The Orthotic Treatment of Juvenile Hallux Valgus

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Abstract

Pronation of the foot is proposed as a possible aetiological factor in hallux valgus. Root type foot orthoses have been shown to restrict foot pronation and therefore have been used to treat hallux valgus.

A controlled prospective 3 year trial tested the value of a Root foot orthosis in the treatment of juvenile hallux valgus.

Six thousand nine year old Kettering children were screened for hallux valgus using goniometric and clinical examination. A clinical diagnosis of hallux valgus was made in 150 children and confirmed using radiography in 122 cases.

Pes planus was as common in children with hallux valgus as children with no hallux valgus. The biomechanical examination of hallux valgus children revealed that a plantarflexed first metatarsal was the only consistent biomechanical abnormality. The sagittal plane position of the first metatarsal did not however relate to the degree of metatarsus primus varus which is apparent in the unaffected feet of children with unilateral hallux valgus prior to the development of hallux valgus in both feet.

The 122 children with hallux valgus were randomised into a non-treatment control group and a treatment group where Root foot orthoses were worn for three years. Compliance and fit of the orthoses were checked every 4 to 6 months. At the end of the 3 year period, 96 children underwent a second weightbearing radiograph of both feet. The same observer measured the intermetatarsal and hallux valgus angle on all radiographs.

The hallux valgus had deteriorated significantly in both the control and treatment group. Though not statistically significant, the deterioration was slightly more marked in the treatment group.

A Root foot orthosis prescribed to restrict foot pronation will not significantly alter the progression of juvenile hallux valgus. This may indicate that pronation of the foot is not an important aetiological factor in juvenile hallux valgus.

Acknowledgements

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This thesis is dedicated to Christine Thackeray.

Candidate's Declaration

All the work contained in this manuscript is my own though the contribution of the following is gratefully acknowledged:

Richard Barrington, Consultant Orthopaedic Surgeon, Kettering General Hospital who performed all the radiographic measurements.

Dr Andrew Rouse, Epidemiologist, Faculty of Health Science, Nene College, who advised on statistical analysis.

Data analysis was performed with the Amstrad Quasar, Amstat and Apple Macintosh Lotus 123 software programmes.

Timothy E. Kilmartin
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PREFACE

The Root foot orthosis is commonly prescribed by podiatrists for a variety of lower limb conditions ranging from knee pain to hallux valgus. While there is increasing evidence that such an orthosis can produce symptomatic relief, little is known about how an orthosis can actually change lower limb function for the better.

Though a very conservative treatment, the Root foot orthosis is an expensive intervention. Compliance with the device often requires compromise in footwear and in growing children regular replacement is required. In 1987 R.L Barrington a Consultant Orthopaedic surgeon at Kettering General Hospital questioned the local Podiatry department's provision of foot orthoses for children identified on school screening as having biomechanical abnormalities of the legs or feet. Richard Barrington was sceptical about the treatment of seemingly healthy children with an appliance of unknown value.

While some evidence was available in the sports medicine literature that lower limb overuse type injuries could be relieved by the use of orthoses, little was known about the effect on children other than a small study completed by Mereday in 1972 which indicated that protracted use of a foot orthoses did not raise the medial longitudinal arch of children with flat feet.

Mereday's study has always been refuted by podiatrists who claim that while an orthosis may not correct flat feet, it will prevent the development of secondary associated conditions. Hallux valgus is considered to be just one of the conditions associated with flat feet. It is also a progressive condition that without treatment will certainly deteriorate. Therefore it is a condition appropriate for controlled prospective study.

If hallux valgus is related to poor biomechanical function and if a Root foot orthosis can improve that function, hallux valgus will not deteriorate and may even regress. If however hallux valgus is not a consequence of the way in which the foot functions or if a Root foot orthosis does not alter foot function appropriately, hallux valgus will continue to deteriorate.

When the Kettering trial began it was thought by most podiatrists that it would merely confirm something that Merton Root, the originator of the Root foot orthosis had once stated..... "even a normal foot will function better with a Root orthosis". The outcome of the Kettering trial has however led many to question the entire biomechanical approach to acquired foot deformity .

CONTENTS

APPENDICES

THE ORTHOTIC TREATMENT OF JUVENILE HALLUX VALGUS

1. Introduction

Hallux valgus is a common foot problem which in its early stages will affect just the first metatarsophalangeal joint. As the condition progresses however, it will involve the whole forefoot and may be associated with lesser toe deformity, plantar callosity, great toe nail pathology, splaying of the forefoot and footwear fitting problems (Massart 1934).

Although hallux valgus has been described for over 100 years (Hueter 1871), the aetiology and indeed definitive treatment remains uncertain. When treatment is required for hallux valgus, surgery is often performed, but the outcome is not always favourable (Rowley 1991). The value of treatment in early or juvenile stages is uncertain. Recurrence may follow surgery on juvenile hallux valgus (Scranton and Zuckerman 1984), but non-surgical treatment is rarely used (Groiso 1992). In recent years, a bespoke in-shoe orthosis, designed to restrict excessive pronation of the foot, has been used in an attempt to stop the progression of hallux valgus (Pratt et al 1993). The value of this intervention has not however been proven.

1.1 Terminology and Definitions

It is first necessary to bring consistency to an increasingly confused and jargonised subject. The terminology, diagnosis and measurement of hallux valgus will therefore be reviewed.

1.1.1 The Definition of Hallux Valgus

The term hallux valgus was introduced into the literature in 1871 when Hueter defined the deformity as an abduction contracture in which the great toe is turned away from the mid-line of the body. The adjective valgus implies a static deformity and should not be used interchangeably with abductus which refers to movement caused by muscle function.

Bunion is another term which is commonly used to describe the hallux valgus deformity. It is a poor term because it is ambiguous. For some it will mean inflammation of the bursa overlying the metatarsophalangeal joint (Butterworth's Dictionary 1978) for others it will refer to the bony medial eminence which becomes apparent at quite an early stage in the development of hallux valgus. For most though, it will be used to describe any painful condition or deformity of the first metatarsophalangeal joint ranging from valgus drift of the hallux to hallux rigidus.

The dividing line between a normal and a hallux valgus foot is contentious. Hardy and Clapham (1951) noted that on dorso-plantar radiographs of the normal foot, the first metatarsophalangeal joint angle formed between the longitudinal bisection of the hallux proximal phalanx and the first metatarsal was less than 15° (Fig.1.1)

Piggott (1960) however, separated a normal from a hallux valgus foot on the basis of first metatarsophalangeal joint congruency. In the normal foot the first metatarsophalangeal joint remained congruent with the articular surface of the first metatarsal head and proximal phalanx of the hallux lying adjacent to one another. Hallux valgus is a deviated joint where the proximal phalanx is moved laterally on the first metatarsal head leaving the medial side of the metatarsal head exposed (Fig.1.2).

Piggott considered Hardy and Clapham's dividing line somewhat artificial as he found a number of congruous joints with first metatarsophalangeal joint angles in excess of 15°.

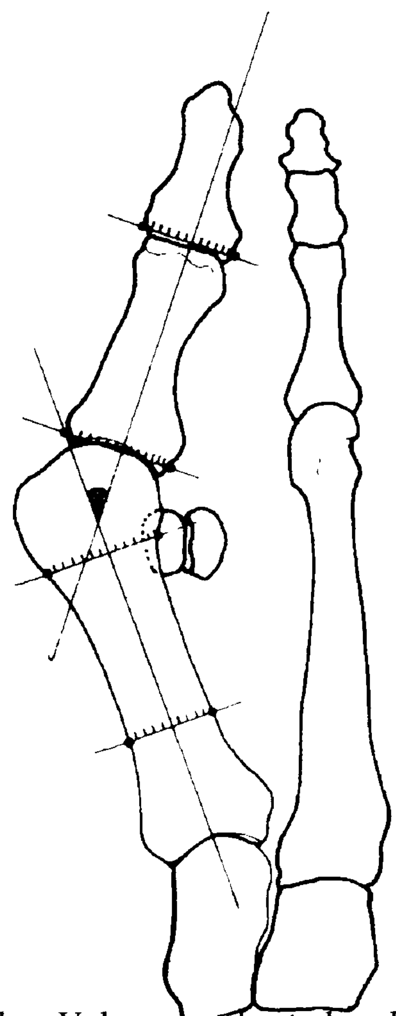


Fig 1.1 Hallux Valgus as charted radiographically

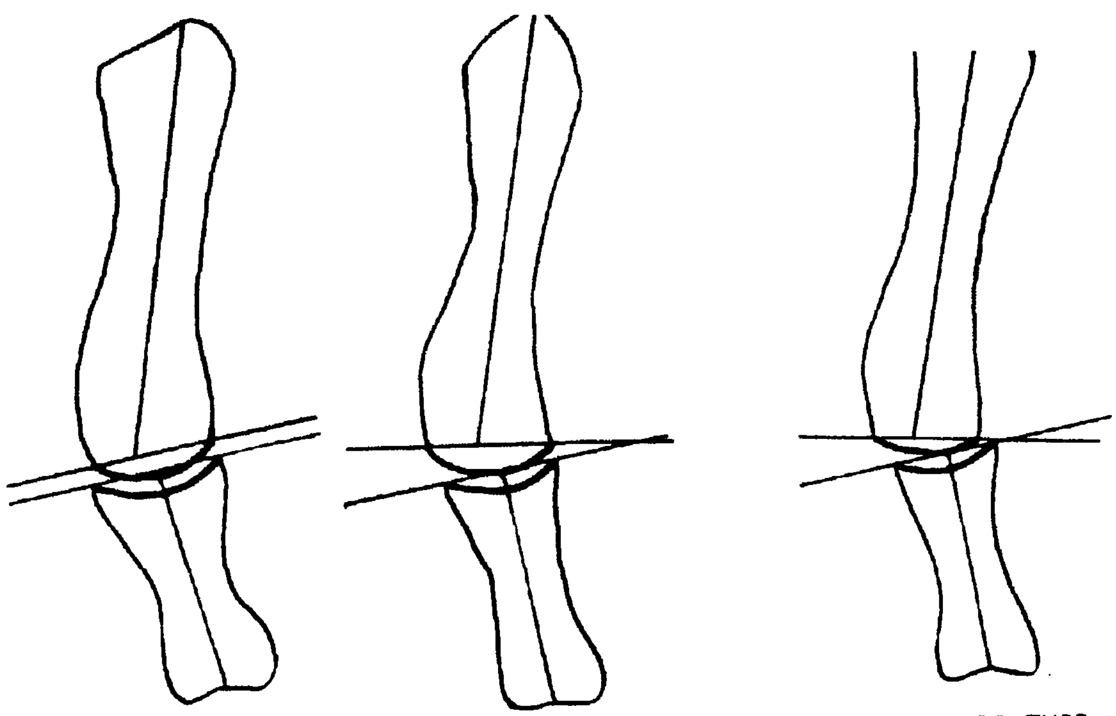


Fig 1.2 Piggott's Metatarsophalangeal Joint Classification based upon Congruity

In a study of 300 South African negro and caucasian children with normal feet, Gottschalk et al (1981) found a mean first metatarsophalangeal joint angle of 13.8°.

Scott, Wilson & Bentley (1989) compared a number of radiographic angles in the feet of 100 women who had surgery for symptomatic hallux valgus with the same angles in 100 women who had "healthy asymptomatic feet". The radiographs were taken with the subjects weight bearing and demonstrated a mean first metatarsophalangeal joint angle of 32° in the hallux valgus group (range 16° - 55°) and 13° (range 2° - 25°) in the control group.

It is likely that hallux valgus is not a yes or no phenomenon but rather represents a continuum of variable severity. The first metatarsophalangeal joint angle alone does not reflect the tendency for the deformity to progress, and cannot be used to separate reliably the truly deformed from the normal foot. Congruity of the first metatarsophalangeal joint is probably more predictive, but radiographic assessment of joint congruity is difficult and unreliable. A statistical study by Armanek et al (1986) found that there was a highly significant difference between the radiographic and the intra-operative assessment of metatarsophalangeal joint congruity.

While not entirely predictive, Hardy and Clapham's "artificial dividing line" of 15° appears to be supported by the epidemiological studies reviewed. Therefore a first metatarsophalangeal joint angle of 15° or more, will, for the purposes of this thesis, be considered abnormal.

1.1.2 Metatarsus Primus Varus

Metatarsus primus varus has been considered in the past to be an important component of hallux valgus. It is a fixed position of the first metatarsal where the bone is displaced toward the mid-line of the body. Some authorities have used the term *metatarsus primus adductus* to describe the abnormal first metatarsal position (Root, Orien and Weed 1977). However *adductus* implies that the first metatarsal can move independently as a result of muscle activity, therefore the term metatarsus primus varus will be used in preference.

Metatarsus primus varus may be quantified by bisecting the first and second metatarsals and measuring the resultant angle. A first-second intermetatarsal angle in excess of 9° is considered abnormal (Gamble, Yale 1978)

1.1.3 <u>Position and Motion of the Foot</u>

A major theme of this thesis is the significance of rearfoot, forefoot and first metatarsal positions in hallux valgus. The terminology used to describe position and motion of these components of the foot is not standardised. For the purposes of this thesis the following reference planes and definitions will apply:

The mid-sagittal plane divides the body vertically into equal right and left halves and touches the ground midway between the two parallel feet.

Medial refers to position or movement toward the mid-sagittal plane of the body while **lateral** refers to position or movement away from it.

The frontal plane passes vertically through the body dividing it into anterior and posterior parts.

The transverse plane is the horizontal plane and divides the body into superior and inferior parts.

Dorsiflexion is a raising of the foot or foot part toward the leg. **Plantarflexion**

is a downward movement of the foot or foot part away from the leg.

Inversion is the motion of the foot or foot part in the frontal or coronal plane causing the plantar surface of the foot to face medially. **Eversion** is motion of the foot or foot part in the frontal plane causing the plantar surface of the foot to face laterally.

Abduction is movement in the transverse plane whereby the distal segment of the foot or foot part moves away from the mid-sagittal plane of the body. **Adduction** is movement of the distal segment of the foot or foot part towards the mid-sagittal plane of the body.

Foot Supination is a motion of the whole foot relative to the leg which involves simultaneous inversion, plantarflexion and adduction. Again the frontal plane movement of inversion is the most clinically appreciable and inversion is often used instead of supination.

Foot Pronation is a motion of the whole foot relative to the leg which involves simultaneous eversion, dorsiflexion and abduction. Clinically because of the nature of the subtalar joints axis, the eversion component of pronation will be most readily appreciable, hence why some texts use eversion instead of pronation (Fig. 1.3).

Rearfoot Movement is usually determined by measuring the angle formed between a vertical bisection of the posterior surface of the calcaneus and a horizontal supporting surface.
Rearfoot Eversion is the motion of the hindfoot in the frontal plane so that the plantar surface of the hindfoot faces laterally. Rearfoot eversion is amenable to clinical measurement and although it is just one component of foot pronation, the everted position of the hindfoot is often used to indicate the degree of foot pronation (Fig. 1.4).

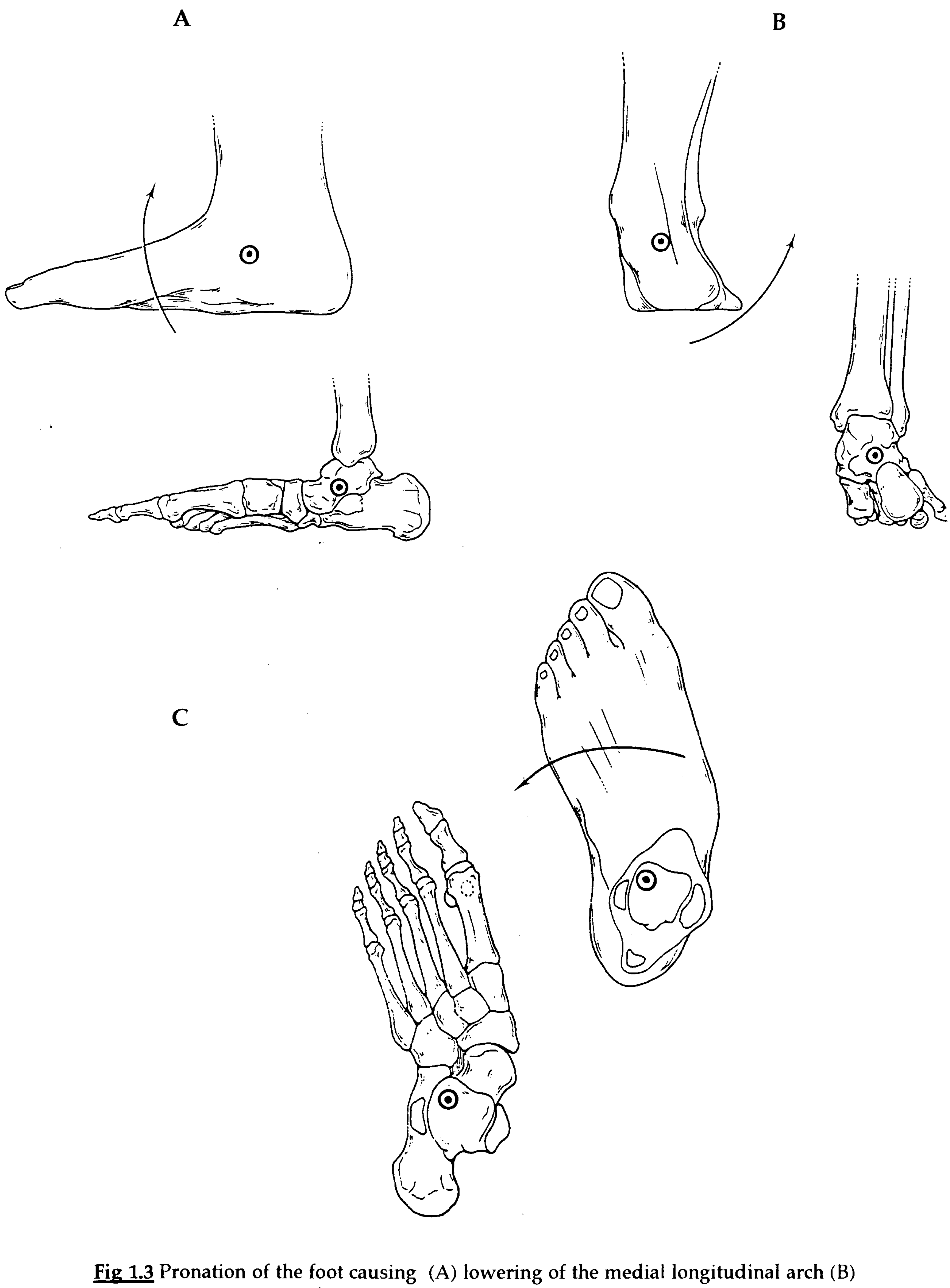


Fig 1.3 Pronation of the foot causing (A) lowering of the medial longitudinal arch (B) eversion of the rearfoot and (C) abduction of the forefoot

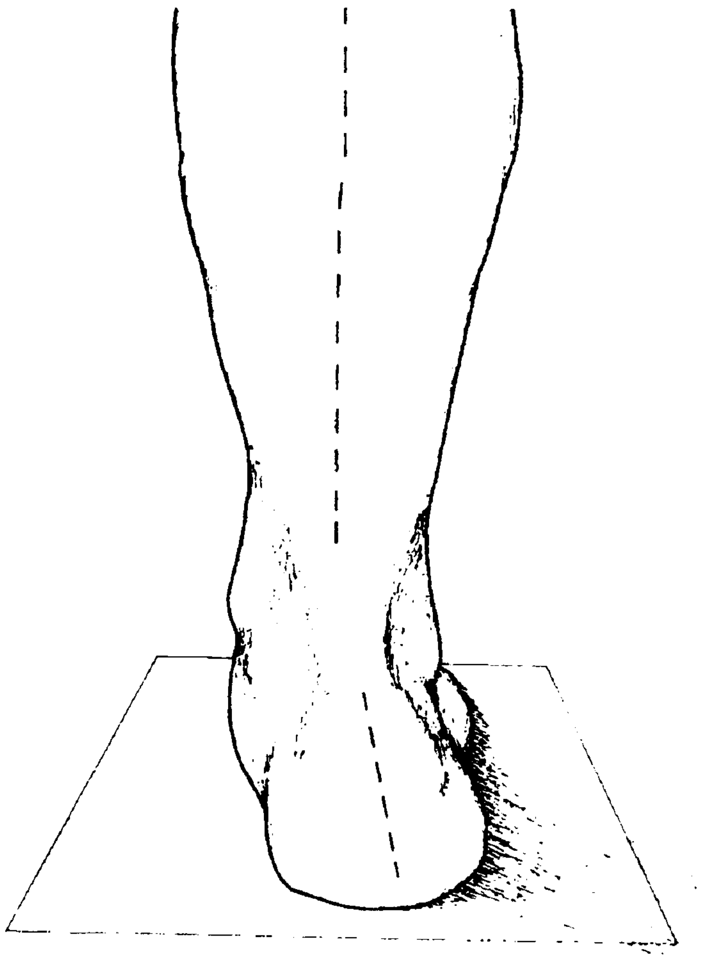


Fig. 1.4 Measurement of Rearfoot Eversion. The angle formed between the vertical bisection of the rearfoot and the vertical bisection of the leg is the degree of rearfoot eversion.

1.2 Excessive Pronation of the Foot as a Cause of Hallux Valgus

In 1951 Jordan and Brodsky wrote "We regard the majority of cases of hallux valgus as acquired deformities resulting from pronation of the foot. The role of footwear is secondary, serving to aggravate in mild deformity or produce manifest deformity where only potential hallux valgus previously existed as a result of foot pronation". This was the clearest statement yet of a co-existence that had previously been observed by Riedl (1886), Goldthwait (1893), Silver (1923), Hiss (1931) and Rogers and Joplin (1947).

In 1965 Kelikian observed that there could be a causal relationship between pronation of the foot and hallux valgus. He suggested that collapse of the inner border of the midfoot, depressed the base of the first metatarsal downwards, while tilting the metatarsal head upwards. The medial capsule of the first metatarsophalangeal joint offered less resistance than the base of the proximal phalanx and the metatarsal head then subluxed medially.

Holstein (1980) described how hallux valgus was acquired once cerebral palsy individuals assumed active weight bearing. His study of 30 cerebral palsy cases observed that individuals who developed flexion adduction of the hip, flexion of the knee and equinovalgus of the foot on active weight bearing also developed hallux valgus. In 11 individuals who developed similar flexion deformities of the leg, but equinovarus of the foot, hallux valgus did not occur. Four of the equinovarus group subsequently underwent posterior tibial tendon lengthening and once their feet adopted an equinovalgus position, they too developed hallux valgus. One case developed equinovalgus of the rearfoot on one side, while maintaining equinovarus on the other, hallux valgus developed in the equinovalgus foot only.

Holstein's observations must be interpreted cautiously. His study population only developed hallux valgus, after a number of operative procedures to their legs and feet, allowed them to actively weightbear for the first time. Holstein claimed the one constant variable which separated individuals who developed hallux valgus, from those who did not, was equinovalgus of the rearfoot. In the context of so many and varied operations being performed on the legs of his subjects, it is difficult to be certain that this variable was the only constant factor. Indeed while Holstein's series of patients indicated a very strong and definite trend, why is it that hallux valgus is not seen in all equinovalgus feet? This consideration must lead us to question whether Holstein's findings can be extrapolated onto the non cerebral palsy population. We must also contrast it with the study of Hoffer and Sequist (1980), who reported that analysis of 100 consecutive cerebral palsy clinic patients, showed 47% with a valgus heel, of those just 18% had hallux valgus.

Kalen and Brechner (1988) sought to establish a radiological relationship between adolescent bunions and pronation of the foot. Sixty six adolescents of mean age 13 years were analyzed. Fifty to sixty percent presented with abnormally low calcaneal inclination and high dorso-plantar talo-navicular angles (Fig. 2.6). Both these radiographic angles were believed to indicate the degree of foot pronation. However because no control values were established it is not certain what was meant by abnormally low or high. No direct correlation between the severity of hallux valgus, and any of the radiological measurements was determined.

Whether Kalen and Brechner's observations can be considered meaningful or otherwise, it is clear that 40% of their series had hallux valgus but not pes planus / excessive pronation.

Root, Orien and Weed (1977) developed the significance of pronation of the foot in hallux valgus far beyond the observations of earlier writers. Pronation of the foot rendered the entire forefoot hypermobile because it prevented the midtarsal joint from locking the foot rigid as the foot transformed from the mobile adaptor of the heel contact phase of gait, to the rigid lever of the push off phase of gait.

According to Root et al, the mechanical lever arm of the peroneus longus muscle was then reduced, as the medial border of the foot sank into pronation and the first metatarsal was left unstable. The hypermobile first metatarsal head inverted relative to the hallux, and subluxation of the first metatarsophalangeal joint developed. The transverse head of adductor hallucis, then pulled the base of the proximal phalanx laterally off the first metatarsal head. The tension necessary for this effect was created by ground reaction forces, which are directed upwardly against the forefoot during the push-off phase of gait and are responsible for splaying of all the hypermobile metatarsals.

Root Orien and Weed (1977) proposed that the inverted and dorsiflexed position of the hypermobile first metatarsal, led to articulation of the tibial sesamoid with the osseous intersesamoidal ridge. Erosion of the ridge followed, further destabilising the first metatarsophalangeal joint. Once the hallux had deviated so far laterally that it lay in contact with the second toe, a retrograde force was directed back across the first metatarsophalangeal joint which forced the first metatarsal into metatarsus primus varus, or metatarsus primus adductus as it was called by Root et al. Severe hallux valgus or even dislocation of the first metatarsophalangeal joint followed, as the first metatarsal moved medially and the hallux laterally.

Excessive pronation of the foot and hypermobility of the first metatarsal was also thought by Root et al to be the cause of hallux rigidus. The degree of forefoot adductus, was the factor which determined whether a pronated foot developed hallux valgus or hallux rigidus. In the forefoot adductus foot the flexor muscles, which insert into the plantar surface of the hallux would bowstring laterally pulling the hallux into valgus (Fig. 1.5). The abductor hallucis muscle would lie more directly under the first metatarsal head effectively reducing its ability, or in mechanical terms its lever arm, to resist the valgus deviation of the hallux.

No clinical research was presented to support this central tenet of Root, Orien and Weed's hypothesis. The role of the transverse head of adductor hallucis in pulling the unstable hallux into valgus and peroneus longus in allowing first metatarsal hypermobility was not substantiated.

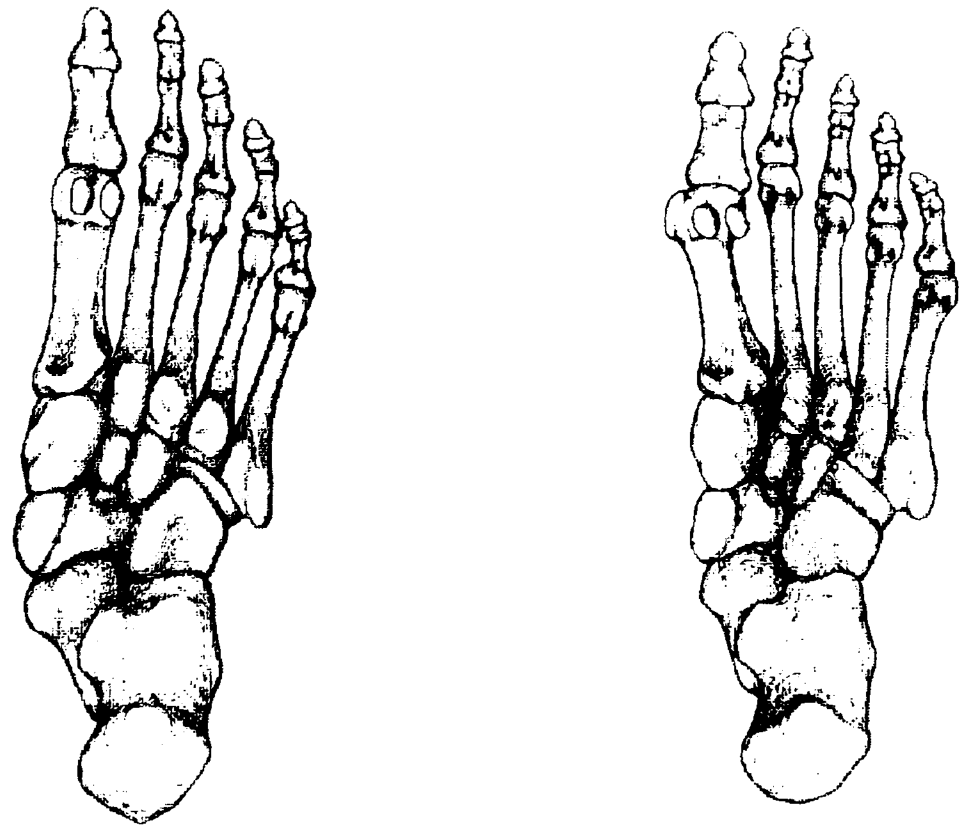
1.2.1 The Use of a Foot Orthosis to Restrict Foot Pronation and Treat Hallux Valgus

Pratt et al (1993) identify three different types of foot pathology which are amenable to orthotic management:

1. Foot instability or deformity due to muscle weakness or imbalance.

2. Foot instability or deformity due to structural malignment.

3. Deformity arising from a loss of structural integrity within the foot.



<u>Fig. 1.5</u> Hypermobility of the first metatarsal in the straight forefoot (Left) leads to hallux rigidus while forefoot adductus (Right) predisposes to hallux valgus according to Root, Orien and Weed 1977

or soft tissue structures, or modify the motion which occurs at one of the foot joints.

By realigning the ground reaction force on the foot, the Root orthosis may change the position about which the subtalar, midtarsal and metatarsophalangeal joints function. Ground reaction force will create a moment at each of these joints. The moment is the turning effect of the ground reaction force. The sense of the moment is determined by whether the ground reaction force passes anteriorly or posteriorly, or medially or laterally to the joint. In Fig. 1.5 the ground reaction force is passing lateral to the subtalar joint. The magnitude of the moment will be determined by the perpendicular distance between the joint centre and the line of action of the force. As the ground reaction force generated at the weightbearing joints during gait may be 2 to 5 times greater than body weight (Veres 1977), the moment on the subtalar, midtarsal and metatarsophalangeal joints will greatly influence both motion and position of those joints. Realignment of the ground reaction force, which may be achieved with a foot orthosis, could in theory change the moment about the joint (Fig. 1.6).

Veres (1977) in a theoretical model of forces acting upon the foot, determined that an arch support may move ground reaction forces anteriorly from the hindfoot and reduce internal loading on the talo-navicular joint. If the talo-navicular joint is prevented from subluxing the osseous segments distal to it will be better able to resist the ground reaction forces expressed upon them, because within the foot, distal hypermobility follows proximal instability (Zitzlsperger 1960).

The so called Root orthosis (Root 1981), used in the study of hallux valgus treatment described in this thesis, was designed to modify the point of application and line of action of ground reaction force during dynamic weight bearing (Fig. 1.6 & 1.7).

It could be argued that all three pathologies could influence the development of hallux valgus, because all three pathologies are known to cause the foot to pronate excessively.

According to Pratt et al (1993), Anthony (1991) and Philps (1990), where the foot is unstable due to muscle weakness, the objective of treatment with a foot orthosis is to substitute the actions of the weak muscles. Where there is structural malalignment, the aim of orthotic treatment is cause the foot to function around a more neutral position i.e. where the foot is neither pronated or supinated.

In juvenile hallux valgus, treatment with a foot orthosis has been recommended by Scranton (1982) who considered that an orthosis will reduce pronation of the foot which in turn reduces the valgus force on the hallux. Root, Orien and Weed (1977) used the biomechanical orthosis to restrict pronation of the foot. Root et al claimed this would prevent hypermobility of the first metatarsal and subluxation of the first metatarsophalangeal joint at the propulsive phase of gait.

Is there evidence to support the theories of Root et al? The following section considers the Root foot orthosis in detail before reviewing the known effect of the Root foot orthosis on foot position and motion.

1.3 The Root Foot Orthosis

An orthosis may be defined as an:

> An externally applied device used to modify the structural or functional characteristics of the neuro-musculo-skeletal system (Bowker, Condie, Bader, Pratt, Wallace 1993).

A foot orthosis may be designed to relieve forces from pathological skeletal or soft tissue structures, or modify the motion which occurs at one of the foot joints.

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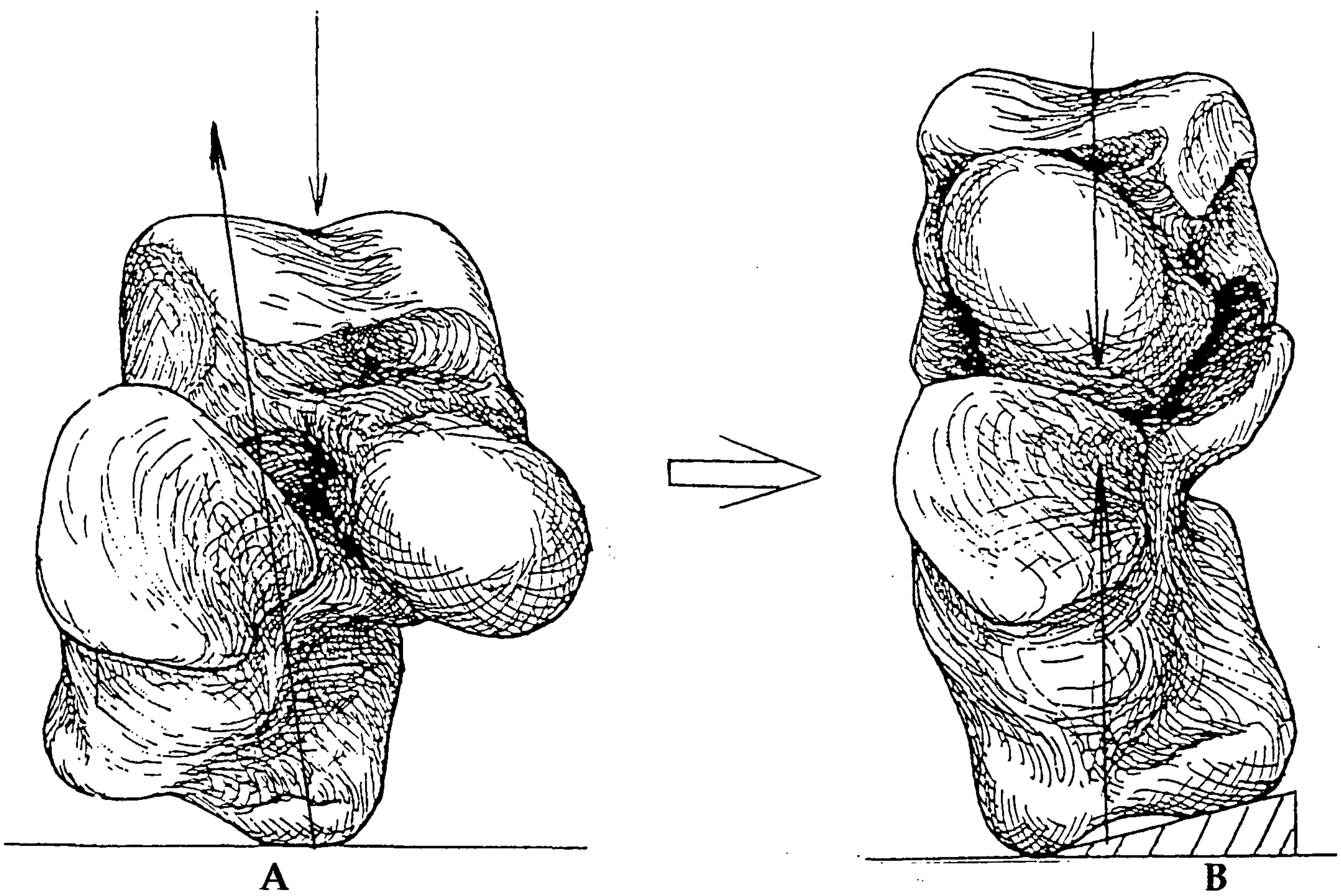
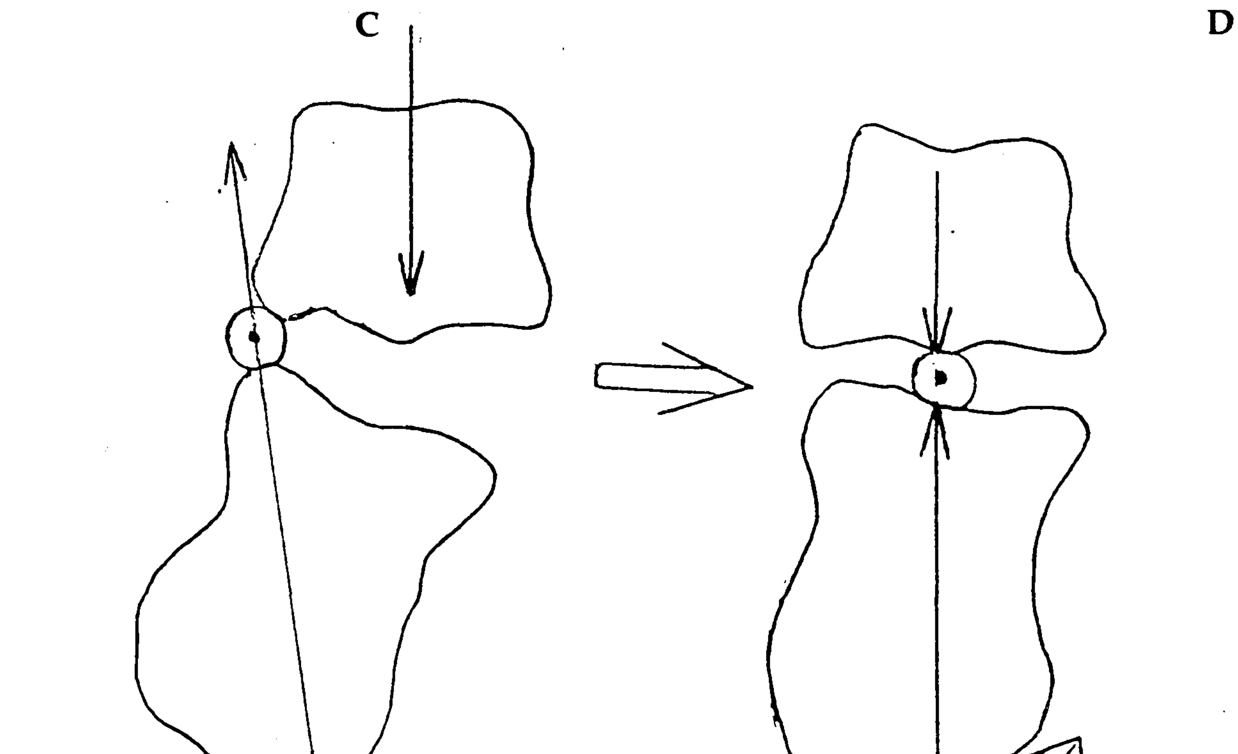
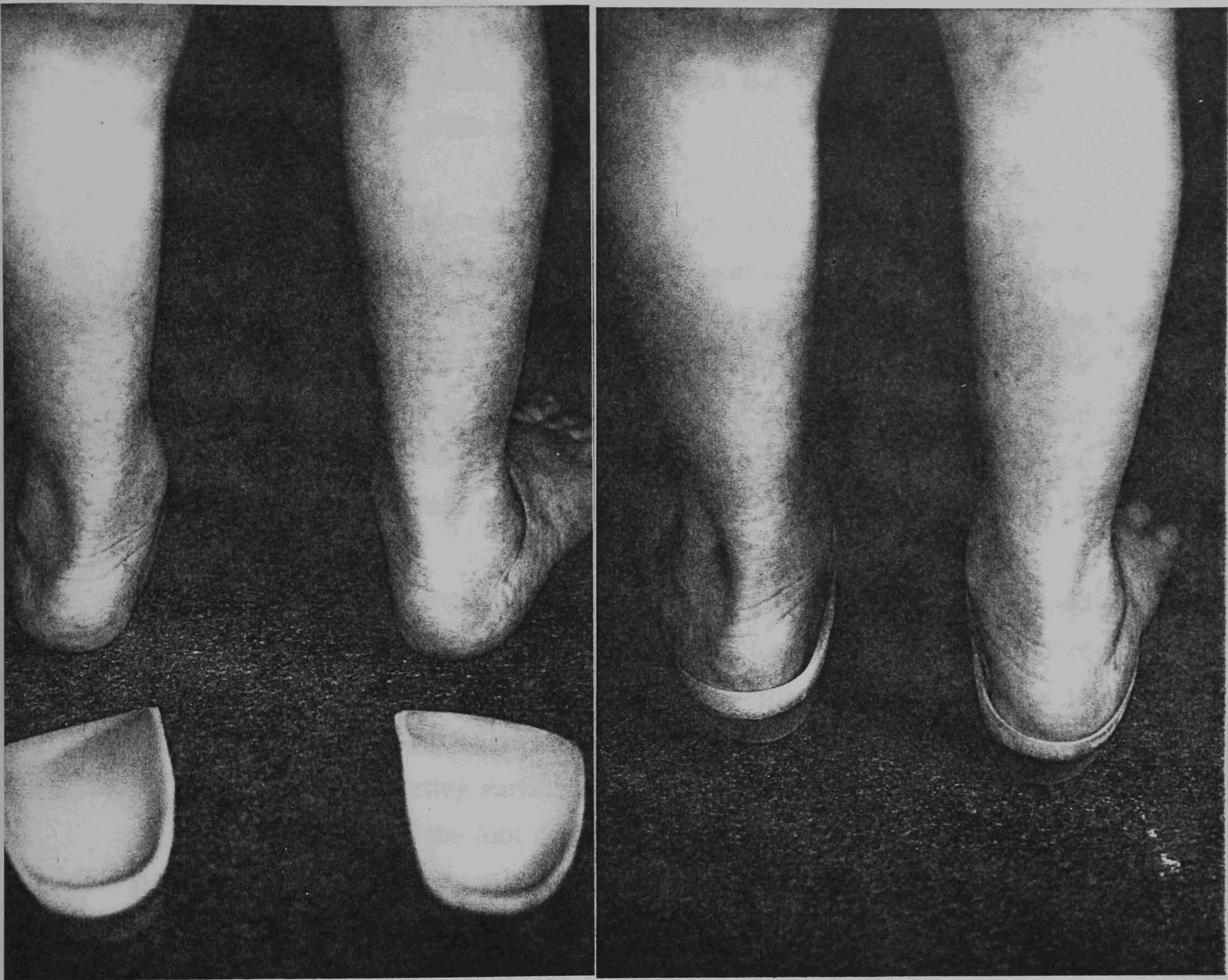
Fig. 1.6 In (a) eversion of the rearfoot has led to abnormal subtalar joint position. When an orthosis with a rearfoot wedge is placed beneath the foot (b) the subtalar joint is realigned into its correct neutral position. (The downward seeking vertical arrow indicates limb load, the upward seeking vertical arrow indicates ground reaction force).



In **(C) and (D)** the diagrammatic representation of the effect of rearfoot pronation, the downward seeking vertical arrow indicates limb load, the upward seeking vertical arrow indicates ground reaction force. Re-positioning of the joint with the medial wedge has reduced the turning effect of both the limb load and ground reaction forces on the joint.





<u>Fig 1.7</u> The Root foot orthoses reduces the rearfoot eversion and forefoot abduction in this child with pronation of both feet.

The process of realigning ground reaction forces on the subtalar, midtarsal and metatarsophalangeal joints involves altering the angular relationships between the plantar surface of the foot and the floor, and between the articulating segments of the foot itself.

A Root orthosis (Fig. 1.8) consists of a heel cup which is wedged or posted on the inferior surface in order to invert the calcaneus. The heel cup extends into an orthotic plate which is shaped in order to support the inclination angle of the calcaneus by applying a moment to the anterior tubercles of the calcaneus. The orthotic plate extends to a point just behind the metatarsal heads where the forefoot wedge or 'post' holds the plantar surface of the forefoot on the same plane as the plantar surface of the rearfoot.

The forefoot post is thought to restrict foot pronation caused by fixed inversion deformities of the forefoot, where the forefoot is inverted relative to the plantar surface of the rearfoot. In order for the medial forefoot to contact the ground the foot rolls into pronation. The forefoot post functions by bringing the supporting surface closer to the medial metatarsal heads and so blocks pronation of the foot (Shaw 1975, Novick & Kelley 1990). Rearfoot posts are thought to position the rearfoot closer to an ideal neutral position (i.e neither everted or inverted) at heel-strike and control rearfoot eversion directly after heel strike (Johanson, Donatelli, Wooden 1994).

Recent research indicates that the most significant restriction of rearfoot eversion is provided by the orthotic plate. However combined rearfoot and forefoot posting can reduce rearfoot eversion significantly more than forefoot posting alone but not more than rearfoot posting alone (Johanson, Donatelli, Wooden 1994). This finding supports the previously held beliefs of Rose (1962) and Smith, Clarke and Hamill (1986) that rearfoot posting and the orthotic plate effectively controls foot pronation.

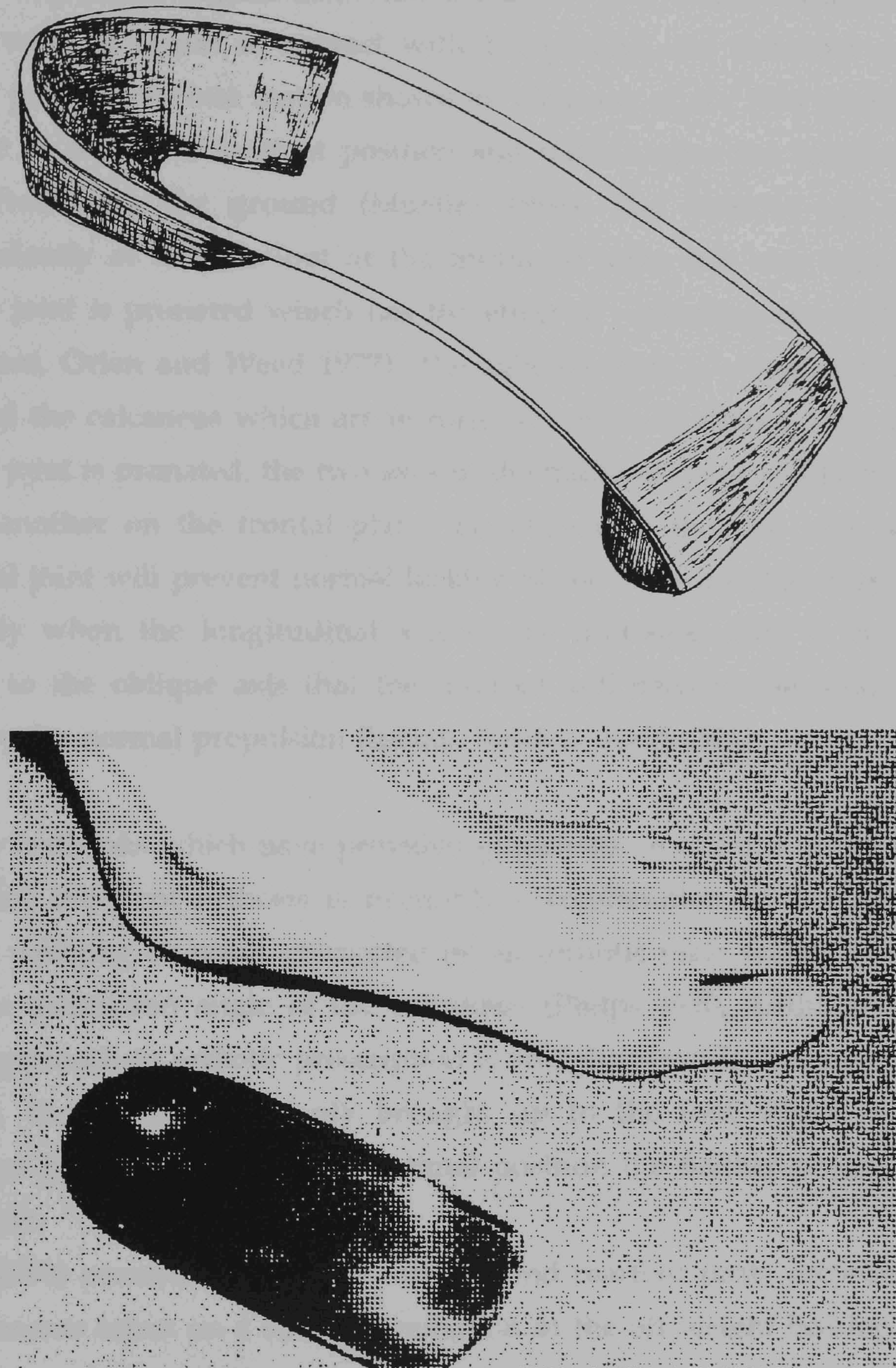


Fig. 1.8 The Root foot orthosis showing the forefoot and rearfoot posts attached to the undersurface of the orthotic plate and the position of those posts relative to the foot

The direct affect of the rearfoot post is lost once the heel lifts from the ground. It could be argued that while a rearfoot post cannot influence foot motion when it is not in contact with the ground, the influence of the rearfoot post on rearfoot motion shown by Johanson et al's 1994 study may continue to influence forefoot position and motion once the rearfoot has been lifted from the ground (Mueller 1994). The forefoot can move independently of the rearfoot at the midtarsal joint, but only when the subtalar joint is pronated which has the effect of unlocking the midtarsal joint (Root, Orien and Weed 1977). The subtalar joint is comprised of the talus and the calcaneus which are in turn part of the midtarsal joint. If the subtalar joint is pronated, the two axes of the midtarsal joint will lie parallel to one another on the frontal plane. Parallelism of the two axes of the midtarsal joint will prevent normal locking of the tarso-metatarsal joints as it is only when the longitudinal axis of the midtarsal joint is inverted relative to the oblique axis that the forefoot will become the rigid lever necessary for normal propulsion (Inman, Ralston, Todd 1981).

The two textbooks which have provided guidelines on orthotic prescription agree that the Root orthosis is primarily a combination of rearfoot and forefoot wedging or posts, connected by an orthotic plate which serves to raise the inclination angle of the calcaneus (Philps 1990, Anthony 1991). Philp's approach to orthotic prescription is straightforward; by posting the orthosis, the ground is simply brought up to the foot which is then supported by the orthosis in an optimal position (i.e neither pronated or supinated).

Philps (1990) prescribed both the forefoot and rearfoot posts according to measurements taken on a static examination of the off weight bearing foot. The rearfoot to leg angle, measured while the subtalar joint is held in a neutral position (Fig. 1.9), determined the size of the rearfoot post, while the forefoot post is prescribed according to the angle of the forefoot relative to the rearfoot (Fig. 1.10).

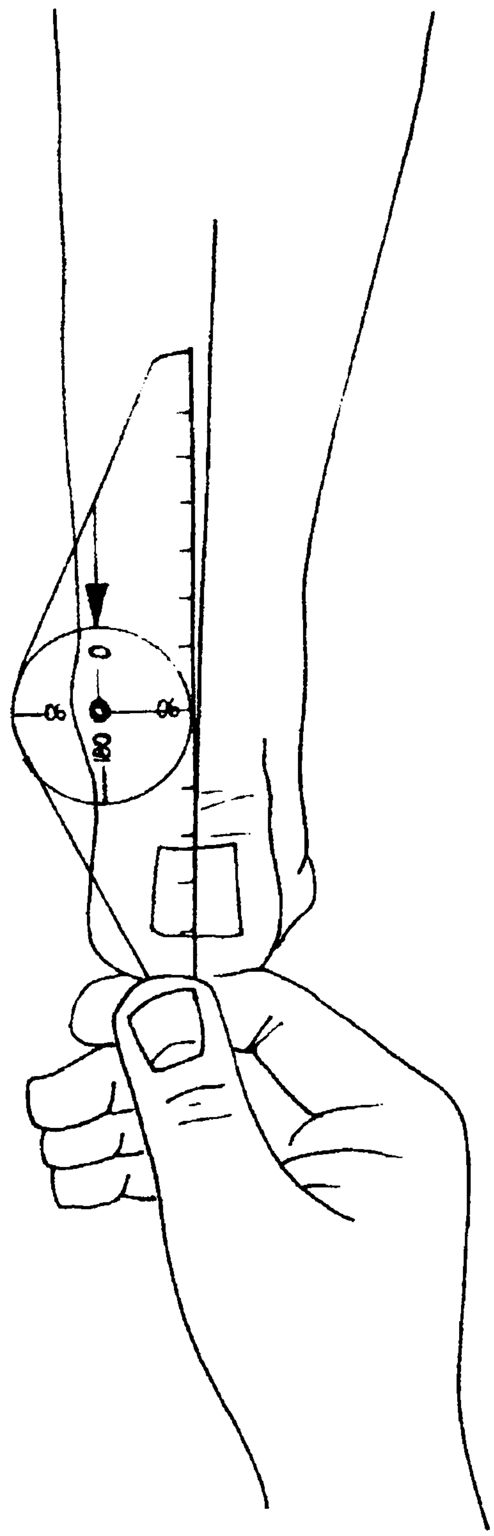


Fig. 1.9 Measurement of rearfoot angle in the subtalar joint neutral position

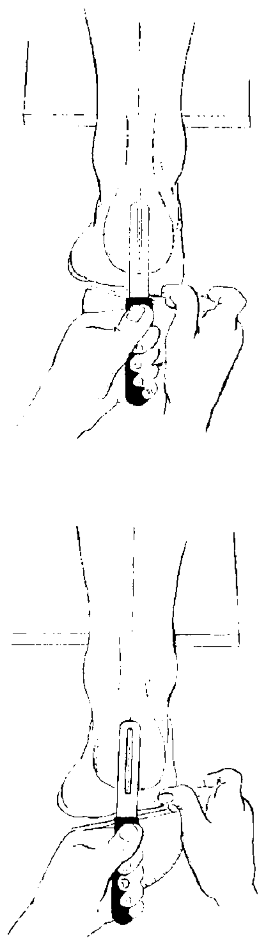


Fig.1.10 Measuring the forefoot to rearfoot angle demonstrating forefoot varus (top) and forefoot valgus (below)

While the development of the Root orthosis has been largely empirical, a number of studies have attempted to identify the effect of the orthosis on rearfoot position and motion. These studies will be reviewed below as it the orthotic effect on rearfoot position and movement which justifies the use of the Root orthosis for the treatment of hallux valgus.

1.3.1 The Known Effects of Foot Orthoses on Foot Position and Motion

In the normal foot, the rearfoot passes from a position of 2° inversion just prior to heel contact, to 4 to 6° of eversion at mid-stance (Root Orien and Weed 1977). Excessive angles of rearfoot eversion, or excessive period or velocity of rearfoot eversion, is thought to be associated with all manner of lower limb complaints ranging from sports injuries of the leg and foot to hallux valgus.

Bates (1979) took six runners with a history of lower limb running injury. Undescribed 'biomechanical orthoses' were prescribed and worn for at least one year, the subjects were then asked to run on a treadmill while their rearfoot eversion was recorded with a high speed cine camera. Rearfoot eversion was recorded by placing markers on the posterior aspect of the running shoe heel counter. An orthosis significantly reduced both the period and the amount of maximum rearfoot eversion by re-orientating the rearfoot relative to the running surface.

In a similar study of 11 selected subjects with no leg or foot pain, Smith (1986) found that foot orthoses reduced rearfoot eversion by 1° while the subjects ran at seven minute mile pace on treadmills. Maximum eversion of the rearfoot was recorded as 12.2 +/-3 °. The rate or velocity of rearfoot movement was more significantly affected, being reduced by 15%.

Kelley and Birke (1992) found a significant decrease in rearfoot eversion when 21 subjects of mean age 30 years, with a minimum of five degrees rearfoot eversion in stance, underwent three dimensional kinematic analysis while wearing foot orthoses. The reduction in the rearfoot eversion was thought to result in a reduction of the moment generated by the opposing supinating muscles, hence the success of orthotic therapy in dealing with overuse muscle syndromes.

Rogers (1982) filmed twenty nine male runners running on a track while wearing their own orthoses and shoes. The mid-line of the leg and the heel of the shoe was marked and the proportion of support time spent in rearfoot eversion, the maximum angular displacement in rearfoot eversion and the angular velocity of rearfoot eversion was calculated from the calibrated film as the subjects ran barefoot, in shoes and in shoes with orthoses.

The orthoses used in this study were not described but they appeared to limit the maximum angular displacement in rearfoot eversion and the support time spent in eversion for the **left** foot only ($p<0.05$). Throughout the rest of the study, the effect of orthoses and shoes came nowhere near achieving statistical significance.

The change in the left foot only is intriguing. Rogers considers that this may be related to leg length difference. It may also have been related to subjects running in the same direction around a curved track.

In alluding to leg length difference, Rogers drew attention to the greatest weakness of her study. No information was given about the structure or function of the athletes. In particular why were the athletes wearing orthoses in the first place? Did some athletes pronate more than others? If so were the orthoses more effective in some than others? Is the prescription of an orthosis, (which should take into account factors like leg length difference), a standardised technique? Are the results noted in some studies and not others the result of a superior prescription technique?

While recognising the weaknesses inherent in these research studies, they are all reporting the same finding: a foot orthosis may restrict eversion of the rearfoot.

1.4 The Research Question

The Root foot orthosis is widely prescribed for hallux valgus (Moraros and Hodge 1993). It is used to restrict excessive pronation of the foot which is thought to be an aetiological factor in hallux valgus. While no research has established how an orthosis may benefit a hallux valgus foot or the efficacy of the Root orthosis in the management of hallux valgus, the ability of this orthosis to restrict pronation of the foot has been studied. The existing research in this area has looked exclusively at the orthotic effect on rearfoot eversion. While hallux valgus is a forefoot deformity, the position of the rearfoot is relevant because one clinical sign of pronation of the foot is rearfoot eversion, which is thought to cause unlocking of the midtarsal joint and hypermobility of the first metatarsal (Inman, Ralston, Todd 1981).

After the heel strike phase of stance and up to the point of mid-stance phase when the whole foot is on the ground, pronation of the foot is desirable as it allows shock absorption. After heel lift the foot should supinate. With supination the foot becomes less flexible which is appropriate for the push off phase of gait when a rigid lever is necessary for effective propulsion. A foot that is pronated excessively in the early phases of stance may not re-supinate adequately for propulsion. If the foot is not supinated by the push off phase of gait, the bones and joints of the forefoot will be unstable or hypermobile. Hypermobility of the first metatarsal may cause hallux valgus (Root, Orien & Weed 1977).

While a Root foot orthosis may restrict rearfoot eversion, the effect on hallux valgus is uncertain, neither it seems has the aetiological role of pronation in hallux valgus been confirmed. What is needed is a study which will determine the incidence of excessive pronation of the foot in hallux valgus as well as measure the value of a biomechanical orthosis in the treatment of hallux valgus. Because the Root foot orthosis is prescribed on the basis of a biomechanical examination of the leg and foot, the validity and repeatability of that examination must also be studied.

In advanced hallux valgus it could be argued that foot pronation is a consequence of the long standing hallux valgus rather than the cause. It is therefore more appropriate to study nine to thirteen year old children because it is unlikely that hallux valgus in this age group will be advanced to the point that secondary conditions such as osteoarthrosis will fudge the assessment and measurement of the condition.

The specific aims, objectives and hypotheses of the study are identified below.

1.5 Aims

The aim of this study is to investigate the aetiology of hallux valgus and, over a 4 year period, measure the effect of a Root foot orthosis on the progression of juvenile hallux valgus.

1.5.1 Objectives

i. To identify and measure juvenile hallux valgus in a representative sample of nine to ten year old Kettering children.

ii. To determine the incidence of pes planus, biomechanical abnormalities and metatarsus primus varus in the Kettering hallux valgus children and consider the aetiological significance of those conditions.

iii. To provide a Root foot orthosis for a randomly selected sample of the children with hallux valgus and measure the effect of three to four years use of the orthosis on the hallux valgus and first - second intermetatarsal angle.

1.5.2 Null Hypotheses

H_0 Biomechanical abnormalities of the foot and ankle are no more common in hallux valgus children than in children with no hallux valgus.

$H_0{}^1$ A Root foot orthosis will not prevent the deterioration of juvenile hallux valgus.

2. THE AETIOLOGY OF HALLUX VALGUS

Since 1912 when Ewald described "a medial slant of the first metatarsal", later referred to as metatarsus primus varus by Truslow (1925), little if anything new has been added to the list of suspected causes of hallux valgus. Even the biomechanical theories which have dominated recent decades, were first discussed in 1886 by Reidel who observed an association between flat foot and hallux valgus.

The following section of the thesis investigates the scientific support for the various causes of hallux valgus which relate to the orthotic treatment of the condition.

2.1 The significance of pes planus in juvenile hallux valgus

The following study was designed to investigate the relationship between hallux valgus and foot pronation by measuring the degree of pes planus in eleven year old children with bilateral hallux valgus. The pes planus value or arch index of 32 children with bilateral hallux valgus was then compared with 32 randomly selected eleven year olds with no first metatarsophalangeal joint deformity or obvious abnormality of the foot or leg.

2.1.1 Patients and Method

The arch index is a measure of the foot to ground contact in the medial longitudinal arch area of the foot. It is usually the case that the more the foot pronates, the more contact there is between the medial longitudinal arch of the foot and the ground. The following foot printing technique was used to determine the arch index. The method described here has been available since 1980 and has been found useful and repeatable (Cavanagh and Rodgers 1987).

The footprint was taken with a Harris mat, the subjects were asked to stand within 5cm of the mat, which was evenly coated in washable ink and covered in white lightly absorbent paper. The subject then placed one foot onto the centre of the mat and stepped forward off the mat. The child then turned around placed the other foot onto the mat and once more stepped forward off the mat.

The footprints were then charted. A longitudinal axis was drawn from the centre of the heel to the centre of the second toe (Fig. 2.1, Line D). Perpendiculars were drawn at the most anterior point of the forefoot (Line E) and at the most posterior point of the heel (Line F). The distance between E and F was divided into equal thirds and a perpendicular line was drawn at each 33.3% point along E,F dividing the foot into rearfoot (A), midfoot (B) and forefoot (C) sections.

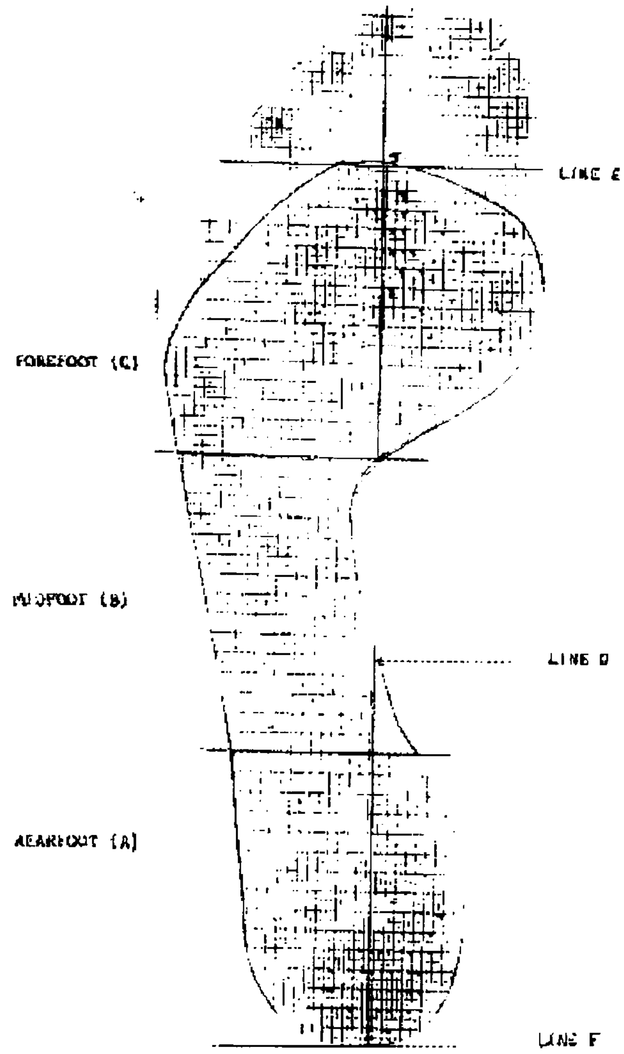


Fig. 2.1. Prior to digitising the foot is divided into (A) rearfoot (B) midfoot (C) forefoot sections. The arch index is the ratio of the midfoot area (B) to the area of the entire foot (A+B+C) excluding the toes. This print represents a normal arched foot (Arch index = 0.25).

A digitiser was then used to measure the area of each foot section. The area of the midfoot was divided by the total footprint area to give the arch index:

$$Arch\ Index = \frac{B}{A+B+C}$$

(Cavanagh and Rodgers 1987)

Within day and between day repeatability of the arch index measurement was calculated.

2.1.2 <u>Sample size.</u>

Sample size was calculated using an Instat Apple Macintosh package. Using 15 foot prints from the left foot of normal children and 15 footprints from the left foot of hallux valgus children, the standard deviation of each population was estimated to be 0.05 and 0.07 respectively. The minimum difference in arch index values that was considered important was 0.05. The following sample sizes for a range of alpha and beta values was calculated.

Power	**Beta**	**Alpha = 0.10**	**Alpha = 0.05**	**Alpha = 0.02**	**Alpha = 0.01**
			Sample	**Size**	
0.80	**0.20**	25	31	40	46
0.90	**0.10**	34	42	52	59
0.95	**0.05**	43	51	62	70

TABLE 2.1 Prospective Calculations of Sample Size

It is conventional to set alpha levels at 0.05 and power at 80%. This indicated a sample size of 31 footprints in order to avoid type I and type II error. Because footprints for both left and right feet were being collected in the hallux valgus group, sample size was rounded up to an even number.

Thirty two hallux valgus children were taken from the control group of the

Kettering Hallux Valgus survey. They had never received any treatment for their feet. Eleven year olds were selected because previous footprint studies indicate that the longitudinal arch is full developed by this age (Staheli, Chew and Corbett 1987)

Hallux Valgus was considered present when: (1) bisection of the proximal phalanx and first metatarsal on a dorso-plantar radiograph produced an angle in excess of 15°. (The radiograph was taken with the child fully weight bearing); and (2) Osteophytic lipping of the metatarsal head indicating early degenerative change was visible on clinical examination. The foot prints were taken from the children with bilateral hallux valgus only.

Using random number tables, 64 normal foot prints were selected from a bank of 150 footprints taken from local school children known to be free of foot pain and first metatarsophalangeal deformity.

Because soft tissue in the medial longitudinal arch has been implicated by Cobey and Sella (1981) as a cause of "variability between individuals". Children outside the normal values for height and weight according to the charts provided by Tanner and Whitehouse (1987), were not included in the study. The mean height and weight for all subjects was 138cm (SD 9cm) and 31Kg (SD 7Kg).

2.1.3 Statistical analysis

A x^2 goodness of fit test indicated that the hallux valgus and normal children's data was normally distributed so parametric statistical testing was appropriate.

The arch indices of the normal and hallux valgus group were compared using a t - test for unpaired or independent samples. Significance levels were set at P = 0.05. Regression analysis was performed on the hallux valgus group to determine any association between the arch index and the degree of hallux valgus.

2.1.4 Results

Intra-observer error study

An intra-observer error was performed on the control group footprints to determine the reproducibility of the digitising measurement technique. Ten footprints were measured on two separate occasions during one day. Another 10 footprints were digitised on two separate days. Table 2.2 demonstrates the correlation between measurements. A paired t test was also performed to determine any statistical significance between repeated measurements. Though very acceptable, the observer (TEK) was found to produce slightly less reproducible measurements than Cavanagh and Rodgers (1987).

The raw data for this study is available in Appendix 1.

Study	**First Measurement (n=10)**	**Second Measurement (n=10)**	**Mean difference & Statistical significance**	**Correlation & Least significant Difference Value**
Within Day Study Mean SD	 0.24 0.06	 0.25 0.07	 0.05 NS	 0.89 0.12
Between Day Study Mean SD	 0.26 0.07	 0.25 0.06	 0.08 NS	 0.84 0.18

TABLE 2.2 Intra-observer error study on foot print measurement

A *least significant difference* value provided an estimate of measurement error or more precisely how much repeated measurements of the arch index must differ before they become statistically significant. Measurement variations of a value smaller than the *least significant difference value* are not considered significant at the 0.05 level (Bland and Altman 1986, Rose 1991).

The *Least significant difference* value is calculated using the following formula :

Least Significant difference value **= t x Standard deviation of the difference between two sets of measurements.**

Where t is derived from the t distribution at the 5% significance level with n - 1 degrees of freedom (Bland and Altman 1986, Rose 1991).

The *least significant difference value* is expressed in the units of measurement, in this case arch index values.

Arch index values of hallux valgus and normal feet

A t test for independent samples indicated that the null hypothesis of no difference between the arch indices of the normal and the hallux valgus feet could not be rejected ($p>0.05$).

Fig. 2.1 & 2.2 provides representative footprints of normal, high arched and low arched feet. The arch index histograms (Figs. 2.3 & 2.4) demonstrate that the majority of feet in both groups had a normal arch index.

Regression analysis determined little if no correlation ($r = 0.07$) between the arch index and the severity of hallux valgus (Fig. 2.5).

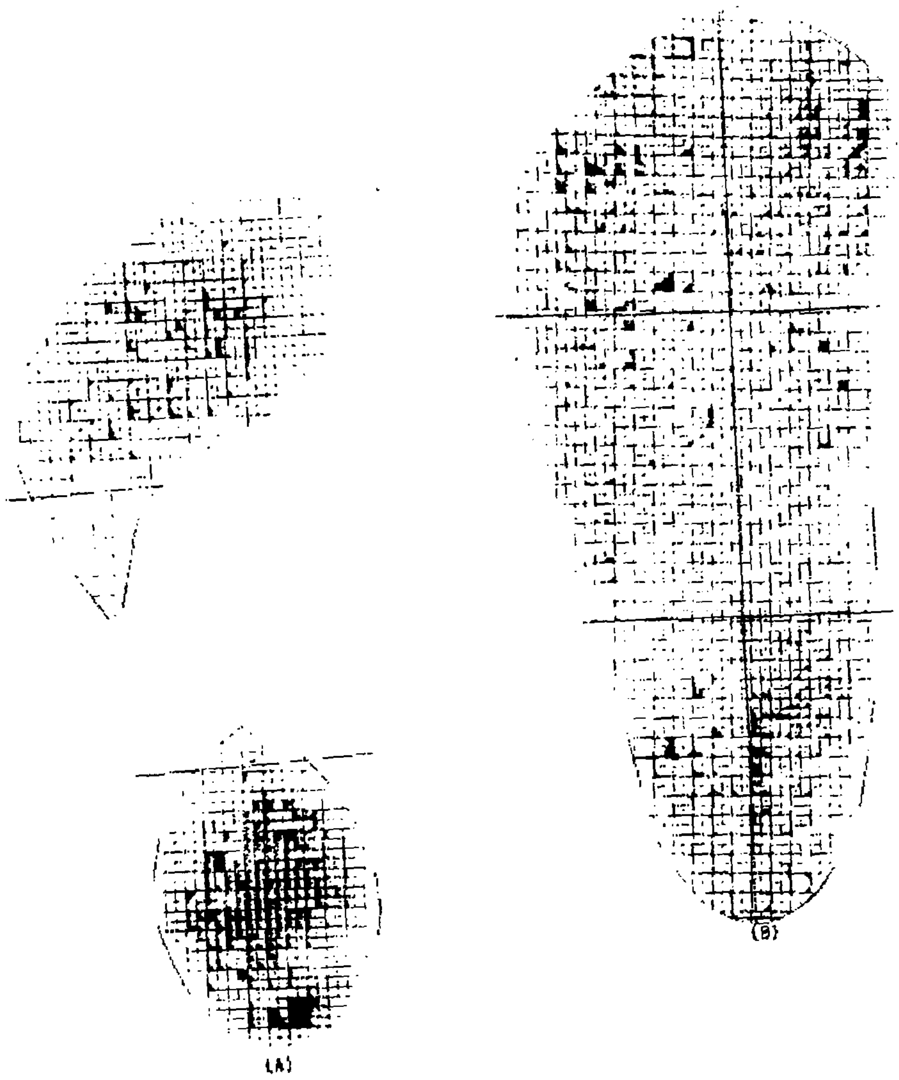


Fig. 2.2. Representative foot prints of (a) high arched (arch index = 0.06) and (b) low arched feet (arch index = 0.38).

Histogram of Frequencies. The Arch Index in Normal Feet
(n = 64)

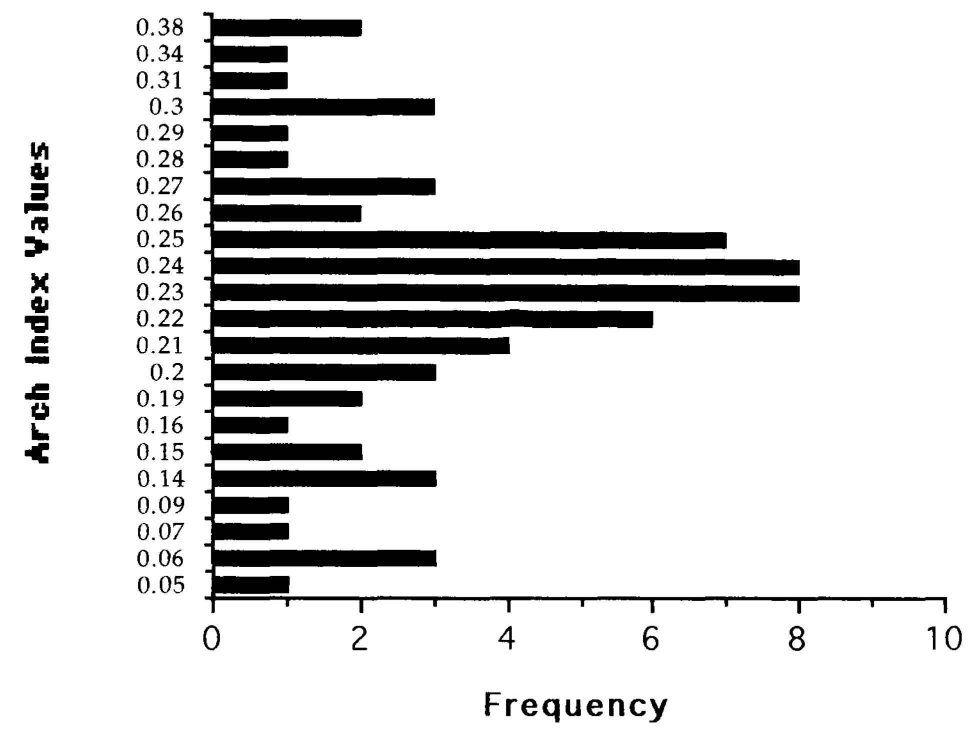


Fig 2.3

Histogram of Frequencies. The Arch Index in Hallux Valgus Feet
(n=64)

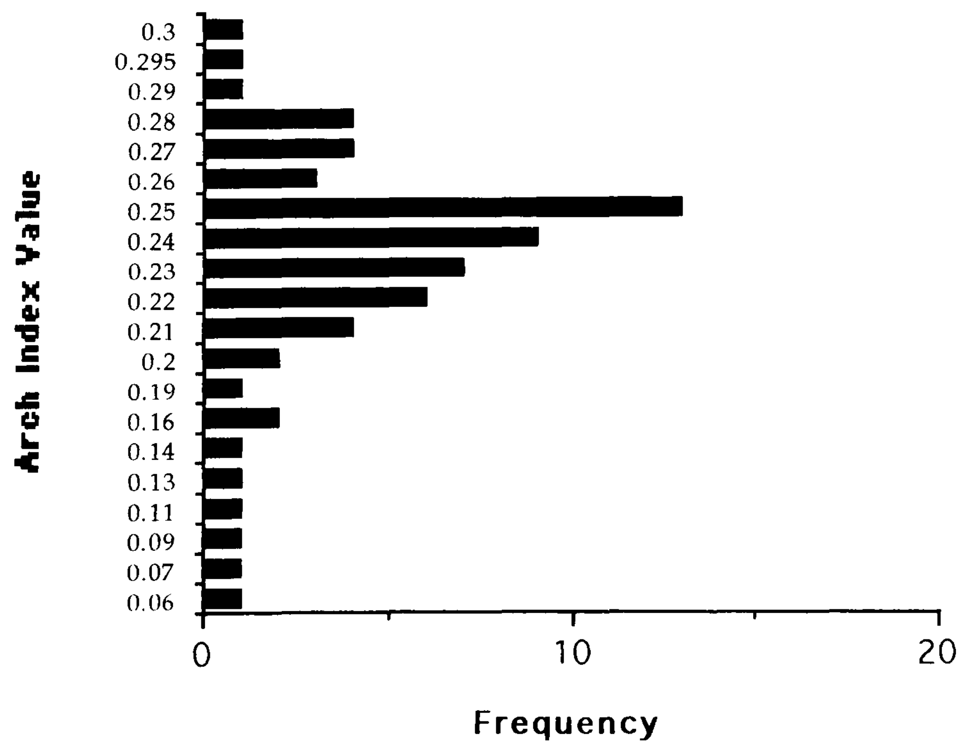


Fig. 2.4

Linear Regression Analysis: Arch Index versus degree of hallux valgus (n=64 hallux valgus feet)

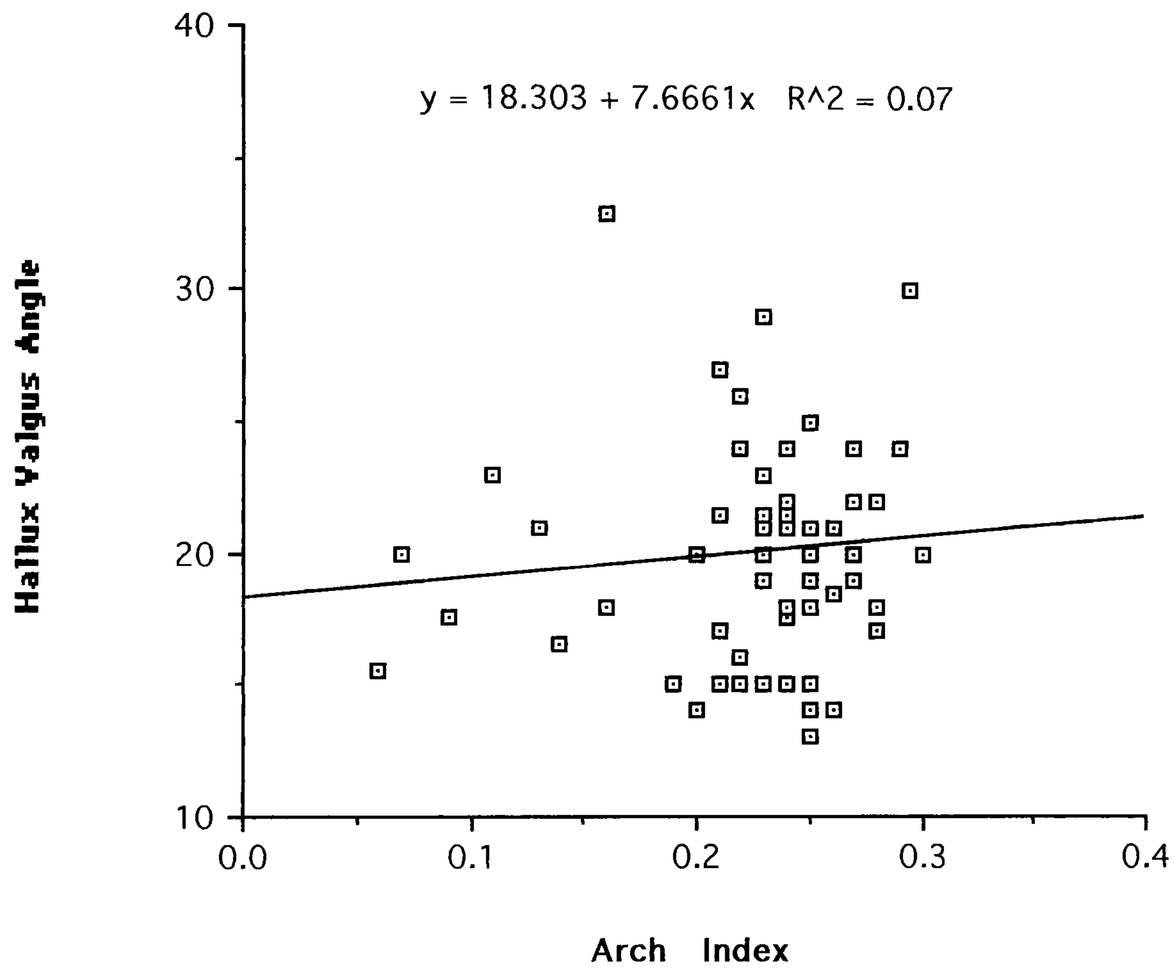


Fig. 2.5

2.1.5 Discussion

While it remains contentious whether the structure of the foot or indeed the height of the arch can be determined by measuring the area of the arch in contact with the ground (Cobey and Sella 1981, Hawes 1992), foot type has traditionally been classified as either low, normal, or high arched (Giladri, Milgrom and Stein 1985). This classification is based upon a subjective evaluation of the space formed between the medial column of the midfoot and the supporting surface while the subject is fully weightbearing (Qamra and Deodhar 1980). In clinical practice the height of the bony arch, which Hawes (1992) found may be quite different from the external arch contour, is seldom if ever used as a means of evaluating whether a foot is normal or pes planus (Joseph 1993). Foot printing has provided a more objective method of assessing the arch and has allowed normal values to be determined (Staheli, Chew and Corbett 1987).

This study could not determine any significant difference between the arch height of 11 year old children with hallux valgus and children with normal feet. Pes planus should, therefore, be discounted as an important aetiological factor in hallux valgus. Moreover the clinical appearance of the arch should be considered quite irrelevant in the assessment of hallux valgus. If the height of the arch bears no relevance to hallux valgus, arch supports should not be expected to prevent or correct the deformity though a palliative role may still be important.

Flat foot is a scientifically meaningless term (Rose, Welton, Marshall 1985). The pronated foot is a more precise term because it takes into account factors other than the height of the arch, such as rearfoot eversion and the congruency of the talo-navicular joint.

While it is possible to have a pronated foot with only a slightly lowered arch, arch height does remain a significant factor which is generally lower when the rearfoot everts and the talar head bulges medially.

While observing that arch height is simply one aspect of the pronated foot, the findings of this study indicate that the relationship between hallux valgus and pronation of the foot is not a strong one. Until radiographic evidence can be produced to support a very real difference in the congruency of the subtalar and midtarsal joints of normal and hallux valgus feet, the importance of pronation of the foot as an aetiological factor in hallux valgus should not be overestimated.

A previous study by Greenberg (1979) attempted to provide radiographic evidence of the association between hallux valgus and pronation of the foot by measuring the angular relationships between certain tarsal bones. Three hundred and twelve dorso-plantar radiographs of subjects awaiting hallux valgus surgery, were selected and divided into groups of severe hallux valgus with metatarsophalangeal joint valgus angles of 28° or more and mild hallux valgus with values of less than 11°, (a value which according to all previous work cannot be considered abnormal, Piggott 1960).

Greenberg measured the following radiographic angles: (Fig. 2.6)

1. Calcaneal inclination angle.
2. Talar declination angle.
3. Lateral talo-calcaneal angle.
4. Dorso-plantar talo-calcaneal angle.
5. Cuboid abduction angle.
6. Talo-cuboid angle.

While the first four angles are widely used as an index of subtalar joint pronation (Gould 1988, Wenger 1989), the cuboid abduction and talo-cuboid angle have never, to the author's knowledge been described before.

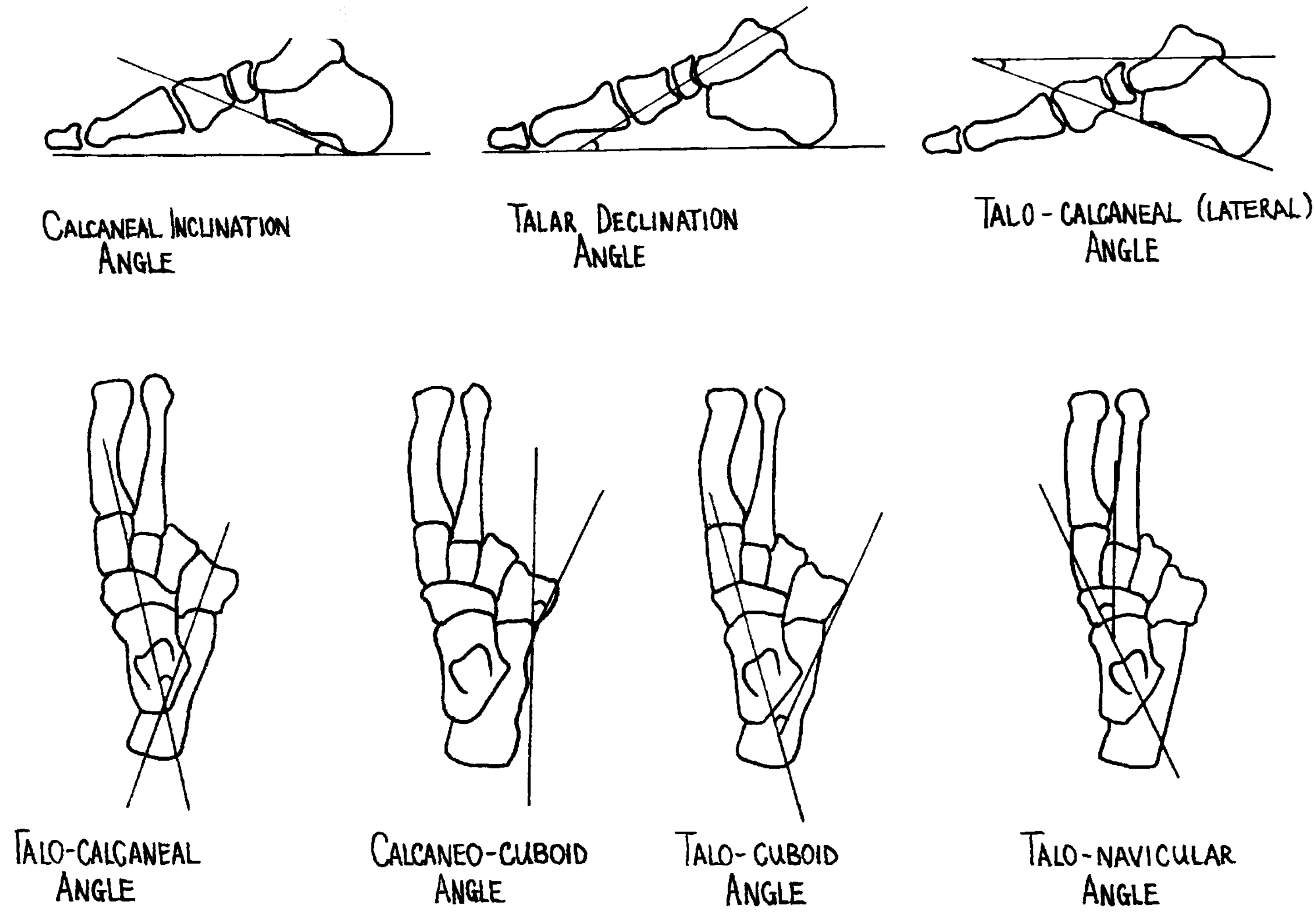


Fig. 2.6 Radiographic charting of the foot to determine the severity of subtalar joint pronation

Greenberg compared his measurements with the normal values presented by another author, and found no statistically significant difference between normal feet and his study group at any level, except the cuboid abduction angle and talo-cuboid angle. On the basis of these radiographic angles Greenberg concluded that there was more pronation than normal in the hallux valgus patients.

While the validity of the cuboid abduction angle and the talo-cuboid angle was not discussed, some of Greenberg's findings could be considered effective proof that there is no link between pronation of the foot and hallux valgus.

Sixty three of the most pronated feet, were selected from the sample of 312 radiographs using high talar declination angle and talo-calcaneal angle values as a measure of subtalar joint pronation. The incidence of mild or severe hallux valgus was no greater than in the group as a whole.

Greenberg defended his use of the talo-cuboid and cuboid abduction angle on the basis that those measurements indicated midtarsal joint pronation, which in the absence of any significant difference between the degree of subtalar joint pronation in normal and study group feet must, Greenberg concluded, be important. Midtarsal joint pronation is however a dependant effect, it occurs as a result of subtalar joint pronation (Inman, Ralston & Todd 1981).

2.1.6 The Relevance of the Study Findings to the Orthotic Management of Hallux Valgus

The findings of this study do not confirm the existence of a relationship between pes planus and hallux valgus nor do they explain which could be the cause or the effect. This has important implications for the orthotic treatment of hallux valgus, because it has meant that an unproven treatment has been prescribed to deal with an unproven cause.

The next section of this thesis investigates further the biomechanical basis for orthotic management of hallux valgus by comparing the incidence of biomechanical abnormalities in children with hallux valgus and children with no obvious abnormalities of the first metatarsophalangeal joint.

2.2 THE INCIDENCE OF BIOMECHANICAL ABNORMALITIES CAUSING EXCESSIVE PRONATION OF THE FOOT IN JUVENILE HALLUX VALGUS

The orthotic management of juvenile hallux valgus uses mechanical principles in the examination and treatment of the condition. The range of motion of the ankle, subtalar and midtarsal joints and the first metatarsal are examined and the spatial position of each part relative to the other joints is measured. Any deviation from the ideal can then supposedly be normalised by a Root foot orthosis (Root, Orien and Weed 1977).

The ideal biomechanical model of the lower limb was presented by Root, Orien and Weed (1971). The relationship of osseous segments in this model would supposedly produce maximum efficiency during locomotion. While the ideal is seldom if ever seen clinically, it represents the basis for evaluation. The more the individual is at variance with the ideal, the greater the expected pathology. The Root orthosis seeks to restore the skeletal alignment to the ideal, its prescription is based on measuring the individual's variation from the ideal and then fabricating an orthosis designed to correct that variation.

<u>Criteria for Normality</u> (Fig. 2.2.1)
With the subject bearing weight equally on both feet:

a. The distal 1/3 of the leg is vertical.

b. The knee, ankle and subtalar joint lie in transverse planes parallel to the supporting surface.

c. The subtalar joint assumes a neutral position (neither pronated nor supinated.)

d. The bisection of the posterior surface of the calcaneus is vertical.

e. The mid-tarsal joint is locked in its maximum position of pronation (therefore the forefoot is locked against the rearfoot during stance).

f. The plantar forefoot plane parallels the plantar rearfoot plane and both parallel the supporting surface.

g. The plantar surface of the second, third and fourth metatarsals lie on a common plane, parallel to the supporting surface.

h. The first and fifth metatarsal heads lie on the same transverse plane as the second third and fourth metatarsal heads.

Refer to letters **a.** to **h.** on diagram over leaf.

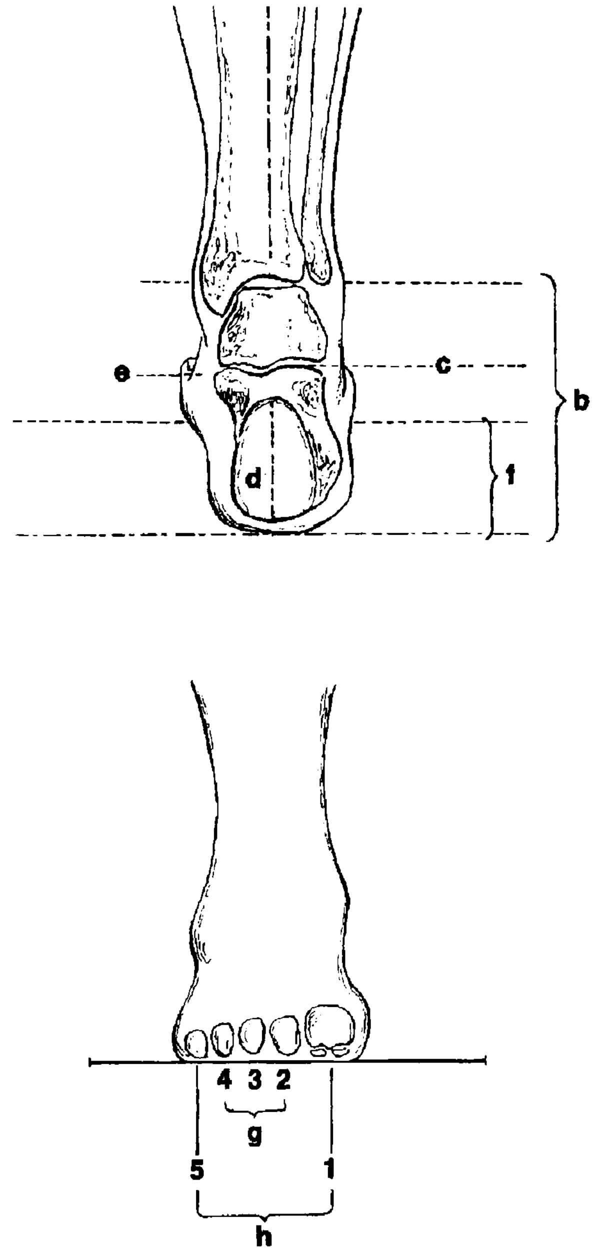


Fig. 2.2.1 Ideal structural alignment of the foot and leg (Root et al 1971)

Biomechanical Assessment	Values
Transmalleolar axis	13 to 18° External Torsion
Ankle	10° dorsiflexion from a baseline where the foot makes a right angle with the leg
Rearfoot to Leg	Vertical to 2° inverted
Frontal plane position of the forefoot relative to the rearfoot	Plantar surface of the forefoot lies parallel to the plantar surface of the heel
First Metatarsal position	Lies on the same frontal plane as the rest of the metatarsals with 5mm plantarflexion and 5mm dorsiflexion available

TABLE 2.2.1 Normal values for the Biomechanical Examination from Root Orien & Weed 1971

2.2.1 The Biomechanical Examination and its Relevance to Hallux Valgus

Aims of the study

The following study compared the biomechanical examination of a group of individuals with entirely normal feet and subjects who had been diagnosed clinically and radiologically as having hallux valgus. The purpose of the study is to determine the value of the biomechanical assessment in the prescription of a Root foot orthosis for juvenile hallux valgus.

Biomechanical abnormality giving rise to pronation of the foot is a suggested aetiological factor in hallux valgus. While the last section of the thesis threw some doubt on the significance of pes planus and pronation of the foot in hallux valgus, the following study explores the incidence of other biomechanical abnormalities in children with hallux valgus. The repeatability of the biomechanical examination is also explored as this has implications for the prescription of a Root foot orthosis in the treatment of hallux valgus.

Objectives of the Study

i. To determine the repeatability of biomechanical measurements of the lower limb.

ii. To determine whether children with hallux valgus present different biomechanical measurements to children with normal feet.

2.2.2 Patients and Methods

Thirty female subjects were randomly selected from the Kettering Hallux Valgus study. All were 10 to 11 years old and had been clinically and radiologically diagnosed as having hallux valgus of both feet. The mean metatarsophalangeal joint angle measured on weightbearing radiographs was 19° (SD 3.7). Using the standard measuring equipment described below, a biomechanical evaluation was completed. All measurements were recorded by one observer (TEK) over a period of one year. Simultaneously a control group of 30 ten to 11 year old girls with no foot pain or obvious deformity were biomechanically evaluated in the same way.

The control group were selected from a directory of local schools using random number tables. Once a school had been selected the first thirty 10 to 11 year old children who were free of leg and foot pain and demonstrated no hallux valgus or hallux rigidus were divided into groups of three children. One group at a time was sent for examination.

The intra-observer error study involved the examination of both legs of all three children on two separate occasions. Because of the type of goniometers used, it was not possible to blind the examiner by obscuring the goniometer measurement scale. This problem was overcome by having the examiner do no more than position the goniometer against the anatomical reference points, the goniometer value was then recorded by an assistant.

The biomechanical assessment comprises the following examinations:

i. Transmalleolar Axis

With the subject lying supine, the knee is placed parallel with the transverse plane. The frontal plane angle formed between the medial and lateral malleoli is then measured using a Martin's gravity goniometer (Fig.2.2.2).
According to Root et al (1977) the transmalleolar axis will indicate the degree of tibial torsion.

Significance: A transmalleolar axis in excess of 18° indicates external tibial torsion. Excessive tibial torsion may pronate the foot by overloading the subtalar joint on its medial side. Subtalar joint pronation is considered a major aetiological factor in hallux valgus (Riedl 1886, Goldthwait 1893, Silver 1923, Hiss 1931, Rogers and Joplin 1947, Jordan and Brodsky 1951, Root et al 1977).

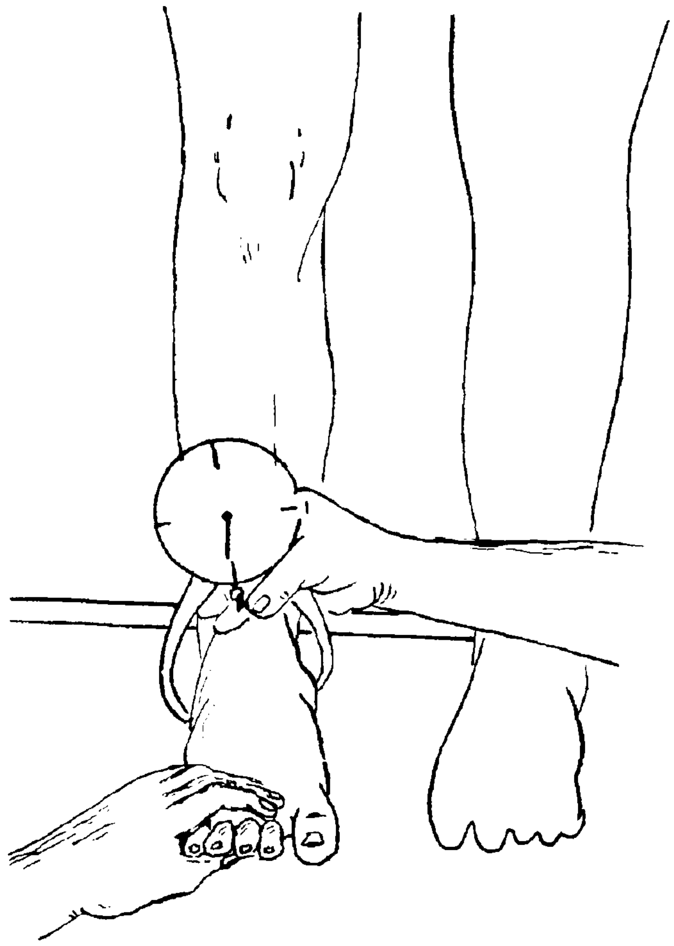


Fig. 2.2.2 Transmalleolar axis measurement

ii. Ankle Dorsiflexion

The patient is then moved into a prone position and with the feet hanging over the edge of the examination couch, the available ankle dorsiflexion is measured. Because maximum ankle dorsiflexion is influenced by the position of the subtalar joint (Tiberio 1989), the rearfoot must first be moved into the neutral position where it is neither pronated nor supinated. The arms of a tractograph goniometer are then placed over a bisection line of the lateral tibia and the lateral side of the rearfoot (Fig.2.2.3). The ankle is then pushed into maximum dorsiflexion and the angle formed between the two bisection lines recorded.

Significance: Ten degrees of ankle dorsiflexion is required for normal walking (Root et al 1977). Restricted ankle dorsiflexion will either cause the subject to walk with a "bouncy" gait due to a premature heel lift, or the ankle joint restriction will be compensated by excessive pronation of the subtalar and midtarsal joints (Sgarlatto 1972, Root et al 1977). These triplanar joints will donate sagittal plane motion in order to overcome the restriction of ankle dorsiflexion, but as a consequence the foot will not transform into the rigid lever required for the push-off phase of gait. Instead the foot will remain in an excessively pronated and hypermobile state. Hypermobility of the forefoot at the push-off phase of gait, is believed to be an important aetiological factor in hallux valgus (Root et al 1977).

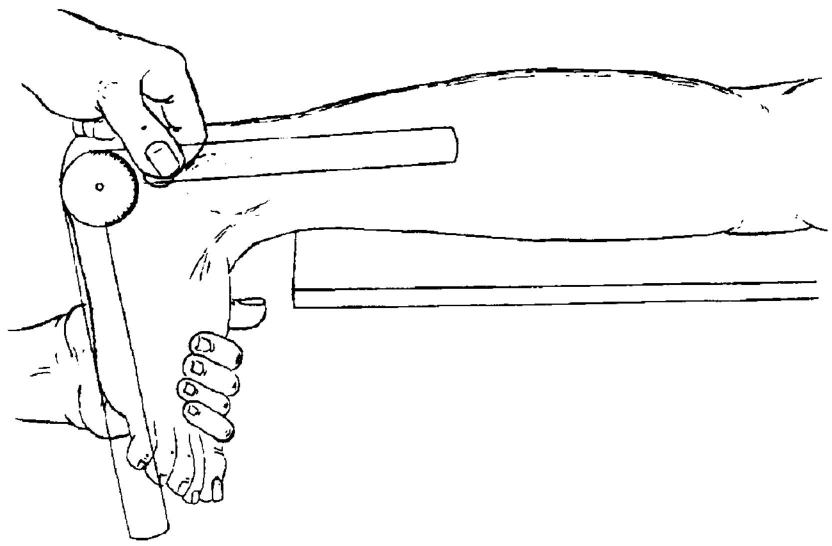


Fig. 2.2.3 Measurement of ankle dorsiflexion

iii. Subtalar joint Neutral Position Measurement

The rearfoot is moved through its range of inversion and eversion. The subtalar joint is considered to be in neutral when the talus is fully congruent with the navicular and the foot is neither pronated nor supinated.

A bisection line is then drawn down the middle of the calf muscle and the posterior surface of the calcaneus (Fig. 2.2.4). The angle formed between the two lines is the measured neutral position.

An inverted neutral position will be compensated for by subtalar joint pronation which will reduce the foot to a flexible pes planus. Hypermobility of the forefoot will result (Sgarlatto 1972, Root et al 1977).

An everted neutral position, though less common, is not compensated for by subtalar joint supination, because even in normal circumstances the centre of gravity falls medial to the subtalar joint creating a slight pronation load of that joint. An everted neutral position will increase this load resulting in a hypermobile forefoot and first ray which according to Root et al (1977) predisposes to hallux valgus.

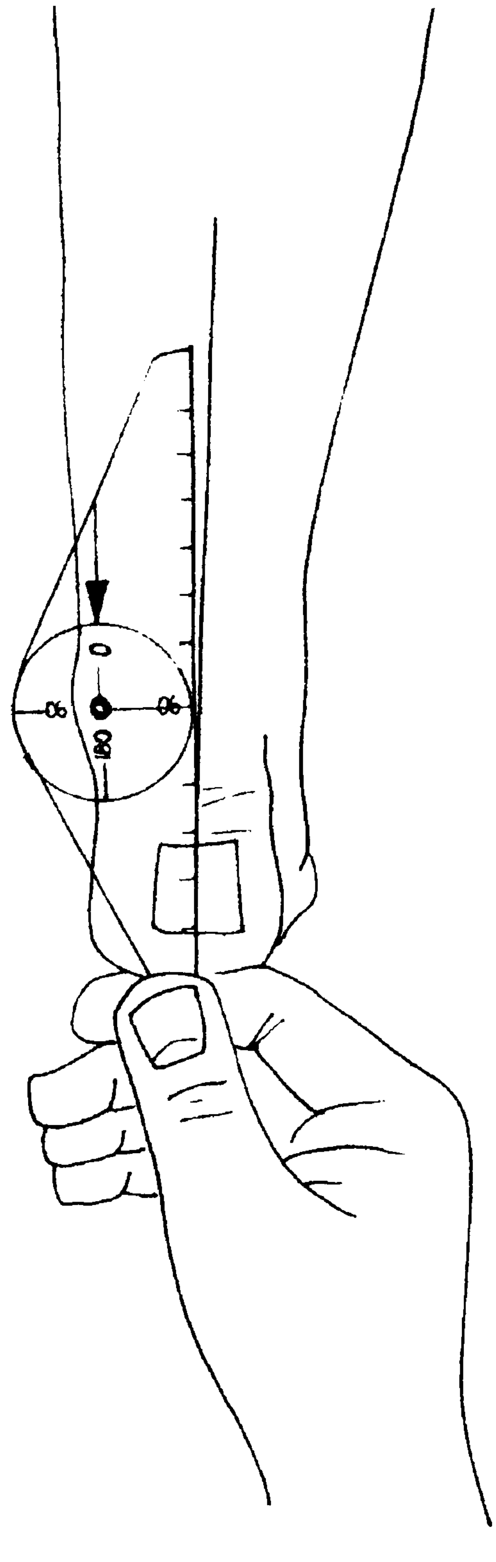


Fig. 2.2.4 Measurement of the subtalar joint neutral position

iv. Frontal plane Position of the Forefoot relative to the Rearfoot

With the subtalar joint in the neutral position and the patient lying prone, the frontal plane position of the forefoot is measured by placing the platform of the forefoot to rearfoot measuring device over the first to fifth metatarsal heads (Fig.2.2.5). A forefoot that lies parallel to the plantar surface of the rearfoot is considered normal.

Significance: Pronation of the subtalar joint may occur in feet where a forefoot varus angle is measured (Fig.2.2.6). The subtalar joint pronation is a compensatory motion which is required before the medial column of the foot will contact the ground.

An eversion angle of the forefoot (Fig.2.2.7) will be compensated for by midtarsal and subtalar joint supination which is required to bring the lateral side of the forefoot to the ground. Such supination will create a cavus foot deformity (Sgarlatto 1972, Root et al 1977).

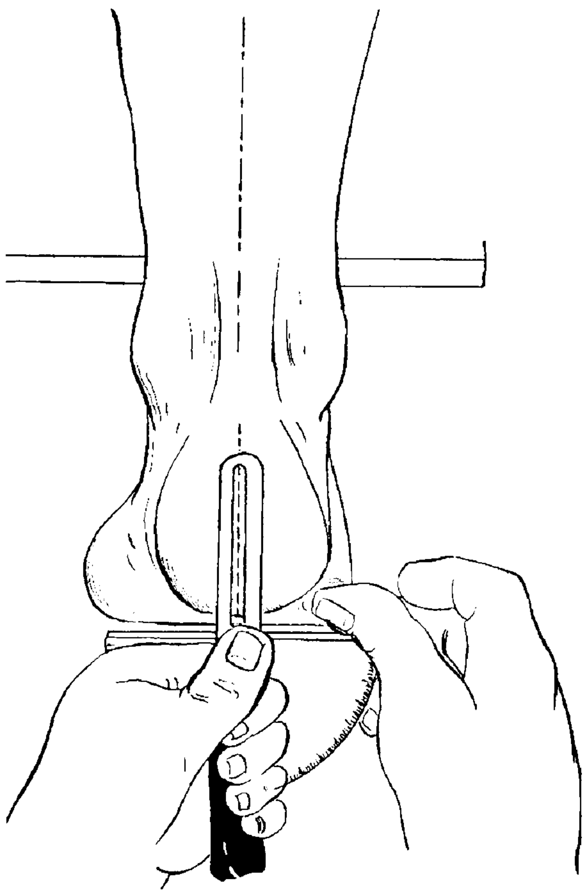


Fig 2.2.5 A forefoot to rearfoot measuring device

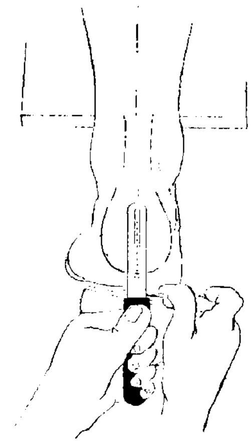


Fig. 2.2.6 Forefoot varus

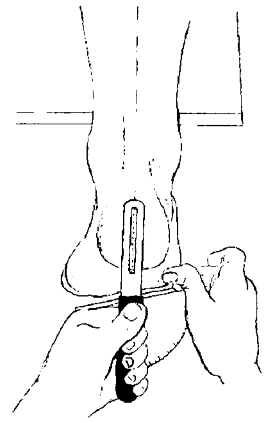


Fig 2.2.7 Forefoot Valgus

iv. First Metatarsal Position

The sagittal plane position of the first metatarsal head relative to the plane of the other lesser metatarsal heads is assessed with the Kilmartin Sagittal Raynger at the metatarsal head level (Fig. 2.2.8). The normal first metatarsal displays 5mm dorsiflexion and 5mm plantarflexion above and below the plane of the other metatarsals. In its neutral position (i.e the halfway point of its entire range of motion) the metatarsal will lie on the same plane as the other metatarsals. More than 5mm of plantarflexion with reduced dorsiflexion indicates a plantarflexed first metatarsal, while 7mm dorsiflexion with just 3mm plantarflexion would indicate a dorsiflexed first metatarsal.

Significance: Root et al (1977) suggested that a plantarflexed neutral position in a first metatarsal which is flexible and can easily be displaced will cause dorsal movement of the metatarsal every time the forefoot loads, the medial column of the forefoot is thus rendered unstable. Moreover the dorsal movement of the first metatarsal will occur at a time when the first metatarsal should normally be plantarflexing to allow the hallux to rotate onto the dorsal articular surface of the metatarsal head. This abnormal movement of the flexible plantarflexed metatarsal may cause subluxation of the metatarsophalangeal joint (Root et al 1977).

In the case of the first metatarsal which is held rigidly in a plantarflexed position (e.g. 7mm plantarflexion below the plane of the other metatarsals with no dorsiflexion available), supination of the midtarsal joint and subtalar joint will be necessary before the lateral forefoot can share any of the weightbearing load (Sgarlatto 1972, Root et al 1977).

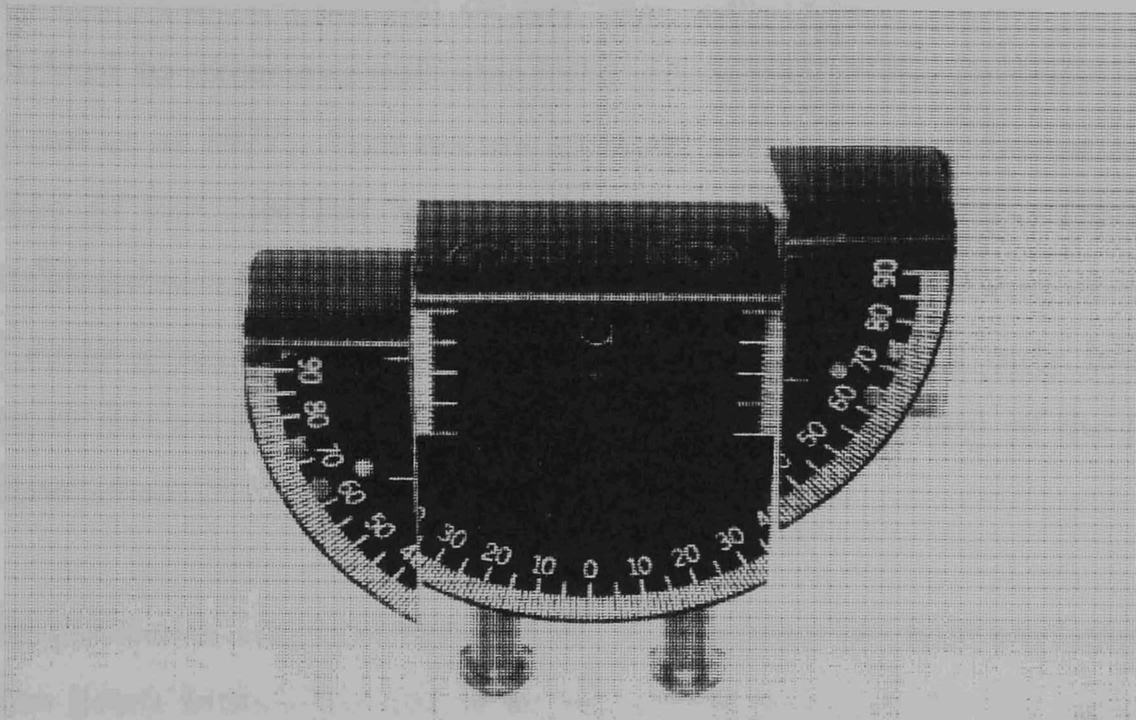


Fig. 2.2.8 The Kilmartin Sagittal Rayngerr

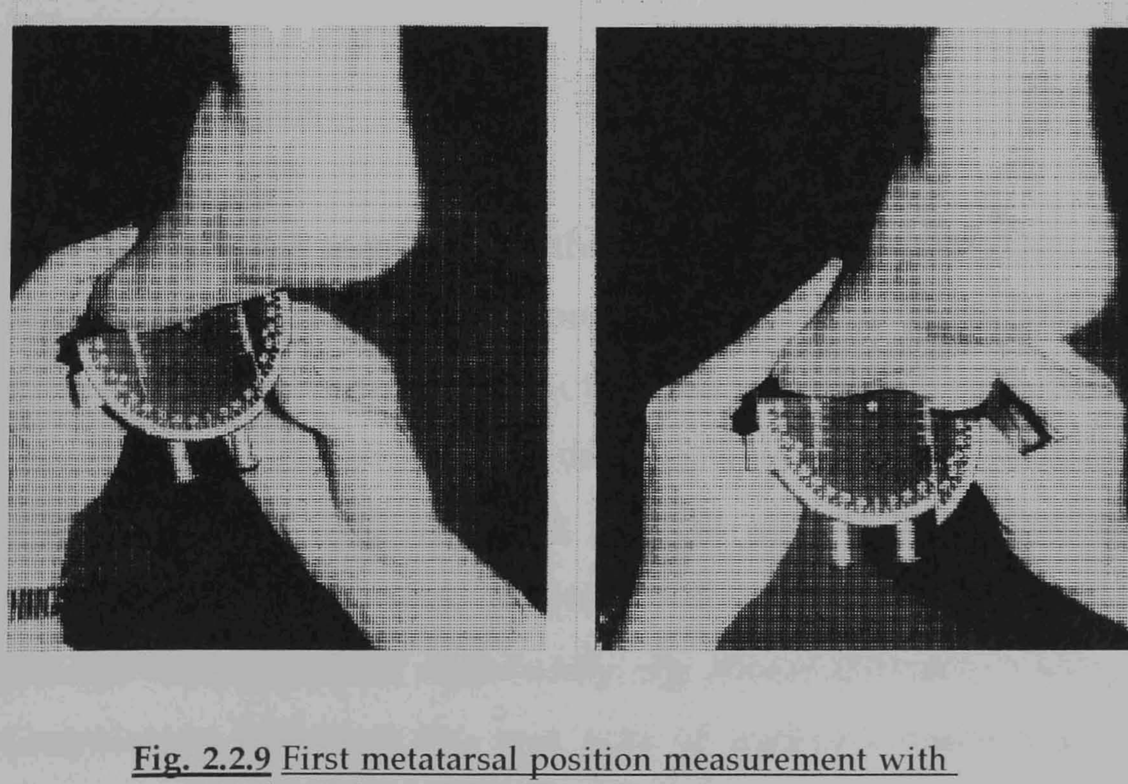


Fig. 2.2.9 First metatarsal position measurement with the Kilmartin Sagittal Raynger

A dorsiflexed neutral position of the first metatarsal whether flexible or rigid will lead to excessive subtalar joint pronation at the propulsive phase of gait (Root et al 1977). This occurs as body weight is transferred from the lateral side of the forefoot to the medial side in preparation for toe off. Smooth transmission of body weight across the forefoot will end abruptly at the first metatarsal, which in its dorsiflexed position will only load after pronation of the subtalar and midtarsal joints. Hypermobility of the forefoot results (Root et al 1977).

A flexible plantarflexed first metatarsal, (e.g where the first metatarsal will plantarflex 8mm below the plane of the other metatarsals but can also be dorsiflexed 2mm above the plane of the other metatarsals), is thought to rapidly progress to a severe first metatarsophalangeal joint deformity because of the repeated subluxatory movement of the metatarsal at every forefoot loading. The dorsiflexed first metatarsal while largely non-functional, assumes a more fixed position which does not sublux the metatarsophalangeal joint so rapidly (Root et al 1977).

2.2.3 Statistical Analysis

Each study subject was assessed for the above abnormalities and the two sets of measurements for the control group children were then compared. The distribution of the difference between the two sets of data was assessed using the x^2 goodness of fit test. The data was normally distributed in the transmalleolar, ankle, subtalar joint neutral and first metatarsal position measurement studies so the difference between the first and second measurement was tested for statistically significant difference using a paired t test. Correlation between the two sets of measurements was calculated using a Pearson Product Moment Correlation test. Right and left legs were analysed separately. In the forefoot to rearfoot position measurement study the difference between first and second measurements was not normally distributed so a Wilcoxon test and Spearman rank correlation test was applied.

The data collected for the control group was then compared with the biomechanical measurements of the hallux valgus children using a t test for independent samples or a Wilcoxon test when the difference between data sets was not normally distributed.

The following null hypothesis was tested: "The control and Hallux Valgus populations provide identical biomechanical data".
Statistical significance was set at $p = 0.05$.

2.2.4 Sample Size

Sample size was calculated by estimating the smallest clinically relevant difference and the standard deviation of each biomechanical measurement on the basis of the intra-observer error study results. Using the Instat Apple Macintosh statistical package, the sample sizes were calculated for each part of the biomechanical examination (Tables available in Appendix 2).

In order to achieve 80% power (at the 5% level) for each joint assessed in the biomechanical examination, a minimum sample size of 30 children was required.

2.2.5 Results

The Intra-observer Error Study of Biomechanical Measurement

The intra-observer error study determined no statistically significant difference between the first and second measurement of each biomechanical parameter. With the exception of the measurement of the subtalar joint neutral position and forefoot to rearfoot position, correlation between repeated measurements was good and least significant difference values were not large (Table 2.2.2 a & b). The raw data is available in Appendix 3.

RIGHT FOOT

	First measurement (n = 30)	Second measurement (n =30)	Mean Difference & Statistical Significance	Correlation & Least Significant Difference
Transmalleolar Axis Mean SD	17.5 2.8	17..3 2.4	-0.86 NS	0.71 4.3
Ankle Mean SD	18.2 5.7	18 6.1	0.16 NS	0.82 7.2
Subtalar Joint Mean SD	6.0 1.56	6.9 2	-0.9 NS	0.21 4.6
Forefoot to Rearfoot Median Range Negative Values =Forefoot Varus Positive Values =Forefoot Valgus	-3 -7 to 7	-4 -7 to 5	6 0 to 12 NS	0.82 11.6
First Ray Mean SD Positive Values=Plantarflexed	1.2 1.3	1.2 1.4	0.01 NS	0.73 2

TABLE 2.2.2 a Intra-Observer Error Study of Biomechanical Measurement in "Normal" Right Foot
(All measurement in degrees)

LEFT FOOT

	First Measurement (n = 30)	Second Measurement (n=30)	Mean Difference & Statistical Significance	Correlation & Least Significant Difference Value
Transmalleolar Axis Mean SD	15.6 2	15.7 2.55	0.86 NS	0.70 4.3
Ankle Mean SD	17.5 5.5	16.8 5.8	0.7 NS	0.79 7.8
Subtalar Joint Mean SD	5.7 1.7	6.5 1.85	-0.6 NS	0.25 4.5
Forefoot to Rearfoot Median Range Negative Values=Forefoot Varus Positive Values =Forefoot Valgus	-3 -7 to 5	-3 -6 to 5	4.5 0 to 23 NS	0.56 10.3
First Ray Mean SD	1.35 1.5	1.5 1.55	-0.15 NS	0.76 2

TABLE 2.2.2 b Intra Observer Error Study of Biomechanical Measurement "Normal" Left Foot

(All measurements in degrees)

The Biomechanical Measurement Study: Normal versus Hallux Valgus Children

The position of the first metatarsal and the ranges of ankle dorsiflexion and rearfoot inversion were significantly different between the hallux valgus and the control groups (see Table 2.2.3). There was also significantly greater forefoot varus but only in the left foot of control group children. Raw data is available in Appendix 4.

	Hallux Valgus Right Foot (n = 30)	Control group Right foot (n = 30)	Statistical Significance	Hallux Valgus Left Foot (n = 30)	Control group Left Foot (n = 30)	Statistical Significance
Transmall Axis Mean SD	 17 1.9	 17.3 2.4	 NS	 17.3 3.7	 16 2.5	 NS
Ankle Dorsiflexion Mean SD	 13.5 3.5	 18 6.1	 p<0.001	 14 3.4	 17.1 5.7	 p<0.05
Subtalar Joint Neutral Mean SD	 4.6 1.9	 6 1.56	 NS	 4.3 2	 5.7 1.7	 NS
Forefoot to rearfoot Median Range Negative values=Varus	 -2 -7 to 5	 -3 -7 to 7	 NS	 -1 -4 to 5	 -3 -7 to 5	 p<0.05
First Metatarsal Mean SD	 3 1.8	 1.4 1.6	 p<0.001	 3 1.9	 1.4 1.5	 P<0.05

TABLE 2.2.3 Biomechanical Measurements (in degrees) for Hallux Valgus and Control group Children

95% Confidence Intervals

In normal children the mean ankle dorsiflexion was 2.2° to 6° greater than in hallux valgus children. The normal children had 0.48° to 2.6° more forefoot varus in the left foot only.

In the hallux valgus children the first metatarsal was more plantarflexed, 95% confidence interval 0.91mm to 2.27mm.

Cumulative Frequency Graphs

The cumulative frequency graphs of the components of the examination which showed a statistically significant difference between the normal and hallux valgus children give a better impression of the individual children's biomechanical measurements. The graphs also indicate that while there is little difference between the number of normal and hallux valgus children with 10° of ankle dorsiflexion, beyond 15° of ankle dorsiflexion there is a much wider difference between groups with a full 40% of normal children having greater than 20° of ankle dorsiflexion as opposed to just 10% of hallux valgus children.

Cumulative Frequency of Range of Ankle Dorsiflexion available in Normal and Hallux Valgus Children (Normal n=60 feet, Hallux Valgus n=60 feet)

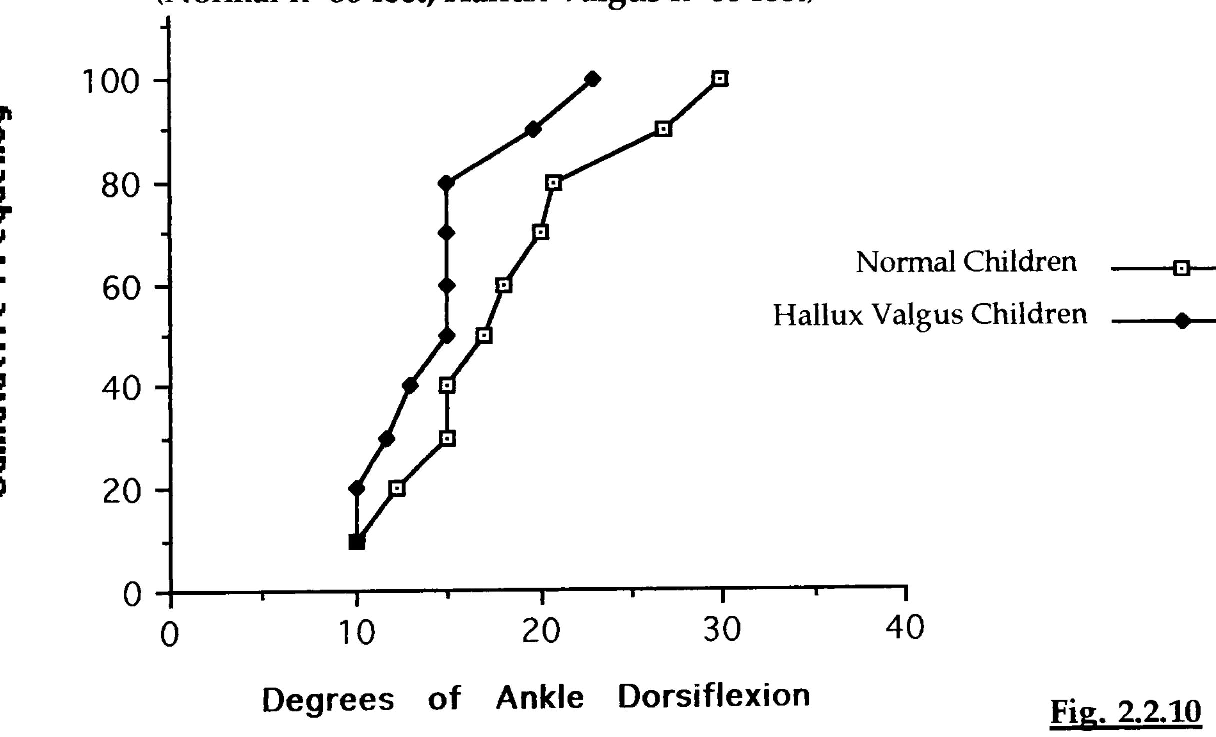


Fig. 2.2.10

Cumulative Frequency of Range of Subtalar Joint Inversion available in Normal and Hallux Valgus Children (Normal n=60 feet, Hallux Valgus n=60 feet)

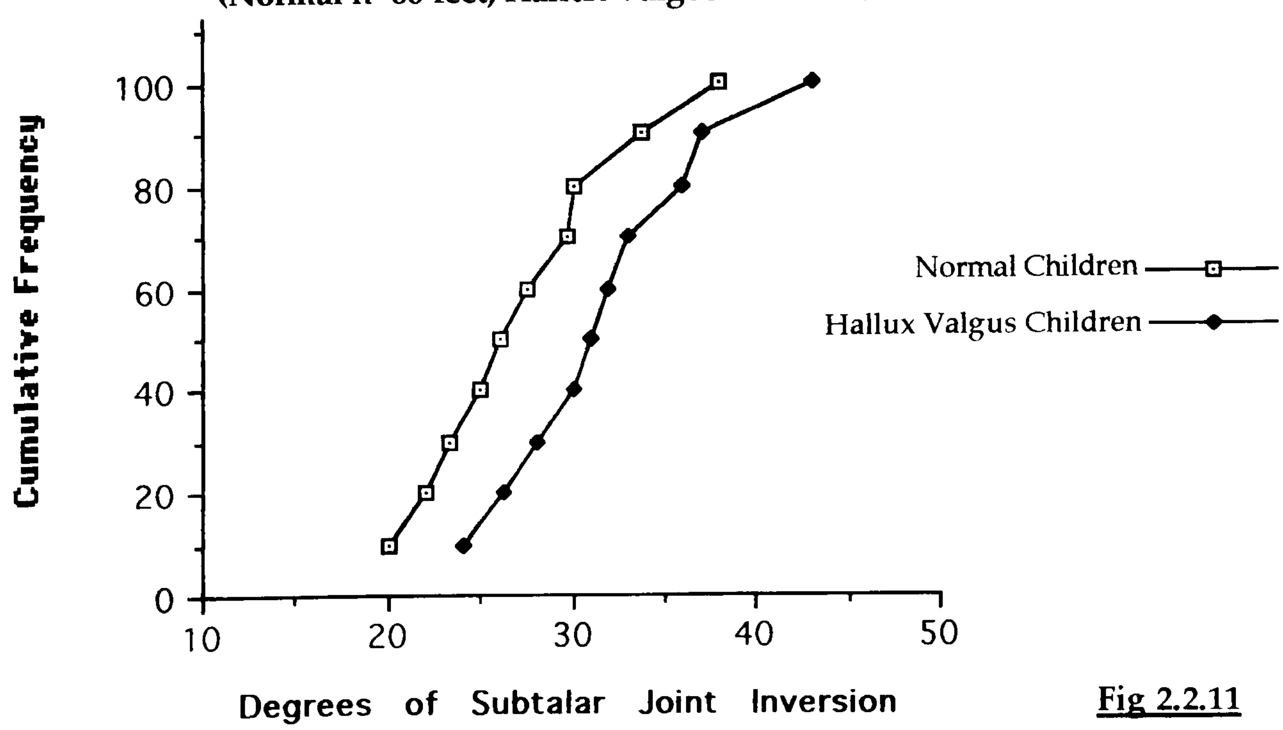


Fig 2.2.11

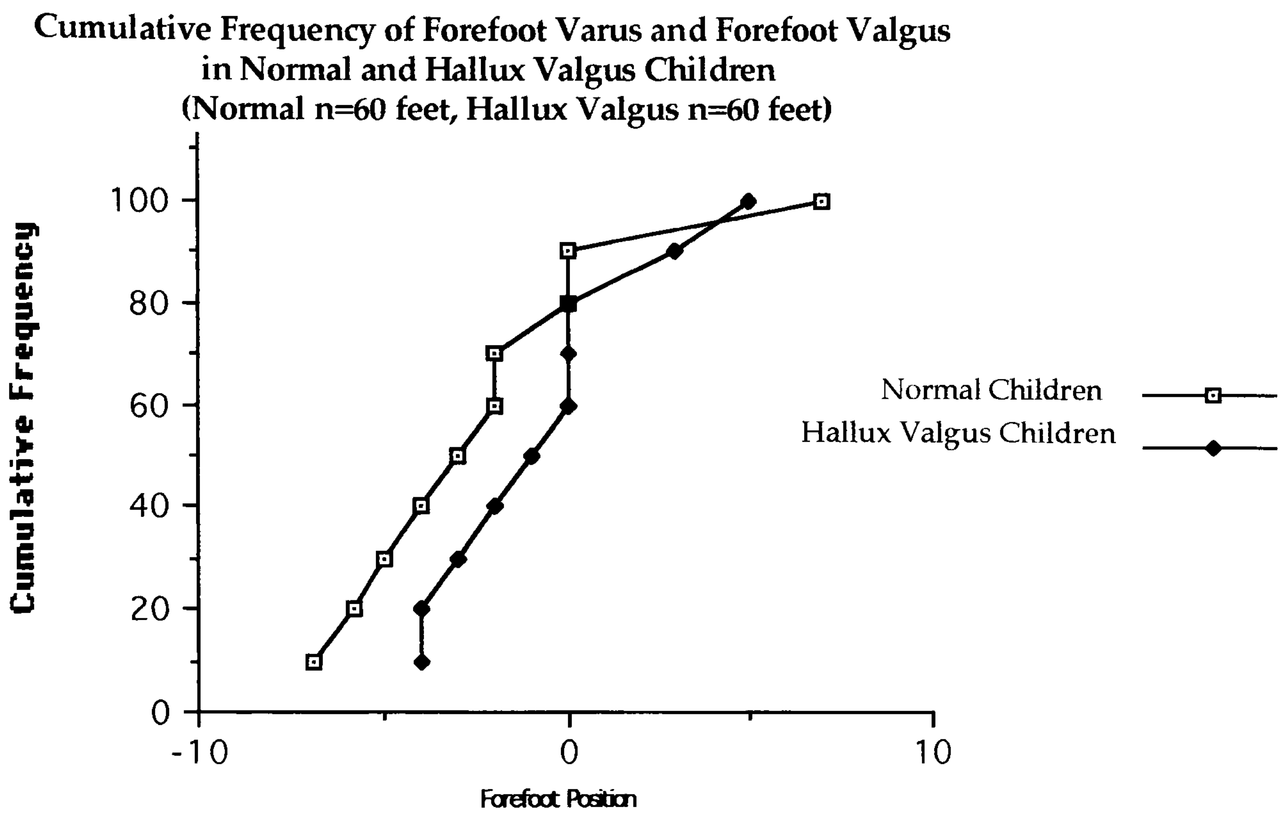


Fig. 2.2.12

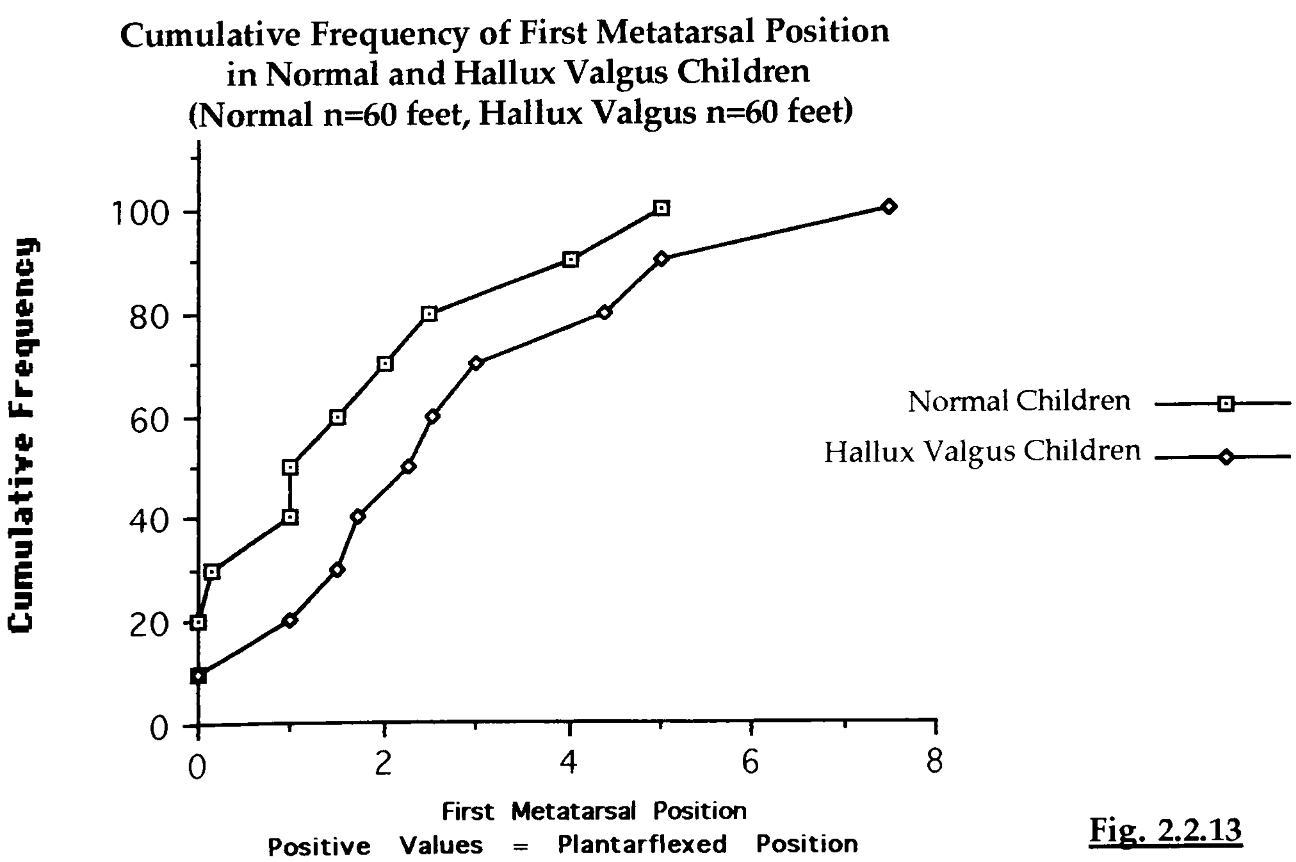


Fig. 2.2.13

2.2.5 Discussion

The design of this experiment did allow some opportunity for measurement bias as the observer knew which children had hallux valgus and which were normal. Avoiding such bias was difficult as the observer could not examine the child's first metatarsal without noticing the presence of hallux valgus.

The Root foot orthosis is essentially a means of preventing the foot from pronating excessively to compensate for any malalignment of the forefoot, rearfoot or leg. The wedging or posting of the rearfoot and forefoot of the orthosis are the factors which differentiate a Root orthosis from an "off the shelf" arch support. Whether a Root orthosis has any advantage over a simple arch support has not yet been confirmed.

The dimensions of the forefoot and the rearfoot posts of the Root foot orthosis have previously been determined by clinical measurement of the subtalar joint neutral position and the forefoot to rearfoot position. This study indicates that both measurements are not easily reproducible.

Although it may not be possible to measure the subtalar joint neutral position and forefoot to rearfoot position reliably this appears to have no detrimental effect on the success of orthotic treatment. The biomechanical foot orthosis has been reported to reduce pronation of the foot (Bates et al 1979, Rogers and Leveau 1982, Smith et al 1986, McPoil et al 1989) and alleviate running injuries (Donatelli et al 1988, Gross 1991). This has occurred despite the inaccuracy of measurement of the subtalar joint neutral position.

The justification for continued measurement of the subtalar joint neutral position is open to question. It would seem more appropriate to simply prescribe a standard sized rearfoot post which could then be modified according to the response of the patient's symptoms or toleration of the orthosis.

The findings of this study lead us to question the relevance of the biomechanical examination for hallux valgus as two of the six measurements (transmalleolar axis and subtalar joint neutral position), showed no difference between the study and control group children.

The other parts of the biomechanical assessment, (namely the assessment of transmalleolar axis, ankle dorsiflexion and first metatarsal position), have been shown in this chapter to be more reproducible with fair to good correlation for one observer's repeated measurements. This is intriguing as the subtalar joint neutral position is considered the reference position into which the foot is manoeuvred prior to measuring ankle dorsiflexion, forefoot to rearfoot position and first metatarsal position. It maybe that the variation recorded in subtalar joint neutral measurement has little implication for the biomechanical assessment of the rest of the foot.

Children with no hallux valgus are more likely to have forefoot varus. The position of the forefoot is however influenced by the first metatarsal position. A plantarflexed first metatarsal will reduce the varus inclination of the forefoot hence the greater varus angle in normal children where a plantarflexed first metatarsal was less common.

Another significant difference occurred at the ankle. Ankle dorsiflexion was restricted in the hallux valgus group, though the range of movement available exceeded the ten degrees necessary for normal walking (Root et al 1977). Considering the age group of the subjects involved, this range of ankle joint movement is not surprising. The minimum ten degree value suggested by Root, Orien & Weed (1977) related to adults.

If the prescription of a Root orthosis for hallux valgus is based upon measuring the individual's variation from the ideal and then making an orthosis designed to reduce that variation, it should only be necessary to measure first metatarsal position.

The aetiological value of the study findings are of interest. In the Hallux Valgus children an increased range of first metatarsal movement was identified; could this be an aetiological factor in the condition? Root et al (1977) have suggested that abnormal movement of a flexible plantarflexed first metatarsal may cause subluxation of the metatarsophalangeal joint. If biomechanical assessment is to be of any value this aetiological role must now be proven.

2.2.6 The Relevance of the Study Findings to the Orthotic Management of Hallux Valgus

Repeatability of the biomechanical examination has concerned some authors (Elveru, Rothstein & Lamb 1988, Griffith 1988). While this study has confirmed that one observer can produce fairly repeatable measurements in some aspects of the biomechanical examination the value of many of those measurements has been shown to be questionable. The biomechanical assessment of 30 children with bilateral hallux valgus has demonstrated only one consistently abnormal feature - a plantarflexed first metatarsal. The precise aetiological role of this finding must now be determined if the biomechanical examination is to remain relevant to hallux valgus.

Traditionally the Root orthosis has only been prescribed after biomechanical examination of the lower limb and foot. If the majority of the biomechanical examination is irrelevant to hallux valgus, what implications does that have for the value of the Root orthosis in the treatment of hallux valgus?

In the next study the significance of first metatarsal position in hallux valgus will be investigated, the effect of a Root foot orthosis on first metatarsal position will also be considered.

2.3 FIRST METATARSAL POSITION IN JUVENILE HALLUX VALGUS; A SIGNIFICANT CLINICAL MEASUREMENT?

The following study was initiated after performing lower limb biomechanical assessments on 30 randomly selected children with no first metatarsophalangeal joint deformity and comparing the findings with 30 similar assessments of children with hallux valgus. The only striking difference between the two groups was the sagittal plane position of the first metatarsal (Section 2.2.5).

Abnormal position and motion of the first metatarsal has long been considered important in the development of hallux valgus. Wanivenhaus and Pretterklieber (1989), determined that transverse plane movement of the first metatarsal could occur with dorsal displacement of the bone. In a cadaver study of 100 feet it was found that while only negligible transverse and sagittal plane motion was available when the tarso-metatarsal joint was normal, in feet where degenerative changes had affected the joint, dorsal displacement of the first metatarsal was accompanied by eversion and adduction of the bone which led to splaying of the forefoot.

Root Orien and Weed (1977), considered that hypermobility of the first ray during the propulsive phase of gait led to subluxation of the metatarsophalangeal joint and the development of hallux valgus. Root et al believed that hypermobility caused displacement of the first metatarsal in the sagittal and frontal plane only; increase in the first to second intermetatarsal angle came much later in the natural history of hallux valgus and was caused by retrograde forces from the abducted hallux being reflected back onto the metatarsal head.

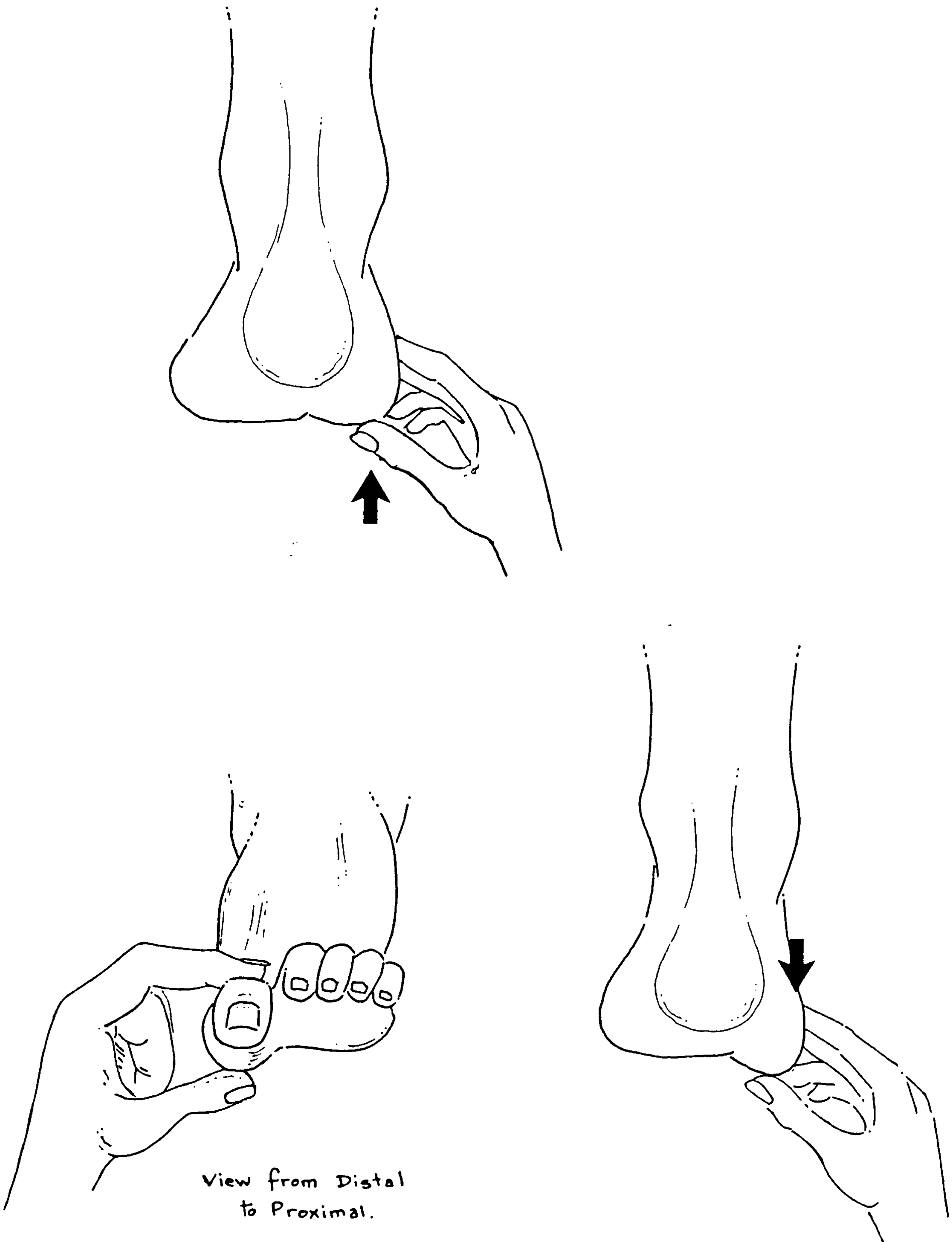


Fig. 2.3.1 A flexible plantarflexed first metatarsal. While a normal first metatarsal should demonstrate 5mm dorsiflexion and 5mm plantarflexion above and below the plane of the other metatarsals. The flexible plantarflexed first metatarsal can be plantarflexed well below the plane of the other metatarsals, but shows restricted dorsiflexion above the plane of the other metatarsals.

A flexible plantarflexed first metatarsal (Fig. 2.3.1) was one of a number of conditions thought to cause first ray hypermobility because as the metatarsal was pushed upwards from its plantarflexed position by the force of the ground, a torque was created at the first metatarsophalangeal joint which was capable of subluxing the joint.

2.3.1 Study Aims and Objectives

In section 2.2 the biomechanical assessment did not reveal any great differences between normal and hallux valgus children, for the biomechanical assessment to maintain any relevance in the management of hallux valgus, it is now necessary to :

1. Determine the incidence of plantarflexed first metatarsal in a larger study / control population.

and

2. Consider the effect, if any, of a flexible plantarflexed first metatarsal on first metatarsal and metatarsophalangeal joint position and function as this may have implications for the orthotic management of deformities of the first metatarsophalangeal joint like hallux valgus.

This study of the significance of first metatarsal position investigates:

1. The theories of Root et al and explores whether first metatarsal position is relevant to hallux valgus, or does a plantarflexed neutral position of the metatarsal occur as frequently in normal children as in children with hallux valgus.

2. The clinical implications of the work of Wanivenhaus and Pretterklieber (1989) on functional biomechanical theories. Does dorsal movement of the first metatarsal from a plantar displaced position cause the metatarsal to adduct and assume the radiographic appearance of a high intermetatarsal angle?

Or

3. As Root suggested, is dorsal movement of the metatarsal unrelated to the intermetatarsal angle, but a cause of hallux valgus and subluxation of the metatarsophalangeal joint.

The link between position of the first metatarsal and deformity of the first metatarsophalangeal joint is explored by clinically assessing the sagittal position of the first metatarsal in children with normal feet and in children with hallux valgus. The association between the first metatarsal sagittal position and the first to second intermetatarsal angle value is also investigated.

2.3.2 Patients and Method

The assessment was performed with the child off weight bearing and lying prone as is standard for the biomechanical examination of the first ray. To enable objective assessment a measuring device was developed and tested for intra - observer error, the results of which are presented in section 2.2.

The first metatarsal position was assessed using the "Kilmartin Sagittal Raynger". This instrument allows the clinician to measure the first metatarsal's independent range of sagittal plane motion (Fig. 2.2.8).

The range of first metatarsal plantarflexion below the plane and then dorsiflexion above the plane of the other metatarsal heads was recorded. The mid-point or neutral position of the first metatarsal was calculated by subtracting the largest range of movement whether it was plantarflexion or dorsiflexion from the smallest. An equal range of plantar and dorsiflexion is thought to represent normal first metatarsal motion and a normal neutral position.

Using the subjects from the Kettering hallux valgus study, one hundred and eighty hallux valgus feet were assessed in this manner. The first metatarsal position of 90 ten year old children with no abnormality of the first metatarsophalangeal joint of either foot, was also measured. The children were selected using random number tables from a bank of 140 school children. These children formed the control group.

Statistical Analysis

A Chi squared test was used to determine if there was a statistically significant difference between the first metatarsal position of the normal and the hallux valgus group.

Using the hallux valgus group, the first to second intermetatarsal angles were compared in the 134 feet which demonstrated plantarflexed first metatarsal and the 74 feet with normal sagittal plane position of the first metatarsal. Chi squared analysis tested the hypothesis that the intermetatarsal angle was not affected by the first metatarsal sagittal position. Intermetatarsal angles were considered normal when less than nine degrees and pathological when in excess of nine degrees (see Section 2.4).

2.3.3 Results

The Chi squared test determined a highly significant difference ($p<0.001$) between the first metatarsal position of children with hallux valgus and children with normal feet (Table 2.3.1). Sixty five percent of the hallux valgus feet presented with a first metatarsal neutral position that was more than 2mm plantarflexed.

First Metatarsal Position	Normal Feet (n=180)	Hallux Valgus Feet (n=180)
Normal or Dorsiflexed	88 (66)	44 (66)
Plantarflexed < 1mm	48 (33)	18 (33)
Plantarflexed >2mm	44 (81)	118 (81)

$x^2 = 62$, $p<0.001$. (Numbers in brackets indicate quantities expected from the null hypothesis)

TABLE 2.3.1 Contingency Table relating Neutral Position of the First Metatarsal in Hallux Valgus and Normal Feet

There is a highly statistically significant incidence of plantarflexed first metatarsal in hallux valgus.

The plantarflexed position of the metatarsal was not however associated with higher intermetatarsal angle values. No significant difference in the intermetatarsal angle value was found between the hallux valgus subjects, whether they had a plantarflexed or a normal sagittal plane range of motion of the first metatarsal (Table 2.3.2).

	Intermetatarsal Angle	
First Metatarsal Position	**9° or less**	**9° or greater**
Normal or Plantarflexed < 1mm	21 (20.99)	53 (53)
Plantarflexed >2mm	38 (38)	96 (95.99)

$x^2 = 0.0004$, $p>0.05$. (Numbers in brackets indicate quantities expected from the null hypothesis)

TABLE 2.3.2 Contingency table relating First Metatarsal Position to First - Second Intermetatarsal angle

2.3.4 Discussion

This study indicates a highly significant relationship between juvenile hallux valgus and the plantarflexed neutral position of the first metatarsal.

It is unlikely that the non weight bearing plantarflexed position of the metatarsal, will be maintained on standing. More likely is that it will be pushed level with the other metatarsals, the necessary motion being provided by the metatarso-cuneiform joint. This dorsal movement, does not however appear to be associated with simultaneous transverse plane displacement as was the finding in the cadaver studies performed by Wanivenhaus and Pretterklieber (1989).

2.3.5 The Relevance of the Study Findings to the Orthotic Management of Hallux Valgus

The significant incidence of flexible plantarflexed first metatarsal in young hallux valgus feet is in harmony with the mechanical theories of foot malfunction advanced by Root et al (1977). They suggested that repetitive dorsal displacement of the first metatarsal was the primary deforming force in hallux valgus as it led to subluxation of the first metatarsophalangeal joint. The Root orthosis was prescribed in an attempt to reduce this hypermobility which according to the theories of Root, Orien and Weed (1977) was caused primarily by excessive pronation of the foot. It has been demonstrated that pronation of the foot can be reduced by the use of an orthosis (Bates, Osternig, Mason 1979, Smith, Clarke and Hamill 1986 and Kelley and Birke 1992). However two studies (section 2.1 and section 2.2) described earlier in this thesis, have questioned the importance of pronation of the foot as an aetiological factor in hallux valgus.

Rather than pursuing foot pronation for the cause of hallux valgus it would seem more reasonable, on the basis of these findings, to direct attention to the flexible plantarflexed first metatarsal, as no other single biomechanical abnormality of lower limb position or function is so strongly associated with the hallux valgus foot.

This may have implications for treatment which perhaps should aim to prevent excessive dorsiflexion of the first metatarsal by protecting the metatarsal from the full force of ground reaction. By minimising movement of the metatarsal, hypermobility will be limited and the progressive subluxation of the first metatarsophalangeal joint may be slowed or even avoided. Preventing excessive dorsiflexion of the first metatarsal has always been a stated objective of the Root orthosis (Root et al 1977, Anthony 1991), whether a Root orthosis can achieve this has not however been proven.

2.3.6 Conclusion

Abnormal movement of the first metatarsal has been indicated in the natural history of forefoot deformity. In juvenile hallux valgus there is a highly significant incidence of plantarflexed first metatarsal. If the plantarflexed first metatarsal is an aetiological factor in hallux valgus, it probably contributes to subluxation of the metatarsophalangeal joint. It does not appear to be directly related to the development of metatarsus primus varus. The importance of metatarsus primus varus as an aetiological factor in hallux valgus will now be reviewed.

2.4 METATARSUS PRIMUS VARUS. AN AETIOLOGICAL FACTOR IN HALLUX VALGUS?

"The wide intermetatarsal angle seems to have a deliciously causal air".

Hardy RH. 1951

The angle between the first and second metatarsals has long been considered an important factor in the development of hallux valgus. With remarkable insight in a time before radiographic examination was available Anderson (1891), observed "an irregularity of development of the first metatarsal, unconnected with any vice in the foot covering which caused severe hallux valgus". With the advent of radiology Steele (1898) could be more definite, stating that "the prominence at the base of the great toe was due to dislocation of the phalanx with marked separation of the first and second metatarsals" (Kelikian 1965).

In 1901 Loison (Kelikian 1965) presented a case of failed hallux valgus surgery. He advised closer attention to the base of the first metatarsal, which he recognised as being a component of the hallux valgus problem. Ewald (1912) observed an oblique angulation of the first metatarsal cuneiform joint, which he believed caused the first metatarsal to slant medially. Medial divergence of the first metatarsal was termed metatarsus primus varus by Truslow (1925), who thought the condition was an anatomical variation inherent in the individual's growth rather than an acquired deformity. Truslow's publication in the *Journal of Bone and Joint Surgery*, provided the first widely accepted suggestion that an abnormality intrinsic to the foot might cause hallux valgus.

While Hawkins, Mitchell and Hedrick (1945) stated that bunion operations failed because of inadequate correction of metatarsus primus varus. Antrobus (1984) performed Keller's arthroplasty on both adolescent and adult bunions, and noticed that post-operatively the increased intermetatarsal angle returned to normal, he concluded that the metatarsal deviation was secondary to the hallux valgus.

Hardy and Clapham (1952) in a statistical study of hallux valgus found a strong correlation between the degree of hallux valgus and metatarsus primus varus. They could not state whether hallux valgus was caused by the medial divergence of the metatarsal, though they did note, that metatarsus primus varus values would increase once the hallux was sufficiently deviated to lie in contact with the second toe. This did not disprove the hypothesis that metatarsus primus varus occurs prior to the development of hallux valgus, it merely demonstrated that the varus deformity deteriorated once a critical angle of hallux valgus has been reached.

Why metatarsus primus varus should cause the development of hallux valgus has never been explained. The biomechanical studies performed by Snijders (1986), proposed a model for the development of metatarsus primus varus. Snijders suggested that once hallux valgus was pronounced, the long flexor tendon acted like a bowstring to pull the hallux into yet more valgus. Whether the slightest medial divergence of the first metatarsal could begin that process has not been demonstrated. What causes the primary deviation of the first metatarsal also requires investigation.

The results of a number of studies on the intermetatarsal and hallux valgus angles are given in Table 2.4.1.

Study	Age	Number of Feet	Mean Hallux Valgus angle	Mean IM angle
Hallux Valgus Feet				
Hawkins 1945	Adults	55	-	13.8
Hardy 1951	40(mean)	165	32	13
Carr 1968	<18	56	-	13.5
	>18	24	-	14.2
Antrobus 1984	45(mean)	183	36.9	12.7
Durman 1957	41(mean)	448	-	12.8
Kilmartin 1994	*10*	*182*	*19.8 (SD 3.8)*	*10.6 (SD 1.9)*
Normal Feet				
Hawkins 1945	Adults	50	-	5 to 6
Hardy 1951	22(mean)	252	15.7	8.8
Antrobus 1984	42(mean)	71	18.7	9
Durman 1957	30(mean)	797	-	8.2
	6 to 10	74	-	7.2(SD 4.5)
At risk"normals"				
Kilmartin 1994	*10*	*62*	*11.4 (SD 3)*	*9.1 (SD 1.7)*

TABLE 2.4.1 Mean Values for Hallux Valgus and Intermetatarsal Angles

2.4.1 Aims of this study

The following study aimed to address the aetiological importance of the intermetatarsal (IM) angle by comparing the angle in the affected foot of children with unilateral hallux valgus with the angle in the unaffected feet. Since hallux valgus usually becomes a bilateral deformity it was presumed that the unaffected feet of unilaterally affected children are at risk, and that both feet should have increased IM angles if abnormality of that angle is the primary defect. The radiographs of children with hallux valgus were also examined to try to discover the cause of the increased intermetatarsal angle.

2.4.2 Objectives of this Study

i. To measure the first-second intermetatarsal angle in children with unilateral hallux valgus to determine whether an increase in the intermetatarsal angle occurs in the unaffected foot.

ii. Compare the intermetatarsal angle in the hallux valgus children with a population of normal children.

iii. Measure the relationships between the bones of the first ray to determine the presence of possible causal factors.

iv. Relate the findings of this study to the use of the Root foot orthosis in the management of hallux valgus.

2.4.3 Patients and Method

Weightbearing radiographs of 122 nine to ten year old Kettering children with hallux valgus of one or both feet were analyzed. Sixty two children had unilateral hallux valgus and 60 bilateral. Most of the children were female (87%), 11 males had unilateral hallux valgus and 5 males bilateral (see Table 2.4.2)

The radiographic criterion of hallux valgus was a metatarsophalangeal joint angle of 15° or more, measured on a dorsoplantar radiograph taken with the child standing comfortably on both feet.

The mean metatarsophalangeal (MTP) joint angle was calculated for the hallux valgus and unaffected feet and the statistical significance for the difference was estimated using a one tailed t test.

The intermetatarsal (IM) angle was measured between lines bisecting the shafts of the first and second metatarsals and the mean angles for the hallux valgus and unaffected feet were calculated. A two tailed t - test was used to estimate the significance of the difference in angle between the hallux valgus and the unaffected foot. A 95% confidence interval was calculated for the mean increase in the intermetatarsal angle on the hallux valgus side. Prior to statistical testing the difference between the relevant data sets was subjected to x^2 goodness of fit test on the Quasar Amstrad statistical package and normal distribution was confirmed.

A t - test was performed to determine whether the intermetatarsal angle of the unaffected foot, in unilateral hallux valgus was significantly different from the angle in 74 normal feet described by Durman (1957). Similar methods were used to compare the intermetatarsal angles of the children with bilateral hallux valgus with the angles of the unaffected and affected feet of the unilateral group.

The children with unilateral hallux valgus were followed up over a 3 to 4 year period (Mean follow-up 39 months SD 5), to determine whether the initially unaffected foot also developed hallux valgus.

The length of the lateral cortex of the first metatarsal (Fig.2.4.1) and the metatarsus adductus angle (M in Fig.2.4.2) were measured on all radiographs.

A third angle, the cuneiform angle measured the obliquity of the metatarsocuneiform joint (C in Fig.2.4.3) and the intercuneiform angle (I in Fig. 2.4.3) measured the divergence of the long axis of the medial and intermediate cuneiforms, to determine if splaying of the first cuneiform could account for an increased intermetatarsal angle.

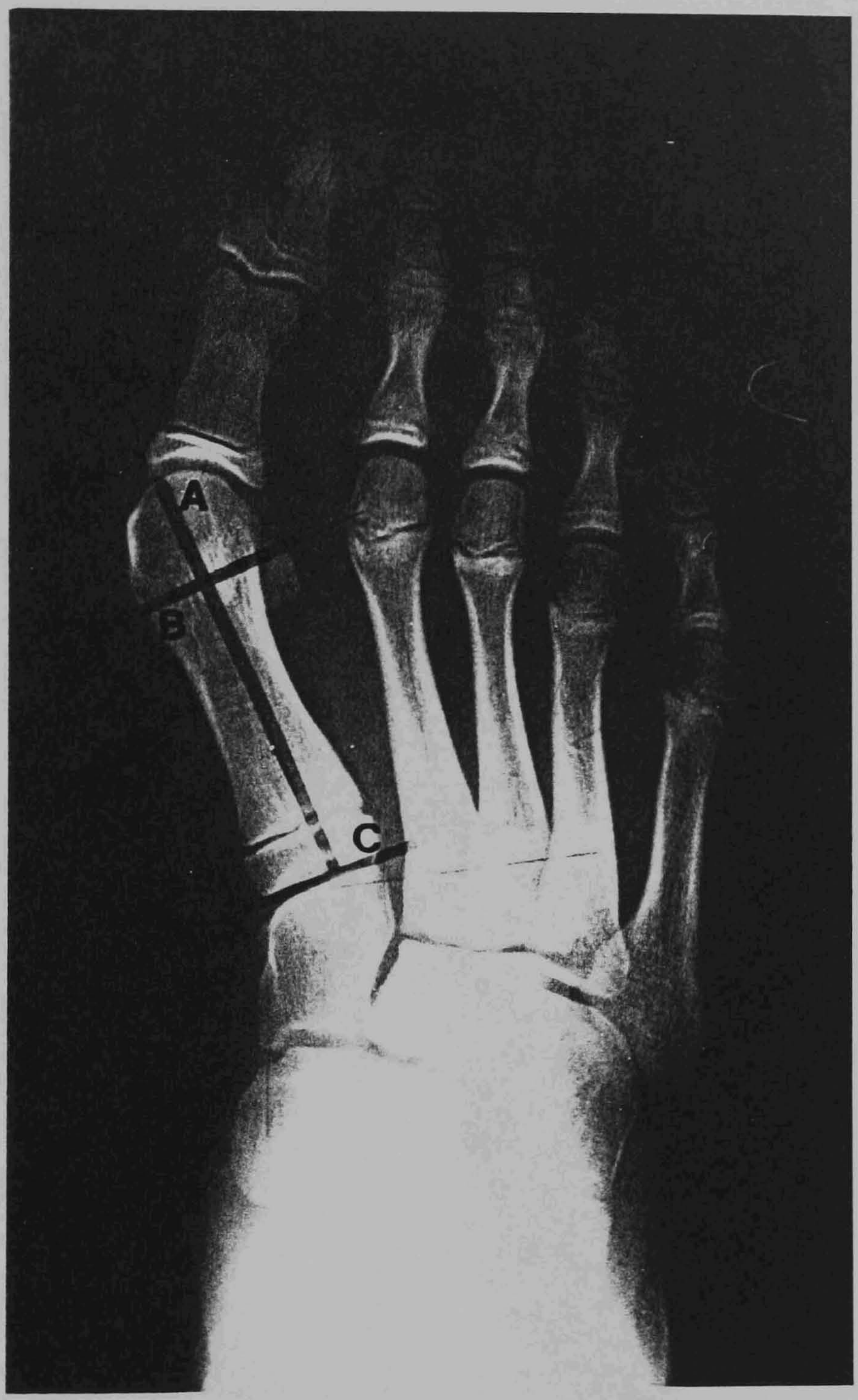


Fig. 2.4.1 Length of the lateral cortex of the first metatarsal. The long axis of the metatarsal is bisected (line A). A perpendicular line bisects the tibial sesamoid (line B). The base of the metatarsal is defined (line C). A ruler placed flush against the cortex and the distance B,C is measured.

Fig. 2.4.2 The metatarsus adductus angle measures the position of the lesser tarsus relative to the midfoot. Line D is between the most distal medial point of the first cuneiform and the proximal point of the navicular. Line E links the distal and proximal lateral points of the cuboid. Line F connects the halfway points of line D and E. The between line F and the second metatarsal bisection gives the metatarsus adductus angle.

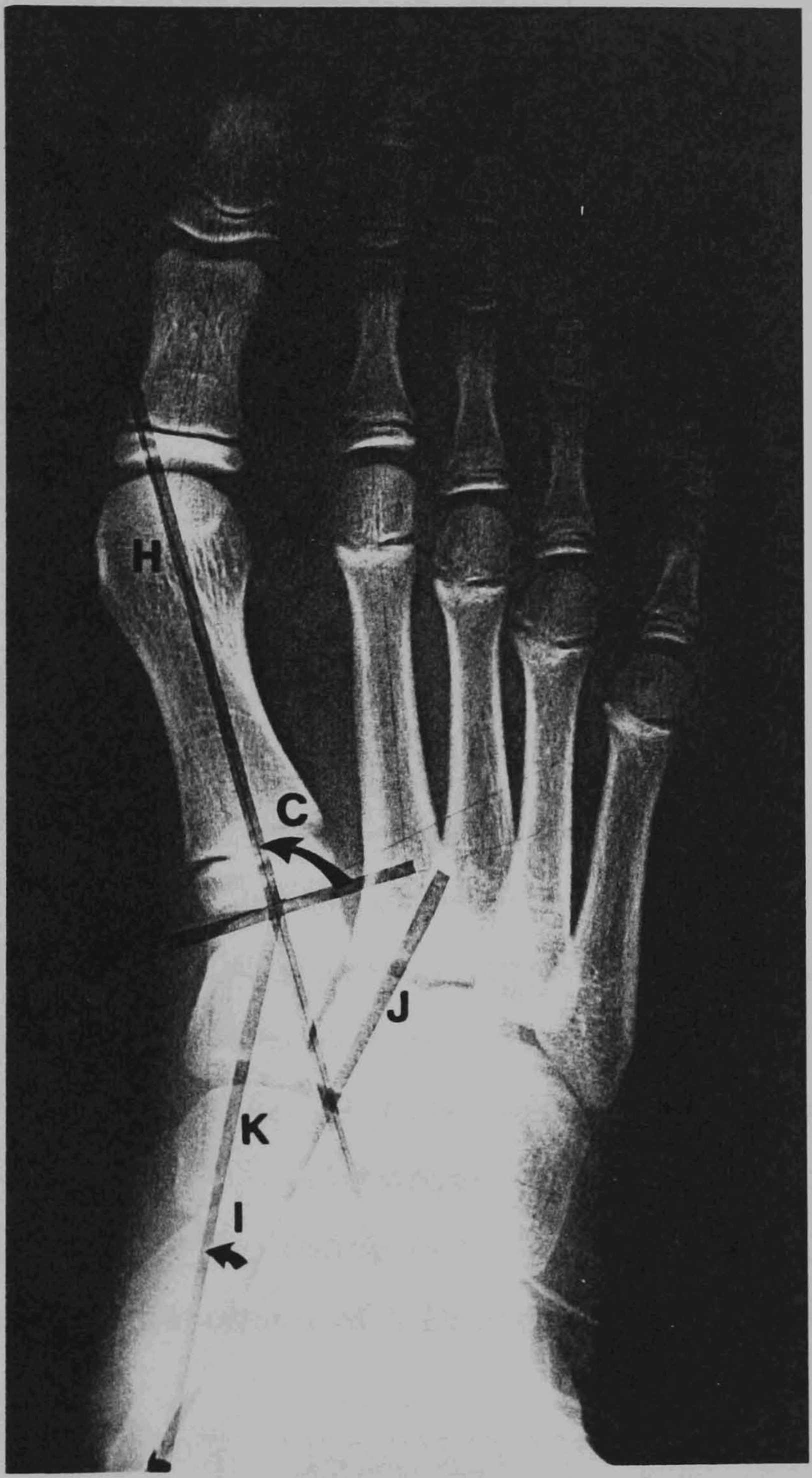


Fig. 2.4.3 The cuneiform angle (C) is that between a line drawn flush with the distal articular surface of the first cuneiform and the long axis bisection of the first metatarsal. Long axis bisections of the medial and intermediate cuneiforms (lines K and J) provided the intercuneiform angle.

The Pearson correlation test was used to determine the association between the length of the lateral cortex of the first metatarsal and the magnitude of the intermetatarsal angle. The correlation between the cuneiform angle, the intercuneiform angle and the intermetatarsal angle was similarly tested, as was the association between the metatarsus adductus angle and the intermetatarsal angle and then between the metatarsus adductus angle and the metatarsophalangeal joint angle.

Finally a t - test compared the metatarsus adductus and cuneiform angles in the bilaterally and in the unilaterally affected feet.

2.4.4 Results

Study 1. In the 62 children with unilateral hallux valgus the Mean MTP joint angle in the affected foot was 18.5° (SD 3); in the unaffected foot it was 11.4° (SD 3). The difference is significant ($p<0.001$, Table 15.2). The mean I.M angle in the affected foot was 10.1° (SD 1.85); in the unaffected foot it was 9.1° (SD 1.7). The IM angle was on average 1.2° greater in the hallux valgus foot. The 95% confidence interval for the mean difference between the affected and the unaffected foot was 0.3 to 2°. The two tailed *t* - test indicated that the observed difference was significant ($p<0.01$).

	Affected Feet (n = 62)	Unaffected Feet (n=62)	Statistical Significance
MTP joint Angle Mean SD	 18.54 2.99	 11.4 3.06	p<0.001
IM Angle Mean SD	 10.1 1.85	 9.1 1.73	p<0.01

Table 2.4.2 Mean Values for Hallux Valgus and intermetatarsal Angles in the Unilateral Group

In cases of unilateral hallux valgus the IM angle is slightly (but significantly) greater in the affected foot.

Study 2.

In the 60 children with bilateral hallux valgus (120 feet) the mean intermetatarsal angle was 10.6° (SD 1.9). This angle does not differ significantly ($p>0.05$) from the IM angle of the affected feet in the unilateral group; it is, however, significantly greater ($p<0.01$) than the IM angle in the unaffected feet in the unilateral group.

Study 3.

In the normal population of six to ten year old children studied by Durman (1957) the mean IM angle was 7.2° (SD 4.47). This value is very significantly smaller ($p<0.001$) than the mean IM angle (9.1°, SD 1.7) for the unaffected feet in our unilateral group. The 95% confidence interval of the difference being 0.9° to 3.5°.

Study 4.

Follow up studies of children with unilateral hallux valgus investigated whether the increased I.M. angle in the unaffected feet preceded the later development of hallux valgus. Fifteen children were lost to follow up so a total of forty seven children underwent a second x-ray examination three to four years after their first x-ray.

Just 21 of those children with unilateral hallux valgus received no treatment between examinations. Over the three to four year period of the study the metatarsophalangeal joint angle deteriorated in 19 of these cases (Table 2.4.3). In a further 26 children who received treatment as part of the Kettering Hallux Valgus study, deterioration of the metatarsophalangeal joint occurred in all cases (Table 2.4.3 & Appendix 5, part 3). 53% of the unilateral study group and 57% of the unilateral control group developed clinical and radiological hallux valgus of both feet indicating that a raised intermetatarsal angle can be seen prior to the development of hallux valgus (see Fig. 3.5).

Raw data for study 1 to 4 are available in Appendix 5 and 6.

	Unaffected Foot MTP Joint Angle 1988	Same Foot MTP Joint Angle 1992	Unaffected Foot IM Angle 1988	Same Foot IM Angle 1992
Unilateral HV. Control group (n= 21)	Mean = 11.85 SD 1.9	20.6 SD 21.1	9.6 SD 1.8	9.86 SD 1.9
Unilateral HV. Study group (n=26)	10.5 SD 4.05	15.68 SD 6.8	8.78 SD 1.55	9.7 SD 2.1

<u>**TABLE 2.4.3** Deterioration of MTP and IM Angles in the Unaffected Feet of the Unilateral Hallux Valgus Children over the period of the Kettering Hallux Valgus Study</u>

Study 5.

In the 60 bilateral hallux valgus children (120 feet), little or no association was found between the length of the lateral cortex and the magnitude of the IM angle. Using the bilateral cases, the Pearson correlation was found to be $r = -0.035$ ($p>0.05$).

Study 6.

In the 60 children with bilateral hallux valgus there was no correlation between the IM angle value and the angle of metatarsus adductus (Pearson correlation $r = -0.2$, $p<0.05$). Nor was there a significant difference between the metatarsus adductus angle in the bilateral group and the unaffected feet of the unilateral group ($p>0.05$)

The Pearson correlation between metatarsus adductus angle and the MTP joint angle was r = 0.26 ($p<0.01$).

Study 7.

In the bilateral group (120 feet), there was no significant association between the IM angle and the cuneiform angle, (r =-0.07, $p>0.05$). The alignment of the first metatarsal is clearly not determined by the metatarsocuneiform joint. The mean cuneiform angle of the bilaterally affected feet did not differ from that for the unilaterally affected feet ($p>0.05$).

Nor did the intercuneiform angle correlate with the IM angle (r = 0.16). Splaying of the cuneiforms cannot be blamed for high IM angle values.

The raw data for studies 5 to 7 is available in Appendix 7.

2.4.5 Sample Size

The power of each of the comparative studies was calculated retrospectively using the smallest clinically relevant difference (based upon the *Least Significant Difference Values* obtained in Section 3), the standard deviation of the difference between study groups intermetatarsal and metatarsophalangeal joint angle measurements and the sample size. Gore and Altman's sample size nomogram available in Appendix 8 indicated that each study achieved at least 80% power (Table 2.4.4).

Study	Smallest clinically relevant difference	SD of Difference between groups	Standardised Difference	Total Sample Size	Power
1. Difference in MTP angle Affected vs. Unaffected Foot	3°	4.28	0.7	124	>80%
1. Difference in IM angle. Affected vs. Unaffected	2°	1.66	1.2	124	>80%
2. Difference in IM angle bilateral HV. vs. Affected feet	2°	2.48	0.8	182	>80%
2. Difference in IM angle bilateral HV. vs. Unaffected feet	2°	2.49	0.8	182	>80%
3. Difference in IM angle Durman's (1957) normal feet vs. Unaffected feet	3°	4.9	0.48	136	>80%

TABLE 2.4.4 Power Calculations for the Statistical Study of Metatarsus Primus Varus

2.4.6 Discussion

Hallux valgus is usually a bilateral deformity (Hardy and Clapham 1951) and children who present with one foot affected must, on the basis of this general observation, be considered at risk of developing deformity in the other.

If an increased intermetatarsal angle is the primary defect of hallux valgus, it would be logical to expect that the intermetatarsal angles in the at-risk foot would be greater than in the feet of normal children and the results of study 3 show that this is so. Children with unilateral hallux valgus should be considered at risk of developing hallux valgus of the unaffected foot. The raised intermetatarsal angle effectively predicts the later development of hallux valgus in clinically normal feet. It is therefore likely that metatarsus primus varus is the primary component of hallux valgus.

In the early stages of hallux valgus development the intermetatarsal angle only changes slightly, while the metatarsophalangeal joint progresses much faster (see Table 2.4.3). A significant increase in the intermetatarsal angle is likely to occur later when the hallux abuts the second toe. This point was identified by Hardy & Clapham (1951), as the critical angle of hallux valgus, when the proximal phalanx of the hallux begins to act like a wedge to drive the first metatarsal into varus, while at the same time subluxing the first metatarsophalangeal joint.

The findings of this study lead me to consider the aetiology of the increased intermetatarsal angle. The fact that the length of the lateral cortex and intermetatarsal angle correlated poorly indicates that it is not due to disturbed growth of the first metatarsal. Similarly, adduction of the medial cuneiform away from the intermediate cuneiform cannot be considered a predisposing factor, for the intercuneiform angle correlates poorly with the intermetatarsal angle.

Metatarsus adductus has been considered significant by a number of authors, some of whom have reported a direct association between the angle of metatarsus adductus and the degree of hallux valgus (Root, Orien and Weed 1977, La Reaux and Lee 1987). Their theory suggests that adductus of the forefoot puts the first metatarsophalangeal joint at greater risk of a valgus deforming force applied by foot wear. Study 5 overturns this theory, a weak and probably irrelevant correlation being found between metatarsus adductus and hallux valgus. The other finding of a weak association between metatarsus adductus and the intermetatarsal angle seems to indicate that an increased intermetatarsal angle is not a consequence of congenital derangement of the whole forefoot.

This study failed to determine the cause of an increased intermetatarsal angle, but has shown that deformity of the first metatarsal and displacement of the cuneiforms bones are both unlikely contenders. The aetiology is unlikely to be detected by further radiographic measurement of the angular relationships of the foot bones. The seat of the deformity and thus the most appropriate point for its correction has yet to be confirmed.

2.4.7 The Relevance of the Findings of this Study to the Orthotic Management of Hallux Valgus

This study, like many before it, does indicate the importance of an increased first-second intermetatarsal angle in hallux valgus. It is difficult however to relate transverse plane movement of the first metatarsal to the Root foot orthosis which appears to have its most significant effect in the control of frontal plane (specifically pronation) movement of the foot.

In 1977 the developers of the Root orthosis stated their belief that metatarsus primus varus was not an important component of hallux valgus in the early stages of the condition. This study of metatarsus primus varus in Kettering children seems to indicate that they may have been wrong. Metatarsus primus varus is significant right from the early stages of hallux valgus although undoubtedly it does become more clinically apparent in the advanced stages. Could this miscalculation of the significance of metatarsus primus varus have implications for the effectiveness of orthotic treatment in juvenile hallux valgus? The following controlled prospective trial of a Root orthosis in the treatment of juvenile hallux valgus explores this possibility further.

3.0 A CONTROLLED PROSPECTIVE TRIAL OF A ROOT FOOT ORTHOSIS IN THE TREATMENT OF JUVENILE HALLUX VALGUS

.... external appliances sometimes allay the discomfort caused by forefoot deformity, but they do not correct them: they merely temporize.

Kelikian, 1965

In the following study the effect of a Root foot orthosis on hallux valgus is measured. Before the orthosis could be provided however it was necessary to collect a study group with the condition. Nine to ten year old school children were chosen because it was assumed that hallux valgus would still be in the early stages and thus less resistant to conservative treatment. Moreover there would be fewer variables in terms of footwear and activity.

3.1 Goniometer measurement of hallux valgus in the Kettering survey

The next two sections of the thesis deal with the technique used for screening school children for hallux valgus as well as the repeatability of the radiographic technique used to measure the effect of orthotic treatment.

Patients and Methods

While recognition of advanced hallux valgus is straightforward, diagnosis of the condition in its early or juvenile stages, when the foot is not very different from normal, requires precise guidelines, especially if a number of different observers are involved. In this study such guidelines were developed and their value tested by determining the reliability of hallux valgus diagnosis when made by a number of specially trained observers.

Six thousand nine to ten year old children residing within the Kettering District Health Authority were screened over a two year period from 1987 to

1989 as part of the Kettering Chiropody Department's Children's Foot Health Survey. This is the total population of state school children in Kettering District.

Twelve chiropodists from the Kettering Health Authority were instructed to screen for hallux valgus using the following criteria as the basis for referral for a second opinion.

1. Visible osteophytic thickening of the first metatarsophalangeal joint.

2. A first metatarsophalangeal joint angle in excess of 15° when measured with a finger goniometer (Fig. 3.1).

An additional guideline was there should be evidence of pushing off from the medial side of the hallux while walking. This helps to establish whether the valgus deviation of the hallux is severe enough to restrict propulsion to the medial border of the hallux rather than the tip of the toe.

Assessment of osteophytic thickening of the first metatarsal head provides a crude method for clinically evaluating first metatarsophalangeal joint degeneration. Thickening of the first metatarsal head is considered to be the early stages of the development of the medial eminence, and when present suggests that the articular surface of the first metatarsal head is no longer congruent with the base of the proximal phalanx (Piggott 1960).

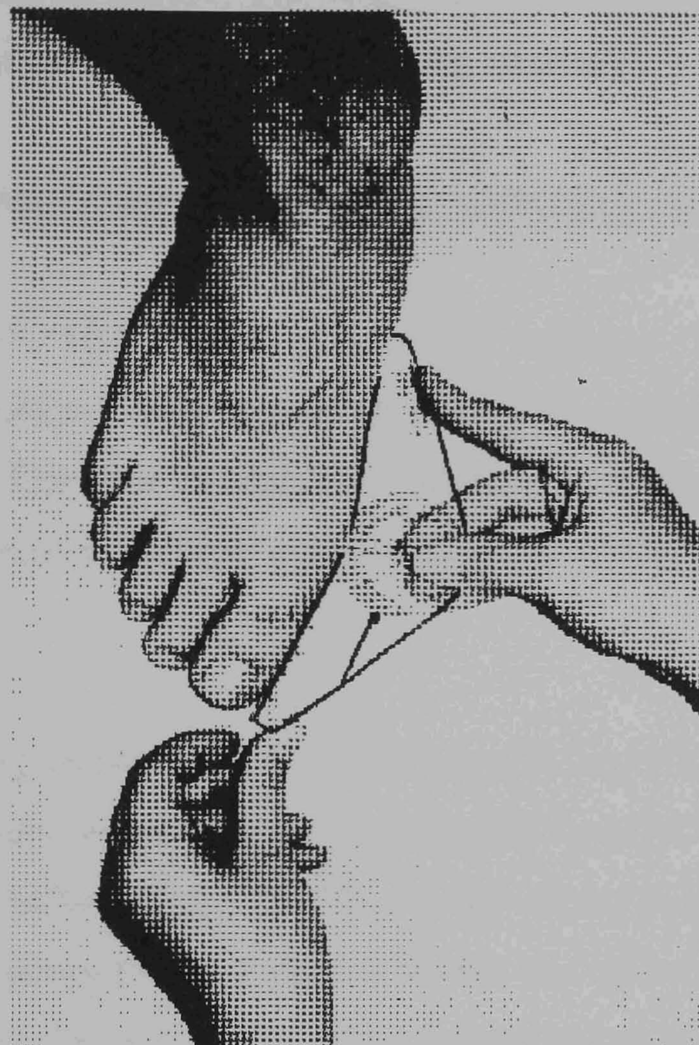


Fig 3.1 The Measurement of Hallux Valgus Using a Finger Goniometer

Goniometric measurement of the first metatarsophalangeal joint angle has not been described before. The finger goniometer's reliability as a measuring instrument was tested in the following manner:

Study 3.1.1 <u>Inter-Observer Variability with the Finger Goniometer</u>

A group of 104 nine year old school children from Corby Northamptonshire, were screened for pain or obvious abnormality of the feet and legs. The first 25 children (50 feet) with no abnormality of the lower limb underwent a further examination of their first metatarsophalangeal joints.

While standing barefoot with their weight taken equally on both feet, one arm of the finger goniometer was brought against the midline of the medial surface of the hallux (Fig. 3.1). The hinge of the goniometer was located over the first metatarsophalangeal joint while the other arm was brought against the mid-line of the medial surface of the first metatarsal. The measurement was recorded after the goniometer was removed from contact with the foot. Both feet were measured in this way.

The child's first metatarsophalangeal joint angle was then measured again with the same goniometer by a second observer. This observer had previously been given instruction in the use of the measuring instrument and had undergone some practice sessions.

Study 3.1.2 <u>Intra-Observer Variability with the Finger Goniometer</u>

Twenty five nine year old children from another Corby school were selected for this study on the basis that they had no obvious foot deformity or pain. One observer (TEK) measured both first metatarsophalangeal joint angles on two occasions separated by one week.

Study 3.1.3 Intra-Observer Variability in the Goniometric Measurement of Hallux Valgus

The goniometer which aligns directly against the bony segments of the first ray proved impractical in advanced hallux valgus where the enlarged medial eminence and bursa, made it impossible to place the arms of the goniometer against the first metatarsal and proximal phalanx. Although a big medial eminence is not a feature of even the more severe cases of hallux valgus in nine year old children, the thickening of the metatarsal head which is present, can affect the way in which the goniometer is aligned. This study attempted to determine whether the goniometer was any less reliable in cases of hallux valgus.

On two separate occasions TEK measured the first metatarsophalangeal joint angles of twenty five nine to ten year old children with visible thickening of both first metatarsal heads, and bilateral metatarsophalangeal joint angles in excess of 15°, when measured with a goniometer. The measurement was repeated within four weeks of the first with no recollection of the earlier measurement.

Study 3.1.4 The Correlation between Radiographic and Goniometric Measurement of Hallux Valgus

In order to test the validity of the goniometer measurements, the values recorded with the goniometer in 38 children with first metatarsophalangeal joint angles in excess of 15°, were compared with angles measured on the weightbearing radiographs of the same children.

3.1.5 Statistical Analysis

All the studies generated two sets of data. The difference between the two sets of data was assessed using a x^2 goodness of fit test and was found to be normally distributed. A paired t test determined any statistically significant difference between the data, while a Pearson Product Moment Correlation test indicated the association between the two sets of measurements. A 95% confidence interval of the difference between repeated measurements as well as a *Least Significant Difference value* was calculated for all levels of the study.

3.1.9 Results

Table 3.1 shows the mean and standard deviation values recorded at all levels of the study. Statistically significant difference between measurements and the correlation between repeated measurements is also shown. Fig. 3.1.2 to 3.1.5 represent graphically the difference between repeated measurements.

No significant difference was found between any of the data sets recorded for the three observer error trials (see Table 3.1). There was however a highly statistically significant difference between the hallux valgus angle measured on x-ray and that recorded with a goniometer. Though the correlation between the two methods was fair (r = 0.63), the two methods recorded significantly different values with the goniometer generating on average a 1 degree smaller value (SD 3.55), the 95% confidence interval being 0.4° to 2°.

A *least significant difference value* of 4.6° was recorded for the intra-observer error study on hallux valgus measurement. This indicates that a difference of greater than 4.6° would have to be recorded between repeated measurements, before it could be accepted that a real difference existed.
The raw data for this study is available in Appendix 9.

	Intra-Observer Error Study (n=50) Normal Subjects	Inter-Observer Error Study (n=50) Normal Subjects	Intra-Observer Error Study (n=50) HV Subjects	Radiographic Vs Goniometric Measurement (n=77)
First measurement Mean° SD	5.6 4	(TEK) 7.4 4	18.3 2.7	X-ray 20.3 4.4
Second measurement Mean° SD	5.7 4.3	8 4	18 3	Goniometer 19.2 4
Mean difference & Statistical Significance	-0.24 NS	-0.7 NS	0.3 NS	1.06 $p<0.05$
Correlation	0.82 $p<0.001$	0.79 $p<0.001$	0.66 $p<0.001$	0.63 $p<0.001$
95% Confidence Interval of mean difference	-0.8 to 0.3°	0.025 to 1.53°	-0.5 to 0.8°	0.4 to 2°
Least Significant Difference Value	3.8°	5.3°	4.6°	7°

TABLE 3.1 Goniometric Measurement an Inter and Intra-Observer Error Study, and Radiographic Measurement vs Goniometer Measurement

Goniometer Measurement of the First Metatarsophalangeal Joint Angle
An Intra-observer Error Trial on Normal Feet
(n=50)

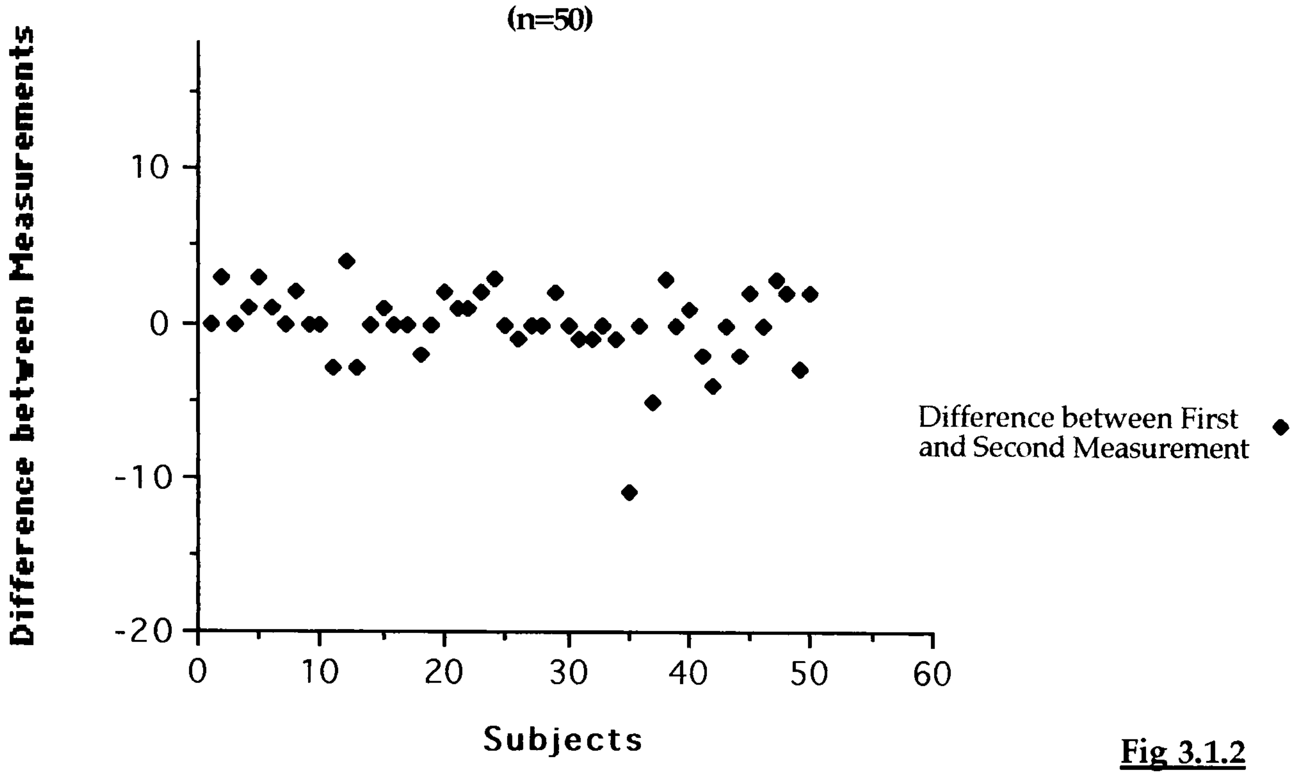


Fig 3.1.2

Goniometer Measurement of First Metatarsophalangeal Joint Angle
An Inter-observer Error Trial on Normal Feet
(n=50)

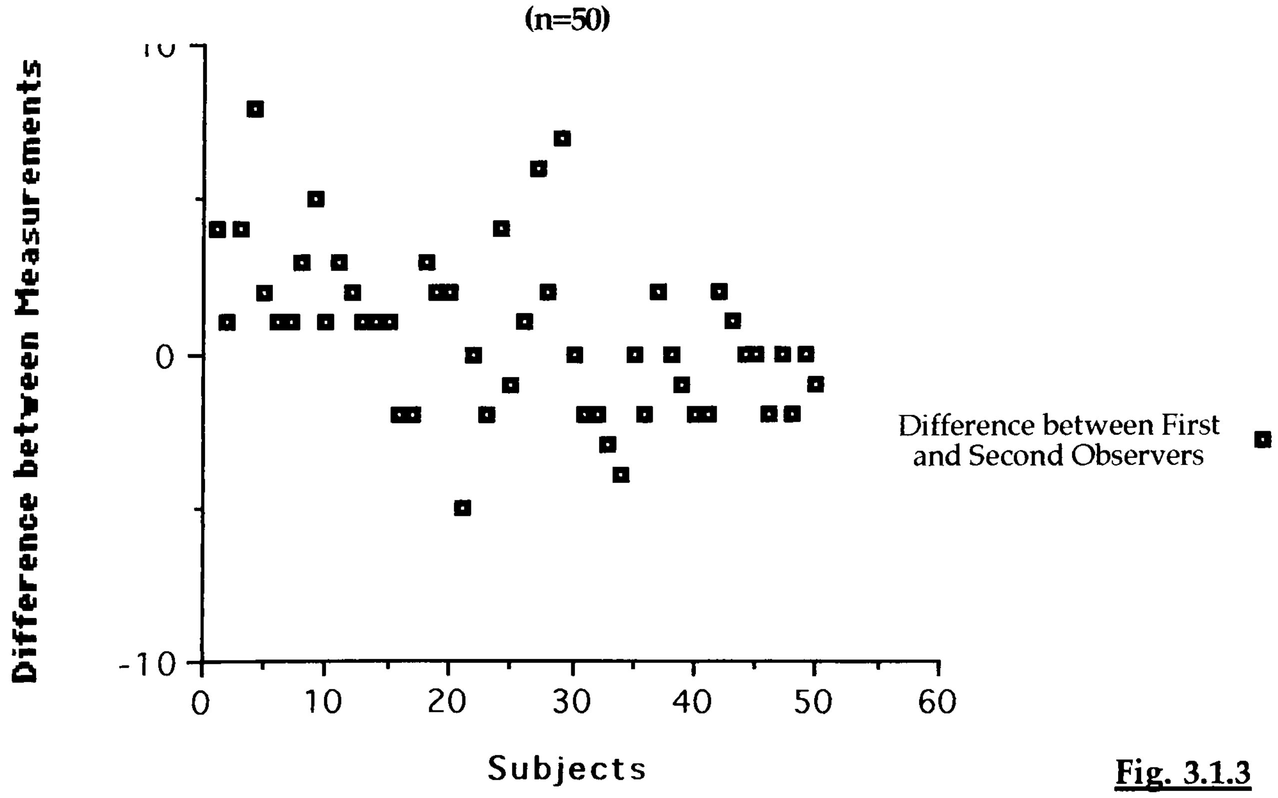


Fig. 3.1.3

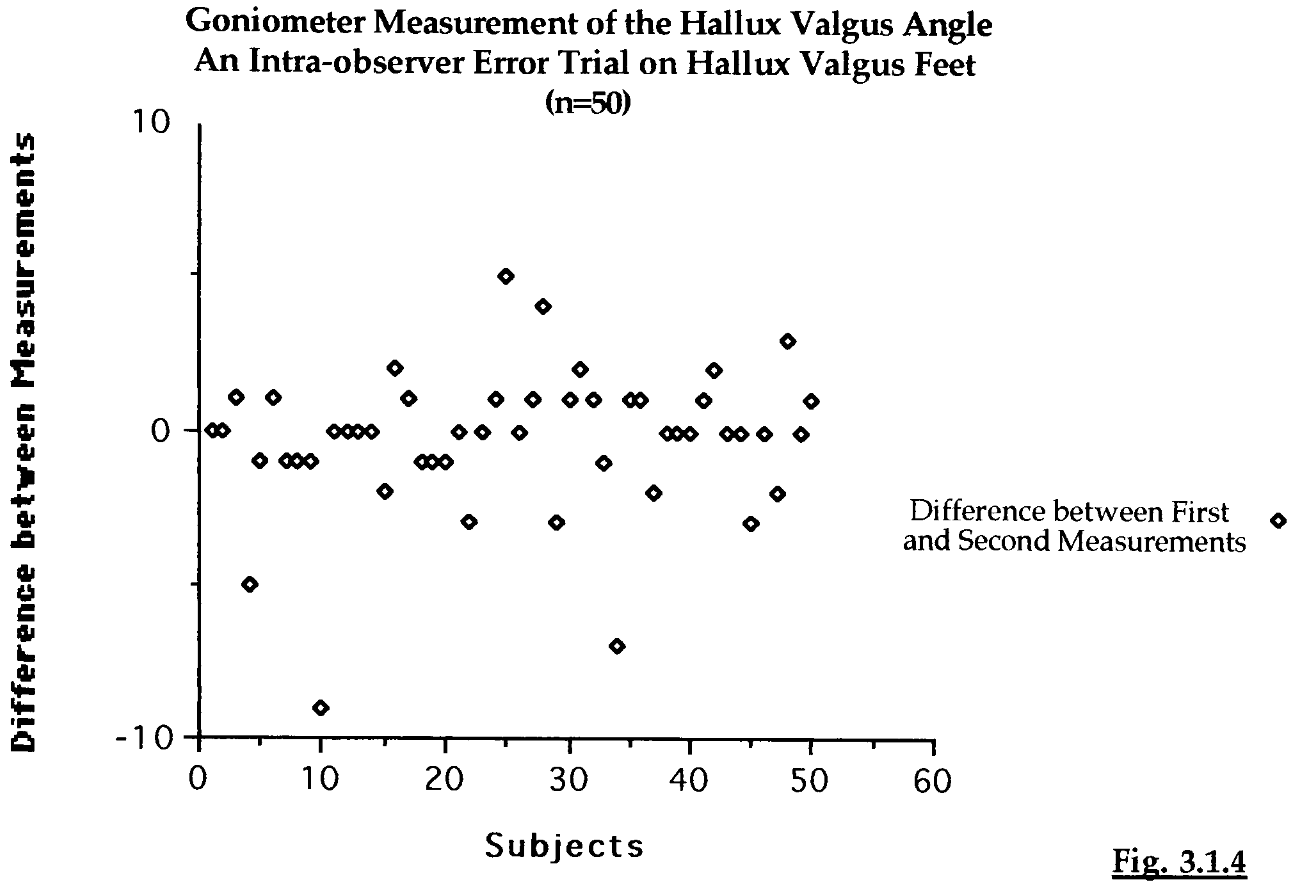


Fig. 3.1.4

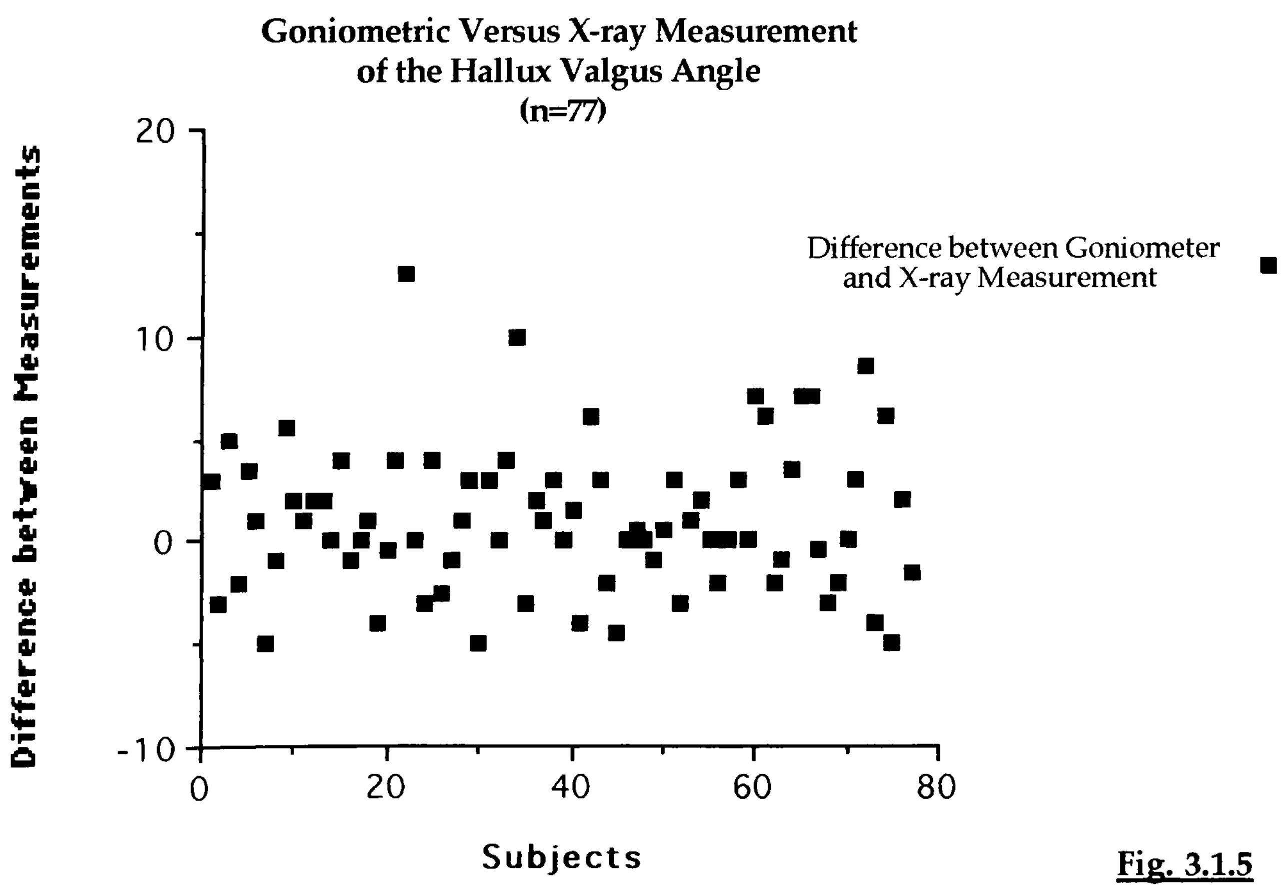


Fig. 3.1.5

The finger goniometer has been shown to be a fairly reliable assessment instrument for measuring the first metatarsophalangeal joint angle. As a screening tool it can be used with reasonable accuracy by more than one observer. A good correlation was found between the goniometer and radiographic measurement of hallux valgus. This suggests that the goniometer is a reasonably valid measuring instrument as long as the tendency for it to underestimate the hallux valgus angle is taken into account.

3.1.7 The Kettering Screening Programme Results

In the Kettering screening programme the diagnostic criteria were set with the aim of differentiating the normal, congruent first metatarsophalangeal joint from the hallux valgus joint. If the screening chiropodists believed the diagnostic criteria were present the child was referred to the author for a second examination. The chiropodists were encouraged to over refer so as no cases of hallux valgus were missed.

When the suspected hallux valgus cases were seen by the author for a second assessment the first metatarsophalangeal joint was once more assessed and if the diagnostic criteria were considered to be present, the child was referred for radiological examination.

The agreement between the screening chiropodists and the "expert" examiner's diagnosis was noted in order to determine the number of false positive diagnosis made by the screening chiropodists. The predictive value of a positive screening test was then calculated.

In turn the agreement between the author's diagnosis and the radiological diagnosis was compared and the number of false positive diagnosis made by the "expert" calculated. The predictive value of an "expert" assessment using the two diagnostic criteria was determined.

Six thousand nine to ten year old children were screened over the two year period. Three hundred and ten of these children were thought to have hallux valgus by the screening chiropodists and were subsequently referred for a second "expert" examination. It would have been helpful if all 310 children were radiographed at this stage so it could be certain how many did not have hallux valgus, however the author found that the clinical criteria for hallux valgus diagnosis was absent in 160 of the children, and it was not plausible for ethical reasons to radiograph clinically normal children. One hundred and fifty children were considered to have met the criteria for hallux valgus and were referred on for radiological examination (Table 3.1.2).

	Hallux Valgus	Normal
Screening Chiropodist Assessment	310	5690
Second Assessment	150	160

False positive diagnosis of hallux valgus by screening chiropodists = 52%
Predictive value of a positive screening test = 48%

Table 3.1.2 False Positive Diagnosis of Hallux Valgus by Screening Chiropodists in the Kettering Survey

On subsequent radiographic measurement of the metatarsophalangeal joint angle, 122 (2% of the total population surveyed) were found to have a metatarsophalangeal joint angle in excess of 15° (Table 3.1.3), 87% of these children were female. Bilateral deformity was present in only 60 children (49%) (Table 3.1.5).

	Hallux Valgus	Normal
Second Examination	150	160
X-ray Examination	122	28

False positive diagnosis of hallux valgus on second "expert" examination = 19%
Predictive value of a positive "expert" examination = 81%

Table 3.1.3 False Positive Diagnosis of Hallux Valgus after a Second "Expert" Examination

	Hallux Valgus	Normal
Screening Examinations	310	5690
X-ray Examination	122	188

False positive diagnosis of the two screening assessments = 61%
Predictive value of the two screening assessments = 39%

Table 3.1.4 The Overall Positive Predictive Value of the Two Screening Assessments

Hallux Valgus Presentation	Males Total number screened = 2,860	Females Total number screened = 3,140	Total (n=6000)
Children with Bilateral Hallux Valgus	5	55	60 (1%)
Children with Unilateral Hallux Valgus	11	51	62

Table 3.1.5 The sex distribution and presentation of radiographically diagnosed hallux valgus in 6000 nine to ten year old school children

3.1.8 Discussion

In nine to ten year old Kettering children there is a 2% incidence of hallux valgus. In 87% of cases the affected child was female. While the greater incidence among females is consistent with other studies, the overall incidence of hallux valgus is much lower than in other surveys. Adult populations certainly have a much higher incidence of hallux valgus with geriatric females having the highest incidence of all (Brodie, Rees, Robbins 1988). Other hallux valgus surveys indicate that between the ages of 10 and 60, the incidence of hallux valgus increases as more of the population acquire the condition.

Marr and D'Abrera's (1985) survey of foot problems in 191 Australian school children detected an 11.8% incidence of hallux valgus in females and 3.5% among males. The study subjects were all aged between 7 and 12 but were not sex matched with only 76 girls being surveyed.

The survey used no fixed criteria for the diagnosis of hallux valgus. The diagnosis was made without measuring instruments or radiological examination of joint congruity.

The University of Vermont epidemiological survey of foot pathology in the USA sought to determine the prevalence of a number of foot problems including hallux valgus (Gould, Schneider and Ashikaga 1980). The information was collected by commercial shoe fitters who completed questionnaires on individual customers. Forty five thousand questionnaires were completed and the findings projected for the total USA population of 186,000,000 people in 1978-79 (Table 3.1.6).

Unfortunately Gould et al's study had several shortcomings. The data collection was performed by shoe fitters who had been briefed to ask the customers certain questions. The customers then assessed their own feet to determine whether they had bunions, a condition which as discussed earlier is open to several different interpretations.

Age Group	Incidence of Bunions according to Race	Male to Female Ratio
4-14	1 in 2500 Whites (0.04%) 5 times as frequent in Blacks and others	1:1
15-30	1 in 33 Whites (3%) 4 times as frequent in Blacks and others	1:2
31-60	1 in 11 Whites (9%) 2 times as frequent in Blacks and others	1:4
60+	1 in 6 Whites (17%) 2 times as frequent in Blacks and others	1:3.5

Table 3.1.6 Incidence of "Bunions" in the United States 1978-79 (Gould et al 1980)

The population sample studied by Gould et al may not have been representative. The 14 stores used in the survey were involved simply because they were listed on the Prescription Footwear Association Directory. Another 36 on the directory were approached but did not cooperate. The selection was not based on any socio-economic, geographic or ethnic factors.

Prescription Footwear stores are likely to serve customers with foot pathology who have special fitting or shoe therapy requirements. The responses collected in such outlets cannot be reliably projected for the total population of the USA.

The Wessex Regional Foot Health Survey of 8 District Health Authority Chiropody departments randomly selected subjects from the electoral register (Brodie, Rees and Robins 1988). A questionnaire was sent and the respondents were then followed up with an interview and examination. No information regarding non-respondents was provided. Of the 700 people interviewed 16.8% of females and 6.8% of males were found to have hallux valgus (Fig 3.1.6).

Percentage Incidence of Hallux Valgus in 700 Wessex Feet (Brodie et al 1988)

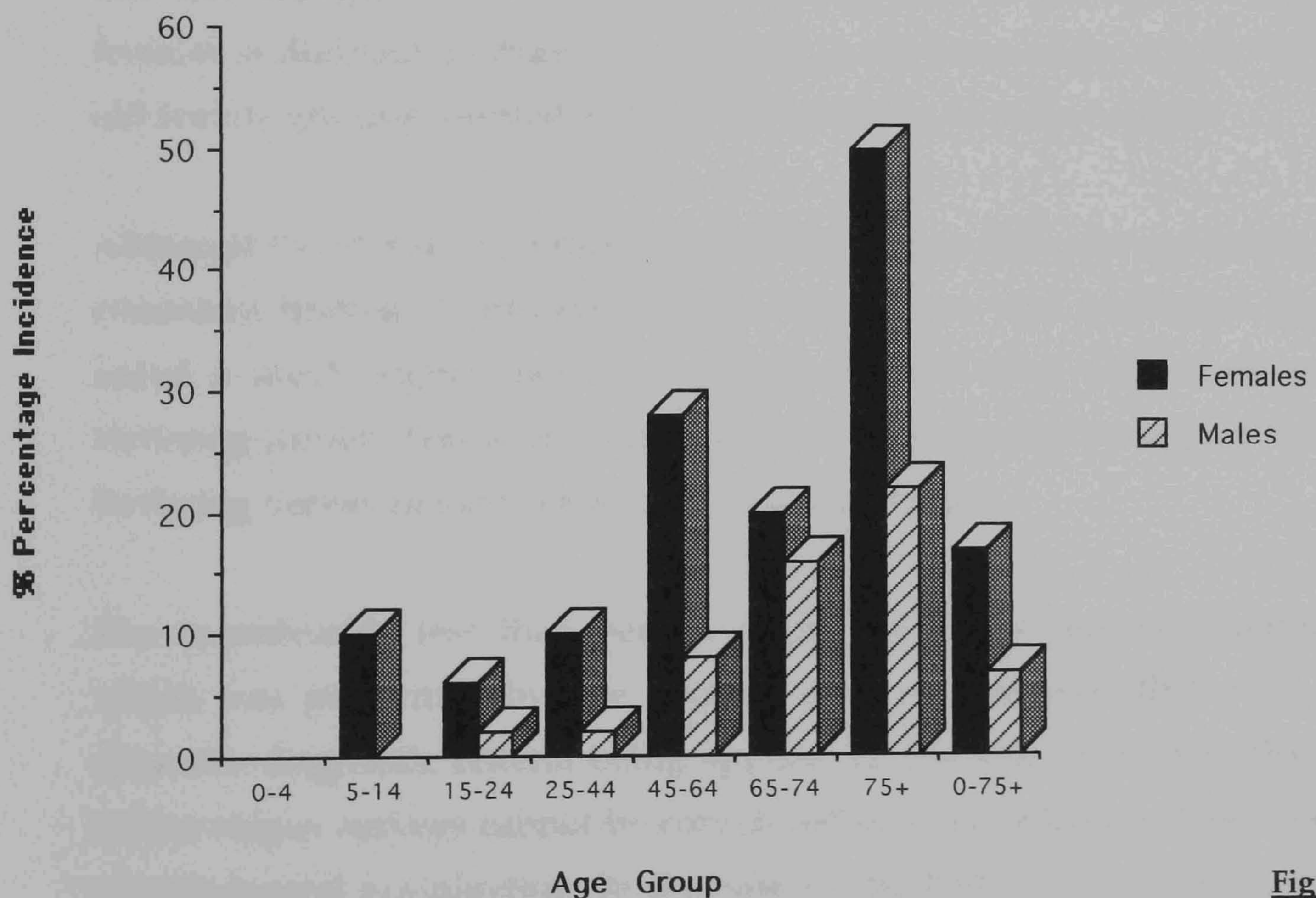


Fig 3.1.6

This diagnosis was made without the use of predetermined criteria, radiological examination or measuring instruments. The repeatability of the data collected by some 30 different chiropodists was not tested.

All three surveys give a very different picture of the incidence of hallux valgus. The Australian survey suggested that hallux valgus was present in one in ten under 12 year old females while the American survey reported an incidence of one in 2,500.

The Wessex survey also found a 10% incidence in girls less than 14 years old. Interestingly this incidence increased to 50% in the over 75 year old females, a dramatic increase especially as in the same survey the 65-74 year old female group presented only a 20% incidence of hallux valgus.

Although the increasing incidence of hallux valgus with age appears to be a consistent finding of previous surveys, the Wessex and Australian surveys noted a much higher incidence among children than was found in the Kettering survey. This is of some concern because it could be argued that the Kettering survey missed some cases of hallux valgus.

The considerably less than perfect sensitivity of the second examination which was performed by one "expert" clinician, suggests that even with objective diagnostic criteria being applied by just one motivated observer, hallux valgus surveys cannot be considered entirely reliable without the use of radiological examination. In the case of the Kettering survey it appears that there was considerable 'over diagnosis' of hallux valgus at the clinical screening stage with 61% of cases being false positively diagnosed prior to x-ray examination, which in this study is rightly or wrongly being cast as the 'gold standard'. On this basis it seems unlikely that cases of hallux valgus were missed by the screening programme.

The 81% predictive value of the second observer's examination does on the other hand support the validity of the clinical criteria used in this study and certainly justifies their use in future surveys of hallux valgus incidence (Table 3.1.3). 81% predictive value is however less than perfect sensitivity but this may be explained by the considerably less than perfect repeatability of the goniometer used to establish the 15° hallux valgus angle which in the intra-observer error study of repeatability was shown to produce a *least significance difference value* of 3.8°.

The even poorer sensitivity of the first chiropody assessment (Table 3.1.2) may be explained by the fact that the chiropodists were encouraged to over refer to the study so no cases of hallux valgus were missed, though again the goniometer used by the screening chiropodists did produce a *Least significant difference value* of 5.3° when more than one observer was involved in first metatarsophalangeal joint measurement.

3.1.9 Conclusion

Hallux valgus occurs infrequently among nine to ten year old children but affects girls more commonly than boys. All future surveys which aim to determine the incidence of hallux valgus should be designed around an objective diagnostic criteria and should at some stage involve a radiological examination of clinically positive cases before the findings from such surveys can be considered entirely reliable. The repeatability of radiographic examination will be reviewed in the next section of the thesis.

3.2 REPEATABILITY OF RADIOGRAPHIC MEASUREMENT IN THE KETTERING HALLUX VALGUS STUDY

The following section explores the repeatability of x-ray measurement of the hallux valgus and intermetatarsal angle, and assesses one observer's measurement variability within one day and between different days. The validity of those measurements is further explored by comparing the first observer's measurement, with those made by three other observers.

In many studies of the management of hallux valgus, the hallux valgus angle, measured before and after treatment, is used to describe the effect of treatment. If the magnitude of any measurement error is known, it is then possible to decide whether any alteration in the angle measured on the radiograph simply falls within the expected measurement error, or is a real change.

3.2.1 Method

As part of the larger Kettering hallux valgus study, one hundred and fifty nine to ten year old children with a clinical diagnosis of juvenile hallux valgus underwent a dorso-plantar weight bearing x-ray of both feet.

To ensure that the radiographs of the 150 subjects were comparable, a standard view was utilised. The technique described, follows the guidelines laid down by the Research committee of the American Orthopaedic Foot and Ankle Society (Smith et al 1984).

The children were asked to stand comfortably with their weight evenly balanced on both feet, the X-ray tube was directed 15° from the vertical in the dorso-plantar direction. The beam was centred on the navicular. The focal distance was 100 cm. The kilovoltage and milliamperage were set at 55 and

6.3 respectively. One radiographer took all the radiographs and strict safety precautions were observed.

Ten radiographs were selected from the bank of 150 using random number tables. Using a ruler and pencil, one observer (TEK), bisected the first and second metatarsals and then the proximal phalanx of the hallux on the radiographs (Fig. 3.2). The intermetatarsal angle and the hallux valgus angle were measured with a protractor. The pencil line bisections were then erased from the radiographs.

3.2.2 Sample size

Sample size was based upon the standard deviations and least significant difference values obtained from the first ten measurements of the right foot intermetatarsal angle:
Estimated standard deviation = 2
Least significant difference = 1.7°
The appropriate sample size was based upon the conventional 80% power at the 5% level of significance.

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	**0.20**	9	10	14	17
0.90	**0.10**	12	15	19	21
0.95	**0.05**	15	18	22	25

TABLE 3.2 Prospective Calculations of Sample Size

Study 3.2.3 The Between Day Intra-Observer Error Study.
All 10 radiographs were measured every day for three consecutive days. The charting began each day at 9.00 am. The data collected provided the between day study.

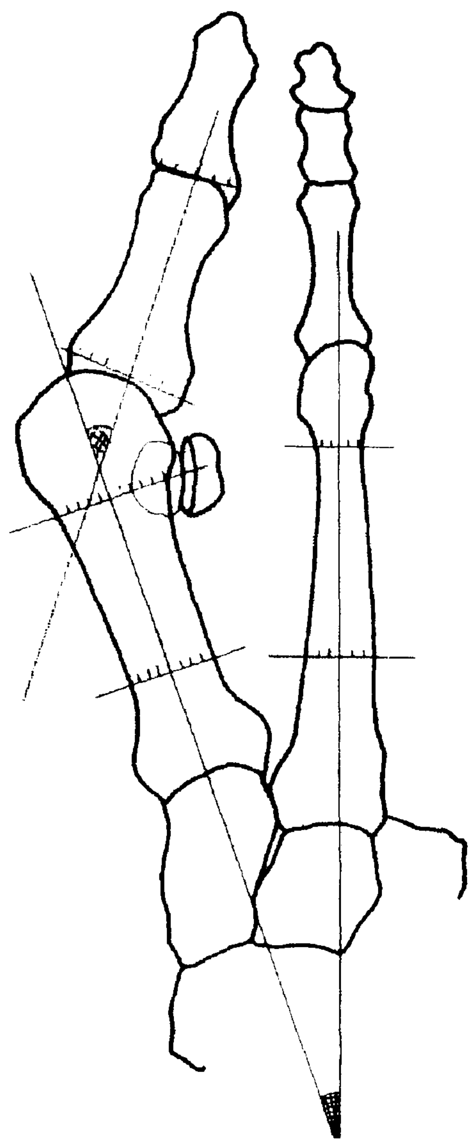


Fig 3.2 Hallux Valgus and Intermetatarsal Angle Measurement

Study 3.2.4 The Within Day Intra-Observer Error Study.

Four days after the between day study, the within day study was carried out. The x-ray measurements were performed on the same day at 9.00 am, 2.00 pm, and 11.00 pm.

In the between day and within day study, the 10 x-rays were measured in the same order at each sitting. Each sitting lasted approximately 70 minutes without any break. No reference to previous measurements was allowed.

Study 3.2.5 The Inter-Observer Error Study.

One set of measurements was randomly selected from the intra-observer between day (Study 3.2.3) and within day study (Study 3.2.4). These were compared with the measurements recorded by a Consultant Orthopaedic Surgeon (RLB). His measurements were collected in a standardised fashion though not under experimental conditions.

Two additional observers were enroled into the study. One a specialist in podiatric surgery (DRT) with 14 years experience and the second a specialist in podiatric surgery with 6 years experience (LAJ). Each was given a set of typed instructions and a verbal explanation. Standard equipment was provided.

3.2.6 Statistical Analysis.

The variability between the mean values recorded at each sitting was calculated using Repeated Measures Analysis of Variance. Post hoc Tukey's test was performed on statistically significant results.

A *least significant difference* value provided an estimate of measurement error or more precisely how much repeated measurements of the hallux valgus angle must differ before they become statistically significant. Measurement variations of a value smaller than the *least significant difference value* are not considered significant at the 0.05 level (Bland 1986, Rose 1991).

95% confidence intervals were calculated for the differences between repeated measurements in the intra-observer and inter-observer error study.

3.2.7 Results.

Table 3.2 shows the mean and standard deviation of all measurements taken during the intra and inter-observer error study with 95% confidence intervals of the difference between repeated measurements. Table 3.2.1 shows the results of Repeated Measures Analysis of Variance on the data.

Statistically significant variance occurred at just one point; between the three different observer's measurements of the left intermetatarsal angle (Table 3.2.1). Because the difference was highly statistically significant, the data was subjected to a Tukey multiple comparisons post hoc test to ensure the analysis of the repeated measures was adequately robust. The size of the difference was not great in clinical terms, as indicated by the 95% confidence interval (Fig. 3.2.1 & 3.2.2) and the fact that the standard deviation was less than 1 degree.

If just one observer performed all radiographic measurements, the *least significant difference values* indicate that if treatment was being provided or if the hallux valgus appeared to be deteriorating, the hallux valgus angle would have to alter by 2° or more before it could be confidently concluded that the position of the bones had really changed (Table.3.2.2). If more than one observer was involved the hallux valgus angle would have to change by as much as 5.3° before it could confidently concluded that a real change had occurred.

The raw data collected for this study is available in appendix 10.

	Right IM Angle°	Right HV Angle°	Left IM Angle°	Left HV Angle°
Between day Study (n = 10)				
Day 1 Mean SD	11 2	16 3.6	11 2.5	17 6
Day 2 Mean SD	11 2	16.4 3.7	11.4 2	18 5.4
Day 3 Mean SD	11.4 2	16 4	11.3 2	17.8 6
95% confidence interval	10.4 to 11.9	14.9 to 17.7	10.4 to 12	15.3 to 19.7
Within Day Study (n=10)				
Am Mean SD	10.8 2	15.4 3.7	11 2	18.5 ±5
Pm Mean SD	10.7 2	15.8 3.6	10.6 ±2	17.5 5.6
Midnight Mean SD	10.7 2	14.6 3.9	10.65 2	18.7 5.3
95% confidence interval	9.8 to 11.7	14 to 17.3	9.8 to 11.7	15.5 to 20.5
Inter-Observer Study (n=10)				
RLB Mean SD	10.75 2	16.8 4	10 2	18.5 6.5
DRT Mean SD	11 1.6	15.8 4	12 1.7	18 5.2
LAJ Mean SD	10.8 2.4	17.6 3.5	12.9 3	18.8 5.7
95% confidence interval	10 to 11.62	15.3 to 18.1	10.75 to 12.7	16.4 to 20.6

TABLE 3.2 Mean and Standard Deviation Values and 95% Confidence Intervals for Radiographic Measurements. The Intra and Inter-Observer Error Study

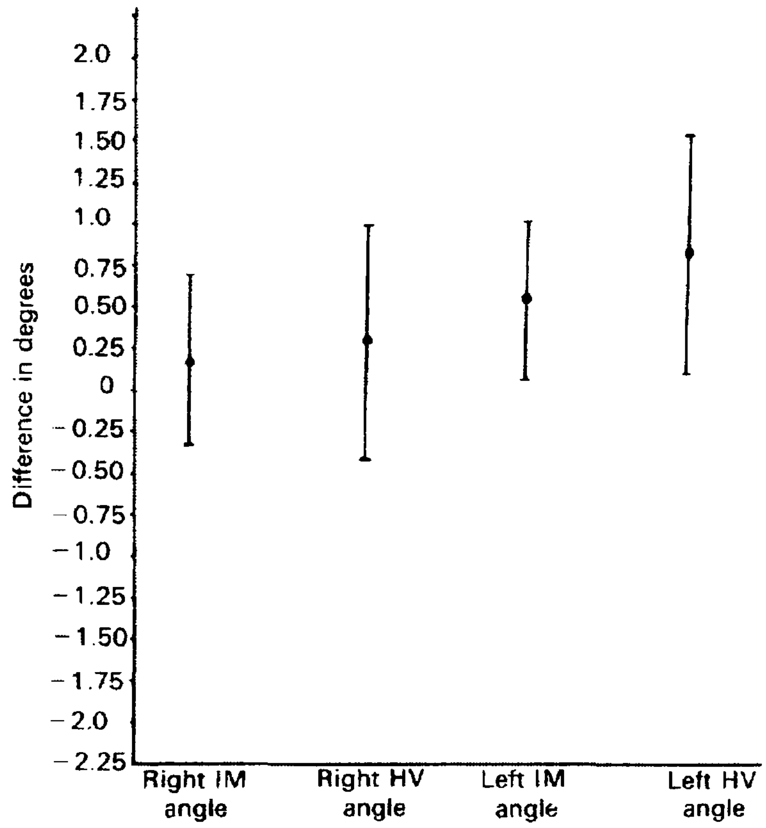


Fig. 3.2.1 Between-day study. Mean Difference between day 1 and day 2 measurements and 95% confidence intervals

Right IM Angle mean measurement difference (MMD) = 0.15° SD ±0.74, 95% confidence interval -0.4 to 0.7°.

Right HV Angle MMD = 0.25°, SD ±1, 95% confidence interval-0.5 to 0.9°.

Left IM Angle MMD = 0.57°, SD ±0.78, 95% confidence interval 0.012 to 1°.

Left HV Angle MMD = 0.85°, SD ±0.94, 95% confidence interval 0.17 to 1.5° ($p<0.05$).

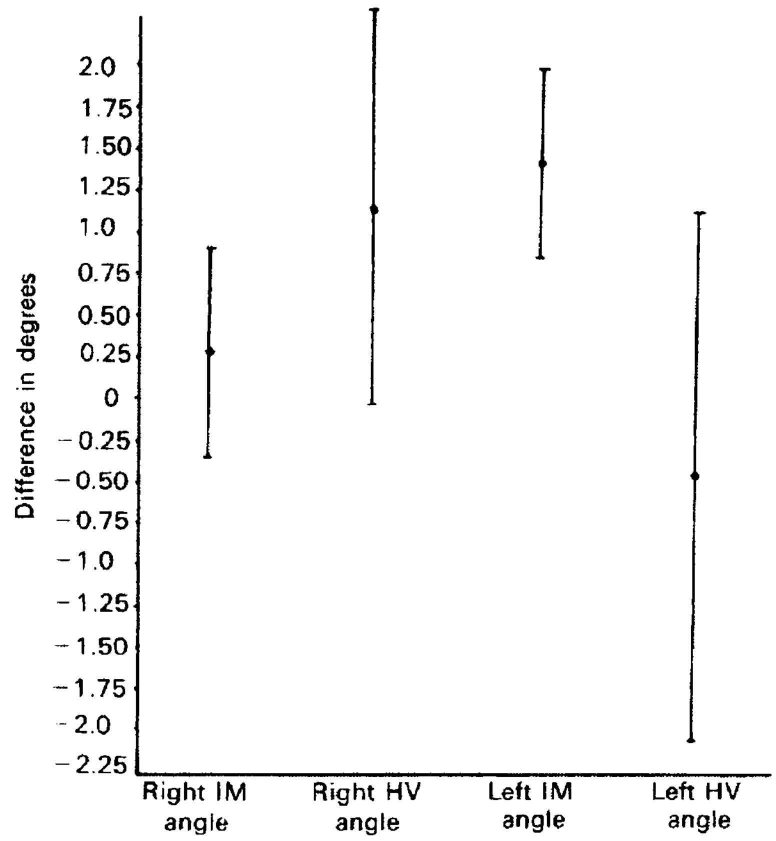


Fig. 3.2.2 Inter-observer error study. Mean difference between RLB and TEK measurements and 95% confidence intervals

Right IM angle MMD between observers = 0.17°, SD ±0.92, 95% confidence interval = -0.5 to 0.8°.
Right HV angle MMD = 1.1°, SD ±1.87, 95% confidence interval = -0.2 to 2.4°
Left IM angle MMD = 1.2°, SD ±0.78, 95% confidence interval = 0.6 to 1.75°, ($p<0.001$)
Left HV angle MMD = -0.6°, SD ±2.38, 95% confidence interval -2.3 to 1.1°.

	Right IM Angle	Right HV Angle	Left IM Angle	Left HV Angle
Between Day Study (n= 10)				
F value	1.84	0.18	0.53	0.95
P value	0.187	0.83	0.59	0.40
Statistical significance	NS	NS	NS	NS
Within Day Study (n=10)				
F value	0.016	1.92	0.82	1.33
P value	0.98	0.17	0.45	0.28
Statistical significance	NS	NS	NS	NS
Inter-Observer Error Study (n=10)				
F value	0.10	1.6	14.8	0.3
P value	0.9	0.2	0.0002	0.7
Statistical significance	NS	NS	Highly Significant	NS

TABLE 3.2.1 Radiographic Measurement Differences in the Intra and Inter-Observer Error Study. Repeated Measures Analysis of Variance with Tukey Multiple comparisons Post Hoc Test where Statistical Significance detected

	Right IM Angle°	Right HV Angle°	Left IM Angle °	Left HV Angle°
Between Day Study (n =10)				
Day1 vs Day 2	1.7	2.0	1.8	2.0
Day 1 vs Day 3	1.0	3.0	2.0	2.0
Day 2 vs Day 3	1.5	2.0	1.0	2.6
Mean Value	1.45	2.6	1.78	2.37
SD	0.25	0.4	0.5	0.23
Within Day Study (n=10)				
Am vs Pm	2.0	2.5	2.6	2.5
Pm vs Midnight	2.3	1.8	1.0	3.0
Am vs Midnight	2.0	1.5	2.0	2.0
Mean Value	2.18	1.94	2.02	2.66
SD	0.16	0.5	0.7	0.44
Inter-Observer Study (n=10)				
TEK vs RLB	2.0	4.0	1.0	5.3
TEK vs DRT	2.9	7.7	3.8	2.9
RLB vs DRT	3.0	6.5	4.0	5.6
TEK vs LAJ	2.7	6.5	4.1	5.6
RLB vs LAJ	3.0	5.0	6.0	7.6
DRT vs LAJ	4.0	3.9	4.0	4.7
Mean Value	3.07	5.29	3.98	5.1
SD	0.67	1.52	1.56	1.5

TABLE 3.2.2 Least Significant Difference Values in Degrees in the Intra and Inter-Observer Error Study

3.2.8 Discussion

The within day study performed by a single observer produced the least variability between the mean values recorded at each measurement session. Fatigue and boredom over the seventy minute period did not seem to adversely affect repeatability.

The finding that measurements taken by one observer are considerably more repeatable than those taken by several different observers compliments the results of a number of clinical investigations of goniometric repeatability in joint measurement (Low 1976, Boone et al 1978, Elveru et al 1988).

While the F values recorded any statistically significant difference between observers or observations, of much greater clinical value is the *least significant difference value*. In units of clinical measurement it represents the real response to treatment after measurement error has been eliminated.

In applying the results of this experiment to the main study of the effect of a biomechanical orthosis on hallux valgus, it is obvious that the lowest possible *least significant difference value* is the most desirable, whether the value is acceptable depends on the magnitude of the difference being recorded for the treated and control groups. A change in bony position producing values less than the *least significant difference value* must be treated with some caution and may even indicate that a more refined measurement technique should be adopted. Although a measurement error of 2° may seem small, it must be set against the fact that some of the angles measured were no greater than 10°. In this study of 10 subjects the mean hallux valgus angle was 17° (SD 4.2) for the right foot and 18° (SD 6.5) for the left foot with an I.M. angle of 11° (SD 2.1) for both feet.

The measurement technique used in this study, though convenient, is far from refined. The degree markings on a protractor are up to 1/3 of a millimetre wide. The millimetre spaces between the increment marks, require the observer to estimate when bisection lines fall between the protractor markings. Reading the protractor thus provides considerable room for variation. Whether this was a source of greater variation than the actual placing of the bisection lines, was not determined.

3.2.9 Conclusion

The most variable sections of the intra-observer error study show that when reproducibility is poor, as it is in the measurement of left foot hallux valgus angles, only values in excess of 2° should be accepted as a real clinical difference. Elsewhere smaller values are acceptable.

The variation occurring between a number of observers is so large, that valid comparison of measurements made by different observers is not possible. In both the clinical and scientific analysis of hallux valgus treatment, pre and post treatment x-ray angles should not be compared unless drawn and measured by just one observer. In the following trial of a Root orthosis, x-rays were taken before and after three years of treatment. Just one observer (RLB), performed all the radiographic measurements.

3.3 THE KETTERING HALLUX VALGUS STUDY DESIGN

3.3.1 Method of Randomisation

Of the 150 children having radiographs, 122 (2% of the number screened) were found to have hallux valgus of one or both feet. Those children were then randomised into a treatment group and a control group using the following sequence:

Subject Number	Group
1	Treatment
2	Treatment
3	Control
4	Control
5	Treatment
6	Treatment
7	Control
8	Control
etc.	

Table 3.3.1 Randomisation of the Study subjects into Control and Study Groups

The treatment group children underwent a biomechanical examination and were prescribed an in-shoe biomechanical orthosis. In recruiting the children for the study the following causes of potential bias were accounted for:

3.3.2 Appropriateness of Population Sample

To ensure the most representative sample, two screening sessions separated by at least one week were organised for every school in Kettering Health Authority. Loss of subjects through absence from school was thus minimised. Parental consent was obtained prior to screening.

If hallux valgus was suspected on screening, the examining chiropodist explained that a follow-up appointment would be sent. If the child failed to attend, a second appointment was arranged and where possible the parents were also telephoned to inform them of why further investigation was necessary. Seven children were lost to follow up at this stage.

ii. Randomisation Bias

The same clinician who decided eligibility for the trial also provided the treatment for the study group. The possibility exists that children with more severe hallux valgus may have been systematically chosen for the study group. Strict adherence to the pre-determined randomisation sequence ensured such a bias did not occur.

3.3.3 Confounding Factors relating to Outcome

A confounding factor is a variable in the study design which has an effect on the outcome of the study, but which is not related to the treatment being studied.

The following confounding factors were identified and allowed for by a process of exclusion, stratification or documentation.

i. Systemic neurological, connective tissue or polyarticular disease.

One child with right foot hallux valgus was excluded from the study because of polio, this manifested clinically as a flexion deformity of her left hip and knee. No other exclusions were made on the basis of systemic pathology.

ii. Poor fitting, pointed or high heeled footwear.

A pilot study on the role of footwear in juvenile hallux valgus was planned. The control and study group subjects were to be subdivided so half the subjects in each group could be sold fitted start-rite lace up shoes with low (less than 12mm) heels and a round toe box.

After fitting these shoes to just six children the pilot was abandoned. The children were unhappy with the shoe style which immediately brought into question their likely compliance. Factory reject shoes were supplied by Start-rite as it was believed that cheaper shoes would provide incentive to the parents to comply with the study. Unfortunately while most of the shoes were not far off shop sold standard, others were very much substandard with absent insocks, faulty finishing and poor placement of the upper on the sole. This immediately presented another highly variable confounding factor.

Contamination of the fitted footwear study group and the control group also occurred as parents, now more informed of their children's foot health, voluntarily provided well fitting foot shaped shoes for their children. The footwear fashions of the late 1980's also played a role, with the study population universally adopting low-heeled, foot shaped shoes or above ankle training shoes. Thus the only real difference between the fitted footwear group and the so called control group was that the latter were arguably better shod.

In order to avoid such contamination it would have been necessary to provide badly fitting, high heeled, pointed toed footwear. Although there is no scientific evidence to suggest that this action would be harmful, it would probably be unethical and it is unlikely that parental consent would have been forthcoming.

This arm of the research project was abandoned and plans were made to stratify the children with poor fitting, pointed or high heeled shoes. In the event this was not necessary as extensive documentation relating to the three footwear parameters of fit, toe box and heel height revealed that no child wore poor fitting or high heeled shoes (greater than 15mm). Pointed shoes were more common with a small number of children wearing pointed lace up shoes as supplied by Clarks Ltd. Clarks shoes claim that this particular shoe design could not harm the foot as the shoe only begins to incurve at a point distal to the terminal phalanx of the hallux.

In 1989 all the hallux valgus study children possessed on average three pairs of shoes (range one to five pairs). Almost all children wore training shoes during out of school hours.

iii. Additional Treatment

The possibility of treatment as a confounding factor was accounted for by documentation.

- Two of the study group females underwent a successful partial nail avulsion and phenol cauterisation for bilateral involuted nails.
- One study group female received several applications of a caustic chemical for symptomatic plantar verrucae which subsequently regressed.
- One control group male who complained of painful ankles was radiologically diagnosed as having bilateral calcaneo-navicular bars, no treatment was given.
- One control group female complained of nocturnal leg pains of a diffuse and non-specific nature, these resolved after a four week programme of hamstring stretching exercises were prescribed.

- No subject received any form of bone surgery to the lower extremity.
- None of the control group were prescribed or issued any form of in-shoe orthoses.

None of the additional treatments were considered to be real confounding factors.

iv. Obesity

All subjects were weighed and measured on entering the study and then again at their three year follow up. On neither occasion did any subjects height or weight fall beyond the normal limits of the growth assessment charts prepared by Tanner and Whitehouse (1987).

v. Imbalanced sex ratio

From the beginning of the study many more girls than boys were being referred and recruited into the trial. Of the 122 subjects randomised, nine of the 16 boys were allocated to the control group and seven to the study group.

vi. Poor compliance with orthotic treatment

For this study it was documented at every follow up appointment whether:

i. The orthoses were being worn in the shoes

ii. Whether the characteristic signs of in-sock damage were present. This damage is caused by the sharp anterior edge of the orthotic and the compressive force of the rearfoot post. An orthosis made from rohadur, that is regularly worn, will also demonstrate a speckling of the orthotic plate.

Such an assessment could not however discriminate between regular and constant wear, which for the purposes of this study was the preferred level of compliance. In an attempt to discern just how regularly the orthoses were being used each patient was asked the following questions:

Do you wear the orthoses?	Compliance Rating
• All the time	Very good
• All day at school	Good
• In the evenings and weekends	Fair
• Just at the weekends	Poor
• Only occasionally	Non - compliant

TABLE 3.3.2 Compliance Rating for use of the Orthoses

Compliance was then classified according to the ordinal scale shown above.

In order to determine whether social class could have any bearing on compliance the occupation of each child's head of the household was recorded. This was then classified according to the HMSO index of occupations (1971 and 1981).

vii. Subjects entering the trial with different degrees of hallux valgus

Hallux valgus is a progressive condition. The condition appears to deteriorate quite slowly at first until it reaches the so called critical angle where the hallux abuts the second toe and the problem begins to progress more rapidly (Hardy & Clapham 1951). Children entering the study with more advanced hallux valgus probably face a worse prognosis than children with less severe deformity. In order to determine the significance of this possible confounding factor, part of the statistical analysis involved stratifying the subjects according to the degree of their hallux valgus deformity on entering the study and analysing the outcome on that basis.

3.3.4 Location of Follow-up Clinics

The follow-up clinics were held in local Health centres in Kettering, Wellingborough, Rushden and Corby, Northamptonshire. The radiological examinations were all held at Kettering General Hospital. The treatment group children were seen every 6 months by the author. Orthotic fit, toleration and compliance were checked and the first metatarsophalangeal joint angle measured with a finger goniometer. After three years of treatment the radiological examination was repeated. The control group children were seen at the beginning of the study and at the end just prior to their second x-ray. At their final visit, the children in the control group were specifically questioned about any advice or treatment they had been given for their hallux valgus by clinicians not involved in the trial.

3.3.5 Follow-up Clinic Non-Attendance

Follow-up clinic defaulters were sent two further appointments. If they still did not attend the parents were telephoned to discuss their reasons for defaulting.

Study group subjects lost to follow-up were asked to attend for radiological examination at the end of the three year study period. If loss to follow-up occurred within six months of their first consultation their radiographic measurements were treated as control group data. All other losses to follow-up were documented but excluded from the data analysis.

3.3.6 Patient Information and Consent

At the first consultation, after referral from the screening programme, it was explained to all parents and children that the screening chiropodist had referred them because of "signs of bunion development".

If the children were free of neurological, connective tissue, systemic or articular disease they were randomised into the control or study group. Information and consent forms were read to the patient, these were worded slightly differently for the control and study group (See Appendix 11).

Table 3.3.3 shows the subsequent procedure for both study and control group subjects.

STUDY GROUP n = 62	CONTROL GROUP n = 60
First consultation less than 4 weeks after screening . Clinical examination: MTP joint angle measured, medical history and family history of hallux valgus documented, height and weight recorded, patient randomised and information sheet read. Consent form signed. Radiological examination ordered. Shoe type and fitting documented.	
Advised on nature of treatment. Biomechanical evaluation and casting appointment booked not more than three weeks later.	Full biomechanical evaluation performed.
Functional orthoses prescribed Orthoses issued and fitted into shoes. Four week follow up. Compliance assessed.	
Six month follow up. MTP joint angle measured. Compliance and orthotic fit assessed and documented.	
Six month follow up continued until the end of the trial	
Final follow up for all subjects. MTP joint angle measured. Footwear type and fitting documented. Patients weight and height recorded. Radiological examination for all subjects organised.	

Table 3.3.3 The Conservative treatment of Hallux Valgus, Patient Follow up (n= 122)

3.3.7 The Orthosis Prescription for the Children in the Treatment Group

On entering the trial each child's subtalar joint neutral position and forefoot to rearfoot angle was assessed using the methods described in Section 2.2, no child presented with subtalar joint valgus. Those with a subtalar joint neutral position of six degrees or greater were prescribed a six degree rearfoot varus post. All values up to six degrees were posted accordingly.

A plaster of paris cast was taken of both feet with the subtalar joint in neutral, the ankle gently dorsiflexed and the midtarsal joint maximally pronated. The technician was then directed to wedge the forefoot of the cast with the so called intrinsic forefoot post which would be angled sufficiently to hold the rearfoot of the positive cast in its prescribed inverted position (Anthony 1991). The finished orthosis would thus prevent excessive pronation of the foot.

3.3.8 Rules for discontinuing the Study

If at the end of the three year study there was a significant difference between the hallux valgus angles of the control and study group children, it was planned to stop the trial and either provide orthotic care for all subjects or withdraw orthotic care. The decision would be made according to the response of the study group.

3.3.9 Outcomes to be studied

- ❑ Change in the first metatarsophalangeal joint angle.
- ❑ Change in the first to second intermetatarsal angle.

The metatarsophalangeal joint angle was measured on all radiographs between lines bisecting the first metatarsal and the proximal phalanx of the hallux. The Intermetatarsal angle was also measured between lines bisecting the first and second metatarsal. All measurements were made by one observer (RLB) who did not know which children had received treatment.

3.3.10 Ethical and Data Protection Issues

The study protocol was given ethical committee approval by Kettering General Hospital Ethical Committee.

No patient entered the trial without signing the consent form approved by the Ethical Committee. All documentation was restricted to medical records though a short hand version was entered into the study organisers index card system. For the computing aspects of the study all subjects were recorded as numbers, except for the follow-up appointment database where name, address, and date of last and next appointment were recorded.

3.3.11 Sample Size

A study sample size is only adequate when it ensures that a true difference of clinical importance can be detected. In this case the magnitude of such a clinically important difference was based largely upon the known measurement error. The method of evaluating the study outcome introduced measurement error, the magnitude of which has already been calculated in Section 3.2. Any difference between control and study group had to be in excess of the error recorded in the between day intra-observer error study on radiographic measurement of hallux valgus. Using Gore & Altman's (1989) sample size nomogram (Appendix 8), the standardised difference of 3.94 which was based on the mean radiographic measurement error and its standard deviation, meant that our sample size of 122 subjects easily surpassed the recommended 85% power at the 0.001 level. The risk of incurring a type II statistical error was thus a small one [1]. Sample size was calculated retrospectively because no previous study had determined the

[1]A type II statistical error relates to the probability of accepting a Null Hypothesis when it is, in fact, invalid. A type I error relates to wrongful rejection of the Null Hypothesis. Increasing the sample size reduces both type I and type II errors.

rate of progression of juvenile hallux valgus so it was not possible to calculate sample size on the known clinical deterioration of hallux valgus with and without treatment. A pilot study would have taken three to four years to complete

3.3.12 Statistical Analysis

The mean first-second intermetatarsal angle and first metatarsophalangeal joint angle was calculated for the treatment and control groups on entry into the trial and at the end of the trial. The difference was then subjected to a x^2 goodness of fit test which determined normal distribution. The statistical significance of the difference was calculated using a paired t test. The 95% confidence interval of the change was also determined.

In children with bilateral hallux valgus, left and right feet were initially analyzed independently, in children with hallux valgus of just one foot, the affected and unaffected foot were also initially analyzed separately.

Because of the possible confounding effect of children beginning the trial with different degrees of hallux valgus, the subjects were stratified into three groups and the change in the hallux valgus angle of the study and control group analysed with a t test for independent samples.

4. THE KETTERING HALLUX VALGUS STUDY.

Results and Analysis

Twenty nine children were lost to follow up, 12 (1 male) from the study group and 17 (1 male) from the control group.

Mean hallux valgus angles deteriorated in all groups, while intermetatarsal angles remained quite static (Fig. 4.1 to 4.3, Table 4.3 and Table 4.4). The 95% confidence intervals indicate that the deterioration was greater in children treated with a Root foot orthosis (Table 4.3 and 4.4). The null hypothesis stated in section 1.5.2 that a Root foot orthosis will not prevent the deterioration of juvenile hallux valgus was accepted.

Statistically significant deterioration was only seen in the unaffected feet of the unilateral hallux valgus children (Table 4.4). Before the trial this group's mean first metatarsophalangeal joint angle was less than 12°. Three years later the mean first metatarsophalangeal joint angle was greater than 15° in both the control and treatment group.

The results are also presented in cumulative frequency graphs in order to give a better visual perception of the individual children's response to treatment (Fig. 4.2 to 4.7). When right and left feet were combined for statistical analysis, the control group showed statistically significant deterioration of the first metatarsophalangeal joint angle ($p<0.05$, Fig. 4.1. and 4.2). In the treatment group the deterioration in the first metatarsophalangeal joint angle was highly statistically significant ($p<0.001$, Fig. 4.1. and 4.2).

95% confidence intervals for hallux valgus angle deterioration when right and left feet were combined indicated 1° to 2.6° deterioration in the control group and 1.3° to 3.4° deterioration in the study group.

The raw data for this study is available in Appendix 5.

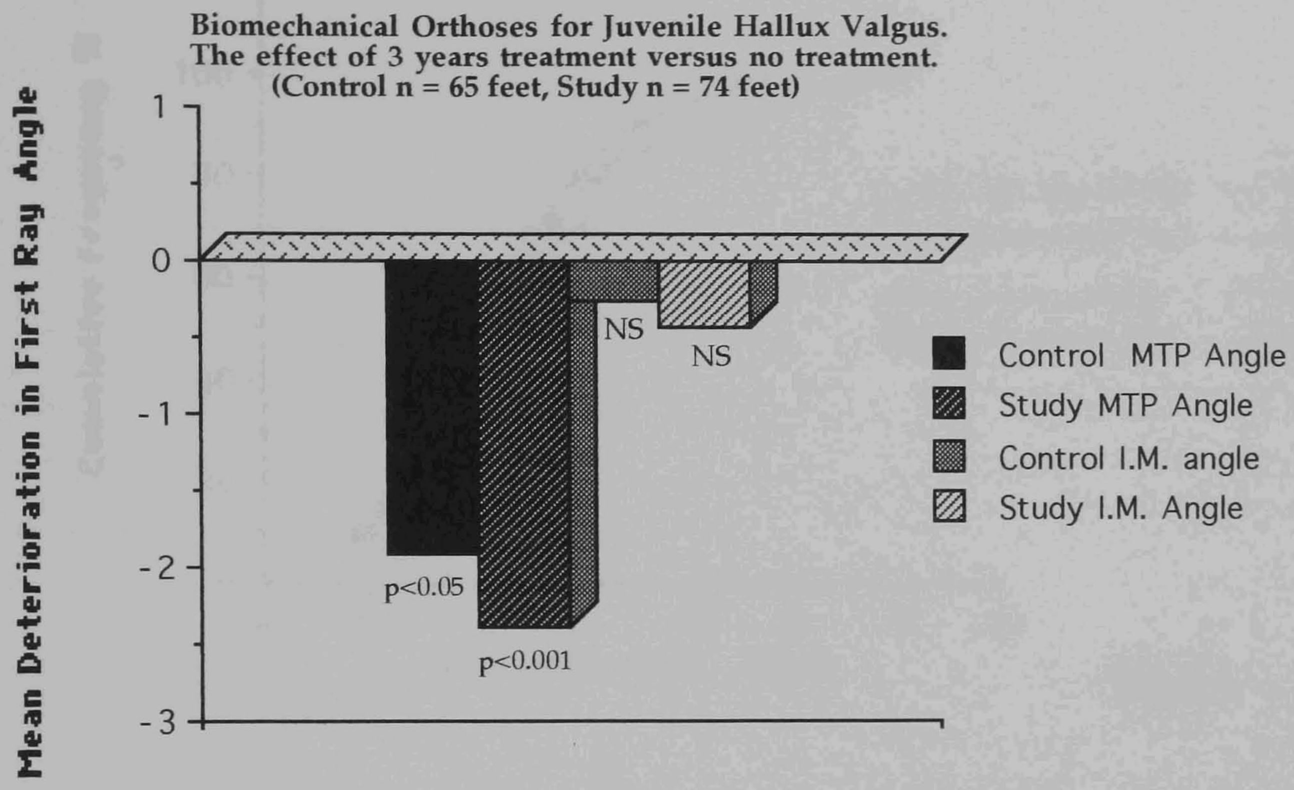

Biomechanical Orthoses for Juvenile Hallux Valgus.
The effect of 3 years treatment versus no treatment.
(Control n = 65 feet, Study n = 74 feet)
Mean Deterioration in First Ray Angle
1
0
-1
-2
-3
NS
NS
p<0.05
p<0.001
Control MTP Angle
Study MTP Angle
Control I.M. angle
Study I.M. Angle

Fig. 4.1

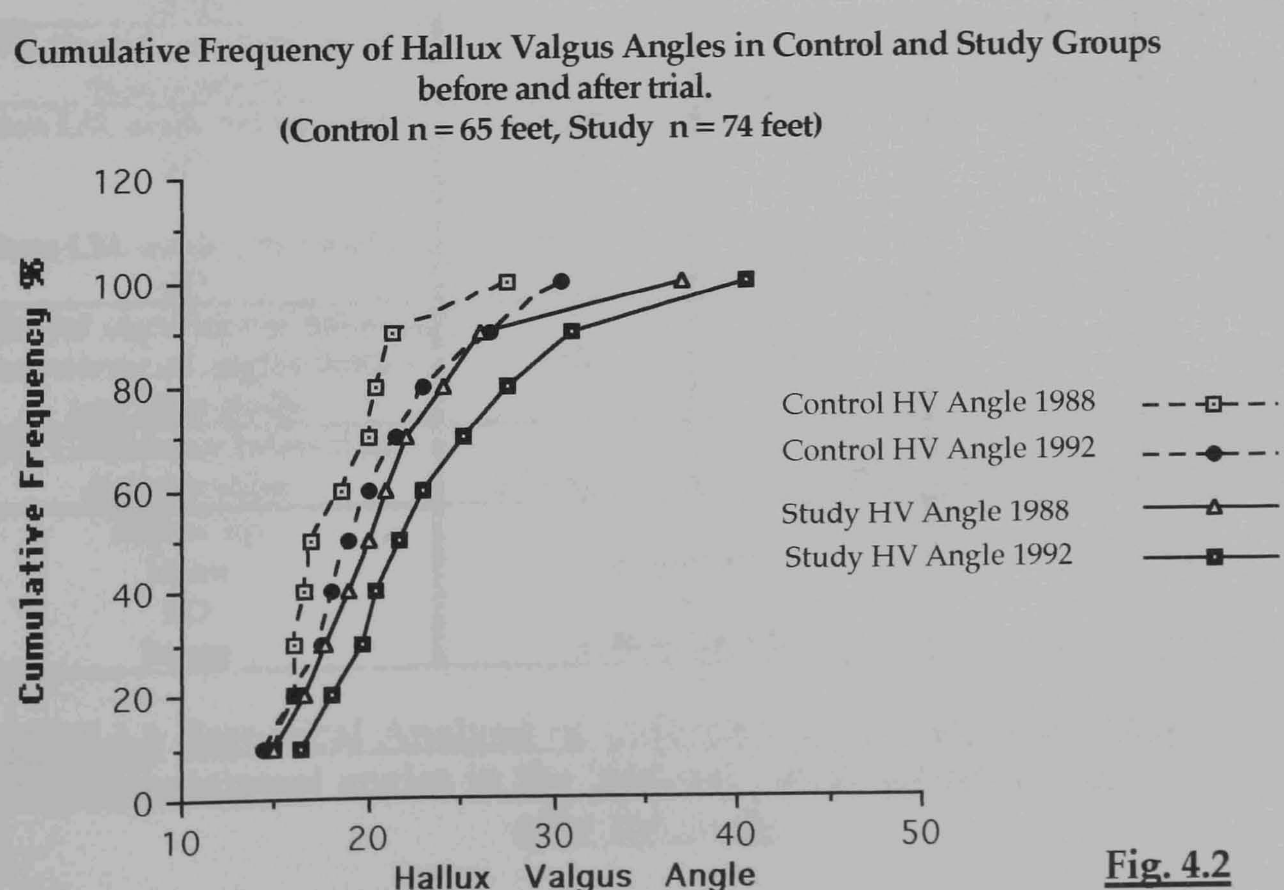
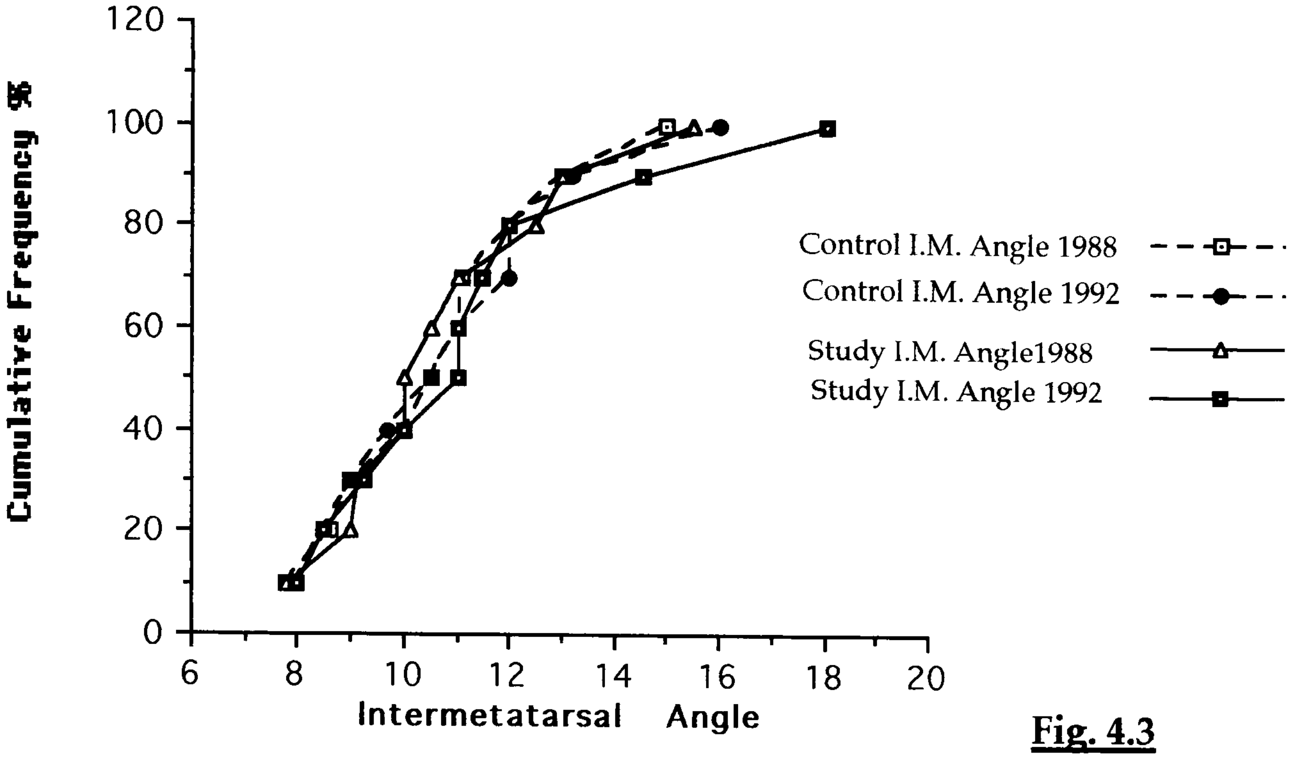

Cumulative Frequency of Hallux Valgus Angles in Control and Study Groups
before and after trial.
(Control n = 65 feet, Study n = 74 feet)
Cumulative Frequency %
120
100
80
60
40
20
0
10
20
30
40
50
Hallux Valgus Angle
Control HV Angle 1988
Control HV Angle 1992
Study HV Angle 1988
Study HV Angle 1992

Fig. 4.2

Cumulative Frequency of Intermetatarsal Angles In Control
and Study Groups before and after trial
(Control n = 65 feet, Study n = 74 feet)



<u>**Fig. 4.3**</u>

	Study Group n = 24		Control Group n= 22	
	Left	Right	Left	Right
Mean MTP angle before study	21°	21.07°	18.22°	18°
SD	4.18	5	3.6	2.3
Mean MTP angle after study	23.5°	22.8°	19.13°	19.85°
SD	6	6	4.3	4.6
Statistical significance between MTP angles before and after study	NS	NS	NS	NS
95% Confidence Interval of deterioration	2 to 5.3°	0.48 to 2.9°	-0.31 to 2°	0.5 to 4°
Mean I.M. angle before study	10.44°	10.9°	10.27°	10.63°
SD	2.2	1.9	1.68	1.98
Mean I.M. angle after study	10.73°	10.79°	10.28°	10.44°
SD	3.1	2.2	2.2	2.1
Statistical significance between Intermetatarsal angles before and after study	NS	NS	NS	NS
95% Confidence Interval of deterioration	-0.56 to 1.2°	-1 to 0.93°	-0.73 to 0.75°	-0.8 to 0.4°
Follow up				
Mean	37 months		38 months	
SD	4		3.1	
Range	32 to 42 months		34 to 47 months	

<u>**TABLE 4.3** Statistical Analysis of difference in Metatarsophalangeal joint and Intermetatarsal angles in the bilateral hallux valgus group before and after the study.</u>

	Study Group n = 26		Control Group n= 21	
	Affected foot	Unaffected	Affected foot	Unaffected
Mean MTP angle before study	18.96°	10.9°	17.88°	11.85°
SD	3.7	4.9	2	1.97
Mean MTP angle after study	21.84°	15.7°	20.35°	15.85°
SD	5.64	6.9	4.6	4.7
Statistical significance between MTP angles before and after study	NS	$p<0.05$	NS	$p<0.001$
95% Confidence Interval of deterioration	0.66 to 5.0°	2 to 6.6°	0.42 to 4.5°	1.82 to 5°
Mean I.M. angle before study	9.74°	8.78°	10.25°	9.64°
SD	1.87	1.58	1.96	1.89
Mean I.M. angle after study	10.8°	9.72°	10.98°	9.89°
SD	2	2.2	2.3	1.96
Statistical significance between Intermetatarsal angles before and after study	NS	NS	NS	NS
95% Confidence Interval of deterioration	0.46 to 1.66°	0.17 to 1.62°	0.11 to 1.35°	-0.66 to 1.2°
Follow up				
Mean	39 months		39 months	
SD	4.6		5	
Range	33 to 52 months		35 to 56 months	

TABLE 4.4. Statistical Analysis of difference in Metatarsophalangeal joint and Intermetatarsal angles in the unilateral hallux valgus group before and after the study

Cumulative Frequency of Hallux Valgus Angles in the affected foot of the Unilateral Hallux Valgus Control and Study Groups. (Control n = 21 feet, Study n = 26 feet)

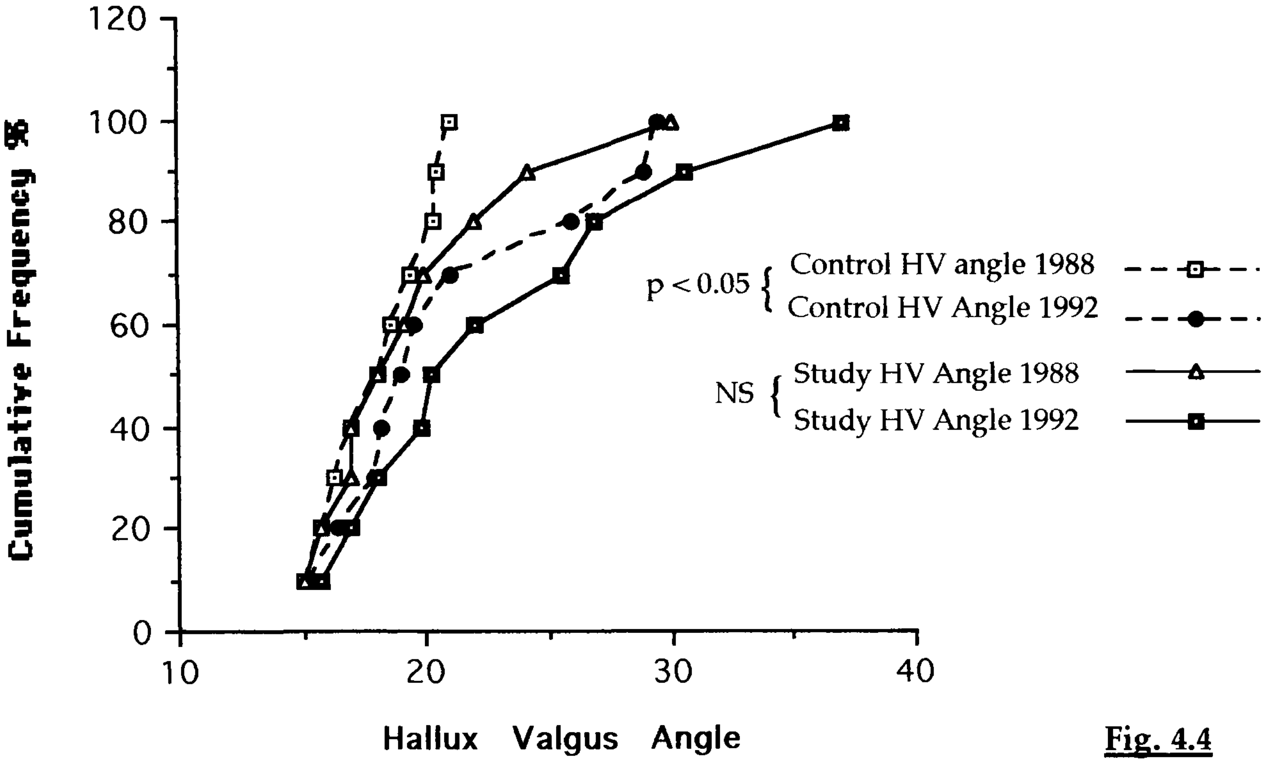


Fig. 4.4

Cumulative Frequency of Hallux Valgus Angles in the unaffected foot of the Unilateral Hallux Valgus Control and Study Groups. (Control n = 21 feet, Study n = 26 feet)

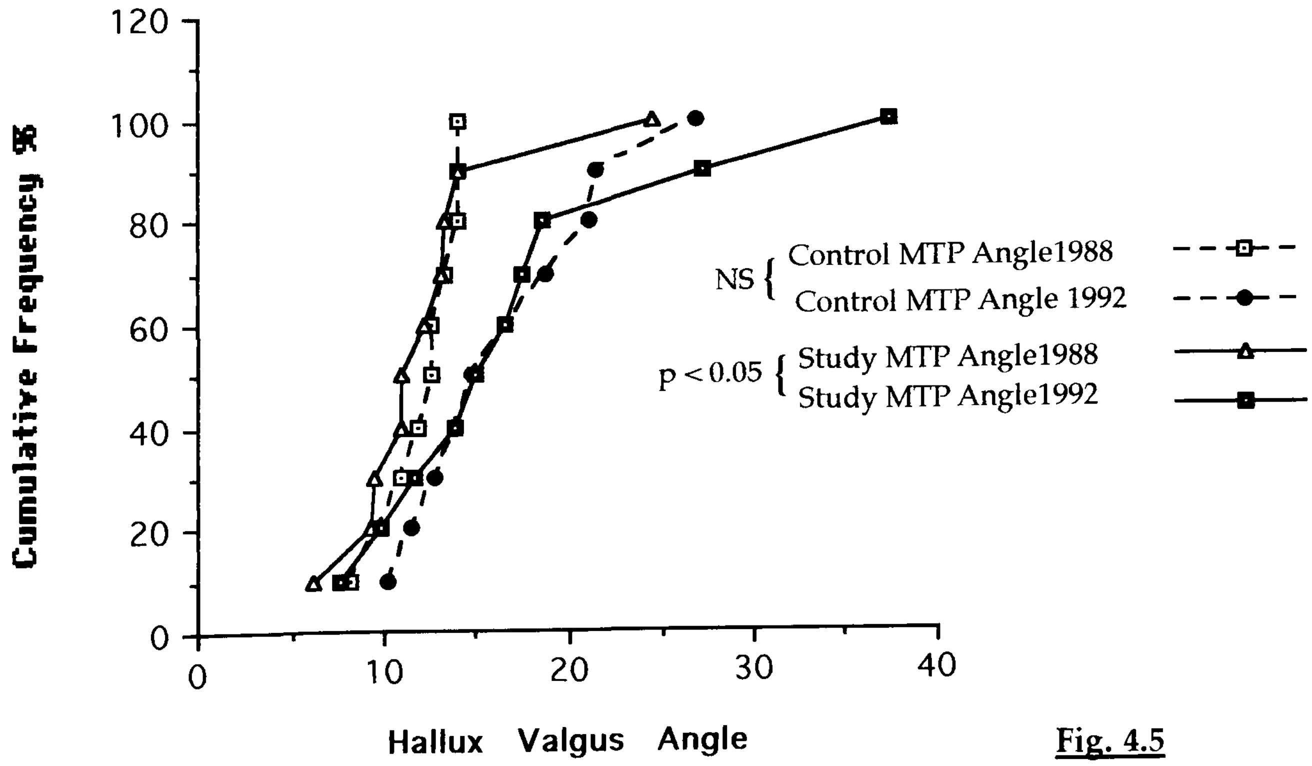


Fig. 4.5

Cumulative Frequency of Intermetatarsal Angles in the Affected feet of the Unilateral Hallux Valgus group before and after the trial. (Control n = 21 feet, Study n= 26 feet)

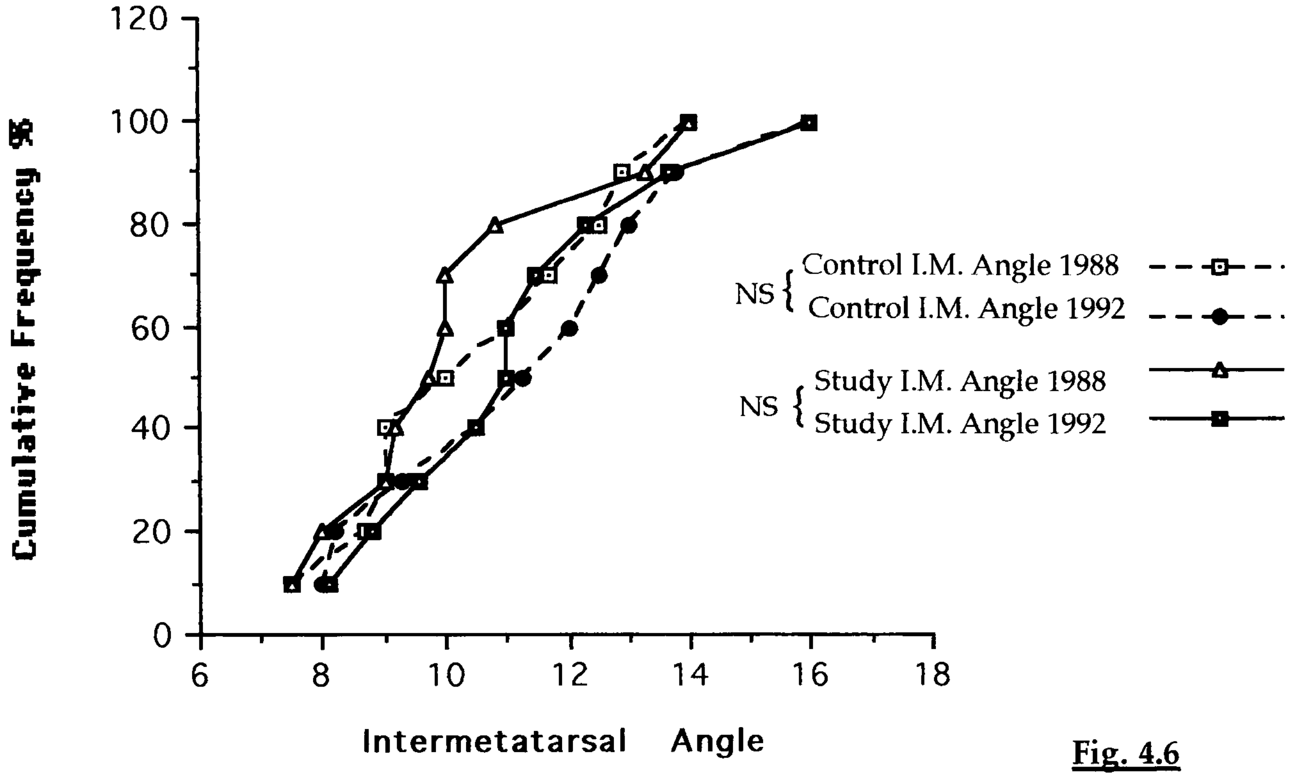


Fig. 4.6

Cumulative Frequency of Intermetatarsal Angles in the Unaffected feet of the Unilateral Hallux Valgus group before and after the trial (Control n = 21 feet, Study n = 26 feet)

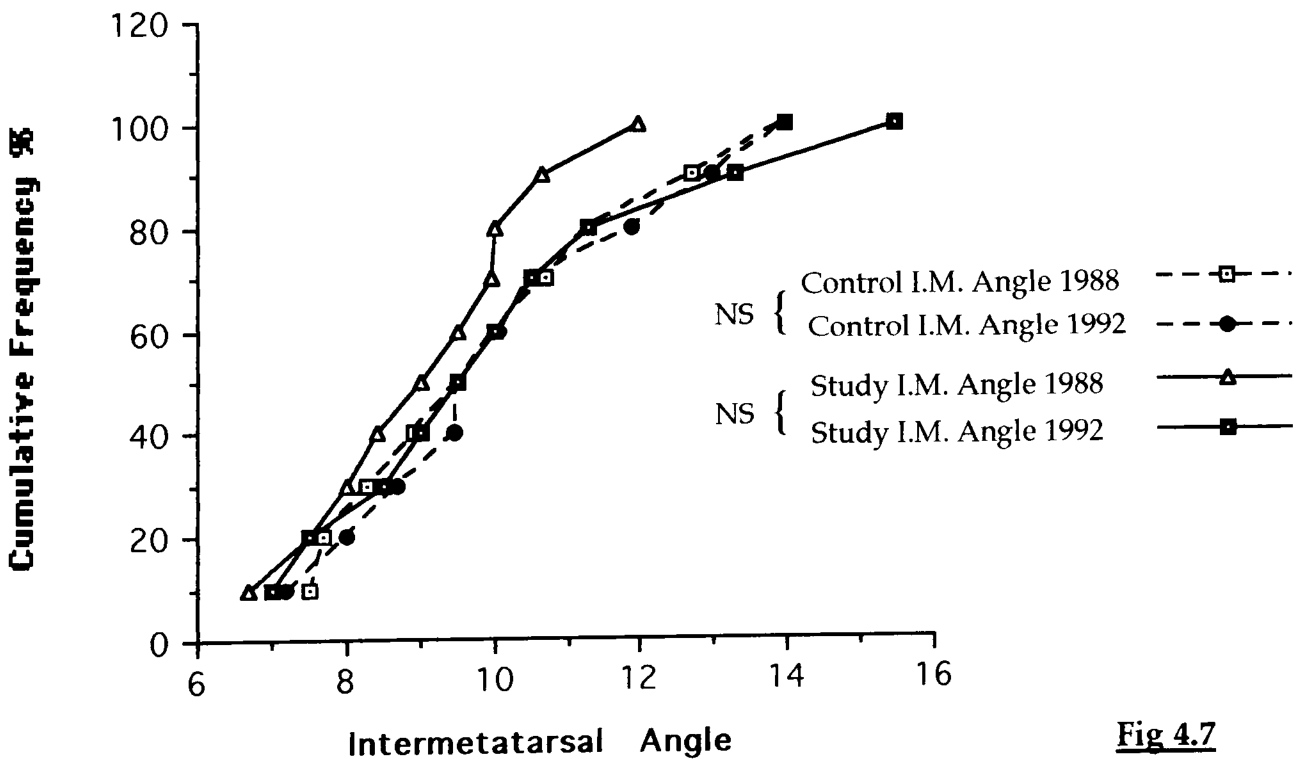


Fig 4.7

While in the majority of the trial subjects the hallux valgus and intermetatarsal angles deteriorated, in some cases the condition remained static or improved (Fig. 4.8 to 4.11).

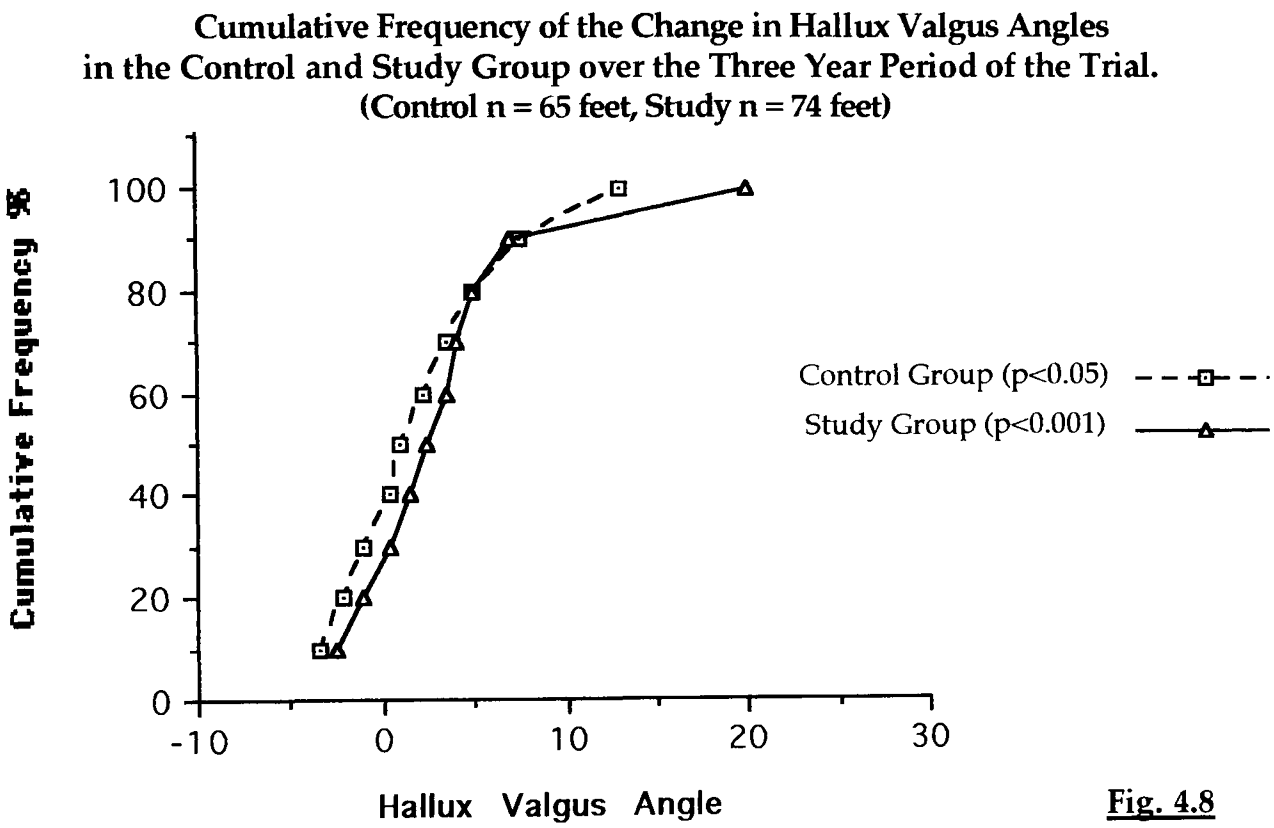


Fig. 4.8

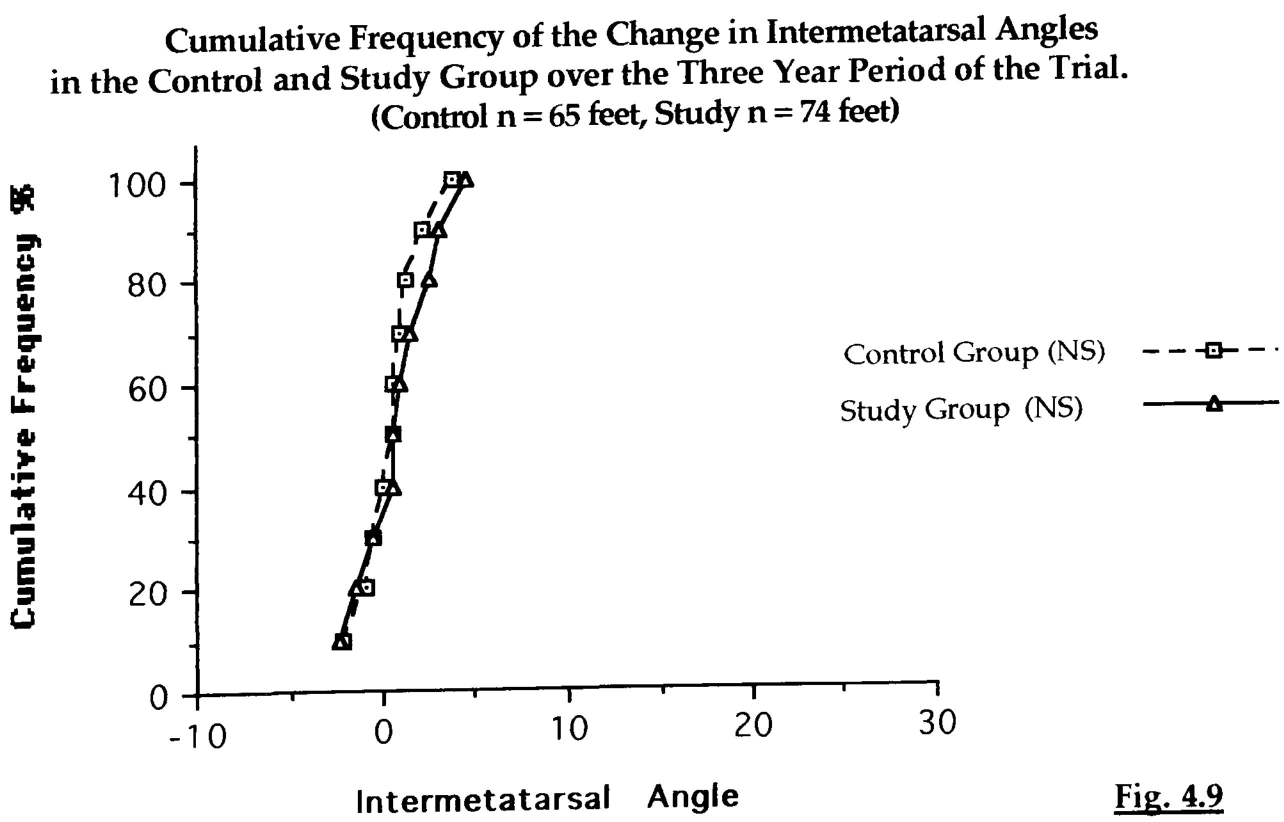


Fig. 4.9

Cumulative Frequency of the Change in Hallux Valgus Angles in the Affected Foot of the Unilateral Hallux Valgus Control and Study Groups.
(Control n = 21 feet, Study n = 26 feet)

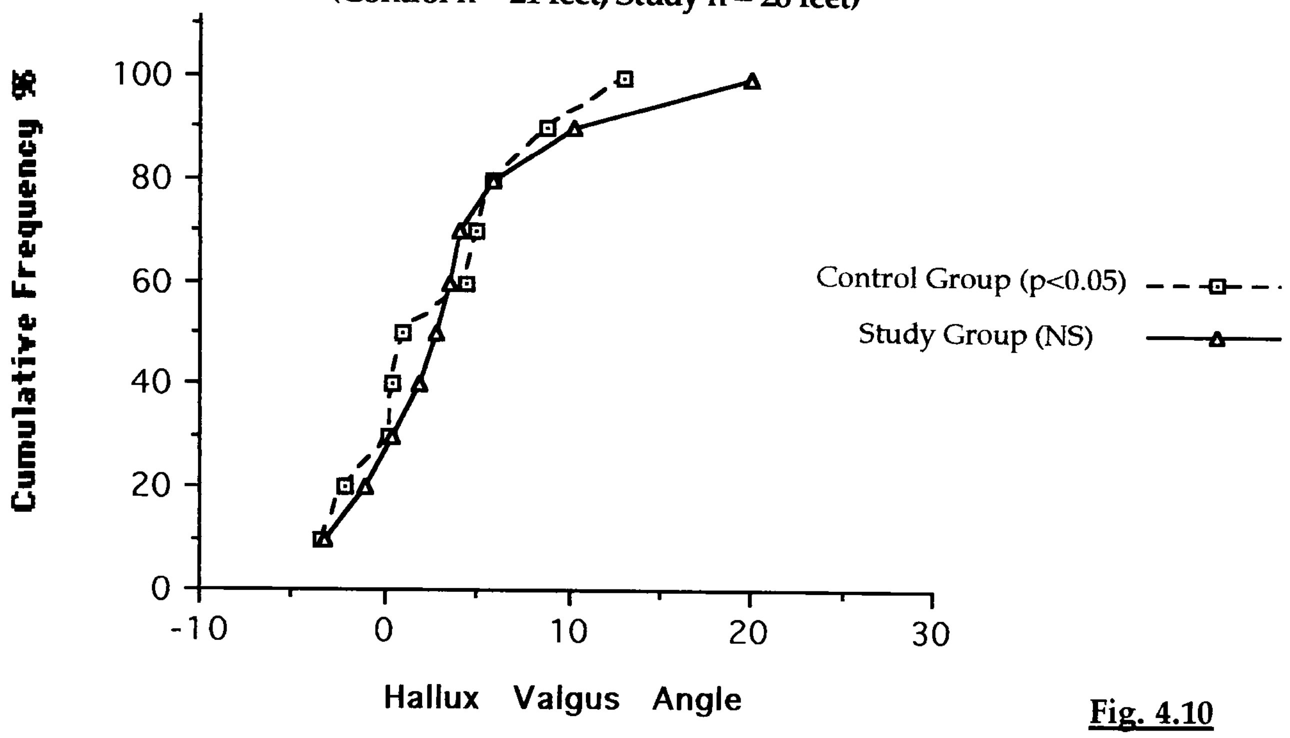


Fig. 4.10

Cumulative Frequency of Change in Hallux Valgus Angles in the Unaffected Foot of the Unilateral Hallux Valgus Control and Study Group.
(Control n = 21 feet, Study n = 26 feet)

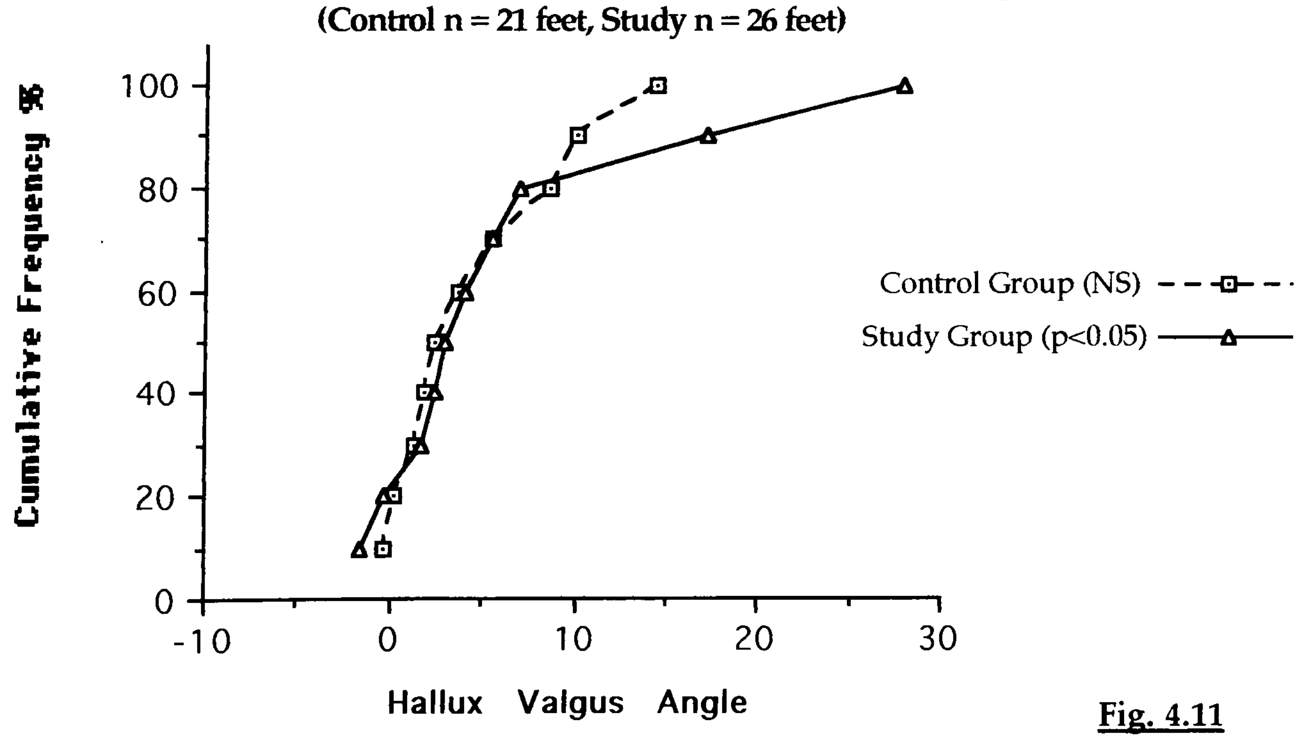


Fig. 4.11

4.1 Analysis of Stratified Data

The data was also analysed in a stratified form in order to reduce the possible confounding effect of the increased hallux valgus in the bilateral hallux valgus study group.

The hallux valgus angle in the Kettering control group ranged from 14.5° to 27°. In the study group it ranged from 14.5° to 37 with just five feet showing greater than 27° hallux valgus. For this data analysis exercise only, the five study group cases with greater than 27° hallux valgus were excluded because they could not be matched against any feet in the control group. The remaining subjects were entered into the following three groups

1. Hallux valgus angle 14.5° to 17°
2. Hallux valgus angle 17.5° to 20°
3. Hallux valgus angle 20.5° to 27°

The stratified data is represented as cumulative frequency graphs with 95% confidence intervals in Fig. 4.12 to 4.14. On viewing these graphs it is clear that the treatment group generally deteriorated more than the control group. However if an unpaired t test is used to compare the mean difference between the pre-trial and post-trial hallux valgus angle for the control and treatment group, statistical significance is not achieved (Table 4.5).

Cumulative Frequency of the Change in the
Hallux Valgus Angle in Feet with 14.5° to 17° Hallux Valgus
(Control n= 34 feet, Study n= 21 feet)

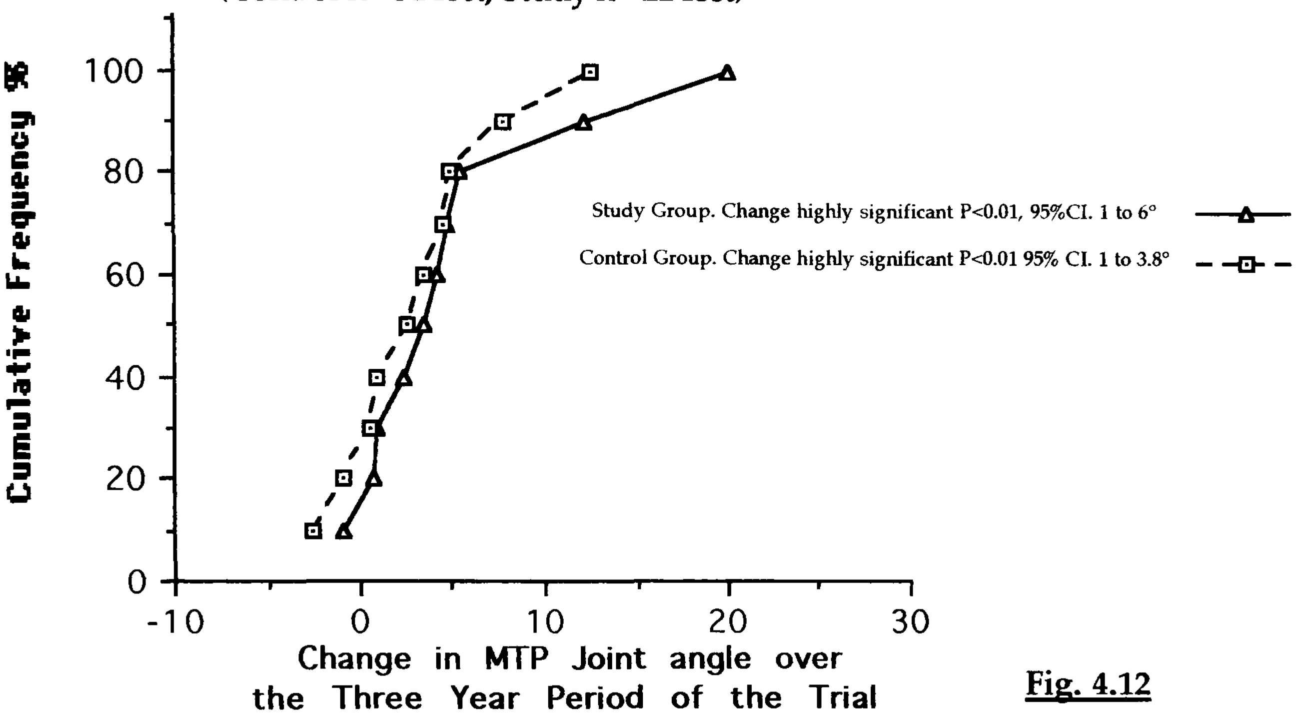


Fig. 4.12

Cumulative Frequency of the Change in the Hallux Valgus Angle
in Feet with 17.5° to 20° Hallux Valgus
(Control n= 18 feet, Study n= 22 feet)

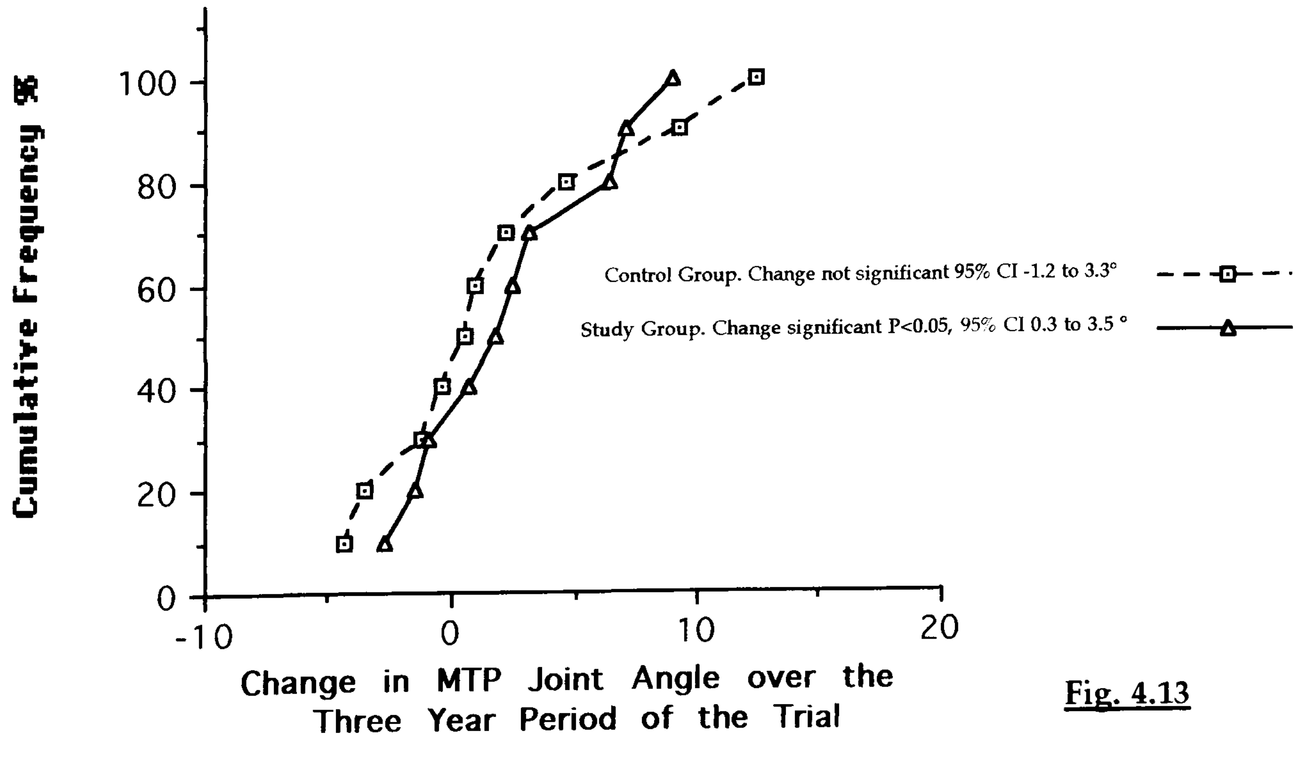


Fig. 4.13

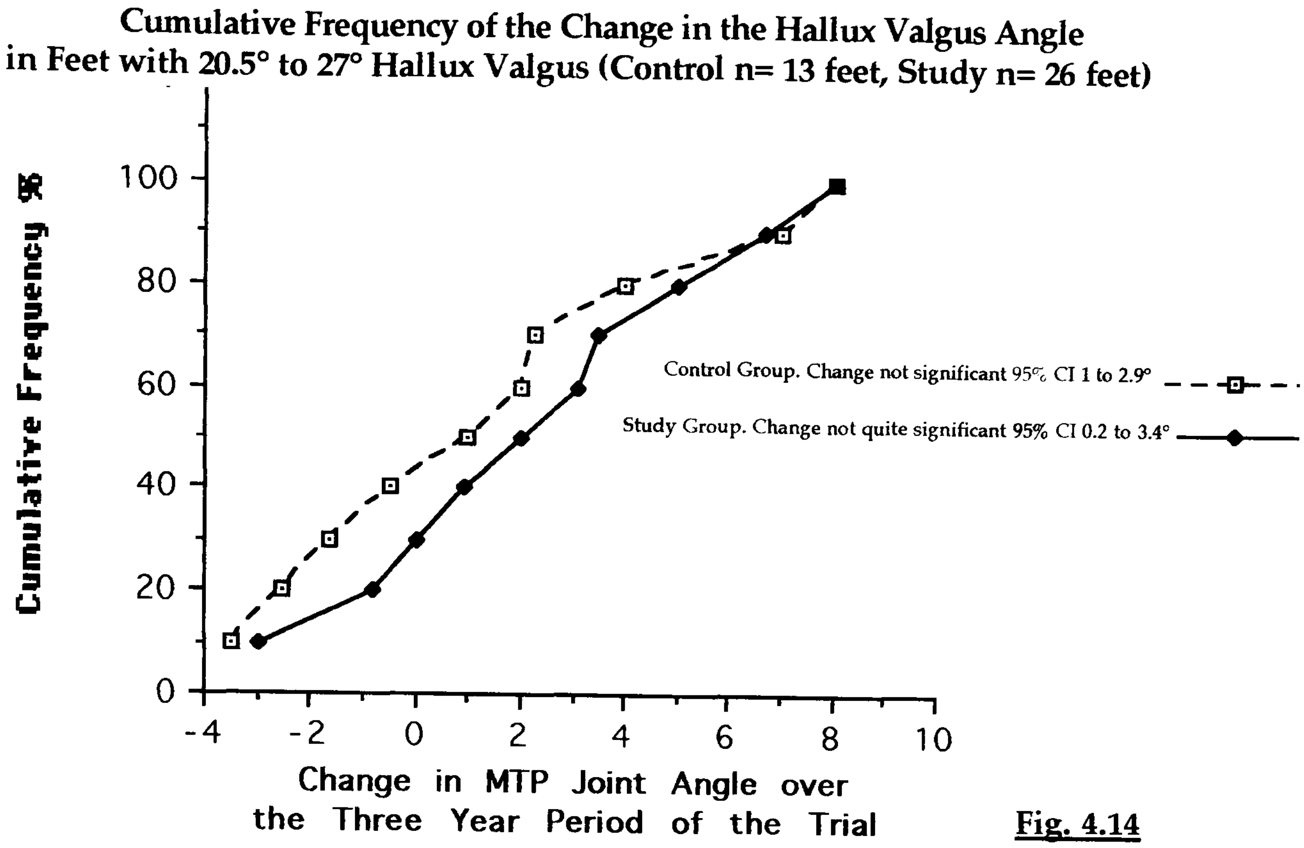


Fig. 4.14

	H. V Angle 14.5 to 17°		H. V Angle 17.5 to 20°		H.V Angle 20.5 to 27°		H.V Angle 14.5 to 27°	
	Control (n = 34)	Study (n = 21)	Control (n = 18)	Study (n=22)	Control (n = 13)	Study (n = 26)	Control (n = 65)	Study (n = 69)
Change in HV Angle°								
Mean	2.47	3.9	1.06	1.9	0.94	1.5	1.7	2.4
SD	4	5	4.5	3.6	3.4	4.5	4	4.5
95% Confidence Interval	1 to 3.8	1.6 to 6.2	-1.2 to 3.3	0.3 to 3.5	-1.06 to 2.95	-0.2 to 3.4	0.76 to 2.7	1.33 to 3.4
P Value of Difference (Unpaired t test)	0.24NS		0.5NS		0.66NS		0.39 NS	

Table 4.5 Difference in pre and post trial hallux valgus angle. Comparison of mean differences in control and study group after stratifying the data

Twenty of the study group children improved over the period of the trial (Fig. 4.8). However 21 of the control group subjects also improved without any treatment (Table 4.6).

Subjects in Study Group who improved (n = 20)		**Subjects in Control Group who improved** (n = 21)	
° Improvement in Hallux Valgus angle	° Improvement in Intermetarsal angle	° Improvement in Hallux Valgus angle	° Improvement in Intermetarsal angle
Bilateral Group		Bilateral Group	
Left Foot		Left Foot	
2	0.5	5	2
3	-0.5	2	-1.25
1.25	-1.5	3	-1
1.5	0	2.5	2.5
Right Foot		2.5	-2
3	1.5	1.5	0
1	1.5	0.5	-2.5
3	1.5	3.5	0.5
1	-2.5	0	-0.5
2	-1.5	Right Foot	
0	-3	1	0
0	-1	2.5	-0.5
0	-2	1	0.5
0	-1	4	2
Unilateral Group		1	3.5
1	2.25	1	0.5
1	-2.5	Unilateral Group	
4	0.5	3	-0.5
0.5	-1	1.75	-0.5
8	-1	4.5	0
3	-0.5	2	0.5
1.5	-0.5	3.5	2.5
		0	0
Mean 1.83	-0.53	2.1	0.2
SD 1.87	1.5	1.4	1.5

An unpaired t test determined no statistically significant difference between control and study group p>0.05, NS.

Table 4.6 Subjects in whom the hallux valgus angle improved or remained stable over the three year period of the trial. Change in intermetatarsal angle also indicated (negative value indicates deterioration)

The intermetatarsal angle improved or remained static in 24 study group children and 28 control group children. There was a statistically significant difference between groups with the study group improvers showing very slightly greater mean improvement ($p<0.05$, Table 4.7 & Fig. 4.9).

Subjects in the Study Group who improved (n = 24)		**Subjects in the Control Group who improved (n = 28)**	
° Improvement in Intermetatarsal angle	° Improvement in Hallux Valgus Angle	° Improvement in Intermetatarsal angle	° Improvement in Hallux Valgus angle
Bilateral Group		Bilateral Group	
Left Foot		Left Foot	
0.5	2	2.5	-1.5
4	-2	2	5
1	-6	1	-3.5
2.25	-5	0.5	0
3	1.5	2.5	2.5
0.75	-5.75	1	-2.5
1.5	1.5	2.5	0.5
2.5	-3	0.5	-5
0.5	-2.5	0.5	3.5
0	-1.5	0	3.5
0	-2.5	Right Foot	
0	-1.5	0	-7.25
Right Foot		0	1
4.5	-3	0	-4
1.5	3	0	-12.5
1.5	1	0	-9
3	0	2	-2.5
1.5	-4	3.25	-0.5
4.5	-2	0.5	-1
2	-2	2	-4
1	-1	3.5	1
0	-1	1.5	-7.5
Unilateral group		0.5	1
2.25	-1	Unilateral Group	
1.5	-4	0.5	-0.5
2	-3.5	0	4.5
		0	0
		0.5	-3.75
		2.5	-3.5
		1	-5.5
Mean 1.69	-1.76	0.99	-1.83
SD 1.28	2.3	1.1	4.1

An unpaired t test determined a statistically significant difference between control and study group $p<0.05$.

Table 4.7 Subjects in whom the intermetatarsal angle improved or remained stable over the three year period of the trial with change in hallux valgus angle also indicated(negative value indicates deterioration)

4.2 Compliance

While 12 study group children were lost to follow up, in a number of other cases compliance with orthotic treatment was variable. To determine which factors may have affected compliance, the socio-economic group as well as the number of shoes owned by the children was reviewed. Compliance was classified according to Table 4.2.

The child's socio-economic group was classified according to the head of household's occupation. The link between socio-economic group and compliance was then analyzed using chi-square statistical analysis (Table 4.8).

Compliance	Social Class I to III Professional & Skilled Occupations	Social Class IV & V Partly or unskilled manual labourers	Total
Very Good	21 (16.3)	13 Plus 3 lost to final follow up (20.8)	37
Good	6 (5.6)	5 Plus 2 lost to final follow up (7.3)	13
Fair	0 (2.1)	4 Plus 1 Lost to final follow up (2.8)	5
Poor	0 (1.3)	1 Plus 2 lost to final follow up (1.6)	3
Non - compliant	0 (1.7)	4 All 4 lost to final follow up (2.2)	4
Total	27	35	62

Numbers in brackets denote observations expected according to the Null hypothesis.
x^2 Value with Yates correction factor = 16.08, ($p<0.01$).
The Null hypothesis that there is no difference in compliance between socio-economic groups I to III and groups IV and V was rejected.

Table 4.8 Compliance with Orthotic Treatment according to Socio-economic group (n= 62, 12 other study group children lost to follow up)

A highly significant difference in compliance was found between socio-economic groups I to III and group IV and V ($p<0.01$). While no study group child from families with a professional or skilled head of household were lost to follow up, 12 study group children of socio-economic group IV and V did not attend their second x-ray appointment.

Table 4.9 indicates that compliance with orthotic treatment can also be affected by the number of shoes owned by the child. Compliance is significantly less in children with three or more pairs of shoes ($p<0.05$).

Compliance	1 or 2 pairs of shoes	3 or more pairs of shoes	Total
Very Good	24 (20.8)	13 (16.1)	37
Good	8 (7.3)	5 (5.6)	13
Fair	1 (2.8)	4 (2.1)	5
Poor	2 (1.69)	1 (1.3)	3
Non - compliant	0 (2.25)	4 (1.74)	4
Total	35	27	62

Numbers in brackets denote observations expected according to the Null hypothesis.
x^2 Value with Yates correction factor = 12.42 ($p<0.05$).
The Null hypothesis that compliance is not affected by the number of shoes possessed by the child was rejected.

Table 4.9 Compliance with Orthotic Treatment according to number of pairs of shoes possessed (n= 62, 12 study group children were lost to follow-up)

There was no statistically significant association between socio-economic group and the number of pairs of shoes owned by the child though quantitatively the children of socio-economic groups I to III tended to have slightly fewer pairs of shoes (Table 4.10).

Compliance	Social Class I to III Professional & Skilled Occupations	Social Class IV & V Partly or unskilled manual labourers	Total
1 or 2 pairs of shoes	15 (15.2)	17 (19.75)	35
3 or more pairs of shoes	12 (11.7)	18 (15.2)	27
Total	27	35	62

Numbers in brackets denote observations expected according to the Null hypothesis.
x^2 Value with Yates correction factor = 1.05, (NS).
The Null hypothesis that there is no difference in the number of shoes owned by socio-economic groups I to III and groups IV and V was accepted.

Table 4.10 Number of Pairs of Shoes owned by each child and their Socio-economic group (n= 62)

5.0 THE KETTERING HALLUX VALGUS STUDY.

Discussion

Hallux valgus was found to deteriorate in children between the ages of 10 and 14 regardless of whether they wore the Root foot orthosis.

The intermetatarsal angle remained more or less stable over the three year study (Fig. 4.3, 4.6 and 4.7). Hardy and Clapham (1951) also found that the intermetatarsal angle remained stable up until the so called "critical angle of hallux valgus" when both the intermetatarsal and hallux valgus angle begin to deteriorate more rapidly. The "critical angle of hallux valgus" probably corresponds to the point where the hallux abuts against the second toe and the proximal phalanx of the hallux acts like a wedge pushing the first metatarsal into varus.

The reason why hallux valgus deteriorated more in the treatment group receiving foot orthotic treatment may be due to the fact that in spite of randomisation the bilateral hallux valgus treatment group children, entered the trial with a statistically significantly greater hallux valgus angle than the control group($p<0.05$, Fig. 4.2). More advanced hallux valgus will reach Hardy and Clapham's critical angle sooner and will deteriorate quicker than less severely affected feet.

However stratifying the data did not confirm the existence of a critical angle in the Kettering hallux valgus subjects. In fact the 95% confidence intervals in Fig. 4.12 to 4.14 indicate that the greatest deterioration occurred in children who entered the trial with hallux valgus angles less than 17°. The stratified data analysis indicates that hallux valgus deterioration in the treatment group was slightly more marked in clinical terms (see 95% confidence intervals Fig. 4.12-14), though that deterioration was not statistically significantly greater than the control group (Table 4.5).

If a critical angle of hallux valgus does exist where there is a mechanical and geometrical inevitability that the deformity will get worse, a Root foot orthosis is unlikely to stop the foot's progression to that critical point.

In the unilateral hallux valgus subjects the metatarsophalangeal joint angle was similar for both control and treatment groups at the start of the trial (Fig. 4.4 and 4.5). Once again deterioration of the condition was slightly more pronounced in the treatment group, though in this case the greatest deterioration did occur in children with the most advanced hallux valgus (Fig. 4.4 and 4.5).

At first glance (Fig. 4.8) it may appear that a Root foot orthosis does not have an "all or none effect" on hallux valgus, as 20 of the treatment group subjects improved; however 21 of the control group subjects also improved without treatment. When study and control group were compared there was no statistically significant difference in the hallux valgus angle improvement (Table 4.5). The finding that hallux valgus could sometimes improve is interesting as the condition is generally thought to be a progressive one. However the improvement was on average less than 2° and could be accounted for by the error inherent in the radiographic measurement. A review of the biomechanical and clinical data collected at the primary examination of the children, shows no obvious factor that may have explained their tendency to improve.

Improvement in the intermetatarsal angle was not necessarily associated with improvement in the hallux valgus angle (Table 4.6 and 4.7). This is of interest as the intermetatarsal angle has in the past, been strongly associated with the degree of hallux valgus (Hardy & Clapham 1951, Lundberg & Sulja 1972). In clinical terms however the improvement was small and again could be accounted for by measurement error.

Measurement errors may have occurred at two separate stages. Firstly, the radiographic examination of the foot is known to produce variation in position of the foot bones if the radiographic technique is not standardised (Perry et al 1992). To overcome this potential source of error the children were asked to stand with both feet on one x-ray cassette and the x-ray beam was directed at the weightbearing feet from a standard distance and angle.

Error may also have occurred on measurement of the hallux valgus and intermetatarsal angles. To overcome this only one observer carried out all the x-ray measurements. A previous intra-observer error study of metatarsophalangeal angle measurement on standardised weightbearing x-rays has shown a measurement error of approximately 2°. Any change in the radiographic angles in excess of this is likely to be a true change.

While reference to the raw data measurements of the children whose hallux valgus improved shows that the change in both hallux valgus and intermetatarsal angles was rarely in excess of 2°, (Table 4.6 and 4.7), the 95% confidence interval of hallux valgus deterioration for the study as a whole shows that hallux valgus joint angle change was commonly in excess of 2° (Table 4.3 & 4.4). The general trend for hallux valgus angle deterioration was therefore not due to measurement error.

Kelikian (1965) considered that external foot appliances were unlikely to prevent or correct deformity. He believed that they would merely 'temporize'. Certainly in the Kettering hallux valgus study a number of the more advanced cases complained of pain from their first metatarsophalangeal joints. While the Root foot orthosis failed to alleviate the pain completely, the patients did feel that their symptoms were in part relieved. However while symptoms may in the short term be alleviated, the progress of the hallux valgus deformity is not likely to be greatly affected by the use of a Root foot orthosis.

In patients where joint pain was relieved by orthotic use it is not surprising that compliance was very good; in other children compliance was less reliable (Table 4.8 to 4.9).

5.2 Compliance with the Root Foot Orthosis

Motivation to comply with orthotic treatment is reduced in the lower socio-economic groups. This has implications for the future use of in-shoe orthoses. Methods for improving motivation and compliance such as increasing health education should be considered, as clearly the prescription of an orthosis is quite pointless if the device is not worn. On the basis of the results of this study, lower socio-economic groups should be targeted for rigorous assessment of their compliance and the development of specific measures which may improve compliance.

One such measure may be advice on restricting the number of shoes bought for the child. Table 4.9 indicates that compliance with orthotic therapy is significantly less in children with three or more pairs of shoes ($p<0.05$).

The greater the number of shoes owned by the child the more often they will need to remember to take the orthoses out of one pair and transfer them to another. A Root foot orthosis will not fit in all shoes. In shoes with a low heel counter the orthosis will cause the rearfoot to slip up and out of the shoe. In sling back shoes with no heel counter the orthosis will slip out altogether. An orthosis will probably not be accommodated in court style shoes with no laces.

In the Kettering hallux valgus study, children with two pairs of shoes wore one pair to school and other formal occasions and another for sport and casual wear. The third, fourth and occasionally fifth pairs of subsidiary footwear tended to be more unsuitable for orthotic therapy because they were likely to be sling back sandals or court type shoes.

Wenger (1989) claimed that North American children were unlikely to wear an in-shoe orthosis beyond the age of 6 years. Groiso (1992) stated that "orthotics are poorly tolerated by youngsters". The Kettering study has proved otherwise, with 50 nine year old children complying with orthotic therapy for three to four years. The compliance in the Kettering study may possibly be a consequence of the following factors which are only likely to be present in such a research project, these factors do however have implications for the more general use of foot orthoses.

- The original consultation when informed consent was obtained, involved parents in their children's treatment from the outset.

- Regular reviews organised and performed by a single clinician who always offered encouragement and reassurance, ensured continuity and a sense of exclusive care which is not always possible in large hospital units.

- The obvious nature of the hallux valgus condition, which is well known to the general public, ensured that parents and children understood the potential seriousness of the condition for which they were being treated.

In spite of reliable compliance, the Root foot orthosis failed to prevent deterioration of hallux valgus, why this happened is discussed in the next section of this thesis.

5.3 Pronation of the Foot as a Cause of Hallux Valgus

It is a widely held belief that excessive pronation of the foot is the single most important cause of hallux valgus (Rogers & Joplin 1947, Root et al 1977, Greenberg 1979, Holstein 1980, Kalen & Brechner 1988). At several stages during this thesis doubt has been cast upon this theory. Firstly in Section 2.2, the type of biomechanical abnormalities which give rise to compensatory subtalar joint pronation were no more prevalent in the hallux valgus children than in the control group of normal children. The single most consistent biomechanical difference between the hallux valgus and the control group was that the hallux valgus children more commonly presented with a plantarflexed first metatarsal. This condition is not an important cause of foot pronation.

The arch height study of Section 2.1 also showed no difference in the arch index of normal and hallux valgus feet. The implications of this study for pronation of the foot must however be considered cautiously. A footprint will not indicate precisely how pronated a foot is. The difference between the neutral calcaneal stance position and the relaxed calcaneal stance position is the only precise indication of this. The word precise in the context of calcaneal position measurement may not however be an appropriate one, as the study of subtalar joint neutral position measurement in Section 2.2 indicates that subtalar joint measurement is neither reliable nor valid.

In the clinical examination of the pronated foot, the arch profile is seen as just one parameter which is considered alongside the other clinical signs of excessive subtalar joint pronation including:

- abduction of the forefoot

- non-congruency of the talo-navicular joint
- rearfoot eversion

(Inman, Ralston, Todd 1981, Stockley et al 1990).

It is the author's observation that feet with low arches may have normal rearfoot and forefoot position with complete talo-navicular congruency, while a pronated foot with eversion of the rearfoot and obvious subluxation of the talo-navicular joint may retain an arch profile. Supinated feet do not however present with a low arch. While the footprint study did not confirm that subtalar joint pronation is not an aetiological factor in hallux valgus, it does contribute to an increasing lack of credibility for the theory.

While Root type foot orthoses has been proved to effectively reduce pronation of the foot (Bates et al 1979), three years of compliance with such an orthosis did not prevent the progression of hallux valgus in 74 adolescents. This casts further doubt upon the importance of subtalar joint pronation as an aetiological factor in hallux valgus. It could be argued that the actual orthoses prescribed for the Kettering children were not shown by any specific study to restrict pronation of the foot, but like all such Root type orthoses they were prescribed with that objective.

Pronation of the foot has been found to be unimportant both in the assessment and treatment of hallux valgus. Though the findings of this thesis are not strong enough to completely rule out pronation of the foot as an aetiological factor in hallux valgus, a very strong case is now required if pronation is to continue to be implicated. But certainly the null hypothesis that biomechanical abnormalities are no more common in hallux valgus children (stated in section 1.5.2) cannot be rejected due to the significant incidence of plantarflexed first metatarsal in the hallux valgus subjects.

5.4 Implications for the Biomechanical Treatment of the Foot and Leg

> *".........Being in the centre of London, we were prewarned of the possibility of bomb scares, but few of the assembly were prepared for the proverbial bombshell that was to be dropped this morning as the results of a four year prospective study of the effect of functional orthoses on juvenile hallux valgus were presented."*

Journal of British Podiatric Medicine

Report of 'The Foot: A Joint Approach Symposium', September 1993

Since the theories of Root, Orien and Weed (1977) were adopted widely for the treatment of mechanically related foot and leg problems, excessive pronation of the foot has been seen as the single most important cause of much lower limb morbidity. Many patients have been helped by an orthosis designed to restrict pronation. This thesis does not seek to reverse that situation but to review it.

The Podiatric profession and allied orthotic services have invested a great deal in establishing themselves as uniquely capable of providing precision made biomechanical orthoses. The results of the Kettering hallux valgus study will not easily be accepted as this communication from a leading protagonist of the Root foot orthosis indicates:

> *"..... I am hoping that the study contains a suitable assessment method of ensuring that the child was correctly controlled on the orthosis and was not abnormally pronating on the device and that the first metatarsal was not being abnormally dorsiflexed during gait due to an inappropriate fabrication protocol or lack of control."*

Correspondence June 29 1993, R.J Anthony.

(Author of 'The functional foot orthosis' 1991).

It is implied that the orthosis failed to prevent progression of hallux valgus because it was incorrectly prescribed. The orthosis for the Kettering children were prescribed according to the podiatric objective of focusing subtalar joint, midtarsal joint and first metatarsal function around a pre-determined neutral position. Measuring instruments with established error margins were used and indeed specifically designed in some cases to facilitate such a prescription. While the prescription of an orthosis continues to be a compromise between what the patient will tolerate and what the shoe will accommodate, the prescription can never be standardised, even if the contesting approach of Philps (1990) and Anthony (1991) to prescribing an orthosis could be resolved.

Root type foot orthoses have been prescribed and found effective by many different sports medicine practitioners all over the world. In the reports describing orthotic success with soft tissue and overuse injuries, the prescription technique is rarely if ever described. Yet the protagonists of orthotic therapy are unlikely to suggest that the orthotic prescription in these studies were somehow incorrect.

While I must admit to my inability to measure the subtalar joint neutral position repeatably I must also point out that I do not appear to be the only one having problems (Griffith 1988, Elveru, Rothstein, Lamb 1988). Although it may not be possible to measure the subtalar joint neutral position reliably this appears to have no detrimental effect on the success of orthotic treatment. The Root type foot orthosis has been reported to reduce pronation of the foot (Bates et al 1979, Rogers and Leveau 1982, Smith et al 1986, McPoil et al 1989) and alleviate running injuries (Donatelli et al 1988, Gross 1991). This has occurred despite the inaccuracy of measurement of the neutral position.

The subtalar joint neutral position has been more seriously undermined by recent research (McPoil & Cornwall 1992), which found that 60 normal subjects never actually attained the subtalar joint neutral position during the midstance phase of gait. It appears that the Root foot orthosis is striving to achieve a positioning of the foot which is never attained in normal subjects.

5.5 Metatarsus Primus Varus as a Cause of Hallux Valgus

In section 2.4, it was shown that the average intermetatarsal angle in the unaffected as well as the affected feet of children with unilateral hallux valgus was significantly greater than in normal children. The point was made that the originator of the Root device played down the significance of metatarsus primus varus because he believed that metatarsus primus varus was just a symptom of advanced hallux valgus. In the Kettering study 53% of the unilateral treated group and 57% of the unilateral control group have subsequently developed clinical and radiological hallux valgus of the initially normal foot, indicating that a raised intermetatarsal angle predicts the later development of hallux valgus.

Perhaps the reason why Root diminished the importance of metatarsus primus varus is that it is hard to explain how a Root orthosis, which controls frontal plane movement of the foot, could effect the transverse plane position of the first metatarsal. Indeed the results of the Kettering study clearly indicate that it will not, rendering the Root orthosis inappropriate for the management of hallux valgus.

5.6 Screening for Hallux Valgus

The findings of the Kettering study relating to metatarsus primus varus may be of interest to those involved in screening children's feet for before the development of clinical hallux valgus. It would however be ethically unacceptable and very costly to expose as many as 98 'normal' children to radiation, for the sake of identifying as few as two children with a raised intermetatarsal angle.

The 2% incidence of hallux valgus in Kettering nine to ten year olds is much less that of older age groups surveyed in other studies. Irrespective of how unreliable previous incidence rates may be, the strong correlation between the incidence of hallux valgus and chronological age appears to be consistent in all studies. Between the ages of 10 and 60 years a significant percentage of the population seems to acquire hallux valgus.

While there are few acquired foot deformities that could be considered more significant than hallux valgus, the incidence among 10 year old children is really too small to justify screening for the condition. Certainly the Kettering study indicates that 98 normal children were examined for every 2 children found to have hallux valgus. It would be more worthwhile to screen older subjects where the incidence is higher. In more advanced cases however, it may be too late, for the deformity may already have affected the entire forefoot.

Family history has long been considered an important factor in hallux valgus. Hardy and Clapham (1951) found a family history of hallux valgus in 63% of patients presenting for hallux valgus surgery. A control group of 84 normal subjects gave a positive family history of hallux valgus in just one case. Mitchell, Fleming and Allen (1958) reported that 34 (58%) patients from a sample of 59 with hallux valgus gave a family history of the condition. In the Kettering study both parents of 39 of the hallux valgus children were examined and hallux valgus was diagnosed in one or both parents in 26 (66%) cases.

5.7 Gender Difference in Hallux Valgus

While hallux valgus occurs infrequently among nine to ten year old children it does affect girls more commonly than boys. In the Kettering study 87% of cases were female. This finding is in agreement with many previously reported investigations which find a much higher incidence among females. Table 5.1 indicates the male:female ratio of subjects undergoing hallux valgus surgery.

Author	Males	Females	Age
Hardy 1952	3	88	20-60
Bonney, McNab 1952	28	253	Adults
Piggot 1960	3	110	<21
Merkel, Katoh 1983	9	135	12-75
Sherman 1984	0	35	44-77
Meier 1985	5	45	13-69
Love, Whynot 1987	0	44	52-75
Wu 1987	28	402	10-90
Wanivenhaus 1988	2	19	16-58
Resch 1989	3	22	20-69
Mauldin 1990	1	29	26-74
O'Doherty 1990	11	70	>45
Conlan, Gregg 1991	0	29	49-79
Vallier 1991	16	44	46-80
Mann, Rudicel 1992	8	67	10-83
Total	117	1392	

TABLE 5.1 Male to Female Ratio in Published Reports of Hallux Valgus Surgery 1952-1992

Table 5.1 shows only the male to female ratio in a survey of hallux valgus surgery, rather than the incidence in large representative populations. The surveys were selected on the basis that they gave comprehensive information on gender and age and used no form of pre-selection on the basis of gender. The results demonstrate the difference in hallux valgus morbidity among the sexes.

Why hallux valgus should be more prevalent among females is not certain. Hardy and Clapham noted a higher average intermetatarsal angle in 14 year old girls with hallux valgus, but this only demonstrated that they have more advanced deformity at that age than boys. Root, Orien and Weed (1977) suggested that the wider pelvis and greater angle of femoral inclination may account for more excessive pronation in women than in men, leading to hallux valgus development. However the Kettering hallux valgus survey, demonstrated the greater female incidence of hallux valgus in nine year old children, long before the development of secondary sexual characteristics alluded to by Root et al.

5.8 Footwear as a Cause of Hallux Valgus

The increased incidence of hallux valgus among females has often been used to support the importance of footwear as an aetiological factor.

Durlacher, Surgeon Chiropodist to Queen Victoria wrote in 1845 "One of the most certain causes of a bunion is the wearing of shoes made too short and with a narrow sole".

Scientific support for Durlacher's observation of 1845 has since been provided by reports of the incidence of hallux valgus in non-shoe wearing populations.

Barnicott and Hardy (1955) used a foot printing technique, to measure the first metatarsophalangeal joint angle in Nigerians who had never worn shoes. The values collected were then compared with age matched Nigerian soldiers, who had worn army boots for an unspecified number of years, and a mixed sex group of European University students and Nurses with clinically normal feet. While in the European and Nigerian groups there was a statistically significant difference between the male and female metatarsophalangeal joint angles, there was no difference between the metatarsophalangeal joint angles of the shod and unshod Nigerians.

The markedly greater valgus deviation in European females as compared to European males, was thought to be caused by the constrictive footwear which the women were assumed to wear. The smaller difference between the sexes in the Africans, was thought to support this conclusion.

The type of footwear worn by the European females was not documented. The possibility that an intrinsic difference in the anatomy and function of the female foot, could account for its predisposition to hallux valgus was not considered, nor was the possibility that racial factors could account for the greater metatarsophalangeal joint angle among Europeans. This could be significant especially as the metatarsophalangeal joint values of the shod Nigerians did not differ significantly from their unshod counterparts.

Sim Fook and Hodgson (1958), compared 107 non-shoe wearing Chinese with 118 Chinese who habitually wore either canvas slip-on shoes, or wooden soled flip-flop type sandals with a leather strap across the forefoot to hold the sandal in position.

The unshod subjects were all chosen from a fishing population who lived aboard boats. Clinical examination of this population revealed a remarkable degree of prehensile strength within the great toe, as it was often used to hold fishing lines taut so that the hands were left free to work. The occupation of the shoe-wearing population was not stated.

Clinical and radiological examination revealed a 33% incidence of hallux valgus among the shod, and 2% among the unshod. Metatarsus primus varus was present in just 6% of the shod, as compared to 24% of the unshod. The criteria for diagnosis of these conditions was not given. Sim Fook and Hodgson concluded that shoes led to the development of hallux valgus.

It is however arguable that the two study populations were poorly matched. Exercise therapy has been shown to be useful in the treatment of hallux valgus (Groiso 1992). The "remarkable degree of prehensile strength" within the great toe of the fishing population, (almost certainly the result of the occupational use of the feet), could be considered to be a form of exercise therapy, capable of preventing the development of hallux valgus. Moreover the shoes worn by the shod population and depicted in the paper, were not in anyway pointed and were unlikely to exert a valgus force on the hallux.

The reported rare combination of hallux valgus and metatarsus primus varus was contrary to the observations of other studies (Hardy and Clapham 1951). This finding cannot however be considered reliable when no diagnostic criteria were given. In a study designed to determine the presence or absence of an orthopaedic condition this is a serious omission.

In Shine's 1965 survey of 3006 St. Helena islanders, the metatarsophalangeal joint angle of 1400 barefoot islanders was compared with 1606 subjects who had worn shoes for between one and 60 years. Shoes were adopted by almost 50% of the population because their jobs as government clerks, teachers or house servants required it. Shine concluded that there was a very considerable difference in the incidence of hallux valgus between the two populations.

Analysis of Shine's raw data demonstrates that 34 male subjects and 176 female shoe wearers had hallux valgus as compared to 35 males and 20 females among the habitually barefoot. All the shoe wearing population were grouped together, even though some subjects had worn shoes for just one year, while others had worn shoes for 60 years. No subject had greater than 30° hallux valgus (mean 10.5°, SD 10.5°). Shine's population spent variable periods of time in footwear, some only wearing shoes on Sundays, while others required them only for their work as government clerks or domestic servants. Why the type of shoes worn in such occupations should cause hallux valgus was not explained.

The most recent study of hallux valgus in shod and barefoot populations, provided clear statistical analysis of metatarsophalangeal joint angles in 50 foot skeletons of Pecos Indians who never wore shoes, and 50 Mediaeval Yugoslav peasants who had worn some type of leather shoe (Meyer 1979). In the barefoot population the mean metatarsophalangeal joint angle was 6.5° (SD 3.2), and in the shod population 14° (SD 3.9).

No definite conclusion can be drawn from Meyer's work because of the influence of racial factors and moreover the population cannot be considered large enough to be truly representative. It is clear however that the metatarsophalangeal joint angle was rarely greater than 18° even in the shod group; this falls only just within the commonly set criteria for hallux valgus.

Hallux valgus is more common among shoe wearers. Whether shoes are responsible for the increased incidence has not yet been confirmed.

In the Kettering Hallux Valgus study, footwear could not have been better with the children wearing trainers or low heeled lace up shoes as the fashion of the period dictated, yet the hallux valgus continued to deteriorate. This leads me to question the importance of footwear as a cause of hallux valgus and the use of footwear as a treatment for hallux valgus.

In no other area of non-surgical treatment is the conflict between vested interest and credible scientific enquiry so apparent as in the discussion of the effect of well fitting footwear on hallux valgus.

5.9 Footwear as a Treatment for Hallux Valgus

In the evidence supplied by Clarks Ltd to the Munro commission (1972) it was suggested that juvenile hallux valgus could be corrected in over 50% of cases, if shoes which had been "fitted" were worn. The age of the children, the definition of hallux valgus and the method of measurement was not described.

Burry (1957) reported to the British Boot, Shoe and Allied Trades Research Association on a case of a female school teacher (age not given) whose painful bunion joints were greatly relieved by the wearing of sandals for six months. While acknowledging that the radiographic measurement of the left foot hallux valgus had increased over that period, Burry showed that the well fitting sandals had corrected the right foot hallux valgus. Radiographs were provided showing before and after dorso-plantar views of a deviated left first metatarsophalangeal joint and a wholly congruous right first metatarsophalangeal joint.

Knowles (1953), described the effect of footwear on one male subject with congruous first metatarsophalangeal joints. On radiographic examination the metatarsophalangeal joint angle was found to be 13° in both feet. After wearing straight lasted shoes for four years, the metatarsophalangeal joint angle measured 5° on the left and 0° on the right.

In a controlled prospective trial, Barnicott (1962) compared the effect of specially supplied round toe shoes on 17 subjects with metatarsophalangeal joint angles in excess of 15°. Using radiographic measurement he found that after three and a half years, the metatarsophalangeal joint angle had deteriorated in seven feet but improved in thirteen. Seven of the eight cases in the control group deteriorated over a two and a half year period. No information was provided regarding congruity of the metatarsophalangeal joint, age or occupation of the control group or what was meant by an ordinary shoe. The accuracy and repeatability of the radiographic measurement technique was not defined.

5.10 Future non-surgical treatment for hallux valgus

The Podiatric profession must now perhaps accept that although the Root foot orthosis may relieve aches and pains in joints and soft tissues (Bates, Osternig, Mason 1979, Donatelli, Hurlbert, Conaway 1988) it will not prevent the progress of a skeletal deformity like hallux valgus. The Root type foot orthosis is not a cure all.

In contrast to the results of this study, Groiso provided custom made night splints for 25 Argentinean children (20 girls, 5 boys) aged between one and 16 years (mean age 11, SD 3), with a radiographic metatarsophalangeal joint angle of 15° or more. The night splints were worn for two years and the children followed up for at least a further two years.

Supplementary treatment consisted of an exercise programme designed to "elongate" the adductor and flexor hallucis brevis muscles for all cases and arch supports for an unspecified number of patients who had excessive pronation of the forefoot.

Fifty percent of the group showed an improvement in the hallux valgus angle while 32% showed improvement in the intermetatarsal angle. Further statistical analysis of the data was not performed. The presentation of the raw data however, allowed the subsequent analysis (Fig. 5.1).

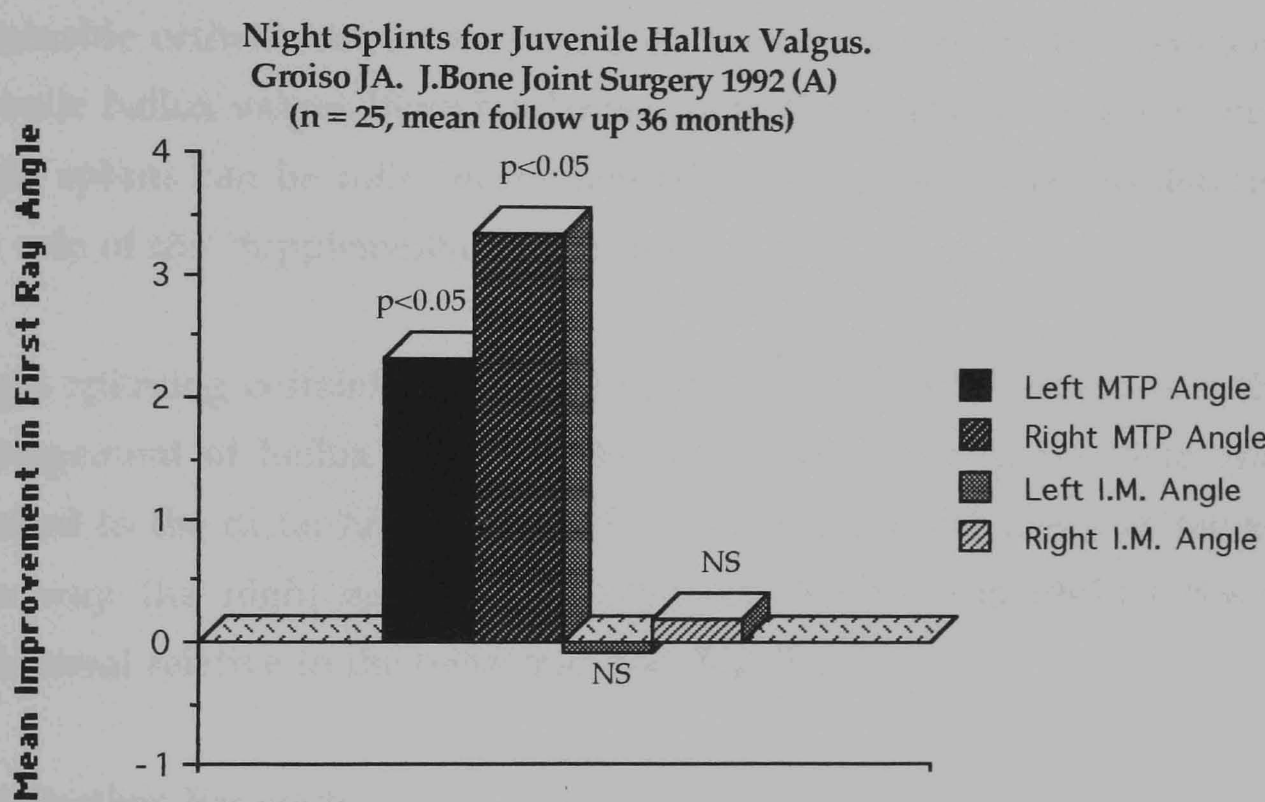

Night Splints for Juvenile Hallux Valgus.
Groiso JA. J.Bone Joint Surgery 1992 (A)
(n = 25, mean follow up 36 months)
Mean Improvement in First Ray Angle
4
3
2
1
0
- 1
p<0.05
p<0.05
NS
NS
Left MTP Angle
Right MTP Angle
Left I.M. Angle
Right I.M. Angle

Fig. 5.1

A paired t test analysis of the angles recorded for both feet indicated a statistically significant improvement ($p<0.05$) in the metatarsophalangeal joint angles after night splint treatment. No significant difference was present in the before and after measurements of the intermetatarsal angle, though the mean value and 95% confidence intervals indicate that the intermetatarsal angle of the left foot was slightly worse after treatment.

Groiso's results indicate that the night splint, a traditional and widely obtainable orthotic device may have an important role in the treatment of juvenile hallux valgus though a larger controlled study is necessary before night splints can be fully recommended. It is also important to determine the role of the 'supplementary' treatment.

Night splinting certainly fits in with Pratt et al's (1993) concept of orthotic management of hallux valgus which involved a three point force system applied to the distal hallux, the fifth metatarsal and the first metatarsal. In this way the night splint will adduct the hallux and abduct the first metatarsal relative to the body mid-line (Fig. 5.2).

5.11 Further Research

In July 1993, the parents of all the Kettering children who had participated in the hallux valgus study group were advised that orthotic treatment would no longer be provided. What should be done for them now? Surgery could be considered but in no single group does the outcome of surgery appear to be more unsatisfactory than in juveniles. Ball and Sullivan (1985) reported a recurrence of deformity or pain in eleven (61%) of the 18 cases on whom they performed Mitchell's osteotomy.

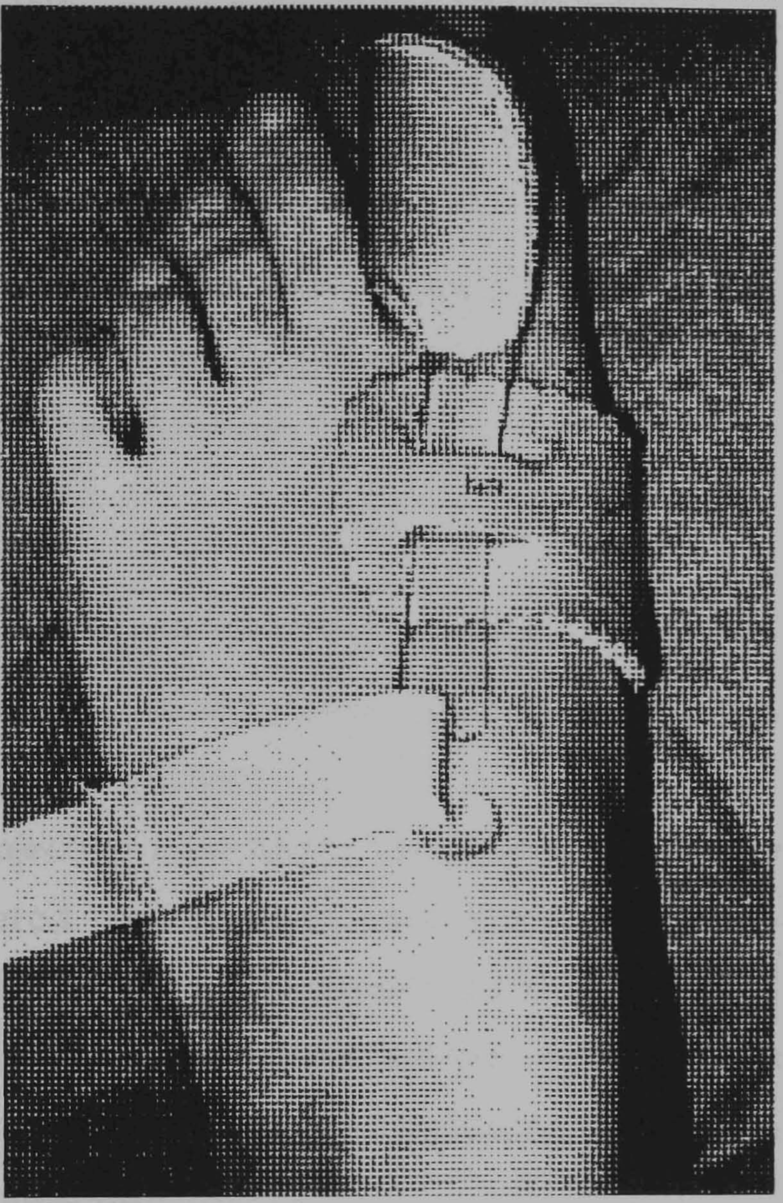


Fig. 5.2 A hallux valgus night splint

Helal (1974,1981) in his review of eight different operations performed on adolescents aged between nine and nineteen reported a poor result in 47% of the 280 feet.

The criteria for grading the surgical outcome included mobility of the metatarsophalangeal joint, narrowing of the forefoot, stability of correction and weightbearing function of the foot as well as the patient's subjective assessment.

Geissele and Stanton (1990) in a review of eight different procedures performed on 23 feet of average age 15, reported that 30% of the patients were unsatisfied because of pain or recurrence of the deformity. The surgeon's objective assessment recorded a 52% incidence of recurrence. It was considered that the best outcome was associated with the greatest reduction of the intermetatarsal angle which manifested clinically as narrowing of the forefoot. Poor outcome was thought to follow inadequate attention to the 'primary' causes including pes planus, hindfoot valgus and heel cord contracture!

Bonney (1952) and Scranton (1984) advised against hallux valgus surgery before bone maturation. In Bonney's case this was because in 63% of his series of 54 feet aged 10 to 17, there was no obvious improvement of the metatarsus primus varus angle following an undescribed metatarsal osteotomy. Twenty two percent of the series required re-operation. Scranton and Zuckerman reported a 36% failure rate and 24% re-operation rate in their series of 50 adolescent feet in which a range of procedures were performed including the McBride, an opening first metatarsal proximal osteotomy, and a closing proximal osteotomy. These results and recommendations must however be placed in the context of other studies which report no recurrence and complete satisfaction with cosmetic appearance. Luba (1984) performed Mitchell's osteotomy on 45 children aged between 9 and 18 years (average age 13) overall excellent results were recorded in 93% of cases.

Undoubtedly technical performance on behalf of the surgeon and procedure selection can greatly influence outcome. Using a combination of distal soft tissue repair with proximal metatarsal osteotomy in girls aged between nine and 18, Simmonds and Menelaus reported 80% subjective and objective success in 33 feet. Trott (1972) using a similar technique, reported success in 91% of cases, while Goldner and Gaines (1976) fused the metatarsocuneiform joint and performed distal soft tissue realignment to achieve success in 88% of 25 juvenile cases. Scranton and Zuckerman (1984) also had success at first. In their series of 50 foot operations the average intermetatarsal angle was reduced from 12° to 4° and the metatarsophalangeal joint angle from 28° to 11°. Scranton and Zuckerman believed that this immediate effect indicated that the surgery was performed technically well. Later recurrence of the hallux valgus however led Scranton and Zuckerman to suggest that reconstructive elective surgery should be avoided in adolescents, possibly because "the presence of an open epiphysis led to an unpredictable outcome", certainly in the eight McBride procedures performed in this series recurrence followed in 75%.

Highly technical surgery was advised against by Helal (1974) who claimed "the more complex the surgery the worse the result". The technically simple Wilson's osteotomy produced the best results of all the operations analyzed by Helal. The procedure was best carried out in the early teens rather than later. Conversely Scranton and Zuckerman (1984) revealed a 25% prevalence of unsatisfactory results in patients operated on before the age of 15.

Clearly there is little agreement about the ideal procedure or the optimum age for hallux valgus surgery. Neither are the indications for the operation clear. Pain is not a consistent problem (Helal 1974) but cosmetic appearance is not a good justification for surgery, and certainly in the Kettering study pain was a very rare finding. It would seem sensible and in keeping with our understanding of the significance of the condition to suggest that surgery should be performed at the stage when the first metatarsophalangeal deformity begins to involve the lesser toes.

The single most effective hallux valgus operation has not yet been identified by research. Instead the side effects and limitations of those procedures currently being practised has been highlighted. This information is of great value because it may at least be possible to predict where an operation or a certain type of operation is inappropriate.

To synthesise a conclusion from the clinical studies presented here is difficult because not one of those studies reported is comparable to another in the research methodology used. This is worrying because the small sample sizes involved also throw some doubt on the reliability of the conclusion which have been reached by some studies. To turn hallux valgus surgery into a real science, where every patient can obtain the most satisfactory outcome, will require a multi-centre collaborative research project involving specific standardised protocols on patient inclusion, between centre standardisation of treatment, and evaluation of outcome.

Until this goal is achieved and while the results of surgery remain less than optimum, an effective non-surgical treatment should also be sought, which will prevent the progression of hallux valgus and so dispense with the need for surgical reconstruction.

5.12 Conclusion

This study aimed to determine the aetiological importance of biomechanical abnormalities in juvenile hallux valgus and the effect of a Root foot orthosis in the treatment of juvenile hallux valgus. The null hypotheses stated in section 1.5.2 can now be rejected or accepted as follows:

***H_0** Biomechanical abnormalities of the foot and ankle are no more common in hallux valgus children than in children with no hallux valgus.*

This null hypothesis is rejected since a plantarflexed first metatarsal is more common in hallux valgus children.

***$H_0 1$** A Root foot orthosis will not prevent the deterioration of juvenile hallux valgus.*

This null hypothesis is accepted as there was no statistically significant difference in the outcome for children who wore a Root foot orthosis for three years.

A Root foot orthosis prescribed to restrict foot pronation will not slow the progression of juvenile hallux valgus probably because pronation of the foot is not an important factor in juvenile hallux valgus. In children with unilateral hallux valgus, a Root foot orthosis will not maintain the metatarsophalangeal joint angle of the clinically normal foot. In time these feet will also develop hallux valgus despite the use of a Root foot orthosis.

Night splint therapy has subsequently been offered as an alternative treatment to the Kettering hallux valgus children. Radiographic evaluation of the hallux valgus and intermetatarsal angles will be repeated for all the Kettering hallux valgus children in 1996.

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APPENDICES

Arch Index Values and Hallux Valgus Angles Children with Bilateral Hallux Valgus

n= 32

	Right MTP Joint	Right Arch Index	Left MTP Joint	Left Arch Index
Bilateral Group	15	0.22	15	0.19
	37	0.25	30	0.295
	19	0.25	15	0.25
	18	0.28	24	0.29
	21.5	0.24	17.5	0.24
	15	0.22	19	0.23
	19	0.25	24	0.22
	22	0.24	23	0.23
	17	0.28	20	0.27
	21	0.24	15	0.25
	33	0.16	18	0.16
	15.5	0.06	17.5	0.09
	26	0.22	27	0.21
	24	0.24	21.5	0.21
	14	0.26	22	0.27
	18	0.25	16.5	0.14
	21	0.23	23	0.11
	21	0.26	20	0.25
	20	0.2	25	0.25
	17	0.21	13	0.25
	21	0.24	19	0.27
	15	0.21	14	0.2
	24	0.27	15	0.25
	21	0.13	20	0.07
	18	0.24	21.5	0.23
	20	0.3	22	0.28
	14	0.25	20	0.23
	24	0.22	29	0.23
	21	0.25	15	0.24
	15	0.23	18	0.24
	22	0.28	20	0.25
	16	0.22	18.5	0.26
Mean	20.16	0.23	19.94	0.22
SD	5	0.04	4.1	0.05

Arch Index Values for Children with no First MTP Joint Deformity

n= 32

	Right Arch Index	Left Arch Index
Control Group	0.22	0.21
	0.06	0.07
	0.22	0.19
	0.2	0.24
	0.27	0.25
	0.15	0.14
	0.09	0.06
	0.23	0.24
	0.22	0.23
	0.27	0.24
	0.25	0.14
	0.22	0.22
	0.23	0.19
	0.21	0.23
	0.29	0.31
	0.23	0.21
	0.05	0.06
	0.3	0.26
	0.16	0.2
	0.23	0.27
	0.21	0.25
	0.23	0.25
	0.26	0.24
	0.24	0.25
	0.3	0.34
	0.24	0.25
	0.22	0.25
	0.38	0.38
	0.3	0.28
	0.2	0.24
	0.24	0.23
	0.14	0.15
Mean	0.22	0.22
SD	0.06	0.07

Appendix 2. See Section 2.2

i. Transmalleolar Axis
Estimated standard deviation of transmalleolar axis measurement 2.25
Smallest clinically relevant difference 2°

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	0.20	23	29	37	43
0.90	0.10	32	39	48	55
0.95	0.05	40	48	58	65

Table 1 Appendix 2 Prospective Calculations of Sample Size for Transmalleolar Axis Measurement

ii. Ankle Dorsiflexion Measurement
Estimated standard deviation of ankle joint measurement = 5.5
Smallest clinically relevant difference 4°

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	0.20	24	30	38	45
0.90	0.10	33	40	50	57
0.95	0.05	41	50	60	68

TABLE 2 Appendix 2 Prospective Calculations of Sample Size for Ankle Joint Dorsiflexion Measurement

iii. Subtalar Joint Measurement
Estimated standard deviation of subtalar joint measurement = 1.7
Smallest clinically relevant difference 2°

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	0.20	9	12	15	17
0.90	0.10	13	16	19	22
0.95	0.05	16	19	23	26

TABLE 3 Appendix 2 Prospective Calculations of Sample Size of Subtalar Joint Measurement

iv. Forefoot to Rearfoot Angle Measurement

Estimated standard deviation of forefoot to rearfoot angle measurement 3.2
Smallest clinically relevant difference 3°

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	0.20	15	18	23	27
0.90	0.10	20	24	30	34
0.95	0.05	25	30	36	41

TABLE 4 Appendix 2 Prospective Calculations of Sample Size of Forefoot to Rearfoot Angle Measurement

v. First Metatarsal Position Measurement

Estimated standard deviation of first metatarsal position measurement = 1.4
Smallest clinically relevant difference 2mm

Power	Beta	Alpha = 0.10	Alpha = 0.05 Sample	Alpha = 0.02 Size	Alpha = 0.01
0.80	0.20	7	8	10	12
0.90	0.10	9	11	13	15
0.95	0.05	11	13	16	18

TABLE 5 Appendix 2 Prospective Calculations of Sample Size for First metatarsal Position Measurement

Intra-Observer Measurement Error: Transmalleolar Axis Measurement

Normal Feet n=30

	First Measurement	Second Measurement	Difference
Right Foot	17	15	2
	12	12	0
	14	13	1
	16	16	0
	17	19	-2
	16	17	-1
	16	16	0
	23	22	1
	20	17	3
	25	22	3
	19	17	2
	20	20	0
	22	20	2
	17	20	-3
	17	16	1
	13	14	-1
	16	17	-1
	16	17	-1
	16	18	-2
	17	17	0
	20	20	0
	16	16	0
	16	15	1
	17	17	0
	20	20	0
	16	20	-4
	16	17	-1
	16	17	-1
	17	16	1
	21	17	4
Left Foot	17	15	2
	12	12	0
	14	10	4
	16	18	-2
	20	19	1
	16	15	1
	15	17	-2
	16	17	-1
	12	22	-10
	20	20	0
	13	15	-2
	15	20	-5
	15	16	-1
	16	16	0
	16	16	0
	13	13	0
	17	13	4
	16	16	0
	16	16	0
	18	17	1
	16	16	0
	16	16	0
	16	15	1
	17	15	2
	15	15	0
	16	14	2
	16	15	1
	11	15	-4
	14	15	-1
	17	11	6
Mean	16.5	16.5	0.01
SD	2.6	2.57	2.3

Appendix 3. See Section 2.2

Intra Observer Measurement Error Ankle Dorsiflexion Measurement

Normal Feet n=30

	First Measurement	Second Measurement	Difference
Right Foot	15	19	-4
	15	15	0
	13	11	2
	25	26	-1
	25	27	-2
	15	15	0
	30	26	4
	30	30	0
	30	30	0
	30	30	0
	15	20	-5
	20	20	0
	17	22	-5
	17	18	-1
	20	17	3
	20	17	3
	10	12	-2
	12	15	-3
	17	20	-3
	15	20	-5
	15	14	1
	15	19	-4
	15	15	0
	17	15	2
	15	15	0
	15	10	5
	15	13	2
	13	13	0
	17	8	9
	19	10	9
Left Foot	10	15	-5
	15	12	3
	10	10	0
	22	20	2
	26	26	0
	20	17	3
	25	21	4
	30	30	0
	20	26	-6
	30	30	0
	22	20	2
	15	20	-5
	16	20	-4
	15	18	-3
	20	15	5
	22	10	12
	10	10	0
	11	10	1
	14	14	0
	10	15	-5
	20	20	0
	20	20	0
	17	15	2
	17	17	0
	15	15	0
	15	10	5
	15	13	2
	13	15	-2
	14	10	4
	16	10	6
Mean	17.7	17.4	0.43
SD	5.5	5.9	3.6

Appendix 3, see Section 2.2.

Intra-Observer Measurement Error: Subtalar Joint Neutral Position Measurement

Normal Feet n=30

	First Measurement	Second Measurement	Difference
Right Foot	9	6	3
	6	6	0
	8	6	2
	6	6	0
	6	9	- 3
	7	8	- 1
	4	6	- 2
	10	12	- 2
	4	4	0
	5	6	- 1
	4	9	- 5
	4	6	- 2
	5	6	- 1
	7	10	- 3
	6	6	0
	7	10	- 3
	6	8	- 2
	7	8	- 1
	4	8	- 4
	4	6	- 2
	8	4	4
	4	10	- 6
	6	4	2
	8	7	1
	6	6	0
	6	6	0
	6	5	1
	6	8	- 2
	6	6	0
	6	4	2
Left Foot	5	8	- 3
	7	6	1
	6	6	0
	7	7	0
	6	6	0
	6	8	- 2
	5	2	3
	7	7	0
	6	5	1
	5	6	- 1
	6	7	- 1
	4	7	- 3
	4	4	0
	6	9	- 3
	6	8	- 2
	6	9	- 3
	8	6	2
	6	10	- 4
	7	6	1
	4	4	0
	5	7	- 2
	7	10	- 3
	5	6	- 1
	4	8	- 4
	7	6	1
	5	4	1
	10	6	4
	5	8	- 3
	6	7	- 1
	0	4	- 4
Mean	5.9	6.7	-0.85
SD	1.6	1.9	2.1

Intra-Observer Measurement Error: Forefoot Position Measurement

Normal Feet n=30

	First Measurement	Second Measurement	Difference
Right Foot	3	-3	6
	7	7	0
	0	0	0
	10	7	3
	3	-6	9
	5	-3	8
	6	-7	13
	3	0	3
	10	-5	15
	13	-14	27
	2	-2	4
	5	-6	11
	5	-7	12
	7	-5	12
	3	-2	5
	7	-7	14
	6	-6	12
	7	-5	12
	4	0	4
	2	0	2
	4	-5	9
	4	-2	6
	4	-4	8
	2	-3	5
	3	-3	6
	5	-2	7
	4	-4	8
	4	0	4
	1	0	1
	0	0	0
Left Foot	3	-3	6
	7	-5	12
	3	0	3
	4	-5	9
	6	-4	10
	4	-5	9
	6	-5	11
	5	-5	10
	6	-10	16
	17	-6	23
	1	0	1
	0	0	0
	3	-4	7
	0	-5	5
	2	-2	4
	6	-6	12
	2	-7	9
	1	-3	4
	2	0	2
	2	0	2
	1	-2	3
	2	-2	4
	4	-4	8
	2	-2	4
	0	-2	2
	5	-2	7
	2	-6	8
	2	-2	4
	2	0	2
	0	0	0
Mean	3.98	-3.06	0.41
SD	3.1	3.3	2.33

Intra-Observer Measurement Error: First Metatarsal Position Measurement

Normal Feet n=30

	First Measurement	Second Measurement	Difference
Right Foot	0	0	0
	0.5	0.5	0
	3	0	3
	0	-1	1
	3	5	-2
	-0.5	0	-0.5
	-1	0	-1
	0	0	0
	1	0	1
	0.5	0	0.5
	4	3	1
	3	4	-1
	2	2	0
	2	3	-1
	1	1.5	-0.5
	3	4	-1
	-0.5	0.5	-1
	1	1	0
	2	1	1
	1.5	1	0.5
	0	0	0
	0.5	1	-0.5
	2	1.5	0.5
	1	2	-1
	2	2	0
	2	0.5	1.5
	0	1	-1
	0	0	0
	1.5	1.5	0
	1.5	1.5	0
Left Foot	0.5	0	0.5
	2.5	0.5	2
	0	0	0
	0	-1	1
	4	5	-1
	0.5	2.5	-2
	-0.5	0.5	-1
	-1.5	-1.5	0
	0	0	0
	0	1	-1
	3	3	0
	4	4	0
	2	4	-2
	3	3	0
	0.5	0	0.5
	5	3.5	1.5
	0.5	1	-0.5
	0	2	-2
	2	1	1
	1.5	1	0.5
	1	0.5	0.5
	0	1	-1
	2.5	2	0.5
	1.5	3	-1.5
	2	2	0
	1.5	2	-0.5
	1.5	1	0.5
	0	0	0
	2	2.5	-0.5
	2.5	2.5	0
Mean	1.3	1.375	-0.08
SD	1.4	1.5	0.96

Positive Values = Plantarflexed First Ray, Negative Values = dorsiflexed First Ray

Appendix 4, see Section 2.2

Biomechanical Measurements of the Lower Limb in Hallux Valgus Children

Hallux valgus Children n=30

	Transmalleolar Axis	Ankle Dorsiflexion	Subtalar Joint Inversion	STJ Eversion	Forefoot to Rearfoot Angle	First Metatarsal Position
Right Limb	18	15	37	10	0	0.5
	17	15	27	8	0	1
	17	15	24	12	5	3.5
	19	23	37	8	- 5	3
	14	10	26	13	- 2	2.5
	16	10	24	8	- 2	0
	16	15	23	10	0	2
	17	14	35	9	0	3
	17	13	20	6	- 4	4.5
	16	15	31	9	- 5	6
	16	15	36	8	- 5	4.5
	16	15	33	4	- 7	0.5
	19	15	20	9	- 4	0.5
	18	10	39	9	- 4	1
	20	10	27	4	- 3	1
	15	13	32	8	- 4	2
	17	11	38	10	- 2	0
	17	14	30	7	4	2.5
	16	15	33	5	0	1
	14	7	37	6	- 4	-1.5
	20	16	30	3	- 4	3
	18	20	40	6	0	5
	15	10	30	12	- 5	0
	15	10	35	6	0	0
	15	16	26	13	- 2	0
	12	10	27	12	- 4	2
	20	10	36	8	- 4	3
	16	20	37	14	2	3
	16	15	30	10	0	1
	17	15	25	12	- 1	5
Left Limb	17	15	43	10	0	2
	17	15	29	10	- 2	4
	17	15	24	12	5	3.5
	19	23	36	8	- 1	2.5
	18	15	28	15	- 3	2
	15	10	32	3	- 3	3
	15	15	29	10	0	1.5
	18	15	37	7	0	5
	17	15	22	5	- 3	7
	17	13	29	12	4	5
	21	13	32	8	3	1.5
	18	15	30	10	- 4	0
	19	15	20	9	- 2	7.5
	17	17	32	10	- 1	1.5
	17	6	28	11	- 3	1.5
	17	13	32	10	0	2.5
	17	13	38	11	- 2	1.5
	16	15	33	5	- 4	4
	16	15	31	8	0	1
	14	10	35	4	2	1.5
	35	10	25	3	4	4.5
	18	20	30	9	0	2
	15	15	27	10	0	1.5
	18	10	32	6	0	2.5
	15	16	28	10	0	0
	13	10	30	11	3	2.5
	15	10	33	14	2	3
	16	20	34	16	1	2.5
	16	15	32	10	0	4.5
	16	13	32	6	- 1	6.5
Mean	16.9	13.9	30.8	8.9	-1.08	2.45
SD	2.9	3.4	5.2	3	2.7	1.9

Forefoot angle, negative value = varus, positive = valgus. First metatarsal negative = dorsiflexed, positive plant [illegible]cal Measurements of the Lower Limb in Normal children

Normal Children n=30

	Transmalleolar Axis	Ankle Dorsiflexion	Subtalar Joint Inversion	STJ Eversion	Forefoot to Rearfoot Angle	First Metatarsal Position
Right Limb	15	19	20	10	-3	0
	12	15	26	6	7	0.5
	13	11	25	8	0	0
	16	26	27	8	7	-1
	19	27	24	12	-6	5
	17	15	22	11	-3	0
	16	26	24	7	-7	0
	22	30	34	7	0	0
	17	30	22	10	-5	0
	22	30	27	10	-14	0
	17	20	20	19	-2	3
	20	20	24	7	-6	4
	20	22	22	6	-7	2
	20	18	20	10	-5	3
	16	17	29	8	-2	1.5
	14	17	34	10	-7	4
	17	12	32	8	-6	0.5
	17	15	24	6	-5	1
	18	20	38	8	0	1
	17	20	32	10	0	1
	20	14	22	16	-5	0
	16	19	30	8	-2	1
	16	15	30	12	-4	1.5
	16	15	30	8	-3	2
	20	15	25	6	-3	2
	20	10	28	5	-2	0.5
	17	13	30	6	-4	1
	17	13	29	8	0	0
	16	8	28	7	0	1.5
	17	10	26	6	0	1.5
Left Limb	15	15	20	6	-3	0
	12	12	27	10	-5	0.5
	10	10	20	6	0	0
	18	20	32	7	-5	-1
	19	26	18	13	-4	5
	15	17	26	11	-5	2.5
	17	21	23	10	-5	0.5
	17	30	21	10	-5	-1.5
	22	26	27	8	-10	0
	20	30	26	10	-6	1
	15	20	20	9	0	3
	20	20	20	6	0	4
	16	20	20	12	-4	4
	20	18	22	9	-5	3
	16	15	25	6	-2	0
	13	10	32	10	-6	3.5
	13	10	35	10	-7	1
	16	10	31	10	-3	2
	16	14	34	10	0	1
	17	15	30	8	0	1
	16	20	22	16	-2	0.5
	16	20	34	8	-2	1
	16	15	24	14	-4	2
	16	17	30	8	-2	3
	15	15	28	7	-2	2
	14	10	23	4	-2	2
	15	13	26	10	-6	1
	15	15	29	7	-2	0
	15	10	30	8	0	2.5
	17	10	26	6	0	2.5
Mean	16.7	17.4	26.1	8.9	-3.06	1.375
SD	2.5	5.9	4.7	2.8	3.3	1.5

Forefoot angle negative value = varus, positive = valgus. First metatarsal negative = dorsiflexed positive = plantarflexed

Appendix 5, Part 1

A Biomechanical Foot Orthosis in the Treatment of Juvenile Hallux Valgus. Control and Study group MTP Joint and IM Angles: 1988 and 1992

n= 122

	MTP Joint Angle1988	MTP Joint Angle 1992	Difference	IM Angle 1988	IM Angle 1992	Difference
Bilateral Control Group	20	21.5	1.5	12.5	10	-2.5
Left Foot	18	13	-5	13	11	-2
	15	18.5	3.5	8	7	-1
	17.5	22	4.5	12	13	1
	17	15	-2	8	9.25	1.25
	15	15	0	10.5	10	-0.5
	16	13	-3	11	12	1
	16	22	6	11	13.5	2.5
	15	12.5	-2.5	11	8.5	-2.5
	21	23	2	9	12	3
	23	25.5	2.5	9	8	-1
	15	17.5	2.5	10	10.5	0.5
	16	19	3	11	12	1
	23.5	21	-2.5	8.5	10.5	2
	20.5	22.5	2	11	8.5	-2.5
	14.5	13	-1.5	8	8	0
	23.5	25	1.5	10	10.5	0.5
	15	20	5	10	9.5	-0.5
	16	19	3	10	8	-2
	16	19.5	3.5	7.5	7.5	0
	27.5	27	-0.5	13.5	16	2.5
	20	16.5	-3.5	11.5	11	-0.5
Right Foot	16.5	9.25	-7.25	10.5	10.5	0
	19	18	-1	15	15	0
	17	17.5	0.5	8.25	8.5	0.25
	20	24	4	11.5	11.25	-0.25
	19	20.5	1.5	7.5	8	0.5
	16.5	14	-2.5	9.5	10	0.5
	16	17	1	14	15.5	1.5
	19.5	20	0.5	10	12	2
	21	25	4	11.5	12	0.5
	18	30.5	12.5	10.5	10.5	0
	16	27	11	8	8	0
	16.5	19	2.5	11	9	-2
	20	20.5	0.5	12.25	9	-3.25
	18	17	-1	10.5	10	-0.5
	22.5	18.5	-4	11	9	-2
	22	21	-1	11.5	9	-2.5
	21	21.5	0.5	9.5	9.5	0
	16	18	2	10.5	12	1.5
	15	23	8	11	12	1
	15.5	17	1.5	7	7.5	0.5
	16	23.5	7.5	13.5	12	-1.5
	16	15	-1	10	9.5	-0.5

A Biomechanical Foot Orthosis in the Treatment of Juvenile Hallux Valgus. Control and Study group MTP Joint and IM Angles° 1988 and 1992

n= 122

	MTP Joint Angle1988	MTP Joint Angle 1992	Difference	IM Angle 1988	IM Angle 1992	Difference
Bilateral Study Group						
Left Foot	22	20	-2	11.5	11	-0.5
	18	20	2	13	9	-4
	29	36.5	7.5	15	18	3
	30	31.5	1.5	10	10	0
	20	22.5	2.5	8	8	0
	14.5	19	4.5	9	11	2
	23	26	3	7	7.5	0.5
	16.5	21	4.5	7	7.5	0.5
	20	26.5	6.5	10	12.5	2.5
	27	24	-3	15	15.5	0.5
	23	29	6	11	10	-1
	22.5	7	-15.5	11.25	9	-2.25
	21.5	25	3.5	11	12	1
	16	23	7	8	11	3
	23.5	24	0.5	9	6	-3
	15	20.75	5.75	10	9.25	-0.75
	19	20.5	1.5	10	11	1
	18	25.5	7.5	7.5	9	1.5
	24	29	5	12.5	17	4.5
	17.5	16.25	-1.25	9	7.5	-1.5
	25	28	3	11	8.5	-2.5
	24	31	7	13	16	3
	18.5	17	-1.5	11	11	0
	19	21.5	2.5	11	10.5	-0.5
Right Foot	20	23	3	13.5	9	-4.5
	16	21	5	9.5	10.5	1
	24	32	8	13	16.5	3.5
	37	40.5	3.5	10	13	3
	23	20	-3	12.5	11	-1.5
	21	22	1	9	11	2
	21	24.5	3.5	8	9	1
	18	24.5	6.5	7.5	9	1.5
	21	26	5	10	11	1
	26	25	-1	15.5	14	-1.5
	22	22	0	12.5	9.5	-3
	15	12	-3	11.5	10	-1.5
	19.5	19.5	0	10	11	1
	14.75	18.5	3.75	9.5	8	-1.5
	26	28	2	12.5	8	-4.5
	21	23	2	10	8	-2
	15	16	1	10	10	0
	30	33.5	3.5	11	11.5	0.5
	19	18	-1	12.5	15	2.5
	21.5	21.5	0	11.5	8.5	-3
	20	18	-2	10	11.5	1.5
	18	19.5	1.5	8.5	12	3.5
	17	18	1	13	12	-1
	21	21	0	11	10	-1

Appendix 5, part 3

A Biomechanical Foot Orthosis in the Treatment of Juvenile Hallux Valgus. Control and Study group MTP Joint and IM Angles° 1988 and 1992

n= 122

	MTP Joint Angle1988	MTP Joint Angle 1992	Difference	IM Angle 1988	IM Angle 1992	Difference
Unilateral Cntrl Group	14	18.25	4.25	9	14	5
Unaffected foot	11	14.5	3.5	9	8.25	-0.75
	14	16.5	2.5	8	8	0
	8	10	2	10	10.5	0.5
	14	14	0	14	10	-4
	11.5	21.5	10	7.5	9.25	1.75
	12.5	11.5	-1	9.5	7	-2.5
	13	14.75	1.75	11.5	13	1.5
	9.5	19.5	10	10	12.5	2.5
	12	113	101	7	10.25	3.25
	13	12.5	-0.5	10.5	10	-0.5
	11	15.5	4.5	11	10.5	-0.5
	12.5	13	0.5	13	13	0
	8	11	3	7.5	9.5	2
	13.5	20.5	7	8	8	0
	12.5	27	14.5	7.5	8	0.5
	14	21.5	7.5	11	11	0
	10	11.5	1.5	10	9	-1
	14	16.5	2.5	8.5	7	-1.5
	12	21.5	9.5	8.5	9	0.5
	9	9	0	11.5	9.5	-2
Mean	11.85	20.6	8.8	9.6	9.86	0.22
SD	1.9	21.1	21	1.8	1.9	1.96
Unilateral Study Group	12.5	10.75	-1.75	7.5	8	0.5
Unaffected foot	12	15	3	9	11.5	2.5
	14	15.5	1.5	10.5	11	0.5
	9.5	7	-2.5	8.5	7.5	-1
	9	15	6	7.5	6.5	-1
	6.5	7	0.5	8	7	-1
	12	17	5	9.5	9.25	-0.25
	9.5	37.5	28	7	7.5	0.5
	11	14	3	8.5	10.5	2
	13	18	5	10	10	0
	14	17.5	3.5	9.5	10	0.5
	13	17	4	10	15.5	5.5
	13	29	16	10	14	4
	14	18.5	4.5	6	9	3
	11	9.5	-1.5	8	8.5	0.5
	5.5	8	2.5	9	9.5	0.5
	7	13	6	12	10	-2
	14.5	26.5	12	7.5	13	5.5
	13.5	16.5	3	5	7	2
	11	10.5	-0.5	7.5	7.5	0
	9.5	9.5	0	9.5	10.5	1
	11	18.5	7.5	10	9	-1
	11	19.5	8.5	11	11	0
	13	12	-1	8	8.5	0.5
	9.5	11.5	2	10.5	11.5	1
	-6	14	20	9	9.5	0.5
Study group Mean	10.5	15.68	5.16	8.78	9.7	0.93
SD	4.05	6.8	6.9	1.55	2.1	1.85
Number of feet = 47						
All unilateral Grp Mean	11.1	17.8	6.7	9.1	9.7	0.5
SD	3.3	15.2	15	1.7	2	1.45

A Biomechanical Foot Orthosis in the Treatment of Juvenile Hallux Valgus. Control and Study group MTP Joint and IM Angles° 1988 and 1992

n= 122

	MTP Joint Angle1988	MTP Joint Angle 1992	Difference	IM Angle 1988	IM Angle 1992	Difference
Unilateral Cntrl Group	20.5	26.5	6	10	11.25	1.25
Affected Foot	21	18	-3	9	9.5	0.5
	16	16.5	0.5	7.5	7	-0.5
	17	22	5	11	12	1
	20.5	18.25	-2.25	12.5	13	0.5
	20.5	28.5	8	8.5	11	2.5
	17	17.75	0.75	10	10.5	0.5
	19	14.75	-4.25	12.5	12.5	0
	15	19.5	4.5	11.5	12.5	1
	19	19	0	9	9	0
	18	16	-2	12.5	13	0.5
	20	25	5	11	12	1
	20	29	9	13	16	3
	16.5	29	12.5	9.25	13	3.75
	15	18.75	3.75	9	8.5	-0.5
	15.5	20	4.5	7.5	8	0.5
	16	16.25	0.25	9	10.5	1.5
	18.5	15	-3.5	14	11.5	-2.5
	15	20.5	5.5	9	8	-1
	17	18	1	7.5	8	0.5
	18.5	19	0.5	12	14	2
Unilateral Study Group	15	20	5	8	11	3
Affected Foot	18	22	4	13	16	3
	15	14	-1	11.5	9.25	-2.25
	16	15	-1	7.5	10	2.5
	20	16	-4	6	6.5	0.5
	22	21.5	-0.5	10	11	1
	19	28	9	9.5	11	1.5
	17	37	20	9	8.25	-0.75
	22	26	4	14	12.5	-1.5
	17	20	3	10	14	4
	24	27.5	3.5	14	12	-2
	15.5	18	2.5	9	12	3
	30	22	-8	10	11	1
	20	17	-3	7.5	8	0.5
	20	20.5	0.5	10	10.5	0.5
	15	17	2	9	9.5	0.5
	19.5	26	6.5	10	11.5	1.5
	24.5	31	6.5	11	13.5	2.5
	18	16.5	-1.5	8	8.5	0.5
	17	18	1	9.25	9.5	0.25
	24	26	2	9	11	2
	16	20	4	9.5	10.5	1
	19	22	3	10	11	1
	17	17.5	0.5	8	8.5	0.5
	15.5	19	3.5	10.5	13	2.5
Number of feet = 139	17	30.5	13.5	10	11.5	1.5
Mean	19.2	21.3	2	10.4	10.7	0.3
SD	3.8	5.4	4.3	1.9	2.3	1.8

Appendix 6, part 1

Metatarsus Primus Varus. Children with Unilateral Hallux Valgus lost to Three Year Follow Up

n=15

	Affected MTP Joint	Affected IM Angle	Unaffected MTP Joint	Unaffected IM Angle
Unilateral Group	14.5	10	10.5	8.5
	22	12.5	13.5	11
	22	11	12	5
	19	13	10.5	8
	19	12.5	14	12.5
	16.75	9.25	13.5	8
	15	10	14	7.5
	21.5	13	9	9.5
	21.25	10.5	14	10
	22	10	13	8.25
	14.75	8.5	11	9
	22	12	11	10.5
	19	8	13.5	9.5
	17.5	8.5	14	8.5
	15	9	11	8
Mean	18.75	10.51	12.3	8.9
SD	2.87	1.66	1.6	1.67

Metatarsus Primus Varus. Children with Bilateral Hallux Valgus lost to Three Year Follow Up

n= 14

	Right MTP Joint	Right IM Angle	Left MTP Joint	Left IM Angle
Bilateral Group	21.5	10	19.5	11
	12	8.5	22	11
	20	11	16.5	12
	24	13	15	10
	17	10	20	13.5
	17	11.5	20.5	12
	20	10.5	15	9.5
	23.75	15	30	13.5
	20.5	13.5	17.5	11.5
	22	10	20	9
	21.75	11	23	12.25
	15	5	15.5	12.5
	20	11	16.5	12
	17	11.5	20.5	12
Mean	19.4	10.82	19.4	11.5
SD	3.2	2.2	3.8	1.3

Metatarsus Primus Varus. The Aetiological Studies on Bilateral Cases

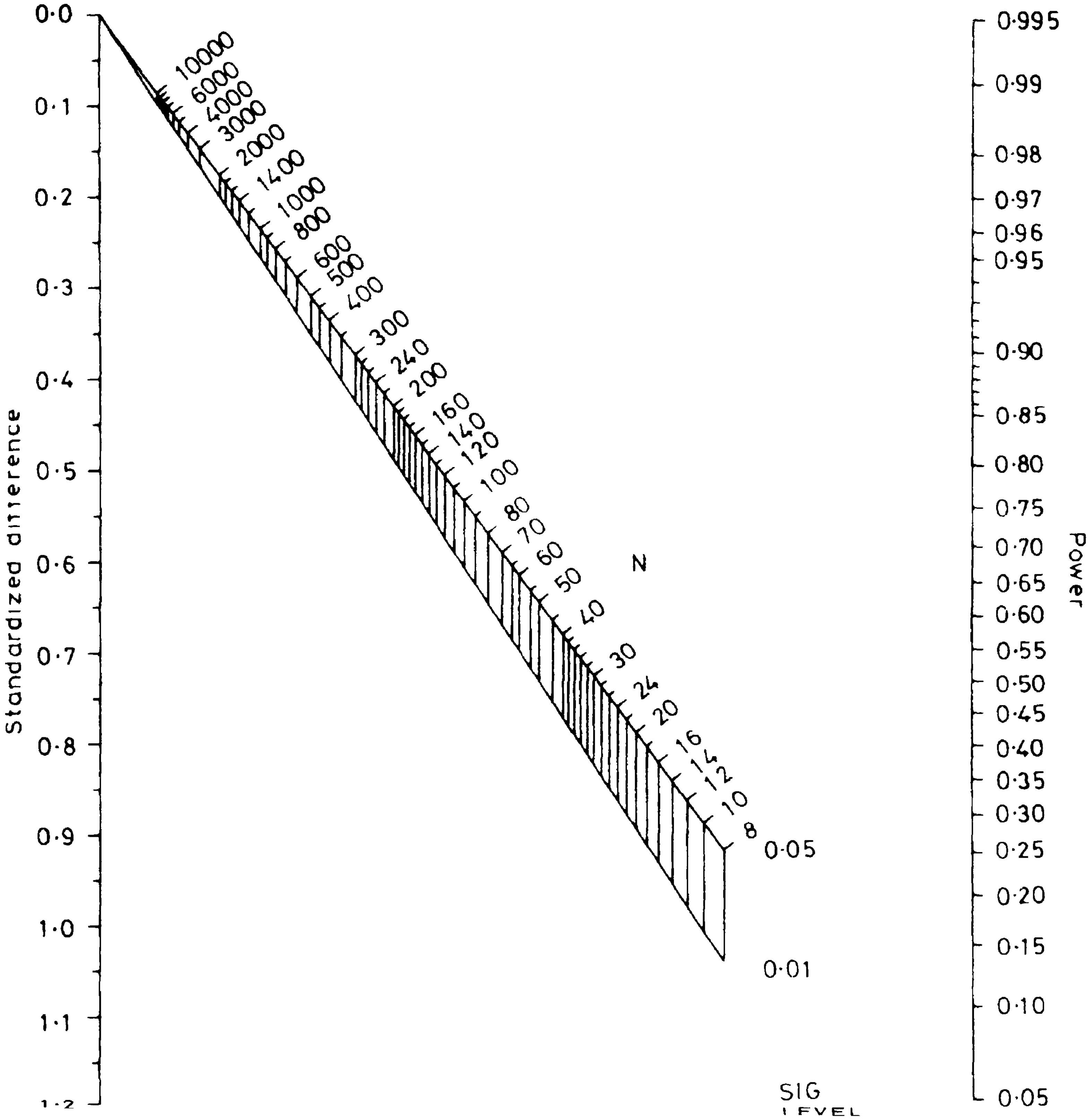
n = 60 (120 feet)

	Lateral Cortex Length (mm)	Metatarsus Adductus Angle °	Cuneiform Angle °
Bilateral Group	4.6	22	2
Left Foot	4.1	17	2
	4.7	13	9
	5	8	19
	4.2	19	4.5
	4.2	11	10
	4.8	13	8
	4	14	8
	4.6	22	7
	4.5	13	6
	4	15	9
	4.6	21	13
	4.1	18	7
	4.6	12.5	5
	4	16	6
	4.6	18.5	9
	4.1	17	4
	4.3	14	14
	4	15	5
	3.9	17	2
	4.1	14	9
	4.5	15	18
	4.7	17	6
	4	14	17
	4.3	16.5	5
	4.3	22	10
	4	20	10
	4.4	20	5
	3.8	14	9.5
	4.6	16.5	15
	4.7	22	12.5
	4.1	19	6
	4	13	5
	4.3	24.5	8.5
	4.8	22	9.5
	5	16.5	10
	4.5	15	22
	4.5	13.5	12
	4.5	16	-2
	5.5	15	3
	4.9	15	7
	4.4	8.5	13
	4.7	24.5	3
	4.6	20	1
	4	13	2
	4.5	22	1
	4.1	20	6
	4.9	14	8
	5	18	4
	4.5	16	4
	4.2	17	2
	3.9	20	9
	4.1	18.5	12
	4.5	16	2.5
	4.6	17	10.5
	4.5	22	0
	4.2	16.5	5
	4	20	4
	5	13.5	4

Metatarsus Primus Varus. The Aetiological Studies on Bilateral Cases

n = 60 (120 feet)

	Lateral Cortex Length (mm)	Metatarsus Adductus Angle °	Cuneiform Angle °
Right Foot	4.4	21	1
	4.4	13	1.5
	4.8	24	5
	5	17	7
	4.2	18	15.5
	4	22	10
	4.8	21	10
	4.1	13	5
	4.4	9.5	9
	4.4	16	10
	3.9	13.5	8
	4.5	13	9
	4	6	7
	4.6	23	7
	4	10	5.5
	4.5	14	11
	4	24	4
	4.4	14	4
	4	12.5	6
	3.9	17.5	4
	4.2	18.5	4
	4.9	22	4
	4.8	16	9
	4.3	16	4.5
	4.6	17	12.5
	4.4	18	5
	4.1	15	4.5
	4.3	19	18
	3.8	18	6.5
	4.4	15.5	8
	4.6	20	14
	4.1	21	16
	4.1	19	8
	4.1	11	3
	4.9	16.5	13.5
	5.1	17.5	10.5
	4.5	15	10
	4.7	18.5	12
	4.5	19.5	8
	5.3	17	-1
	5.2	14	7
	4.4	17	4
	4.7	8.5	12
	4.6	24	3.5
	4	17	1
	4.4	12	0
	4.6	17	0
	4.6	20	7
	5	21.5	11
	5	15	3.5
	4.3	12.5	6
	3.9	15	3
	4.2	17	8
	4.7	21	8
	4.3	14	1.5
	4.4	18.5	6
	4.4	18.5	5
	4	14	3
	3.8	26	2
	4.7	15.5	4
	4.2	15.5	1
Mean	4.4	16.8	7
SD	2	3.8	4.5



Appendix 8. The Sample Size Nomogram

Appendix see Section 3.1

Goniometer Measurement Intra-Observer Error Trial

Normal Feet n=50

		First Measurement	Second Measurement	Difference
Right Foot				
Subject	1	14	14	0
	2	8	5	3
	3	5	5	0
	4	8	7	1
	5	9	6	3
	6	4	3	1
	7	10	10	0
	8	10	8	2
	9	3	3	0
	10	6	6	0
	11	3	6	-3
	12	0	-4	4
	13	6	9	-3
	14	0	0	0
	15	6	5	1
	16	6	6	0
	17	0	0	0
	18	4	6	-2
	19	4	4	0
	20	9	7	2
	21	2	1	1
	22	2	1	1
	23	10	8	2
	24	3	0	3
	25	0	0	0
Left Foot	26	13	14	-1
	27	5	5	0
	28	5	5	0
	29	4	2	2
	30	8	8	0
	31	5	6	-1
	32	13	14	-1
	33	14	14	0
	34	2	3	-1
	35	1	12	-11
	36	10	10	0
	37	0	5	-5
	38	11	8	3
	39	2	2	0
	40	9	8	1
	41	6	8	-2
	42	6	10	-4
	43	4	4	0
	44	2	4	-2
	45	8	6	2
	46	2	2	0
	47	3	0	3
	48	10	8	2
	49	-1	2	-3
	50	2	0	2
Mean		5.52	5.52	0
SD		4.1	4.2	3.9

Goniometer Measurement Inter-Observer Error Trial

Normal Feet n = 50

		First Measurement	Second Measurement	Difference
Right Foot		Observer 'TEK	Observer LTS	
Subject	1	3	7	- 4
	2	15	16	- 1
	3	7	11	- 4
	4	8	16	- 8
	5	6	8	- 2
	6	3	4	- 1
	7	4	5	- 1
	8	0	3	- 3
	9	1	6	- 5
	10	5	6	- 1
	11	7	10	- 3
	12	0	2	- 2
	13	7	8	- 1
	14	8	9	- 1
	15	3	4	- 1
	16	10	8	2
	17	10	8	2
	18	5	8	- 3
	19	8	10	- 2
	20	4	6	- 2
	21	17	12	5
	22	18	18	0
	23	9	7	2
	24	0	4	- 4
	25	8	7	1
Left Foot	26	7	8	- 1
	27	9	15	- 6
	28	6	8	- 2
	29	9	16	- 7
	30	6	6	0
	31	8	6	2
	32	4	2	2
	33	7	4	3
	34	10	6	4
	35	6	6	0
	36	11	9	2
	37	0	2	- 2
	38	9	9	0
	39	11	10	1
	40	3	1	2
	41	8	6	2
	42	10	12	- 2
	43	7	8	- 1
	44	10	10	0
	45	5	5	0
	46	14	12	2
	47	15	15	0
	48	7	5	2
	49	7	7	0
	50	9	8	1
Mean		7.28	7.98	-0.7
SD		4	3.9	2.7

Goniometer Measurement Intra-Observer Error Trial

No Feet n = 50

		First Measurement	Second Measurement	Difference
Right Foot				
Subject	1	18	18	0
	2	24	24	0
	3	23	24	- 1
	4	20	15	5
	5	19	18	1
	6	15	16	- 1
	7	16	15	1
	8	20	19	1
	9	16	15	1
	10	21	12	9
	11	16	16	0
	12	16	16	0
	13	16	16	0
	14	23	23	0
	15	17	15	2
	16	22	24	- 2
	17	19	20	- 1
	18	18	17	1
	19	18	17	1
	20	15	14	1
	21	16	16	0
	22	23	20	3
	23	16	16	0
	24	15	16	- 1
	25	16	21	- 5
Left Foot	**26**	17	17	0
	27	16	17	- 1
	28	18	22	- 4
	29	17	14	3
	30	17	18	- 1
	31	16	18	- 2
	32	15	16	- 1
	33	20	19	1
	34	22	15	7
	35	20	21	- 1
	36	15	16	- 1
	37	18	16	2
	38	16	16	0
	39	19	19	0
	40	20	20	0
	41	19	20	- 1
	42	20	22	- 2
	43	15	15	0
	44	24	24	0
	45	21	18	3
	46	15	15	0
	47	22	20	2
	48	16	19	- 3
	49	17	17	0
	50	21	22	- 1
Mean		18.28	17.98	0.3
SD		2.7	3	2.3

Radiographic Vs Goniometric Measurement of Hallux Valgus

HV Feet n =77

		X-ray Measurement	Goniometer Measurement	Difference
Right Foot				
Subject	1	22	19	3
	2	15	18	- 3
	3	26	21	5
	4	18	20	- 2
	5	21.5	18	3.5
	6	18	17	1
	7	18	23	- 5
	8	21	22	- 1
	9	21.5	16	5.5
	10	21	19	2
	11	21	20	1
	12	24	22	2
	13	15	13	2
	14	22	22	0
	15	20	16	4
	16	17	18	- 1
	17	24	24	0
	18	17	16	1
	19	20	24	- 4
	20	24.5	25	-0.5
	21	16	12	4
	22	33	20	13
	23	22	22	0
	24	21	24	- 3
	25	18	14	4
	26	19.5	22	-2.5
	27	22	23	- 1
	28	21	20	1
	29	17	14	3
	30	24	29	- 5
	31	22	19	3
	32	18	18	0
	33	37	33	4
	34	30	20	10
	35	19	22	- 3
	36	15	13	2
	37	17	16	1
	38	15	12	3
Left Foot	39	23	23	0
	40	17.5	16	1.5
	41	15	19	- 4
	42	27	21	6
	43	22	19	3
	44	17	19	- 2
	45	15.5	20	-4.5
	46	16	16	0
	47	17.5	17	0.5
	48	24	24	0
	49	20	21	- 1
	50	16.5	16	0.5
	51	23	20	3
	52	20	23	- 3
	53	16	15	1
	54	24	22	2
	55	15	15	0
	56	20	22	- 2
	57	15	15	0
	58	25	22	3
	59	15	15	0
	60	29	22	7
	61	20	14	6
	62	17	19	- 2
	63	20	21	- 1
	64	18.5	15	3.5
	65	18	11	7
	66	23	16	7
	67	21.5	22	-0.5
	68	15	18	- 3
	69	19	21	- 2
	70	22	22	0
	71	20	17	3
	72	22.5	14	8.5
	73	15	19	- 4
	74	30	24	6
	75	17	22	- 5
	76	16	14	2
	77	21.5	23	-1.5
Mean		20.3	19.2	1.06
SD		4.4	3.95	3.6

The X-ray Measurement Repeatability Study

The Intra-Observer Error Study

Between Day	Right IM °	Right HV °	Left IM °	Left HV°
Day1				
x-ray 1	8	19	15.5	26
2	10.5	17	7.5	6
3	11.5	18.5	10.75	18
4	14	22	13.5	26
5	12.5	20	11	10.5
6	13.5	11.5	13	19
7	8.5	15	8.5	16
8	10	13	10.5	17
9	12	11.5	12.5	16.5
10	9.5	15	8	17
Mean	11	16.25	11	17.2
SD	2	3.5	2.5	6
Day 2				
x-ray 1	9	19.5	14	25.5
2	11	18	8.5	8.5
3	11.5	16.5	12	19.5
4	15	22	13.5	26.5
5	12	21	11	12
6	13	12.5	13	19.5
7	7.5	14.5	8.5	17.5
8	9.5	12	10.5	17.5
9	11	12	12.5	15.5
10	10	16	10	12.5
Mean	10.95	16.4	11.4	17.95
SD	2.1	3.7	1.9	5.4
Day 3				
x-ray 1	9.5	20	14.5	27.5
2	11.5	19.5	8	7.5
3	13	16.5	13	19.5
4	15	20.5	12.5	27
5	13	21	11	11.5
6	12	10.5	13	18.5
7	8	15.5	8.5	17
8	10.5	12	10	18.5
9	11.5	11	12.5	16
10	10	16	10	15.5
Mean	11.4	16.25	11.3	17.85
SD	2	4	2	6.1
Within Day				
Morning				
x-ray 1	8.5	18.5	14	25
2	11	17.5	8.5	7
3	11.5	16.5	10.5	19.5
4	14.5	23.5	11.5	26
5	10.5	12	13	21
6	12.5	12.5	12.5	19.5
7	7.5	15.5	7	17
8	10.5	13	10	17
9	11.5	11.5	12	16.5
10	10	14	10.5	17
Mean	10.8	15.45	10.95	18.55
SD	1.9	3.7	2.1	5.2
Afternoon				
x-ray 1	9.5	18.5	13	25
2	11	17	7.5	7.5
3	11.5	18	9	18.5
4	14.5	22.5	12.5	26.5
5	12.5	18.5	10.5	11.5
6	12.5	11.5	13	19
7	7	14.5	7.5	17.5
8	9.5	12.5	10	17.5
9	10.5	11.5	12	14.5
10	9	14	11	18
Mean	10.75	15.85	10.6	17.55
SD	2.1	3.6	2	5.6
Midnight				
x-ray 1	7.5	17.5	13.5	25.5
2	10	16.5	7.5	7.5
3	11	16.5	9	18.5
4	14	23	12	27
5	13	10	11	20
6	12.5	10.5	12	20
7	7.5	14	8	17.5
8	10.5	12.5	9.5	17
9	11	12	12.5	18
10	10.5	13.5	11.5	16.5
Mean	10.75	14.6	10.65	18.75
SD	2.12	3.9	2	5.3

The X-ray Measurement Repeatability Study

The Inter-Observer Error Study

		Right IM°	Right HV°	Left IM°	Left HV°
Observer 1	**RIB Data**				
	X-ray 1	8.5	18	13	24
	2	9.25	16.5	7.5	8
	3	10	21.5	10	19.5
	4	15	23.75	12	30
	5	13	21.5	9.5	9
	6	13	12.5	13	20
	7	8.5	14	7.5	20
	8	10	15	10	19
	9	11	11	11	20
	10	9.5	14.5	8	16
	Mean	10.75	16.8	10.15	18.55
	SD	2.1	4.2	2.09	6.47
Observer 2	**DRT Data**				
	X-ray 1	8	10	14	25
	2	11	16.5	10	10
	3	11.5	19	11.5	20
	4	13	22	12	25
	5	12.5	20	12.5	10
	6	13	13	16	20
	7	11	15	12	18
	8	9	15	11	20
	9	10	10	11	15
	10	11	17.5	10.5	18
	Mean	11	15.8	12.05	18.1
	SD	1.6	4	1.7	5.2
Observer 3	**LAJ Data**				
	X-ray 1	8.5	22	16	28
	2	9	15	10	12
	3	13	19	11.5	18
	4	14	22.5	13.5	26.5
	5	13	22	15	12
	6	12.5	15	18.5	24
	7	6.5	17	8.5	17
	8	12	13.5	13	20
	9	10	13.5	13.5	14.5
	10	9.5	16.5	10	16
	Mean	10.8	17.6	12.95	18.8
	SD	2.4	3.5	3	5.7

Appendix 11, see Section 3.3

Bunions in Children.
Research Information sheet.

Your child has been diagnosed as having a bunion of one or both big toe joints. This foot problem may get worse as your child gets older and can sometimes cause pain in the big toe joint or pressure on the other smaller toes.

Mr Kilmartin and Mr Barrington would like to monitor your child's foot problem using x-rays and other measurements. A first x-ray will be taken in the next few weeks and another x-ray will be taken in three years time.

At present surgery is the only treatment which has been proven effective for this condition. By regularly monitoring your child's foot problem we will be able to advise you on whether such treatment is necessary.

We also hope to use the x-rays and measurements for research purposes in order to learn more about the nature of this particular foot problem in children.

You are invited to take part in this research, if you decide to do so, an x-ray will be taken by Mr Barrington at Kettering General Hospital and Mr Kilmartin will take some other measurements of your child's legs and feet at your local health centre.

Should you not wish to take part in this research, it will not affect your future care or treatment in any way. Once you have started on the study you may stop at any time for any reason and, again, this will not affect your future treatment in any way.

I hereby volunteer to take part in this research project.

Signed. Date

Bunions in Children.
Research Information sheet.

Your child has been diagnosed as having a bunion of one or both big toe joints. This foot problem may get worse as your child gets older and can sometimes cause pain in the big toe joint or pressure on the other smaller toes.

At present surgery is the only treatment which has been proven effective for this condition. Bunion surgery is a serious operation and we would like to try a non-surgical treatment that may prevent further deterioration of the bunion and avoid the need for such an operation. The non-surgical treatment involves making a special insole called an orthotic which is designed to make the joints of the foot function better and stop any further deterioration of the bunion.

Orthotics are widely used for the treatment of athletic and sports injuries and to date there have been no reported side effects.

After supplying the orthotics Mr Kilmartin and Mr Barrington would then like to monitor your child's foot problem using x-rays and other measurements. A first x-ray will be taken in the next few weeks and another x-ray will be taken in three years time.

We also hope to use the x-rays and measurements for research purposes in order to evaluate the usefulness of the orthotics.

You are invited to take part in this research, if you decide to do so, an x-ray will be taken by Mr Barrington at Kettering General Hospital and Mr Kilmartin will take some other measurements of your child's legs and feet before prescribing the orthotic which will be made by a special laboratory. The orthotic will probably need to be replaced every 6 to 9 months, all this will be done at your local health centre.

Should you not wish to take part in this research, it will not affect your future care or treatment in any way. Once you have started on the study you may stop at any time for any reason and, again, this will not affect your future treatment in any way.

I hereby consent for my child to take part in this research project.