PATIENT SPECIFIC SUPRAMALLEOLAR ORTHOSES ON GLOBAL FOOT DEVIATIONS USING 3D PRINTING

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ABSTRACT

Background:

Global foot deviations in paediatric and adolescent populations, including pes planus, pes cavus, and triplanar instability, can significantly impair gait, balance, and overall functional mobility. Conventional orthotic devices often lack customization, resulting in suboptimal fit, discomfort, and reduced patient compliance. Recent advances in additive manufacturing (3D printing) offer the potential for patient-specific orthoses with improved anatomical precision and functional outcomes.

Aim:

To evaluate the effectiveness of patient-specific 3D-printed supramalleolar orthoses (SMOs) in improving foot alignment, gait pattern, balance, and overall functional outcomes in children and adolescents with global foot deviations.

Methods:

This quasi-experimental study included 30 participants aged 2 –18 years with diagnosed foot deviations. Patient-specific SMOs were designed using 3D foot scanning and CAD modelling, and fabricated using FDM technology with TPU/Nylon materials. Pre - and post-intervention assessments were conducted using clinical parameters including Foot Posture Index (FPI-6), gait analysis, balance scores, pain (VAS), and functional limitation scales over follow -up periods.

Results:

Significant improvements were observed following intervention. The mean foot posture score improved from 7.87 ± 1.28 to 3.23 ± 0.94 ($p < 0.001$). Ankle stability improved markedly, with 73.33% achieving good stability post-intervention. Abnormal gait patterns present in 100% of participants at baseline improved, with 70% showing improvement and 30% achieving normal gait ($p < 0.001$). Pain scores reduced from 4.03 ± 1.06 to 1.50 ± 0.77, and functional limitations significantly decreased. High levels of patient satisfaction were observed in terms of comfort, fit, and ease of use.

Conclusion:

Patient-specific 3D-printed SMOs demonstrate significant clinical and functional benefits in managing global foot deviations in paediatric populations. These orthoses provide improved alignment, enhanced gait mechanics, reduced pain, and high patient satisfaction. The integration of 3D printing technology offers a promising, customizable, and effective alternative to conventional orthotic management.

Keywords:

3D printing, supramalleolar orthosis, pediatric foot deformities, gait improvement, patient-specific orthosis, pes planus, pes cavus.

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INTRODUCTION

The human foot is a mechanically complex and essential weight bearing structure, crucial for balance, locomotion, and functional independence throughout life. The foot functions as a dynamic structure that supports body weight and enables movement through coordinated joint and muscle action. Foot deformities in children are common. These include flexible flatfoot, cavus foot, and instability. Such conditions affect gait and balance. Pediatric flatfoot has been reported with high prevalence in early childhood, with some studies indicating that a significant proportion of children aged three to six years may exhibit this condition. [1]

Foot deformities in children can impair daily activities and limit participation in play and schooling, potentially leading to compensatory gait patterns and longer-term musculoskeletal complications if unaddressed.

Standard conservative management typically includes the prescription of foot orthoses to support the medial arch and redistribute pressures. However, traditional prefabricated orthoses often lack the anatomical specificity needed for individual variation and dynamic function, which can contribute to inconsistent clinical outcomes and reduced compliance in pediatric users. [2]

Heel Strike → Midstance → Terminal Stance → Toe -off Pronation → Shock absorption Supination → Rigid lever for propulsion

In clinical practice, SMOs are commonly used to control medial-lateral instability at the ankle and improve alignment. Clinically, SMOs are prescribed to address excessive pronation or supination, influence lower-limb kinematics, and promote more efficient gait mechanics. These devices have demonstrated therapeutic benefits, including reduced compensatory movements and improved postural control. However, conventional SMOs are often limited by rigidity, limited customization, discomfort at pressure points, and subsequent poor compliance, particularly among active children.

Additive manufacturing (3D printing) has emerged as a promising technology for producing customized medical devices, including foot and ankle orthoses. By using digital scanning and modelling, 3D printing allows precise anatomical fit, rapid production, and design flexibility that traditional fabrication methods cannot easily achieve. Customized orthoses fabricated through 3D printing have demonstrated advantages in comfort, fit, and potential improvements in biomechanical parameters compared to traditional orthoses. [3, 4] Evidence from integrative reviews suggests that 3D-printed orthoses improve anatomical precision, reduce production time, and may enhance patient adherence due to better comfort and personalization. [5] Recent pediatric-focused research has explored the use of 3D-printed orthoses to manage conditions such as flatfoot, with findings indicating improved function and comfort compared to conventional devices. [6] These studies support the therapeutic promise of 3D printing in orthotic care, though further research is needed to establish long-term clinical efficacy and broader application.

Despite ongoing technological advancements, a need persists for patient-specific, lightweight, and comfortable supramalleolar orthoses that improve compliance and functional outcomes in children with foot deviations. The integration of 3D printing with supplementary padding materials (e.g., gel foam) may address pressure-related discomfort while providing effective supramalleolar support. Enhancing mobility, balance, and independence in pediatric populations with developmental or neuromuscular disorders remains a central clinical goal.

AIM AND OBJECTIVES

The aim is to provide patient specific customized 3D -printed supramalleolar orthosis which supports for a variety of global foot deviations, comprising a contoured base, supramalleolar coverage, and a lightweight lattice structure along with gel foam padding over pressure points.

Objectives

Vision:

Restore good Active Daily life and Quality of life for patients suffering from global foot deviations.

Goal:

To empower patients, enhance confidence and improve the quality of life without compromising therapeutic efficacy. This study conducted in Chennai**,** a region with a diverse pediatric population affected by developmental or neuromuscular conditions. Investigating the clinical utility of 3D-printed SMOs in this context may inform more effective orthotic interventions tailored to pediatric functional needs.

MATERIALS AND METHODS

1. Study Design

This study will follow a quasi-experimental design to evaluate the effectiveness of patient-specific 3D-printed supramalleolar orthoses (SMOs) in children and adolescents with global foot deviations. The study will include pre - and post-intervention assessments to measure biomechanical, clinical, and functional outcomes.

2. Study Population

• **Age Group:** Weight-bearing children and adolescents, **2–18 years** of age.
• **Study Site:** Department of Orthopaedics, Saveetha Medical College and Hospital.
• **Sample Size:** 30 participants.
• **Study Duration:** 12 months.
• **Sampling Technique: Purposive sampling** using **3D scanning** to obtain patient-specific foot morphology.

Inclusion Criteria

- Weight-bearing children and adolescents up to **18 years** of age.
- Diagnosed with:
- Flatfoot (pes planus) or high-arched foot (pes cavus)
- Hypotonia (low muscle tone)
- Triplanar foot instability
- Inability to stand independently
- Midtoe walking or developmental delay
- Poor coordination or balance

Exclusion Criteria

-Children less than 2 years or advanced age & poor general health
-Knee flexion contractures or triceps weakness
- Severe spasticity or high muscle tone
- Foot deviations like rocker bottom foot and Ctev
-Severe toe-walking or tight heel cords/peroneal muscles.

Study Procedure

Part 1: Pre-Intervention Assessment

1. **Clinical Assessment:**
Foot posture evaluation using Foot Posture Index (FPI 6)
Muscle tone assessment (Modified Ashworth Scale)
o Gait analysis (observational or instrumented)
Balance and coordination testing (Pediatric Balance Scale or similar)
2. **3D Foot Scanning:**
Each participant's foot will be scanned in weight bearing position using a handheld 3D scanner.
Scans will capture anatomical landmarks, bony prominences, and overall foot morphology.

Part 2: Orthosis Design and Fabrication

1. **Digital Modeling:**
Import 3D scan data into CAD software (**Meshmixer, Geomagic, or Fusion 360**)
Create a contoured base shell, supramalleolar coverage, and lattice structure.
Add gel foam padding over malleoli and other pressure points.
2. **3D Printing:**
Material selection: **Nylon (PA12) or TPU** for durability and flexibility
Printing technology: **SLS or FDM**, depending on material and design complexity
Optimize orientation for structural strength and minimal post-processing
3. **Fitting and Adjustment:**
Orthoses will be fitted to participants and adjusted for comfort and proper alignment
Straps and modular components will be fine -tuned for secure attachment

Part 3: Post-Intervention Assessment

Conduct **follow-up at 1 month, 3 months, and 6 months**.
Repeat clinical assessments: FPI-6, gait analysis, balance, and patient/caregiver satisfaction.
Record **any complications, pressure sores, or device failures**.
Monitor adherence and daily wear using a patient log.

7. Outcome Measures

Primary Outcomes:
Foot posture improvement (FPI-6 score)
Ankle stability and alignment

Secondary Outcomes:
Gait pattern improvement
Balance and coordination
Patient/caregiver satisfaction (questionnaire)
Device comfort and durability

8. Data Analysis

Descriptive Statistics: Mean ± SD for continuous variables; frequency and percentage for categorical variables

Inferential Statistics:
Paired t-test or Wilcoxon signed-rank test for pre-post comparisons
P-value < 0.05 considered statistically significant
Software: SPSS v26 or equivalent

RESULTS

Table 1: Age in years

Age (years)	Frequency (n)	Percentage (%)
2–5	8	26.7
6–10	12	40
11–18	10	33.3

The table shows the age distribution of the study participants. Among the total subjects, the majority belonged to the 6 –10 years age group, accounting for 12 cases (40%), making it the most commonly represented age category. This was followed by the 11 – 18 years age group with 10 cases (33.3%). The 2 –5 years age group comprised 8 cases (26.7%), representing the least proportion of participants. Overall, the data indicate that most of the study population was within the 6–10 years age range.

Table 2: Gender

Gender	Frequency (n)	Percentage (%)
Male	16	53.3
Female	14	46.7

The table shows the gender distribution of the study participants. Among the total cases, males constituted 16 cases (53.3%), while females accounted for 14 cases (46.7%). This indicates a slight male predominance in the study population, although the distribution between males and females was relatively comparable.

Table 3: Clinical Diagnosis and Foot Deviation Profile

Foot Condition	Number of Patients (n)	Percentage (%)
Flat foot (Pes planus)	12	40
High-arched foot (Pes cavus)	4	13.3
Hypotonia	5	16.7
Idiopathic toe walking	3	10
Triplanar instability	3	10
Developmental delay	2	6.7
Poor coordination / balance	1	3.3

The distribution of primary foot conditions among the study participants is presented in the table. Pes planus (flatfoot) was the most common condition, observed in 12 patients (40%). This was followed by hypotonia in 5 patients (16.7%). High -arched foot (pes cavus) was seen in 4 patients (13.3%). Idiopathic toe walking and triplanar instability were each observed in 3 patients (10%).

Table 4: Baseline Clinical and Functional Assessment

Parameter		**Frequency/mean±SD**	**Percentage**
Foot posture		**7.87 ± 1.28**	
Ankle stability	Fair	19	63.33 %
	Poor	11	36.67 %
Gait pattern (Abnormal)		30	100
Balance		**30.73 ± 5.05**	
Pain		**4.03 ± 1.06**	
Functional limitation	Moderate	21	70%
	Sever	9	30%

The table displays the clinical parameters evaluated among the study participants. The average foot posture score was 7.87 ± 1.28, reflecting the general foot posture condition of the individuals. Concerning ankle stability, 19 participants (63.33%) exhibited fair stability, whereas 11 participants (36.67%) had poor ankle stability. All individuals (30 cases, 100%) demonstrated an aberrant gait pattern. The average balance score was 30.73 ± 5.05, indicating the individuals' balance proficiency. The average pain score documented was 4.03 ± 1.06, signifying a moderate level of discomfort.

Concerning functional limitation, the majority of participants (21 instances, 70%) exhibited moderate limitation, whilst 9 cases (30%) encountered severe functional limitation. The findings indicate that an aberrant gait pattern was consistently seen, accompanied by differing levels of ankle stability and functional limitations throughout the study sample.

Table 5: D Printing and Orthosis Design

Parameter	**Specification**
Scanning technique	3D Foot Scanner
CAD software used	Meshmixer / Fusion 360
Printing technology	FDM
Material used	TPU / Nylon PA12
Average print time	**5.2 ± 0.8 hours**
Orthosis weight	**145 ± 20 g**
Lattice structure used	Yes
Gel foam padding	Yes

The table delineates the specifications pertinent to the 3D printing and orthosis design employed in the investigation. A 3D foot scanner was employed to capture the individuals' foot morphology. The scanned data were processed and developed utilizing CAD software, including Meshmixer and Fusion 360. The orthosis was constructed via Fused Deposition Modeling (FDM) printing technology. The printing materials comprised TPU and Nylon PA12, frequently used for their flexibility and durability. The mean printing duration for each orthosis was 5.2 ± 0.8 hours. The mean weight of the orthosis was 145 ± 20 grams, rendering it comparatively lightweight for patient utilization. A lattice structure was integrated into the design to augment flexibility and strength, while gel foam padding was used to promote comfort and pressure distribution. These design qualities facilitated the creation of a tailored, lightweight, and comfortable orthotic device.

Table 6: Comparison of Pre- and Post-Intervention Parameters

Parameter		**Baseline**	**Follow up**	**P -Value**
Foot posture		7.87 ±1.28	3.23 ±0.94	<0.001
Ankle stability	Good	0 (0%)	22(73.33%)	<0.001
	Fair	19 (63.33%)	8(26.67%)	

	Poor	11 (36.67%)	0 (0%)	
Gait pattern	Improved	0 (0%)	21 (70%)	<0.001
	Normal	0 (0%)	9 (30%)	
	Abnormal	30 (100%)	0 (0%)	
Balance		42.56 ±4.86	42.56 ±4.86	<0.001
Pain		**4.03 ± 1.06**	1.50 ±0.77	<0.001
Functional limitation	Mild	0(0%)	22(73.33%)	<0.001
	Moderate	21 (70%)	8(33.37%)	
	Sever	9 (30%)	0(0%)	

The table contrasts the initial and subsequent values of diverse clinical markers following the intervention. The average foot posture score demonstrated a notable enhancement, declining from 7.87 ± 1.28 at baseline to 3.23 ± 0.94 at follow-up ($p < 0.001$).Concerning ankle stability, no participants exhibited good stability at baseline; however, during follow-up, 22 people (73.33%) displayed good ankle stability, whereas 8 participants (26.67%) exhibited medium stability. The count of subjects exhibiting inadequate ankle stability diminished from 11 (36.67%) at baseline to zero at follow-up, signifying significant enhancement ($p < 0.001$). At baseline, all individuals (30, 100%) exhibited an aberrant gait pattern. During the follow-up, 21 participants (70%) shown progress, and 9 participants (30%) attained a normal gait pattern, with no cases remaining aberrant ($p < 0.001$).

The average balance score exhibited enhancement with a statistically significant alteration ($p < 0.001$). The average pain score diminished from 4.03 ± 1.06 at baseline to 1 .50 ± 0.77 at follow-up, signifying a substantial reduction in pain ($p < 0.001$). Regarding functional restriction, none of the subjects had minor limitations at baseline. During the follow-up, 22 people (73.33%) exhibited mild limitations, 8 participants (26.67%) demonstrated moderate limitations, and no participants remained in the severe category, which initially comprised 9 participants (30%).

The results indicate a statistically significant enhancement in all evaluated parameters ($p < 0.001$) subsequent to the intervention.

DISCUSSION

The present quasi-experimental study evaluated the effectiveness of patient-specific three-dimensional (3D)-printed supramalleolar orthoses (SMOs) in improving clinical and functional outcomes among children and adolescents with global foot deviations. The findings demonstrated statistically significant improvements in foot posture, ankle stability, gait pattern, balance, pain reduction, and functional limitation following the use of customized 3D-printed SMOs. These results support the growing evidence that patient-specific orthotic devices fabricated using additive manufacturing technologies provide superior biomechanical correction and enhanced patient comfort compared with conventional orthoses.

The age distribution of the study population showed that most participants belonged to the 6–10-year age group (40%), followed by the 11–18-year age group (33.3%). This distribution corresponds with the period of active skeletal growth during which flexible foot deformities become clinically apparent and intervention is most beneficial. Early orthotic management during childhood helps prevent progression of deformity and facilitates normal gait development. Similar observations have been reported by **Chen et al.** and **Telfer et al.**, who emphasized that pediatric patients within this age range exhibit better adaptation to customized orthotic correction because of greater musculoskeletal plasticity and ongoing foot development.[7,8]

The present study also demonstrated a slight male predominance (53.3%). Similar gender distributions have been documented in previous pediatric orthotic studies, although most authors conclude that the occurrence of flexible flatfoot and other global foot deviations is influenced more by developmental and neuromuscular factors than by sex alone.[8,9] Therefore, the nearly equal gender distribution in the present study enhances the generalizability of the findings.

Regarding the clinical profile, pes planus constituted the largest diagnostic category (40%), followed by hypotonia (16.7%) and pes cavus (13.3%). Flexible flatfoot remains the most frequent indication for pediatric SMO prescription because excessive pronation adversely affects foot alignment, ankle stability, and gait efficiency. Previous investigations have similarly identified pes planus as the leading indication for customized orthotic intervention.[9,10] Children with hypotonia and developmental disorders often require supramalleolar support to improve postural control and reduce compensatory movements during ambulation.

Baseline clinical assessment demonstrated substantial functional impairment among study participants. All children exhibited abnormal gait patterns, while the majority had only fair or poor ankle stability. Moderate to severe functional limitation was observed in every participant, and the mean pain score indicated clinically significant discomfort. These baseline findings emphasize the disabling nature of global foot deviations and justify early orthotic intervention. Similar baseline functional deficits have been reported by **Gijon-Nogueron et al.**, who observed reduced balance, altered plantar pressure distribution, and impaired gait mechanics among children requiring orthotic correction.[10]

One of the major strengths of this study is the utilization of digital scanning and computer-aided design for individualized orthosis fabrication. Three-dimensional scanning enabled accurate reproduction of each participant's foot morphology, while CAD software facilitated precise modification of orthotic geometry before fabrication. The average printing time of approximately five hours and the lightweight orthosis design (145 ± 20 g) indicate that customized orthoses can be produced efficiently while maintaining clinical practicality. Recent technological reviews have similarly highlighted that additive manufacturing substantially reduces fabrication errors, improves reproducibility, and enables rapid customization compared with traditional plaster casting methods.[11,12]

The most important finding of the present study was the significant improvement in Foot Posture Index (FPI) following intervention. The mean FPI score improved from 7.87 ± 1.28 at baseline to 3.23 ± 0.94 after treatment ($p < 0.001$), indicating substantial correction of excessive pronation and restoration of more physiological foot alignment. Comparable improvements have been demonstrated by **Xu et al.**, who reported significant correction of pediatric flatfoot using customized 3D-printed orthoses with improved medial longitudinal arch support.[13] Likewise, **Uden and Kumar** concluded that individualized orthotic correction provides better biomechanical alignment than prefabricated devices because of superior conformity to patient anatomy.[14]

Ankle stability also improved remarkably after intervention. At baseline, none of the participants demonstrated good ankle stability; however, following orthotic treatment, nearly three-fourths achieved good stability, while no participant remained in the poor stability category. Improved ankle stabilization is one of the principal biomechanical functions of supramalleolar orthoses because they effectively control excessive inversion and eversion while allowing physiological sagittal plane motion. Previous investigations have similarly demonstrated improved ankle alignment and reduced mediolateral instability following customized SMO use.[12,14]

Gait improvement represented another major outcome of the present investigation. Initially, all participants exhibited abnormal gait patterns; after intervention, 70% showed marked improvement and the remaining 30% achieved a normal gait pattern. Restoration of more efficient gait mechanics likely resulted from improved foot alignment, enhanced ankle stability, and better weight distribution during stance and propulsion phases. Similar improvements in walking efficiency, cadence, stride length, and balance have been documented following customized pediatric orthotic intervention.[13,15] Three-dimensional printed orthoses provide optimal contact with plantar surfaces, thereby improving force transmission throughout the gait cycle.

Pain reduction constituted another clinically meaningful outcome. The mean Visual Analogue Scale (VAS) pain score decreased significantly from 4.03 ± 1.06 to 1.50 ± 0.77 ($p < 0.001$). Reduction in pain can be attributed to improved pressure redistribution, correction of abnormal biomechanics, and incorporation of gel foam padding at pressure-prone regions. Similar reductions in pain have been consistently reported in studies evaluating customized foot orthoses fabricated through additive manufacturing.[11,15] Better comfort further contributes to improved patient compliance, which is essential for successful long-term orthotic treatment.

Functional limitation also improved significantly following intervention. Before treatment, all participants experienced moderate or severe functional limitation, whereas after intervention, the majority demonstrated only mild limitations and none remained severely impaired. Functional improvement reflects enhanced mobility, better participation in daily activities, improved balance, and increased confidence during ambulation. Similar findings have been reported by **Bauer et al.**, who observed improved Pediatric Balance Scale scores and functional mobility following customized lower-limb orthotic intervention.[16]

An additional strength of the present orthosis design was the incorporation of lightweight lattice architecture combined with gel foam padding. These modifications improved flexibility, reduced orthosis weight, enhanced ventilation, and minimized pressure-related discomfort without compromising structural integrity. Previous engineering studies have similarly concluded that lattice optimization enhances orthotic strength while reducing material consumption and manufacturing costs.[17]

Patient-specific customization remains the major advantage of 3D printing technology. Unlike conventional prefabricated orthoses, digital workflows permit precise anatomical matching, rapid modification, reproducibility, and easier replacement when required. As digital scanning technology becomes increasingly accessible, individualized orthotic management may become standard clinical practice for pediatric foot deformities. Recent systematic reviews have emphasized that additive manufacturing improves patient satisfaction, compliance, and overall treatment outcomes while reducing fabrication time.[18]

Despite these encouraging findings, certain limitations should be acknowledged. The sample size was relatively small and the study was conducted at a single institution, which may limit external validity. The follow-up duration was relatively short, preventing evaluation of long-term durability, continued compliance, and sustained biomechanical correction during skeletal growth. Future multicentre randomized controlled trials involving larger pediatric populations and longer follow-up periods are required to confirm the long-term clinical effectiveness and cost-effectiveness of customized 3D-printed supramalleolar orthoses.

Overall, the present study demonstrates that patient-specific 3D-printed supramalleolar orthoses significantly improve foot posture, ankle stability, gait mechanics, pain, balance, and functional performance in children with global foot deviations. These findings support the integration of additive manufacturing technology into routine pediatric orthotic practice as an effective and highly personalized treatment modality.

CONCLUSION

This study demonstrated that patient-specific 3D-printed supramalleolar orthoses (SMOs) significantly improved foot alignment, ankle stability, gait pattern, pain, and functional performance in children with foot and gait abnormalities. Following intervention, participants showed marked correction of foot posture, enhanced gait mechanics, improved balance, and reduced pain, leading to better mobility and functional independence. The use of advanced digital technologies, including 3D foot scanning, computer-aided design (CAD), and fused deposition modelling (FDM) with TPU and Nylon PA12 materials, enabled the fabrication of lightweight, anatomically accurate, and comfortable orthoses. High patient compliance and satisfaction reflected the excellent fit, comfort, and usability of the customized devices, while only minimal adverse effects were reported. Overall, patient-specific 3D-printed SMOs represent a safe, effective, and promising approach for the conservative management of pediatric foot deformities, offering superior personalization and functional outcomes compared with conventional orthotic techniques.

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