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CLINICAL BRIEF

Evaluation of a Customized 3D Printed ORGAN-Hand Orthotic Device for Unilateral Cerebral Palsy: a Pilot Study

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Abstract
To achieve intensive activity-based and goal-directed rehabilitation for unilateral cerebral palsy (UCP), several static and functional upper limb orthoses have been used but with limited robust evidence-base. The current pilot study evaluated the feasibility and efficacy of a customized 3D-printed orthotic device in children with UCP. The attainment of a prespecified goal and Shriners Hospital Upper Extremity Evaluation (SHUEE) at 3 and 6 mo were the efficacy measures. Of the 14 screened children, 5 (median age: 7.9 y; 3 boys) were included. The 3-mo follow-up could be completed for 3 children while 6-mo follow-up could be completed for 1 child. Rest could not be assessed due to pandemic restrictions. Although none attained set goals till the last follow-up, all 3 children (at 3-mo follow-up) showed improvement in SHUEE scores without any significant safety concerns. Further studies on 3D-printed orthosis in UCP are the need of the hour.

Keywords Hemiplegic cerebral palsy · Orthosis · 3D printed · Children

Introduction

Cerebral palsy (CP) comprises a group of disorders of movement and posture secondary to an insult to the developing brain [1]. It is often accompanied by comorbid problems such as epilepsy, impaired cognition, etc. Unilateral cerebral palsy (UCP) is characterized by unilateral affection and relatively preserved cognition. Intensive activity-based and goal-directed rehabilitation is the key approach for upper limb rehabilitation in UCP [2]. Constraint-induced movement therapy and bimanual intensive therapy are more effective than standard care in improving upper limb function [3].

With the advent of newer technology, other modalities such as virtual reality therapy, 3-dimensional (3D) printed orthotics, etc., are emerging [2, 4]. However, the use of 3D printed orthotics is limited [4, 5]. Although several static and functional upper limb orthoses have been used in small trials, there is a lack of robust evidence for the same in children with UCP [6]. The current pilot study aimed to evaluate the feasibility and use of a customized 3D printed orthotic device for UCP.

Methods

This pilot study was conducted at a tertiary care center in Northern India after ethical approval and prospective CTRI registration (CTRI/2018/10/015924). Children (aged 4–12 y) with UCP and Gross Motor Function Classification System level 1 or 2 were enrolled after informed consent.

ORGAN-hand, a customized thermoplastic (acrylonitrile butadiene styrene and biodegradable polylactic acid) orthosis with braces for elbow, wrist, and fingers, was designed (Fig. 1). Following 3D scanning of anatomical geometry, reconstruction (of missed part), and surface forming, fabrication was carried out using a 3D printer. Postprocessing, quality assurance, and final assembly were done for each subject. The final device was a functional-cum-static orthosis customized according to spasticity in different muscle groups. The mechanical screw tensioners equipped with elastic tendons

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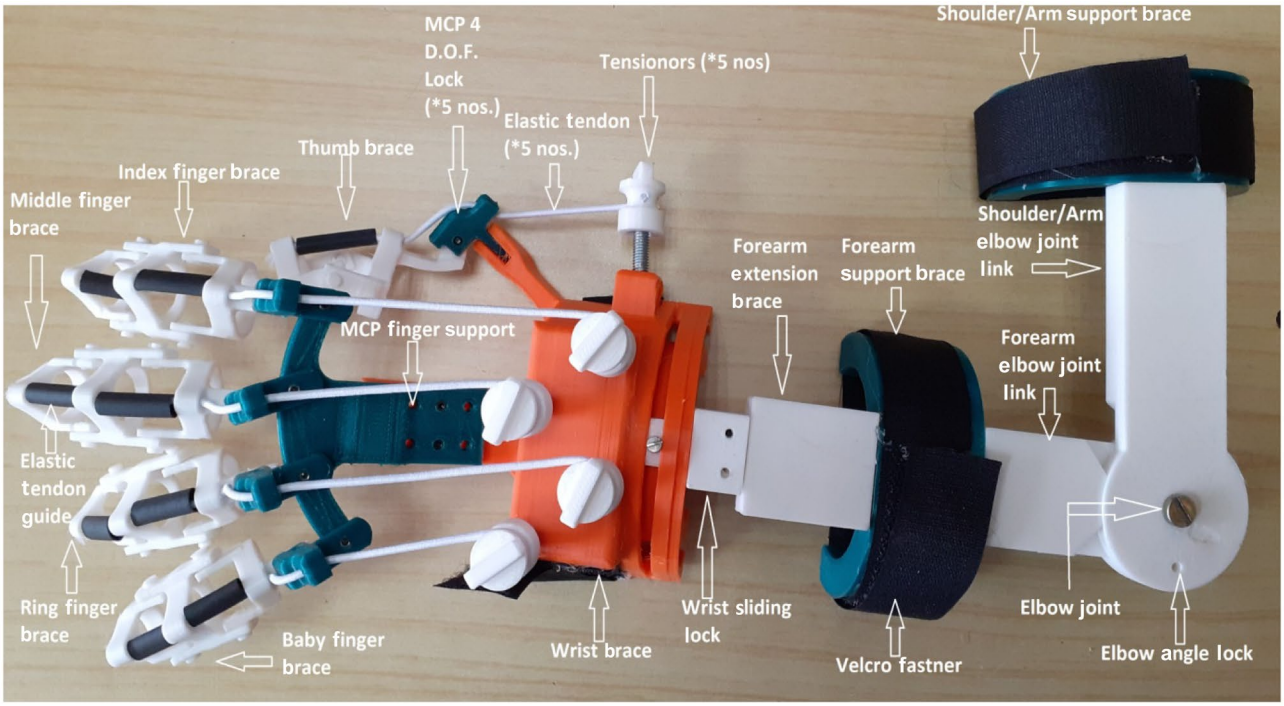

Fig. 1 The design of ORGAN-hand orthosis. ORGAN-hand orthosis consists of a universal elbow brace (facilitating anatomical range of motion), a wrist brace (providing external fixation in extension and adjustable forearm wrist angle for supination, pronation, and neutral position), and dynamic finger braces with lock mechanism for each finger to allow movements at metacarpophalangeal, proximal, and distal interphalangeal joints. Tension between the braces is adjustable with the help of individual variable resistance mechanism to achieve desired position for each joint

helped titrate the orthosis resistance for fingers. The key focus was on finger flexors, wrist flexors, and forearm pronators.

Parents were informed regarding the handling and use of the device. In addition to the standard therapy, maximum daily use of orthosis was advised with a minimum of 2–3 h for function and mobility along with overnight immobilization (by locking orthosis). Compliance and adverse events were assessed by weekly calls, video sharing by parents, parental reporting, and hospital visits where required. Each child was evaluated for the attainment of a specified goal (like the use of spoon without spilling) at 3 and 6 mo along with Shriners Hospital Upper Extremity Evaluation (SHUEE) testing [7]. SHUEE consists of 16 manual function tasks, which were video-recorded and jointly analyzed to provide a score for spontaneous functional analysis (SFA), dynamic positional analysis (DPA), and grasp/release (GRA).

Table 1 Follow-up duration, results of Shriners Hospital Upper Extremity Evaluation in the study subjects, and number of breakages of orthosis in each study subject

Patient	Follow-up (in months)	Shriners hospital upper extremity evaluation scores (in percentage)									Breakage frequency
		Baseline			3 mo			6 mo			
		SFA	DPA	GRA	SFA	DPA	GRA	SFA	DPA	GRA	
1	6	53.3	48.6	66.7	53.3	48.6	66.7	57.8	54.2	66.7%	FB: 20 WB: 3
2	3	97.7	93	83.3	100	97.2	100	-	-	-	WB: 4
3	3	37.8	65.3	66.7	44.4	63.9	66.7	-	-	-	FB: 10 WB: 2
4	2	26	43.1	33.3	-	-	-	-	-	-	FB: 16 WB:1
5	2	66.7	80.6	50	-	-	-	-	-	-	FB:4 WB:2

DPA Dynamic position analysis; *FB* Finger brace; *GRA* Grasp release analysis; *SFA* Spontaneous function analysis; *WB* Wrist brace

Higher scores indicate better function

Results

Of 14 children screened, 5 were included [excluded (9): uncontrolled epilepsy (3), minimal spasticity (4), finger hyperextension (1), difficult follow-up (1)]. The median age of enrolled children was 7.9 y (range: 4.2–9 y; 3 boys). Three had left-sided hemiplegia, while two had right-sided. All children were advised customized orthosis. However, the 3-mo follow-up could be completed for 3 children and a 6-mo follow-up for 1 child. The rest of the children could not be assessed at the specified time points due to COVID-19 pandemic restrictions. All children used the orthosis beyond their school timings and overnight during sleep (approximately 8–10 h/d). Although none of the children attained set goals till the last follow-up, all 3 children (with a minimum follow-up of 3 mo) showed improvement in SHUEE score without any significant safety concerns (Table 1). There were no new deformities, pressure sores, or injury/bruises secondary to the use of orthosis. However, there were other problems like a misfit (2/5) and frequent breakage requiring repair (Table1).

Discussion

Customization of orthosis is essential to achieve a desirable outcome and improve tolerability (none of the patients had pressure sores/injury due to orthosis). Although the use of ORGAN-hand was associated with some functional improvement, no meaningful change was observed in the child who completed follow-up. However, frequent breakage (probably due to delicate design with multiple hinges in finger brace) affected compliance during the study period since frequent repairing was required. The lack of a comparator control group was also a limitation since it is difficult to interpret whether the observed effect was due to ongoing standard therapy or the orthosis.

The current study highlights the difficulties in research on orthoses in CP. Considering the multiple exclusions at screening, appropriate candidate selection is crucial besides customizing the device according to patient needs. Possible solutions to the problem of frequent breakage of orthosis include the use of flexible but sturdy material, modification of design with removal of redundant brace or hinges, etc.

Conclusion

CP in children constitutes a significant burden of disability and necessitates a quest for better rehabilitation solutions [8]. Further studies on 3D printed customized orthosis in CP are the need of the hour.

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Authors' Contribution PM: Conduct of study, data acquisition and analysis, and writing of the initial draft of manuscript and revision; AC and HS: Orthosis development and designing, conduct of the study, and critical review of the manuscript; NRG, LS, NK, and JKS: Planning of the study, orthosis development and designing, conduct of the study, data analysis, and critical review of the manuscript. All authors approved the final version of the manuscript to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. JS will serve as the guarantor for this paper.

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Declarations

Conflict of Interest None.

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