CLUBFOOT PATIENTS' DEMOGRAPHIC PROFILE AND OUTCOMES OF USING THE PONSETI METHOD AT THREE SELECTED HOSPITALS IN ZIMBABWE.

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Science in Physiotherapy.

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DECLARATION

I, Debra Mudariki declare that this research report is my own work. It is being submitted for the degree of Master of Science in Physiotherapy in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.


Signature of Candidate

25th day of June 2020

DEDICATION

To Soman, Mudiwa, Angeline and Danai. And to all the children born with clubfoot.

ABSTRACT

Background: Clubfoot is the most common musculoskeletal congenital abnormality and the Ponseti method is regarded as the gold standard of treatment. It has proven to be affordable, simple, and effective in correcting this deformity, particularly in low resource settings similar to Zimbabwe.

Aim: The aim of this study was to establish the demographic profile and outcomes of patients with clubfoot treated using the Ponseti method at 3 hospitals in Zimbabwe, as well as determine whether results obtained were similar to those from regional and international research.

Methodology: A descriptive retrospective records review of patients with clubfoot treated between January 2013 and December 2015 at Parirenyatwa, Harare Central and Mutare Provincial Hospitals was conducted. The main outcome was the final Pirani score at the end of the corrective phase. Data was analysed using STATISTICA Version 13.5.

Results: There were 310 participants, mostly male (64.2%), with the majority (79.7%) in the maintenance phase of treatment. A total of 88.3% of the were participants between zero and two years of age at initial presentation, and the median (IQR) age was 3months (0.15-11months). Clubfoot was mostly of idiopathic (90.5%) and bilateral (55.2%) presentation, with positive family history of the deformity reported in 14.5% of participants. Mean (SD)Pirani scores at initial assessment for the right and left feet were 3.92 (1.33) and 3.99 (1.25) respectively. The Mean (SD) number of casts applied before tenotomy was 7.14 (4.48) ranging from 0-26 casts, and 72.5% of the participants had a tenotomy done. The proportion of left and right feet that attained a Pirani score of one or less at the end of the corrective phase was 79.2% and 82.5% respectively. Relapse was reported for 42.6% of participants in braces. At time of data collection, as many as 73.6% of the participants had stopped attending the clinics.

Conclusion: Clubfoot treated using the Ponseti method had a good outcome at the end of the corrective phase. The demographic profile of patients managed at the three clinics and their treatment outcomes were in line with literature findings. There is, however, evidence of poor compliance and a high loss to follow up during the bracing phase and these need to be addressed to improve long term results.

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CHAPTER 1

1. Introduction

1.1 Background and need

Clubfoot is the most common congenital orthopaedic deformity (Dobbs and Gurnett, 2009; Zhao *et al.*, 2014). The affected foot is medially rotated and plantarflexed, and has four characteristic deformity components- mid-foot cavus, forefoot adductus, hind foot varus and equinus (Dobbs and Gurnett, 2009). The deformity can occur in isolation as idiopathic clubfoot or in conjunction with other congenital disorders like arthrogryposis and spina bifida as secondary clubfoot (Zhao *et al.*, 2014;Lu *et al.*, 2010).

Clubfoot incidence ranges between 1- 6.8 per 1000 live births and varies among ethnic groups (Dobbs and Gurnett, 2009; Shabtai, 2014), with nearly 80% of all children with clubfoot being born in developing countries (Penny, 2005), and this is mainly based on the higher birth rates of these developing countries. Literature search on clubfoot incidence in Zimbabwe found it to be 0.9/1000 live births in a study that looked at minimal incidence at one hospital (Madzivire *et al.,* 2002). There were no other incidence studies done in the country since then.

Treatment of clubfoot aims to obtain feet which are flexible with normal function (Lu *et al.*, 2010; Rasit *et al.*, 2012). The treatment has evolved from the use of forceful manipulations and surgery in the mid- 1800s, the Kite method from 1939, and the resurgent use of surgery again in the 1970s (Dobbs and Gurnett, 2009). Poor treatment outcomes such as relapse or incomplete correction of the deformity, were a common result of these historical treatment options (Morcuende *et al.*, 2004; Dobbs and Gurnett, 2009; Lehman *et al.*, 2016). This led to the development and introduction of the Ponseti technique by Dr Ignacio Ponseti in the late 1940s (Dobbs and Gurnett, 2009).

The Ponseti method is a specific method of foot manipulation, serial casting, tendo-achilles tenotomy and foot bracing that is aimed at correcting the clubfoot deformity (Dobbs and Gurnett, 2009; Göksan et al., 2015). Ponseti and Smoley, (2009), state that the goal of this treatment method is to “obtain a supple, well corrected foot in the

shortest possible time". The method is renowned for being safe and efficient in the correction of the clubfoot deformity (Shabtai, 2014). It has also led to a significant reduction in the need for major extensive surgical intervention to correct residual deformities (Morcuende *et al.*, 2004). As such, it is currently referred to as the "gold standard" of clubfoot treatment (Radler et al., 2013; Shabtai, 2014; Zhao et al., 2014). The Ponseti method has widely spread to numerous countries worldwide, some of which have documented and published positive treatment outcomes (Mathias *et al.*, 2010; Sætersdal *et al.*, 2012; Shabtai, 2014).

Zimbabwe saw the introduction of its first Ponseti Clinic at the largest referral hospital, Parirenyatwa, in March 2011. Medical doctors and rehabilitation staff (physiotherapists, occupational therapists, rehabilitation technicians) underwent requisite training to equip them with theoretical knowledge and practical skills to manage clubfoot using the Ponseti Method. The process of training and establishing clinics was the decentralised to other provinces over time to increase capacity to manage clubfoot country-wide. To date, a total of 13 Ponseti clinics (five at central hospitals, eight at provincial hospitals and one at a district hospital) have been established in the country's 10 provinces.

There are numerous studies that investigated clubfoot outcomes following the use of the Ponseti method (Ponseti and Smoley, 2009; Firth and Eltringham, 2009;Adewole *et al*.,2009; Adegbehingbe *et al*., 2010; Ayana and Klungsoyr, 2014; Smythe et al, 2016). These outcomes include improvement of foot function, passive range of motion, as well as the reduction in the need for major surgery at the end of treatment (Double, 2014). Literature however reveals a lack of uniformity in the reported outcomes measured after the Ponseti treatment of clubfoot. Changes in the Pirani score have been used in some studies as the primary outcome or measure of treatment success (Kouamo II *et al.*, 2014; Smythe, Chandramohan, *et al.*, 2016). For this study, the primary outcome was regarded as that defined in the study by Smythe, Chandramohan, *et al.*, (2016) -a Pirani score of one or less at the end of the corrective stage. Hence success of treatment was determined as the proportion of clubfeet that achieved a Pirani score of one or less at the end of the manipulation and casting (corrective) phase.

1.2 Research Problem

The demographic profile of the clubfoot patient population, treatment progression as well as the treatment outcomes of the Ponseti clubfoot treatment, are not known. It is also not known whether the afore-mentioned variables at Ponseti clinics in Zimbabwe are like those in published research. Other countries that have adopted the Ponseti technique as the method of choice for clubfoot management have analysed and published data on their patient populations and the treatment outcomes (Lu *et al.*, 2010; Akintayo *et al.*, 2012; Rasit *et al.*, 2012), and yet despite its widespread adoption in Zimbabwe, the effectiveness of this method has only been studied and reported for one centre- Parirenyatwa hospital (Smythe, Chandramohan, *et al.*, 2016).

1.3 Research question

What is the demographic profile and outcome of patients with clubfoot treated at Parirenyatwa, Harare Central and Mutare Provincial hospital Ponseti clinics in Zimbabwe?

1.4 Aim of the study

To establish the demographic profile and treatment outcomes of clubfoot treated at the selected Ponseti clinics in three major hospitals in Zimbabwe

1.4.1 Objectives of the study

The objectives of the study are : -

1. To establish the demographic profile of patients treated at the selected Ponseti clinics between January 2013 and December 2015.
2. To determine the outcome processes of the Ponseti clubfoot treatment at the selected hospitals as follows
    - Mean number of casts before tenotomy.
    - Mean number of tenotomies per patient at selected clinics.
3. To establish the outcomes of Ponseti treatment at the selected hospitals as follows-:

- The proportion of left and right clubfeet that attained a Pirani score of 1 or less at the end of the corrective phase.
- The proportion of patients who had a relapse in the maintenance phase.
- The proportion of patients lost to follow up.

1.5 Significance of the study

Profiling patients with clubfoot and establishing treatment processes and outcome was intended to 1) provide information on the demographic characteristics of patients treated and 2) analyse the treatment outcomes within the selected Ponseti clinics.

Establishing the outcome of Ponseti treatment will help to determine whether results obtained (Pirani score at end of casting, relapse during maintenance, patient loss to follow up), as well as outcome processes, are in line with published regional and international trends. If there are major deviations, the causes of these can be explored by further research. If the results are in line with those in published literature, this finding will strengthen the recommendations to support and strengthen the adoption of the Ponseti method as the “Gold standard” to manage clubfoot in the Zimbabwean setting. It was also hoped that the results from the study would inform the local, regional, and international community on the impact of Ponseti management of Clubfoot in Zimbabwe.

Without a detailed analysis of the demographic characteristics of patient population, and the treatment outcomes, it is difficult to evaluate treatment results. It is consequently difficult to adequately plan for treatment as well as mobilise and provide enough resources for the management of clubfoot in Zimbabwe.

CHAPTER 2

2. Literature Review

2.1 Introduction

A literature search was conducted on CINHAL, EBSCO, PubMed, ResearchGate, and Google Scholar. The literature was from the period ranging from 2000 to 2019.

The researcher reviewed the aetiology and epidemiology of clubfoot deformity, how it is treated using the Ponseti Method and the outcome of treatment in various settings. Studies with clubfoot patient demographic profiles as well as treatment outcomes were also included. The findings are presented below.

2.2 Aetiology of the Clubfoot Deformity

Clubfoot is a congenital deformity of the foot that is characterised by cavus and adduction deformities of the forefoot; as well as varus and equinus deformities of the hindfoot. These four clubfoot deformity characteristics are also denoted by the mnemonic “CAVE” for Cavus, Adductus, Varus and Equinus. (Docker, Lewthwaite and Kiely,2007). Dietz (2002) further described it as a foot deformity that cannot be passively corrected and lacks spontaneous resolution. The aetiology of clubfoot is still unknown; however, molecular-biology studies have reportedly confirmed the presence and activity of the foot deforming genes in the second trimester of gestation making the condition a developmental malformation (Biruk, 2007). According to Werler *et al.*, (2013), the feet start to develop in week nine of the gestational period with limb buds which are vertically oriented and facing each other, however by week 14 of gestation, the feet must medially rotate and assume the normal adult- like foot position. Should this developmental change fail to occur, the feet attain the clubfoot deformity. As clubfoot is said to develop in the middle of the second trimester of pregnancy (Ponseti, 2001), it can reportedly be detected in utero by ultrasound scanning at 20 to 24 weeks gestation (Double, 2014). Ultrasound scanning is reported to have an 85% positive predictive value for the deformity (Bridgens and Kiely, 2010).

Other literature on clubfoot aetiology describes the deformity as a multifactorial deformity resulting from a mixture of genetic and environmental factors (mainly maternal smoking)(Dobbs and Gurnett, 2009). Genes involved in limb patterning and

muscle contraction have been identified as possible genetic players, however the actual mechanism through which these factors interact to bring about the deformity remains unclear (Bacino and Hecht, 2018). About 25% of all clubfoot cases are reported to be familial (Dobbs and Gurnett, 2009), and the probability of another sibling being born with the deformity is said to increase by 10-20% if one family member, other child or both parents have clubfoot (Dietz, 2002). A previous study in Zimbabwe (Smythe, Chandramohan, *et al.*, 2016) found a positive family history of the deformity in 10.5% of study participants. In neighbouring South Africa, Firth and Eltringham, (2009), found that 15% of the study participants had a positive family history while other studies found familial incidence ranging between 9% and 22% (Harnett *et al.*, 2011; Evans *et al.*, 2016; Jaqueto *et al.*, 2016). The differences in proportion of participants with a positive family history of the deformity may differ due to the variations in study population sizes and types of studies. What is however common in most studies is that clubfoot has been found to have a familial link.

Clubfoot can be classified as idiopathic, when it occurs in isolation in an otherwise normal individual (Dobbs & Gurnett, 2009). It can however also occur in association with syndromes or dysplasia of the neuromusculoskeletal tissues, as secondary or non-idiopathic clubfoot. This was found in Nigeria by Adewole et al., (2009) and in South Africa by Firth and Eltringham (2009) where secondary clubfoot occurred in 18% and 17% of the study populations respectively. In Ethiopia, Biruk, (2007) found secondary clubfoot in 15% of the study population. In all these studies that included patients with secondary clubfoot, the Ponseti method was found to be useful in correcting the deformity, with very little or no need for additional surgical intervention. Hence the inclusion of participants with secondary clubfoot in this current study.

2.3 Epidemiology of Clubfoot

Clubfoot is reportedly the most common congenital musculoskeletal condition affecting lower limbs (Dobbs and Gurnett, 2009). The deformity occurs approximately twice as much in males as it does in females, and the cause of this discrepancy remains unclear. Some research has however found that the male predisposition is because clubfoot is of polygenic inheritance, and females seem to need a greater genetic load to be affected by the condition. This is known as the Carter effect.(Kruse, Dobbs and Gurnett, 2008). The majority of clubfoot cases (80%) are estimated to

occur in low to medium income countries (LMICs) (Jowett, Morcuende and Ramachandran, 2011). A recent systematic review (Smythe, Kuper, *et al.*, 2017) calculated weighted pooled estimates from birth prevalence studies done in different world regions found that the birth prevalence of the deformity in LMICs ranges between 0.5 to 2 cases per 1000 live births. The estimate for Africa, in which Zimbabwe lies, was also found to be 1.1/1000 live births. Literature search found only a single previous study (Madzivire *et al.*, 2002), that aimed to determine the minimal incidence of clubfoot at a hospital in Harare, Zimbabwe, and it was found to be 0.9/1000 live births. Closer to Zimbabwe, Mathias *et al.*, (2010) measured the overall incidence of clubfoot in Uganda through prospective recruitment of all children born with foot abnormalities at eight regional hospitals over a 20-month period and found a similar clubfoot incidence of 1.2/1000 live births. The systematic review by Smythe, Kuper, et al., (2017), is currently reported to be the only systematic review of its magnitude having analysed 48 studies from 20 countries and summing information from over 13 million children. This study and others like it, however, highlight a general paucity of uniformity of birth defects surveillance in developing countries which makes it challenging to acquire the exact birth prevalence. In some instances, there is also a probability of under- reporting in some of the studies reviewed due to variation in data capturing practices as well as the presence of home deliveries in developing countries, hence there is still a need to work on establishing actual birth prevalence of clubfoot in Zimbabwe and different parts of the world.

2.4 Clubfoot and the Ponseti method of treatment

2.4.1 The Ponseti Method

Clubfoot treatment using the Ponseti method aims to correct the deformity and attain a foot that is free of pain and functional. Historically, treatment options have ranged from extensive surgery, manipulation and casting with the Kite method, and the French method, among others. All these options have had varying degrees of success, with overall fair to poor long-term outcomes. The Ponseti technique was then introduced in the 1950s by Doctor Ignacio Ponseti in Iowa, after the orthopaedic surgeon noted that patients treated using extensive orthopaedic surgery later developed painful feet with residual deformities. (Dobbs and Gurnett, 2009). It was adopted in many other countries around the world from 1997 (Shabtai, 2014).

The Ponseti Method of clubfoot treatment has two phases, a corrective phase as well as a maintenance phase. In the corrective phase, the cavus, adductus and heel varus elements of the deformity are corrected by use of specific gentle manipulation and casting, then a tenotomy is performed to correct the remaining equinus deformity. The maintenance phase involves the use of foot abduction braces to prevent relapse. The foot is reportedly best treated in the first few weeks of life before the child begins to walk and the deformity worsens. Toe-to- groin casts are applied weekly for an average period of four to eight weeks. These long leg casts are applied with the knees flexed to 90 degrees to prevent slippage as well as maintain the foot in the corrected position. This is followed by casting the foot in abduction, while applying counterpressure to the lateral talar head to correct adductus (Radler, 2013). The cavus deformity is corrected by elevating the pronated first metatarsal thereby supinating the forefoot and bringing it into alignment with the hindfoot. This is followed by correction of the adductus by casting the foot into abduction. The hindfoot varus is simultaneously corrected as the foot is being abducted through the principle of kinematic coupling. Kinematic coupling refers to the automatic movement that occurs in one part of the foot because of manipulation and movement in another part. In this instance, there is abduction of the calcaneum as the entire foot is abducted around the talus, thereby correcting the heel varus. It occurs due to the structure of the joint between the calcaneum and the talus (Ponseti and Smoley, 2009). When the foot can passively abduct to 50 degrees, the equinus deformity is subsequently corrected by a surgical percutaneous Achilles tenotomy which is a total sectioning of the tendon. The foot is then cast in 70 degrees abduction and 5-10 degrees dorsiflexion for three weeks to allow healing of the Achilles tendon. (Dobbs and Gurnett, 2009; Ponseti and Smoley, 2009; Radler, 2013). The correction is maintained using a foot abduction brace which has been shown to be crucial in the management of the deformity (Thacker et al., 2005).

2.4.2 Assessment of clubfoot using the Pirani score

After birth, the Pirani score is one of the methods that is commonly used to assess the deformity. This is the score used to assess patients at Ponseti clinics in Zimbabwe. It is a severity scoring system comprising six elements, three for hindfoot scores and three for midfoot scores. Each of these elements is assigned a score of 0, 0.5 or 1, hence a clubfoot is scored out of a possible maximum total of 6. The hindfoot elements

are the posterior crease, empty heel, and rigidity of the equinus. The midfoot scores are the medial crease, lateral head of talus and curvature of the lateral border. The Pirani score has been found to be quick, easy and reliable to use, without need for any specialised equipment (Hussain, 2007). Detailed description of the scoring process for each of the hindfoot and midfoot contracture elements is well detailed in Chapter 4 of the Africa Clubfoot Training Manual of 2017 which is attached as appendix 8.

2.5 Outcomes of Clubfoot treatment using the Ponseti Method

Good results of clubfoot treatment using the Ponseti technique have been reported in many studies (Jowett, Morcuende, Ramachandran, 2011). These authors performed a systematic review of the results of Ponseti management of clubfoot. They found the earliest recorded outcome of Ponseti Method was documented in a study by Ponseti and Smoley (1948-1956) which reported good results in 71% (94 feet). They also found Ponseti treatment studies with the longest follow-up periods to date which were performed by Laaveg and Ponseti (10-27 years follow up), and Cooper and Dietz (30 years follow-up) along with numerous other studies from 74 articles. The review showed good results with an initial correction rate of approximately 90% in the treatment of idiopathic clubfoot. Though this systematic review by Jowett, Morcuende and Ramachandran (2011) shows a high initial correction of the clubfoot deformity, the study does not specify the exact outcome measures used to define a “good result”. It also does not include studies that evaluated the outcome in treatment of non-idiopathic clubfoot. As a result, this may account for higher reported success rates when compared to studies that include results of treatment of non-idiopathic or neglected clubfoot.

There is widespread consensus that clubfoot treatment using the Ponseti Method achieves very good or successful outcome (Ponseti and Smoley, 2009; Adewole *et al*.,2009; Adegbehingbe *et al*., 2010; Ayana and Klungsoyr, 2014; Smythe et al, 2016). Literature reviewed, however, describes outcomes of treatment in different ways. Successful treatment has either been described based on multiple evaluation techniques such as the use of x-rays and goniometry, need for further surgical intervention, degree of flexibility of the foot and/ or the Pirani score attained at a specific stage of treatment. Smythe, Wainwright, *et al.*, (2017b), found lack of consensus in definition of success in the treatment of clubfoot. Their study however

found that clubfoot management practitioners from 10 African countries regarded the attainment of a plantigrade foot, ability to wear normal footwear, absence of pain and parent satisfaction as measures of success in the management of clubfoot. Some of the studies detailing success of clubfoot treatment were reviewed and the findings presented below.

2.5.1 Outcomes based on Multiple evaluation techniques

Literature on outcomes of using the Ponseti technique in the treatment of clubfoot includes some studies that have used more than one outcome measure or evaluation of more than one parameter to determine and describe success. An earlier study done by Ponseti in 1963, used X-rays (anteroposterior and lateral views), patient foot photographs and clinical examination of feet to evaluate the result of treatment. Good results (defined as obtaining a combination of ankle dorsiflexion greater that 10 degrees, heel valgus of zero degrees, zero to 10 degrees of forefoot adduction and zero degrees of tibial torsion) were reportedly found in 67 (71%) of the feet at the end of the corrective phase. (Ponseti and Smoley, 2009).

Similarly, another study by Church *et al.*, (2012), also used multiple methods for evaluation of treatment success that included five tests (gait analysis, pedobarographic evaluation, physical assessment, radiographic assessment and outcome questionnaires to retrospectively compare outcomes of clubfoot treated surgically (26 patients) and those treated with the Ponseti Method (22 patients). The comparator group had 34 children with normal feet. The Ponseti-treated group was found to have overall superior outcome compared to the surgically treated group. Despite the high quality of the afore-mentioned studies, the technical expertise and equipment required as well as time taken to evaluate outcome of Ponseti treatment using multiple evaluation methods makes it difficult to reproduce them in low resource settings. In most low- and middle-income countries, it is also expensive and difficult to use evaluation methods such as x-ray imaging and pedobarographic imaging to determine the final foot position hence this not used in many studies.

In a study carried out in Malaysia by Rasit *et al.*, (2012), treatment outcome was assessed using quantitative clubfoot assessment of the deformity (QCAD), which consists mainly of limb anthropometry measurements of leg length, midcalf

circumference, foot length and midfoot circumference, in combination with the Pirani score. Their study investigated a total of 30 patients of which 12 were managed conservatively using only the Ponseti method and the remainder required surgical management due to resistance to manipulation and casting only. Calf atrophy and foot length discrepancy were found to be significantly different between the surgically treated patients and those managed conservatively, with those patients in the conservatively managed group having a favourable outcome. Another study by Sætersdal *et al.*, (2012) also made use of a combination of the Pirani score, ankle and foot range of motion to evaluate success of treatment of clubfoot using the Ponseti method at eight hospitals in Norway. They found that 77% of the feet evaluated had a good outcome of a Pirani score of 0.5 or less, good dorsiflexion and external rotation without forefoot adduction. This study however, deviated slightly in their bracing protocol as some of their patients (32%, n=116) were issued with a unilateral above knee dynamic brace to maintain correction.

The studies reviewed so far used a combination of evaluation techniques to distinguish and describe the outcome of clubfoot treatment using the Ponseti method. There is a clear variation in the methods and techniques used and some of the methods are technically demanding and may take more time to perform. This makes them difficult to reproduce in low income settings. Because of the variation in evaluation methods, it also makes it challenging to draw a comparison of outcomes across studies. Despite this though, the common denominator remains the fact that all the studies reportedly obtained superior outcomes after using the Ponseti technique.

2.5.2 Outcome based on the need for Surgical Intervention

The use of the Ponseti method to manage clubfoot has reportedly seen a reduction in the need for extensive surgical intervention (Morcuende *et al.*, 2004). This has been investigated and reported as the main outcome measure in some studies reviewed in this section.

In 2004, Morcuende *et al.*,performed a study in which they evaluated the results of using the Ponseti method in the treatment of 157 patients with clubfoot. They found that only 2.5% of these patients required extensive surgery. In a Nigerian study, (Adegbehingbe *et al.*, 2010) aimed to determine how the Ponseti management of

clubfoot affected the frequency of surgical management of the condition. The primary outcome was the number of patients with clubfeet treated without the need for extensive surgery. This study was a randomised double blinded comparative study and participants were randomly assigned to two treatment groups- one treated with the Ponseti technique (55 patients) and another treated by other techniques (50 patients). Of the Ponseti treated group, only 5.5% required some form of surgical intervention. As many as 68% of the non- Ponseti treated group however, needed surgical intervention.

Similarly, Firth and Eltringham, (2009), sought to determine the proportion of patients with clubfoot with an indication for further surgery after treatment with the Ponseti method. This was based on whether the patients had residual deformity at the time of follow-up. A total of 70 patients (106 feet) were included in the study and the absence of residual deformity was attained in 61% of the patients. Only seven feet (7%) had residual deformities that required additional surgery, while the remainder had minor residual deformities that did not need surgical intervention. These studies all show that a greater proportion of participants treated using the Ponseti method did not require any surgical intervention.

2.5.3 Foot flexibility

According to Ponseti and Smoley (2009), clubfoot is considered fully corrected when the affected foot can be pronated and dorsiflexed fully. This means there is resolution of the fixed deformities and the foot and ankle can be freely moved. Several authors have defined foot and ankle flexibility as the primary outcome of Ponseti treatment in their studies. One such study was conducted in 2014, by Ayana and Klungsøyr. They evaluated the effectiveness of the Ponseti technique in the management of neglected clubfoot in Ethiopia. The primary outcome was the attainment of feet that were flexible, plantigrade and had no pain. The Ponseti treatment was reported to be 100% successful in this study. Another study which defined the attainment of a plantigrade foot as its primary outcome was carried out by Tindall *et al.*, 2005 in Malawi. The study found a very high correction rate of 98% in clubfoot managed by Ponseti-trained orthopaedic clinical officers (OCOs). Lavy *et al.*, (2007) also performed a study in Malawi where he found that 68% of the patients that had been treated managed to attain plantigrade or better foot position. Attainment of the plantigrade foot position in

patients with clubfoot correlates to foot function as this is the position that is required for an individual to stand, walk as well as wear shoes. As such, it is an important fundamental of foot function, and the Ponseti Method has proven useful in achieving this as evidenced above.

2.5.4 The Pirani Score as a primary outcome measure

There are also studies that defined their primary outcome measure as the Pirani score obtained at a specific stage of treatment. Success is often defined by the proportion of participants who attain a certain Pirani score at the defined stage. One such study was conducted by Kouamo II *et al.*, (2014) in Lome, Togo. The aim of the study was to evaluate the preliminary results of using the Ponseti method at their institution. The primary outcome was attainment of a Pirani score of less than 3 at the end of the corrective phase and this was achieved for 97.8% of the cases treated. Smythe, Chandramohan, *et al.*, 2016, also used the Pirani score at the end of the corrective phase as the primary outcome, however in that study, success was defined as the proportion of feet that had a total Pirani score of 1 or less at the end of the corrective phase. This result was obtained in 85% of the feet. The Pirani score has been used in isolation to measure success of treatment as shown in the studies above. It can be used in combination with other outcome measures (Rasit *et al.*, 2012; Sætersdal *et al.*, 2012) and as such it can provide valuable information with regards to patient progress.

2.6 Relapse of the clubfoot deformity and patient loss to follow up

Dr Ponseti, from his earliest treatments, also noted that the clubfoot deformity had a strong tendency to relapse (Ponseti, 2001; Ponseti and Smoley, 2009). Relapse was defined by Bhaskar and Patni, (2013), as “recurrence of any component of the deformity requiring treatment after commencement of foot abduction orthoses”. Ponseti and Smoley, (2009), found recurrence in 53(56%) of the feet in their study. This occurred during the bracing stage possibly due to poor brace use as this study showed some deviation in the duration of brace use compared to later studies. Chand *et al*., (2019), also reported a higher proportion of relapse in 86% of their study population that failed to use braces consistently According to Kim et al., (2014), there is a reported link between relapse and brace use and consequently follow up. Patients who are lost to follow up usually fail to continue with brace use and are more likely to

experience relapse. The same sentiment is also shared by Eidelman, Kotlarsky and Herzenberg (2019) who cited inability to comply with the bracing protocol, inadequate bracing and insufficient follow up as major reasons for release in the treatment of clubfoot.

Though reasons for the relapse are reportedly poorly understood, they are mainly related to non-compliance with braces during the maintenance phase (Ponseti, 2001; Thacker *et al.*, 2005; Ponseti and Smoley, 2009; Zhao *et al.*, 2014) The cause is possibly due to the persistence of same pathology that resulted in the deformity initially, as this dysfunction has been found to last into third or fourth year of life (Ponseti, 2001). Clubfoot relapse has however also been found to occur in some patients who are compliant with foot abduction orthoses during the maintenance phase. The probability of the recurrence of the deformity greatly increases in instances where brace compliance is poor. Göksan *et al.*, (2015) found that higher chances of relapse were experienced in non-compliant patients (32%) compared to compliant patients (9%). Ponseti also noted a 78% relapse in non-compliant patients, compared to only 7% in compliant participants (Ponseti, 2001).

2.7 Conclusion

There is considerable literature which dwells on the outcomes of clubfoot treated using the Ponseti method but there are fewer published researches on the subject in sub-Saharan Africa, despite the widespread adoption of the technique on the African continent. There is a clear need to standardise a set of outcome measures that can be used and compared in such studies. Literature reviewed however, shows that clubfoot can be successfully managed with the Ponseti technique in Africa and in the rest of the world.

CHAPTER 3

3. Methodology

3.1 Study design

A descriptive retrospective review of clubfoot patient treatment records was conducted.

3.1.1 motivation for the research design

A retrospective records review was used because it was an easier and quicker way of obtaining data for a large sample size, considering that the patients were already undergoing various stages of treatment. The patients' treatment records were readily available and accessible at all three Ponseti clinics hence it was an ideal way to gather the data for analysis. This design also allowed data collection to be carried out at three different locations over a short period of time, which may not have been possible with other study designs. This study type was, however, had a risk of finding poorly completed or incomplete records, which would reduce the quality of data collected.

3.2 Study Setting

The study was conducted at three government hospitals in Zimbabwe where rehabilitation professionals (physiotherapists, occupational therapists, rehabilitation technicians) and doctors have been trained in the Ponseti method of clubfoot management, and where Ponseti clinics had been established. These Ponseti clinics are based within the rehabilitation departments at Parirenyatwa Central hospital, Harare Central hospital and Mutare Provincial hospital. The clinics were strategically set up at these hospitals because they are major referral centres within the public health sector, and they were also staffed with the ideal professionals required to apply the technique (rehabilitation professionals and doctors).Parirenyatwa and Harare Hospital are located in the capital city of Zimbabwe, Harare. They are the largest training institutions and major referral hospitals for patients from the entire country. Mutare is a provincial hospital that serves as a referral institution for the Eastern Highlands province of Manicaland. All three hospitals serve a mixture of urban and rural-dwelling patients from diverse socio-economic backgrounds.

The selected hospitals were chosen for the study because according to clinic establishment records (which indicate when each clinic started operating), these were the first three Ponseti clinics to be set up in Zimbabwe. They also had the highest numbers of patients with clubfoot enrolled hence were likely to have more patient treatment records available to use for such a study. The availability of more participants meant that the study would have a larger sample size and the results could be generalised. The patients at the selected clinics were treated using the Ponseti protocol as described in the study by Smythe *et al.,* 2016.

3.3 Study Population

The study population comprised of all patients with clubfoot who had been referred for management at the respective hospitals' rehabilitation departments.

3.3.1 Sample size and selection

Patients with clubfoot treatment records, who were enrolled at the selected Ponseti clinics between 1January 2013 and 31 December 2015 were included in the study. Using 100000 as the total patient population, a 5% error margin and 95% Confidence Interval, the minimum required sample size was generated using an online sample size calculator and determined to be 301 and the researcher decided to use 310 patient records. A total of 352 records were obtained from the three hospitals. These were all randomly numbered from 1 to 352, entered onto a computer. All the available records were included which meant we could generalise the findings to the major centres that use the Ponseti method to manage club foot. An online random sample generator was then used to select the final 310 records used in the study, to minimise bias.

Inclusion Criteria

Patient records were used for the study if they indicated that:

- The patients with clubfoot enrolled at the Ponseti clinics between 1 January 2013 and 31 December 2015, inclusive of all ages.
- The patients attended clinic more than once.

Exclusion criteria.

Patient records were excluded if they indicated that the patients had postural clubfoot and metatarsus adductus.

3.4 Instrumentation

Information from individual patient treatment records was entered onto a data collection form designed by the researcher (Appendix 1). The form had sections to collect information on the following:

- Section A-Socio-demographic detail.
- Section B-Patient physical assessment findings.
- Section C-Treatment Progress.

3.4.1 Pilot study

A pilot study was conducted at Parirenyatwa Hospital where data from 30 randomly selected patient records were entered onto the data collection forms by the researcher and research assistant. The researcher and assistant each entered data from 15 patient records on to data collection forms.

The aim of the pilot was to determine feasibility of the study design and data collection process, as well as to establish the amount of time needed to collect data from each file. It was also intended to ensure that the research assistant understood the data collection form and practised data collection. The original order and wording of some questions was revised before commencement of the main study.

The pilot study showed it was possible to obtain all the data required from the patient records. The sequence of questions on the pilot data collection form, however, did not match the order of data on the patient records and it took more time to gather information. As a result, the original order and wording of some questions was revised before commencement of the main study. The pilot study showed that it took at least two minutes to collect data from a single patient record using the revised data collection form.

3.5 Procedure

3.5.1 Main study procedure

Upon approval of the research proposal, the researcher applied for permission to perform the study at the identified Ponseti Clinics. Letters seeking approval for the study and access to patient treatment records at the hospitals were sent to the Clinical

Directors/ Medical Superintendents (Appendix 2). Approval was also sought and obtained from the Medical Research Council of Zimbabwe (MRCZ) (Appendix 4) and lastly from the Human Research Ethics Committee (HREC) from University of Witwatersrand (Appendix 5). The researcher then proceeded with the data collection once permission was granted by the hospitals, the respective ethics committees (Appendix 3), and ethical clearance had been obtained from MRCZ and the HREC.

The researcher went on to train a research assistant who would help to extract patient information from the hospital treatment records and enter it onto data collection forms, for the both the pilot and main study. The research assistant carried out 30% of data extraction, while the researcher did the remainder of the data collection. The training included explanation of questions in different sections of the data collection form and a description of the information that was to be collected. Data collection was then carried out at each of the individual clinics included in the study between May and July 2017. Data collection commenced in Mutare, followed by Parirenyatwa and finally at Harare hospital. The researcher approached the respective Head of Rehabilitation departments at each of the hospitals and presented them with copies of the Hospital authorisation as well as ethical clearance to carry out the study. The researcher then sought permission from the department heads to access all clubfoot treatment files. These were paper records stored in the rehabilitation departments of the three hospitals. The researcher then selected only those treatment records that met the inclusion criteria. A total of 353 treatment records were obtained and these were all numbered from one to 353. The numbers were entered into a computer to generate a list of random numbers. The patient records with the selected numbers were used to make up the required sample of 310 records. The final sample had 47 patient record forms from Mutare, 170 from Parirenyatwa and 93 from Harare hospital. The researcher then proceeded to check if any of the patients with selected records were still undergoing the corrective phase of the Ponseti treatment. There were no patients undergoing the corrective phase of treatment hence there was no need to contact any parents to obtain assent. Relevant information from the selected records was entered onto the data collection sheets by the researcher and the assistant. The data collection sheets were then assessed for completeness by the researcher. All data collection forms were stored under lock and key at the researcher's residence.

The data was then coded, entered onto an Excel spreadsheet and cleaned by the researcher between August and October 2017. Data analysis was done thereafter using STATISTICA Version13.5 with assistance from a statistician.

3.6 Ethical considerations

- Ethical clearance for the study was sought from the University of the Witwatersrand (Appendix 5).
- Letters seeking permission to carry out the study were sent to all the individual hospital Clinical Directors/ Medical Superintendents (Appendix 2).
- Approval to carry on with the research was obtained from Mutare Provincial Hospital, the Joint Research Ethics Committee of the College of Health Sciences and Parirenyatwa Group of Hospitals, and from the Harare Hospital Ethics Committee (Appendix 3). This was then forwarded to the MRCZ for final ethical clearance.
- Ethical approval was sought and granted by MRCZ (Appendix 4).
- University of Witwatersrand HREC approval was also obtained (Appendix 5).
- Information sheets (Appendix 6) and consent forms (Appendix 7) were to be given to parents of participants who were still receiving corrective treatment (manipulation and casting) from their respective clinics.
- No patient names or any identification detail were entered on to the data sheets, they were instead represented by codes to ensure confidentiality.

3.7 Data analysis

STATISTICA Version 13.5 was used to analyse data. Most of the data analysis was descriptive in nature and where possible proportions were reported. Categorical data such as gender and types of clubfoot was presented as percentages and frequencies. A summary of Data analysis is shown in Table 3.1 below.

Table 3. 1: Summary of the data analysis

Objective	Variables	Type of data	Data analysis
To establish the demographic profile of patients with clubfoot treated at the selected Ponseti Clinics between January 2013 and December 2015.	Gender	Categorical data,	Percentages and Frequencies
	Age	Numerical data	-Mean and standard deviation -Kolmogorov Smirnov and Lilliefors Test for Normality
	Age categories	Categorical data	-Frequencies and percentages
	Source of study participants	Categorical data	Frequencies and percentages
	Family history of clubfoot	Categorical data	Frequencies and percentages
	History of previous clubfoot treatment	Categorical data	Frequencies and percentages Chi-square tests for association with participant age
	Type of previous treatment	Categorical data	Frequencies and percentages
	Foot affected	Categorical data	Frequencies and percentages Chi-square test for association with gender
	Initial Pirani scores	Numerical data	Mean, SD

			t- test for association with gender; t-test for association with History of previous treatment ANOVA for mean Pirani score by age category
	Type of clubfoot	Categorical data	Frequencies and percentages
	Reason for attending clinic	Categorical data	Frequencies and percentages
	Pirani score at Initial Bracing	Numerical data	Mean, Standard deviation
	Length of patient follow-up	Numerical data	Mean, Standard deviation
	Patient reason for last clinic visit	Categorical data	Frequencies and percentages
	Stage patient lost to follow-up	Categorical data	Frequencies and percentages
To determine the outcome processes of the Ponseti clubfoot treatment	Mean number of casts before tenotomy	Numerical Data	Mean, SD t-tests for association with gender; history of previous treatment ANOVA of mean casts before tenotomy and age at presentation ANOVA of mean casts before

			tenotomy foot affected
	Tenotomy required	Categorical Data	Frequencies and percentages
	Mean number of tenotomies	Numerical data	Mean, Standard deviation
To establish outcomes of the Ponseti treatment at selected hospitals	Proportion of left and right clubfeet that attained a Pirani score of 1 or less	Categorical data	Frequency and percentage
	Participants still attending clinic	Categorical data	Frequencies and percentages
	Proportion lost to follow up Stage patient lost to follow-up	Categorical data Categorical data	Frequencies and percentages Frequencies and percentages

CHAPTER 4

4. Results

4.1 Introduction

This chapter presents results of a retrospective study conducted to establish the demographic profile and treatment outcomes of patients with clubfoot treated at the selected Ponseti clinics in Zimbabwe. The results are presented based on the study objectives specified in Chapter 1 and are also presented according to the variables captured in the data collection sheet.

4.2. Participants demographics and clubfoot related information

Table 4.1 below depicts data on sample demographics and clubfoot-related information for the participants.

Table 4. 1: Sample demographic and clubfeet related information (N=310)

Variable	Responses	Frequency n (%) [a]
Gender	Females	111 (35.8)
	Males	199 (64.2)
*Age of participants at initial presentation	0-24 months	272 (88.3)
	25-59 months	26 (8.4)
	60+ months	10 (3.3)
Median age (IQR) months = 3 (0.15-11)		
Source of participants	Parirenyatwa Group of Hospital	170 (54.8)
	Harare Central Hospital	94 (30.4)
	Mutare Provincial Hospital	46 (14.8)
**Family history of clubfoot	Yes	44 (14.5)
	No	260 (85.5)
***History of previous treatment	Yes	151 (50.2)
	No	150 (49.8)
****Type of previous treatment	Below knee cast only	74 (53.2)
	Full leg cast only	49 (35.3)
	Full and below knee cast	13 (9.4)
	Surgery and casting	2 (1.4)
	Stretching	1 (0.7)
Patient foot affected	Left only	66 (21.3)
	Right only	73 (23.5)
	Bilateral (both left and right)	171 (55.2)
*****Type of clubfoot	Idiopathic	267 (90.5)
	Secondary	28 (9.5)

[a]Percent excluding missing values
*missing for 6 children
**missing for 6 children
***missing for 9 children
****missing for 12 children
*****missing for 15 children

The final sample had 310 participants, of which 199 (64.2%) of the participants with clubfoot were males. The age data on initial presentation at the Ponseti clinics for the participants was not normally distributed according to the normality tests of Kolmogorov Smirnov and Lilliefors tests (K-S D=0.3, $p<0.01$; Lilliefors, $p<0.01$). Therefore, the median age and interquartile range of the participants at the initial presentation to the various selected Ponseti Clinics are shown in Table 4.1. However,

there was no significant difference in the median age at initial presentation between males (boys) and females (girls) as indicated by the Mann Whitney U test (U =10838, Z =0.13, p =0.90).

Table 4.1 also shows that the majority of the participants who had been attending the Ponseti clinics for clubfeet management had idiopathic type of clubfeet (n=267, 90.5%), which was mainly bilateral (n=171, 55.2%). However, for those who had unilateral clubfoot, the right foot was commonly affected (n=73, 23.5%). Gender had a significant effect on the leg affected (whether unilateral or bilateral) for the participants as shown in Table 4.2 below.

Table 4. 2: Association between gender and leg affected (N=310)

Leg affected	**Male n (%)**	**Female n (%)**	**Total**	**Chi-square (df=1)**	**P value**
Unilateral	80 (40.2)	59 (53.2)	139	4.83	0.03
Bilateral	119 (59.8)	52 (47.8)	171		
Total	199 (64.2)	111 (35.8)	310		

Most of the participants had a previous history of treatment at other clinics before attending the selected Ponseti clinics (n=151, 50.2%), mainly receiving below knee casts (Kite casts) (n=74, 53.2%) as treatment for their clubfoot condition. In this current study, there was an association between history of previous treatment and the age of presentation of the child at the selected Ponseti clinics [$X^2(1) =9.97$, P=0.002]. For this relationship, age of the child was dichotomised as less than two years and greater than two years.

Most of the participants indicated having no history of clubfoot in the family (n=260, 85.5%).

4.2.1 Length of follow up

Figure 4.1 shows a histogram of participants' length of follow up (months) for Ponseti treatment in months.

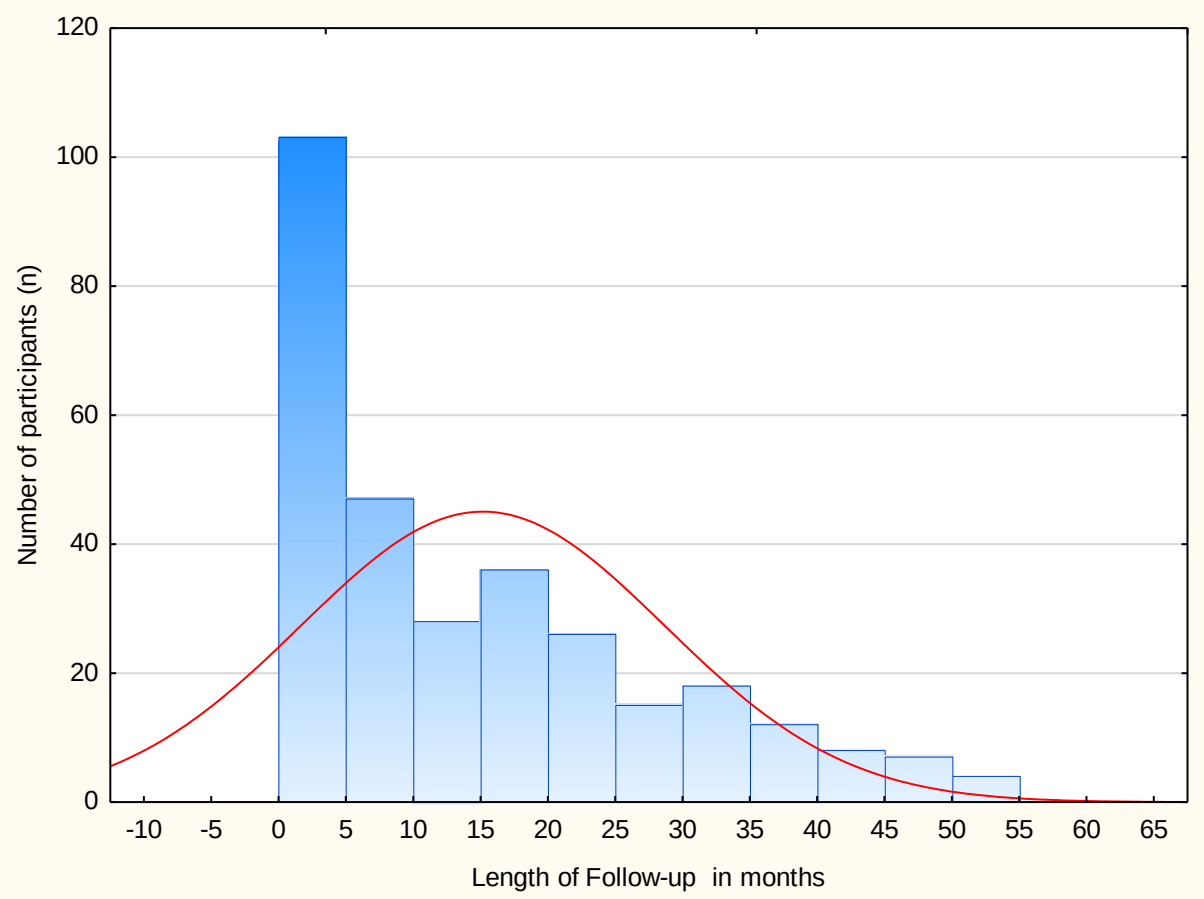


Figure 4. 1: Participants' length of follow-up

The median length of follow up in months for the Ponseti treatment for the 304 participants who had complete data on this variable was 11 months (Interquartile range, IQR= 4.0-23.5 months).

4.2.2 Reasons for attending last appointment

Table 4.3 shows the reasons for attending the last appointment at the Ponseti clinic with regards to the treatment received on that appointment.

Table 4. 3: Reason for attending last appointment

Ponseti phase	**Reason (Treatment received)**	**Frequency n (%)**
Corrective Phase	Corrective Casting (POP application)	45 (14.5)
	Relapse Casting (POP application)	4 (1.3)
	Corrective Tenotomy	10 (3.2)
Total in corrective Phase		59 (19.0)
Maintenance Phase	Brace Review	233 (75.2)
	Initial Bracing	14 (4.5)
Total in maintenance phase		247 (79.7)
*Other reasons		4 (1.3)

*any other reason not mentioned, for example, brace exchange

At the time of data collection, most of the participants attending the selected Ponseti Clinics were in the maintenance phase of their Ponseti treatment and had attended their last recorded clinic appointment mainly for Brace Review (n=233, 75.2%). Some, however, had attended for initial bracing. For the participants in the corrective phase of the Ponseti treatment, some had attended for either corrective casting (n=45, 14.5%) or relapse casting (n=4, 1.3%), as well as corrective tenotomies (n=10, 3.2%).

4.2.3 Severity of the clubfoot at initial assessment

For ease of understanding, results for the severity of the clubfoot at initial assessment (evaluation performed during first contact with the clinic), of the participants at the selected Ponseti clinics are presented per feet. The range of Pirani scores at initial assessment for the right feet, appearing either unilaterally or in bilateral clubfoot, was from 0.5 to 6, with a mean (SD) Pirani score of 3.92 (1.33). There was no significant difference in the mean Pirani scores between males (M=3.99, SD=1.32) and females (M=3.82, SD=1.33) as indicated by the independent *t*-test [t (243) =0.95, p=0.34]. There was, however, a significant difference in the mean Pirani scores at initial assessment for the right feet between the participants who had a history of previous treatment (M=3.55, SD=1.22) as compared to those who did not have a history of previous treatment (M=4.38, SD=1.30) as evidenced by the *t*-test [t (235) =-5.04, p<0.01].

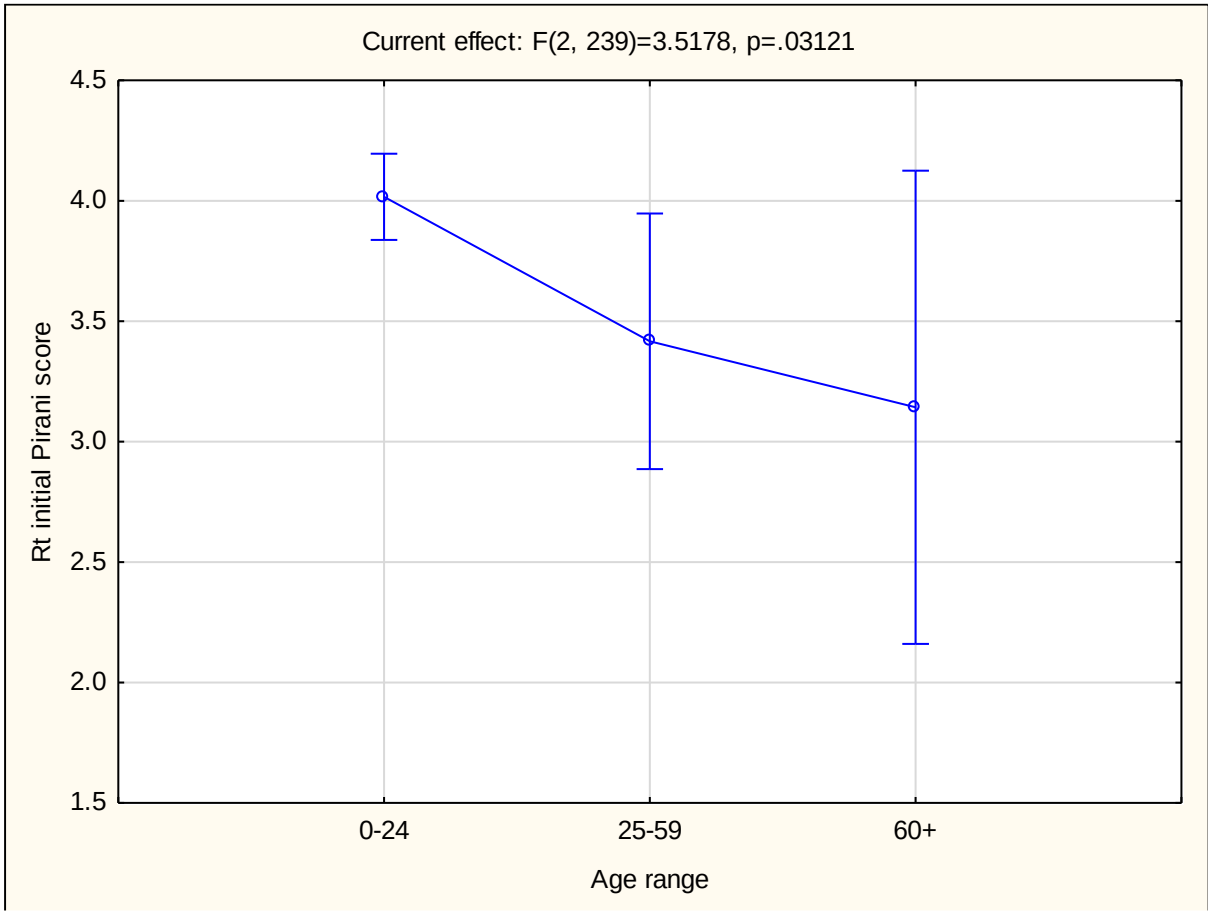


Figure 4. 2: ANOVA results for the right feet mean Pirani scores by age category

In addition, there was a significant difference in the mean Pirani scores at the initial assessment for the right feet by age category [F (2, 239) = 3.52, P=0.03] as shown in Figure 4.2. On the other hand, the mean (SD) Pirani score for the left feet, appearing either unilaterally or in bilateral legs, at the initial assessment at the Ponseti clinics was 3.99 (1.25). The range for the Pirani scores for the left leg was from 1 to 6. In addition, there was no significant difference in the severity of the clubfoot at initial presentation for the left feet between the sexes [t (232) =0.61, p=0.54]. However, there was a significant difference in the mean Pirani scores at initial assessment for the left leg between the participants who had a history of previous treatment (M=3.60, SD=1.17) and those without (M=4.48, SD=1.18) as indicated by the Independent t-test [t (227) = -5.64, p<0.01]. There was also a significant difference in the mean Pirani

scores at the initial assessment for the left feet by age category [F (2, 231) = 3.21, P=0.04] as shown in Figure 4.3.

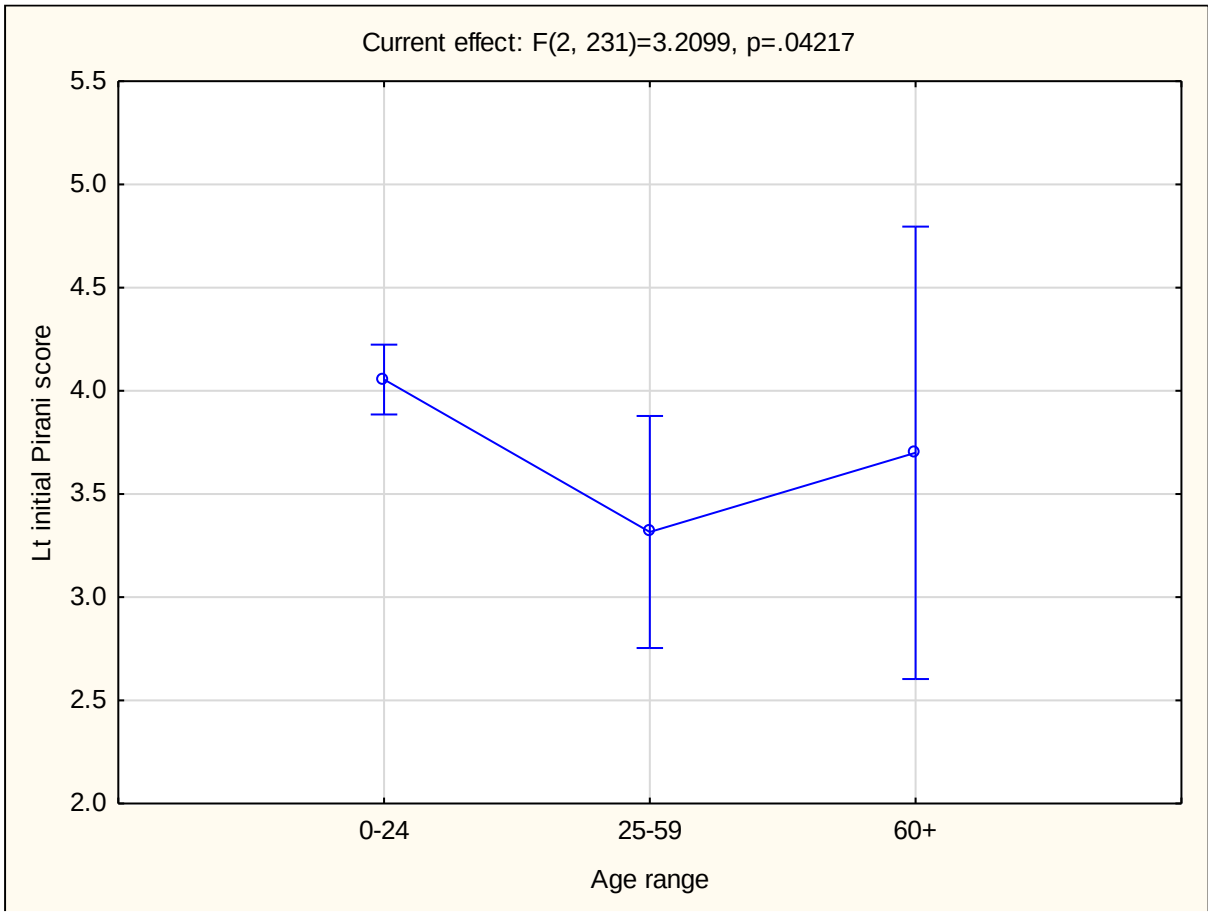


Figure 4. 3: ANOVA results for left feet mean Pirani scores and age category

4.3 Process measures for Ponseti management of clubfoot

Process measures for the Ponseti entailed gathering data on the number of corrective casts and tenotomies experienced by the 247 participants who were in braces at their last visit.

4.3.1 Mean number of casts before tenotomy

Of the 179 participants who had a tenotomy done, 172 (96.1%) had complete data in terms of the number of casts applied before tenotomy. The mean (SD) number of casts was 7.14 (4.48) with range between 0 to 26 casts. There was no significant difference in the mean number of casts before tenotomy by gender [t (170) =1.23, p=0.22], but

there was a significant difference in the mean number of casts by history of previous treatment [t (163) =-2.80, p=0.006]. Participants who had no previous treatment history had significantly more casts before tenotomy (M=8.2, SD=4.5) as compared to those who had a previous treatment history (M=6.3, SD=4.3), see Figure 4.4 below.

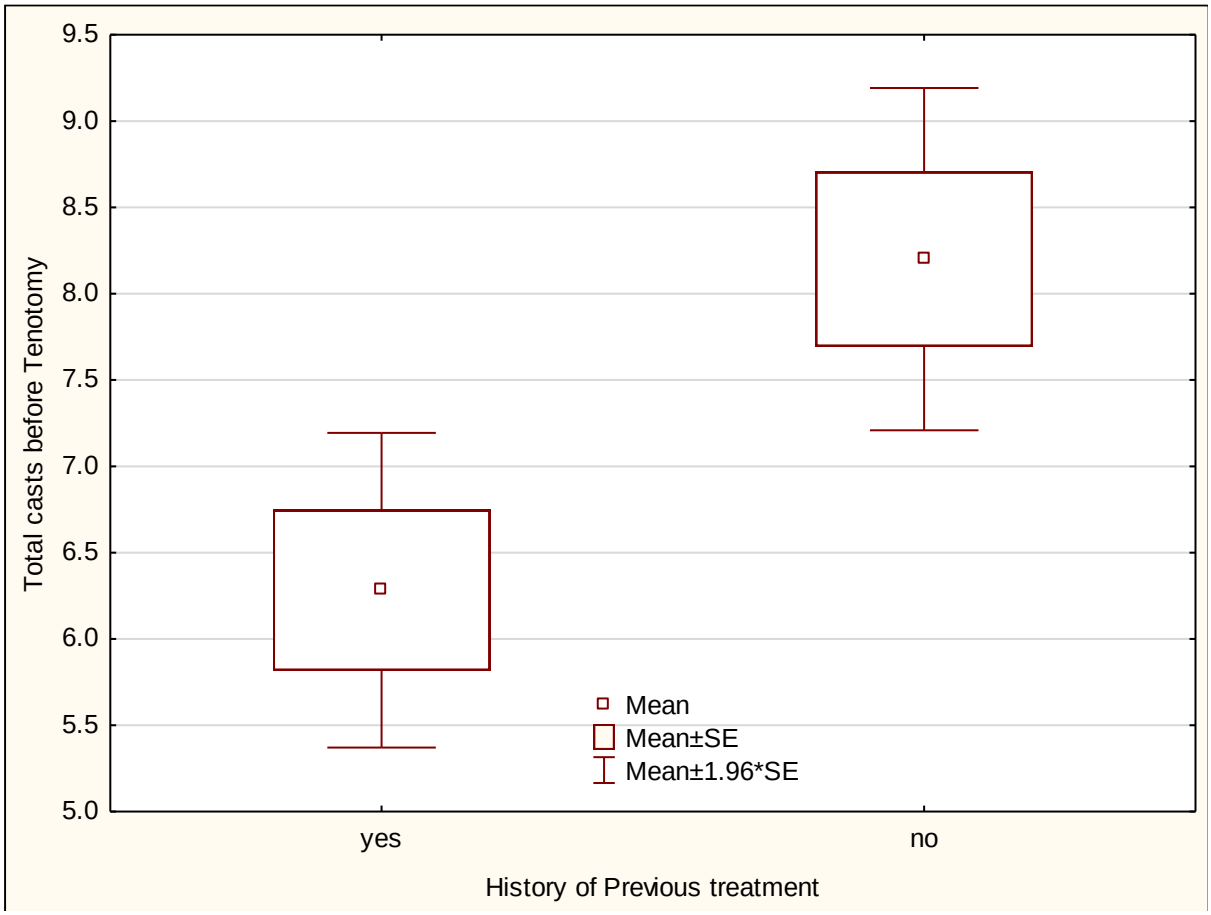


Figure 4. 4: Relationship between total casts before tenotomy and History of previous treatment

There was no association between age at presentation and total casts before tenotomy as shown in the Figure 4.5 below.

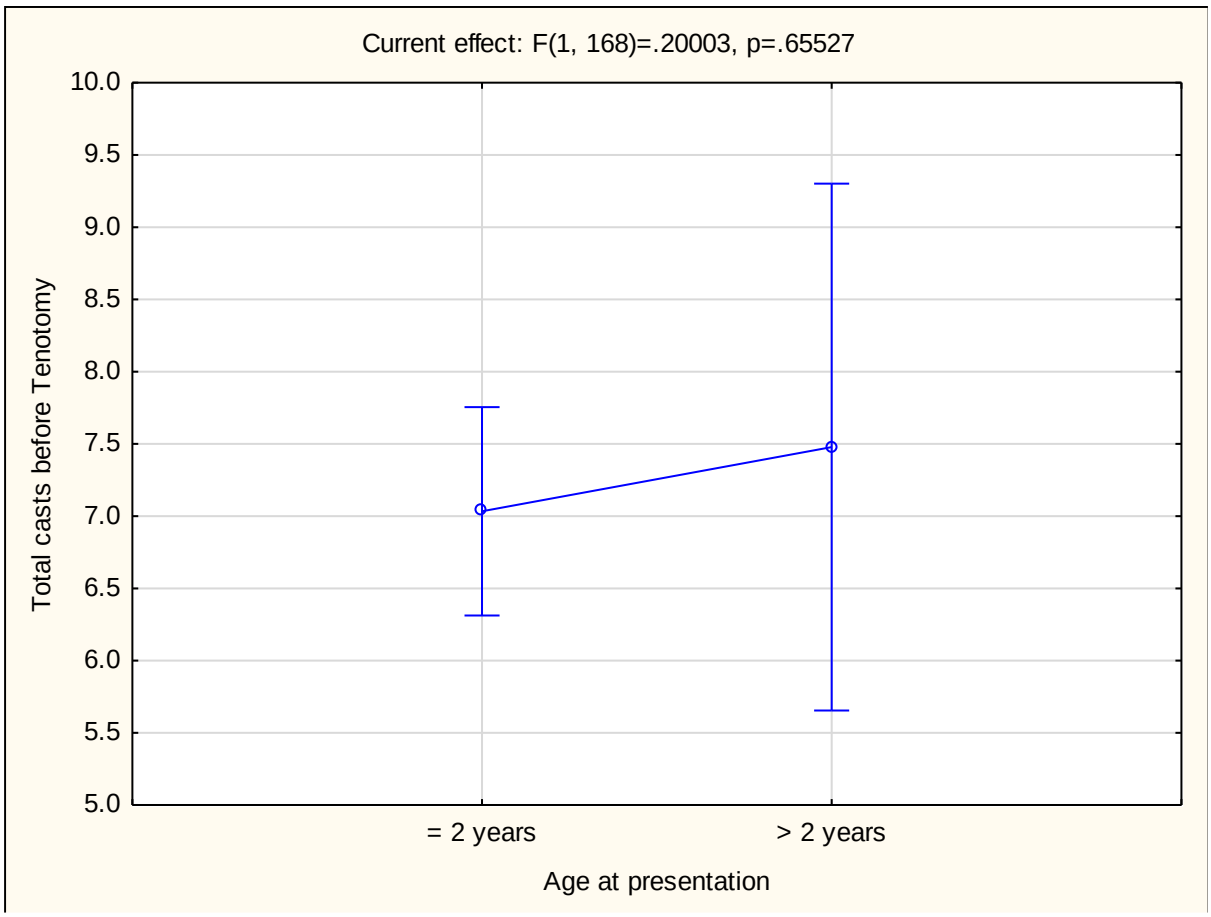


Figure 4. 5: ANOVA results for total casts before tenotomy and Age at presentation.

In addition, there was no association between number of casts before tenotomy and the foot affected as shown in Figure 4.6 below.

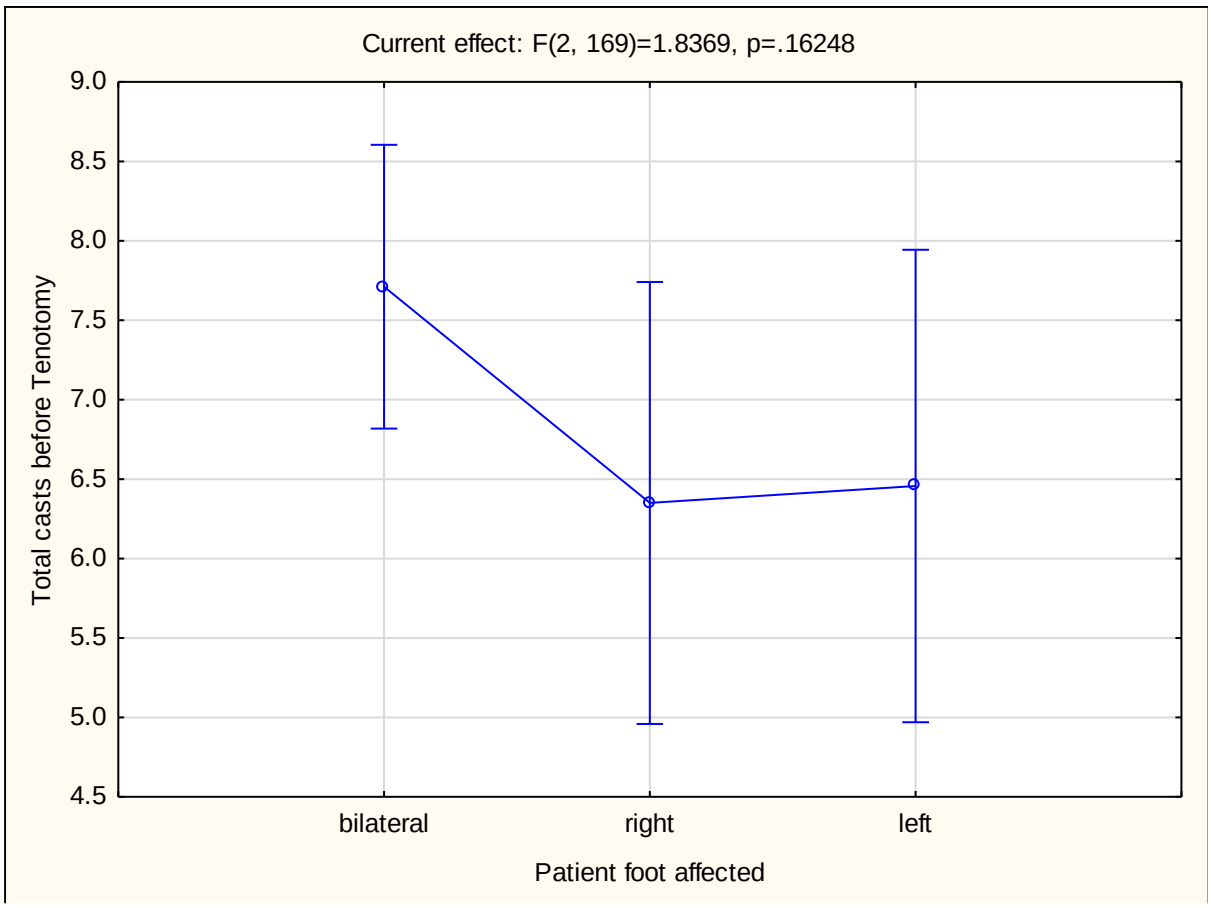


Figure 4. 6: ANOVA results for total casts before tenotomy and patient foot affected

4.3.2 Mean number of tenotomies

Of the 247 participants in braces, 179 (72.5%) had a tenotomy done, and the mean number of tenotomies per patient was 1.09 (SD=0.31, range: 1-3).

4.4 Ponseti outcomes

4.4.1 Proportion of clubfeet with a Pirani score of 1 or less

Table 4.4 depicts the Pirani scores at initial bracing as the primary outcome measure for the Ponseti treatment.

Table 4. 4: Ponseti outcomes

Ponseti outcomes	**Frequency n (%)**
Pirani Score at Initial Bracing for Left Leg	n=192
≤ 1	152 (79.2)
1.5 ≤ *x* ≤ 2	36 (18.8)
>2	4 (2.0)
Pirani Score at Initial Bracing for Right Leg	n=194
≤ 1	160 (82.5)
1.5 ≤ *x* ≤ 2	28 (14.4)
>2	6 (3.1)
Participant still attending clinic	n=310
Yes	63 (20.3)
No	228 (73.5)
Discharged	8 (2.60)
Transferred	8 (2.60)
Deceased	3 (1.00)
Stage lost to follow-up	n=228
Corrective	58 (25.4)
Maintenance	170 (74.6)

Of the 310 participants assessed at the Ponseti clinics, 247 (79.7%) had progressed from corrective casting to bracing stage. Of these 247 participants, there were 386 clubfeet in total of which 192 were left-sided feet and 194 were right-sided. Overall, the proportion of left and right feet that attained a Pirani score of 1 or less at initial bracing was 79.2 and 82.5%, respectively. However, the mean (SD) Pirani scores at Initial bracing for the left feet was 0.90 (0.60) compared to 0.84 (SD=0.58) for the right feet. There was no significant difference in the mean Pirani score at initial bracing for left [t (190) =-0.61, p=0.54] and right feet [t (196) =-1.67, p=0.29] by gender.

Additionally, although there was a change for the left feet in the mean Pirani score from initial casting to bracing in both genders, the difference was not significant F (1, 190) = 0.50, P=0.48). The difference was also not significant for the right foot, F (1, 191) =2.05, P=0.15), as shown in Figure 4.7 and Figure 4.8 below.

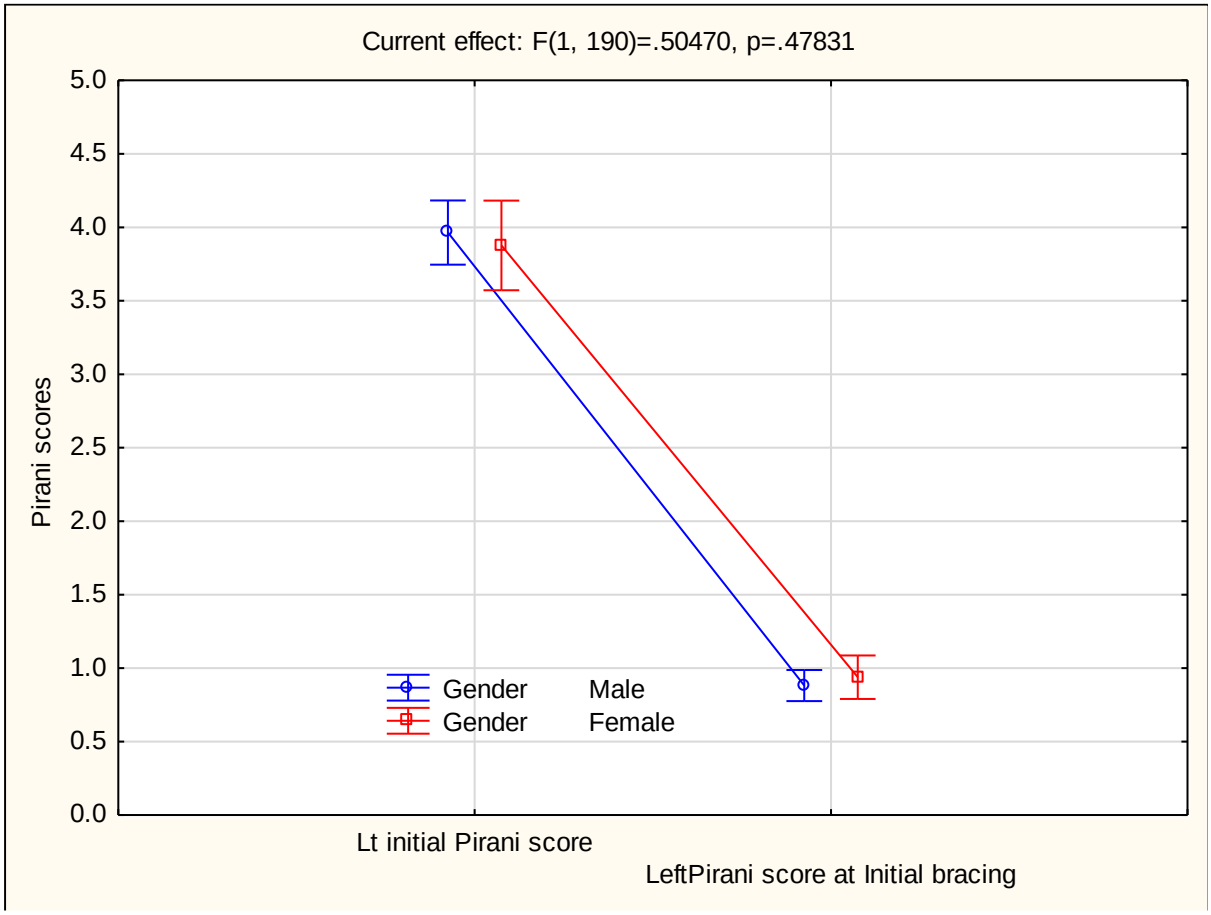


Figure 4. 7: Change of left Pirani scores (from initial assessment to initial bracing) by gender.

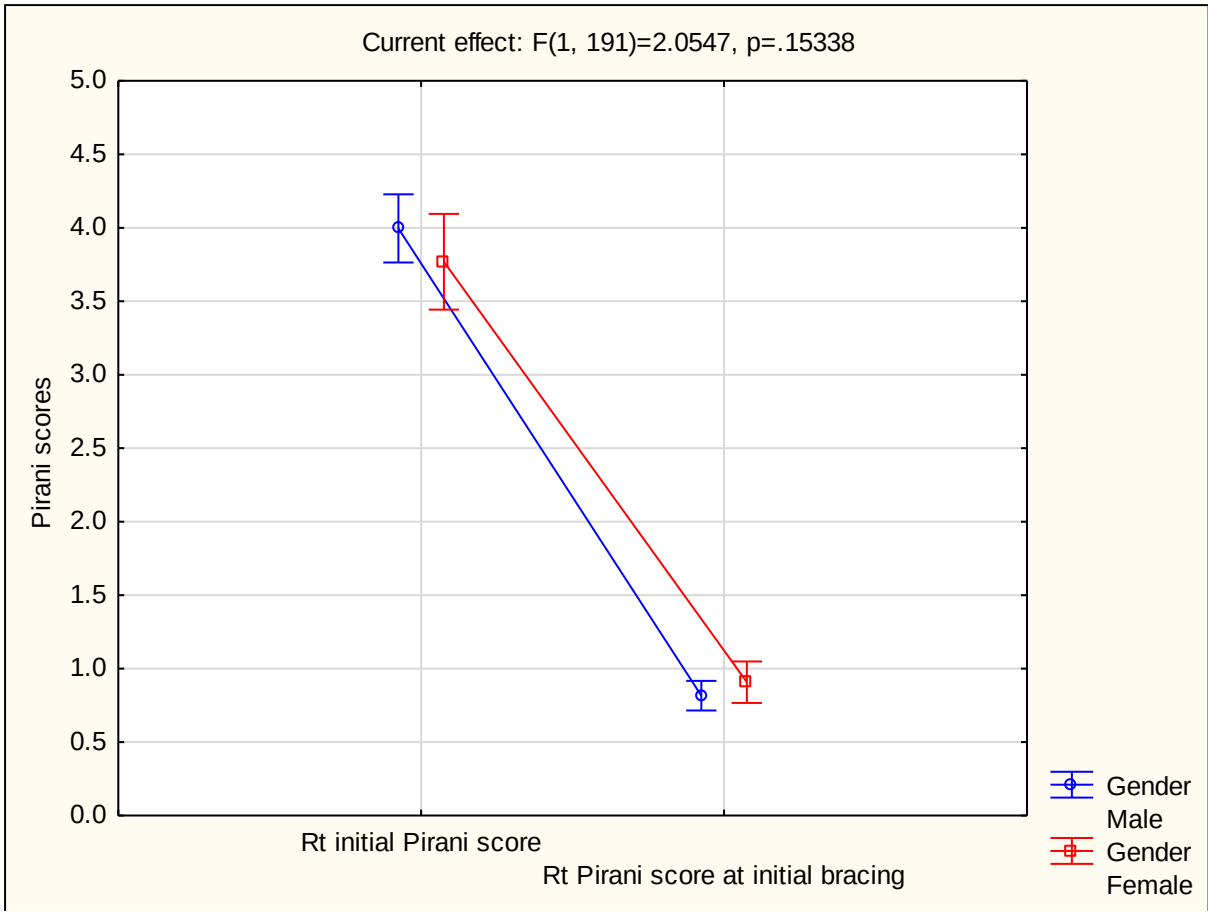


Figure 4. 8: Change of right Pirani scores (from initial assessment to initial bracing) by gender.

Figure 4.9 below is comparing the mean left Pirani score at initial assessment and at initial bracing by age at presentation.

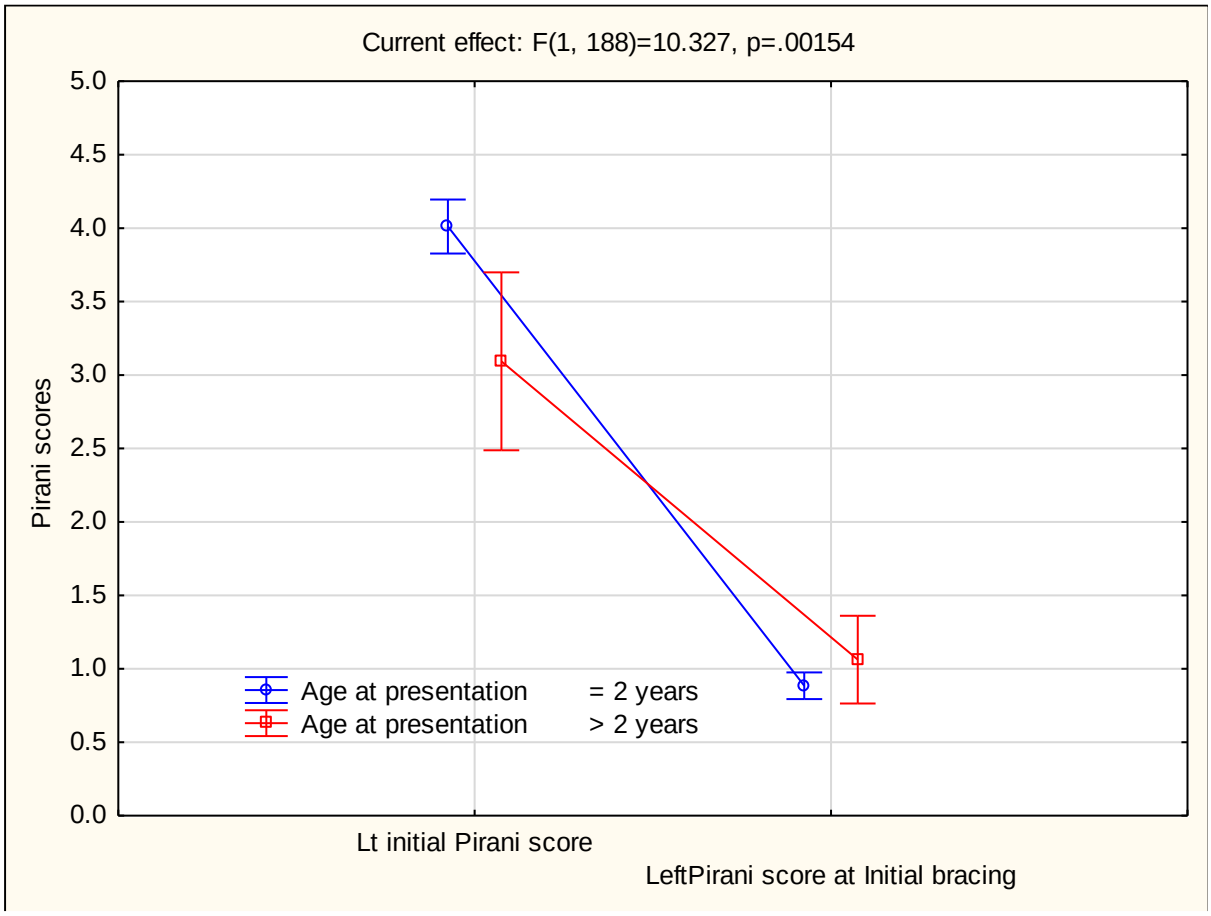


Figure 4. 9: Comparison of mean left Pirani score (at Initial assessment and at Initial bracing) by age at presentation.

It appears that there was a significant decline in the mean Pirani scores for the left feet from initial assessment to bracing for those who presented to hospital below two years as compared to those that came after two years. This was also the same finding for the right feet as shown in the Figure 4.10 below.

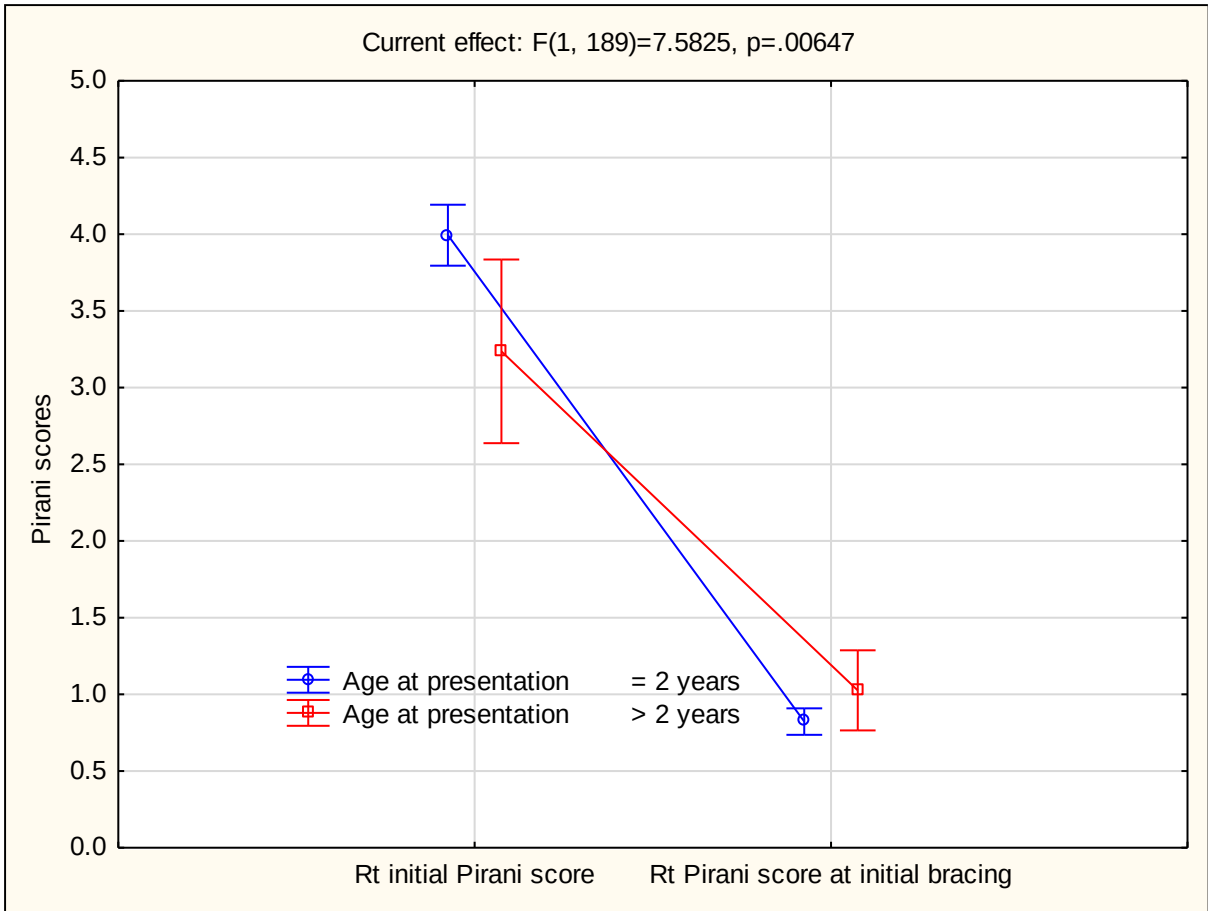


Figure 4. 10: Comparison of mean right Pirani score (at Initial assessment and at Initial bracing) by age at presentation.

4.4.2 Proportion of patients who had a relapse

Information on relapse of the clubfoot deformity was recorded for 244 participants. Of these, 42.6% (n=104) were recorded to have had a relapse of the clubfoot deformity during the maintenance phase**.**

Chi-square tests showed no association between relapse and gender [$X^2(1) = 1.32$, P=0.25]; as well as history of previous treatment [$X^2(1) = 0.002$, P=0.96]. There was no significant association found between relapse and the total casts applied before tenotomy [t (157) =-1.23, p=0.22], as well as with the left initial Pirani score [t (189) =-1.47, p=0.14], and the right initial Pirani score [t (187) =-0.59, p=0.55]. There was, however, significant association between relapse and patient loss to follow up[$X^2(1) = 5.56$, P=0.02], as the study found that those patients who had relapse of the clubfoot deformity were also likely to have stopped attending the clinics.

4.4.3 Proportion of patients lost to follow up.

Data regarding to whether participants were still attending clinic was collected for all the study participants (N=310). Patients were regarded as being lost to follow up if they were no longer attending clinic without being transferred, discharged, or deceased. A total of 228 (73.5%) of the participants were lost to follow up, with the majority (74.6%) being lost in the maintenance (bracing) phase.

CHAPTER 5

5. Discussion

5.1 Introduction

The following chapter discusses the results obtained in this study which was aimed at establishing the demographic profile and treatment outcome of patients with clubfoot treated at the selected Ponseti clinics in Zimbabwe.

5.2 Participants demographic profile

The study had a total of 310 participants with 481 clubfeet. This sample size was like that in the study by carried out in Malawi by Lavy *et al.*, (2007) which had 307 participants. Like most previous studies (Morcuende *et al.*, 2004; Evans *et al.*, 2016; Jaqueto *et al.*, 2016), there were more males than females with clubfoot with a male to female ratio of 1.7 to 1. This ratio was also found in other previous studies (Lavy *et al.*, 2007; Firth and Eltringham, 2009). The current study finding on higher incidence of clubfoot in males than females (approximately 2:1) agrees with the general trend in most studies, and the presence of the Carter effect in which females need a greater genetic load to be affected by the clubfoot deformity (Kruse, Dobbs and Gurnett, 2008).

The median age of participants at presentation for initial treatment was 3 months and their ages ranged from 0 to 139 months. Though there was a wide age range, most of the participants (88.6%) presented between zero and 24 months. This finding is like that by Smythe, Chandramohan, *et al.*, (2016) and Evans *et al.*, (2016) in which the study participants were in that same age range (82% and 85.9% respectively). Similarly, Adewole *et al.*, (2009) also found that 95.8% of the participants in his study were below the age of two years. The current study finding showed that most of the participants were presenting for treatment below the age of two years. This can possibly mean that there is more awareness within the referring communities that clubfoot can be successfully treated, hence they are referring patients earlier. The fact that some of the participants that were older than 24 months but still managed to achieve a good outcome also supports the recommendation of using the Ponseti method in older children (Ayana and Klungsøyr, 2014).

A positive family history of clubfoot was found in 14.5% of the current study participants. This is closer to findings obtained in studies by Firth and Eltringham, (2009) and Smythe, Chandramohan, *et al.*, (2016) which reported familial clubfoot of 16% and 10.5 % respectively. This current study finding also suggests a familial link in the incidence of the clubfoot deformity in Zimbabwe.

The current study also found secondary clubfoot in 9.5% of study participants. This is slightly less than Adewole *et al.*, (2009)., and Firth and Eltringham, (2009) who found secondary clubfoot in 18% and 17% of their participants respectively. The majority of other studies reviewed did not include data for secondary clubfoot as they only analysed patients with idiopathic clubfoot. Secondary clubfoot often poses challenges in its treatment as it is associated with other abnormalities, in most cases patients may require more casts and possibly some degree of corrective surgery.

Slightly over half of the study participants (50.2%) had been previously treated elsewhere before presenting to the Ponseti clinics included in this study. In both the current study and that by (Smythe, Chandramohan, *et al.*, 2016), the below knee cast (Kite) method was the most common type of previous treatment accounting for 49% and 69.8% of all previously administered treatments respectively. This is possibly because before the introduction of the Ponseti method in Zimbabwe, the patients were being treated using other treatment methods, mainly the Kite method. The use of the Ponseti method in Zimbabwe has also not yet spread to all treatment centres and is mostly practiced at provincial and central hospitals. As a result, other centres may still be using the Kite Method before referring patients to Ponseti clinics.

The history of previous treatment was also found to be significantly associated with lower Pirani scores at initial presentation to the Ponseti clinics, as well as reduced number of casts required before tenotomy. This finding may suggest that using other methods of treatment (like the Kite method) before patients can access Ponseti treatment, leads to resolution of some of the clubfoot deformities and consequently speeds up resolution when the Ponseti method is eventually used. The downside, however, is that this can also lead to late referrals and complication of simple deformities if the clinicians create pressure sores or if the Kite casts slip off the feet and result in complex clubfoot.

The proportion of study participants with a history of previous treatment in the current study is slightly less than the participants in the study by Smythe, Chandramohan, *et al.*, (2016) in which 76.3% of the participants had been previously treated. The difference may suggest that more patients are now being referred earlier to Ponseti clinics than was previously the case. Firth and Eltringham, (2009) found that only 37% of his study participants had been treated elsewhere prior to presentation.

The median length of follow up for the participants was 11 months and hence most participants (79.7%) had completed the corrective phase of treatment and gone onto the bracing (maintenance) phase. The duration of follow up ranged from 0.25 months to 55 months at the time of data collection though most participants had been followed up for about five months. This finding shows that there are some participants who were compliant with treatment and remained in the clinics through the entire period of the maintenance phase. Such participants with longer term of follow up can serve as a source of encouragement for other patients as they demonstrated that it is indeed possible to adhere to the follow up schedule and complete the treatment. Their parents/guardians can encourage other families by sharing ideas and strategies that helped them to cope with the entire treatment program. Where possible, such exemplary parents/guardians can lead or become part of support groups which encourage their peers to adhere to all stages of treatment.

5.3. Outcomes of Ponseti treatment at the 3 clinics

On initial assessment (evaluation performed during first contact with the clinic), the mean right and left Pirani scores were 3.93 and 3.99, respectively. In Bangladesh, Evans *et al.*, (2016) found slightly higher Mean (SD) initial Pirani scores for the right and left feet in their study of 4.71(0.93) and 4.64 (1.01). This could possibly be as a result of patients coming to the three Ponseti clinics after having been treated at other clinics using other treatment methods. At the end of the corrective phase, the proportion of participants who attained a Pirani score of one or less at initial bracing was 79.2% and 82.5% for the left and right feet, respectively. This indicates a high initial correction rate at the three clinics and is comparable to findings by Smythe, Chandramohan, *et al.*, (2016) in which 85% of feet attained a Pirani score of one or less at the end of the corrective phase. This finding indicates effective treatment using the Ponseti Method during the corrective phase.

Tenotomy was performed on 72.5% of the 247 patients who went into braces. Most studies performed within the sub Saharan region also found tenotomy rates of 70% and above. Firth and Eltringham, (2009) found a tenotomy rate of 74% in a single-surgeon led practice. Smythe, Chandramohan, *et al.*, (2016) also found a tenotomy rate of 78.9% in her study. Studies with a high tenotomy rate attributed the higher figures to the availability of doctors at the treatment centres to perform the procedure. This was also possibly the case in the current study. The doctors who perform the tenotomies are an integral part of the Ponseti treatment team and they need to be readily available to be called to perform the procedure when the need arises. There were a few studies also in which the tenotomy rates were lower. Lavy *et al.*, (2007) found a lower tenotomy rate of 37% in Malawi and this was attributed their doctors being reluctant to perform the surgical procedure.

Participants in the current study required a mean of 7.14 casts (range 0-26) before tenotomy. This is a commendable finding considering that the current study participants were drawn from three separate clinics with numerous practitioners treating participants. The study by Smythe, Chandramohan, *et al.*, (2016) had a mean of 7.27 casts. Firth and Eltringham, (2009) had slightly less casts with a mean of 6.5 casts per participant, possibly because it was a single practitioner led treatment centre compared to the other studies. In one of the earlier studies by Ponseti and Smoley, (2009b), the participants required a range of 5 to 10 casts (mean 7.6). Results of the current study show that correction of the clubfoot deformity was achieved using similar number of casts as that found in most studies.

Relapse was reported in 42.6% of the current study participants. Similarly, Firth and Eltringham, (2009) reported mild relapse in 39% of study participants at their last follow-up and Ponseti and Smoley,(2009) also found a relatively high relapse rate of 56% in their earlier studies. The nature and severity of relapse in the current study could however not be determined or physically assessed as this study was a records review.

According to the records reviewed in the current study, 73.6% of the study participants had stopped attending clinic at the time of data collection. Most of the clinic dropouts were in the bracing stage of treatment (74.6%), however, there were a few others lost to follow up during the corrective phase (25.4%). This finding shows poor compliance

with the treatment and review schedule, in both stages of treatment but mostly during the maintenance stage which could well be a major reason for the elevated relapse rate. A lack of compliance with the review schedule during the maintenance phase could mean that reappearance of any component of the clubfoot deformity is not picked up or corrected early enough. Smythe, Chandramohan, *et al.*,(2016) found 8.9% loss to follow up at the end of the corrective phase, however, that study did not investigate this outcome beyond the corrective phase into the bracing (maintenance) phase. Most participants tend to follow through with treatment during the corrective phase relative to the maintenance phase, despite all treatment being provided for free. It is possible that when caregivers see the change of the foot after the corrective phase, they assume the deformity has fully corrected. As a result, they stop complying with the maintenance phase of treatment and drop out. It could also be that caregivers struggle to cope with the transferred responsibility of care during the maintenance phase in contrast to the corrective stage where clinicians are responsible for all the treatment. There could be other challenges like lack of funds for transport particularly if the patients stay far from the clinic. There is a need to further research and explore reasons for clinic dropout, possibly by following parent/ caregivers who have stopped attending clinics. This can be done through physical visits where possible, or through phone calls. It is also necessary to encourage compliance to the follow up schedule throughout the entire treatment processes by giving continued parent education and support. This can reduce both relapse and clinic dropout rates.

CHAPTER 6

6. Conclusion

The following chapter concludes the study entitled “Clubfoot patients’ demographic profile and outcomes of using the Ponseti method at three selected hospitals in Zimbabwe”. It also highlights the current study limitations and gives recommendations for future study.

6.1 Conclusion

The demographic profile of patients attended to at the three clinics is similar to that in published literature. There are no peculiar differences to children with clubfoot studied elsewhere.

Outcome processes like casts before tenotomy, tenotomy rate are also in line with literature findings. This points towards similarities in the management processes of patients with clubfoot in the studied centres and those from outside Zimbabwe.

Clubfoot treated using the Ponseti Method has a good outcome at the end of the corrective phase. However, there is evidence of poor compliance and a high loss to follow up during the maintenance (bracing) phase. Effort should be put into improving compliance and reducing loss to follow up to improve chances of success in clubfoot correction.

There is need to invest in reinforcing compliance with treatment in the bracing stage to ensure permanent correction of the deformity as well as early identification and efficient management of relapse. Longer term follow-up studies may also be useful to ascertain the outcome of the clubfoot deformity treated using the Ponseti Method in these clinics in later years of life.

Limitations of the current study

The study was a retrospective records review and as such, was highly dependent on the quality and completeness of the paper records used to gather data at the clinics. While the records were randomly drawn for inclusion in the study, the records were not always complete in terms of the required data and hence the fluctuating numbers for some of the result sections.

The basis of patient assessment in all clinics was the Pirani score regardless of patient age. However, this assessment tool is not validated for assessing clubfoot in patients older than two years. The outcome of treatment was mainly based on the Pirani score at the end of the corrective phase, but this may not give a clear indication of the actual physical and functional status of the patients' feet.

a. Recommendations for clinical practice

- The establishment of an electronic patient record system and clubfoot database may help to improve data quality and hence monitoring of patients undergoing clubfoot treatment.
- Long term follow-up as well as physical and functional patient evaluations after discharge from treatment are necessary to assess the progress of patients with age.
- Effort should be put in curbing loss to follow up and improving compliance. Awareness raising on the effects of non-compliance may also deter potential defaulters.

b. Recommendations for future research

- There is need for future studies to investigate actual reasons for patient loss to follow up particularly during the maintenance phase so that supportive mechanisms can be put in place.

References

Adegbehingbe, O. O., Oginni, L. M., Ogundele, O. J., Ariyibi, A. L., Abiola, P. O., & Ojo, O. D. (2010). Ponseti clubfoot management: changing surgical trends in Nigeria. *The Iowa Orthopaedic Journal*, *30*, 7–14.

Adewole, O. A., Giwa, S. O., Kayode, M. O., Shoga, M. O., & Balogun, R. A. (2009). Congenital club foot in a teaching hospital in Lagos, Nigeria. *African Journal of Medicine and Medical Sciences*, *38*(2), 203–6.

Africa Clubfoot Training Project. Chapter 4. How To Assess the Severity of a Clubfoot using the Pirani Score. Africa Clubfoot Training Basic & Advanced Clubfoot Treatment Provider Courses - Participant Manual. University of Oxford: Africa Clubfoot Training Project, 2017.

Akintayo, O. A., Adegbehingbe, O., Cook, T., & Morcuende, J. A. (2012). Initial program evaluation of the Ponseti method in Nigeria. *The Iowa Orthopaedic Journal*, *32*, 141–149.

Ayana, B., & Klungsøyr, P. J. (2014). Good results after Ponseti treatment for neglected congenital clubfoot in Ethiopia. *Acta Orthopaedica*, *85*(6), 641–645.

Bacino, C. A., & Hecht, J. T. (2018). European Journal of Medical Genetics Etiopathogenesis of equinovarus foot malformations. *European Journal of Medical Genetics*, *57*(8), 473–479.

Bhaskar, A., & Patni, P. (2013). Classification of relapse pattern in clubfoot treated with Ponseti technique. *Indian Journal of Orthopaedics*, *47*(4), 370.

Biruk, W. L. (2007). Management of club-foot at Tikur Anbessa Hospital; Addis Ababa, Ethiopia. *East and Central African Journal of Surgery*,12(1),24-29

Bridgens, J., & Kiely, N. (2010). Current management of clubfoot (congenital talipes equinovarus). *BMJ (Online)*. https://doi.org/10.1136/bmj.c355

Chand S, Mehtani A, Sud A, Prakash J, Sinha A, Agnihotri A. (2018) Relapse following use of Ponseti method in idiopathic clubfoot. *Journal of Children's Orthopaedics.* 2018 Dec;12(6):566-574. DOI: 10.1302/1863-2548.12.180117.

Church, C., Coplan, J. A., Poljak, D., Thabet, A. M., Kowtharapu, D., Lennon, N., Miller, F. (2012). A comprehensive outcome comparison of surgical and Ponseti clubfoot treatments with reference to pediatric norms. *Journal of Children's Orthopaedics*, *6*(1), 51–59.

Dietz, F. (2002). The genetics of idiopathic clubfoot. *Clinical Orthopaedics and Related Research*. *(401)* 39–48.

Dobbs, M. B., & Gurnett, C. A. (2009). Update on clubfoot: Etiology and treatment. *Clinical*

Orthopaedics and Related Research, *467*(5), 1146–1153.

Evans, A. M., Chowdhury, M. M. H., Kabir, M. H., & Rahman, M. F. (2016). Walk for life - the National Clubfoot Project of Bangladesh: The four-year outcomes of 150 congenital clubfoot cases following Ponseti method. *Journal of Foot and Ankle Research*, *9*(1), 1–10.

Firth, G. B., & Eltringham, E. (2009). Early results of the Ponseti technique for a clubfoot clinic in South Africa. *SA Orthopaedic Journal*, *8*(4), 67–71.

Göksan, S. B., Bilgili, F., Eren, I., Bursali, A., & Koç, E. (2015). Factors affecting adherence with foot abduction orthosis following Ponseti method. *Acta Orthopaedica et Traumatologica Turcica*. *49*(6), 620–626.

Harnett, P., Freeman, R., Harrison, W. J., Brown, L. C., & Beckles, V. (2011). An accelerated Ponseti versus the standard Ponseti method . *The Journal of Bone and Joint Surgery. British Volume*, *93-B*(3), 404–408.

Double, S. (2014). A Literature Review of the Ponseti Method of Clubfoot Treatment. *APCP Journal*, *5*(1), 38–49.

HUSSAIN, F. N. (2007). The role of the Pirani scoring system in the management of club foot by the Ponseti method. *The Journal of Bone and Joint Surgery. British Volume*, *89–B*(4), 561–561.

Jaqueto, P. A., Bittar, C. K., Zabeu, J. L. A., Martins, G. S., & Mennucci, F. S. (2016). Functional and clinical results achieved in congenital clubfoot patients treated by Ponseti's technique. *Revista Brasileira de Ortopedia (English Edition)*, *51*(6), 657–661.

Jowett, C. R., Morcuende, J. A., & Ramachandran, M. (2011). Management of congenital talipes equinovarus using the Ponseti method. *The Journal of Bone and Joint Surgery. British Volume, 93-B(9), 1160–1164.*

Kouamo II, E. I., Doumbouya, N., Nour, M., Nimpa, T. P., Gnassingbe, J. P., Moh, E., & Aguehounde, C. (2014). Pirani scoring in the evaluation of the morphological results of congenital Falipes Equinovarus taken care by the Ponseti method. *Cotation de Pirani Dans l'evaluation Des Resultats Morphologiques Des Pieds Bots Varus Equins Pris En Charge Selon La Methode de Ponseti.* La Seyne sur Mer. Retrieved from http://www.santetropicale.com/revue.asp?revue=man&id_article=2598&action=lire

Kruse, L. M., Dobbs, M. B., & Gurnett, C. A. (2008). Polygenic threshold model with sex dimorphism in clubfoot inheritance: The Carter effect. *Journal of Bone and Joint Surgery - Series A*, *90*(12), 2688–2694.

Lavy, C. B. D., Mannion, S. J., Mkandawire, N. C., Tindall, A., Steinlechner, C., Chimangeni,

S., & Chipofya, E. (2007). Club foot treatment in Malawi - A public health approach. *Disability and Rehabilitation*. *29*(11–12), 857–862.

Lehman, W. B., Mohaideen, A., Madan, S., Scher, D. M., Van Bosse, H. J. P., Iannacone, M.,Bazzi, J.,Feldman, D. S. (2003). A method for the early evaluation of the ponseti (Iowa) technique for the treatment of idiopathic clubfoot. *Journal of Pediatric Orthopaedics Part B*, *12*(2), 133–14

Lu, N., Zhao, L., Du, Q., Liu, Y., Oprescu, F. I., & Morcuende, J. A. (2010). From cutting to casting: impact and initial barriers to the Ponseti method of clubfoot treatment in China. *The Iowa Orthopaedic Journal*, *30*, 1–6.

Madzivire D., Useh D., Mashegede P., Siziya S.,(2002). Minimum incidence of congenital talipes equino-varus (CTEV) and post treatment evaluation of residual deformities in a population in Zimbabwe. *The Central African Journal of Medicine*, *48(3-4), 33-38.*

Mathias, R. G., Lule, J. K., Waiswa, G., & Naddumba, E. K. (2010). Incidence of clubfoot in Uganda. *Canadian Journal of Public Health*. 101(4), 341–345.

Morcuende, J. A., Dolan, L. A., Dietz, F. R., & Ponseti, I. V. (2004). Radical reduction in the rate of extensive corrective surgery for clubfoot using the Ponseti method. *Pediatrics*, *113*(2), 376–80.

Penny, J. N. (2005). The Neglected Clubfoot. *Techniques in Orthopaedics 20*(2), 153–166.

Ponseti, I.V. (2001). Relapsing Clubfoot: Prevention and Treatment. *The Iowa Orthopaedic Journal*, *22*, 55–56.

Ponseti, I. V., & Smoley, E. N. (2009). The classic: Congenital club foot: The results of treatment. *Clinical Orthopaedics and Related Research*, *467*(5), 1133-1145

Radler, C., Mindler, G. T., Riedl, K., Lipkowski, C., & Kranzl, A. (2013). Midterm results of the Ponseti method in the treatment of congenital clubfoot. *International Orthopaedics*, *37*(9), 1827–1831.

Rasit, A., Azani, H., Zabidah, P., Merikan, A., & Nur Alyana, B. (2017). Clubfoot: The Treatment Outcome Using Quantitative Assessment of Deformity. *Malaysian Orthopaedic Journal*, *6*(4), 2–5.

Sætersdal, C., Fevang, J. M., Fosse, L., & Engesæter, L. B. (2012). Good results with the Ponseti method. *Acta Orthopaedica*, *83*(3), 288–293.

Shabtai, L. (2014). Worldwide spread of the Ponseti method for clubfoot. *World Journal of*

Orthopedics, *5*(5), 585.

Smythe, T., Chandramohan, D., Bruce, J., Kuper, H., Lavy, C., & Foster, A. (2016). Results of clubfoot treatment after manipulation and casting using the Ponseti method: experience in Harare, Zimbabwe. *Tropical Medicine and International Health*, *21*(10), 1311–1318.

Smythe, T., Kuper, H., Macleod, D., Foster, A., & Lavy, C. (2017). Birth prevalence of congenital talipes equinovarus in low- and middle-income countries: a systematic review and meta-analysis. *Tropical Medicine and International Health,22 (3), 269-285*.

Smythe, T., Wainwright, A., Foster, A., & Lavy, C. (2017). What is a good result after clubfoot treatment? A Delphi-based consensus on success by regional clubfoot trainers from across Africa. *PLoS ONE*, *12*(12), 1–9.

Thacker, M. M., Scher, D. M., Sala, D. A., Van Bosse, H. J. P., Feldman, D. S., & Lehman, W. B. (2005). Use of the foot abduction orthosis following ponseti casts: Is it essential? *Journal of Pediatric Orthopaedics*, *25*(2), 225–228.

Tindall, A. J., Steinlechner, C. W. E., Lavy, C. B. D., Mannion, S., & Mkandawire, N. (2005). Results of manipulation of idiopathic clubfoot deformity in Malawi by orthopaedic clinical officers using the Ponseti method: A realistic alternative for the developing world? *Journal of Pediatric Orthopaedics*, *25*(5), 627–629.

Werler, M. M., Yazdy, M. M., Mitchell, A. A., Meyer, R. E., Charlotte, M., Anderka, M.,Kasser, J. R., Mahan, S. T. (2013). Descriptive epidemiology of idiopathic clubfoot. *American Journal of Medical Genetics, Part A*, *161*(7), 1569–1578.–1578

Zhao, D., Li, H., Zhao, L., Liu, J., Wu, Z., & Jin, F. (2014). Results of clubfoot management using the Ponseti method: Do the details matter? A systematic review. *Clinical Orthopaedics and Related Research*, *472*(4), 1329–1336.

Appendix 1: Data Collection Form

Data Collection Form.

Data record number_____

Section A: General Patient Information and history

Fill in the required details in the space provided

1. Patient's age at Initial assessment (*months*) _____

2. Date of initial assessment *(Month and year)* _____

3. Sex (***Circle one option***) M / F

4. Is there a history of clubfoot in the patient's family?

Yes ☐ No ☐ Not recorded ☐

5. Is there any history of previous clubfoot treatment?

Yes ☐ No ☐ Not recorded ☐

6. If answer to question 5 is yes, *tick to indicate* specific type of previous treatment.

Full leg casts ☐ Below knee casts ☐

Surgery ☐ Surgery and casting ☐

Not recorded ☐

Section B: Physical assessment findings

For questions 7 and 8, Tick to indicate response

7) Patient foot affected

Unilateral Left ☐

Unilateral Right ☐

Bilateral ☐

8. Type of clubfoot

Idiopathic ☐ Secondary ☐ Not recorded ☐

Section C: Treatment progress

Enter the appropriate response into the box provided.

9. Initial total Pirani score out of 6.

Left foot ☐ Right foot ☐

10. What is the patient's current stage of treatment? *Tick box with appropriate response.*

a) Corrective phase- casting ☐

b) Corrective phase –tenotomy done and awaiting bracing. ☐

c) Bracing stage ☐

11. If patient has had a tenotomy done, what was the total number of casts before tenotomy? *Enter number into box provided.* ☐

12. If Patient is currently in braces, indicate if a tenotomy was performed. *Tick appropriate response*.

Yes ☐ No ☐ Not recorded ☐

13. If answer to 12 above is Yes, indicate total number of tenotomies performed before bracing. *Tick one option.*

1 ☐ 2 ☐ more than 2 ☐

14. If patient is currently in braces,

a) Indicate the total Pirani score out of 6, recorded at the initial brace fitting.

Left foot ☐ Right foot ☐

b) Indicate if patient has had any relapse since they started wearing braces. Tick appropriate response.

 ☐

Yes ☐ No ☐

15. Is the patient still attending the clinic for treatment?

Yes ☐ No ☐

16. If patient has stopped attending clinic, indicate the stage in which they were lost to follow-up. *Tick where applicable.*

Corrective phase ☐ Bracing Phase ☐

Not recorded ☐

Appendix 2: Letter requesting Permission from Research site

University of Witwatersrand

Faculty of Health Sciences

Department of Physiotherapy

Johannesburg South Africa

23 March 2016

The Clinical Director / Medical Superintendent

_____ Hospital

Zimbabwe

Dear Sir/Madam

RE: PERMISSION TO ACCESS CLUBFOOT PATIENT TREATMENT RECORDS AND CONDUCT RESEARCH STUDY- CLUBFOOT PATIENTS' PROFILE AND OUTCOMES OF USING THE PONSETI METHOD IN AT THREE HOSPITALS IN ZIMBABWE.

I am an MSc Physiotherapy student at University of Witwatersrand in South Africa. In partial fulfilment of this degree, I am required to conduct a research study. My study title is referenced above.

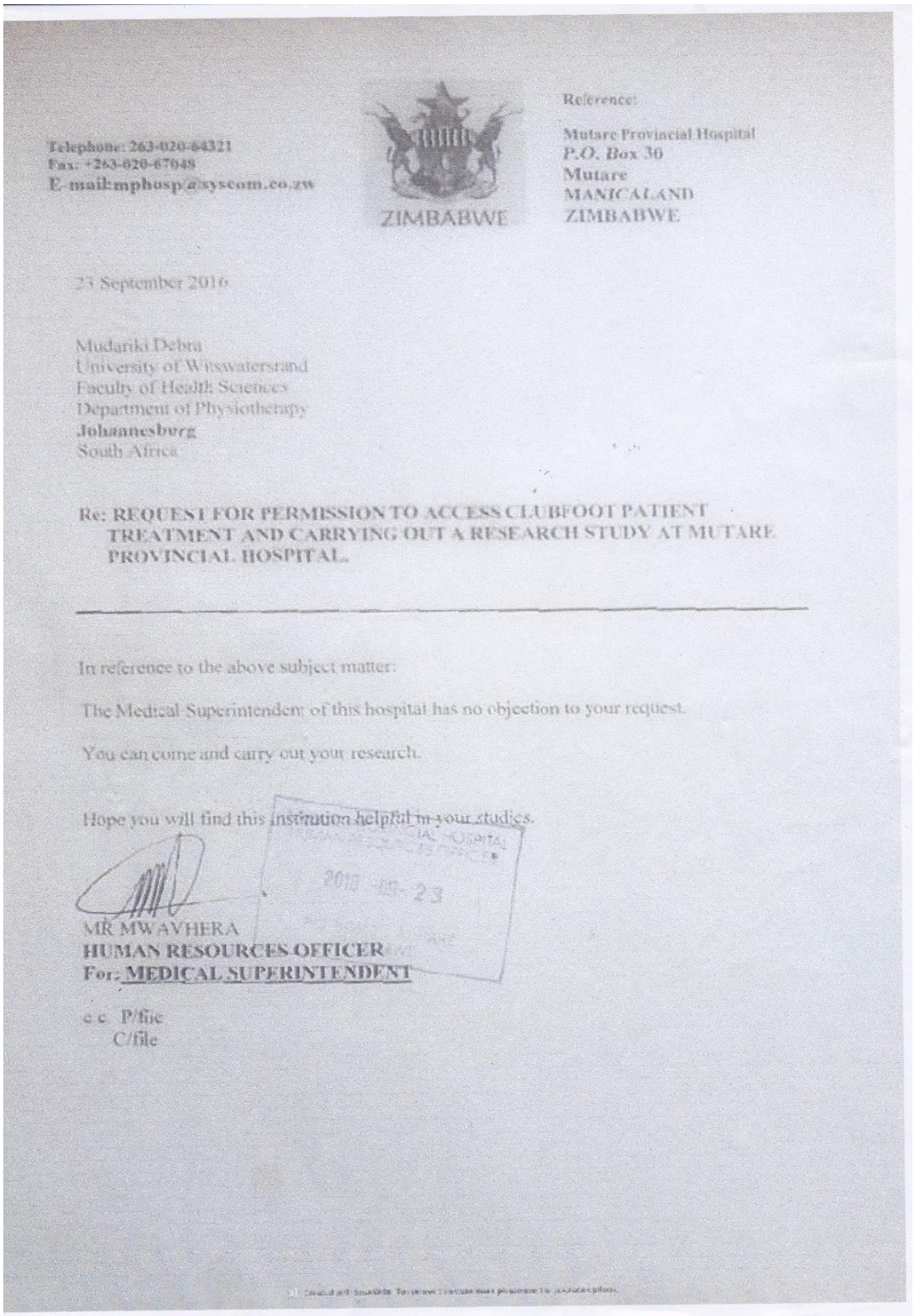
I am kindly requesting to conduct this study at your institution using clubfoot patient treatment records in the Physiotherapy department.

Should you require further information with regards to the study, kindly contact me.

Thank you

Debra Mudariki Email: debramashoro@ymail.com

Appendix 3: Approval to carry out study from Hospitals



Telephone: 263-020-64321
Fax: +263-020-67049
E-mail:mphosp@syscom.co.zw

ZIMBABWE

Reference:

Mutare Provincial Hospital
P.O. Box 30
Mutare
MANICALAND
ZIMBABWE

23 September 2016

Mudariki Debra
University of Witswatersrand
Faculty of Health Sciences
Department of Physiotherapy
Johannesburg
South Africa

Re: REQUEST FOR PERMISSION TO ACCESS CLUBFOOT PATIENT TREATMENT AND CARRYING OUT A RESEARCH STUDY AT MUTARE PROVINCIAL HOSPITAL.

In reference to the above subject matter:

The Medical Superintendent of this hospital has no objection to your request.

You can come and carry out your research.

Hope you will find this instruction helpful in your studies.

MR MWAVHERA
HUMAN RESOURCES OFFICER
For: MEDICAL SUPERINTENDENT

c c P/file
C/file

Joint Research Ethics Committee
For The University of Zimbabwe,
College of Health Sciences and
Parirenyatwa Group of Hospitals

Parirenyatwa
Group of Hospitals

JREC Office No. 4, 5th Floor College of Health Sciences Building
Telephone: +263 4 708140/ 791631 Exts 2241/2242
Email:jrec.office@gmail.com/jrec@medsch.uz.ac.zw, website:www.jrec.uz.ac.zw

University of Zimbabwe
College of Health Sciences

APPROVAL LETTER

Date: 7th October 2016

JREC Ref: 245/16

Names of Researcher: Debra Mudariki
Address: Parirenyatwa Group of Hospitals, Department of Physiotherapy

RE: CLUBFOOT PATIENTS' PROFILE AND OUTCOMES OF USING THE PONSETI METHOD AT THREE HOSPITALS IN ZIMBABWE

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ approval and if required by the nature of your study, RCZ approval as well, before you commence the study.

- **APPROVAL NUMBER:** JREC/245/16
- **APPROVAL DATE:** 7th October 2016
- **EXPIRY DATE:** 6th October 2017

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

e) Completed application form
f) Full Study Protocol
g) Informed Consent in English and/or appropriate local language
h) Data collection tool version:

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

d. A Progress report
e. A Summary of adverse events.
f. A DSMB report

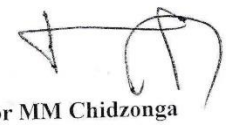
- **MODIFICATIONS:**

  Prior approval is required before implementing any changes in the protocol including changes in the informed consent.

- **TERMINATION OF STUDY:**

  On termination of the study you are required to submit a completed request for termination form and a summary of the research findings/ results.

Yours sincerely,



Professor MM Chidzonga
JREC Chairman

Telephone: 621100-19
Fax: 621157

ZIMBABWE

Reference: HCHEC 070916/60

HARARE CENTRAL HOSPITAL
P. O. Box ST 14

SOUTHERTON

Harare

08 September 2016

Ms Debra Mudariki
Flat C4 Celebrity Mews
Denoon Road
Avondale
Harare

Dear Ms Mudariki,

REF: CLUBFOOT PATIENTS' PROFILE AND OUTCOMES OF USING THE PONSETI METHOD AT THREE HOSPITALS IN ZIMBABWE

I am glad to advise you that your application to conduct a study entitled: **Clubfoot Patients' Profile and Outcomes of Using the Ponseti Method at Three Hospitals in Zimbabwe (Ref: HCHEC 070916/60),** has been approved by the Harare Hospital Ethics Committee.

This approval is premised on the submitted protocol. Should you decide to vary your protocol in any material way please submit these for further approval.

You are advised to avail the results of your study whether positive or negative to the hospital through the committee for our information.

Yours sincerely,

HARARE CENTRAL HOSPITAL
DEPARTMENT OF MEDICINE
12 SEP 2016
P.O. BOX ST 14, SOUTHERTON
HARARE

DR. C. Pasi
Chairman Harare Central Hospital Ethics Committee

Appendix 4: Medical Research Council of Zimbabwe Approval

Telephone: 791792/791193
Telefax: (263) - 4 - 790715
E-mail: mrcz@mrcz.org.zw
Website: http://www.mrcz.org.zw

Medical Research Council of Zimbabwe
Josiah Tongogara / Mazoe Street
P. O. Box CY 573
Causeway
Harare

APPROVAL LETTER

Ref: MRCZ/B/1263 **12 April, 2017**

Mrs Debra Mudariki
Physiotherapy Department
University of the Witwatersrand
South Africa

RE: - Clubfoot patients' Profile and Outcomes of Using the Ponseti Method at Three Hospitals in Zimbabwe

Thank you for the above titled proposal that you submitted to the Medical Research Council of Zimbabwe (MRCZ) for review. Please be advised that the Medical Research Council of Zimbabwe has **reviewed** and **approved** your application to conduct the above titled study. This is based on the following documents (among others) that were submitted to the MRCZ for review:

a) Research Protocol
b) Study Questionnaires
c) Informed Consent Forms

- **APPROVAL NUMBER : MRCZ/B/1263**

This number should be used on all correspondence, consent forms and documents as appropriate.

- **TYPE OF REVIEW : EXPEDITED**
- **EFFECTIVE APPROVAL DATE : 12 April, 2017**
- **EXPIRATION DATE : 11 April, 2018**

After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the MRCZ Website should be submitted three months before the expiration date for continuing review.

- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the Institutional Ethical Review Committee (IERC) as well as the MRCZ within 3 working days using standard forms obtainable from the MRCZ Website.
- **MODIFICATIONS**: Prior MRCZ and IERC approval using standard forms obtainable from the MRCZ Website is required before implementing any changes in the Protocol (including changes in the consent documents).
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the MRCZ using standard forms obtainable from the MRCZ Website.
- **QUESTIONS**: Please contact the MRCZ on Telephone No. (04) 791792, 791193 or by e-mail on mrcz@mrcz.org.zw
- **Other**
- Please be reminded to send in copies of your research results for our records as well as for Health Research Database.
- You're also encouraged to submit electronic copies of your publications in peer-reviewed journals that may emanate from this study.

Yours Faithfully

.....

MRCZ SECRETARIAT
FOR CHAIRPERSON
MEDICAL RESEARCH COUNCIL OF ZIMBABWE

MEDICAL RESEARCH COUNCIL OF ZIMBABWE
2017 -04- 12
APPROVED
P.O. BOX CY 573 CAUSEWAY, HARARE

PROMOTING THE ETHICAL CONDUCT OF HEALTH RESEARCH

Appendix 5: Human Research Ethics Committee (Medical) Clearance

R14/49 Mrs Debra Mudariki

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160785

NAME: (Principal Investigator)	Mrs Debra Mudariki
DEPARTMENT:	Physiotherapy Parirenyatwa Hospital, Zimbabwe Harare Central Hospital, Zimbabwe Mutare Provincial Hospital, Zimbabwe
PROJECT TITLE:	Clubfoot Patients' Profile and Outcomes of Using the Ponseti Method at Three Hospitals in Zimbabwe
DATE CONSIDERED:	29/07/2016
DECISION:	Approved unconditionally
CONDITIONS:	South African Human Research Ethics Committees (HRECs) have no standing outside South Africa. Ethics approval is also required from local HRECs in Zimbabwe
SUPERVISOR:	Dr L. Godlwana
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	29/05/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review June and will therefore be due in the month of June each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 6: Parent Information Forms

INFORMATION DOCUMENT

Study title:

CLUBFOOT PATIENTS' DEMOGRAPHIC PROFILE AND OUTCOMES OF USING THE PONSETI METHOD AT THREE SELECTED HOSPITALS IN ZIMBABWE.

Good day to you Sir or Madam

Introduction:
My name is Debra Mudariki. I am doing a research study entitled "Clubfoot patients' demographic profile and outcomes of using the Ponseti method at three selected hospitals in Zimbabwe". In this study I want to establish the demographic profile and treatment outcomes of clubfoot patients treated at the selected Ponseti clinics in Zimbabwe. This study is intended to inform researchers of clubfoot patient demographic characteristics, different types and severity of clubfoot managed in Zimbabwe and establishing clubfoot treatment outcomes.

Invitation to participate:
I am asking for your permission to include your child in this research study.

What is involved in the study?
In this study, your child's clubfoot treatment information will be collected. Some personal information such as age, gender and treatment details will be collected. Your child's name will not be recorded on the sheet where the clubfoot treatment information will be recorded. A code number will be used to record the treatment data. Before the data collection starts you will be asked to sign an assent form to show that you have agreed for your child's records to be used. This is always done for a research study. It will show that you understand what the study is about and how your child's information will be used in the study.

Risks
There is no risk of harm from your child's participation.

Benefits
There are no immediate benefits from your participation in the study. However, I hope that this study will be helpful in promoting the understanding of clubfoot treatment in Zimbabwe.

Participation is voluntary

Appendix 7: Parent's Consent Form

Parent's Consent Form

Please fill in and return the reply slip below indicating your willingness to allow your child to participate in the research project entitled : **Clubfoot patients' demographic profile and outcomes of using the Ponseti method at three selected hospitals in Zimbabwe.**

I, _____ the parent of _____

Permission to review/collect documents/artifacts	**Circle one**
I agree that my child's clubfoot treatment record can be used for this study only.	YES/NO

Informed Consent

I understand that:

- My child's name and information will be kept confidential and safe and that my name will not be revealed.
- He/she can withdraw from the study at any time.
- All the data collected during this study will be destroyed within 3-5 years after completion of my project.

Sign_____ Date_____

Appendix 8: Assessment of the clubfoot deformity using the Pirani score

4. HOW TO ASSESS THE SEVERITY OF A CLUBFOOT USING THE PIRANI SCORE (BPC)

A. Introduction

When treating clubfeet it is important to be able to measure how severe the deformity is. This is important so that you can see if the clubfoot is improving with treatment. It is also important that all members of the team use the same scoring system for severity as the child may be seen by different members of the team at different times. There are several scoring systems but we have chosen to use the Pirani system.

Shafique Pirani, the inventor of the Pirani scoring system, is a Canadian orthopaedic surgeon who helped start clubfoot services in Uganda and Malawi

B. How to use the Pirani scoring system

The Pirani scoring system is based on 6 well-described clinical signs of contracture characterizing a severe clubfoot:

- If the sign is severely abnormal it scores 1
- If it is partially abnormal it scores 0.5
- If it is normal it scores 0.

Scoring the foot at each visit during treatment enables the health care worker treating the child to document how the foot is responding to manipulation and casting.

Many degrees of severity and rigidity of clubfoot are found at birth. Failures in treatment are related more often to faulty technique of manipulation and casting rather than severity of deformity.

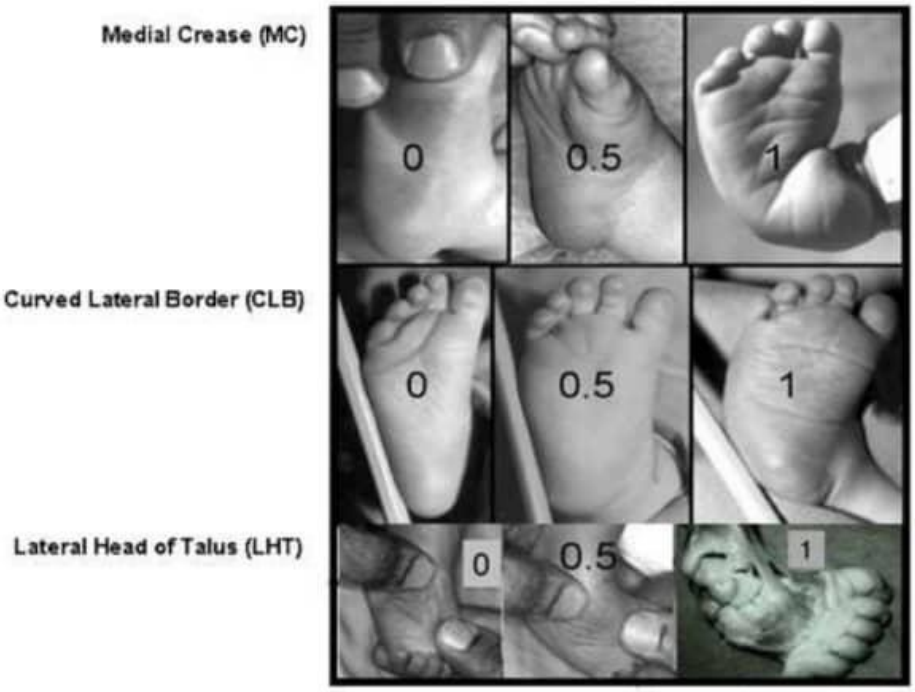
Technique of examination

The examiner is seated. The infant is on the mother's lap. A feeding, relaxed infant allows a more precise examination. The measurements are made while the examiner is gently correcting the foot with minimal effort, and no discomfort.

The Pirani score key features:

- Six "signs" are assessed, and each is scored 0, 0.5, or 1, depending on severity. 3 of the signs are in the midfoot and 3 in the hindfoot.
- Total Score (TS) varies from 0 to 6 and is the sum of midfoot and hindfoot contracture scores:
  - Midfoot Contracture Score (MFCS) varies between 0 and 3
    - 3 signs are each scored 0, 0.5, or 1
    i. Medial Crease (MC)
    ii. Curved Lateral Border (CLB)
    iii. Lateral Head of Talus (LHT)
  - Hindfoot Contracture Score (HFCS) varies between 0 and 3
    - 3 signs are each scored 0, 0.5, or 1
    i. Posterior Crease (PC)
    ii. Empty Heel (EH)
    iii. Rigid Equinus (RE).

C. Midfoot contracture score (MFCS)



Medial Crease (MC):

- Gently correct the foot, e.g. by lifting the foot holding the second toe
- Assess the depth of the crease and the presence of other creases
- The presence of several fine creases is scored 0, two or three moderate creases is scored 0.5, and a single, deep crease where you cannot see the bottom is scored 1.

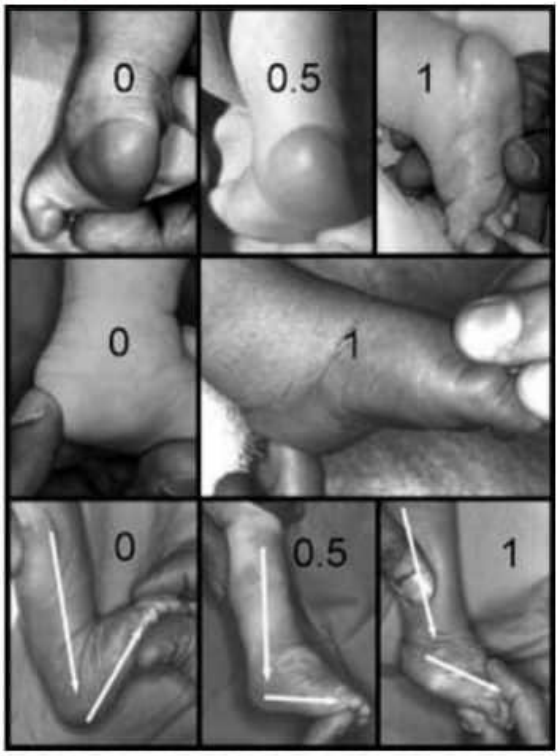
Curved Lateral Border (CLB):

- Make sure the child's foot is relaxed
- Observe from the plantar aspect, and use a pen held against the lateral edge of the calcaneum
- Assess the point on the lateral border of the foot at which it deviates from a straight line
- If the border of the foot (excluding the phalanges) is straight and without deviation, score 0. If it deviates at the level of the metatarsals, score 0.5. If it deviates at the calcaneo-cuboid joint, score a 1.

Lateral Head of Talus (LHT):

- Palpate the head of the talus with the foot uncorrected (it may be easier to find initially if you move the foot into a more deformed position)
- Keeping your finger / thumb on the talus, gently correct the foot
- If the talus completely sinks away under the navicular, score 0. If it moves partially but doesn't completely sink, score 0.5. If it remains fixed and does not sink, score 1.

D. Hindfoot contracture score (HFCS)



Posterior Crease (PC):

- Gently correct the plantarflexion (equinus)
- Assess the depth of the crease and the presence of other creases
- The presence of several fine creases is scored 0, two or three moderate creases is scored 0.5, and a single, deep crease where you cannot see the bottom is scored 1.

Empty Heel (EH):

- Hold the foot in mild correction and palpate with a single index finger
- Ascertain how much flesh there is in the heel between your finger and the calcaneum
- If it is easy to palpate the calcaneum, which is not far under the skin, score 0. Score 0.5 for a palpable calcaneum which is just felt through a layer of flesh. If the calcaneum is deep under a layer of tissue and very difficult to feel, score 1. (0 is like touching your own chin, 0.5 like touching the tip of your nose, and 1 like touching the soft part of your palm below the base of your thumb.)

Rigid Equinus (RE):

- Correct the plantarflexion as much as is comfortable for the child, holding the knee straight
- Assess the degree of dorsiflexion obtained: able to dorsiflex beyond plantigrade = 0, able to reach plantigrade (or 90°) = 0.5, unable to reach plantigrade (or 90°) = 1.