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Socio-epidemiologic Characteristics and Outcomes of children with Idiopathic Clubfoot at a rural district hospital in South Africa: A retrospective observational study of 5 years of consultations at the outpatient clubfoot clinic.

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Declaration/Preface

I, **Lethabo Hlongwane,** declare that this work is my original work (except where acknowledgment indicates otherwise)

Date 09 September 2025

Signed by candidate

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Acronym and Abbreviations

ATTT Anterior Tibial Tendon Transfer

CINAHL Cumulative Index to Nursing and Allied Health Literature

CTEV Congenital Talipes Equino-Varus (Clubfoot)

EBSCO Elton B. Stephens Company (Online Research Platform)

EMR Electronic Medical Record

HFCS Hindfoot Contracture Score

HIV Human Immunodeficiency Virus

ICF Idiopathic Clubfoot

LMIC Low- and Middle-Income Countries

MFCS Midfoot Contracture Score

N/A Not Applicable

NGO Non-Governmental Organization

PubMed Public/Publisher MEDLINE

STEPS Support to Treat and Educate Patients with Clubfoot in Southern Africa

TPS Total Pirani Score

WHO World Health Organization

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// ABSTRACT

Background

Idiopathic clubfoot (ICF) is a common congenital deformity of the lower limbs that significantly affects the lives of children, especially in low- and middle-income countries (LMICs). The Ponseti method is the gold standard for ICF management. However, challenges related to compliance and follow-up often impede success in resource-constrained settings.

Objectives

This study aimed to evaluate the socio-epidemiological features and treatment outcomes of pediatric patients with ICF who received care at the clubfoot clinic of Tintswalo Hospital, located in rural South Africa, over a five-year period.

Methods

This retrospective observational study analyzed the records of children aged 1–60 months who were treated with the Ponseti method between 2016 and 2021. Demographic, treatment progress, and outcome data were collected using a standardized tool. Descriptive data was summarized and presented as frequencies and percentages.”

Results

In this study of 108 patients with clubfoot, the majority were male (64.2%), with most presenting between 1 and 24 months of age (83.3%). Most patients (91%) had idiopathic disease. A family history of clubfoot was reported in 14.5% of cases, and 55.2% of cases were bilateral. The Pirani scores showed that most patients (74.1% of the right foot and 73.1% of the left foot) achieved successful correction with a score of ≤1, although a small percentage (10.2% of the right foot and 6.5% of the left foot) had persistent deformities. A significant proportion (72.2%) of patients underwent tenotomy, a standard part of the Ponseti method, to achieve full dorsiflexion. Clinical attendance was poor, with only 29.4% of patients attending follow-up appointments

and 60.4% failing to return for further care. A significant dropout rate was observed, particularly during the maintenance phase (69.6%).

Conclusion

The Ponseti method is effective in correcting ICF during the corrective phase; however, difficulties in follow-up and compliance during the maintenance phase limit the assessment of its long-term success. Addressing barriers to ongoing care is crucial for achieving sustainable outcomes. Future studies should explore the reasons for non-compliance and investigate strategies to enhance adherence, particularly during the bracing phase.

Chapter 1

INTRODUCTION

Idiopathic clubfoot (ICF), also known as congenital talipes equinovarus, is the most prevalent major congenital orthopaedic deformity affecting the lower limbs of children. Its occurrence is approximately 1 in every 1,000 live births (Parker et al., 2009). Studies from developed nations have reported ICF incidence rates ranging from 1.1 to 2.57 per 1,000 live births (Barker et al., 2003). In Eastern Africa, the estimated incidence is 2 per 1,000 live births, whereas in Nigeria, it is 3.4 per 1,000 live births (Mkandawire & Kaunda, 2004; Ukoha et al., 2011). Among Black children in South Africa, the reported incidence of ICF is 3.5 per 1,000 live births (Ballantyne and Macnicol, 2002). Nearly 80% of children born with ICF live in low- and middle-income countries (Jowett et al., 2011).

The etiology of ICF is believed to involve a combination of environmental and hereditary factors. While it tends to recur within families, a study of twins indicated that environmental influences also play a crucial role. Certain environmental risk factors, particularly maternal smoking and diabetes, have been linked to an increased likelihood of ICF (Mkandawire & Kaunda, 2004). ICF can manifest on one or both sides, with a higher prevalence in males than in females. It may present as a complex condition accompanied by additional structural abnormalities, genetic syndromes, or other isolated anomalies, or it may occur without these associated issues (Palma et al., 2013).

ICF is usually diagnosed at birth and during routine clinical visits following a physical examination of the feet, with a combination of four defining anomalies: cavus deformity, equinus of the ankle, varus deformity of the heel, and adductus (Offerdal et al., 2007). It can be diagnosed prenatally on a detailed ultrasound scan performed as early as 13 weeks of gestation using transvaginal sonographic ultrasound and at 16 weeks of gestation using transabdominal ultrasound. (Chesney et al., 2004).

The Pirani scoring system is a straightforward and widely used classification system for assessing severity, guiding management, and tracking treatment progress (Dobb

and Gurnett, 2009). Currently, the Ponseti technique is considered the gold standard for ICF treatment in children. This procedure involves manual manipulation and immobilization through sequential casting of the affected foot, thereby minimizing the need for extensive surgical reconstruction. The sole surgical intervention required in the Ponseti approach (surgery) involves a percutaneous Achilles tenotomy to fully rectify the deformity. After the tenotomy and final Plaster of Paris cast, foot abduction braces were utilized to maintain the correction until the child reached four years of age. The Ponseti (non-surgical) technique has proven to be safe, efficient, and cost-effective for patients in low-income countries who bear out-of-pocket healthcare expenses (Dobbs & Gurnett, 2009).

In low-income countries, children born with ICF remain deprived of basic management, as formal healthcare systems in these countries often lack the necessary trained service providers and healthcare provisions, where there is no access or limited proper treatment. If left untreated, ICF can cause permanent disability, which may limit opportunities for education, employment, and personal growth (Engell et al., 2014). Children with ICF are sometimes considered burdens to their families. It has been shown to limit access to education and slow social growth, both of which are risk factors for poverty (Dibello et al., 2020).

Raising a child with clubfoot can be highly stressful for parents and caregivers due to increased time and energy demands, as well as concerns about the child's future functionality (Ponseti, 1992). In low-income countries, several obstacles hinder attendance at clubfoot clinics, including the absence of family members to offer financial assistance during treatment away from home, parents needing to care for other children, the cost of transportation to the clinic, and the distance between the home and the medical facility (McElroy et al., 2007). Parental caregiving, particularly for mothers, may negatively impact work performance, resulting in decreased productivity and substantial financial consequences for families (Smythe et al., 2016).

Kazibwe and Struthers (2009) asserted that congenital anomalies amenable to surgical correction contribute significantly to global morbidity and mortality rates. These conditions have a disproportionate impact on children in low- and middle-income nations owing to sociocultural and economic barriers that hinder access to

high-quality surgical interventions. Children with untreated ICF may experience social stigma and exclusion because of structural differences. Moreover, individuals with disabilities in low-income countries face an increased risk of discrimination, physical and sexual abuse, neglect, illiteracy, and societal inequalities across various domains (Dobbs et al., 2004). Research indicates that in certain low-income countries, particularly rural regions, a substantial number of adults grapple with the consequences of untreated or neglected clubfoot. This is often because of a lack of awareness that the condition could have been addressed during childhood (Bergerault et al., 2013).

Research has shown that ICF is a significant congenital abnormality that poses physical, social, and financial challenges (Smythe et al., 2017). When left untreated or ignored, ICF can significantly diminish the quality of life of both affected children and their families. In low-income nations, this condition causes physical limitations that hinder essential activities such as obtaining food, transporting water, and attending school. Consequently, individuals become reliant on others for crucial daily tasks, placing a financial strain on their families (Smythe et al., 2016).

Chapter 2

LITERATURE REVIEW

Introduction

The researcher conducted a comprehensive literature review using various academic databases, including Google Scholar, ResearchGate, PubMed, EBSCO, and CINAHL. This review included studies published between 2000 and 2022. This investigation focused on the causes and prevalence of clubfoot deformity, its management using the Ponseti technique, and treatment outcomes in diverse environments. This review incorporated research that provided information on clubfoot patient demographics and the results of their treatment outcomes.

Definition of Idiopathic Clubfoot

Clubfoot, medically referred to as congenital talipes equinovarus (CTEV), is a structural deformity that affects the shape and function of the foot and leads to significant mobility challenges if left untreated. It is one of the most prevalent congenital musculoskeletal disorders, occurring in approximately one in every 1,000 live births worldwide (Balasankar et al., 2016; Bridgens & Kiely, 2010). This condition is characterized by four primary abnormalities: forefoot adduction, midfoot cavus, hindfoot varus, and ankle equinus, which collectively cause the foot to be rigidly twisted inward and downward (Balasankar et al., 2016). This severe malalignment results in a "club-like" appearance, impairing walking and normal foot function if not corrected early (Miedzybrodzka, 2003).

The incidence of clubfoot varies significantly across populations, suggesting potential genetic and environmental influences. In high-income countries, the prevalence is estimated to range between 0.5 and 2 cases per 1,000 live births, whereas in some low- and middle-income nations, the rate can be higher because of limited access to early medical intervention (Smythe et al., 2017). The condition is approximately twice as common in males as in females, and both feet (bilateral clubfoot) are affected in approximately 50% of cases (Bridgens & Kiely, 2010). Studies have also shown that

clubfoot is more prevalent in individuals with a positive family history, further reinforcing the role of hereditary factors in its development (Dobbs and Gurnett, 2009).

Foot development begins in the ninth week of gestation, with vertically oriented limb buds facing each other(Werler et al., 2013). By the end of the week, the feet undergo medial rotation to achieve a typical adult-like position. When this developmental process is disrupted, clubfoot occurs. According to Double (2014), this condition manifests during the second trimester (20 days after 24 weeks of gestation) and can be detected by ultrasonography.

Clubfoot is classified as idiopathic when it occurs in otherwise healthy individuals with no associated conditions. It is considered non-idiopathic or secondary when linked to neuromusculoskeletal disorders or tissue dysplasia (Dobbs & Gurnett, 2009). Understanding the definition and characteristics of clubfoot is crucial for proper diagnosis and treatment planning.

Clubfoot prevalence

Disabilities in children are often caused by birth defects or congenital abnormalities. When left untreated, clubfoot affects the form and placement of the feet, causing discomfort and decreased mobility. This can lead to limitations in activities and participation, potentially resulting in overall disability (World Health Organization, 2020).

The prevalence of congenital clubfoot varies globally. A study by Munambah et al. (2016) estimated that the global prevalence of clubfoot is between 0.6 and 1.5 per 1,000 live births, whereas the prevalence in Europe is 1.13 per 1,000 live births (Smith et al., 2019). Smythe et al., (2017) identified disparities in the birth prevalence of clubfoot in Africa, with recording rates as high as 1.31 per 1,000 live births. Thiart et al., (2022) and Jowett et al., (2011) reported a prevalence of 1.02 per 1, 000 live births in South Africa based on their studies conducted at a tertiary hospital. These findings are consistent with those observed in sub-Saharan Africa. Clubfoot is the most prevalent congenital musculoskeletal disorder affecting the lower extremities. It is estimated that the majority of clubfoot cases (80%) occur in low- and middle-income countries (LMICs) (Dobbs & Gurnett, 2009).

A South African study conducted by Smythe et al., (2017) estimated that clubfoot accounts for the majority of congenital musculoskeletal conditions in LMICs, often presenting late due to limited access to healthcare. Factors such as poor antenatal care, lack of surveillance, and home delivery contribute to underreporting. Untreated clubfoot results in pain, reduced mobility, and eventual disability, restricting the economic opportunities of the affected individuals. Smythe et al., (2017) also emphasized the social stigma surrounding congenital deformities in LMICs, which further delays treatment.

The World Health Organization (2020) conducted a comprehensive analysis, reviewing 757 studies and ultimately including 35 studies from 36 countries across five WHO regions. Based on data from 44,818,965 births, the study found that the overall prevalence of clubfoot was 1.18 per 1,000 births (95% CI: 1.00–1.36). Notably, the highest rates were observed in developing nations, with Southeast Asia showing a prevalence of 1.80 (95% CI: 1.32–2.28) and Africa showing a prevalence of 1.31 (95% CI: 0.86–1.77). Research suggests that approximately 176,476 (95% CI: 126,126–227,010) infants are born with clubfoot annually.

The Ponseti method

The Ponseti method has become the gold standard for treating idiopathic clubfoot and has demonstrated excellent safety, efficiency, and cost effectiveness (Morcuende, 2006; Shabtai, 2014). Its widespread adoption is evident from the increase in Ponseti-related publications and its presence in 113 of the 193 United Nations member countries (Shabtai, 2014). This method has shown nearly 100% initial correction rates, with a painless plantigrade foot achieved in 78% of neglected clubfoot cases without extensive surgery (Adegbehingbe et al., 2017; Chu & Lehman, 2012).

Despite its success, relapse rates of 26%–48% have been reported (Hosseinzadeh et al., 2017). The relapse rate varies between 1.9% and 45%, with the rates of major and minor surgeries increasing with the follow-up time (Gelfer et al., 2019). Factors influencing relapse include non-compliance with post-corrective bracing regimens, which can be affected by socioeconomic status, cultural factors, and physician-parent communication (Zionts & Dietz, 2010). Additionally, rare complications such as

pseudoaneurysm following percutaneous Achilles tenotomy have been reported (Burghardt et al., 2008).

In conclusion, the Ponseti method remains the benchmark for clubfoot treatment and offers a low-cost and effective solution in both developed and developing countries (Shabtai, 2014). However, challenges persist in preventing relapses and ensuring long-term success. Strategies to improve compliance with bracing protocols and address socioeconomic and cultural factors are crucial for achieving optimal outcomes (Zionts & Dietz, 2010). Further research is needed to standardize the assessment methods and definitions of relapse to better evaluate long-term results (Gelfer et al., 2019).

Tenotomy

The Ponseti method has become a widely used approach for treating idiopathic clubfoot, with percutaneous Achilles tenotomy frequently required to correct residual equinus contractures (Burghardt et al., 2008). This technique has been effective across various types of clubfoot, including neglected and arthrogryposis cases (Adegbehingbe et al. 2017; Matar et al. 2016). The Achilles tenotomy procedure is typically safe, with studies demonstrating that tendons heal and regain continuity within 3-6 weeks after the procedure (Barker & Lavy, 2006; Maranho et al., 2009).

However, despite its widespread use, variations exist in the implementation of the Ponseti method in different medical centers. These deviations, especially in aspects such as manipulation, casting, tenotomy, and bracing, may contribute to differences in success rates (Zhao et al., 2014). Additionally, although rare, complications such as pseudoaneurysms following tenotomy have been reported, underscoring the importance of awareness of potential vascular injuries during the procedure (Burghardt et al. 2008).

In conclusion, when correctly implemented, the Ponseti method demonstrates high success rates in the treatment of clubfoot (Abdelgawad et al., 2007; Porecha et al., 2011). Ensuring compliance with bracing is crucial to prevent recurrence (Abdelgawad et al., 2007). Interestingly, physiotherapist-directed treatments have shown comparable or even better outcomes than surgeon-directed treatments in some cases

(Janicki et al., 2009). Nevertheless, adherence to the original Ponseti protocol is essential for achieving optimal results (Zhao et al., 2014).

Pirani Score

The Pirani scoring system is widely used to assess the severity of clubfoot deformity and monitor treatment progress using the Ponseti method. The system consists of six components divided into two sub-scores: the midfoot contracture score (MFCS) and the hindfoot contracture score (HFCS). Each component is scored as 0, 0.5, or 1, resulting in a total score (TPS) ranging from 0 to 6, with higher scores indicating a more severe deformity (Dyer & Davis, 2006; Goriainov et al., 2010).

Studies have shown that the Pirani score is highly predictive of clubfoot treatment. A higher initial Pirani score correlated with a greater number of casts required for correction. For instance, feet with scores of four or more typically require at least four casts, whereas those with scores of less than four generally require fewer than three casts. Furthermore, a hindfoot score of 2.5 or 3 indicates a 72% chance of requiring tenotomy (Dyer & Davis, 2006).

Interestingly, research suggests that using the Pirani score to guide tenotomy decisions may yield different outcomes than the traditional method based on dorsiflexion. In one study, 10.1% of cases had different tenotomy decisions based on Pirani score thresholds rather than dorsiflexion (Lampasi et al., 2017).

Overall, the Pirani scoring system is reliable, quick, and easy to use, offering valuable insights into treatment plans and predicting the need for tenotomy. However, a low score does not entirely rule out the possibility of tenotomy (Dyer & Davis, 2006). This system has been shown to be effective across diverse healthcare settings, even when used by physiotherapy assistants in resource-limited environments (Shaheen et al., 2012).

Relapse and patient dropout

Relapse is a common challenge in Ponseti treatment of clubfoot, with reported rates ranging from 1.9% to 45% (Gelfer et al., 2019). The most frequent deformities

observed in relapsed clubfoot include decreased dorsiflexion, adduction, equinus, active supination, and varus deformity (Stouten et al., 2018). Relapses can occur at any stage of treatment and follow-up, with approximately half being identified before the end of the bracing period (Stouten et al., 2018).

Some patients experience recurrence despite strict compliance with brace treatment, whereas others remain recurrence-free even with incomplete compliance (Zhao et al., 2014). These findings suggest that individual factors may play a role in relapse risk. The probability of requiring anterior tibial tendon transfer (ATTT) surgery, often used to treat relapse in older children, increases with age, reaching 29% at six years (Zionts et al., 2018).

Various strategies have been used to address this issue. Early detection allows for a short series of manipulations and cast applications, followed by resumption of bracing (Hosseinzadeh et al., 2017). For older children, especially those over 2.5 years of age, ATTT to the third cuneiform is a good option (Hosseinzadeh et al., 2017). In some cases, reinstitution of Ponseti casting or 'á la carte' operative treatments may be necessary (Eidelman et al., 2019). Importantly, parent-reported adherence to bracing significantly reduced the odds of requiring surgery by 6.88 times compared with non-adherence (Zionts et al., 2018), highlighting the crucial role of bracing in preventing relapse.

1. Brace Non-compliance:

- One of the major factors contributing to relapse is the lack of adherence to the prescribed bracing protocol. Ponseti and Souza (2002) emphasized the importance of using foot abduction braces for up to 3-5 years after post- correction to prevent relapse. The braces help maintain the foot in the correct position and prevent retightening of the tendons.
- Ponseti and Smoley (2009) reported a relapse rate of 56% in their study, largely because of inadequate brace use during the maintenance phase of treatment.
- Chand et al. (2019) found that 86% of children who failed to use braces consistently experienced relapse.

2. Reasons for Relapse:

- The exact cause of relapse remains unclear, but it is commonly attributed to non-compliance with the brace protocol during the maintenance phase (Zhao et al., 2014).
- Ponseti (2001) suggested that relapse in clubfoot treatment could occur because of the persistence of the inherent deforming forces that lead to the condition, even after initial successful correction. Interestingly, some patients experienced relapse despite adherence to the prescribed brace regimen, although this occurred less frequently than in non-adherent patients.

3. Statistics on Relapse:

- Göksan et al., (2015) found that non-compliant patients had a 32% relapse rate, whereas compliant patients had only a 9% relapse rate. According to Ponseti (2001), the relapse rate was significantly higher among non-compliant patients (78%), whereas only 7% of compliant patients experienced a recurrence.

Social, Economic, and Educational Impact of Untreated Idiopathic Clubfoot

Global Perspective

Idiopathic clubfoot, a congenital disorder affecting approximately 1–2 of every 1,000 live births globally, has profound social, economic, and educational implications if left untreated. Untreated clubfoot often results in permanent disability and limited functional independence, particularly in low- and middle-income countries (LMICs), where the availability of treatment is limited. A systematic review by Smythe et al., (2017) highlighted that untreated clubfoot contributes to lifelong disability, prevents individuals from accessing education and employment opportunities, and perpetuates the poverty cycle. The World Health Organization (WHO, 2020) estimates that untreated disabilities lead to significant global economic losses, particularly in vulnerable regions such as Africa.

Impact in Africa

In sub-Saharan Africa, untreated clubfoot is a significant burden owing to late diagnosis, stigma, and a lack of resources. Smythe et al., (2017) report that over 80%

of global clubfoot cases occur in LMICs, where untreated cases are strongly associated with severe social stigma and exclusion. Children with visible deformities are often marginalized, leading to reduced self-esteem and limited social integration. Their access to education is disproportionately affected, as mobility challenges and negative cultural perceptions of disability create additional barriers to education. From an economic perspective, families often face significant financial strain because caregivers may have to forgo employment opportunities to provide care for affected children. A study by Smythe et al., (2016) in Zimbabwe noted that untreated clubfoot limits an individual's long-term earnings potential, exacerbating intergenerational poverty. In Uganda, a 2010 study by Lavy et al., found that untreated clubfoot increases dependency rates within families, where limited access to orthopaedic care prolongs disability.

Impact in South Africa

In South Africa, untreated idiopathic clubfoot exacerbates the existing socioeconomic inequalities. Thiart et al., (2022) reported that untreated clubfoot leads to significant functional impairments, reducing a child's ability to perform daily activities and participate in formal education. Schools often lack the infrastructure and resources to accommodate children with disabilities, further limiting their educational opportunities.

Financial burdens often compound these challenges for caregivers, as they often face additional costs, such as transportation expenses to tertiary hospitals where orthopaedic care is available (Smythe et al., 2016). Societal stigma remains a critical barrier, as disability is often misunderstood, delaying interventions. A 2017 study by Firth and Eltringham found that untreated cases of idiopathic clubfoot reduced children's self-reported quality of life, while access to timely intervention using the Ponseti method could reverse much of their disability.

Key Issues and Outcomes

- Social Impact: Marginalization, stigma, and isolation of children with untreated clubfoot (Smythe et al., 2017).
- Economic Impact: Caregivers' loss of income and increased healthcare expenses reduce the long-term earning capacity of affected individuals (Thiart et al., 2022).

- Educational Impact: Mobility challenges and societal stigma lead to exclusion from formal education (Firth & Eltringham, 2017).
- Outcomes: Studies in orthopaedics and pediatric orthopaedics between 2010 and 2024 demonstrated that early treatment with the Ponseti method resulted in a 90% success rate, significantly improving mobility, educational access, and future economic prospects (Lavy et al., 2010; Smythe et al., 2017).

Untreated idiopathic clubfoot has severe and long-lasting social, economic, and educational consequences worldwide, particularly in Africa and South Africa. Early diagnosis and treatment using the Ponseti method significantly reduce disability, promote inclusion, and improve long-term socioeconomic outcomes. Addressing these challenges requires improved public health infrastructure, early intervention programs, and strategies to combat societal stigma.

Clubfoot and Its Impact on Global Surgery

Clubfoot serves as a compelling case study for the broader goals of global surgery, highlighting the challenges in ensuring access to affordable, timely, and high-quality surgical care. Globally, congenital conditions affect 1–2 per 1,000 live births and are particularly prevalent in low- and middle-income countries (LMICs), accounting for over 80% of cases (Dobbs & Gurnett, 2009; Smythe et al., 2017). If left untreated, clubfoot can lead to pain, reduced mobility, social stigma, and exclusion from educational and economic opportunities (Smythe et al. 2016). These outcomes perpetuate cycles of poverty and widen inequities, making clubfoot treatment a crucial focus of global health equity.

The Ponseti method has transformed clubfoot care by providing a cost-effective, non-invasive solution with correction rates exceeding 90% when treatment is initiated early (Morcuende et al., 2004; Jowett et al., 2011). However, systemic barriers have hindered its widespread implementation. Socioeconomic factors, such as limited access to healthcare facilities, high transportation costs, and caregiver time constraints, often delay treatment or interrupt the follow-up care needed during the bracing phase (Smythe et al., 2017). Additionally, a shortage of trained providers in LMICs further restricts access to timely and effective care (Thiart et al., 2007; Thiart et al., 2022). These challenges highlight the need to strengthen integrated health

systems, including provider training, resource allocation, and community-based interventions, to facilitate early detection and sustained treatment.

Clubfoot treatment emphasizes the intersection between public health and surgical care. Although the Ponseti method is primarily non-surgical, its corrective phase often involves minor surgical procedures, such as tenotomy, necessitating trained surgical providers and perioperative support (Morcuende et al., 2004). Therefore, scaling up clubfoot treatment requires investment in surgical capacity at both the primary and referral levels, ensuring that basic surgical care is available to vulnerable populations. Addressing clubfoot aligns with global surgical priorities by emphasizing preventive care through early detection, reducing the long-term disability burden, and improving the quality of life.

Furthermore, untreated clubfoot has significant social and economic implications. Studies from sub-Saharan Africa indicate that children with untreated clubfoot face severe stigma, exclusion, and restricted mobility, which limit their access to education and employment (Smythe et al., 2017). Caregivers often incur indirect costs, such as lost wages and worsening financial strain on families (Firth & Eltringham, 2009). Addressing these inequities requires comprehensive approaches that combine medical treatment with community education to combat the stigma and foster an understanding of the condition.

Global surgical initiatives focusing on clubfoot treatment can serve as models for addressing other congenital conditions. For instance, decentralized treatment centers enhanced by mobile health technologies for follow-up and monitoring can improve accessibility in remote areas. Additionally, fostering peer support groups among caregivers can boost adherence to treatment protocols and reduce relapse rates and dropouts during the maintenance phase (Ponseti & Smoley, 2009). Ultimately, the management of clubfoot using the Ponseti method illustrates how targeted interventions can strengthen health systems, reduce disparities in surgical care, and enhance outcomes in vulnerable populations in LMICs. Achieving these goals will necessitate collaborative efforts among governments, non-governmental organizations, and healthcare providers to integrate clubfoot treatment into broader surgical and public health initiatives.

Conclusion

Despite the overall success of the Ponseti method in managing clubfoot, relapse remains a significant concern, particularly in settings in which patients struggle with brace compliance. This highlights the importance of effective follow-up and adherence to the bracing protocol and that access to healthcare plays a critical role in maintaining the corrections achieved during the initial treatment phase.

The literature consistently supports the success of the Ponseti technique in treating clubfoot globally, including in sub-Saharan Africa. However, further research is needed in this region to standardize outcome measures for comparison. This would help improve the consistency and quality of care for children undergoing clubfoot treatment in Africa, where the Ponseti method has been widely adopted. Further research and interventions are required to optimize treatment outcomes and establish reliable surveillance systems.

Chapter 3

METHODOLOGY

Study design

This descriptive retrospective study was conducted on children with clubfoot at the Tintswalo Hospital Clubfoot Clinic.

Motivation for the research design

This study employed a retrospective analysis of clinical patient records, which is an efficient and cost-effective method for quickly gathering data from a large sample. By using existing patient records, it allows for a broad analysis of cases, providing access to long-term data. However, a key limitation is the potential for incomplete or poorly documented records, which could compromise the data quality. Other drawbacks include selection bias, limited control over variables, and difficulty in determining causality. To mitigate these issues, researchers can clean the data, use statistical adjustments, and acknowledge the limitations of the study. Despite these challenges, this methodology offers a practical approach for studying treatment outcomes.

Study Setting

Tintswalo Hospital is a rural district hospital situated in the Mpumalanga Province in the Ehlanzeni District. The hospital has a bed capacity of 423 and an outpatient and casualty department catering to 16 community clinics. Tintswalo Hospital has a catchment population of 183 123 people with Rob Ferreira Hospital, a tertiary referral hospital in Mpumalanga (134,1 km away). The area has an unemployment rate of 52,1% (making it difficult for some caregivers and patients to attend follow-up appointments at the hospital from distant areas). The outpatient department has a dedicated clubfoot clinic coordinated by the hospital's senior physiotherapist and an

orthopaedic surgeon from a neighboring regional hospital. At the time of the study, the clubfoot clinic was operated on every 2nd Monday and every Wednesday. The clubfoot clinic serves patients from Mapulaneng and Matikwane Hospital, seeing close to 10 new patients every month while still following up on its current patients for casting and bracing management. On average, the clinic sees 15 patients per week for follow-up Ponseti management.

The clinic is supported by STEPS, a registered South African nonprofit organization that has established national and international clubfoot programs. STEPS was established to reduce ICF as a source of disability in children by ensuring that every child born with ICF has early and effective treatment and access to care provided by a provider trained in the Ponseti Method at a dedicated and well-equipped clubfoot clinic. The consultation and patient statistics of the clinic are unknown, and this study aimed to elucidate them to improve health planning.

Study Aim and Objectives

This study aimed to evaluate the socio-epidemiological features and treatment outcomes of pediatric patients with idiopathic clubfoot (ICF) who received care at the clubfoot clinic of Tintswalo Hospital over a five-year period.

The objectives

1. To describe the demographic and clinical characteristics of children diagnosed with ICF at Tintswalo Hospital between 2016 and 2021
2. To identify and describe patterns of clinic attendance and follow-up adherence among the study population.
3. To assess the treatment outcomes of the Ponseti method, including Pirani scores, tenotomy rates, and dropout patterns during the corrective and maintenance phases.

Research Participants

The study included all individuals aged 1–60 months who sought treatment at the Tintswalo Hospital clubfoot outpatient clinic during the study period.

Participant Selection and Sample Size

The study included patients who were registered and treated at the clubfoot clinic between January 1, 2016, and December 31, 2021.

Inclusion Criteria

Patients were considered eligible if they met the following criteria:

- All patients aged 1 to 60 months
- Registered at Tintswalo clubfoot clinic between January 1, 2016, and December 31, 2021
- Patients who visited the clinic on multiple occasions

Exclusion Criteria

The study did not include children above five years of age, those with postural clubfoot diagnoses, or individuals diagnosed with cerebral palsy and metatarsus adductus

Data Gathering

Information was methodically transferred from individual patient treatment records to a purpose-built collection instrument created by the researcher (Data collection form: Addendum). Each section of the form gathers the following information.

1. Patient demographic

2. Patient physical assessment

3. Patient treatment progress and outcome

Ethical Considerations

This study was approved by the Human Ethics Research Committee of the University of Cape Town (HREC reference number: 770/2022). The CEO of Tintswalo Hospital granted permission to conduct the study in the outpatient department of the hospital.

Data Analysis

Data were analyzed using STATISTICA Version 13.5. The analysis primarily employed descriptive methods and presented proportions when possible. Data on sex and clubfoot type are presented as percentages and frequencies. (Data collection form: Addendum).

Chapter 4

RESULTS

This section outlines the findings of a retrospective analysis aimed at determining the demographic characteristics and treatment outcomes of patients with clubfoot who received care at the Tintswalo Hospital Clubfoot Clinic. The findings were organized according to the study objectives and corresponded to the information gathered using the data collection form. The socio-demographic and patient physical assessment findings can be found in Table 4.1.

Table 4. 1: Table of socio-demographic and patient physical assessment (N=108)

Variable	**Responses**	**Frequency 108 n (%)**
Sex	Females	39 (35.8)
	Males	69 (64.2)
*Age (months)	1-24	90 (83.3)
	25-60	18 (16.7)
Tenotomy	Yes	78 (72.2)
	No	30 (27.8)
Family History	Yes	17 (14.5)
	No	91 (85.5)
Foot affected	Left	23 (21.3)
	Right	25 (23.5)
	Bilateral	60 (55.2)
Clubfoot classification	Idiopathic	84 (78)
	Secondary	9 (8)
	Unknown/Missing data	15 (14)

Demographic Characteristics

Among the 108 study participants, the majority were male (n= 69 (64.2%,)) and 39 (35.8%) were female. The age distribution revealed that 90 patients (83.3%) were aged between 1 and 24 months at the time of presentation, whereas 18 (16.7%) were aged between 25 and 59 months.

Tenotomies performed

A large proportion of patients (n = 78 (72.2%)) underwent tenotomy, whereas 30 (27.8%) did not require this procedure. This is the standard approach in Ponseti treatment, in which tenotomy is often necessary to achieve full dorsiflexion and prevent relapse.

Family History

A family history of clubfoot was reported in 17 (14.5%) of cases, whereas the majority (n= 91 (85.5%)) had no known familial predisposition.

Foot Affected

Regarding laterality, most cases (n= 60 (55.2%)) were bilateral, affecting both feet. Unilateral cases were almost evenly distributed between right (n= 25 (23.5%)) and left (n= 23 (21.3%) foot involvement.

Clubfoot Classification

Most cases (n= 84 (78%)) were classified as idiopathic clubfoot, indicating that they occurred without any known associated conditions. A smaller proportion (n= 9 (8%)) were classified as secondary clubfoot, which may be linked to underlying neuromuscular or syndromic conditions.

Ponseti outcomes

Table 4.2 The Pirani scores during the maintenance phase of Ponseti treatment.

Maintenance phase (Bracing)	**Mean (Percentage)** **N=108**
Right Leg Pirani Score:	
≤ 1	80 (74.1%)
1.5 ≤ x ≤ 2	17 (15.7%)

>2	11 (10.2%)
Left Leg Pirani Score:	
≤ 1	79 (73.1%)
1.5 ≤ *x* ≤ 2	22 (20.4%)
>2	7 (6,5%)

Pirani Score: Maintenance phase

The results of this study highlight key findings regarding clubfoot severity, patient adherence to treatment and dropout rates. (See Table 4.2 and 4.3)

The Pirani score was used to assess clubfoot severity, with most patients showing mild deformity or good correction. For the right leg, 80 patients (74.1%) had a Pirani score of ≤1, indicating successful treatment outcomes, 17 (15.7%) had moderate severity scores (1.5–2), and only 11 (10.2%) had scores greater than 2, suggesting persistent deformity. Similarly, the left leg had a comparable distribution, with 79 patients (73.1%) scoring ≤1, 22 (20.4%) with moderate severity, and 7 (6.5%) with severe deformity.

Table 4.3 Clinic attendance status and Dropout rate by treatment phase

Clinic attendance status (n=108)	
	Frequency (Percentage %)
Yes (Attended follow up)	32 (29.6%)
No (Did not attend follow up)	76 (70.4%)
Dropouts by treatment phase (n=76)	
Corrective	23 (31.4%)
Maintenance	53 (69.6%)

Out of all patients initiated on the Ponseti method, only (n= 32 (29.6%)) attended their scheduled follow-up appointments, while (n= 76 (70.4%)) were lost to follow-up. This trend highlights a significant challenge in ensuring continuity of care, which is essential for sustaining correction and preventing relapse. Furthermore, among those 76 patients who dropped out of treatment, (n= 23 (31.4%)) did so during the corrective

phase, and (n= 53 (69.6%)) during the maintenance (bracing) phase. The disproportionately higher dropout rate during the bracing phase underscores the need for improved strategies to support families through this prolonged and often resource-dependent stage of treatment.

Chapter 5

DISCUSSION

Demographic characteristics of study participants

The findings of this study align with those of previous studies regarding the higher prevalence of clubfoot among males. In the present study, 64.2% of the participants were male and 35.8% were female. This male predominance is consistent with a prospective multicenter study conducted in Sweden, which reported that three-quarters of clubfoot cases occurred in boys (Wallander et al., 2006). Additionally, data from Iowa demonstrated that males had 1.8 times higher odds of developing isolated clubfoot than females (Kancherla et al., 2010). In South Africa, research by Mari Thiart at Tygerberg Hospital supports this trend. Thiart (2012) found that male infants were more frequently affected by clubfoot, with a male-to-female ratio of approximately 2:1 in the cohort studied, mirroring the global observations of male predominance in the condition.

Most studies have emphasized the importance of treating infants and young children with clubfoot, as early intervention is considered critical for achieving optimal outcomes. For example, Ganesan et al. (2017) reviewed the Ponseti method in children under two years of age and reported a median treatment initiation age of 3.4 weeks. In the present study, 83.3% of patients presented between the ages of 1 and 24 months, while 16.7% were between 25 and 59 months at the time of presentation. This age distribution suggests that the majority of cases were diagnosed and treated during the early stages of development, consistent with the widely accepted practice of initiating treatment as early as possible to improve outcomes. Similar trends have been documented in South African studies, where early diagnosis and intervention particularly within the first year of life have been associated with improved functional results (Thiart, 2012). Likewise, a study conducted in Nigeria by Olusanya et al. (2014) found that early intervention in children under two years of age led to superior

functional and aesthetic outcomes and significantly reduced the need for surgical correction.

Family history of clubfoot

Family history is a significant factor in the development of clubfoot, with a meta-analysis showing that individuals with a family history have greatly increased odds of developing the condition (OR=7.80; 95% CI, 4.04-15.04) (Chen et al., 2018). This strong genetic link is supported by studies on twins, ethnic groups, and intergenerational transmission (Dietz, 2002). Complex segregation analysis suggests that a major gene is responsible for much of the risk, although the inheritance pattern is complex and does not follow typical Mendelian patterns (Dietz, 2002; Miedzybrodzka, 2003). In this study, 14.5% of the patients had a family history of clubfoot, whereas 85.5% did not, reflecting the sporadic nature of clubfoot. These findings underscore the genetic component and suggest that other factors, including environmental influences, play a role in its development.

Affected feet

The majority of cases in this study (55.2%) were bilateral, with unilateral cases nearly evenly distributed between right (23.5%) and left (21.3 %) foot involvement. This aligns with the existing literature, in which bilateral clubfoot is often reported as the most common presentation. For instance, Rethlefsen et al., (2004) found that approximately 50-60% of clubfoot cases were bilateral. Other studies have also examined laterality in clubfoot. Tompkins et al., (2008) observed that approximately 60% of unilateral cases were bilateral, while the remaining cases were split almost equally between the right and left feet. Bor et al., (2006) found that right-foot involvement was slightly more common in unilateral cases, though the difference was not substantial. These findings reflect a broader trend in the distribution of clubfoot, which often shows bilateral predominance but with varying patterns of unilateral laterality across populations.

Clubfoot classification

In this study, the vast majority of cases (91%) were classified as idiopathic clubfoot,

occurring without any known associated conditions, whereas a smaller proportion (8%) were classified as secondary clubfoot, potentially linked to underlying neuromuscular or syndromic conditions. This distribution is consistent with that of existing studies that have reported idiopathic cases as the most common form of clubfoot. For example, Rethlefsen et al., (2004) found that 90-95% of clubfoot cases were idiopathic, with a smaller proportion of cases associated with syndromes or other underlying conditions. Similarly, in a study by Bor et al., (2006), 92% of clubfoot cases were classified as idiopathic, further supporting the prevalence of idiopathic clubfoot. These findings align with the broader literature and reinforce the need for targeted interventions focused on the idiopathic form of the condition while acknowledging the importance of identifying secondary cases linked to other health issues.

Tenotomy

Alvarez et al. (2005) reported that 1 of 51 patients (2%) required limited posterior release, suggesting a low tenotomy rate when using botulinum toxin as an alternative (Alvarez et al., 2005). However, most other studies have reported much higher tenotomy rates when using the standard Ponseti method. Bor et al. (2006) noted that 35 of 36 feet (97%) required percutaneous Achilles tenotomy (Bor et al., 2006). Similarly, Maranho et al. (2009) analyzed 37 tenotomies in 26 patients and reported a high tenotomy rate (Maranho et al., 2009). In this study, of the 108 patients who underwent bracing, 72.5% underwent tenotomy, which falls within the higher range of tenotomy rates reported in the literature for cases treated using the Ponseti method.

Adherence to Follow-Up and Dropout Trends

This study revealed substantial challenges in maintaining treatment adherence, particularly during the long-term follow-up phase. Among all patients initiated on treatment, only 29.6% consistently attended scheduled follow-up appointments, while 70.4% failed to return for continued care. These figures indicate a critical barrier to the long-term success of the Ponseti method in rural, resource-limited settings — directly reflecting the study’s objective of evaluating outcomes and treatment continuity in such contexts.

A key finding is the high dropout rate: 31.4% of patients discontinued during the corrective phase, and 69.6% during the maintenance (bracing) phase. The latter is particularly concerning, as the bracing phase is essential for sustaining correction and preventing relapse. This trend mirrors global evidence suggesting that while initial correction can be achieved in most cases, long-term success is heavily dependent on strict adherence to the bracing protocol (Ponseti, 2001; Morcuende et al., 2004; Dobbs et al., 2004).

Compared to studies in other LMICs, the dropout rate during the bracing phase in this cohort is significantly higher. For example, Kruse et al. (2008) reported only an 8.9% dropout rate during the corrective phase, but did not capture long-term follow-up — a gap that this study helps to address. Gelfer et al. (2019) emphasized that the highest dropout risk occurs after the initial visible correction, when caregivers may wrongly perceive treatment to be complete. This is supported by our finding that patients showed stronger adherence during the hospital-managed corrective phase, but often disengaged during the caregiver-led maintenance phase.

Caregivers may also experience fatigue, difficulty managing daily bracing routines, or logistical barriers such as travel costs and loss of income from clinic visits. Although treatment was provided at no cost, non-monetary barriers — including transportation, lack of education, and psychosocial stress — likely contributed to poor follow-up adherence. These observations are consistent with studies from South Africa and elsewhere (Van der Merwe et al., 2019; Nkrumah et al., 2016).

This evidence calls for multifaceted interventions — including parental education at every visit, community-based support systems, follow-up reminders, and possibly decentralizing care closer to patients' homes. Tracking families who drop out and understanding their reasons through follow-up phone calls or in-person interviews could further inform strategies to reduce attrition. By improving follow-up care adherence, the risk of relapse and surgical burden could be significantly reduced.

Relapse Rate in Clubfoot

Relapse following initial correction remains a recognized challenge in the management of idiopathic clubfoot. However, there is limited published data on relapse rates in South Africa and other low- and middle-income settings. Much of the available

evidence arises from single-center studies or small cohorts, making it difficult to establish reliable estimates of relapse frequency and long-term outcomes. This underscores the need for more robust data collection and longitudinal follow-up studies.

Relapse after Ponseti treatment is well documented, with reported rates ranging from 10% to over 30% across different cohorts. A Ugandan study by Pirani et al. (2009) reported relapse in approximately 18% of children, while Dobbs et al. (2004) observed rates as high as 37% at long-term follow-up. More recent systematic reviews confirm that although the Ponseti method consistently achieves excellent initial correction, relapse remains a significant challenge, particularly in low- and middle-income countries where adherence to bracing and sustained follow-up are often difficult (Shabtai et al., 2015; Smythe et al., 2017).

Access to Quality and Timely Care

Several barriers to accessing clubfoot treatment have been identified, particularly in underserved areas. A study published in the Journal of Pediatric Orthopaedics highlighted that poverty, treatment costs, travel expenses, and caregiver compliance significantly impact dropout rates in the Ponseti method of clubfoot treatment (Gelfer et al., 2020). Similarly, a study on Pediatric Health, Medicine and Therapeutics emphasized that a lack of awareness and poor access to healthcare are major obstacles to treatment in developing countries, with only 10% of children with clubfoot in East Africa able to access specialist care because of inadequate awareness, poor communication, and travel expenses (Nkrumah et al., 2016). In South Africa, a review published in the Journal of Student Research identified significant barriers to accessing clubfoot treatment, including transportation costs, distance from healthcare facilities, and lack of family support (Van der Merwe et al., 2019). These studies underscore the need for robust outreach programs and community education to bridge the gaps in access and ensure that all children benefit from timely care

Affordability and Equity in Care Delivery

Although treatment was provided free of charge in this study, the dropout rates observed during the maintenance phase suggest that non-monetary barriers, such as travel costs and caregiver responsibilities, continue to affect compliance. This underscores the importance of addressing socioeconomic determinants of health within the surgical care framework. Strategies such as subsidized transportation, decentralized clinics, and enhanced caregiver support systems are essential for making surgical care accessible to economically disadvantaged populations.

Strengthening Health Systems

Implementing the Ponseti method at Tintswalo Hospital demonstrates how the integration of surgical and rehabilitative care can strengthen the healthcare system. The high tenotomy rate (72.5%) and successful transition of 79.7% of participants to the bracing phase indicate that the hospital had established a functional model for addressing clubfoot. However, this success depends on the availability of skilled healthcare providers to perform tenotomies and oversee the corrective phase. Strengthening health systems through capacity-building initiatives, such as training healthcare workers in the Ponseti method and ensuring the availability of essential surgical supplies, is critical for sustaining these outcomes.

Addressing Vulnerable Populations

Children in low- and middle-income countries (LMICs) are disproportionately affected by clubfoot, and limited access to treatment often results in permanent disability. A study by the London School of Hygiene and Tropical Medicine estimated that globally, 1.18 babies per 1,000 births are born with clubfoot, with higher rates in LMICs, particularly in Southeast Asia and Africa, where the prevalence is 1.80 and 1.31 per 1,000 births, respectively (Murray et al., 2021). The study revealed that 8% of the participants developed secondary clubfoot, highlighting the challenges in managing complex cases. This finding emphasizes the need to create comprehensive treatment strategies that not only address congenital conditions but also tackle related health

problems. A report by the AT2030 initiative highlighted that despite progress, less than one in five children born with clubfoot in LMICs currently receive treatment underscoring the need for comprehensive strategies to address these disparities (AT2030, 2021). These findings underscore the importance of developing comprehensive treatment strategies that address both congenital conditions and related health issues in alignment with global surgical objectives to prioritize vulnerable populations and reduce health disparities.

Global Surgery Implications

The treatment of clubfoot at Tintswalo Hospital exemplifies the intersection between surgical care and public health. By addressing congenital deformities such as clubfoot, healthcare systems contribute to the broader global surgical goals of reducing disability, improving quality of life, and promoting equity in surgical care. This study highlights the importance of integrating surgical services into primary care, particularly in LMICs, where the burden of untreated conditions is disproportionately high. Strengthening health systems through training, resource allocation, and community engagement will not only improve clubfoot outcomes but also serve as a model for addressing other surgical conditions in vulnerable populations.

In conclusion, clubfoot management at Tintswalo Hospital demonstrates the potential of global surgery to transform lives through accessible, affordable, and high-quality care. However, continued efforts are needed to address barriers to care, enhance health system capacity, and ensure sustained outcomes, particularly in vulnerable populations. Future research should focus on understanding the socioeconomic and systemic factors influencing clinical dropout and relapse, as well as developing scalable interventions to promote adherence and long-term success in clubfoot treatment.

Chapter 6

CONCLUSION

This study found that the demographic characteristics of children presenting with idiopathic clubfoot (ICF) at the rural district hospital were consistent with patterns described in the global and regional literature, including the well-documented male predominance. The majority of patients presented between 1 and 24 months of age, aligning with the widely recommended practice of initiating treatment during early developmental stages to optimize outcomes. The findings also suggest that early diagnosis and initiation of treatment using the Ponseti method contributed to favourable outcomes at the end of the corrective phase.

The Ponseti Method yielded favorable outcomes for clubfoot treatment at the conclusion of the corrective phase. However, the maintenance (bracing) phase is characterized by poor adherence and significant patient attrition. To address high dropout rates, this study proposes implementing targeted strategies, such as mobile health follow-ups and community-based educational initiatives, aimed at enhancing treatment compliance and reducing patient loss during follow-up.

Emphasis should be placed on reinforcing treatment adherence during the maintenance phase to ensure lasting treatment outcomes and facilitate early detection and effective treatment of relapses. Additionally, long-term follow-up studies may prove beneficial for evaluating the clinical outcomes of children with ICF treated using the Ponseti Method in later years.

Study constraints

This study relied on a retrospective examination of records, which was significantly influenced by the thoroughness and accuracy of the paper documentation used for data collection at the medical facility. Some result sections had varying numbers because of incomplete information in certain records.

The Pirani score was used as the primary assessment tool for all patients. However,

this scoring system has not been validated for the evaluation of clubfoot in individuals over two years of age. The treatment outcome was primarily determined by the Pirani score at the conclusion of the corrective phase; however, this may not accurately reflect the actual physical and functional condition of patients' feet

Recommendations

- Implementing a digital electronic patient record-keeping system would enhance data accuracy and consistency.
- Establishing a dedicated clubfoot registry could improve data quality and facilitate better monitoring of patients undergoing treatment.
- Extended follow-up evaluations to assess patients' physical and functional progress post-treatment are essential for tracking long-term outcomes.
- Strategies should be implemented to reduce patient dropout rates and improve treatment adherence. Educating patients about the potential consequences of non- compliance may discourage the early abandonment of treatment.
- Additional research is necessary to examine the specific causes of patient dropout, particularly during the maintenance stage, to enable the implementation of appropriate, tailored support systems.

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ADDENDUM

1. Data Collection Tool

Clinic data:

Patient study number: ________

Evaluation date: ___________/______/______

Healthcare worker: Surgeon / Medical officer / Physiotherapist / Nurse

---

Patient data:

DOB: ___________/______/______ Gender: Male / Female

Family history: Yes / No If yes specify relationship: ______________

Address: ____

Home language: ________________________

Affected side: Unilateral / Bilateral Left / Right

Birth history: ____

Medical history: ____

Surgical history: ____

X-rays done: Yes / No

Physical examination:

Spine: ______________________ Neurology: ______________________

Hip: ________________________ Lower extremities: ________________

Upper extremities: ______________________

Developmental Milestones:

Gross motor: __________________ Fine motor: __________________

Language: ____________________ Social/Cognitive: ______________

Clubfoot diagnosis:

Idiopathic clubfoot: [ ] Syndromic/Neuropathic clubfoot: [ ]

Metatarsus adductus: [ ] Recurrent clubfoot: [ ] Postural / positional clubfoot: [ ] Neglected clubfoot: [ ]

____

Treatment data:

Age at which clubfoot was first noticed: ______

Referred to clinic by: Parent / Surgeon / Medical officer/ Nurse /Physiotherapist Age at which patient referred to clinic: _______

Previous clubfoot treatment; Y / N ,if yes age: _____

Where did patient receive treatment: ____________________________

Specify the type of treatment received, number of casts, and surgery

____

Initial treatment date: _____/_____/_____ Initial treatment age: ______

Initial Pirani score: _______

Treatment complication: Yes / No

If yes specify:____

Total number of clinic follow ups: ______ Total number of cast: ______

Tenotomy: Yes / No ,if yes age: ______ Pirani score: ________

Tenotomy complication: Yes / No

If yes specify: ____

Brace: Yes / No ,if yes age: ______ Pirani score: ________

Bracing details : hours ______ / days ______

Bracing Duration: ________________ Brace shoe size: ________

Bracing compliance: Yes / No

If yes specify: ____

Bracing complication: Yes / No

If yes specify:

____

Latest clinic date: ______/______/______ Age: ______

Latest Pirani sore: _______

Is patient walking independently: Yes / No

If no, is an assistive devices or walking aid used: ______________________

2. Data analysis table

Objective	Variables	Type of data	Data analysis
To establish the demographic profile of patients with clubfoot treated at the selected Ponseti Clinics between 1st January 2016 and 31st December 2021.	Gender	Categorical data,	Percentages and Frequencies
	Age	Numerical data	Mean and standard deviation Frequencies and percentages
	Family history of clubfoot	Categorical data	Frequencies and percentages
	Foot affected	Categorical data	Frequencies and percentages
	Initial Pirani Scores	Numerical data	Mean, SD
	Type of clubfoot	Categorical data	Frequencies percentages
	Pirani score at Initial Bracing	Numerical data	Mean, Standard deviation
	Length of patient follow-up	Numerical data	Mean, Standard deviation
	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, Standard deviation

3. Letter from DRC

UNIVERSITY OF CAPE TOWN

Department of Surgery
Departmental Research Committee
A/Prof Maritz Laubscher
Groote Schuur Hospital
Observatory 7925
South Africa
Tel (021) 404 5108
Email: maritz.laubscher@uct.ac.za

16 Oct 2022

DR L Hlongwane

Department of Surgery
University of Cape Town

Dear DR Hlongwane

RE: Project 2022/096

PROJECT TITLE: Socio-Epidemiologic Characteristics And Outcomes Of Children With Idiopathic Clubfoot At A Rural District Hospital In South Africa—A Retrospective Observational Study On 5 Years Of Consultations At The Outpatients Clubfoot Clinic

The above protocol has been reviewed by the Department of Surgery Research Committee. I am pleased to inform you that the committee approved the scientific merit of the study, and endorse the protocol for submission to the relevant ethics committee.

Although this letter serves as confirmation that the above protocol has successfully passed through the surgical DRC, respective ethics committees still require DRC chair signature before submission.

Please use the above project number in all future correspondence,

A/PROF MARITZ LAUBSCHER
CHAIR SURGICAL DRC

"OUR MISSION is to be an outstanding teaching and research university, educating for life and addressing the challenges facing our society."

4. HREC Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room 45 E-52-E-Floor- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-submissions@uct.ac.za
Website: www.health.uct.ac.za/home/human-research-ethics

28 November 2022

HREC REF: 770/2022

Prof S Maswime
Department of global Surgery
Email: Salome.maswime@uct.ac.za
Student: dr.lhlongwane@gmail.com

Dear Prof Maswime

PROJECT TITLE: SOCIO-EPIDEMIOLOGIC CHARACTERISTICS AND OUTCOMES OF CHILDREN WITH IDIOPATHIC CLUBFOOT AT A RURAL DISTRICT HOSPITAL IN SOUTH AFRICA—A RETROSPECTIVE OBSERVATIONAL STUDY ON 5 YEARS OF CONSULTATIONS AT THE OUTPATIENTS CLUBFOOT CLINIC-
(MASTERS CANDIDATE-DR LETHABO HLONGWANE)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, subject to providing Form A for this study.

Approval is granted for one year until the 30 November 2023.

Please submit a progress form, using the standardised Annual Report Form (FHS016) if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Lethabo Hlongwane will also be involved in this study.

Please quote the HREC REF 770/2022 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

HREC/ref 770.2022

Federal Wide Assurance Number: FWA00001637. Institutional Review Board (IRB) number: IRB00001938 NHREC-registration number: REC-210208-007
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2020), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

5. Letter of approval CEO

No.3, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel l: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo | Departement van Gesondheid | UmNyango WezeMaphilo

Letter of Support (To be signed by relevant Senior Managers/Responsibility Managers)

1. Study Details	
1.1 Name of Applicant	Lethabo Hlongwane
1.2 Contact Number:	**(0)** 769800641
1.3 Study Title:	Socio-epidemiologic Characterisitics and Outcomes of children with Idiopatic Clubfoot at a rurual district hospital in South Africa. A
1.4 Data collection period to undertake the study:	**Start:** 30 November 2022 **End:** 20 November 2023

1.5 Provide summary **of the study, study area,** and how data will be collected (**your response** should not be more than the space **provided:**

This study is aimed to assess the socio-epidemiologic characteristics and treatment outcomes of children with Idiopatic Clubfoot who were treated at the Tintswalo Hospital clubfoot clinic in rural south africa over a five-year period. This is a retrospective observational study analyzing the records of children aged 1–60 months who were treated with the Ponseti method between 2016 and 2021. Data on demographics, treatment progress, and outcomes will be gathered using a standardized tool. Descriptive statistics and proportions will be calculated utilizing statistica software. Data from individual patient treatment records was entered onto a data collection tool designed by the researcher.

2. Resources Required from Facility/Sub-district/Community		
2.1 Facility Staff Required to assist with the Study	**Yes** ☐ **How many:** Nurses: Doctors: Space: Other, please specify: none	**NO** ●
2.2 Patients / Researchers' Records/Files	**Yes** ● Year: From: To:	**NO** ☐
2.3 Interviewing Patients/ participants at Facilities	**Yes** ☐	**NO** ●
2.4 Interviewing Patients/ participants at Home	**Yes** ☐	**NO** ●
2.5 Other, please specify:		

3 Resource flow/benefits to the Provincial Department		
3.1 The research is responsive to which National/Provincial/departmental priority/strategy/research agenda. • **State your response:** None, this is a purly academic research study.		
3.2 Resource Flow (Are there benefits to Patients/community)	**Yes** ☐ Please list: all potential remedial ideas emanated from research will be taken up for healthcare practice and policy	**NO** ●
3.3 Resource Flow (Are there benefits to Facility/District)	**Yes** ☐ Please list: to create a linkage between all research stakeholders	**NO** ●

4 Availability of Required Clearance/s			
4.1 Ethical Clearance	**Yes** ● Clearance Number: 770/2022	**Pending** ☐	**NO** ☐
4.2 Clinical Trial	**Yes** ☐ Clearance Number: 770/2022	**Pending** ☐	**NO** ●
4.3 Vaccine Trial	**Yes** ☐ Clearance Number: 770/2022	**Pending** ☐	**NO** ●
4.4 Is conducted in a village led by tribal authority?	**Yes** ☐ Date tribal authority engaged:	Not Applicable ☐	**NO** ●

5 Declaration

Declaration by Applicant:

I Mr/Ms/Dr/Prof/Adv. Lethabo Hlongwane agree to submit/present the result of this study back to the CEO/Institution/District.

Estimated date of feedback: 1 June 2025

To be signed by a relevant CEO/District Manager/Programme Manager/Senior Manager in Mpumalanga Province

Supported / Not Supported

Signature:

Date: 17-01-2025

Name: __

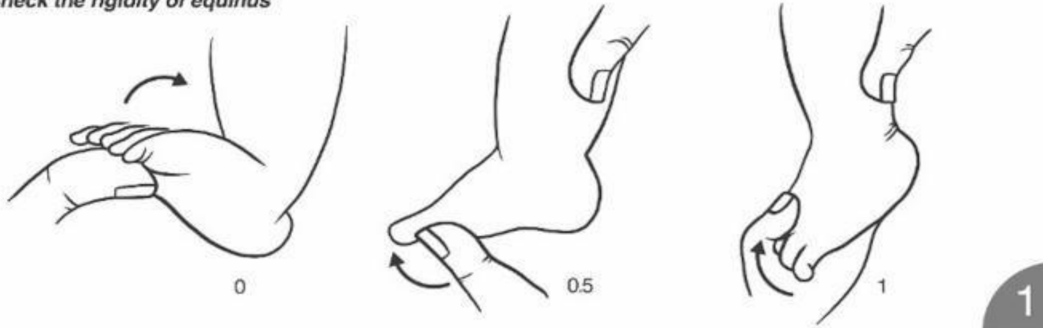
Stamp

A duly signed form can be uploaded on the nhrd website by the researcher or emailed to: JerryS@mpuhealth.gov.za or ThembaM@mpuhealth.gov.za

6. Pirani score

MOVE

Check the rigidity of equinus

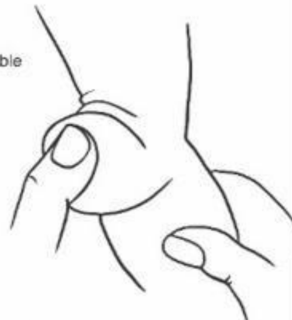


1

FEEL

The heel

0 Tuberosity palpable
0.5 Tuberosity partially palpable
1 Tuberosity non palpable

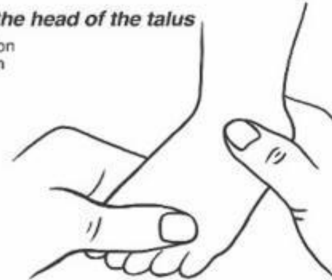


2

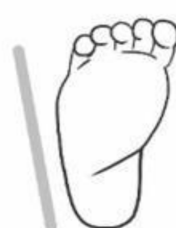
FEEL

Lateral part of the head of the talus

0 Complete reduction
0.5 Partial reduction
1 Fixed subluxed



3

EVALUATE	Normal 0	Moderate 0.5	Severe 1
Curvature of lateral border (4)			
Medial plantar crease (5)			
Posterior ankle crease (6)