

**THE IDIOPATHIC CLUBFOOT: SHORT-TERM RESULTS OF  
TREATMENT WITH THE PONSETI METHOD AT MULAGO  
HOSPITAL**

**By**

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**A dissertation submitted to the School of Post-Graduate Studies in partial  
fulfillment for the award of Master of Medicine (Orthopaedics) of Makerere  
University.**

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## DECLARATION

I declare that the work embodied in this dissertation was carried out by me.  
Unless otherwise stated, the views and opinions expressed are mine. This work  
in this form has never been presented in any other university for a similar award.

Signed

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## **DEDICATION**

This book is dedicated to God whose example of love for mankind has influenced my responses to the needs of people around me. I dedicate this book also to my wife Lillian Njoki Theuri and my son Daniel Macharia, who are my most important source of inspiration, strength and support.

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## DEFINITIONS

- Clubfoot - a foot with a complex deformity of cavus, forefoot adduction, hindfoot varus and equinus.
- Idiopathic clubfoot - a clubfoot deformity present at birth in a child with no congenital or acquired neuromuscular or other musculoskeletal abnormalities.
- Cavus - an abnormally deep medial longitudinal arch of the foot.
- Forefoot adduction - medial angulation of the anterior part of the foot.
- Hindfoot varus - inversion of the heel.
- Forefoot abduction - anterior part of the foot is turned outward (laterally).
- Equinus deformity - plantar-flexion of the foot at the ankle.
- Short-term results - outcomes of treatment within a maximum follow-up period of 14 weeks.
- Hindfoot contracture - less than 15 degrees of dorsiflexion at the ankle.
- Midfoot contracture - forefoot adduction with curved lateral border of the foot.

## ABBREVIATIONS

- AP - anteroposterior
- CCS - Columbian Clubfoot Score
- CTEV - congenital talipes equinovarus
- PoP - Plaster of Paris
- HFC - Hindfoot contracture
- MFC - Midfoot contracture

## ABSTRACT

This was a descriptive follow-up study conducted over a nine month period (May 2002 – January 2003) to determine the outcomes of conservative treatment of idiopathic clubfoot using the Ponseti method at Mulago hospital.

Consecutive recruitment of patients into the study was done at the Talipes clinic in Lower Mulago. Follow-up of patients was done in the course of treatment for a maximum period of 14 weeks at the same venue. The clubfeet were evaluated weekly and the amount of deformity measured using the Columbian Clubfoot Score (CCS). Any complications to treatment were noted.

A total of 53 patients were recruited into the study. Their mean age at presentation was 2.8 months (range 1 week – 15 months). Male to female ratio was 5:1 and bilateral involvement was found in 47.2% of patients. The right foot was affected 2.5 times more frequently than the left.

Nine patients were lost to follow-up. The remaining 44 patients had a total of 67 clubfeet. Good results were obtained in 52 feet (77.6%) in an average length of treatment of 8.7 weeks and an average of 6.2 manipulation and PoP cast applications. Six feet (9%) had only persistent hindfoot contracture and nine feet (13.4%) had both midfoot and hindfoot contractures. Complications to treatment were few and minor.

This study reveals that conservative treatment of idiopathic clubfoot using the Ponseti method could significantly reduce the disability burden caused by idiopathic clubfeet. A long-term follow-up study to assess the maintenance of correction and recurrence rates of clubfoot deformity at Mulago hospital is recommended.

## CHAPTER ONE

### 1.1 INTRODUCTION

Idiopathic clubfoot is a common congenital foot deformity with a worldwide incidence of 1:1000 live births though some racial differences in incidence have been reported.<sup>1</sup> Calculations made using the projected Uganda population of 20.1 million in the year 2000, the population growth rate of 2.5%<sup>2</sup> and the worldwide incidence of 1:1000 live births give a figure of over 600 children with idiopathic clubfoot born in Uganda each year.

Treatment of this deformity consists of conservative management with surgical correction performed on those feet whose deformities persist or on neglected clubfeet.

The Ponseti method of treatment of idiopathic clubfoot was introduced at the Talipes clinic in Mulago hospital through the Uganda Clubfoot project in 1999. Due to the shortage of orthopaedic surgeons in Uganda, most children with idiopathic clubfoot cannot have access to specialized treatment. The Ponseti method is easy to teach to orthopaedic clinical officers and physiotherapists who would then manage the majority of idiopathic clubfeet.

A neglected clubfoot has both social and medical implications. A person with a neglected clubfoot may suffer ridicule by peers especially in childhood, and may be considered physically disabled which could lead to his being discriminated against. His feet have poor cosmesis and need for modified shoes. He has an abnormal gait with poor lateral stability and a predisposition to tripping on his feet. He may develop painful callosities, ulcerations and bursae from walking on the lateral aspect of his feet.

This study has sought to establish the short-term outcomes of treatment of idiopathic clubfoot using the Ponseti method at Mulago hospital. Follow-up of patients was done from initiation of treatment for a maximum of 14 weeks.

### 1.2 Epidemiology

Worldwide incidence of idiopathic clubfoot is generally considered to be 1:1000 live births. However, wide racial differences have been reported.<sup>1</sup> South African blacks have a reported incidence of 3.5 in 1000 live births. Male to female ratio is 2:1, bilateral involvement occurs in 50% of the affected children and the right foot is more commonly affected than the left.<sup>1</sup>

The incidence in the Ugandan population is unknown. However, male to female ratio is reported to be 1.88:1, bilateral involvement occurs in 60% and right and left feet are affected equally in unilateral cases.<sup>3</sup> Mulimba in Nairobi reported similar sex and side affected ratios.<sup>4</sup> Bitariho in Kampala reported a male to female ratio of 6:1.<sup>5</sup>

### **1.3 Justification of the study**

The vast majority of children with idiopathic clubfoot who come to Mulago hospital are treated using the Ponseti method. The results of treatment at Mulago hospital are as yet unknown. 89% satisfactory long-term results have been reported elsewhere with this method.<sup>6</sup>

The results of this study will be useful in guiding decisions about future investment of human and material resources in the treatment of idiopathic clubfoot, which is a common congenital deformity in our society.

The Ponseti method has the following advantages:

1. It is easy to teach to orthopaedic clinical officers and physiotherapists
2. It can be practised in any health facility in the country. Where there is need for tendo Achilles tenotomy, the patient can be referred to a doctor.
3. Materials used in this form of treatment can be made easily available to any health facility in the country.
4. It does not require specialized manpower and equipment, which would tend to limit its accessibility by affected patients.
5. The treatment leaves the foot supple and without scars.

### **1.4.0 Statement of the problem**

Review of literature gives widely varying results of treatment by conservative methods and authors of main orthopaedic textbooks have cast doubts about the success of non-operative management with or without tendo Achilles tenotomy in the treatment of idiopathic clubfoot.

The Ponseti method of treatment was introduced at the Talipes clinic, Mulago hospital, two years ago. Short-term and long-term results of treatment of idiopathic clubfoot using this method are not known at this clinic.

The author, through this study, has sought to establish the short-term outcome of treatment using the Ponseti method. Long-term results would require many years of follow-up and the results of this study will provide a basis for such a study.

#### **1.4.1 Study question**

What are the short-term results of treatment of idiopathic clubfoot using the Ponseti method at Mulago hospital?

#### **1.5 Scope of the study**

The treatment of idiopathic clubfoot consists of two phases which are:

1. The achievement of correction of the clubfoot deformity
2. The maintenance of correction and treatment of recurring deformity

Evaluation of the maintenance of correction would require a long period of follow-up. Due to the limited amount of time available to the author, this study has sought to evaluate only the first phase of treatment.

#### **1.6.0 Objectives**

### **1.6.1 General objectives**

To establish the results of treatment of idiopathic clubfoot using the Ponseti method so as to provide information that would influence its application in this country.

### **1.6.2 Specific objectives**

1. To determine the short-term outcomes of treatment of idiopathic clubfoot using the Ponseti method at Mulago hospital
2. To establish the average number of manipulation and cast applications required to achieve correction of idiopathic clubfoot treated using the Ponseti method at Mulago hospital.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

Idiopathic clubfoot has been known since ancient times. Its earliest description in the literature is attributed to Hippocrates.<sup>1</sup>

Idiopathic clubfoot is a complex foot deformity comprising cavus, forefoot adductus, hindfoot varus and equinus. These can be remembered by the mnemonic CAVE (cavus, adductus, varus, equinus). The hindfoot varus causes supination (inversion) of the entire foot. Cavus is due to the relative pronation of the forefoot on the supinated hindfoot with relative plantarflexion of the first ray.<sup>6</sup>

### 2.1 Aetiology

Several aetiological theories have been proposed for idiopathic clubfoot and these are:

#### 1. Heredity

This theory was proposed by Wynne-Davis who concluded that idiopathic clubfoot is inherited in a polygenic pattern with a threshold effect.<sup>7</sup>

#### 2. Germ-plasm defect

This theory proposes that the deformity in clubfoot is caused by a primary defect in the cartilagenous anlagen of tarsal bones early in embryonic development.<sup>7, 8</sup>

#### 3. Developmental arrest

Bohm observed a clubfoot-like deformity of the feet of normal five-week-old embryos and proposed that idiopathic clubfoot is caused by developmental arrest. This theory was disapproved because abnormal medial displacement of the navicular seen in clubfoot was not seen at any stage of development of a normal foot.<sup>7</sup>

#### 4. Neurogenic cause

Histochemical and electron microscopic studies on the musculature of the legs in clubfoot show abnormal distribution of type I and type II muscle fibres and ultrastructural abnormalities which are thought to be caused by abnormal patterns of innervation.<sup>1, 9</sup>

#### 5. Intrauterine mechanical factors

This theory has been disapproved due to lack of evidence that conditions that cause 'overcrowding' in the uterus result in an increased incidence of idiopathic clubfoot.<sup>1,10</sup>

## **2.2 Pathoanatomy**

The abnormal anatomy in idiopathic clubfoot consists of bony deformities, articular malalignments and soft tissue contractures.<sup>1, 8, 11</sup>

### **2.2.1 Bony deformities**

The talus is the most abnormally shaped of the tarsal bones. Its neck is short, sometimes unidentifiable so that the head appears to be fused with the body. Its neck is also medially deviated.<sup>1, 8</sup>

The calcaneus is slightly short and widened. In general, its contour is relatively normal with its articular facets normally oriented on its body.<sup>1, 8</sup>

The navicular is normal in shape. Its medial tuberosity may be hypertrophied. In severe cases, it may have an articular facet for the medial malleolus.<sup>1, 8</sup>

The other tarsal bones are essentially normal in shape.<sup>1, 8</sup>

### **2.2.2 Articular malalignments**

The talus is in equinus position and slightly rotated laterally around a vertical axis. The navicular is displaced medially and plantarward, leaving the anterior part of the lateral globular end of the talus uncovered. The calcaneus is rotated medially and tilted into equinus position beneath the talus. In addition, it is inverted in that the heel tips into varus. The cuboid is displaced medially in relation to the anterior facet of the calcaneus, which is inclined medially.<sup>1, 8, 11</sup>

### **2.2.3 Soft tissue changes**

The soft tissues on the medial and posterior aspects of the foot and ankle are shortened. These include ligaments, articular capsules, muscles, tendons,

tendon sheaths, vessels, nerves and skin. There is also atrophy of calf muscles.<sup>1,</sup>

11

Routine histologic stains of tissues in idiopathic clubfoot have shown no pathologic changes.<sup>8</sup> Histochemical and electron microscopic studies of leg muscles in clubfoot revealed evidence of neurogenic disease in most instances.<sup>9</sup>

#### **2.2.4 Differential diagnosis**

It is important to distinguish idiopathic clubfoot from acquired types of clubfeet or clubfeet that are part of more extensive syndromes. The following are the differential diagnoses that may be considered:<sup>1</sup>

1. Paralytic clubfoot as seen in myelomeningocele, intraspinal tumours, diastematomyelia, poliomyelitis, injection neuritis, cerebral palsy, the distal type of progressive muscular atrophy, Charcot-Marie-Tooth disease.
2. Syndromic clubfoot as seen in arthrogryposis multiplex congenita, Streeter's dysplasia (congenital annular constricting bands), diastrophic dwarfism, tibial hemimelia, Sheldon syndrome (cranio-carpotarsal dysplasia), Larsen's syndrome, Mobius syndrome.

### **2.3 Examination of a child with clubfoot deformity**

A good history and a thorough physical examination would help to exclude secondary causes of clubfoot.<sup>1</sup>

Specific examination of feet is done to assess severity and monitor response to treatment of the clubfoot deformity. While many clinical systems of assessing the severity of clubfoot deformity have been developed, no single method is universally used.<sup>12, 13</sup> The Columbian Clubfoot Score (Appendix III)<sup>14</sup> was used in this study. It was initially developed as a purely clinical ten-point scoring system by Pirani who later modified it into a six-point system to make it more practical and increase its reliability (personal communication – Pirani). An independent assessment of this system found it to have excellent inter-observer reliability.<sup>13</sup>

Standard anteroposterior (AP) and lateral radiographs have been used in the past to assess the clubfoot deformity. These have to be taken in a specific manner to be of any use, and the angles made by the longitudinal axes of the

ossification centres of the tarsal bones are measured. The most commonly used angles are the AP talocalcaneal angle (normal  $20^{\circ} - 40^{\circ}$ ) and lateral talocalcaneal angle (normal  $35^{\circ} - 50^{\circ}$ ). Both are reduced in idiopathic clubfoot.<sup>1</sup>

Radiographic method of assessment of clubfoot deformity will not be used in this study because

- (i) clinical assessment has been shown to generally correlate well with radiographic assessment<sup>15</sup>
- (ii) where clinical and radiographic assessments differ, more weight is put on the clinical assessment<sup>6, 16, 17</sup>
- (iii) radiographic assessment in our setting is cumbersome and expensive and lack of accurate views would give erroneous measurements<sup>5</sup>
- (iv) inadequate reliability was observed with this method in our setting<sup>5</sup>
- (v) the ovoid ossification centres may not represent the true orientation of the largely cartilagenous tarsal bones<sup>6, 16</sup>

#### **2.4.0 Treatment**

Initial treatment of idiopathic clubfoot is conservative. Surgical correction is employed for persistent deformities after a fair trial of conservative treatment. The type of operative procedures carried out depend on the type of persisting deformity and the age of the patient and they include tendon transfers, posteromedial release, calcaneocuboid fusion, cuboid wedge osteotomy and triple arthrodesis.<sup>1, 11</sup>

Early initiation of treatment has been emphasized for easy correction and good results.<sup>6, 18</sup> Since the time of Hippocrates who believed that clubfeet could be corrected by gentle manipulations and bandaging,<sup>19</sup> many techniques of conservative treatment have been developed. These include use of physiotherapy, use of adhesive taping, use of Denis Browne splints and use of manipulation and PoP cast immobilization.<sup>1</sup>

The highlights of serial manipulation and PoP cast immobilization technique, which is the method commonly used today, are the Kite method, the modification of the Kite method by Lovell and Hancock and the Ponseti method.

Kite advocated complete correction of the forefoot deformity before dorsiflexion was attempted. Manipulation was done by abducting and pronating the foot while applying resistance (counter-pressure) at the prominence of the head of talus; then a toe-to-groin PoP cast was applied with the forefoot in maximum correction. Further correction was achieved by weekly cast wedging. When valgus position was achieved then wedging the foot into dorsiflexion would be done.<sup>16, 20, 21, 22, 23</sup>

Lovell and Hancock modified the Kite technique by introducing the use of below knee PoP casts and weekly cast changes instead of wedging.<sup>24</sup>

#### **2.4.1 The Ponseti technique**

The goal of treatment is to reduce or eliminate clubfoot deformity so that the patient has a functional pain-free, plantigrade foot, with good mobility and without calluses, and does not need to wear modified shoes.<sup>6</sup>

Ponseti advocated correction of the clubfoot deformity starting with cavus, the forefoot adduction and hindfoot varus and finally equinus using a specific method of manipulation and PoP cast immobilization (Appendix ii).<sup>6</sup> He commented that correction of cavus deformity is usually not addressed in the literature on the conservative treatment of clubfoot.<sup>6</sup> He hinted that it is much easier to correct a clubfoot deformity in the first days of life than after even a few weeks.<sup>6</sup>

Ponseti performed percutaneous tendo Achilles tenotomy in approximately 70% of his patients to facilitate correction of equinus deformity.<sup>6</sup> This minor surgical procedure was advocated by Stromeyer in 1831.<sup>19</sup> Ponseti carried it out under general anaesthesia initially<sup>15</sup> but later performed it under local anaesthesia.<sup>6</sup> Tendo Achilles tenotomy obviates rocker bottom deformity which often results from prolonged forceful manipulation into dorsiflexion. The defect of tendo Achilles healed in three weeks. Scar in the tendon after this procedure is minimal as observed in several instances where a tendo Achilles lengthening was performed several years later to correct a recurrence.<sup>15</sup>

The structural deformities of the tarsal bones and joints in a clubfoot cannot be corrected fully, and a completely normal foot should not be expected.<sup>6</sup> When the clinical correction of the foot and the motion of the ankle are satisfactory, even though the correction may not be perfect on roentgenograms, the result of treatment should be considered successful.<sup>6</sup> A recent study in which magnetic resonance imaging was used to demonstrate the pathoanatomy in idiopathic clubfoot and the effects of treatment with the Ponseti method showed correction of not only the abnormal relationship of the tarsal bones but also correction of the abnormal shapes of individual tarsal bones.<sup>25</sup>

#### **2.4.2 Results**

Bradford is reported to have written the following statement: <sup>12</sup> “The literature on the treatment of clubfeet is that of unvarying success. It is often as brilliant as an advertising sheet. Yet in practice there is not lack of half-cured or relapsed cases, sufficient evidence that the methods of cure are not universally understood.”

From the review of literature the two authors who have achieved the highest rates of correction through conservative treatment of idiopathic clubfoot are Ponseti and Kite, who reported 89% satisfactory results after long term follow-up and 90% satisfactory results respectively.<sup>6, 20, 26</sup> Short-term results of treatment with the Ponseti method were better although no figure was given in the literature.<sup>15</sup>

Authors of main orthopaedic text books believe that only 5-10% of idiopathic clubfoot can be corrected by non-operative treatment alone and/or together with tendo Achilles tenotomy and the confusion mainly lies in reporting correction of postural clubfoot and metatarsus adductus deformities instead of restricting the study to only true idiopathic clubfoot.<sup>1, 11</sup>

Mulimba reported that 48% of 307 idiopathic clubfeet treated at Kenyatta National Hospital (Nairobi) were successfully corrected by conservative means and did not require surgery.<sup>4</sup> The rest of the authors reported widely differing correction rates.<sup>1, 11</sup>

Kite in his writings suggested the need for the orthopaedic surgeon to put as much effort in the development of manipulation and casting skills of clubfoot treatment as a musician does in the development of his skills.<sup>27</sup> He commented that clubfeet treated by his assistants took longer to correct than those he handled himself.<sup>16</sup>

It took 5-12 weeks (average 9.5) and five to ten casts (average 7.6) to correct all feet in a 1963 study using the Ponseti method.<sup>15</sup> Kite method required a longer period to correct idiopathic clubfoot.<sup>22</sup> However Ponseti reported a 56% recurrence rate at 10 months to five years of age.<sup>15</sup>

## CHAPTER THREE

### **3.0 METHODOLOGY**

#### **3.1 Study design**

This was a descriptive follow-up study to determine the short-term results of treatment of idiopathic clubfoot using the Ponseti method of treatment at Mulago hospital. The study was conducted between May 2002 and January 2003.

#### **3.2 Study site**

The study was carried out at Mulago hospital. Mulago hospital is situated in Kampala city and is a national referral and teaching hospital with a bed capacity of 1500. Participants for the study were recruited and followed up at the Talipes clinic, which is held every Thursday morning at 4<sup>th</sup> floor in Lower Mulago. This clinic was established by Professor Huckstep over 30 years ago. The Ponseti method of conservative treatment of idiopathic clubfoot was introduced in November 1999 through the Uganda Clubfoot Project. An average of 35 patients are seen at the clinic every week, some of whom have other musculoskeletal abnormalities. The clinic is run almost entirely by orthopaedic clinical officers. The services of a doctor are sought when percutaneous tendo Achilles tenotomy is necessary or for consultation regarding management of an unusual patient. Approximately 70 new patients with idiopathic clubfoot are treated at the clinic each year.

#### **3.3 Study population**

Children born with clubfoot deformity who presented at the Talipes clinic during the study period and fulfilled the selection criteria.

### **3.4 Patient selection criteria**

#### **3.4.1 Inclusion criteria**

1. Children two years or younger with untreated idiopathic clubfoot or partially treated clubfoot by non-surgical means.
2. Children two years or younger whose initial CCS total score is equal to or greater than four.
3. Children whose parents or guardians consent to the study.

#### **3.4.2 Exclusion criteria**

1. Children with other associated musculoskeletal congenital anomalies.
2. Children suffering from significant medical or surgical illnesses apart from the clubfoot deformity.
3. Children who due to distance from home to the hospital or socioeconomic problems cannot attend the clinic weekly as required for treatment.
4. Children older than two years.

### 3.5 Sample size

The records at the Talipes clinic, Mulago hospital, showed that 130 children two years of age and below with a diagnosis of CTEV attended the clinic between 1<sup>st</sup> of December 2000 and 30<sup>th</sup> of November 2001. The author noted that about half of those patients were actually postural clubfeet, metatarsus adductus and some talipes calcaneovalgus misclassified as CTEV. He estimated the number of children with CTEV seen during the above period to be around 70. Assuming that 50% of these patients had bilateral clubfeet, the 70 patients represented 105 feet.

The sample size (n) was determined using the formula described by Leslie Kish as follows:<sup>28</sup>

$$n = \frac{k}{1 + k/N} \quad \text{where } k = \frac{z^2 \times p(1-p)}{d^2}$$

$z = 1.96$  ( the normal standard deviation at 95% confidence level)

$p =$  prevalence of obtaining correction which was determined from previous studies to be 89%

$d = 5\%$  ( minimum acceptable error )

$N =$  number of idiopathic clubfeet treated in one year = 105 feet

This gave 61.84

Therefore the sample size was a minimum of 62 idiopathic clubfeet.

### 3.6 Sampling procedure

Every Thursday at the Talipes clinic, the author would take a clinical history and conduct a physical examination of all new patients and facilitate their management. Those that fulfilled the patient selection criteria were recruited into the study consecutively. The study protocol was explained to the parent / guardian of the child who was required to give informed written consent before

being recruited into the study. Treatment of the clubfoot deformity was done by orthopaedic clinical officers trained in the Ponseti method.

### **3.7 Study variables**

These include:

1. Socio-demographic characteristics:  
Name, age, sex, names of parents / guardians and their addresses
2. Clinical evaluation:
  - History
  - General examination of the child
  - Specific evaluation of the affected foot using the CCS
3. Photographs of the feet of selected patients were taken before treatment and at the end of treatment.

### **3.8 Data collection**

The parents / guardians of affected children were interviewed by the author or his assistant to solicit the demographic information and history. A general physical examination of the child was done at the initial visit by the author. Only patients with a normal general and musculoskeletal examination apart from the clubfoot deformity were recruited in the study. Evaluation of the amount of deformity using the CCS was done at each visit by the author. The information obtained was recorded in a questionnaire. Photographs of feet of selected patients were taken at the beginning and end of treatment. Serial manipulation and PoP cast application using the Ponseti method was done by specially trained orthopaedic clinical officers. Percutaneous tendo Achilles tenotomy where required was done by a doctor.

### **3.9 Follow-up**

The patients were followed up at the Talipes clinic, Mulago hospital, every Thursday morning as they came for treatment. Follow-up was done for a maximum of 14 weeks. Patients were considered lost to follow-up if their treatment was interrupted for more than two consecutive weeks or if they did not complete treatment.

### **3.10 Measures of outcome**

1. The result was rated good when correction of midfoot contracture and dorsiflexion of at least 15<sup>0</sup> were achieved, and CCS total score was one or less.
  2. Feet with persistent deformity were grouped into
    - (i) Feet with only persistent hindfoot contracture
    - (ii) Feet with both persistent hindfoot contracture and midfoot contracture
- Complications to treatment were also noted.

### **3.11 Data management**

- The data collected was stored in a secure place by the author.
- Analysis of data was done with the help of a statistician using SPSS computer software.
- The information was presented using percentages, pie charts, tables, and graphs.

### **3.12 Quality control**

- Almost all the data collection questionnaires were filled by the author, who personally evaluated all the patients.
- The data collected was edited after each clinic day by the author.
- Analysis of results was done with the help of a statistician.

### **3.13 Ethical considerations**

- (i) The parents or guardians were required to give informed written consent before their children were recruited into the study.
- (ii) The study was carried out with the approval of the following bodies:
  - (a) Orthopaedic Department Research Committee.
  - (b) Faculty of Medicine Research and Ethics Committee.
  - (c) Uganda National Council of Science and Technology.
  - (d) Hospital Research Committee.

### **3.14 Study limitations**

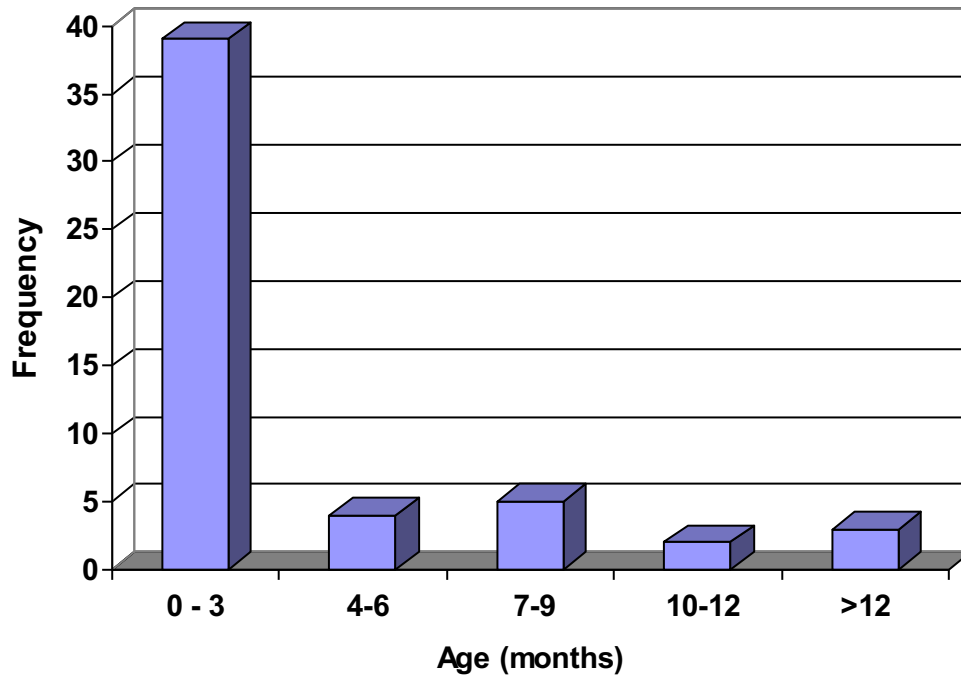
- (i) Subjective errors in scoring of feet using the CCS.  
Since all the feet were evaluated regularly by the author, these errors may not influence the interpretation of the results.
- (ii) Inadequate follow-up period.  
The follow-up period was a maximum of 14 weeks, but a few patients with persistent deformities had their feet fully corrected through continued serial casting after they were discharged from the study.
- (iii) Loss of patients to follow-up.  
This denied the author the opportunity to look at the results of more feet than are presented in this study.

## CHAPTER FOUR

### 4.0 RESULTS

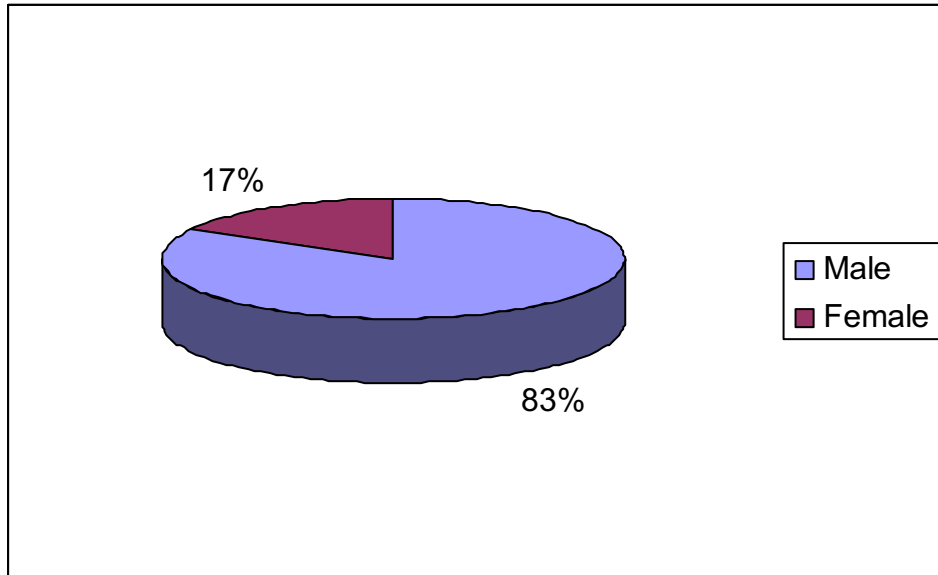
The total number of patients recruited into the study was 53. Nine patients were lost to follow-up and the remaining 44 patients had a total of 67 feet whose results of treatment will be presented. Demographic information will include all the 53 patients.

#### 4.1 Age at initial presentation



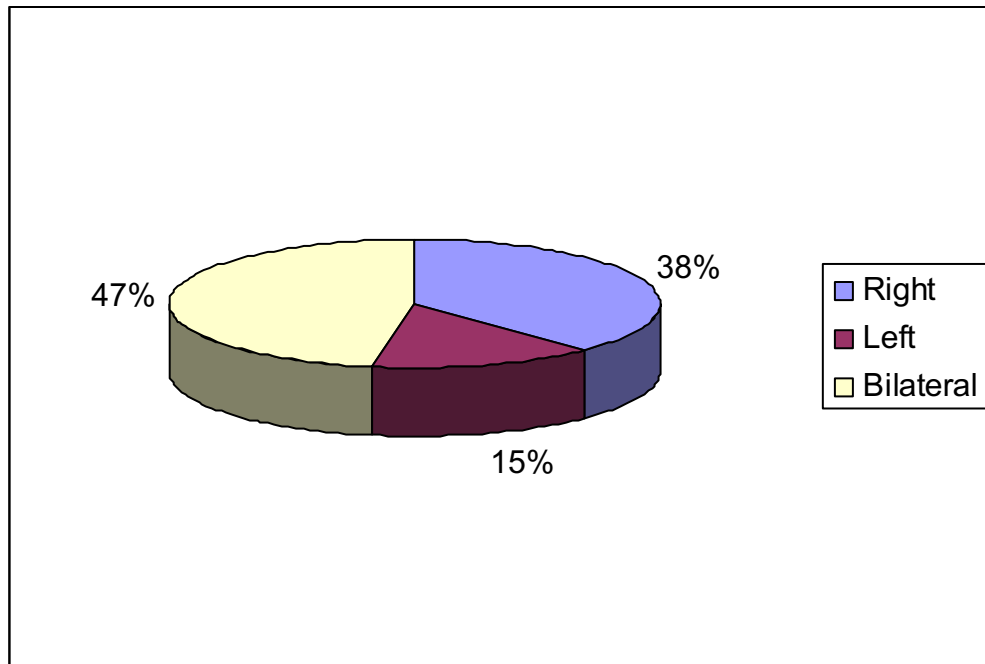
The mean age was 2.8 months (range: 1 week – 15 months). Thirty nine patients (73.6%) presented at three months of age or less.

#### 4.2 Sex distribution



*Male to female ratio was 5:1.*

#### 4.3 Foot involvement



*The right foot was 2.5 times more frequently affected than the left in unilateral cases.*

#### 4.4 Outcomes of treatment

<b>Result</b>	<b>Frequency (feet)</b>	<b>Percentage</b>
Good	52	77.6
HCF	6	9.0
Both MFC and HFC	9	13.4
<b>Total</b>	<b>67</b>	<b>100</b>

#### 4.5 Previous treatment

Only two out of 53 patients (3.8%) had previous conservative treatment before coming to Mulago hospital.

#### 4.6 Number of casts

The feet were corrected with an average of 6.2 manipulation and PoP cast applications. The minimum number of manipulation and PoP cast applications was three and the maximum was 11.

#### 4.7 Length of treatment

The average length of treatment to full correction was 8.7 weeks with a minimum of 4 weeks and a maximum of 14 weeks.

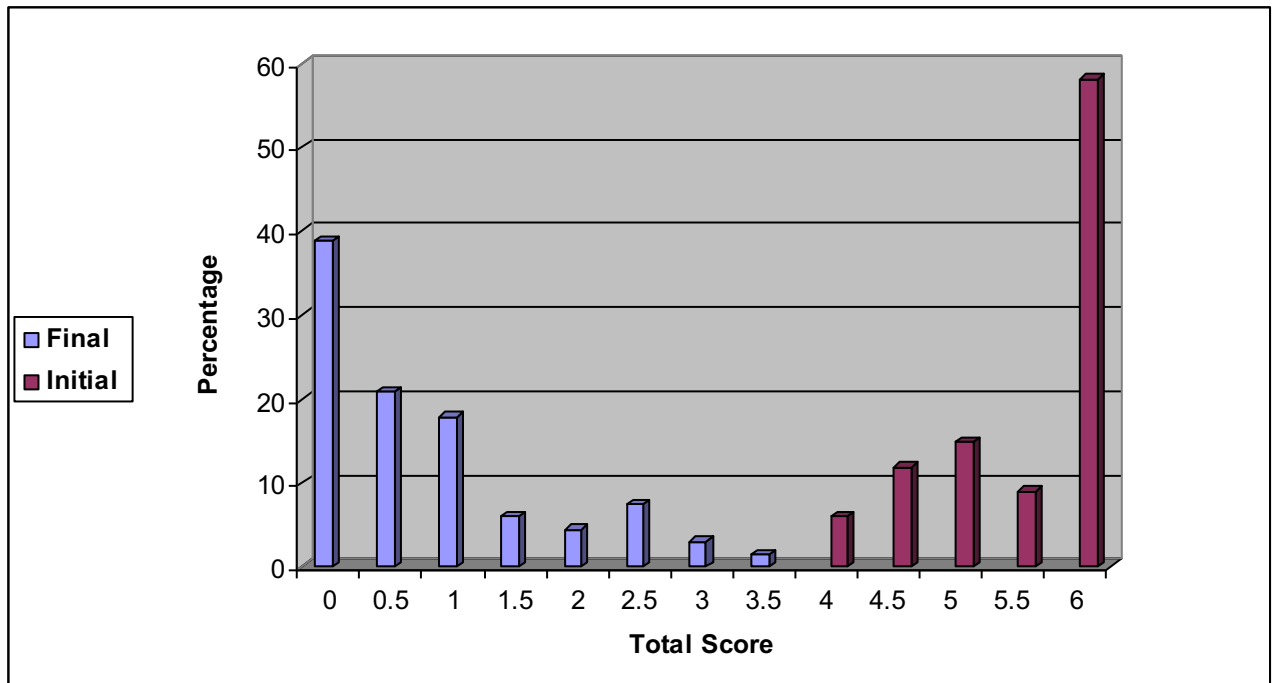
#### 4.8 Tendo Achilles tenotomy

	<b>Good results (feet)</b>	<b>Persistent deformity (feet)</b>	<b>Total (feet)</b>
Tenotomy	67.3% (35)	33.3% (5)	59.7% (40)
No tenotomy	32.7% (17)	66.7% (10)	40.3% (27)
<b>Total</b>	<b>100% (52)</b>	<b>100% (15)</b>	<b>100% (67)</b>

## Regeneration of tendo achilles

Tendo Achilles tenotomy was done in 40 feet and of these the tendon was palpable in 39 feet at three to five weeks after tenotomy and in one foot it was difficult to palpate the tendo Achilles.

### 4.9 Total CCS (TS) at beginning and end of treatment



The mean initial score was 5.5 and the final total score was 0.8.

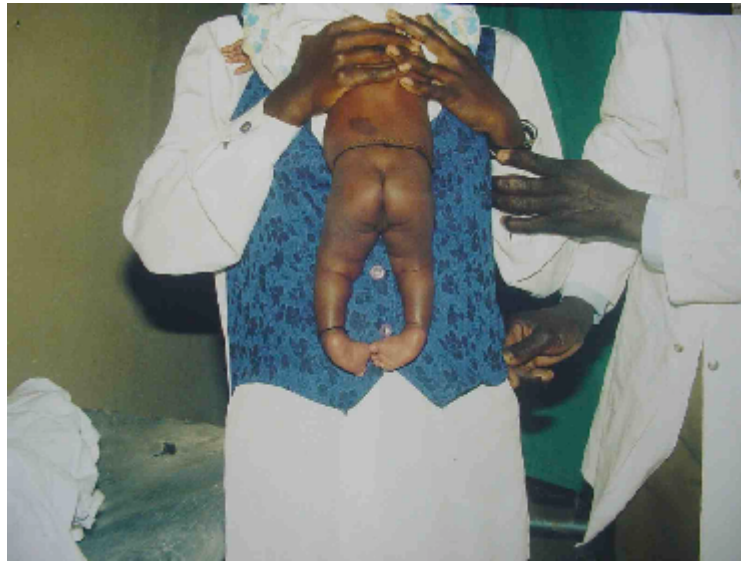
### 4.10 Complications

Pressure sores were observed as a result of casting in three feet. In two of these feet the sores were less than 2 cm diameter and in one foot the ulcer was slightly more than 1cm in diameter. These ulcers were superficial and did not necessitate specific treatment or interruption of treatment of the clubfeet.

#### **4.11 Parent / guardian assessment of correction**

38/44 of the parents / guardians were satisfied with the correction. The rest admitted that there was significant improvement in the feet though the feet still had persistent deformity.

PLATE 1



Pictures of baby A with bilateral idiopathic clubfoot. Total score was 5.5.

PLATE 2



Pictures of the left foot of baby A. Good results were obtained in both feet. Total score was 1.0.

**PLATE 3**



*Picture of the baby B with bilateral idiopathic clubfeet. TS was 6.0.*

**PLATE 4**



***Picture of baby B after 14 weeks of treatment. Midfoot contractures completely corrected.***

**PLATE 5**



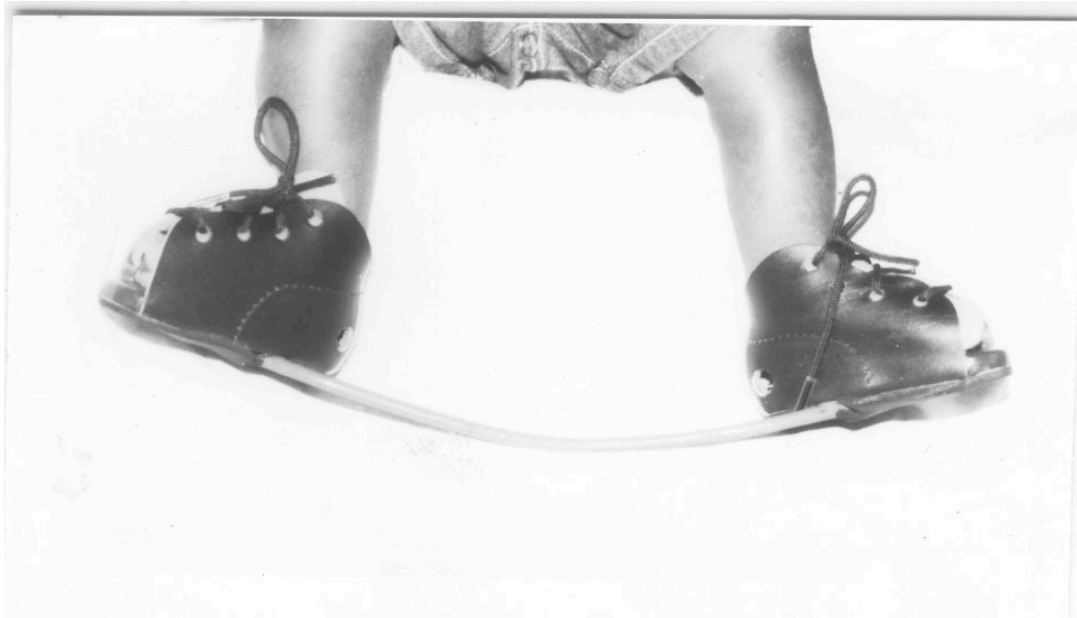
*Baby B after 14 weeks of treatment with the Ponseti method. Both feet could not passively dorsiflex beyond neutral.*

PLATE 6



*Picture of feet of baby C. Persistent midfoot and hindfoot contractures.*

## PLATE 7



***Steenbeek Foot Abduction Brace (SFAB), a locally produced form of Denis Browne splint, for maintenance of correction. The hole at the heel is used to visualize the heel to make sure it is properly captured in the shoe.***

## CHAPTER FIVE

### 5.0 DISCUSSION OF RESULTS

#### 5.1 Age

Thirty nine out of 53 patients (73.6%) presented at age three months and below, and only three patients (5.7%) were above one year. Early presentation for treatment is thought to result in easy correction and good results.<sup>6, 18</sup>

#### 5.2 Sex distribution

Male to female ratio was 5:1. The male sex is more frequently affected according to the literature than female sex.<sup>1</sup> Musitwa (1982) reported a male to female ratio of 1.88:1 in his study in Mulago hospital,<sup>3</sup> while Bitariho (2001) reported a male to female ratio of 6:1 although he studied a much smaller sample size.<sup>5</sup> One might wonder whether there is a significant increase in idiopathic clubfoot in the male sex given that these studies were done in the same place but ten years apart.

#### 5.3 Side affected

Bilateral involvement occurred in 47.2% and this is not different from the 50% involvement reported in the literature<sup>1</sup> or the 60% bilateral involvement reported by Musitwa, Mulimba or Bitariho.<sup>3, 4, 5</sup> The right foot was 2.5 times more frequently affected than the left. In the literature the right foot is involved more often than the left<sup>1</sup> although Musitwa<sup>3</sup> and Mulimba<sup>4</sup> reported equal involvement of right and left foot in unilateral cases.

#### 5.4 Previous treatment

Only two out of 53 patients had previous conservative treatment before coming to the Talipes clinic at Mulago hospital. This suggests that Mulago hospital was the main centre that offered treatment for the clubfoot deformity in the region.

## 5.5 Follow-up

Nine out of 53 patients were lost to follow-up. The treatment of one child was interrupted because the mother was sick. The parents of another child had separated (difficult social circumstances). Two patients dropped out of the study because of inability of their parents to raise money for fare. No reason for the loss to follow-up could be given for the other five patients.

## 5.6 Results of treatment

Good results of treatment were obtained in 52 out of 67 feet (77.6%). It is not possible to compare this with the 89% satisfactory long-term results reported in the literature on Ponseti method.<sup>26</sup> There is evidence that good short-term results with the Ponseti method were obtained in a percentage of feet greater than 89%.<sup>15</sup> Our results were poorer than those reported elsewhere with the Ponseti method possibly because

- our clinic received slightly older children.
- especially with a large number of patients and few experienced people to handle them, sometimes not a lot of concentration was put into treating each patient.

However, far superior results were obtained at Mulago hospital than those reported in the literature where other techniques of conservative treatment were used. Examples include those reported by Mulimba<sup>4</sup> (48% correction rate by conservative treatment) and the 5 – 10% correction rate by conservative means given in orthopaedic textbooks.<sup>1, 11</sup>

## 5.7 Columbian Clubfoot Score

The CCS was found to be practical and easy to use as a tool for assessment of clubfoot deformity and monitoring response to treatment. There was, however, some difficulties in scoring the empty heel (EH) sign when some clubfeet were approaching full correction. Some babies had thick heel pads and in unilateral cases the normal foot would score 0.5 in the EH sign and this caused some confusion.

## 5.8 Cast changes and length of treatment

The average number of manipulation and PoP cast applications, and the average length of treatment to obtain correction was similar to that reported in the literature on Ponseti treatment.<sup>15</sup>

### **5.9 Tenotomy**

Ponseti reported that tendo Achilles tenotomy was done in 70% of the feet<sup>6</sup> and this is comparable to the 67.2% done in the feet that had good results in this study. However, five of the 15 feet that did not correct fully had tenotomy done. There was evidence of regeneration of tendo Achilles three to five weeks after tenotomy in 39 out of 40 feet in which tenotomy was done. No significant complications of tendo Achilles tenotomy have been reported in the literature.<sup>6,15,19</sup>

### **5.10 Parent/ guardian assessment of treatment**

38 out of 44 parents / guardians were satisfied with the correction of their children's feet. 37 out of 44 parents/guardians considered the deformities of their children's feet had been fully corrected.

## **CHAPTER SIX**

### **6.0 CONCLUSIONS AND RECOMMENDATIONS**

#### **6.1 Conclusions**

Based on the results of this study, the following conclusions have been reached:

1. Good results of treatment were obtained in the vast majority (77.6%) of idiopathic clubfeet treated using the Ponseti method.
2. The Columbian Clubfoot Score was helpful in assessing and documenting the amount of clubfoot deformity and monitoring response to treatment, and was easy to apply repeatedly and faithfully.
3. The Ponseti method has few and minor complications.

#### **6.2 Recommendations**

The following recommendations have been made based on the results of this study:

1. The Ponseti method of treatment of idiopathic clubfeet should be employed in other health facilities across the country. This can be expected to significantly reduce the country's physical disability burden caused by idiopathic clubfoot.
2. A long-term follow-up study should be carried out to assess the maintenance of correction and deformity recurrence rates at Mulago hospital.

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## APPENDICES

### Appendix I: Consent form

I,.....have been requested to have my.....(state relationship) take part in the study which Dr. Macharia is carrying out on children born with deformed feet.

The investigator has discussed the study with me and I agree to have my child take part in the study. I may be given a copy of the consent form to keep if I so wish.

I also understand the following:-

- Joining the study is entirely voluntary and I will not be paid or charged to participate in the study.
- I may drop out of the study at any time if I change my decision.
- If I decline participation in the study, my child or I will not be denied any form of medical care.

#### **Nature of the study**

This study will take a period of 10 months but my child will be evaluated by the investigator every week for a maximum period of 14 weeks.

#### **Purpose of the study**

To find out the results of treatment of foot deformity with the method of treatment currently employed in Mulago Hospital.

#### **Study procedure**

I understand that treatment of the foot deformity will involve my bringing the child every week to the clinic for a period of six to 14 weeks. Treatment will involve application of plaster casts to the affected foot at every clinic visit and a small operation may be performed at the back of the ankle of the affected leg in

the course of treatment. I understand that the same medical treatment will be offered to all affected children whether they participate in the study or not.

I understand also that if my child participates in the study, the investigator will examine my child at every visit to the clinic, keep a copy of his/her medical records and may take some photographs of the child.

### **Research related risks**

There are no research-related risks to the child or to me, however, treatment carries the risk of development of wounds and infection and bleeding after the small operation at the back of the ankle.

### **Benefits of the study**

- The results of treatment of clubfoot deformity at the clinic will be known.
- Monitoring of the patients' progress during treatment may be improved.
- No cash payments will be offered to me for participation in the study.

### **Confidentiality**

I understand that the research records will be kept strictly confidential. The investigator will keep all information obtained confidential in accordance to medical ethics. Any publications arising out of this study will not identify my child or me.

### **Problem and/or questions**

I understand that if I have problems or questions about this study, I may contact the doctor responsible for the study.

The doctor is:

Dr. Macharia Joseph Theuri

Senior House Officer,

Department of Orthopaedics

P.O. Box 7051, KAMPALA.

Personal telephone: 071-879294

**Statement of consent**

The purpose of this study, the procedure to follow, the study benefits and risks have been fully explained to me. I understand that I may withdraw participation from the study at any time and that this will not affect my rights or the rights of my child to receive adequate medical care.

.....  
Signature of parent/guardian

.....  
Date

I have explained the purpose, procedure, benefits and risks of this study to the respondent. To the best of my knowledge and conviction he/she has understood and has given his/her informed consent.

.....  
Signature of investigator/assistant

.....  
Date

## Appendix II: The Ponseti Method

*The clubfoot deformity is evaluated using the CCS (Appendix III) and then serial manipulations and PoP cast application is done. All this is done weekly.*

The clubfoot is a complex deformity consisting of cavus, adductus of the forefoot, hindfoot varus, and equinus which can be remembered by the mnemonic CAVE (cavus, adductus, varus, equinus). Correction of the deformities is done in the same order.

The cavus deformity must be corrected with the first cast. Since the cavus deformity is caused by the relative pronation of the forefoot with respect to the hindfoot, it is corrected by placement of the forefoot in supination in proper alignment with the hindfoot. An attempt to correct the inversion of the foot by forcible pronation of the forefoot should not be made because it increases the cavus deformity as the first metatarsal is plantar-flexed further.

Forefoot adductus and hindfoot varus are corrected together. For proper correction of the varus deformity of the hindfoot, it is necessary to displace the navicular laterally together with the cuboid and the anterior aspect of the calcaneus. Once the cavus has been corrected, the metatarsals, cuneiforms and navicular are on the same plane and form the lever arm that is necessary for this lateral displacement. The lateral shift of the navicular, the cuboid and the calcaneus in relation to the talus will be possible when the tight joint capsules and ligaments yield gradually to manipulations before the plaster cast is applied. This abduction or lateral shift entails an external rotation of the foot distal to the talus. A thumb placed on the lateral aspect of the head of the talus is used as a fulcrum. A toes-to-groin PoP cast with knee flexed 90 degrees is necessary to maintain this position.

To prevent recurrence of the cavus deformity and a breach in the mid-part of the foot, the foot should never be pronated. Rather it must be abducted and externally rotated. To ensure that the foot is not pronated, the plane of the metatarsal heads, which is in supination at the onset of treatment, should be gradually turned into a neutral position, so that it is at a right angle to the leg in

the last few casts. The plane of the metatarsal heads should never be turned into pronation.

Complete reduction of the extreme medial displacement of the navicular is not possible with manipulation in most severe feet. With a partially reduced navicular, the forefoot can be brought into proper alignment with the hindfoot, because the ligaments in front of the navicular yield and allow lateral displacement and lateral angulation of the cuneiforms with respect to the navicular. The cuboid falls into normal position with respect to the anterior tuberosity of the calcaneus. The anterior aspect of the calcaneus should be laterally displaced and rotated enough to correct the varus deformity of the heel.

The equinus is corrected by dorsiflexion of the foot with the heel in valgus after the adduction of the foot and the varus deformity of the heel have been corrected. The correction entails stretching of the tight posterior capsules and ligaments of the ankle and subtalar joints and the tendo Achilles. Two or three PoP casts that carefully mold the heel, applied after manipulation, are usually needed to correct the equinus deformity. . A simple percutaneous tenotomy of the tendo Achilles, performed with the patient under local anaesthesia, facilitates correction of the equinus.

Care should be taken not to cause a rocker-bottom deformity, which can occur when dorsiflexion of the foot is attempted with pressure under the metatarsals rather than under the mid-part of the foot, particularly when the varus deformity of the heel has not been corrected

After the last PoP cast has been removed, the degree of correction is evaluated clinically.

To prevent relapse after correction of the foot, a Steenbeek Foot Abduction Brace (SFAB), which is a locally produced form of Denis Browne splint is used. The splint is worn full time for three months and thereafter at night for two to four years. The splint should maintain the foot in 60 – 70 degrees of external rotation, to prevent recurrence of varus deformity of the heel, adduction of the foot, and in-toeing. The ankle should be in at least 15<sup>0</sup> dorsiflexion to

prevent equinus and this is accomplished by bending of the splint with the convexity of the bar directed distally.

Careful supervision and cooperative and responsible parents who follow instructions faithfully are necessary to prevent relapse. A relapse is detected when slight equinus and varus deformity of the heel is observed, usually without increased cavus and adduction deformity of the forefoot. Most relapses are treated successfully with additional manipulations and applications of casts for four to eight weeks. When the anterior tibial muscle tends to supinate the foot strongly, a transfer of the anterior tibial tendon to the third cuneiform will prevent additional relapses in most patients.

Operative correction of a clubfoot is indicated when the deformity has not been treated successfully with proper manipulations and serial application of casts, supported by limited operative intervention. Most of these resistant clubfeet can be corrected with the use of an extensive posteromedial release with satisfactory functional results.

### **Tendo Achilles tenotomy**

This may be done in the outpatient clinic. The orthopaedic officer or physiotherapist should co-ordinate this with local medical officer at the local hospital.

Indications:

- child under one year of age
- Lateral Head of Talus sign is zero in the CCS assessment
- Residual posterior contracture such that ankle dorsiflexion is less than 15 degrees

An assistant holds the leg with the knee extended and the foot dorsiflexed. A small amount of local anaesthesia (about a third to half a ml) is injected through the skin medial to the heel cord and 2cm above the tendo Achilles insertion after prepping the foot. A number 11 or 15 blade is then introduced. One has to keep in mind that the posterior tibial neurovascular bundle passes just posterior to medial malleolus. The blade is kept parallel to the tendo Achilles and passed

deep to it. The blade is then turned so that the sharp edge faces posteriorly to the tendon and the tendon is severed from front to back. Successful division of the tendon will result in a sudden give. The puncture wound is covered with a small sterile dressing and the leg casted (after wrapping with cotton), with the foot externally rotated by 70 degrees and in maximum dorsiflexion. The cast is maintained for three weeks. After three weeks, the cast is removed and the foot placed in a Denis Browne splint full time for three months and then at night only for two to four years.

### Appendix III: The Columbia Clubfoot Score

The congenital clubfoot undergoing treatment can be assessed at each visit and assigned:

- a) A *Total Score* (TS) of up to 6 (0 = normal, 6 = severe deformity).
- b) A *Midfoot Contracture Score* (MFCS) of up to 3 (0 = normal, 3 = severe deformity).
- c) A *Hindfoot Contracture Score* (HFCS) of up to 3 (0 = normal, 3 = severe deformity).

This quantifies not only how much medial and posterior contracture is present before treatment begins, but also what happens to these contractures with treatment.

**Table 1. The 6 signs are divided by area of involvement into 2 groups of 3 signs.**

<u>Signs of Hindfoot contracture (HFC)</u> Posterior Crease (PC) Empty Heel (EH) Rigid Equinus (RE)
<u>Midfoot contracture (MFC)</u> Curvature of Lateral Border of Foot (CLB) Medial Crease (MC) Lateral part of the Head of the Talus (LHT)

#### Technique of Examination

The examiner is seated. The infant is on mother's lap. A feeding relaxed infant allows for a more precise examination.

**a) Curvature of the Lateral Border of the foot (CLB) (Figs. 1a,b,c)**

The lateral border of the foot is normally straight. A curved border implies medial contracture. The amount of curvature can indicate the amount of medial contracture.



Figure 1b - In the abnormal foot the lateral border of the forefoot moves away from the straight edge. A mildly curved lateral border is scored 0.5 (the curvature appears to be in the distal part of the foot in the area of the metatarsals)



Figure 1c - A pronounced curvature of the lateral border is given a score of 1. (The curvature appears to be at the level of the calcaneocuboid joint.)

**b) Medial Crease of the foot (MC) (Figs. 2a, b, c)**

Normally the skin of the area of the foot displays multiple fine lines. Deeper skin creases may imply more medial contracture.

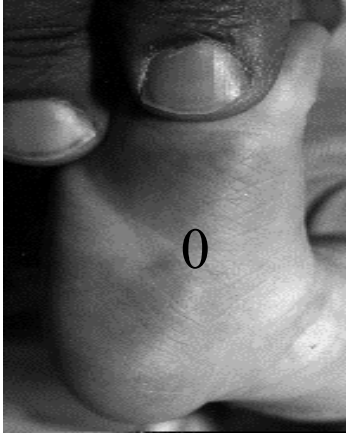


Figure 2b - In the abnormal foot there are one or two deep creases. If these deep creases do not appreciably change the contour of the arch, the Medial Crease sign is scored as a 0.5.



Figure 2c - if these deep creases appreciably change the contour of the arch, the MC sign is scored as a 1.

### c) Posterior Crease of the ankle (PC)

Normally the skin of the posterior ankle shows multiple fine creases – Deeper creases imply more posterior contracture. (Figs. 3a, b, c).

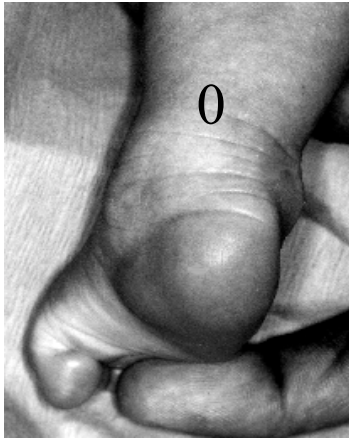


Figure 3a - Look at the back of the heel with the foot in the corrected position. Normally one sees multiple fine creases that do not change the contour of the heel. They allow the skin to adjust and stretch as the ankle dorsiflexes. In this case, the Posterior Crease sign is scored as 0.

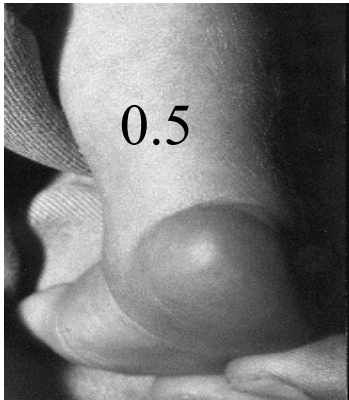


Figure 3c - If these deep creases appreciably change the contour of the heel, the Posterior Crease sign is scored as 1.

**d) Lateral part of the Head of the Talus (LHT) (Figs. 4a, b)**

The talar head is uncovered laterally in the untreated clubfoot (4a and 4b). As the deformity corrects the navicular reduces onto the head of the talus and covers it. This sign is a measurement of how far the navicular reduces onto the talar head.



**Figure 4a**



Hold the foot deformed and palpate the lateral part of the head of the talus, with the pulp of the thumb. It lies anterior to the tip of the fibula. Abduct the foot with the other hand and note if the navicular reduces onto the head of the talus. (Figures 5a and 5b). The LHT sign is scored 0 if there is complete reduction of the navicular onto the head of the talus as indicated by loss of the ability to palpate the lateral edge of the head of the talus in the sinus tarsi. The LHT sign is scored 0.5 if there is partial reduction of the navicular onto the head of the talus as indicated by reduction of the ability to palpate the lateral edge of the head of the talus in the sinus tarsi. The LHT sign is scored 1 if there is fixed medial subluxation of the navicular as characterised by an easily palpable talar head, even with the forefoot in as much correction as is allowed by the deformity.

**e) Rigidity of Equinus (RE) (Figs. 5a, b, c)**

This sign is a measure of the posterior contracture. The more the residual posterior contracture, the less the foot will dorsiflex.

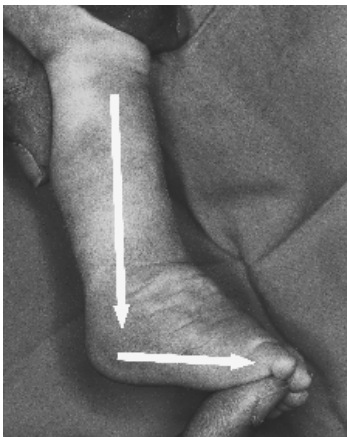
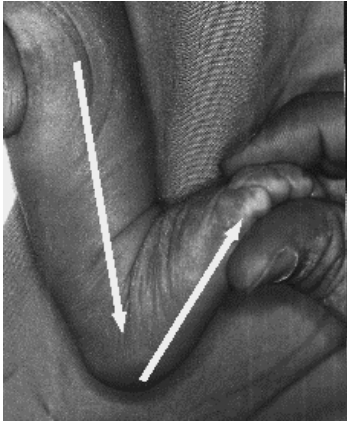


Figure 5b - The RE sign is scored 0.5 when the ankle dorsiflexion is not full but sufficient to allow the lateral border of the foot to make an angle of 90 degrees or less with respect to the long axis of the leg as viewed from the lateral side.



Figure 5c - The RE sign is scored 1 when the ankle dorsiflexion is severely limited and the lateral border of the foot makes an angle of greater than 90 degrees with respect to the long axis of the leg as viewed from the lateral side.

**f) Emptiness of the Heel (EH) (Figs. 6a, b)**

This sign is a measure of posterior contracture. With the talus fully plantarflexed, the calcaneus is also in equinus and the posterior aspect of the calcaneus is drawn up and out of the heel pad. As the talar plantar flexion corrects, the calcaneus fills the heel pad. Palpating the heel pad therefore can give an estimation of how plantar flexed the talus is, and hence, an estimation of residual posterior contracture.



*Source: A reliable method of assessing the amount of deformity in congenital clubfoot. With written permission from professor Pirani<sup>14</sup>.*

## Appendix IV: Questionnaire

Medical Record No.....

Research No.....

Orthopaedic Officer.....

Date of initial exam.....

### 1.0 Socio-demographic information:

Name.....

Name of parent/guardian.....

Date of birth.....Age.....

Sex.....

Place of residence.....

Address.....

### 2.0 History

Has the child ever had non-operative treatment of clubfeet before?

Yes            [   ]            No            [   ]

### 3.0 Evaluation and monitoring of correction of the clubfoot deformity.

A record of the scores obtained by evaluation of the affected feet using CCS (Appendix III) at each visit to the clinic will be kept by filling the following table.

**RECORD OF RESPONSE TO TREATMENT USING CCS (APPENDIX IV)**

Date															
Foot affected R=Right L=Left	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L	R L
Weeks of treatment	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	6 <sup>th</sup>	7 <sup>th</sup>	8 <sup>th</sup>	9 <sup>th</sup>	10 <sup>th</sup>	11 <sup>th</sup>	12 <sup>th</sup>	13 <sup>th</sup>	14 <sup>th</sup>	
Posterior Crease															
Empty heel															
Rigid equinus															
Medial crease															
Lateral head of talus															
Curved lateral border															
Total score															
Treatment performed															

**Key:** For the row on 'treatment performed', fill in MC for manipulation and casting, T for tenotomy and B for application of a brace.

4.0 Record of photograph

Date:.....Photograph identification.....

Date:.....Photograph identification.....

1. Complications to treatment

5.1 Pressure sores

(a) < 1 cm diameter

(b) 1-2cm diameter

(c) > 2 cm diameter

Right foot [ ] Left foot [ ]

5.2 Infection at site of tenotomy

(a) Mild- no treatment required

(b) Moderate - antibiotic treatment required

(c) Severe - antibiotic + debridement required

Right foot [ ] Left foot [ ]

6.0 Clinical evidence of tendo achilles regeneration

(a) Palpable at three to five weeks after tenotomy

(b) Not palpable at three to five weeks after tenotomy

Right foot [ ] Left foot [ ]

7.0 Types of persisting deformity.

7.1 Mid-foot contracture

(a) Forefoot adduction passively correctable to beyond neutral

(b) Forefoot adduction passively correctable to neutral

(c) Rigid forefoot adduction

Right foot [ ] Left foot [ ]

7.2 Hindfoot contracture

- (a) Dorsiflexion justly beyond neutral
- (b) Dorsiflexion to neutral
- (c) Rigid equinus

Right foot                      [   ]                      Left foot                      [   ]

8.0 Assessment of correction by parent/guardian

- (a) Satisfied, well corrected
- (b) Some improvement but still deformed  
[   ]
- (c) No improvement

