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The Clinical Effectiveness of the Dennis Browne Splint for the Management of Idiopathic Clubfoot in the Eastern Cape: A Retrospective Cohort Clinical Evaluation

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Abstract

Background/Objectives: Congenital Talipes Equinovarus (CTEV) is a prevalent musculoskeletal deformity requiring precise management to prevent lifelong disability. While the Ponseti method and Dennis Browne Splint (DBS) are global standards, relapse remains a critical challenge in resource-constrained regions like the Eastern Cape. This study aimed to evaluate the clinical effectiveness of the DBS in maintaining foot correction, preventing relapse, and promoting functional mobility in paediatric patients post-Ponseti treatment at two Eastern Cape hospitals. **Methods:** A retrospective clinical evaluation was conducted of the medical records of 33 paediatric patients (51 feet) aged 2–12 months, diagnosed with idiopathic clubfoot. Participants were sampled from Frere Tertiary Hospital (n=23) and Bedford Orthopaedic Hospital (n=10). Outcome measures included changes in Pirani scores and goniometric dorsiflexion angles. Adherence was categorised by follow-up frequency, and qualitative clinical notes were reviewed to identify systemic barriers to successful bracing. **Results:** The Frere Hospital cohort showed a statistically significant improvement in Pirani scores, decreasing from a mean of 4.20 (±0.90) to 0.59 (±0.47) ($p < 0.001$), with a relapse rate of 13%. In contrast, the Bedford Hospital cohort exhibited non-significant improvements and a 50% relapse rate. Adherence was strongly associated with outcomes; patients with high follow-up frequency achieved significantly better correction. Systemic factors, including fitting errors and supply chain issues, were identified as primary drivers of poor outcomes. **Conclusions:** The DBS is biomechanically effective for maintaining correction, but its clinical success is highly contingent on systemic support, practitioner expertise, and caregiver adherence.

Keywords: clubfoot; Dennis Browne Splint; paediatric rehabilitation; eastern cape

1. Introduction

Congenital Talipes Equinovarus (CTEV), or idiopathic clubfoot, remains one of the most common congenital orthopaedic deformities globally. Worldwide, between 150,000 and 200,000 babies are born with clubfoot each year; a significant contribution to this figure comes from low- and middle-income countries [1–4]. The global incidence rate is estimated at 1.18 per 1000 live births [4], while in South Africa, there is no exact local incidence, but estimates suggest it is within or slightly above the global rate, ranging from 1.1 to 1.5 per 1000 live births [2–4]. The deformity is characterised by a complex three-dimensional malalignment of the foot, involving cavus, adductus, varus, and equinus components.

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The development of idiopathic clubfoot reflex is a complex interplay of genetic susceptibility and in-utero environmental exposures, broadly consistent across global and South African settings. Epidemiologic and meta-analytic studies indicate that a positive family history confers approximately a 7- to 8-fold increase in risk, highlighting a strong component of heritability [5,6]. These studies supported the findings of Werler et al. (2013) of a strong association with primiparity, with firstborn babies at higher risk of being affected than second and third borns. Beyond these non-modifiable traits, maternal health and environmental factors during pregnancy make a significant contribution to aetiology. Mothers who smoke during pregnancy, and exposure to nicotine remains one of the most important modifiable risk factors, increasing the likelihood of clubfoot development in fetuses by approximately 1,5 to 2,0 fold in pooled analyses and case-controlled studies [5,6,8]. Collectively, the genetic, demographic and pregnancy-related drivers provide a plausible aetiological framework for the observed birth prevalence and incidences of clubfoot in South Africa, which is comparable to, and in some settings higher than, estimates reported in African low and middle-income countries [2–4]

When left untreated, clubfoot does not correct spontaneously, but persists into adulthood, leading to significant disability, impaired mobility, pain, social disadvantage and reduced quality of life [9,10], which validates the need for treatment tracking to identify early relapse, neglected deformities, and recurrence [11–13]. Children with clubfoot often walk on the lateral border or dorsum of the foot, with severe gait disturbance, difficulty walking, and reduced mobility [13,14] These consequences of untreated clubfoot extend to uneven loading during gait, predisposing to progressive joint stiffness and early joint degenerative changes, with long-term functional limitations and pain [15,16]. In low- and middle-income countries, treatment has been shown to significantly improve mobility, mental health, social inclusion, and education indices compared with the counterfactual of no treatment [17].

For the treatment of clubfoot, the Ponseti method of serial casting and manipulation has been widely established as the gold standard for initial correction for decades, with success rates exceeding 90% [12,18,19]. When started early, especially in the first year of life, serial manipulation and casting, plus Achilles tenotomy followed by foot abduction bracing, achieve initial correction in ~90–98% of idiopathic clubfeet [20–22]. However, the long-term success of clubfoot management is critically dependent on the subsequent bracing phase, which maintains the correction and prevents relapse. Non-adherence to this bracing protocol is the most cited risk factor for recurrence, with relapse rates in low- and middle-income countries (LMICs) reaching up to 22.8% [23,24].

The Dennis Browne Splint (DBS) is often preferred post-Ponseti as a static abduction brace and is widely used in South African public hospitals as the primary post-Ponseti orthotic device. While its biomechanical principles are sound, involving sustained abduction and dorsiflexion to maintain correction [16], its real-world effectiveness is mediated by a complex interplay of clinical, behavioural, and systemic factors. These include correct brace fitting, caregiver education, socio-economic status, and access to consistent follow-up care [2]. Optimal support models, such as education packages, follow-up schedules, and cost subsidies, that are key to improving adherence to DBS in resource-constrained settings, are not yet well defined. Understanding the efficacy of DBS in the Amathole and OR Thambo regions of the Eastern Cape, including the behaviours and systemic barriers that contribute to adherence and non-adherence, is key to the future development of support models and frameworks for the public health care system.

The Eastern Cape province, characterised by its rurality and resource constraints, presents unique challenges for clubfoot management. Despite the widespread use of DBS in hospitals such as Frere and Bedford Orthopaedic Hospital, there is a conspicuous lack of localised, empirical data on its clinical outcomes. This study sought to bridge this data gap by providing a systematic evaluation of the DBS's effectiveness in this specific context. The study aimed to evaluate the clinical efficacy of Dennis Browne splints (DBS) in maintaining foot correction and preventing relapse in paediatric patients post-Ponseti treatment at two hospitals in the Eastern Cape, serving the Amathole and OR Thambo districts. We hypothesised that consistent DBS use would lead to lower relapse rates and

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improved functional mobility compared to inconsistent use. Furthermore, the study sought to assess functional mobility outcomes through dorsiflexion measurements and to identify contextual and systemic issues influencing treatment adherence and success in these resource-limited settings.

2. Materials and Methods

Study Design and Setting

A retrospective clinical evaluation design conducted for paediatric patients with Idiopathic congenital clubfoot deformity who underwent Dennis Browne splint (DBS) treatment after the Ponseti method. The study was conducted at two public hospitals in the Eastern Cape: Frere Hospital in East London, an urban tertiary institution, and Bedford Orthopaedic Hospital in Mthatha, a semi-rural hospital.

Hypothesis

It was hypothesised that the Dennis Browne Splint would be clinically effective in maintaining structural correction and promoting functional mobility in post-Ponseti patients, provided there was high treatment adherence.

Study Population and Sampling

The target population for this study comprised of paediatric patients, who are between 2 and 12 months old, diagnosed with idiopathic clubfoot, who completed the Ponseti serial casting phase and were prescribed a DBS. A non-probability purposive sampling technique was used to include a total of 33 participants (51 feet): 23 from Frere and 10 from Bedford. Patients with secondary clubfoot or incomplete medical records with 6 months of missing data were excluded.

Study Procedures and Outcome Measures

The data was extracted retrospectively from clinical files containing practitioner-recorded assessments:

- Structural Correction (Primary Outcome): The Pirani Scoring System was used to assess foot deformity, where scores range from 0 (normal) to 6 (severe).
- Relapse Definition: For the purpose of this evaluation, relapse was identified based on clinical notes and rising Pirani scores indicating a loss of initial correction.
- Functional Outcome: Goniometer measurements recorded by an orthopaedic surgeon were used to measure active and passive ankle dorsiflexion. A "functional range" was interpreted as normalising these angles away from excessive dorsiflexion associated with deformity.
- Adherence Categorisation: Adherence was assessed by the frequency of follow-up visits and categorised as Low (0–5 visits), Moderate (6–9 visits), or High (≥ 10 visits).
- Qualitative Data: A qualitative review of practitioner clinical notes was performed to identify specific barriers to adherence, such as fitting errors or socio-economic constraints.

Statistical Analysis

Data were analysed using IBM SPSS Statistics (Version 30.0).

- Intra-group Analysis: Paired t-tests compared pre- and post-intervention Pirani scores and dorsiflexion angles within each cohort.
- Inter-group and Association Analysis: Descriptive statistics summarised adherence levels. Fisher's exact test examined associations between adherence categories and relapse rates, while the contrast between hospital outcomes was evaluated through comparative descriptive analysis.
- Missing Data: In cases of incomplete entries, such as missing goniometric data in the Bedford records, analysis was limited to the available subsets.

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- A p-value of <0.05 was considered statistically significant.

Ethical Considerations

Ethical approval was obtained from the Walter Sisulu University Health Research Ethics Committee (Ref: WSU HREC 017/2015) and the Eastern Cape Department of Health (Ref: EC_202506_022). Site-specific approvals were granted, and patient confidentiality was maintained through data anonymisation. The data used in this study are available upon reasonable request from the corresponding author, subject to ethical clearance and institutional data-sharing agreements.

GenAI Disclosure

Generative AI was used for superficial text editing, including grammar, spelling, punctuation, and formatting of this manuscript.

3. Results

Demographic and Clinical Characteristics

A total of 33 pediatric patients with idiopathic clubfoot, 51 feet in length, were included in the study, including 23 from Frere Hospital and 10 from Bedford Orthopaedic Hospital. The cohort from Frere Hospital was notably older, with a mean age of 10.61 months (±1.59 SD), compared to the Bedford cohort, which had a mean age of 5.20 months (±2.86 SD). Male patients constituted the majority in both settings, representing 60.9% of the Frere group and 70% of the Bedford group. Regarding the laterality of the deformity, bilateral clubfoot was the most common presentation, affecting 56.5% of patients at Frere and 50% at Bedford. Unilateral involvement was also observed, with right-sided cases at 26.1% (Frere) and 40% (Bedford), and left-sided cases at 17.4% (Frere) and 10% (Bedford). Tables 1 &2 below show a representation of the data.

Table 1. Patient demographics in Frere Provincial Hospital.

Variable	Category / Statistic	n (%) / Mean ± SD
Age (months)	Mean ± SD	10.61 ± 1.59
Gender	Male	14 (60.9%)
	Female	9 (39.1%)
Affected side	Right	6 (26.1%)
	Left	4 (17.4%)
	Bilateral	13 (56.5%)

Table 2. Patients demographics in Bedford Orthopaedic Hospital.

Variable	Category / Statistic	n (%) / Mean ± SD
Age (months)	Mean ± SD	5.20±2.86
Gender	Male	7 (70%)
	Female	3 (30%)
Affected side	Right	4 (40%)
	Left	1 (10%)
	Bilateral	5 (50%)

Clinical Effectiveness: Structural Correction (Pirani Scores)

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The results demonstrated a stark contrast in clinical outcomes between the two hospitals. Tables 3 & 4 below show the clinical outcomes.

At Frere Hospital, a statistically significant improvement was observed. The mean Pirani score decreased from 4.20 (±0.90) to 0.59 (±0.47), with a mean difference of 3.61 ($p < 0.001$). The relapse rate was 13%. Bedford Hospital, which showed less improvement and was not statistically significant. The mean Pirani score decreased from 2.6 (±1.47) to 1.20 (±1.27), with a mean difference of 1.44 ($p = 0.108$). The relapse rate was 50%. Qualitative notes cited brace placement at a wrong angle and the unavailability of splints as contributing factors.

Table 3. A comparison of the Pirani score between pre- and post-Ponseti in Frere Provincial Hospital.

Score	Mean (SD)	95%CI for Mean	Min–Max	Mean Difference (95% CI)	p-value
Pre-Pirani score	4.20 (0.90)	3.81–4.59	3.00–6.00	—	—
Post-Pirani score	0.59 (0.47)	0.38–0.79	0.00–2.50	—	—
Change	—	—	—	3.61 (3.20–4.02)	0.000

Table 4. A comparison of the Pirani score between the pre- and post-Ponseti treatment in Bedford Orthopaedic Hospital.

Score	Mean (SD)	95% CI for Mean	Min–Max	Mean Difference (95% CI)	p-value
Initial Pirani score	2.6(1.47)	1.59 -3.69	0.5–4.5	—	—
Final Pirani score	1.20 (1.27)	0.29–2.11	0.0–3.5	—	—
Change (Initial–Final)	—	—	—	1.44 (-0.39-3.27)	0.108

Functional Mobility Outcomes (Dorsiflexion Angles)

A subset of 18 patients from Frere Hospital with complete goniometer data was analysed. A statistically significant change in dorsiflexion was found. The mean dorsiflexion decreased from 49.78° (±17.91) pre-treatment to 40.44° (±8.62) post-treatment ($p = 0.043$). This reduction indicates a normalisation towards a functional range, moving away from the excessive dorsiflexion sometimes permitted by uncorrected deformity. Table 5 shows the data as interpreted.

Table 5. The dorsiflexion angle before and after treatment (DBS) in the Frere Provincial Hospital corhot.

Dorsiflexion	Mean (SD)	95% CI for Mean	Min–Max	Mean Difference (95% CI)	p-value
Pre-treatment dorsiflexion (°)	49.78 (17.91)	40.87–58.69	30.0–90.0	—	—
Post-treatment dorsiflexion (°)	40.44 (8.62)	36.16–44.73	30.0–60.0	—	—

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Change	—	—	—	9.33 (0.34–18.33)	0.043

Association Between Adherence and Relapse

High adherence (≥10 visits): 47.8% of patients; relapse rate 9.1%, moderate adherence (6-9 visits): 43.5% of patients; relapse rate 20.0%, low adherence (0-5 visits): 8.7% of patients; relapse rate 0%. Despite a trend suggesting better outcomes with higher adherence, statistical tests found no significant association between adherence category and final Pirani score (p=0.857), final dorsiflexion (p=0.450), or relapse rate (p=0.689), likely due to the small sample size.

Table 6. categorisation of patient adherence according to the number of clinic visits.

Adherence category	**n (%)**	**Mean Final Pirani score (SD)**	**Mean Final Dorsiflexion ± (SD)**	**Relapse n (%)**
Low (0–5 visits)	2 (8.7%)	0.50 (0.00)	36.00 (—)	0 (0.0%)
Moderate (6–9 visits)	10 (43.5%)	0.65 (0.67)	37.71 (7.11)	2 (20.0%)
High (≥ 10 visits)	11 (47.8%)	0.55 (0.27)	42.80 (9.61)	1 (9.1%)
Total	23 (100%)	0.59 (0.47)	40.44 (8.62)	3 (13.0%)
p-value (ANOVA / Fisher) *	—	0.857	0.450	0.689

** p-values represent: ANOVA test for Final Pirani and Final Dorsiflexion. Fisher's exact test for Relapse.*

Qualitative data from Bedford (Table 7, Figure 1) provided crucial context, highlighting reasons for non-adherence such as "transport is costly," "skin lesion patient stopped wearing," and "wears shoes without bar."

Table 7. Patient compaints as stated in the files.

REASON	CASE NUMBER	PATIENT DETAILS
BRACE ISSUES	3	Brace placed at the wrong angle.
		Unavailability of splints
		Shoes are adjusted in the wrong position.
PATIENT COMPLIANCE ISSUES	2	Skin lesion patient stopped wearing the brace; transport is costly.
		Wears shoes without a bar; the shoes are bigger.

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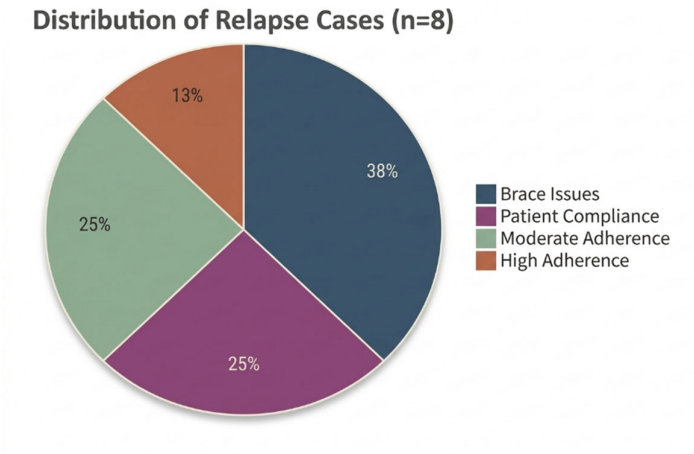

Figure 1. The distribution of relapse cases based on reasons for non-adherence.

In summary, the findings presented in this chapter illuminate both the clinical efficacy and the contextual contingency of the Dennis Browne Splint (DBS) in the management of idiopathic clubfoot among paediatric patients in the Eastern Cape. Quantitative analyses from Frere Hospital demonstrated marked reductions in Pirani scores and measurable improvements in dorsiflexion, affirming the device's biomechanical capacity to sustain post-Ponseti correction and enhance functional mobility. By contrast, the Bedford Hospital dataset revealed a heterogeneous pattern of outcomes characterised by high relapse rates and inconsistent adherence, largely attributable to procedural errors, resource constraints, and limited caregiver education. These two contexts underscore a pivotal insight: the DBS functions effectively not as an isolated biomedical intervention but as a component of an interdependent system shaped by technical fidelity, adherence behaviour, and institutional support. Figure 1 shows that, together, these findings confirm the study's central argument that orthotic effectiveness in paediatric rehabilitation is determined as much by the social and organisational ecology of care as by the device's material design.

4. Discussion

4.1. Overview

The study sought to evaluate the clinical effectiveness of the Dennis Browne splints within two contrasting healthcare settings in the Eastern Cape province of South Africa. The findings reveal a strong context-dependent pattern in outcomes. The discrepancy in the number of study participants between the two settings may be a cause for concern, indicating delayed clubfoot treatment or under-reporting. Across all study objectives, the findings reaffirm the established effectiveness of the combined Ponseti and DBS treatment sequence in achieving and maintaining correction; however, this efficacy was not uniform across the two settings. Frere Provincial Hospital demonstrated significant clinical improvements and a reduced relapse rate, whereas Bedford Hospital (an orthopaedic unit of the Nelson Mandela Academic Hospital) exhibited poorer outcomes and a higher relapse rate. A central insight of the study emerged from the observed divergence in clinical outcomes, that the biomechanical design of orthotic devices does not solely determine success; however, a complex interplay of environmental factors, systemic barriers, and patient education may determine successful intervention.

4.2. Biomechanical Efficacy and Clinical Outcomes

The findings from Frere Provincial Hospital demonstrate that the DBS is a biomechanically effective orthotic intervention in achieving structural correction. A significant mean reduction in Pirani scores was observed at Frere Provincial Hospital (average difference = 3.61, $p < 0.001$),

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consistent with outcomes reported in literature [23,25], indicating that DBS effectively maintains foot alignment and prevents relapse when applied correctly.

The DBS not only improves structural correction but also provides functional benefits to the ankle-foot complex. This was evident in the findings of this study, reporting an improvement in the ankle dorsiflexion angle of approximately 9 degrees. This method of tracking clinical outcomes has been validated by [26,27], identifying goniometry as a reliable tool for range of motion assessment in resource-limited contexts. Functionally, the improvements in ankle mobility and early ambulation are similar to those reported by Yu-Bin Liu (2018), who found that children who commence Ponseti-based bracing at younger ages experience fewer developmental delays. However, there is consensus amongst researchers that DBS is not primarily intended for correction, but rather remains a crucial orthotic device for maintaining the structural correction achieved through repetitive casting and thereby preserving ankle function[21,28,29]. The apparent improvements in ankle structure/mobility observed in this study may reflect better baseline correction and broader functional assessments within modern Ponseti-based protocols, rather than a new corrective role for the DBS. Importantly, the Frere Provincial Hospital cohort demonstrated the feasibility of achieving clinical outcomes comparable to those in high-income countries under optimal conditions. However, the positive outcomes were not reproducible in Bedford Orthopaedic Hospital, indicating that biomechanical effectiveness alone does not guarantee clinical success.

4.3. Socio-Structural Barriers: Rurality, Poverty, and Distance

The disparity in clinical outcomes between Frere Provincial Hospital and Bedford Orthopaedic Hospital findings foregrounds the contextual fragility of biomedical interventions. The high relapse rate at Bedford mirrors the challenges outlined by Dreise et al. and Testa et al. [22,30], who reported that delayed bracing initiation and inconsistent follow-up in remote areas of low- and middle-income countries diminish long-term outcomes. This contextual dependency aligns with the findings of an audit conducted in Bangladesh [31], which identified socio-economic barriers and health system limitations as major impediments to consistent adherence.

These studies further reported that non-adherence was the most significant determinant of relapse, often linked to socio-economic disadvantage and long distance from nearest care centres. These contextual factors were replicated in the current study, in which guardians frequently discontinued brace use, citing logistical and financial constraints, such as transport costs. This idea echoes the findings of the study by Manxusa and Botha [32], which show that this population is dependent on government grants, thereby further restricting health-seeking initiatives because the grants are insufficient. This is the reality of patients living in rural settings; however, in Tanzania, decentralisation of healthcare services has improved adherence by 50% and indicates that distance to the hospital is a leading predictor ofon-adherence [33]. The decentralisation of orthotics and prosthetics services is an ongoing activity in Amathole and OR Thambo districts through outreach programs. The difference may be in the frequency of these visits and how often the DBS needs to be changed. Further, the provincial department of health offers free patient transport for public health care; however, the findings suggest logistical issues that exacerbate the effects of rurality, poverty, and distance.

This finding aligns with a study by Manxusa and Botha [32], who indicate that in rural Eastern Cape communities, structural barriers such as inaccessible infrastructure, inadequate transport, and reliance on scarce disability grants limit access to crucial health and rehabilitation services for individuals living with disabilities. These intersecting barriers compound patterns of exclusion and diminish opportunities for sustained engagement with healthcare systems.

4.4. Contextual Variability in Clinical Outcomes

The stark contrast in findings between Frere Provincial Hospital and Bedford Orthopaedic Hospital is the most critical finding of this study. While Frere Provincial Hospital demonstrated a statistically significant improvement and a low relapse rate (13%), Bedford Orthopaedic Hospital

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showed a non-significant improvement in the Pirani score ($p = 0.108$) and a markedly higher relapse rate (50%). The observed difference between the two settings highlights the key principle that the same othotic device can yield varying outcomes depending on the systemic and clinical context. The high relapse rate (50%) and lack of significant improvement at Bedford were not due to device inefficacy but to systemic failures, including technical errors such as incorrect brace fitting and alignment. The study's findings thus confirm that, while the DBS is biomechanically effective, its real-world success is mediated by systemic and behavioural determinants, such as adherence to device-specific fitting guidelines and caregiver understanding.

Clinical notes from Bedford hospital resonate with the adherence literature of Smythe et al.[2], which emphasised that education and caregiver reassurance are important for sustaining compliance. Collectively, these points confirm that under optimal clinical and behavioural conditions, the DBS yields outcomes equivalent to those achieved in high-income settings.

5.4. Systemic Barriers: Supply Chain and Brace Access

The scope of this study, however, limited its ability to identify the systemic issues affecting the supply chain in Bedford, such as DBS running out of stock. This limitation is important because the poor clinical outcomes and high relapse rate observed in the Bedford Orthopaedic Hospital cohort could partly be explained by these system-level issues. It is alarming that two hospitals in the same province can have varying issues. South African researchers have identified abrupt decentralisation, which has expanded primary care in rural districts, but clinical capacity and staffing vary across space, affecting how well supply systems function locally [34,35]. This finding, together with studies from other LMICs, is consistent with the identification of these systemic factors as primary determinants of treatment failure [36,37]. When the system fails to provide accessible, well-fitting braces and education, factors that influence adherence, this leads to non-compliance and relapse. In this study, the unavailability of DBS or its components may have disrupted continuity of care, particularly post-Ponseti management, thereby increasing the risk of relapse. Long-term adherence to the Ponseti–DBS treatment sequence in sub-Saharan Africa depends on sustained patient education, accessible services, and the availability of trained clinicians. These findings highlight the need for improved supply chain coordination and institutional support to ensure that orthotic devices are consistently delivered across facilities.

5.5. Reconceptualising Adherence in Resource-Limited Settings

Adherence has been defined solely on the basis of behavioural choices such as wearing the DBS for the prescribed duration, ensuring proper fit, and attending follow-ups, which identify the caregiver as the sole responsible person. Following this definition positions Bedford as a facility with a high number of "drop out" patients, while Frere has demonstrated high adherence. The findings from both sites affirm that adherence is the principal determinant of treatment durability. High adherence correlates with sustained correction, improved range of motion, and minimal relapse, as exemplified by the Frere cohort. Low adherence driven by discomfort, technical errors, and socio-economic constraints precipitates relapse and functional regression, as evidenced in Bedford.

While the quantitative analysis did not show a statistically significant link between visit frequency and relapse, the clinical trend and qualitative evidence strongly support the established principle that adherence is pivotal [38]. This lack of statistical significance is likely attributable to the small sample size rather than the absence of a meaningful relationship between adherence and treatment outcomes[39].

The Bedford data illustrate that adherence is not merely a behavioural choice but a consequence of systemic support. Adherence serves as the critical bridge between the DBS's biomedical mechanism and the realised therapeutic outcome. Current findings are consistent with broader evidence that the major challenge of non-compliance typically arises after the short-term corrective phase has been completed, when treatment shifts from being supervised to long-term self-management [40].

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5. Conclusions

The Dennis Browne Splint is a clinically effective orthotic intervention for maintaining clubfoot correction in the Eastern Cape when implemented within a supportive clinical system. Its ability to prevent relapse and promote functional mobility is proven in contexts of technical competence and consistent follow-up, as demonstrated at Frere Hospital. However, its effectiveness is severely compromised by systemic barriers, including supply shortages, fitting errors, and socio-economic challenges, as evidenced at Bedford Hospital. Therefore, the DBS's success is not guaranteed by its design alone but is contingent on the strength of the health system that supports its use.

5.1. Recommendations

Based on the findings, the following recommendations are proposed:

Technical Capacity Building: Implement regular, mandatory training for orthotists and technicians on proper DBS fitting and alignment. Standardise fitting protocols across the province. Supply-Chain Integration: Designate a central hub (e.g., Frere Hospital) to procure and redistribute DBS and components to peripheral hospitals (e.g., Bedford) to prevent stock-outs. Enhanced Caregiver Education: Develop and distribute simple, pictorial, and multilingual educational materials for caregivers, emphasising adherence, proper brace use, and skin care. Incorporate structured education sessions into the clinic workflow. Decentralisation of Services: Explore establishing satellite orthotic clinics in more rural areas to reduce the travel burden on families, thereby improving access and adherence.

5.2. Dissemination

The results of this study will be disseminated to the participating hospitals, the Walter Sisulu University Department of Health Sciences, and the Eastern Cape Department of Health and shared through national and international academic platforms to inform clinical practice and health policy.

5.3. Limitations

Although the present study employed a systematic and triangulated approach to assess the clinical effectiveness and adherence of the Dennis Browne Splint (DBS) in paediatric clubfoot management, several limitations must be acknowledged. These constraints, methodological, contextual, and systemic, inevitably influenced the scope, consistency, and interpretive generalisability of the findings. Recognising them enhances the transparency and credibility of the research process.

5.3.1. Contextual and Resource-Related Limitations

The comparative design across Frere Hospital (urban, tertiary) and Bedford Orthopaedic Hospital (semi-rural) provided valuable contextual contrast but also introduced heterogeneity in infrastructure, staff capacity, and follow-up systems. Frere Hospital benefited from more stable supply chains, greater practitioner continuity, and regular supervision, whereas Bedford experienced intermittent splint shortages, inconsistent technical oversight, and limited record-keeping capacity. These systemic disparities, while analytically instructive, likely affected the comparability of quantitative indicators, such as Pirani and goniometric scores, across the two settings.

5.3.2. Sample Size and Representativeness

The study ultimately analysed 33 participants, exceeding the 20-participant sample initially stated in the methodology section. This variation arose from the inclusion of additional eligible cases encountered during data verification and record auditing. While the larger sample strengthened the analysis's internal robustness, the small absolute number nonetheless constrains the results' external

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validity. The findings should therefore be interpreted as representative of these two Eastern Cape hospitals rather than generalisable to all South African paediatric orthotic contexts.

5.3.3. Data Source and Documentation Quality

A hybrid dataset that combines prospective and retrospective elements introduces additional complexity. Although the study design was largely retrospective, the Pirani and goniometer readings were drawn directly from practitioner-recorded clinical files, ensuring that the measurements reflected authentic, real-time clinical assessments rather than researcher-generated values. However, variability in practitioners' recording practices occasionally led to incomplete entries, missing measurements, or inconsistent evaluation timing, especially in Bedford's records. These inconsistencies limited longitudinal continuity and occasionally required cautious interpretation of numerical trends.

5.3.4. Temporal Scope and Follow-Up Duration

The quantitative and qualitative datasets were tracked for approximately 1 year, with up to 17 follow-up visits at Frere Hospital. Unlike monthly visits typical in other contexts, Frere and Bedford scheduled follow-ups every two to three months, resulting in extended observation intervals. The Pirani scores captured the entire correctional progression from the initiation of the Ponseti casting phase through the transition to DBS, enabling a more comprehensive evaluation of post-Ponseti maintenance. Nonetheless, while this longitudinal coverage enriched the dataset, differences in visit frequency and variable follow-up durations across patients limited comparability of progression patterns and may have affected relapse detection in later months.

5.3.5. Measurement and Observer Bias

Although standardised instruments such as the Pirani and goniometers were used, the precision of these measures depended on practitioner expertise and consistency. Differences in orthopaedic surgeons' or physiotherapists' clinical experience and interpretive thresholds may have introduced minor measurement bias. The absence of a formal inter-rater calibration protocol between hospitals further increased the risk of observer variability. Similarly, qualitative clinical notes, such as "brace placed at a wrong angle," were interpretive rather than standardised, introducing subjective variation across records.

5.3.6. Behavioural and Socio-Economic Confounders

Adherence and clinical outcomes were also shaped by unquantified behavioural and socio-economic factors such as caregiver understanding, travel cost, and perceptions of disability. These contextual influences, though visible in qualitative notes, were not systematically measured or statistically modelled. Their omission limits the ability to isolate the effects of purely clinical variables from those of social determinants of adherence. Future research would benefit from mixed-methods or ethnographic designs that integrate these dimensions quantitatively and qualitatively.

6. Patents

There are no patents resulting from the work reported in this manuscript.

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