health Status Questionnaire
Dated: 18/08/2004
Date Received: 18/08/2004

Document Type: GP/Consultant Information Sheets
Version: 1, Phase 1
Dated: 01/06/2004
Date Received: 18/08/2004

Document Type: GP/Consultant Information Sheets
Version: 1, Phase4-5
Dated: 01/06/2004
Date Received: 18/08/2004

Document Type: Participant Information Sheet
Version: 2, Phase 1
Dated: 09/10/2004
Date Received: 18/10/2004

Document Type: Participant Information Sheet
Version: 2, Phase4-5
Dated: 09/10/2004
Date Received: 18/10/2004

Document Type: Participant Consent Form
Version: 2
Dated: 09/10/2004
Date Received: 22/10/2004

Document Type: Response to Request for Further Information
Version: 1
Dated: 09/10/2004
Date Received: 18/10/2004

Management approval
You should arrange for all relevant host organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant host organisation before commencing any research procedures. Where a substantive contract is not held with the host organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Notification of other bodies
We shall notify the research sponsor, University College Northampton, that the study has a favourable ethical opinion.

Statement of compliance *(from 1 May 2004)*
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number: 04/Q2501/93 **Please quote this number on all correspondence**

Yours sincerely,

Dr Carl Edwards
Chairman

Cc Research & Development Department, University College Northampton, Park Campus, Broughton Green Road, Northampton, Northants NN2 7AL

Enclosures Standard approval conditions [SL-AC1 or SL-AC2]

Appendix 12: Medical Advisory Committee – Three Shires Hospital

BMI Three Shires Hospital

MS/SAA

4th August 2005

Professor Bill Ribbans
Consultant Orthopaedic Surgeon
Three Shires Hospital
The Avenue
Cliftonville
Northampton
NN1 5DR

Three Shires Hospital
The Avenue
Cliftonville
Northampton NN1 5DR

Tel 01604 620311
Fax 01604 629066
www.bmihealthcare.co.uk

Dear Bill

Mr Paul Beeson

The details of Paul Beeson's PhD study was placed before the Medical Advisory Committee on 13th July for consideration and was generally well-received. I am pleased to confirm MAC approved the research project and were fully in support of encouraging research as long as there is no inconvenience to the patients.

Yours sincerely

Michael Sheldon
Executive Director

Cc: Mr Paul Beeson

Appendix 13: Research & Development Northampton Acute and Primary Care Trusts

Mr Paul Beeson
Senior Lecturer
Faculty of Health
University College Northampton
Park Campus
Boughton Green Road
Northampton NN2 7AL

Julie Wilson
R&D Manager
NGH Trust
Northampton General Hospital
Northampton NN1 5BD

20/10/04

Dear Julie,

Re: Development and validation of a classification system to aid surgical decision making in hallux limitus/ rigidus – (REC reference number: 04/Q2501/93).

I am writing to confirm that I have received full ethical approval. The Leicester REC is now happy for me to proceed with my research project.
I have enclosed a copy of the REC approval letter for your records.

I have also enclosed copies of the following for your records:

1) Study Protocol + copy of letter to LREC indicating amendments.
2) LREC application form.
3) CV's for Paul Beeson + 1st Supervisor's CV.
4) Letter confirming Honorary contract with NGH Trust.
5) Patient information sheet + Consent.
6) Locality contact letter to patients GP.
7) LREC part D.

If you require any further information please let me know.

Many thanks for your help.

Kind regards,

Yours sincerely,

Paul Beeson BSc (Hons), MSc, DPodM, MChS
(Senior Lecturer)

Appendix 14: Consent form - Studies 1 and 2

THE UNIVERSITY OF NORTHAMPTON
School of Health

Centre number: 1/ 2 **CONFIDENTIAL**
Study Number: 04/Q2501/93
Patient ID Number for this trial: __________

CONSENT FORM

Development & validation of a classification system to aid surgical decision making in hallux rigidus

Chief Researcher: Paul Beeson

Please tick boxes

1. I confirm that I have read and understand the information sheet dated 20/10/05 (Version 3) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that sections of my medical notes may be looked at by the chief researcher at Three Shires Hospital and Northampton General Hospital or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study.

______________________	________	______________________
Name of Patient	Date	Signature
______________________	________	______________________
Name of Person taking consent (if different from researcher)	Date	Signature
______________________	________	______________________
Researcher	Date	Signature

Copies: 1 for patient; 1 for researcher; 1 to be kept in hospital notes.
If you would like to receive a copy of the research results please tick the box ☐

Version 3. (20/10/05)

Appendix 15: GP letter – Studies 1 and 2

Prof. W J Ribbans MCh PhD FRCS Orth
Consultant Orthopaedic Surgeon
Northampton General Hospital
Three Shires Hospital Northampton
School of Health, The University of Northampton

Private Consulting Rooms
Three Shires Hospital
The Avenue, Cliftonville
Northampton NN1 5DR

PA: Gill Hurnell
Direct Line: 01604 885019
Fax: 01604 637734
Hospital switchboard: 01604 620311
e-mail: wjribbans@uk-consultants.co.uk

Our ref: WJR/PB

Date

Dear Dr

Re:

I am writing to inform you that the above patient who is currently under your care has agreed to participate in the following study:

Development & validation of classification system to aid surgical decision making in hallux rigidus.

The condition being studied is hallux rigidus, a common condition of the first MTP joint which can cause pain and restriction of movement.

The purpose of the research is to develop and validate a classification system to help surgical decision making in hallux rigidus. The study will last for four years. Your patient has been chosen for this research study because they have been diagnosed with a hallux rigidus deformity.

A number of clinical parameters of the first MTP joint will be tested and standard X-rays of their feet will be taken. These findings will be correlated with the hallux rigidus deformity. Your patient will also be asked to complete a questionnaire to evaluate a range of health-related quality-of-life dimensions. For the purposes of this study your patient will only be seen once.

Should you wish to speak to me to discuss the involvement of your patient in this research study, I can be contacted at the above address.

Yours sincerely,

Professor W J Ribbans MCh PhD FRCS Orth
Consultant Orthopaedic Surgeon

Mr Paul Beeson BSc MSc DPodM
(Chief Researcher/ Senior Lecturer

Version 2 (20/10/05)

Appendix 16

HISTORY/ CLINICAL DATA COLLECTION SHEET

Subject number:______________

GENERAL DATA

Tick *Tick*

1. Age

- 18-30 ☐
- 31-40 ☐
- 41-50 ☐
- 51-60 ☐
- 61-70 ☐
- Retired Yes ☐ No ☐

2. Gender

- Male ☐
- Female ☐

3. Height ____________metres

Weight ____________Kg

BMI Kg/m² _____________

4. Medication for joint pain:

5. Occupation?______________ ____

5.1 Has occupation contributed to painful 1st MTP joint? Yes ☐ No ☐

HISTORY DATA *Circle*

6.0 Family History of HIHR Y N If yes, more details

6.1 **Bi**/ **Uni**lateral involvement **B** or **U**

6.2 Age of onset symptoms or deformity ______yrs

6.3 **I**nsidious or **A**cute onset **I** or **A**

6.4 Duration of symptoms ______yrs ______mths

6.5 Factors aggravating HR?

6.6 Factors providing relief of symptoms?

6.7 Are activity levels restricted by painful 1st MTPJ? Never Rarely Somedays Most days Everyday

6.8 If yes, what types of activities are restricted?

6.9 Has footwear contributed to 1st MTPJ pain? Never Rarely Somedays Most days Everyday

6.9.1 Characterize type of footwear restrictions?

7.0 Is subject unhappy with cosmetic appearance of 1st MTP joint? Yes ☐ No ☐

7.1 If yes, why? (soft tissue swelling / increased size of joint/ other?____

8.0 Has subject had any of the following complaints in their 1st MTP joint? (within last 6 months)

8.1 1st MTP joint pain Circle None (0) Mild (1) Moderate (2) Severe (3)

8.1.2 Is joint pain variable? Never Rarely Somedays Most days Everyday

8.1.3 Percentage of the day during which joint pain is present _____ (if variable Jt at its worst) _______%

8.1.4 Pain at rest? Never Rarely Somedays Most days Everyday

8.1.5 Pain on movement? Never Rarely Somedays Most days Everyday

8.2 Joint Stiffness Never Rarely Somedays Most days Everyday

8.2.1 Grade joint stiffness on scale 1-10 (1= easy to move 10 = unable to move) [if variable at worst] __________

8.2.2 Morning joint stiffness? Never Rarely Somedays Most days Everyday

8.2.3 Evening joint stiffness? Never Rarely Somedays Most days Everyday

8.2.4 Joint stiffness during the day? Never Rarely Somedays Most days Everyday

8.3 Does subject experience locking of 1st MTP joint?

Never Rarely Somedays Most days Everyday

8.4 Spasm/ cramp 1st MTPJ experienced? Never Rare Rarely Somedays Most days Everyday

9.1 Timing of pain during passive ROM

Beginning ☐ Mid-range ☐ End-of-range ☐ All-of-range ☐

10.0 Passive ROM using tractograph

Dorsiflexion (0-90º) L ________º R ________º Total ROM L ______º

Plantarflexion (0-17º) L ________º R ________º Total ROM R ______º

10.1 Active ROM using goniometer Dorsiflexion L ______º R ______º

10.2 Is subject able to raise on tip toes without supinating?

Never Rarely Somedays Most days Everyday

11.0 Hallux:

Tick

11.1 Rotational malalignment (Valgus)

Yes ☐

No ☐

11.2 Hallucal IP joint hyperextension

Absent ☐

Mild >5º ☐

Moderate >10º ☐

Severe >15º ☐

11.3 Hallucal IP joint Valgus

Absent ☐

Mild >5º ☐

Moderate >10º ☐

Severe >15º ☐

11.4 Hallucal interphalangeal joint pain

Absent ☐ Mild ☐

Moderate ☐ Severe ☐

11.5 Hallucal Flexor function

Weak (easy) ☐

Medium (resistent) ☐

Strong (not moveable) ☐

12. Location of plantar callosities:

None ☐

Plantar medial hallucal IP joint ☐

2nd MTP joint ☐

3rd MTP joint ☐

5th MTP joint ☐

Lateral border ☐

Other area?

14. Lesser toe deformities:

	2nd	3rd	4th	5th
None	☐			
Hammer	☐	☐	☐	☐
Mallet	☐	☐	☐	☐
Claw	☐	☐	☐	☐
Adducto-varus		☐	☐	☐
2nd toe CT hallux		☐	☐	☐

15. Ankle joint dorsiflexion:

Knee extended L________º R______º

Knee flexed L_______º R______º

16. Lesser MTP joint pain

Never ☐ Rarely ☐ Somedays ☐

Most days ☐ Everyday ☐

17. Gait analysis (propulsion):

Normal ☐ MTJt pronation ☐

Supination ☐

Delayed heel lift ☐

Vertical toe-off ☐

Ab/Adductory twist at toe-off ☐

Knee flexion ☐

17.1 Has walking pattern changed due to pain in 1st MTP joint?

Never ☐ Rarely ☐ Somedays ☐

Most days ☐ Everyday ☐

17.2 Is pt able to push off through the ground during gait?

Never ☐ Rarely ☐ Somedays ☐

Most days ☐ Everyday ☐

17.3 Does pt find they tend to roll outwards during propulsion?

Never ☐ Rarely ☐ Somedays ☐

Most days ☐ Everyday ☐

13. Foot Posture Index (FPI):

Factor	**Plane**	**SCORE** -2	-1	0	1	2
Rearfoot score						
Talar head palpation	Transverse	☐	☐	☐	☐	☐
Curves above/below lat malleoli	Frontal/ Trans	☐	☐	☐	☐	☐
Calcaneal frontal plane	Frontal	☐	☐	☐	☐	☐
Forefoot score						
Talo-navicular joint congruence	Transverse	☐	☐	☐	☐	☐
Medial arch height	Sagittal	☐	☐	☐	☐	☐
Forefoot Abd/Adduction	Transverse	☐	☐	☐	☐	☐

Final FPI aggregate score

(-5) to (-12) Severely supinated ☐
(-1) to (-4) Supinated ☐
(0) to (+ 5) Normal ☐
(+6) to (+9) Pronated ☐
(10+) Severely pronated ☐

18. Does the subject present with hip, knee or hand OA? Yes ☐ No ☐
18.1 If Yes, which? Hip ☐ Knee ☐ Hand ☐

19. Type of sports?
19.1 Frequency of sports?

Version 4 - 24/01/06

Appendix 17: Foot Posture Index (FPI)

The FPI is a diagnostic multiple plane clinical tool based on 6 observations measured on a 5-point scale, ranging from -2 to +2. The final score ranges between –12 and +12 and indicates the posture of the foot (Table 3.5). Assessment is made with the patient standing in relaxed calcaneal stance position (RCSP). Each observation is assigned a numerical value indicating pronation, neutral or supination. The following six observations are used:

1. Talar head palpation.
2. Supra and infra lateral malleolar curvature.
3. Calcaneal frontal plane position.
4. Prominence in the region of the talonavicular joint.
5. Congruence of the medial longitudinal arch.
6. Abduction/adduction of the forefoot on the rearfoot.

Foot Posture Index	
Foot Posture	Score
Severely pronated	10+
Pronated	+6 to +9
Normal foot	0 to +5
Supinated foot	-1 to -4
Severely supinated foot	-5 to -12

Appendix 18: FPI observations (Adapted from Redmond et al, 2001)

Talar head palpation

Score	-2	-1	0	+1	+2
	Head palpable on lateral side/not medial side	Head palpable on lateral side/slightly palpable on medial side	Head equally palpable on medial and lateral sides	Head slightly palpable on lateral side/ palpable on medial side	Head not palpable on lateral side/ palpable on medial side

Curves above (supra) and below (infra) lateral malleoli

Score	-2	-1	0	+1	+2
M  L	Infra-malleolar curve markedly straighter than supra	Infra-malleolar curve slightly straighter than supra	Both infra and supra malleolar curves roughly equal	Infra-malleolar curve slightly more curved than supra	Infra-malleolar curve markedly more curved than supra

Calcaneal frontal plane position

Score	-2	-1	0	+1	+2
M  L	Markedly inverted	Slightly inverted	Vertical	Slightly everted	Markedly everted

Bulging in the region of the talonavicular joint (TNJ)

Score	-2	-1	0	+1	+2
M  L	Area of TNJ markedly indented	Area of TNJ slightly indented	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly

Congruence of the medial longitudinal arch

Score	-2	-1	0	+1	+2
	Arch high and acutely angled towards the posterior end of the medial longitudinal arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in central portion	Arch very low with severe flattening in central portion

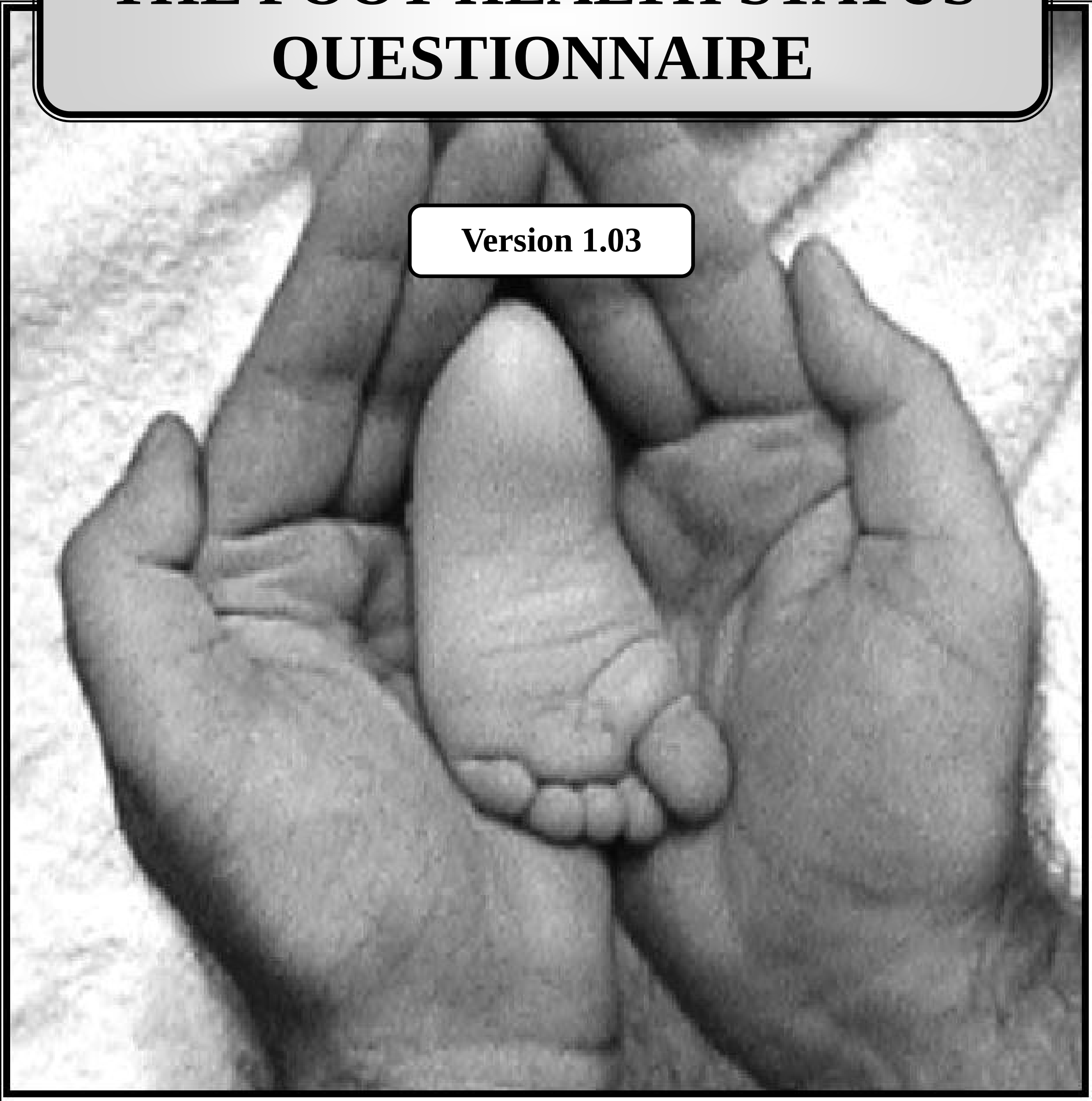
Abduction / adduction of the forefoot on the rearfoot

Score	-2	-1	0	+1	+2
M  L	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

Appendix 19

THE FOOT HEALTH STATUS QUESTIONNAIRE

Version 1.03



Thank you for taking the time to complete this questionnaire.

The answers you provide will help us to understand how hallux rigidus affects your foot.

The questionnaire is very simple to complete and there are no right or wrong answers. The questionnaire takes less than 10 minutes to complete.

All answers are strictly confidential.

The Foot Health Status Questionnaire

OFFICE USE
Centre number: 1 2

Study No: 04/Q2501/93

Patient ID No:

INSTRUCTIONS ON HOW TO COMPLETE THE QUESTIONNAIRE

- This questionnaire asks for your views about your foot health.
- All you need to do is circle your answer to each question.

The following questions are about the foot pain you have had <u>during the past week.</u>

1. What level of foot pain have you had <u>during the past week</u> ?

(circle number)

None……………………………………1

Very Mild……………………………… 2

Mild……………………………………. 3

Moderate…………………………….. 4

Severe………………………………… 5

Indicate on the line below the level of foot pain you have had in the past week

No Pain ______________________________ Severe Pain

(circle a number for each question below)

<u>DURING THE LAST WEEK</u>...	Never	Occasionally	Fairly Many Times	Very Often	Always
2. How often have you had foot pain ?	1	2	3	4	5
3. How often did your feet ache?	1	2	3	4	5
4. How often did you get sharp pains in your feet?	1	2	3	4	5

These questions are about how much your feet interfere with activities you might do during a typical day.

(circle a number for each question below)

DURING THE LAST WEEK…….

		Not at All	Slightly	Moderately	Quite a bit	Extremely
5.	Have your feet caused you to have difficulties in your work or activities?	1	2	3	4	5
6.	Were you limited in the kind of work you could do because of your feet?	1	2	3	4	5

DURING THE LAST WEEK…

		Not at All	Slightly	Moderately	Quite a bit	Extremely
7.	How much does your foot health limit you walking?	1	2	3	4	5
8.	How much does your foot health limit you climbing stairs?	1	2	3	4	5

9. How would you rate your overall foot health ? (circle number)

Excellent…………………………. 1

Very Good……………………….. 2

Good………………………..… 3

Fair……………………………….. 4

Poor………………………………. 5

Please turn to the next page

The following questions are about the <u>shoes that you wear</u>. Please circle the response which best describes your situation.

		Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
10.	It is hard to find shoes that do not hurt my feet.	1	2	3	4	5
11.	I have difficulty in finding shoes that fit my feet.	1	2	3	4	5
12.	I am limited in the number of shoes I can wear.	1	2	3	4	5

13. In general, what condition would you say your feet are in ?

(circle number)

Excellent……………………… 1

Very Good……………………. 2

Good………………………….. 3

Fair……………………………. 4

Poor…………………………… 5

Please write some comments about the <u>current state of your feet</u>:

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

……………………………………………………………………………………

14. In general, how would you rate your <u>health</u>:

(circle number)

Very Good.. 1

Fair.. 2

Poor... 3

15. The following questions ask about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

(circle a number on each line)

<u>ACTIVITIES</u>	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities**, such as running, lifting heavy objects, or (if you wanted to) your ability to participate in strenuous sports	1	2	3
b. **Moderate activities**, such as cleaning the house, lifting a chair, playing golf or swimming	1	2	3
c. Lifting or carrying bags of shopping	1	2	3
d. Climbing a steep hill	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Getting up from a sitting position	1	2	3
g. Walking **more than a kilometer**	1	2	3
h. Walking **one hundred meters**	1	2	3
i. Showering or dressing yourself	1	2	3

16. This next question asks to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or social groups?

(circle number)

Not at all... 1

Slightly.. 2

Moderately... 3

Quite a bit... 4

Extremely... 5

Please turn to the next page

17. These questions are about how you "feel" and how things have been with you <u>during the past month</u>. For each question, please give the one answer that comes closest to the way you have been "feeling". How much of the time during the <u>past 4 weeks:</u>

	All of the time	**Most of the Time**	**Some of the Time**	**A little of the Time**	**None of the Time**
a. Did you feel tired?	1	2	3	4	5
b. Did you have a lot of energy?	1	2	3	4	5
c. Did you feel worn out?	1	2	3	4	5
d. Did you feel full of life?	1	2	3	4	5

18.During the <u>past 4 weeks</u>, how much of the time has your <u>emotional problems</u> or <u>physical health</u> interfered with your social activities (like visiting with friends, relatives, social groups etc.)?

(circle number)

No time at all.. 1

A small amount of time.. 2

Moderate amount of time... 3

Quite a bit of the time.. 4

All of the time... 5

19. How TRUE or FALSE is <u>each</u> of the following statements for you?

(circle a number on each line)

	True or Mostly True	**Don't Know**	**False or Mostly False**
a. I seem to get sick a little easier than other people	1	2	3
b. I am as healthy as anybody I know	1	2	3
c. I expect my health to get worse	1	2	3
d. My health is excellent	1	2	3

Please complete the following details.

20. Are you… Male O Female O

21. What is your age? _______________

22. Do you currently take any medicine prescribed by your doctor for foot pain?
Yes O No O

If yes, please list the drug names:

Please list any other conditions you take medicine for:

1.

2.

3.

For the next questions, please tick either **YES** or **NO**

	Yes	No
23. Do you smoke?	O	O
24. Do you do any regular physical exercise ?	O	O

If yes, what is it?

25. Do you have any comments? Please write below:

Thank you for completing this questionnaire

This questionnaire is designed to be analysed by:
The Foot Health Status Questionnaire
Data Analysis Software © (Version 1.03) and is
supported by Microsoft Windows™ 3.11. 95 and 98.

Appendix 20: Four domains of Foot Health Status Questionnaire

Pain

This domain evaluates type, severity and duration of foot pain. The lowest score (0) is defined as extreme and significant foot pain that is acute in nature. The highest score (100) is defined as no pain or discomfort in any part of the foot.

Physical function and appearance

This domain evaluates the feet in terms of impact on physical function. The lowest score (0) is defined as severe limitation in performing a broad range of physical activities (walking, working and moving about). The highest score (100) is defined as the ability to perform all desired physical activities (walking, working and moving about, including climbing stairs).

Footwear

This domain evaluates lifestyle issues related to footwear and feet particularly shoe choice and comfort. The lowest score (0) is defined as extremely limited access to suitable footwear. The highest score (100) is defined as no problems with obtaining suitable footwear.

General foot health

This domain evaluates self perception of feet (individual's subjective assessment of body image related to their feet). The general foot health domain can be seen as a composite personal expression of well-being in terms of foot related function, pain and footwear related health status. The lowest score (0) is defined as general perception of feet to be in a poor state of health and condition. The highest score is defined as a perception of the feet to be in an excellent state of health and condition.

There are thirteen questions Four for Pain, four for Function, three for Footwear and two for General Foot Health). The subject selects the most appropriate response from a Likert scale e.g. None, Very Mild, Mild, Moderate, Severe, and circles the associated number i.e. 1 to 5. There are four steps to obtaining scale scores for domains.

Item responses were summed for each scale respectively. The score then has the scale range subtracted from it. The score is multiplied by a factor of 100. To perform the analysis, respondents scores were entered into a computer program (FHSQ version 1.3) that essentially recodes, sums and transforms the data to a scale from zero (poorest foot health) to 100 (best possible foot health) in the relevant domains.

Appendix 21: Five forms of gait compensation seen in HR

1) Delayed heel lift

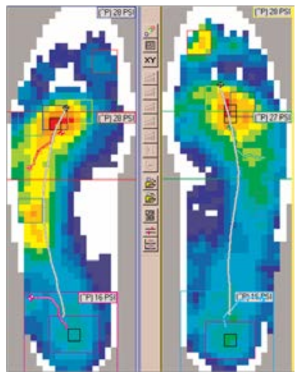
The mid-tarsal joint is the closest to the first MTP joint which allows sagittal plane motion. This is seen as delayed heel lift with late midstance pronation and navicular adduction/ plantarflexion.

2) Vertical toe-off

Denotes continuation of delayed heel-lift where foot is lifted vertically off the ground. An apropulsive, laborious, slow gait can present where there is a lack of heel-off by the time of contra-lateral heel contact.

3) Inverted step

Patients with increasingly severe HR may supinate their foot during gait to avoid extending the first MTP joint and propulse from the lateral four toes. Weight-flow is directed to the lateral column and fails to shift medially to the first web space prior to heel lift. Lateral shoe wear results despite excessive foot pronation. This explains the paradox of a flexible pronated foot with lateral forefoot shoe wear and bulging. Dynamic in-shoe pressure measurement systems such as the F-Scan® show reduced pressure under the first MTP joint and lateral deviation of centre of pressure (CoP) line.



4) <u>Abductory or adductory hip rotation twist at toe-off</u>

Seen during mid-stance/ propulsion producing ‘medial roll-off’ following path of least resistance. This form of compensation is responsible for medial hallucal IPJ pinch callus.

5) <u>Flexion compensation of the body (seen during single limb support</u>

Appendix 22: Radiology data collection sheets – Study 2

Radiology data collection sheet

Subject number:

Tick

1. 1st MTPJ:

1.1 Joint space narrowing

None ☐ Definitely narrowed ☐

Severely narrowed ☐ Joint fusion 1 Pnt ☐

Joint space D/P____mm Lateral______mm

1.2 Joint space asymmetry

None ☐

Medial narrowing ☐

Lateral narrowing ☐

1.3 Periarticular subchondral sclerosis

Absent ☐

Present ☐

1.4 Osteophytes (met & phal)

None ☐ Medial ☐

Lateral ☐ Dorsal ☐

~~Severity~~ Minimal ☐

Moderate ☐

Severe ☐

1.5 Loose bodies

None ☐ Medial ☐

Central ☐ Lateral ☐

(Lateral view) Dorsal ☐

1.6 Subchondral cysts

1st metatarsal head Absent ☐

Present ☐

Proximal phalanx Absent ☐

Present ☐

2. Hallux:

(length ratio prox:distal phalanges)

Proximal phalanx mm

Distal phalanx mm

P/**D** ratio

3. Hallucal IPJ:

3.1 Hallucal IPJ valgus

Absent ☐

Mild > 5º ☐

Moderate >10º ☐

Severe >15º ☐

3.2 Hallucal IPJ OA None ☐

Mild ☐

Tick

6. 1st metatarsal:

6.1 Shape of 1st metatarsal head

Oval ☐

Chevron ☐

Flat Minimal ☐

Moderate ☐

Severe ☐

6.2 Length of 1st metatarsal ______mm

6.3 Length of 1st metatarsal compared to:

	2nd	3rd		
Shorter	☐	☐	_____mm	_____mm
Equal	☐	☐		
Longer	☐	☐	_____mm	_____mm

6.4.1 Sagittal plane position of 1st metatarsal (in relation to 2nd met - lateral view)

Lateral/ sagittal position _____mm

(normal value ≤ 8mm)

6.4.2 1st met declination angle

(normal range 19-25º) _____º

7. 1st MC joint position:

Flat ☐

Angled ☐

7.1 1st MC joint OA None ☐

Mild < 0.5mm Joint narrowing ☐

Moderate 0.5-1.0mm Jt narrowing ☐

Severe ☐

7.2 1st MC joint sag (Lat view)

Absent ☐ Present ☐

7.3 Nav/Cunieform sag (Lat view)

Absent ☐ Present ☐

8. 2nd met/ interm cunieform OA

Absent ☐ Present ☐

9. General features

9.1 Metatarsus adductus

Absent ☐

Mild (16º-19º) ☐

Moderate (20º-25º) ☐

Severe (>25º) ☐

(normal 16º-18º dorsiflexion) ______º

5. Sesamoids:

5.1 Shape

Normal ☐ Irregular ☐

Cystic ☐ Osteopaenic ☐

Hypertrophic ☐ Bi/Tri/Quadipartite ☐

5.2 Tibial Sesamoid distance ______mm

5.3 Fibular Sesamoid distance ______mm

9.3 Transverse plane angulation 2nd MTPJ (Normal 0-7º lateral) - º lat / + º med

9.4 Presence of medial/intermediate cuneiform diastasis

No ☐

Yes ☐

9.5 Presence of gross alterations in tarsal morphology

No ☐

Yes ☐

If yes describe:

Version 3 : 20/01/2006

Appendix 23: Grading criteria for first metatarsal cuneiform joint OA

Grade	Joint changes
1	No degenerative changes
2	Degenerative changes with < 0.5mm of joint space narrowing
3	0.5 – 1.0 mm joint space narrowing
4	Severe degenerative changes

Appendix 24

STUDY INFORMATION SHEET (Study 3)

CONFIDENTIAL

Study Title: *Development and validation of a classification system to aid surgical decision-making in hallux rigidus.*

You are being invited to take part in the above research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the research is to test the reliability of measuring certain clinical and radiological parameters of hallux rigidus. This part of the study will last for one year. Hallux rigidus is a common condition of the big toe joint which can cause pain and restriction of movement. It can be caused by structural or mechanical problems associated with the joint.

Why have I been chosen?
You have been asked to take part in the study because you have a hallux rigidus deformity. A minimum of 20 patients with this condition will be used in the study.

Do I have to take part?
Taking part in this research is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will receive a copy of the signed consent form. You are free to withdraw from the study at any time and without giving a reason. It will not affect the type/ standard of care you receive.

What will happen to me if I take part?
Clinical tests of your feet will be undertaken. These will not be over and above those involved in standard diagnosis and treatment.
You will only need to be seen twice for 20 minutes. Overall the study will last 4 years.

What do I have to do?
No lifestyle restrictions or special requirements are necessary. You will be asked to complete one questionnaire. You will need to remove your shoes/ socks so the clinician can undertake some clinical tests on your feet.

What is being tested?
Weight bearing and non-weight bearing tests will be undertaken on your foot joints.

What are the possible disadvantages and risks of taking part?
There are no risks associated with this study. The clinical tests will not be over and above those involved in standard diagnosis and treatment. If as a result of the clinical tests a condition is found that you are unaware of we will inform your GP.

What are the possible benefits of taking part?
The information gained from this study will be used to develop a classification system for hallux rigidus. It will also be used to help surgeons gain a greater insight into the surgical management of this condition and aid in surgical decision making.

What if new information becomes available?
Sometimes during the course of research, new information becomes available about the treatment of the condition that is being studied. If this happens, your research clinician will tell you about it immediately. This will not affect your involvement in the study as the study is not making decisions about your management.

What happens when the research study stops?
The research findings will be written-up as a PhD.

What if something goes wrong?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?
All clinical information which is collected about you during the course of the research will be reviewed by other health professionals but kept strictly confidential. Your GP will be notified of your participation in the study.

What will happen to the results of the research study?
The research findings will be written-up and published in a professional Journal.

Who is organising and funding the research? The University of Northampton.

Who has reviewed the study?
- Leicestershire, Northamptonshire & Rutland Research Ethics Committee.

Chief Researcher/ Senior Lecturer- Mr Paul Beeson MSc, BSc(Hons), MChS
The University of Northampton

Thank you for reading this

Version 3 (20/10/05)

Appendix 25: Patient Consent form - Study 3

Northamptonshire NHS
Primary Care Trust

Centre number: 3 **CONFIDENTIAL**
Study Number: 04/Q2501/93
Patient ID Number for this trial: __________

CONSENT FORM

Development & validation of a classification system to aid surgical decision making in hallux rigidus

Chief Researcher: Paul Beeson

Please tick boxes

1. I confirm that I have read and understand the information sheet dated 20/10/05 (Version 3) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of my medical notes may be looked at by the chief researcher at Northampton General Hospital or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study.

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Copies: 1 for patient; 1 for researcher; 1 to be kept in hospital notes.
If you would like to receive a copy of the research results please tick the box ☐

Version 4 (30/03/07)

Appendix 26: Rater invitation letter (Study 3)

THE UNIVERSITY OF NORTHAMPTON
School of Health

Dear Dr/ Mr/ Mrs……..,

Study Title: *Development and validation of a classification system to aid surgical decision-making in hallux rigidus.*

You are being invited to take part in the above research study. You are being asked to take part because you are a clinician who is familiar with the diagnosis and management of hallux rigidus.

A study information sheet is enclosed. It includes information on the purpose of the study and provides answers to questions that participants may typically ask.

You will be asked to make a number of clinical and/ or radiological measurements of the parameters of HR to determine their reliability and value for inclusion in a classification framework for HR.

Taking part in this study is entirely voluntary. Please take time to decide whether or not you wish to take part.

Please ask us if there is anything that is not clear or if you would like more information.

Thank you for your help,

Yours sincerely,

Paul Beeson

(Chief researcher)

Appendix 27: Rater Consent form - Study 3

THE UNIVERSITY OF NORTHAMPTON
School of Health

Centre number: 1/ 3
Study Number: 04/Q2501/93

CONFIDENTIAL

CONSENT FORM

Development & validation of a classification system to aid surgical decision making in hallux rigidus

Chief Researcher: Paul Beeson

Please tick boxes

1. I confirm that I have read and understand the information sheet dated 30/03/07 (Version 4) for the above study and have had the opportunity to ask questions.
2. I understand that my participation as a rater is voluntary and that I am free to withdraw at any time, without giving any reason.
3. I give permission for the chief researcher to keep a copy of my collected data.
4. I agree to take part as a rater for the above study.
5. I understand the answers will be kept confidential and anonymous in the final report.

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Copies: 1 for participant; 1 for researcher.

If you would like to receive a copy of what is entered on the data collection form please tick the box.

Version 1 (27/02/07)

Appendix 28: Rater guidelines

RELIABILITY STUDY – CLINICIAN GUIDELINES

The Following guidelines are provided to ensure clinicians adopt a standard protocol when collecting clinical and/or radiological data.

CLINICAL

Use a plastic goniometer (2º increments) to measure joint angles.
Please document the following clinical data:

1. First MTPJ ROM

1.1 Passive first MTPJ range-of-motion (ROM)

Use the proximal phalanx (medial mid-axis) and plantar surface of the foot as reference points. Measure and document both dorsiflexion and plantarflexion and calculate the total ROM - dorsiflexion + plantarflexion (Figure 1A & 1B).

Figure 1A: Dorsiflexion

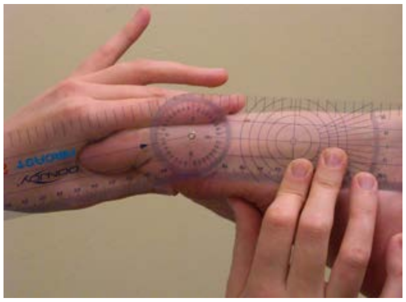


Figure 1B: Plantarflexion

Active first MTPJ dorsiflexion

Measure in a static weight bearing position and ask subject to push forward onto the ball of the foot (avoiding supinating) to obtain maximum first MTPJ dorsiflexion. Document the value obtained.

1.3 Magnitude of first MTPJ pain

Document first MTPJ pain as: none, mild, moderate, severe.

1.4 Timing of first MTPJ pain

Document when pain occurs during first MTPJ movement as: beginning, mid-way, end-of-range or all-of-range of motion.

1.5 Location of first MTPJ pain

Document location as: Dorsal bump, Joint, Sesamoids, Proximal phalanx or Dorsal capsule/ EHL. Indicate if a combination presents.

2. Hallux

2.1 Rotational hallucal malalignment

Document frontal plane hallucal position as: none, valgus or varus.

2.2 Hallucal interphalangeal joint hyperextension (HIJH)

Use the medial mid-axial line of the proximal and distal phalanges as reference points (weight bearing) to measure the HIJH angle with the goniometer. Grade as: absent (0º), mild (>5º), moderate (>10º), severe (>15º).

2.3 Hallux abductus interphalangeus (HAI)

Use the dorsal mid-axial line of the proximal phalanx and distal phalanges as reference points to measure the HAI angles. Grade as: absent (0º), mild (>5º), moderate (>10º), severe (>15º).

3. Callosities associated with HR

Restricted first MTPJ ROM and pain can change patterns of weight distribution, resulting in development of callosities. Document the location of callosities as: none, plantar medial hallucal IPJ, 2nd MTPJ, 3rd MTPJ, 5th MTPJ, lateral border, other area (document).

4. Second toe length

Document 2nd toe length as: longer then hallux, equal to hallux or shorter than hallux.

5. Ankle joint dorsiflexion

Measure ankle joint dorsiflexion with the knee extended then flexed. Hold the foot in a neutral position (right angle to the leg) with the talonavicular joint reduced to eliminate transverse tarsal or subtalar motion. Use the fibula and plantar-lateral border of the foot as landmarks (Figure 2).

Figure 2: Measurement of ankle joint dorsiflexion

6. Lesser MTPJ pain

Document as: never, rarely, some days, most days, or every day.

7. Gait

Undertake a brief assessment of the patients' gait at propulsion. Document your findings as shown in Table 1.

Table 1: Observed gait parameters at propulsion
• Normal
• Mid-tarsal joint pronation
• Supination.
• Delayed heel lift.
• Vertical toe-off.

- Ab/Adductory twist.
- Knee flexion.

RADIOLOGICAL

Assess radiological variables from **AP** and **lateral** foot X-rays using **either**:

1) A plain film marker, plastic goniometer (2º increments for angles, 1mm increments for length). Place a clear acetate sheet over the X-ray.

2) Digital workstation with high-resolution computer monitor, Picture Archiving Communication System (PACS), VISAGE for diagnostic interpretation.

1. First MTPJ

1.1 Measurement of joint width (2 methods)

1. Measure joint space narrowing between bone end plates, not osteophyte bridging. Objectively grade joint space: none, definitely narrowed, severely narrowed or joint fusion at one point at least.
2. Summation method using six separate measurements. Place three points along corresponding articular joint surfaces on AP and lateral views (Figure 1A-1B). On a perpendicular line connecting each pair of corresponding points, measure joint width in millimeters. Calculate the average joint width.

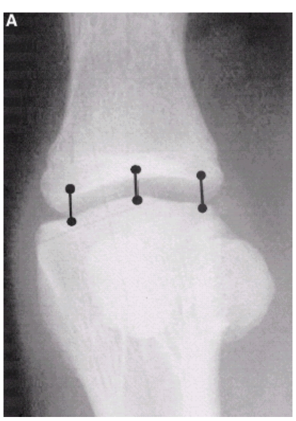


Figure 1A AP view

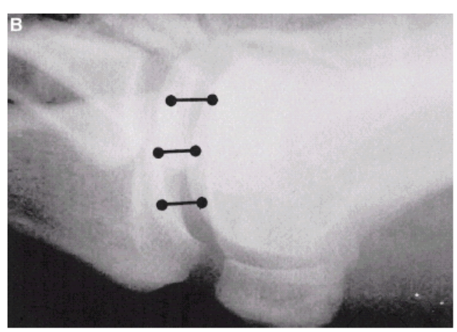


Figure 1B: lateral view

1.2 Joint symmetry

Document as: symmetrical, medial or lateral narrowing.

1.3 Subchondral sclerosis

Document for metatarsal head & base of proximal phalanx as: none, minimal, moderate or severe.

1.4 Osteophytes

Document location (medial, lateral and/ or dorsal), & severity (minimal, moderate or severe).

1.5 Loose bodies in MTPJ

Document as present/ absent and their location on AP and lateral views.

1.6 Bone cysts

Document presence/ absence in metatarsal head and proximal phalanx base.

2. <u>Hallux</u>

2.1 Hallucal phalanx length ratio

Draw longitudinal axis of proximal and distal phalanges using two metaphyseal-diaphyseal reference points. Using these lines calculate the length of each phalanx in millimeters. Then divide the length of proximal phalanx by distal phalanx.

3. <u>Hallucal IPJ</u>

3.1 Hallux abductus interphalangeus (HAI) angle

The HAI angle (orthopaedic texts refer to as hallucal IPJ valgus) is formed by intersection of longitudinal bisections of the hallucal phalanges. Grade as: absent, mild (>5º), moderate (>10º), severe (>15º).

4. Hallux equinus angle

Measure the angular difference between the longitudinal bisections of the proximal hallucal phalanx and first metatarsal (Figure 2). Hallux equinus = $\leq 15^{o}$.

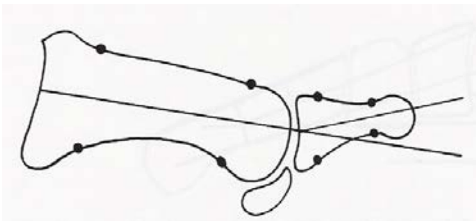


Figure 2: Hallux equinus angle

5. Sesamoids

5.1 Sesamoid morphology

Grade sesamoid shape as: normal, irregular, cystic, osteopaenic, hypertrophic or bipartite/ tripartite/ quadripartite.

5.2 Distance between sesamoids and metatarsal head (AP view)

Draw a line at the articular surface of the metatarsal head perpendicular to the first metatarsal longitudinal axis. Measure the distance from this line to the distal edge of each sesamoid (Figure 3) in millimeters and document.

5.3 Inter-sesamoidal distance (ISD)

Measure the shortest distance between the two sesamoids. Make all measurements to the closest 0.5mm (Figure 3).

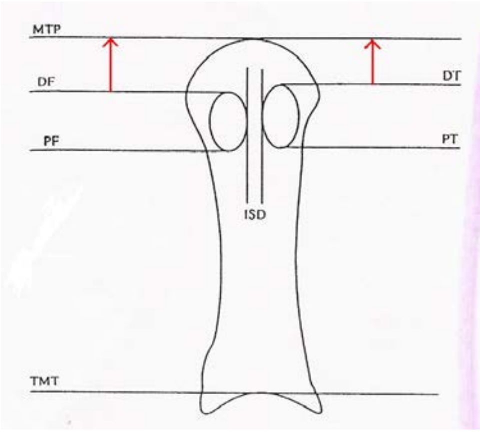


Figure 3: Distance from distal sesamoid margin to metatarsal head & inter-sesamoidal distance.

6. First metatarsal

6.1 First metatarsal head shape

Document first metatarsal head morphology as: oval, chevron or flat (Figures 4A - 4C). If flat grade the degree of flatness as: minimal, moderate or severe.

Figure 4A: Oval

Figure 4B: Chevron

Figure 4C: Flat

6.2 First metatarsal length

Measure the length of the first metatarsal in millimeters using the longitudinal bisection line.

6.3 Length ratio of first metatarsal and proximal phalanx

Measure the length of the first metatarsal and proximal phalanx. Calculate the length ratio by dividing the value for the first metatarsal by the proximal phalanx.

6.4 First metatarsal length relative to the 2nd and 3rd metatarsals

Method for digitized x-rays:

Draw separate horizontal lines across the top of the 1st, 2nd & 3rd metatarsal heads. Next draw a perpendicular line between the respective lines and measure in millimeters to calculate the difference in lengths between the 1st and 2nd & 1st and 3rd metatarsals. A positive value indicates that the 1st metatarsal is longer relative to the 2nd and 3rd metatarsals and negative values indicate that the 1st metatarsal is shorter. Length measurements within 1mm of each other are considered to be equal.

Method for plain x-rays

See Figure 5. Make a transverse reference line by bisecting two points (lateral base calcaneocuboid joint & medial base talonavicular joint). Draw the longitudinal axis of the 2nd metatarsal using two metaphyseal-diaphyseal reference points. Where the 2nd metatarsal axis intersects the transverse reference line, this point acts as the center of rotation for the axis. The axis line is rotated (using a compass) and three arcs are drawn, at the most distal extent of the first, second, and third metatarsal heads. This measures the protrusion distance between the first and second, and first and third metatarsals. Draw a perpendicular line between the three arcs and measure in millimeters. A positive value indicates that the 1st metatarsal is longer relative to the 2nd and 3rd metatarsals and negative values indicate that the 1st metatarsal is shorter. Length measurements within 1mm of each other are considered to be equal.

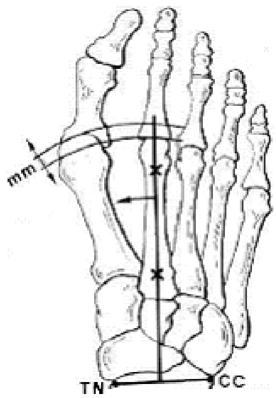


Figure 5 Metatarsal protrusion measurement

6.5.1 Sagittal plane position of 1st metatarsal in relation to 2nd metatarsal

Using lateral X-ray measure difference between the distal dorsal metaphyseal cortex (head-neck junction) of the 1st and 2nd metatarsals. Draw a perpendicular line between the two dorsal cortical lines, and measure the difference in millimeters (Figure 6). A positive value is when the 1st metatarsal is higher.

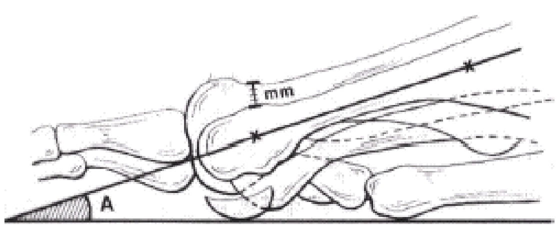


Figure 6: First metatarsal sagittal plane position

6.5.2 First metatarsal declination angle

Using lateral X-ray measure 1st metatarsal relative to the plantar surface of the foot (Figure 6 Angle A). Draw the lateral longitudinal axis of the 1st metatarsal by using mid-metaphyseal-diaphyseal reference points. Draw a second line estimating the plantar surface of the foot (on supporting surface) using intersecting reference points on the plantar calcaneus and medial sesamoid. Normal range = 19°-25°.

6.5.3 Lateral Talus-1st metatarsal angle (talar declination or Meary's angle)

Using the lateral X-ray measure the angle formed between the bisection of the talus and 1st metatarsal (Figure 7). Normal = 0° where the midline axis of the talus and 1st metatarsal are in line.

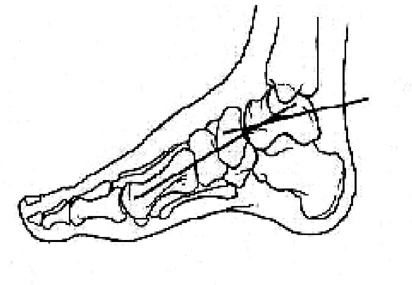


Figure 7: Talar declination angle

7. First metatarsal cuneiform joint (MCJ)

7.1 First MCJ position

Document the morphology (flat or angled) of the first MCJ.

7.2 First MCJ angle

Measure the first MCJ angle. This is represented by intersection of 1st metatarsal longitudinal bisection with a line perpendicular to the medial cuneiform proximal articular surface (Figure 8).

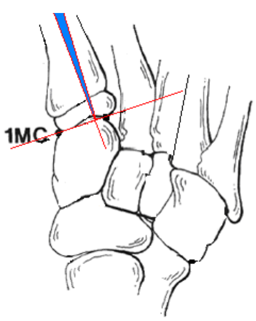


Figure 8: First MCJ angle

7.3 First MCJ sag (lateral view)

Document the presence/ absence of first MCJ sagging (sagittal plane alignment). Normal joint position is represented by parallel dorsal cortices of the medial cuneiform and first metatarsal base. A difference in height between the two bones with joint gapping plantarly is described as sagging.

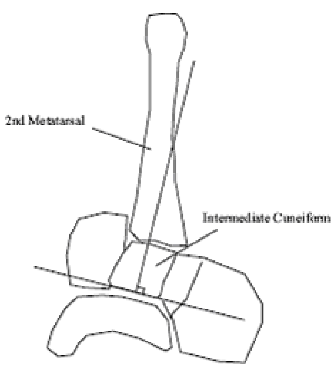
7.4 Navicular cuneiform joint (NCJ) sag

Document the presence or absence of NCJ sagging (sagittal plane alignment). Normal NCJ position is represented by parallel dorsal cortices of navicular and medial cuneiform. A difference in height between the two bones, with joint gapping plantarly is described as sagging.

8. General features

8.1 Metatarsus adductus (MA)

Draw a line perpendicular to the articular surface of the base of the intermediate cuneiform (Figure 9). This is used as the forefoot reference line. The angle formed between the intersections of this perpendicular line and a line longitudinally bisecting the 2nd metatarsal is used to represent the degree of metatarsus adductus (Figure 10). Grade as: absent, mild (16º – 19º), moderate (20º- 25º), or severe (>25º).



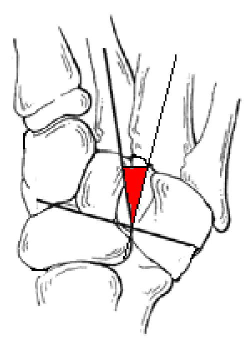


Figure 9: Forefoot reference line   Figure 10: MA angle

8.2 Transverse plane angle of deviation of second MTPJ

Measure the angle formed between the bisection (proximal and distal metaphyseal–diaphyseal junctions) of the proximal phalanx second toe and the longitudinal bisection of the 2nd metatarsal shaft (Figure 11).

Lateral deviation of the 2nd toe is denoted as negative and medial deviation as positive. Normal value = 7º lateral.

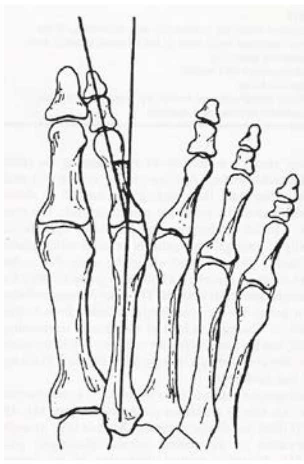


Figure 11: Transverse plane angle deviation 2nd MTP joint

8.3 Medial/ intermediate cuneiform diastasis

Document the presence/ absence of this feature.

8.4 Gross alterations in tarsal morphology

Document the presence/ absence of this feature.

Appendix 29 : Leicestershire Primary Care Research Alliance

NHS

Leicestershire Primary Care Research Alliance

Third Floor
Enkalon House
92 Regent Road
Leicester
LE1 7PE

Telephone: 0116 295 4080
Fax: 0116 295 4177

27/01/07

LNR PCRA - REF 0636 (Please quote this reference on all correspondence)

6, The Claylands
Cogenhoe
Northampton
Northants
NN7 1LD

Dear Paul

Development and validation of a classification system to aid surgical decision-making in hallux rigidus

We are pleased to advise you that, under the authority delegated to us as the designated RM&G PCT (hosted by Leicester City PCT) for the three PCTs in Leicestershire, Northamptonshire and Rutland, PCT approval for the above research project is now in place. We therefore advise that approval from the Leicestershire, Northamptonshire and Rutland Primary Care Research Alliance to carry out your study within Northamptonshire PCT is now granted.

It is required, under the terms of the Research Governance Framework, that all researchers undertaking work within an NHS organisation which impacts upon patient care must have an NHS contract for the term of the research study. ***Therefore The Leicestershire Northamptonshire and Rutland Primary Care Research Alliance (LNR PCRA) will require study researchers to hold an honorary contract with the LNR PCRA in order for the study to take place in the Leicestershire, Northamptonshire and Rutland primary care sector.*** It is the responsibility of the Chief Investigator to ensure that all study staff have a valid contract in place with the LNR PCRA before they start work within the Primary Care Trusts of Leicestershire, Northamptonshire and Rutland. Please note that this applies when there is ***any*** change in the research staff working in the primary care sector for the duration of the study. Requests for honorary contracts need to be made to the LNR PCRA office, address as above.

Could you please ensure that any interim or final reports, protocol amendments or any documents that require submission to a REC are channelled through this office. In addition can any adverse event relating to this study be reported to us, please. We will undertake to forward any documentation to the REC as well as advise the relevant PCT/s in accordance with Research Governance requirements.

Please also be aware that, where required under NHS obligations, we will submit details of this study to the National Research Register to log PCT involvement in this study. The Alliance is also currently implementing new systems for research governance on behalf of local PCTs, so the study may be subject to some follow up and/or auditing during its field work stage.

May I take this opportunity to wish you the very best of luck with this study.

Yours sincerely

Sue Palmer-Hill
Research & Development Manager

Appendix 30: GP letter – Study 3

Mr Ian Reilly FCPodS DMS
Consultant Podiatric Surgeon

PODIATRY HEADQUARTERS
Battle House
Northampton General Hospital
Billing Road, Northampton NN1 5BD
Tel: 01604 545422
Fax: 01604 545835

Our ref: IR/PB

Date

Dear Dr

Re:

I am writing to inform you that the above patient who is currently under your care has agreed to participate in the following study:

Development & validation of classification system to aid surgical decision making in hallux rigidus.

The condition being studied is hallux rigidus, a common condition of the first MTP joint which can cause pain and restriction of movement.

The purpose of the research is to develop and validate a classification system to help surgical decision making in hallux rigidus. The study will last for four years. Your patient has been chosen for this research study because they have been diagnosed with a hallux rigidus deformity.

A number of clinical parameters of the first MTP joint will be tested and standard X-rays of their feet will be taken. These findings will be correlated with the hallux rigidus deformity. Your patient will also be asked to complete a questionnaire to evaluate a range of health-related quality-of-life dimensions. For the purposes of this study your patient will only be seen once.

Should you wish to speak to me to discuss the involvement of your patient in this research study, I can be contacted at the above address.

Yours sincerely,

Mr Ian Reilly FCPodS DMS
Consultant Podiatric Surgeon

Mr Paul Beeson BSc MSc DPodM
(Chief Researcher/ Senior Lecturer)

Version 2 (20/10/06)

Appendix 31: Study 3 – Clinical data collection sheet

Joint	☐	☐
Sesamoids	☐	☐
Dor cap/EHL	☐	☐
Proximal Phal	☐	☐
Combination	☐	☐

2.0 Hallux *Tick*

2.1 Rotational malalignment

R	None	☐	Valgus	☐	Varus	☐
L	None	☐	Valgus	☐	Varus	☐

2.2 Hallucal IP joint hyperextension

	R	**L**
Absent	☐	☐
Mild >5º	☐	☐
Moderate >10º	☐	☐
Severe >15º	☐	☐

2.3 Hallucal IP joint Valgus

Absent	☐	☐
Mild >5º	☐	☐
Moderate >10º	☐	☐
Severe >15º		

3. Location of plantar callosities:

	R	**L**
None	☐	☐
Plantar medial hallucal IP joint	☐	☐
2nd MTP joint	☐	☐
3rd MTP joint	☐	☐
5th MTP joint	☐	☐
Lateral border	☐	☐

4. Second toe length:

	R	**L**
Longer than hallux	☐	☐
Equal to hallux	☐	☐
Shorter than hallux	☐	☐

5. Ankle joint dorsiflexion:

Knee extended **R**______º **L**______º

Knee flexed **R**______º **L**______º

6. Lesser MTP joint pain

	L	**R**
Never	☐	☐
Rarely	☐	☐
Somedays	☐	☐
Most days	☐	☐
Everyday	☐	☐

7. Gait (propulsion): *Add **R** or **L** in box*

Normal	☐
MTJt pronation	☐
Supination	☐
Delayed heel lift	☐
Vertical toe-off	☐
Ab/Adductory twist at toe-off	☐
Knee flexion	☐

Version 2 - 06/04/07

Severe >15º

2.3 Hallucal IP joint Valgus

Absent
Mild >5º
Moderate >10º
Severe >15º

~~**3. Location of plantar callosities:**~~

R L

None
Plantar medial hallucal IP joint
2nd MTP joint
3rd MTP joint
5th MTP joint
Lateral border

L R

Never
Rarely
Somedays
Most days
Everyday

7. Gait (propulsion): *Add **R** or **L** in box*

Normal
MTJt pronation
Supination
Delayed heel lift
Vertical toe-off
Ab/Adductory twist at toe-off
Knee flexion

Version 2 - 06/ /07

Appendix 32: Radiological data collection sheet (Study 3)

Subject number: ____________

Tick

1. 1st MTPJ:

1.1 Joint space narrowing

None ☐ Definitely narrowed ☐

Severely narrowed ☐ Joint fusion 1 Pnt ☐

Joint space A/P____mm Lateral______mm

1.2 Joint space symmetry

Symmetrical ☐

Medial narrowing ☐

Lateral narrowing ☐

1.3 Subchondral sclerosis (MH +PP)

None ☐ ☐ Moderate ☐ ☐

Minimal ☐ ☐ Severe ☐ ☐

1.4 Osteophytes (met & phal)

None ☐ Medial ☐

Lateral ☐ Dorsal ☐

~~Severity~~ Minimal ☐

Moderate ☐

Severe ☐

1.5 Loose bodies

None ☐ Medial ☐

Central ☐ Lateral ☐

(Lateral view) Dorsal ☐

1.6 Subchondral cysts

1st metatarsal head Absent ☐

Present ☐

Proximal phalanx Absent ☐

Present ☐

2. Hallux:

2.1 Hallucal phalanx length ratio

Proximal phalanx mm

Distal phalanx mm

P/D ratio ________

3. Hallucal IPJ:

3.1 Hallux abductus interphalangeus (HAI)

Absent ☐

Mild > 5º ☐

Tick

6. First metatarsal:

6.1 Shape of 1st metatarsal head

Oval ☐

Chevron ☐

Flat Minimal ☐

Moderate ☐

Severe ☐

6.2 Length of 1st metatarsal ______ mm

6.3 Length ratio 1st met & Pphal ________

6.4 Length of 1st metatarsal compared to:

	2nd	3rd	2nd	3rd
Shorter	☐	☐	____mm	____mm
Equal	☐	☐		
Longer	☐	☐	____mm	____mm

6.5.1 Sagittal plane position of 1st metatarsal (in relation to 2nd met - lateral view)

Lateral/ sagittal position ____mm

(normal value ≤ 8mm)

6.5.2 1st met declination angle

(normal range 19-25º) ____º

6.5.3 Lateral Talus-1st met angle

(Meary's angle) ____º

Normal = 0º, Abnormal > 4º)

7. 1st MC joint (MCJ):

7.1 1st MCJ position Flat ☐

Angled ☐

7.2 1st MCJ angle ____º

7.3 1st MC joint sag (Lat view)

Absent ☐ Present ☐

7.4 Nav/Cunieform sag (Lat view)

Absent ☐ Present ☐

8. General features

8.1 Metatarsus adductus

Absent ☐

Mild (16º-19º) ☐

Moderate >10º ☐
Severe >15º ☐

4. Hallux equinus angle: Degrees
(normal 16º-18º dorsiflexion) ____º

[redacted]

5.1 Shape

Normal ☐ Irregular ☐
Cystic ☐ Osteopaenic ☐
Hypertrophic ☐ Bi/Tri/Quadripartite ☐

5.2 Tibial Sesamoid distance ______mm
Fibular Sesamoid distance ______mm
5.3 Intersesamoidal distance ______mm

Moderate (20º-25º) ☐
Severe (>25º) ☐

8.2 Transverse plane angulation 2nd MTPJ (Normal 0-7º lateral) - ____º lat / + ____º med

[redacted] medial/intermediate cuneiform diastasis
No ☐
Yes ☐

8.4 Presence of gross alterations in tarsal morphology
No ☐
Yes ☐
If yes describe:

Version 2 : 14/09/2007

Appendix 33: Notice of substantial amendment

NHS
National Research Ethics Service
Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1

1 Standard Court
Park Row
Nottingham
NG1 6GN

Tel: 0115 9123344 ext. 39428
Fax: 0115 9123300

19 March 2008

Mr Paul Beeson
Senior Lecturer
University of Northampton
Park Campus
Boughton Green Road
Northampton
Northamptonshire, NN2 7AL

Dear Mr Beeson,

Study title:	**Development and validation of a classification system to aid surgical decision making in hallux limitus/ rigidus.**
REC reference:	**04/Q2501/93**
Amendment number:	**1**
Amendment date:	**21 January 2008**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 12 March 2008.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	6	21 January 2008
Participant Information Sheet	1	21 January 2008
Participant Consent Form	1	21 January 2008
Notice of Substantial Amendment (non-CTIMPs): changes to data collection methods	1	21 January 2008

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

This Research Ethics Committee is an advisory committee to East Midlands Strategic Health Authority.
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

04/Q2501/93:	**Please quote this number on all correspondence**

Yours sincerely,

J Mckie

Miss Jeannie McKie
Committee Co-ordinator

E-mail: jeannie.mckie@nottspct.nhs.uk

Enclosures — List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: — *University of Northampton*

Leicestershire, Northamptonshire & Rutland Research Ethics Committee 1

Attendance at Sub-Committee of the REC meeting on 12 March 2008

Name	Profession	Capacity
Mr Carl Edwards	Director, NHS Innovations East Midlands	Expert
Mr Jonathan Barratt	Senior Clinical Research Fellow/Honorary Consultant Nephrologist	Expert

Appendix 34: Semi-structured interview schedule

1) Current use of a HR classification

a) What HR classification do you currently use and how does it compare with the proposed system?
Complexity? Clinical vs radiological parameters?

b) **What are you looking for in your ideal HR classification?**
Clear structure? Easy to use? Easy to score? Inclusion of history, clinical & radiological parameters? Combining or separating parameters? Evidence-based? Reliability? Goniometric measures +/-? Observation only?

c) **In what ways would the proposed classification meet your requirements?**
Uptake? Purpose – clinical vs research application? Balance between history, clinical & radiological parameters?

d) **What do you consider to be the most ideal scoring system for HR severity? *Why?***
Problems in devising scoring system? Weighting of each parameter to stratify different stages of HR? Different modes of scoring complicate comparison of studies?

2) Classification type, scale and interpretation 12

a) What do you consider to be the purpose of classifying HR?
TYPE: Grade severity? Evaluate change in HR over time? Help aid management decisions? Comparisons between pre & post surgery states? Comparisons between treatment strategies?

b) What do you consider are the most important parameters/ questions for making up a HR classification?
SCALE: Sub-division of parameters? Number of sub-scales or domains? Weighting applied to each subscale or domain? Scoring of parameters (nominal, ordinal, categorical, qualitative)?

c) What do you consider to be the optimal mode of interpretation?
INTERPRETATION: Higher scores indicate greater HR severity? Certain scores pertain to level of HR management complexity? Each subscale normalized to 100? Each subscale or domain scored separately?

3) Construction of HR classification 21

a) **How well does the proposed HR classification measure what it is supposed to measure**?
CONTENT VALIDITY – Comprehensiveness of content? All necessary elements included? Relevance of content? Adequacy in reflecting purpose? Should clinician based outcomes & patient reported outcomes be included? Is proposed classifications' construction appropriate for condition? What extent should patient's participate in creating & substantiating content?

b) **Do you consider that the proposed HR classification is adequate in its quantitative assessment? If not why?**
CONSTRUCT VALIDITY – How well is concept of pain measured? Does it correlate with same concept in FHSQ (convergent validity)? How well is concept of restricted 1^{st} MTPJ motion measured? Does it correlate with same concept in AOFAS rating system (divergent validity)?

c) **How well does the proposed HR classification correlate with a "gold standard" or next best measure?**
CRITERION VALIDITY - Ability to accurately predict current status of pt's HR (concurrent validity)? Ability to predict future state of affairs (predictive validity)?

d) **How consistent is the proposed HR classification in measuring the same outcome?**
Overall internal consistency? Internal consistency of components in measuring same parameter?

e) **How reproducible do you think results of the proposed HR classification would be for the same or different raters?**
Test-retest? Inter-rater?

f) **Do you consider the proposed HR classification to be sensitive to change? If not why?**
RESPONSIVENESS – Able to change as status of pt changes?

4) <u>Clinical usefulness (utility)</u> 39

a) **In what ways is the proposed HR classification patient friendly?**
ACCEPTABILITY - Questions clear, concise & easy to understand? Comfortable for patient's? Completed in relatively short time period?

b) **In what ways is the proposed HR classification clinician friendly?**
FEASIBILITY – How easy to use? How easy to understand? Time consuming to complete? Is training required? Should classification be scalable (clinical features linearly related to radiological appearance)?

c) **Would the proposed system be acceptable to different disciplines with an interest in managing HR? If not why?**
Training required? Different construction for clinical versus research disciplines? Standardisation of assessment system itself? 45

Appendix 35: Proposed HR classification system

HALLUX RIGIDUS CLASSIFICATION PARAMETERS		
HISTORY Findings		**Present / absent**
Activity levels restricted by HR (change in lifestyle)		
First MTPJ pain on movement (level – VAS 1-10)		
Variable frequency of first MTPJ pain		
Presence first MTPJ stiffness		
Change in walking pattern		
Footwear aggravating HR		
CLINICAL Parameters		
Markers of HR severity	Restricted first MTPJ dorsiflexion	
	First MTPJ pain during passive ROM	
	First MTPJ pain (active ROM) toe-off & heel lift	
	Location first MTPJ pain: Bump (early HR)	
	Sesamoid (established HR)	
	Increased first MTPJ size	
	Hallux abductus interphalangeus	
Associated with or secondary to HR	Frontal plane deformity of hallux	
	Hallucal IPJ hyperextension	
	Callosity – medial plantar hallucal IPJ	
	Lesser toe clawing & medialisation 3^{rd}-5^{th} toes	
	Lesser MTPJ pain	
	Altered gait: Delayed heel lift Vertical toe-off Inverted step Ab/adductory twist at toe-off Failure of knee to fully extend	
Contribute to HR development	Pronated foot (Foot Posture index)	
	Hallux equal or longer than second toe	
RADIOLOGICAL parameters		
First MTPJ	Narrowing	
	Subchondral sclerosis	
	Asymmetry of joint	
	Osteophytes (severity?)	
Hallux	Long proximal phalanx	
	Hallux abductus interphalangeus angle >10°	
	Hallux equinus angle <16°	
Sesamoids	Abnormal morphology (irregular/ hypertrophic) Proximal displacement (transverse plane)	
First metatarsal	Head shape - Flat/ chevron-shaped	
	First metatarsal longer than third metatarsal	
	Metatarsus primus elevatus > 8mm	
Naviculo-cuneiform joint	Sagittal plane sag	
Second MTPJ	Increased medial deviation	
Medial/ intermediate cuneiform diastasis	Increased diastasis	

Appendix 36: Participant invitation letter

Dear ……,

Thank you for agreeing to take part in the hallux rigidus (HR) study.
This is to confirm that your interview has been arranged for:
Date:
Time:
Venue:
Interviewer: Mr Gary Denby

The four themes that will be covered in the structured interview include:
1. *Your current use of a HR classification.*
2. *Classification type, scale and interpretation.*
3. *Construction of HR classification.*
4. *Clinical usefulness (utility).*

You will be shown a clinical picture and two X-ray views of a patient with HR. The key findings of this patients history include:
- Activity levels restricted by HR
- First MTPJ pain on movement
- Presence of First MTPJ stiffness
- Reported change in walking pattern
- Footwear aggravates HR

I have attached the following for your information:
- Participant information sheet
- Parameters (supported by earlier research) for proposed HR classification.
- Consent form

Please print and sign a copy of the consent form and give to the interviewer.

Thank you for your help,

Kind regards,

Paul Beeson BSc (Hons), MSc, DPodM, MChS

Appendix 37

PARTICIPANT INFORMATION SHEET (Study 4)

CONFIDENTIAL

Study Title: *Development and validation of a classification system to aid surgical decision-making in hallux rigidus.*

You are being invited to take part in the above research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and discuss it with others if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of the research is to develop and validate a classification system to help surgical decision making in treating hallux rigidus a common condition of the big toe joint which can cause pain and restriction of movement.

Why have I been chosen?
You have been asked to take part in this phase of the study (semi-structured interview) because you are a clinician who is familiar with and treats hallux rigidus. A total of 17 clinicians will be interviewed (from 4 different professional groups).

Do I have to take part?
Taking part in this research is entirely voluntary. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will receive a copy of the signed consent form. You can receive a copy of what is entered on the interview form if you wish. You are free to withdraw from the study at any time and without giving a reason.

What will happen to me if I take part?
We will be asked a series of questions using a structured interview format about the classification of hallux rigidus. You will only need to be interviewed **once** for 45 minutes.

What do I have to do?
You will be asked to answer a series of specific questions about the clinical and radiological aspects of hallux rigidus. A structured interview format will be used.

What is being tested?
Your interpretation of, the importance of various clinical and radiological variables of hallux rigidus which could be used in its classification.

Version 1 (21/01/08)

What are the possible disadvantages and risks of taking part?
There are no risks associated with this study. The questions you are asked will not be over and above those used in standard diagnosis and treatment of hallux rigidus.

What are the possible benefits of taking part?
The information gained from this study will be used to develop a classification system for hallux rigidus. It will also be used to help surgeons/ clinicians gain a greater insight into the surgical management of this condition and aid in surgical decision making.

What if new information becomes available?
Sometimes during the course of research, new information becomes available about the treatment of the condition studied. This will not influence the interview process.

What happens when the research study stops?
The research findings will be written-up as a PhD.

What if something goes wrong?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms should be available to you.

Will my taking part in this study be kept confidential?
All information which is collected from you during the process of the interview will be kept strictly confidential. You can receive a copy of what is entered on the interview form if you wish.

What will happen to the results of the research study?
The research findings will be written-up and published in a professional Journal.

Who is organising and funding the research? The University of Northampton.

Who has reviewed the study?
- Leicestershire Northamptonshire & Rutland Research Ethics Committee.
- Medical Advisory Committee Three Shires Hospital.
- Leicestershire Northamptonshire & Rutland Primary Care Research Alliance.

Chief Researcher/ Senior Lecturer
Mr Paul Beeson MSc, BSc(Hons), DPodM, MChS, FCPodMed
The University of Northampton

Thank you for reading this

Version 1 (21/01/08)

Appendix 38: Consent form - Study 4

Centre number: 1/ 2/ 3 **CONFIDENTIAL**
Study Number: 04/Q2501/93

CONSENT FORM

Development & validation of a classification system to aid surgical decision making in hallux rigidus

Chief Researcher: Paul Beeson

Please tick boxes

1. I confirm that I have read and understand the information sheet dated 21/01/08 (Version 1) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation in a semi-structured interview is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I give permission for the chief researcher to keep a written copy of my interview. ☐
4. I agree to take part in semi-structured interview for the above study. ☐
5. I understand the answers will be kept confidential and anonymous in the final report. ☐

Name of Participant	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Copies: 1 for participant; 1 for researcher.

If you would like to receive a copy of what is entered on the interview form please tick the box. ☐

Version 1 (21/01/08)

Appendix 39 - Opinions about most important parameters

	Outright rejection	Outright acceptance	Conditional acceptance
HISTORY			
Pain level	0	13	4
Effects on lifestyle	2	10	5
Functional limitation	1	10	6
Patient expectations	14	3	0
Obesity	15	2	0
Ease wearing shoes*	2	10	5
CLINICAL			
Passive 1st MTPJ ROM*	0	11	6
First MTPJ size	12	3	2
Active DAP*	2	14	1
Location of pain	1	12	4
Foot posture	2	10	5
Goniometer used	12	2	3
First MTPJ DOS	12	3	2
Change in gait	9	3	5
HAI	3	5	9
SFA with HR	3	6	8
RADIOLOGICAL			
Magnitude of JSN	0	14	3
JSA	2	7	8
SS	15	2	0
Osteophytes	0	15	2
First metatarsal length	0	12	5
PP length	2	9	6
MPE	14	1	2

Consensus opinion (Max = 17)

JSN = Joint space narrowing, JSA = Joint space asymmetry, SS = Subchondral sclerosis, DAP = Dorsiflexion at propulsion, DOS = Degree of stiffness, HAI = Hallux abductus interphalangeus, SFA = Secondary features associated, PP = Proximal phalanx, MPE = Metatarsus Primus Elevatus, * = rejected after subsequent analysis.

Appendix 40: HR parameters remaining following each study

STUDY/ Domain	Parameter	Why considered?	Why removed?	Keep
CLINICAL (Study 1)				
History	HR restricts activity levels	Effect on lifestyle		√
	Magnitude of first MTPJ pain	May effect activity		√
	Variability of first MTPJ pain	Effected by activity	Idiosyncratic	
	Presence first MTPJ stiffness	Effects dorsiflexion	Unable to measure	
	Frequency of first MTPJ pain	Effect on activity		√
	Functional limitation	Changes in function		√
	Change in walking pattern	Effect on foot joints	Influence of proximal joints	
	Footwear aggravating HR	Difficulty fitting shoes	In only 23% patients	
Clinical	Restricted first MTPJ dorsiflexion	**Potential markers of severity**		√
	Passive first MTPJ ROM			√
	Active first MTPJ ROM			√
	Timing of pain during 1st MTPJ ROM			√
	Location first MTPJ pain			√
	Magnitude 1st MTPJ pain during AD			√
	Increased first MTPJ size		Affects other 1st MTPJ conditions	
	HAI			√
	Frontal plane deformity of hallux			√
	Hallucal IPJ hyperextension			√

	Hallucal IPJ pain	**Associated with or secondary to HR**	Not associated with HR	
	Location of plantar callosities			√
	Lesser toe clawing/ medialisation		Idiosyncratic	
	Lesser MTPJ pain			√
	Ankle joint dorsiflexion		Not associated with HR	
	Altered gait			√
	Magnitude of pronation (FPI)	**May contribute to HR development**		√
	Hallux equal or longer than 2^{nd} toe			√
RADIOLOGICAL (Study 2)	JSN	**Specific to 1^{st} MTPJ**		√
	Subchondral sclerosis		Difficult to quantify	
	Joint space symmetry			√
	Osteophytes (severity)			√
	Subchondral cysts		Low incidence	
	Loose bodies		Only found in 13% of 1^{st} MTPJ's	
	Proximal/distal phalanx length ratio	**Hallux**		√
	HAI angle			√
	IPJ OA		Low incidence	
	Hallux equinus angle			√
	Abnormal morphology			√

	Proximal displacement (TP)	**Sesamoids**		√
	ISD		Difficult to measure	
	Head shape	**First metatarsal**		√
	First metatarsal length			√
	First metatarsal length CT 2^{nd} met			√
	First metatarsal length CT 3^{rd} met			√
	1^{st} met/ prox phalanx length ratio			√
	1^{st} met sagittal plane position			√
	1^{st} metatarsal declination angle			√
	Lateral talus-first metatarsal angle			√
	MCJ sag		Only 5% of feet	
	MCJ angle		Difficult to interpret	
	Metatarsus adductus angle	**General features**	Association between HR & MA?	**?**
	TP deviation 2^{nd} MTPJ			√
	NCJ sag			√
	Medial-intermediate cuneiform diastasis		Difficult to assess	
	Gross alterations tarsal morphology		Only presents in 18% patients	

RELIABILITY (Study 3)				
Clinical	Passive & active first MTPJ ROM	**Goniometric measures**	Only valid for intra-observer	
	HAI			√
	Hallucal IPJ hyperextension		Poor reliability	
	Ankle joint dorsiflexion			
	Magnitude 1st MTPJ pain during AD	**Observations**	Variable – poorly reliable	
	Timing 1st MTPJ pain during AD			√
	Location 1st MTPJ pain			√
	Frontal plane deformity of hallux		Poor reliability	
	Location of plantar callosities			√
	Second toe length CT hallux			√
	Lesser MTPJ pain		Poor reliability	
	Gait at propulsion		Poor reliability	
Radiological	JSN			√
	1st MTPJ space symmetry		Suitable internal consistency only	
	Proximal/distal phalanx length ratio			√
	HAI angle		Poor reliability	
	Hallux equinus angle			
	Proximal displacement (TP)			
	ISD			

	First metatarsal length	**Goniometric measures**		√
	1st met/prox phalanx length ratio			√
	First metatarsal length CT 2nd met			√
	First metatarsal length CT 3rd met			√
	1st met sagittal plane position		**Poor reliability**	
	1st metatarsal declination angle			
	First MCJ angle			
	Metatarsus adductus angle			
	Lateral talus 1st metatarsal angle			
	TP deviation second MTPJ			
	First MTP JSN	**Observations**		√
	First MTPJ symmetry		Suitable internal consistency only	√
	Subchondral sclerosis		Poor reliability	
	First MTPJ osteophyte position			√
	First MTPJ osteophyte severity			√
	First MTPJ loose body		Poor reliability	
	Sesamoid morphology			√
	Metatarsal head shape			√
	Severity of first met head flatness		Suitable internal consistency only	
	M-I cuneiform diastasis		Poor reliability	
	NCJ sag			√

QUALITATIVE (Study 4)				
History	Magnitude of first MTPJ pain	Effects activity levels		√
	Frequency of first MTPJ pain	Linked to activity		√
	Functional limitation	Changes in function		√
	Change in walking pattern	Effect on foot joints	Too many variables	
	Ease of wearing shoes	Difficulty fitting shoes	Clinicians perception differs from patients (see clinical study 1)	
	Effects on lifestyle	Emphasizes functionality		√
Clinical	Passive first MTPJ ROM	Marker of HR severity	Not valid for inter-observer <u>but</u> pain quantification during passive joint movement may be of value	
	Active DAP	Marker of HR severity	Not valid for inter-observer	
	Location of first MTPJ pain	Marker of HR severity		√
	Magnitude of pronation (FPI)	Contributes to HR		√
	Location of plantar callosities	Secondary factor	Variable, seen in non-HR	
	Altered gait	Secondary factor	Comp gait mechanisms not useful	
Radiological	Magnitude of JSN	Specific to 1st MTPJ		√
	Osteophytes	Marker of severity		√
	First metatarsal length	Literature supports	Only use if CT lesser metatarsal	

REMAINING PARAMETERS FOR CLASSIFICATION FRAMEWORK	
HISTORY	
Markers of severity	Pain magnitude
	Pain frequency
Changes in function	Functional limitation
	Effects on lifestyle
CLINICAL	
Contributory factors	Hallucal length CT second toe
	Magnitude of pes planus
Markers of severity	Pain location (B,J,S, FHL)
	Timing of pain during AD
	HAI
RADIOLOGICAL	
Markers of severity	First MTPJ JSN
	Osteophytes
	First metatarsal head morphology
	Sesamoid morphology
Contributory factors	1^{st} met length CT 3^{rd} met

AD = active dorsiflexion, B = bump, CO = Component observation, CT = Compared to, DAP = Dorsiflexion at propulsion, FHL = Flexor hallucis longus, FPI = Foot Posture Index, HAI = Hallux abductus interphalangeus, J = joint, JSN = Joint space narrowing, met = metatarsal, MCJ = metatarsal cuneiform joint, M-I = Medial-intermediate, MPE = Metatarsus primus elevatus, NCJ = Navicular cuneiform joint, RFA = Radiographic foot atlas, S = sesamoids, TP = Transverse plane, * = validated methods

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