



**The University of Zambia
School of Medicine
Department of Surgery**

**EARLY OUTCOME OF PONSETI
MANAGEMENT OF IDIOPATHIC CLUBFOOT
AT THE UNIVERSITY TEACHING HOSPITAL
LUSAKA, ZAMBIA**

By

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**Dissertation submitted in partial fulfillment of the requirements of
Degree of Master of medicine Degree in Orthopaedics and Trauma
Surgery**

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DECLARATION

I, BRIAN SONKWE, hereby declare that this dissertation represents my own work and that it has not previously been submitted for a degree at this or any other university

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CERTIFICATE OF COMPLETION OF THE DISSERTATION

I, BRIAN SONKWE, hereby certify that this dissertation is a product of my own work and that it has never been submitted in part or whole to any other university.

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ABSTRACT

Ponseti technique as a management method of Congenital Talipes equinovarus had not been evaluated as a treatment tool for the clubfoot in Zambia.

The study set out to look at the early clinical outcome of Ponseti management of virgin idiopathic clubfoot.

The study was a prospective cohort study carried out at University Teaching Hospital orthopaedic clinic for a period of six months from April 2009 to October 2009.

Convenience sampling was used to select cases, 42 cases representing 62 feet were recruited for the study. The average age at which manipulations were started was 10.52 weeks and patients were followed up for an average of 8 weeks before the early clinical outcome could be assessed. Feet that progressed to Pirani score of zero and had supple mobile joints were considered a satisfactory outcome and those that needed further surgery, an unsatisfactory outcome.

The study findings showed satisfactory outcome in 89% of the feet. There was an association between age (at which manipulations were started), severity of clubfoot and the early clinic outcome. Poor outcome was associated with severe feet when manipulations were commenced late. There was no association found between clubfoot type (unilateral or bilateral) and early clinical outcome. Percutaneous tenotomy of tendo achilles was done in 66% of the feet with 0% complication rate. Patients with severe clubfoot were more likely to undergo percutaneous tenotomy of tendo achilles (PTAT).

This dissertation is dedicated to my Wife – Hazel and my Sons; Chembe and Yamba.

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ACRONYMS/ ABBREVIATIONS

CTEV	Congenital Talipes Equinovarus
LORET	Lusaka Orthopaedic Research and Educational Trust
MFC	Mid foot Contracture
PMR	Posterior Medial Release
POP	Plaster Of Paris
PTAT	Percutaneous Tenotomy of Achilles Tendon
TA	Tendo- Achilles
UTH	University Teaching Hospital

CHAPTER ONE

1.0 INTRODUCTION

Congenital Talipes Equino Varus (CTEV) also known as clubfoot is the commonest congenital musculoskeletal malformation (Parekh, 1985).

It affects about 1-2/1000 live births in the general population worldwide and incidence as high as 3.5/1000 has been reported in black South Africans (Ballantyne, 2002).

Actual incidence of CTEV in Zambia has not been documented but in the last 20 years as many as 5000 children are living with CTEV with another 500 born each year (Pirani, 2006).

The aetiology of CTEV is not known and because this deformity of the foot is a complex one, treatment remains a challenge as indicated by the spectrum of treatment methods available yet none being singled out as treatment of choice for CTEV.

1.1 Aetiology

The true aetiology of CTEV is not known. Most of the infants who have CTEV have no identifiable genetic, syndromic or extrinsic cause.

However, there are many theories that have been advanced which range from intrauterine moulding, germ plasm defects, and intrauterine developmental arrest to neurological, myogenic and vascular explanations (Ballantyne, 2002).

1.1.1 Moulding

This is usually associated with milder forms of CTEV. The predisposing factors include oligohydramnios and multiple pregnancies (Ballantyne, 2002). This type of clubfoot usually corrects with conservative measures only.

1.1.2 Neuromuscular

It is vital to distinguish the two forms of CTEV i.e. Idiopathic and Syndromic. The syndromic type is associated with neuromuscular conditions like spinal dysraphisms, arthrogryposis and poliomyelitis suggesting the role of neuromuscular anomalies in its aetiology (Ballantyne, 2002).

Type I slow twitch, high tension fibres have been demonstrated to be predominant within the deforming posteromedial muscle groups. It has been suggested that preoperative manipulation and casting alters the proportion of these muscle fibres thereby justifying this intervention (Ballantyne, 2002).

1.1.3 Delayed Intrauterine Development

The fetal foot between 8th and 10th week appears to resemble the clubfoot.

There is medial deviation and plantigrade orientation of the talar neck and head; also there is varus alignment of the calcaneus and adduction of the forefoot. By the 11th week the foot is expected to have resumed the normal position and so failure of progression from this stage may result in clubfoot (Ballantyne, 2002).

1.2 Pathoanatomy

Clubfoot (CTEV) represents a spectrum of disease with varying degree of severity. Vascular anomalies have been reported in 90% of the patients, mainly affecting the anterior tibial artery where there is proximal termination and hypoplasia. The incidence of vascular congenital anomalies in the general population is much lower (2.4- 7.0%) (Ballantyne, 2002).

The anatomical anomalies in the cartilaginous anlage and bone determine the morphology of the deformity in clubfoot regardless of the aetiology. The principal bony deformity in CTEV is in the talus. The talar neck is medially deviated and plantigrade and the whole bone is in equinus. In addition, the cartilaginous anlage and ossification centre of the talus is smaller than that of the normal foot suggesting developmental delay. The deformity is seen in the calcaneus which is medially rotated, adducted and is in equinus.

The deformities of clubfoot foot are obvious to see. They are cavus, adductus, varus and equinus. These are the deformities defining a clubfoot. The cavus is a midfoot deformity and results from the contracted plantar fascia and short abductor of the great toe. The adductus deformity arises from the subluxation of talonavicular and the calcaneocuboid joints; this deformity is also compounded by the thickened and contracted medial structures. The degree of subluxation is related to the severity of the clubfoot and is predictive of the outcome of treatment (Ballantyne, 2002). Therefore any intervention selected should aim at reducing these joints. The equinovarus is the deformity of the hindfoot and is as a result of the medial rotation of the calcaneus and the talus.

Changes in the ligaments, fasciae and tendons have been seen. The lateral ligaments are attenuated while the medial structures are thickened and contracted (Ballantyne, 2002). Particularly contractures are seen in the calcaneofibular, talofibular, deltoid, plantar, spring and the bifurcate ligaments.

Thickened tendon sheaths and contractures around the peroneal group and tibialis posterior have been identified. These changes restrict the external rotation of the calcaneus during dorsiflexion leading to equinus and varus deformity of the hindfoot (Ballantyne, 2002).

The thickening in the joint capsules has been reported from MRI studies, surgical observations and cadaveric dissections. The main joints which are involved are posterior ankle capsule, subtalar capsule, and talonavicular and calcaneocuboid capsules.

Nearly all movements in the foot are centered at the talus. The forefoot moves as a unit with the calcaneus (calcaneal pedal block). The calcaneal pedal block moves around the talus; therefore motion of the intertarsal joints and the tarsometatarsal joints can be disregarded. Subtalar motion occurs between the calcaneal pedal block and the talus, this permits simultaneous rotation at the talocalcaneal and talonavicular joints. The talonavicular joint is the fulcrum in the Ponseti technique because abducting the forefoot about the joint takes the foot through the normal kinematics at the subtalar joint from clubfoot position of adduction, inversion and flexion to abduction, eversion and

extension. Therefore correction of the forefoot adduction at the talonavicular joint will bring about correction of the equinovarus deformity in the hindfoot (coupled kinematics).

1.3 Treatment

There is generally no consensus in Zambia as far as the treatment of clubfoot is concerned. The recommended treatment for clubfoot ranges from non-operative to complete peritalar release (Ballantyne, 2002).

1.3.1 Nonoperative

The principle of serial manipulation and holding the foot in the corrected position remains the basis of non-operative treatment today. Even in the severe cases, casting may prevent progression of the deformity prior to surgical intervention.

Most orthopaedic surgeons agree that the initial treatment of clubfoot should be non-operative (Attenborough, 1966). The treatment described by Ponseti has shown great promise and involves sequential cast applications at 1 week intervals for 5 weeks. The foot is then splinted in modified

Abduction braces for 3 months, followed by night splinting for up to 4 years. The deformity is due to twisting of the calcaneus, navicular and cuboid around the talus, the repeated manipulation of the foot reduces the tension in the tight tissues and ultimately leads to correction of the deformity.

The deformities of the foot are dealt with sequentially aiming at graduated correction. The key is the reduction of the cavus deformity by the dorsiflexion of the 1st metatarsal.

Correction of the equinus and supination of the hindfoot should wait until full flexion of the 1st metatarsal is achieved. This unlocks the mid-foot allowing subsequent correction using the uncovered lateral head of the talus as a fulcrum. The forefoot is gently abducted allowing divergence of both the talus and calcaneus.

The correction of fore foot adduction leads to external rotation and dorsiflexion of the calcaneus ultimately resulting in the correction of equinus and varus deformities (coupled kinetics). However, in 70% of the patients Tendo Achilles (TA) tenotomy is required to achieve full correction of the equinus deformity (Ponseti, 1992).

1.3.2 Operative Management

There is no agreement on the timing of surgery. Some authors have advocated for early operative treatment (Attenborough, 1966). However, at this stage the neonate's foot is small and identification of the anatomical structures is difficult. In many centres surgery is deferred until the foot is of reasonable size and some correction of the deformity may have been achieved with preoperative splintage. Furthermore, surgery done when the child is about to stand or walk has the advantage that weight bearing is a corrective factor in its own right and waiting

until the child is able to stand independently may help maintain the correction post-operatively. Recurrence of the deformity occurs if major surgery is performed before the child is able to walk (Ballantyne, 2002).

1.4 Classification (Pirani)

The Pirani score was used to clinically measure the severity of the clubfoot deformity.

This is because it describes the initial deformity reproducibly, is practical to implement and it gives an indication of the likely prognosis. (See appendix c for detailed scoring).

This classification method relies exclusively on clinical assessment and does not involve additional radiological assessment. The score is based on 6 clinical signs of contracture.

The clubfoot is divided into the midfoot contracture and hindfoot contracture. Each of the contracture of the foot has 3 categories which are used for the assessment of the severity of the clubfoot. The midfoot contracture comprises measuring of the curvature of the lateral border (CLB) of the foot, the medial crease (MC) and how subluxed the lateral head of the talus (LHT) is at the talonavicular joint. The hindfoot contracture is made up of the posterior crease (PC), the emptiness of the heel (EH) and the rigidity of the equinus (RE). Each category is scored 0, 0.5 and 1 in increasing severity. Therefore a normal foot would score 0 and severe clubfoot would score 6.

The Pirani score has been assessed for inter observer reliability using the kappa score which showed this to be almost perfect and better than any previous scoring system (Dyer, 2006). For this reason and that because it is quick simple scoring system, the Pirani score is the scoring system of choice for the proponents of the Ponseti treatment of clubfoot.

CHAPTER TWO

2.0 RESEARCH QUESTION

Does the Ponseti method of treatment of clubfoot work for the clubfoot in Zambia?

2.1 LITERATURE REVIEW

The Ponseti technique for the treatment of clubfoot in its form today was devised by the late Ignacio Ponseti, Professor at the University of Iowa (USA). This technique has been used to treat tens of thousands of children with clubfoot with good long term results. Ponseti believed 85% of clubfoot can be treated by this method (Ballantyne, 2002).

The goal of this technique is to eliminate all elements of clubfoot producing a functional, pain free, normal looking and normally shoeable foot.

Between 2002 and 2004, Changulani and team at Royal Liverpool hospital looked at 66 children with 100 clubfeet and applied the Ponseti technique. Of 100 clubfeet, 96 responded to initial casting (responsive group) and the four that did not respond underwent surgery. Relapse of the responsive was noted in 31 feet (32%), 16 were corrected by repeat casting and/ or tenotomy of the Tendo Achilles and/ or Tibialis anterior tendon transfer. The remaining 15 feet had to undergo surgical correction. Of the 16 feet, 4 needed only repeat casting, 7 repeat casting and tenotomy, 5 required repeat casting and transfer of tibialis anterior tendon to lateral cuneiform. The remaining 15 required extensive soft tissue release. Of the 31 clubfeet that relapsed after initial

treatment 21 (68%) were considered to have problems of compliance with the abduction braces (Changulani, 2006).

Several factors that influence the outcome of treatment of clubfoot by Ponseti method have been looked at, including severity and age at presentation.

Lehman and Mohaideen (2003) found that patients compliant with Ponseti technique and treated before the age of 7 months had 92% success rate at an early follow up after casting was completed. They also showed that no matter how severe the initial classification is if the Ponseti technique is done properly a good result could be anticipated (Lehman, 2003). Radler and Suda assessed their outcome by Pirani score and Radiology and found that treatment (Ponseti) initiated within 3 weeks of age had 93% success rate (Radler, 2006).

Harrold and Walker (1983) attempted to correlate severity of the deformity to clinical outcome. They divided feet into three grades of severity using a simple grading system. Even though this system was not sensitive enough to show subtle changes in the clubfoot after manipulation, it showed a basic distinction between the various grades of severity of clubfoot and the likely prognosis. Surgical intervention was related to the correctability of the deformity. Only 10% of grade 1 (mild) feet required surgical intervention compared to 90% of grade 3 (severe) feet (Harold, 1983).

Laaveg and Ponseti (1980) described a 10-27 year result in patients who had undergone manipulation and casting. Only 12.5% were treated purely with serial casting 40%

required additional Percutaneous tenotomy of the Tendo Achilles, 47% required a tibialis anterior tendon transfer and 16% required a variety of limited surgical releases (Laaveg, 1980). Ponseti (1992) believed that 85-90% of idiopathic clubfoot can be treated by manipulation, Tendo Achilles tenotomy and tibialis anterior tendon transfer as indicated. The Ponseti technique is more a superior method of management of clubfoot as compared to traditional manipulation and casting. In one study by Herzenberg and Radler, patients undergoing Ponseti were compared with patients undergoing traditional casting. Traditional casting was defined as any manipulation and casting method not following the Ponseti protocol. Casting was started within 3 months of age and the outcome was assessed by the need for surgical management (PMR). The results showed that in the Ponseti group only 3% needed PMR as compared with 94% in the traditional group even after longer duration of casting (Herzenberg, 2002).

Locally, there is limited data and literature on studies done on clubfoot. One study done by Mulwanda JL (1997) looked at the effect of tenotomy of tibialis posterior and tendo achilles tendons on children under the age of 3 months undergoing traditional (non Ponseti) manipulation and casting. Clubfoot severity was graded using a modified Walker and Harold classification system. Foot appearance and plantigrade attitude were used as parameters for good outcome. The study showed good results in 72% of the sampled population with minimal complications.

2.2 STATEMENT OF THE PROBLEM

Zambia, like any other developing country has limited health resources in general and very few orthopaedic surgeons in particular. There is one orthopaedic surgeon per one million Zambians and Ministry of Health statistics show that trauma is among the top five causes of mortality in Zambia.

Until recently, the treatment of clubfoot in Zambia has been predominantly operative. On average ten new cases per month of CTEV are seen in our clubfoot clinic and also a great many patients are seen in the upcountry sites. The latter usually coming in late and usually needing surgery for treatment of their clubfoot. Therefore the burden of clubfoot cases on the few orthopaedic surgeons who are already overwhelmed with a backlog of trauma cases cannot be over emphasized.

Since Ponseti is a simple, cost-effective and potent way of treating clubfoot, the plan is to train various cadres in this technique so that the management can be initiated as soon as possible and as close as possible to the patient's home.

2.3 RATIONALE

Clubfoot is one of the commonest birth defects affecting 150 000 children worldwide each year. It causes the infants foot to be in equinus, supinated, have cavus and forefoot adduction. Left untreated, a child with clubfoot will have difficulty walking, a less mobile foot and possible psychological distress. The method described by Ponseti has reported excellent results using sequential cast application (Ballantyne, 2002).

The Ponseti method of treatment of clubfoot offers an alternative in the treatment of clubfoot in that it is safe, simple, cost effective and yet a potent way of treating clubfoot. This method of treating clubfoot has evolved over the years from the 1950s. Despite the success of Ponseti method, surgery remains the preferred method among orthopaedic specialists for decades. However, Ponseti method of treatment of CTEV has become the mainstream of treatment of clubfoot in North America.

Treatment of clubfoot with surgery has a costly effect in the number of complications and hospital stay that come with it. There are a number of complications that come with surgery. Relapse of clubfoot after operative management stands out above all of these complications because it makes it difficult for subsequent interventions to succeed.

Series done in Africa and elsewhere reveal a relapse rate of up to 50% after operative treatment of clubfoot (Ponseti, 1992; Parekh, 1985). Besides there are no long term follow up results available to suggest that extensive surgery has added benefit when conservative means have failed (Ponseti, 1992). The Ponseti method is an outpatient

department procedure performed by anybody trained in this treatment method of clubfoot.

This study will aim at identifying optimal conditions for Ponseti management of clubfoot in Zambia with the available resources. Success of this intervention in the management of clubfoot will entail decentralization of the treatment by training more personnel in the peripheral up country places thereby lifting the load off the limited number of orthopaedic specialists who are able to perform operative management of CTEV.

2.4 HYPOTHESIS/ OBJECTIVES

2.4.1 Hypothesis

Virgin Idiopathic Clubfoot can successfully be treated by the Ponseti method in children below 2years.

2.4.2 Objectives

2.4.2.1 General Objectives

1. To evaluate the early clinical outcome of Ponseti management of virgin idiopathic clubfoot.

2.4.2.2 Specific Objectives

1. To establish the relationship of severity of clubfoot to early clinical outcome.
2. To determine whether the age at commencement Ponseti treatment has an effect on early clinical outcome.
3. To determine whether unilateral clubfoot has better early clinical outcome than bilateral clubfoot of the same age range and severity.
4. To determine the most common form of clubfoot in terms of severity.
5. To determine the need for percutaneous tenotomy of tendo achilles in Ponseti treatment of clubfoot.

CHAPTER THREE

3.0 METHODOLOGY

3.1 Study Design

This was an observational descriptive study conducted over a period of 6 months from April 2009 to October 2009.

3.2 Study Site

This study was carried out at UTH in the orthopaedic clinic.

3.5 Case definition

The case was defined as any child less than 2 years with virgin idiopathic clubfoot.

3.6 Sample size determination

There was no information on the prevalence of idiopathic clubfoot in Zambia that could be used to determine sample size for this study. Therefore, sample size was estimated using the average number of new cases of clubfoot seen in the clinic per month. On average 10 new cases were seen in the clinic per month; therefore, for 6 months 60 new cases were expected. Because the sample size had to be reported in terms of feet and not the actual cases, the size of population from which sample size was estimated was calculated using the known proportions of clubfoot type distribution i.e. 50% of clubfoot is bilateral (Ballantyne, 2002). With this in mind the size of population was estimated at 90 feet. The reported success rate of the Ponseti technique is 89% as reported by Ponseti (Ponseti, 1992). Using EPI Info 6 the sample size was estimated at **66 feet**.

3.5 Sampling

Convenience sampling was used to recruit children with clubfoot for this study.

All children with virgin idiopathic clubfoot meeting the inclusion criteria (see below) were enrolled. Therefore, any child who was seen in the clinic by the investigator and met the inclusion criteria was asked to enroll. There was no third party that recruited participants for the study on behalf of the investigator. There was no randomization because of the limited time for the study.

3.6 Data Collection

The information was collected by interviewing mothers and by clinical evaluation. A structured questionnaire which is a modification of clubfoot assessment record form from the manual of health workers treating clubfoot was used to enter demographic information as well as the history. The questionnaire was only administered after getting consent to participate in the study. Pirani classification was used to determine the initial clinical state and also to monitor the response to the intervention. The information was entered on the chart and analyzed (see appendices).

3.7 Data processing/ analysis

Data was entered in the computer using SPSS statistical 17.0 package. The questionnaire was given identification numbers from 1-42. Questions were coded by using numbers to the response categories. This made data analysis much easier.

Analysis was done to determine the most common form of clubfoot in Zambia, to determine associations between age at the beginning of manipulations and outcome, clubfoot type and outcome, and severity of clubfoot and outcome.

The associations were determined by using the Chi square test. The cut off point for statistical significance was put at 5% and exact confidence intervals were used.

3.8 The Procedure of Manipulation and Casting

The standard Ponseti technique was used in this study. Serial weekly manipulation and casting were done initially to correct the forefoot adduction, cavus and supination – midfoot contracture (MFC) before correcting the equinus deformity. An above knee cast with knee in 90° flexion was applied each time the patient came in for manipulation and casting. The correction of the MFC was centered at the Talo-navicular joint instead of the Calcaneo-cuboid joint (Kite's error). Before each manipulation and casting the foot was assessed by the Pirani score to assess the response and guided subsequent manipulations and castings. The foot was only ready for correction of the equinus deformity once the forefoot adduction, cavus and supination had been corrected. At the time of applying the last cast the equinus was corrected by either percutaneous tenotomy of the tendo achilles (PTAT) or manipulating the foot in plantigrade position. The PTAT was done under local

anaesthesia and aseptic conditions. The last cast stayed on for 2 weeks before review, at which date early clinical outcome was assessed.

3.9 Follow up

Average follow up time was 8 weeks from the time of enrolment.

3.10 The protocol

Week 1: Counseling was conducted during the first contact with the patient. This involved explaining in detail what the study is all about. The consent was then obtained and the child enrolled for the study. The severity of clubfoot was scored using the Pirani score and then the first manipulation and casting was done. The patient was allowed home and review date was set for the following week.

Week 2: The POP was removed in the clinic prior to the second review. The foot was scored again to determine any improvement with the first manipulation and casting. The second manipulation and casting was done and child allowed home.

Week 3 and week 4: Involved a similar routine as for the earlier weeks except the foot was held in more abducted position to correct the forefoot adduction and supination.

Week 5: Severity of clubfoot was assessed, when it was found that there was residual equinus the percutaneous tenotomy of tendo achilles was done and the final cast applied and stayed on for two weeks.

Week 7: It was during this visit that the final assessment for clinical outcome was done.

During each visit all the information was entered on the chart and complications and other issues such as non compliance were noted.

3.11 Criteria for selection of cases

3.11.1 Inclusion Criteria

- (a) Virgin idiopathic clubfoot i.e. clubfoot that has never undergone any type of treatment.
- (b) Clubfoot in children < 2years of age.

3.11.2 Exclusion Criteria

- (a) Complex clubfoot i.e. clubfoot which has undergone any form of surgery.
- (b) Neglected clubfoot i.e. clubfoot in patients more than 2 years.
- (c) Syndromic clubfoot i.e. clubfoot as a result of other associated congenital disorders e.g. polio, arthrogyriposis, spinal bifida etc.

3.12 Criteria for satisfactory outcome

All feet that were graded as good to excellent were regarded as satisfactory outcome.

3.12.1 Excellent Outcome

- a. Pirani score of zero
- b. Normal position of the Heel
- c. Normal/ good range of motion of the foot joints
- d. Patients (parents) satisfaction

3.12.2 Good Outcome

All feet with Pirani score zero not meeting criteria 'c' and 'd' above.

3.12.3 Poor Outcome

All feet needing further surgery for correction were considered poor outcome.

3.13 Ethical considerations

Ethical clearance was granted by the University of Zambia Biomedical Research and Ethics committee. Informed consent was obtained from the guardians of the participants who were at the same time assured of confidentiality. It was explained that no participant would be identified by name and that a coding system was to be used on the questionnaires to protect the identity of their child. It was further explained that they had the right to withdraw from the study without giving notice to the investigator and that it was purely up to them to decide to have their child on the study. Furthermore, guardians were assured that they could still seek the same treatment even after they chose to withdraw from the study. The part of the percutaneous tenotomy of the tendo achilles was also explained at the time of enrolment to avoid anxiety at the time when the child was operated on.

CHAPTER FOUR

4.0 LIMITATIONS

The following were some of the limitations encountered during the study:

- (i) Some of the patients were lost to follow up because of transport cost.
- (ii) Limited research done on the Zambian clubfoot.
- (iii) The majority of the cases enrolled were below the age of 4 weeks, so the initial objective to compare outcome in different age groups was adjusted from 3 months to 4 weeks.

CHAPTER FIVE

5.0 RESULTS

5.1 Demographics

42 cases representing 62 feet were enrolled in the study of which 20 had bilateral club feet and 22 had unilateral club feet. Of the 22 unilateral feet, 68% were right sided.

Table 1: Distribution of feet

	Cases	Percentage
Bilateral	20	48%
Unilateral	22	52%
Total	42	100%

Gender Distribution

Of the enrolled cases there were more male cases than the female cases.

Table 2: Gender distribution

	Cases	Percentage
Female	15	36%
Male	27	64%
Total	42	100%

Age at Recruitment

The average age at the start of enrolment for manipulations was 10.52 weeks ranging from 1-88 weeks. Table 1.3 represents the distribution of feet of those who enrolled at or before 4 weeks of age and those enrolling after 4 weeks of age.

Table 3: Distribution of feet and age at start of manipulations

	Feet	Percentage
Less/ equal 4 weeks	41	66%
Above 4 weeks	21	34%
Total	62	100%

Birth Places

Of the 42 cases 31 were born in the health facility (hospital/ clinic) and so the awareness of the feet abnormality and treatment is expected to be high.

Table 4: Places of Birth of the Cases

	Cases	Percentage
Health facility	31	74%
Home	11	26%
Total	42	100%

Of the 31 born at the health facility 68% were ≤ 4 weeks at the start of the intervention representing 50% of the cases in the sample population.

There was no association between age at the beginning of manipulation and birth place (p-value 0.28).

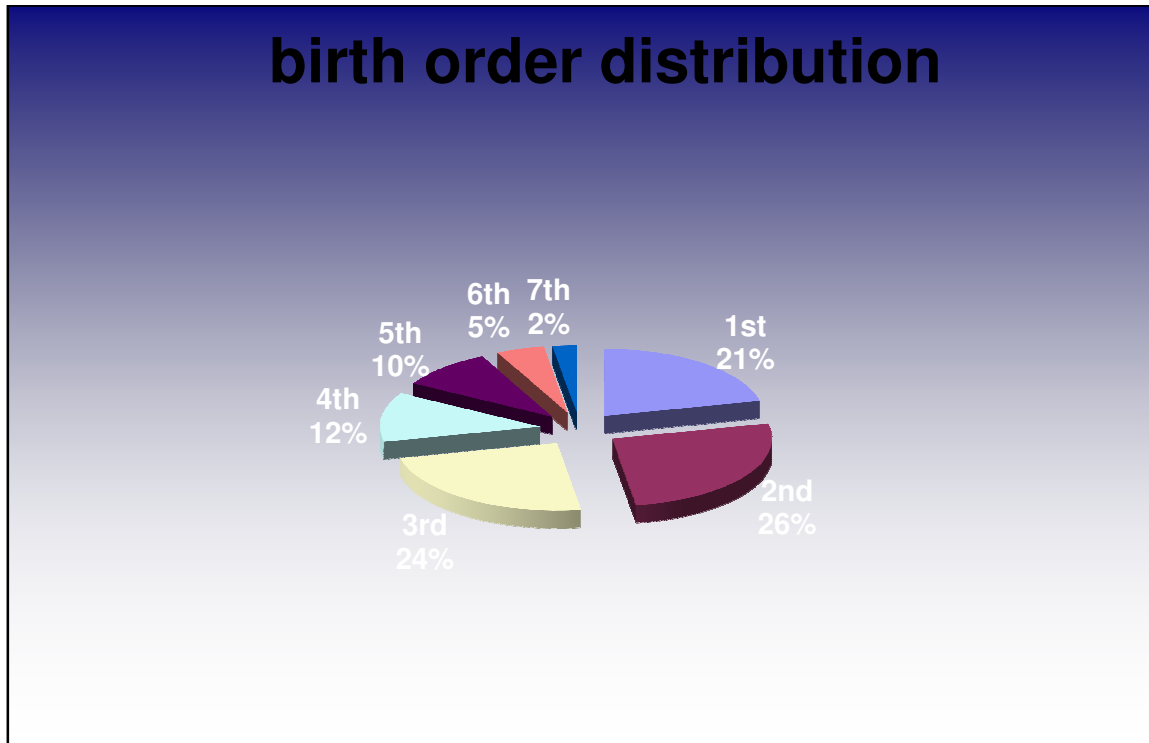
Table 5: Birth places and Age at the start of manipulations

	Health facility	Home	p-value
≤ 4 weeks	21 (68%)	5 (45%)	
Above 4 weeks	10 (32%)	6 (55%)	0.28
Total	31 (100%)	11 (100%)	

Birth Order of the Cases

The majority of the cases were of second birth order. Three quarters (75%) of the cases were 1, 2 or 3 birth order.

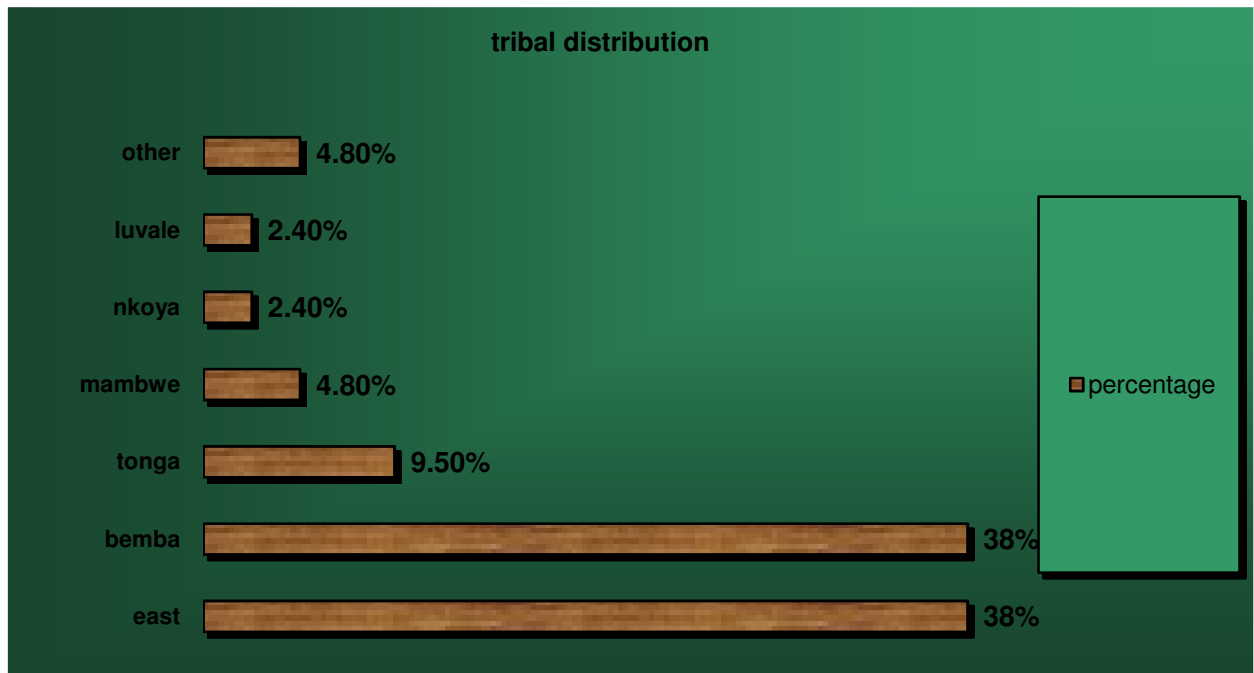
Figure 1: Distribution of order of birth



Tribal Distribution of the Cases

The tribal distribution of the cases makes an interesting finding in that 76% of the cases either hailed from the Eastern group or the Bemba tribe group.

Figure 2: Distribution of tribe of cases



Residential distribution of cases

Most of the cases recruited were from high-density population areas of Lusaka and represented 62% of the cases.

Table 6: Residential Distribution

	Cases	Percentage
High density	26	62%
Medium density	8	19%
Low density	3	7%
Other (out of town)	5	12%
Total	42	100%

5.2 Feet Data

62 feet were enrolled and followed up for average of 8 weeks after which early clinical outcome was assessed. The average age at the start of enrolment for manipulations was 10.52 weeks ranging from 1-88 weeks. 66% of cases enrolled were 4 weeks or younger. Bilateral clubfoot was found in 48% of the cases and severe clubfoot was found in 61% of the enrolled clubfoot. However there was no association found between clubfeet type (unilateral or bilateral) and severity (p-value 0.6).

Table 7: Distribution of feet and age at the start of manipulations

	Feet	Percentage
Less/ equal 4 weeks	41	66%
Above 4 weeks	21	34%
Total	62	100%

Table 8: Distribution of clubfoot type

	Cases	Percentage
Bilateral	20	48%
Unilateral	22	52%
Total	42	100%

Table 9: Distribution of Severity of the clubfoot

	Feet	Percentage
Severe	38	61%
Mild/ Moderate	24	39%
Total	62	100%

Table 10: Severity and clubfoot type

Severity	Clubfoot type		p- value
	Bilateral n (%)	Unilateral n (%)	
Severe	26 (65)	12 (55)	0.6
Mild/ Moderate	14 (35)	10 (45)	
Total	40 (100)	22 (100)	

5.2.1 Need for PTAT

Ponseti believed 70% of the cases will undergo PTAT to correct the equinus deformity; this study shows that 66% of the feet enrolled underwent surgery (PTAT) to correct the equinus deformity.

No association was found between the age at which manipulations were started and the need for PTAT (p value 0.74); also no association was found between need for PTAT and the type of clubfoot (p value 0.27). However there was an association found between severity of CTEV and the need for PTAT (p value 0.02) and those patients with severe CTEV are 4.4 times more likely to undergo PTAT than those with mild or moderate feet. There were no complications noted which were purely as result of the PTAT.

Table 11: Need for PTAT

CTEV variables	PTAT		p-value	OR
	Yes n (%)	No n (%)		
Age				
≤ 4 weeks	18 (60)	8(67)		
> 4 weeks	12 (40)	4(33)		
Total	30 (100)	12(100)	0.74	0.7
Type of CTEV				
Bilateral	24 (59)	16(76)		
Unilateral	17 (41)	5(24)	0.27	0.4
Total	41 (100)	21(100)		
Severity				
Severe	11 (27)	13 (62)		
Mild/moderate	41 (100)	21 (100)	0.02	4.
Total				

5.3 Outcome

The results show that 55 (89%) of the feet enrolled had satisfactory outcome after the initial manipulation and casting was completed. Further, results were analysed according to the age at which manipulations were started, type of clubfoot (Bilateral or Unilateral) and the severity of the clubfoot. The results show that there was an association between age at which manipulations were started and the outcome (p- value 0.04).

Manipulations started at 4 weeks or younger were 6.1 times more likely to have a satisfactory outcome than manipulations started after 4 weeks (Table 15).

An association was found between severity of clubfoot and the outcome (p-value 0.04).

Of the feet that had unsatisfactory results, 100% were severe CTEV (Table 16).

There was no association found between the club foot type (Bilateral or Unilateral) and the outcome (Table 17).

Table 12: Outcome

	OUTCOME	
	Satisfactory n (%)	Unsatisfactory n (%)
Feet	55 (89)	7 (11)

5.3.1 Age and Outcome

There was no association between age and outcome when feet were broken down in severity and club foot type (tables 13-14).

Table 13: Outcome of bilateral clubfoot of same severity in different age groups

CTEV	Outcome		p- value	OR
	Satisfactory n (%)	Unsatisfactory n (%)		
Bilateral severe feet				
≤ 4 weeks	20 (87)	1 (33)		
> 4 weeks	3 (13)	2 (67)		
Total	23 (100)	3 (100)	0.08	13.3`
Bilateral mild/moderate				
≤ 4 weeks	9 (64)	0		
> 4 weeks	5 (36)	0		
Total	14 (100)			
Bilateral (all feet)				
≤ 4 weeks	29 (78)	1 (33)		
> 4 weeks	8 (22)	2 (67)		
Total	37 (100)	3 (100)	0.15	7.3

Table 14: Outcome of unilateral clubfoot of same severity in different age group

CTEV	Outcome		p- value	OR
	Satisfactory n (%)	Unsatisfactory n (%)		
Unilateral severe feet				
≤ 4weeks	5 (63)	1 (25)	0.55	5.0
> 4weeks	3 (37)	3 (75)		
Total	8 (100)	4 (100)		
Unilateral mild/moderate				
≤ 4weeks	5 (50)	0		
> 4weeks	5 (50)	0		
Total	10 (100)			
Unilateral (all feet)				
≤ 4weeks	10 (56)	1 (25)	0.6	3.8
> 4weeks	8 (44)	3 (75)		
Total	18 (100)	4 (100)		

Table 15: Outcome of clubfoot in different age groups

Age Range	Outcome		p- value	OR
	Satisfactory n (%)	Unsatisfactory n (%)		
≤ 4weeks	39 (71)	2 (29)	0.04	6.1
> 4weeks	16 (29)	5 (71)		
Total	55 (100)	7 (100)		

5.3.2 Severity and Outcome

There was no association found between severity of clubfoot and outcome when feet were split to look at feet with the same clubfeet type (table 2.64).

However an association was found between severity and outcome when all feet were analysed regardless of clubfoot type (p-0.04).

Table 16: Severity and Outcome

Severity	Outcome		p- value	OR
	Satisfactory n (%)	Unsatisfactory n (%)		
Bilateral feet				
Severe	23 (62)	3 (100)		
Mild/moderate	14 (38)	0 (0)		
Total	37 (100)	3 (100)	0.54	0.0
Unilateral feet				
Severe	8 (44)	4 (100)		
Mild/moderate	10 (56)	0 (0)		
Total	18 (100)	4 (100)	0.10	0.0
All feet (Bilateral/Unilateral)				
Severe	31 (56)	7 (100)		
Mild/moderate	24 (44)	0 (0)		
Total	55 (100)	7 (100)	0.04	0.0

5.3.3 Clubfoot Type and Outcome (Same Age Range)

In order to evaluate the association between clubfoot type and outcome, clubfoot type in the same age range was analysed (table 17). There was no association found between the clubfoot type and the clinical outcome when this was done. Equally there was no association found between clubfoot type and outcome when all feet regardless of age were analysed (p=0.23).

Table 17: Clubfoot Type and Outcome (Same Age Range)

Age Range Categories	Outcome		p-value	OR
	Satisfactory n (%)	Unsatisfactory n (%)		
≤ 4weeks				
Bilateral	29 (74)	1 (50)		
Unilateral	10 (26)	1 (50)		
Total	39 (100)	2 (100)	0.47	2.9
> 4weeks				
Bilateral	8 (50)	2 (40)		
Unilateral	8 (50)	3 (60)		
Total	16 (100)	5 (100)	1.00	1.5
All Age groups				
Bilateral	37 (67)	3 (43)		
Unilateral	18 (33)	4 (57)		
Total	55 (100)	7 (100)	0.23	2.7

CHAPTER SIX

6.0 DISCUSSION

6.1 Demographics

6.1.1 Sample Size

42 cases representing 62 feet were recruited for the study. The sample size was initially estimated at 66 feet. The sample size for this study was almost adequate and representative of the size of the population under study. There was no randomization in the sampling of these cases because of limited time in which the intended sample size was to be achieved.

6.1.2 Gender Distribution

Of the 42 cases recruited 64% were male giving male to female ratio of almost 2:1. Literature search findings (Mulwanda, 1997; Biruk, 2006; Ballantyne, 2002) are consistent with one thing that more males are affected in most of the studies under review, the only question coming out of the reviews is by how much?

6.1.3 Bilateral CTEV

Almost half (48%) of the cases had bilateral clubfoot which in keeping with the general view that about 50% of the clubfeet are bilateral (Ballantyne, 2002; Biruk, 2006).

6.1.4 Age at recruitment

The result that most of the patients seen came early for the intervention is encouraging in that the level of awareness is high in the community. The fact that most of the cases in the study were born at a health facility means that most of the cases could have been identified at the time of birth. However, Biruk et al 2006, reports that about 25% of the cases in the study were missed even though they were born at a health institution.

This level of awareness is impressive because instead of the initial objective to compare how age influences outcome, the high percentage of patients coming early for the intervention meant adjusting the initial age range of 3 months to 4 weeks.

6.1.5 Birth Order Distribution

The findings of the study done in Ethiopia (Biruk, 2006) showed 50% of the cases were first born. This study does not establish a clear pattern as the majority of the cases were of second birth order at 26%. More studies are required to evaluate this finding by Biruk.

6.1.6 Tribal Distribution

The results show that most of the cases hailed from either the Eastern group or the Bemba tribe group. This is an interesting finding and may suggest a genetic predisposition within the two tribes. There role of genetics in the aetiology of clubfoot is a complex one, however, racial variations in the incidence has been

seen (Ballantyne, 2002). The other reason why there is such a large contribution to the population sample by these two tribes may be that, they are the most popular tribes in Lusaka and naturally, would contribute more to any given population sample.

6.1.7 Area of Residence

The majority of the cases for this study came from high-density areas of Lusaka. Could this have aetiological implications? Herpes simplex virus has been implicated in the aetiology of clubfoot. The transmission of this virus is favored by overcrowding, poor ventilation and general hygiene which is the situation in the high-density areas of Lusaka.

6.2 Feet

Satisfactory results of 89% obtained in this study, reaffirms the already known overwhelming results that studies about the clinical outcome of Ponseti management of clubfoot around the world have reported (Changulani, 2006; Ballantyne, 2002; Radler, 2006). Most studies have reported that excellent results could be anticipated when the manipulations are started early. In this study, the majority of the patients who had satisfactory outcome started manipulations when they were four weeks or younger. Radler et al 2006 reported 93% success rate when manipulations are started earlier than 3 weeks.

Manipulations started earlier stand a good chance of correcting because the ligaments and joint capsules are still soft and stretch easily. The younger children are less active and so the manipulated foot is not disturbed in the POP whereas in more active older children, the properties of the cast are changed, usually leading to more manipulations and castings.

The majority of the cases enrolled had severe CTEV (66%), most studies (Mulwanda, 1997; Biruk, 2006) report that this is the most common form of CTEV. There was an association found between severity and the clinical outcome of Ponseti treatment. This is expected because in the severe foot the deformity is more, meaning the ligaments and joint capsules are severely contracted and so make correction difficult. However from this study one can confidently state that good outcome can be anticipated even for a severe CTEV provided the child is brought early for manipulation and casting.

The child with unilateral CTEV is more comfortable and able to tolerate the POP than when both feet are casted as in the child with bilateral CTEV. On this basis one expects that the outcome for unilateral CTEV to be better than bilateral CTEV. In this study there was no association found between clubfoot type (unilateral or bilateral) and outcome. This is expected because each foot is independent of the other even though they are part of the same individual. This means the quality of correction and outcome is the same as for individuals with unilateral CTEV. Therefore any child enrolling for Ponseti management of CTEV stands an equal chance of having their feet corrected regardless of the clubfoot type. There was no literature found on previous studies that looked at the outcome in unilateral and bilateral feet.

Correction of equinus deformity follows the correction of fore-foot deformity. This is so because; one of fundamental principles of the Ponseti technique is based on 'coupled kinetics'. The unlocking of the talo-navicular joint and its subsequent reduction brings about correction of the hind-foot deformity. However Ponseti himself believes that 70% of cases undergoing treatment by Ponseti technique will undergo PTAT for correction of their equinus deformity. This study reports 66% need for PTAT for correction of hind foot deformity. In general the need for tenotomy will increase with factors which restrict movement during manipulation at the talonavicular joint. Even though there was no association between need for tenotomy and age, age plays a big role in determining which foot needs tenotomy. The older the child is, the more difficult the correction, hence the need for PTAT. The study shows association between need for PTAT and severity. The more severe the foot the more difficult it is to correct hind foot deformity by

manipulation alone. There were no complications which were purely as a result of the PTAT. This was expected because numerous studies have shown how safe this procedure is (Dobbs, 2004).

CHAPTER SEVEN

7.0 CONCLUSION

1. Virgin idiopathic CTEV can successfully be treated by ponseti technique.
2. Excellent results can be anticipated when manipulations are started earlier than 1 month old.
3. Mild-moderate CTEV has a better clinical outcome than severe CTEV.
4. Severe CTEV is the most common form.
5. There is no difference in clinical outcome between unilateral and bilateral CTEV.
6. The majority of clubfoot undergoing Ponseti treatment of clubfoot will need PTAT for the correction of equinus deformity.

7.1 RECOMMENDATIONS

1. More studies about treatment for CTEV need to be done; especially looking at the long term effect of Ponseti treatment of idiopathic clubfoot.
2. Treatment of idiopathic CTEV should be started as soon as possible after birth. This can only be achieved when there is awareness of the condition and its treatment, both to the health workers and the general public.
3. Training personnel in Ponseti treatment of CTEV will ensure treatment is started as early as possible and as close as possible to the patients home.

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APPENDICES

Appendix A QUESTIONNAIRE

Medical Record Number
Research Number

UNTREATED CLUBFOOT ASSESSMENT AND TREATMENT RECORD

i. Demographics

Date of initial Exam:

Name:	Sex: Female /Male DOB:
Address:	Town:
District:	Clinic Name:
Mother's Name:	Telephone:
Father's Name:	Tribe:
Ortho Officer/ Physio:	Birth attendant:
Place of Birth:	Hosp () Clinic () Home ()

ii. History

(a) Pregnancy:

Term/Preterm

Single/Multiple

(b) Delivery:

SVD/ Operative

(c) Family History:

Number of Child in Family _____

Any of the siblings with clubfoot? Yes/ No

Which one (number) _____

Examination

Spine _____

Hips _____

Up extreme _____

Low extreme _____

Other _____

CLUBFOOT

- Bilateral/ Unilateral

-Right foot: Mild/Moderate/Severe

-Left foot: Mild/Moderate/Severe

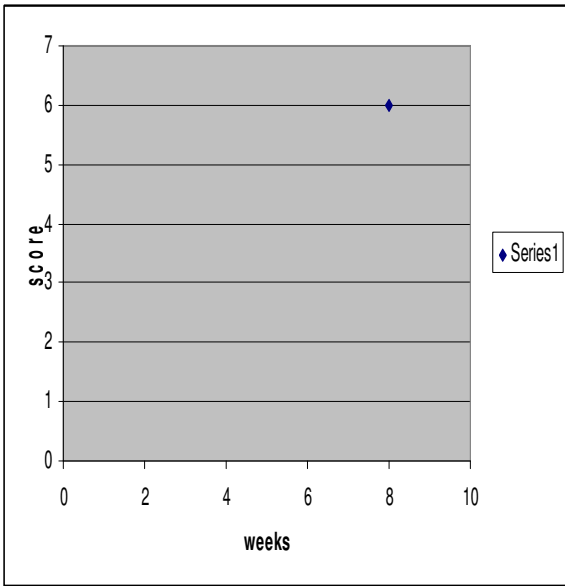
Treatment. Graph Recording TS, HFCS & MFCS during Ponseti Treatment

Key: MC (Manipulative & cast); SFAB (Steenbeek Foot Abduction Brace); R (Refer); O (Other). If other, please clarify in notes.

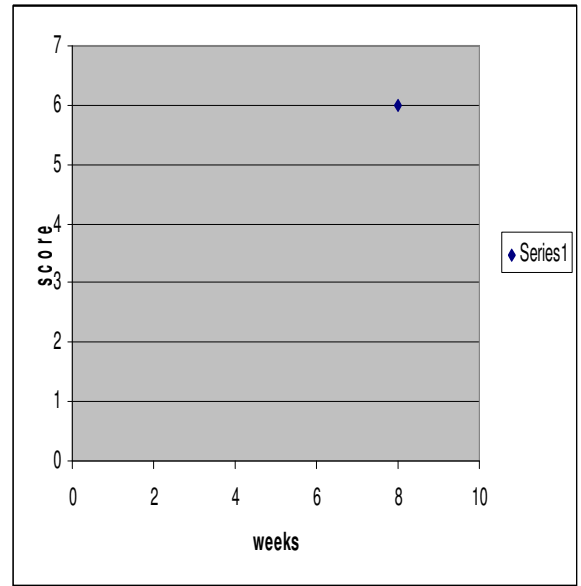
DATE																	
SIDE																	
Age in Weeks																	
HFCS																	
EH																	
RE																	
PC																	
MFCS																	
LHT																	
CLB																	
MC																	
TS																	
Treatment Performed																	

Treatment Sheet (comments)

Follow up Charts



Right



Left

Comment on Tendo Achilles Tenotomy

Date Performed _____

Performed in clinic/OT

If OT GA/ LA

Performed by_ medical officer/ other (specify) _____

Complications?

Details:

Appendix B

Date _____

Outcome Assessment Sheet

Criteria	Right foot	Left foot
Pirani Score	<ul style="list-style-type: none">• Zero• > Zero	<ul style="list-style-type: none">• Zero• > Zero
Patients satisfaction	<ul style="list-style-type: none">• Satisfied• Not satisfied	<ul style="list-style-type: none">• Satisfied• Not satisfied
ROM	<ul style="list-style-type: none">• Normal• Stiff	<ul style="list-style-type: none">• Normal• Stiff
Heel Position	<ul style="list-style-type: none">• Normal• Altered	<ul style="list-style-type: none">• Normal• Altered

General Comments

Appendix C

THE PIRANI SCORE

1. Hindfoot contracture (HFC)

Posterior Crease (PC)

Empty Heel (EH)

Rigid Equinus (RE)

2. Midfoot Contracture (MFC)

Curvature of Lateral Border of Foot (CLB)

Medial Crease (MC)

Lateral part of the Head of the Talus (LHT)

- Hindfoot contracture score (HFCS) between 0 and 3
- Midfoot contracture score (MFCS) between 0 and 3
- Total score (TS) between 0 and 6

A higher score indicates a more severe deformity.

Appendix D

CLASSIFICATION OF SEVERITY OF CLUBFOOT

- (i) **Mild clubfoot** is any clubfoot with Pirani Score ≤ 2 .
- (ii) **Moderate clubfoot** is any clubfoot with Pirani Score between 2 and 4.
- (iii) **Severe clubfoot** is any clubfoot with Pirani Score ≥ 5 .

Appendix E

CONSENT FORM

Iof
having read the information sheet/having had information sheet read and explained to me, and having been availed with all information regarding the procedure, risks and benefits involved, do hereby accept to enroll my child in the research, and agree to have the full procedure performed on my child by the principle investigator.

I understand that i can opt out if I feel the need to, without discrimination or withholding of medical treatment for my child.

Signature/Thumb print of guardian.....

Signature/Thumb print of witness.....

Date.....

Appendix F

INFORMATION SHEET

PID # _____

**TITLE OF RESEARCH : THE EARLY CLINICAL OUTCOME OF
PONSETI MANAGEMENT OF CLUBFOOT AT
UTH LUSAKA ZAMBIA**

INVESTIGATOR : BRIAN SONKWE (BSc HB, MBChB, MCS)

**SUPERVISORS : (i) Dr. J. MUNTHALI
(ii) Prof. MULLA**

Introduction

Your child is being asked to participate in a research study to evaluate the clinical outcome of Ponseti management because they have clubfoot. Ponseti management of clubfoot is a non surgical management of clubfoot that has shown great promise as an alternative treatment method to surgical treatment.

During this period of study we hope that your child's feet will improve both in function and appearance.

Purpose of the Study

The purpose of this study is to evaluate the clinical outcome of Ponseti management of clubfoot. Results from other parts of Africa (Malawi and Uganda) show that this method of treatment is able to straighten the child's foot by serial casting and manipulation within fairly short period of time. The outcome of this study will determine whether we adopt this cheap and safe method of treatment as the treatment of choice of clubfoot in Zambia.

Study Procedures

If you agree that your child enroll for this study you will be required to bring your child to the clinical every week for 5 weeks. At each visit your child's feet will be manipulated and plaster applied, there will be no need for your child to stay in hospital. At application of the 5th plaster a small operation of the heel tendon will be performed in the clinic to prevent the foot from pointing downwards. The operated site will be numbed with an anaesthetic before the small operation.

Risks

When the heel tendon is cut, there is a small risk of pain and infection at the site of incision. However antibiotics and analgesics will be given to make the child comfortable.

Benefits

Children who will be enrolled will in general be closely monitored in terms of how they are responding to treatment.

Aside from this other children with similar condition will benefit if the Ponseti method is adopted as the method of managing clubfoot in Zambia.

Confidentiality

The information collected in the study will be kept confidential. However, the research assistants will be able to inspect the medical records of your child and have access to confidential information that identifies your child by name. Such information may also be availed to the University of Zambia Research and Ethics Committee. Before information is analysed, your child's name will be replaced by a numerical code which will remove your child's identity by name. In addition your child's name will not be used if any information about your child is published in journals, and neither will your child's name be used by the government if it uses the information from the study to implement treatment of clubfoot by Ponseti method.

Withdrawing from the Study

You are free to withdraw your consent for your child and to discontinue participation in this project at any time without prejudice against further care that you may receive at this institution.

Cost of Participation

There will be no cost to you for participating in this study. All study related examinations and tools will be provided at no cost at all.

Payment for Research Related Injuries

It is unlikely that your child will be injured because of participating in the study. However, in an event that injury occurs, the study team is qualified to institute treatment immediately and further care will be provided at UTH or any other GRZ institution will be provided at no cost to you.

Persons to contact for Questions/ Problems

If you are not clear about anything before and after enrolling your child in the project, please contact **Dr. Brian Sonkwe** Department of Surgery Orthopaedic Unit P/B RW 1X UTH Lusaka, you can also contact him on Cel. 0977798236. If you have any doubts about your child's rights as a research participant, you may contact the Secretary UNZA Research and Ethics Committee Box 50110, Lusaka Zambia; Tel 256067 email unzarec@zamtel.zm.

Legal Rights

It must be made clear that you are not waiving any of your legal rights by signing this form. Your signature below indicates that you have agreed to enroll your child to participate in the study. You will receive a copy of this signed informed consent if you so wish.