11-8-2017

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ABSTRACT

Introduction: There is limited knowledge on the use of 3 D-printed transitional prostheses, as they relate to changes in function and strength. Therefore, the purpose of this study was to identify functional and strength changes after usage of 3 D-printed transitional prostheses for multiple weeks for children with upper-limb differences.

Materials and methods: Gross manual dexterity was assessed using the Box and Block Test and wrist strength was measured using a dynamometer. This testing was conducted before and after a period of 24 ± 2.61 weeks of using a 3 D-printed transitional prosthesis. The 11 children (five girls and six boys; 3–15 years of age) who participated in the study, were fitted with a 3 D-printed transitional partial hand ($n = 9$) or an arm ($n = 2$) prosthesis.

Results: Separate two-way repeated measures ANOVAs were performed to analyze function and strength data. There was a significant hand by time interaction for function, but not for strength.

Conclusion and relevance to the study of disability and rehabilitation: The increase in manual gross dexterity suggests that the Cyborg Beast 2 3 D-printed prosthesis can be used as a transitional device to improve function in children with traumatic or congenital upper-limb differences.

- Children’s prosthetic needs are complex due to their small size, rapid growth, and psychosocial development.

- Advancements in computer-aided design and additive manufacturing offer the possibility of designing and printing transitional prostheses at a very low cost, but there is limited knowledge on the function of this type of devices.
- The use of 3D printed transitional prostheses may improve manual gross dexterity in children after several weeks of using it.

KEYWORDS

Additive manufacturing, computer-aided design, motor control, reaching, custom-made prostheses, hand, arm, paediatric, biomechanics

Introduction

Children’s prosthetic needs are complex due to their small size, rapid growth and psychosocial development [1]. Independent of the type of limb deficiency (congenital or traumatic) loss of mobility, function, atrophy, and asymmetry are typical characteristics of the affected limb [2]. Most upper-limb prostheses for children include a terminal device, with the objective to replace the missing hand or fingers [3]. Electric-powered units (i.e., myoelectric) and mechanical devices (i.e., body-powered) have been improved to accommodate children’s needs, but the cost of maintenance and replacement makes access difficult for many families [3]. The term “transitional prosthesis” has been widely used in the field of prosthodontics, specifically with hemimaxillectomy patients [4]. For upper-limb prostheses, however, these types of devices are referred as a “temporary prosthesis” or “initial prosthesis” [5].

Previous investigations have used transitional prosthetic or assistive devices, such as opposition poles and orthoses, with the objective of restoring and preserving strength and range of motion (ROM) in children with upper-limb reduction deficiencies [6,7]. Zuniga et al used a transitional wrist-driven 3 D-printed hand prosthesis to examine changes in wrist range of motion (ROM) and forearm cross-sectional area due to muscle size changes. They found significant increases in these two variables in a small sample of five children with upper-limb differences following 6 months of use [8]. These findings suggest that the use of transitional prostheses may play an important role in patient rehabilitation and improvement of clinical outcomes.

The introduction of 3 D printing for the manufacturing of prostheses has resulted in the development of new cost reduction strategies and better accessibility and customization of prosthetic designs [8–11]. The Cyborg Beast 3 D-printed hand prosthesis is inexpensive and easy to manufacture [8,10]. This transitional prosthesis requires simple anthropometric measures of the upper limb for its fitting, scaling and adjustments facilitating remote fitting procedures [8–10]. Furthermore, due to the open source nature of its 3 D-printing files, and the increasing online resources and instructional materials available on the Internet, it has been manufactured, assembled, and used by individuals and clinical facilities around the world [11]. Previous publications have suggested that the Cyborg Beast 3 D-printed hand prosthesis could have a positive impact on the function and activities of daily living [8–10,12]. However, there is no quantitative data regarding the function of this transitional prosthesis after a period of use.

Thus, the purpose of the present study was to identify functional and strength changes after usage of 3 D-printed transitional prostheses for multiple weeks for children with upper-limb differences. Specifically, we hypothesized that there will be increases in manual gross dexterity and strength after using 3 D printed transitional prostheses for several weeks. This hypothesis was motivated by previous investigations [8–10] that have shown improvements in the range of motion of the affected wrist and forearm circumference [8], as well as case reports indicating improvements in function [9,10] after using 3 D-printed transitional prostheses.

Methods

Experimental design

Functionality and strength were assessed before and after 24 ± 2.6 weeks of using a 3 D-printed transitional prosthesis.

Participants

Eleven children (five girls and six boys, 3–15 years of age) participated in this study and were fitted with a 3 D-printed transitional prostheses (wrist-driven or elbow-driven; Table 1). From the eleven children recruited, all performed the testing for function and eight performed the testing for strength (Table 2). Two subjects had trans-radial reductions, thus wrist strength measurements were not acquired. One child was not compliant and strength data were not obtained.

Table 1. Characteristics of research participants ($n = 11$). (Table view)

ID	Gender	Age	Diagnosis	Ability to pinch
1	F	3	Congenital deficiency left hand.	No
2	F	4	Amputation of fingers of the right hand. Functional thumb.	No
3	F	4	Congenital deficiency left hand.	No
4	F	6	Agenesia left hand	No
5	F	6	Congenital left trans-radial deficiency	No
6	M	7	Poland Syndrome right hand	No
7	M	7	Congenital deficiency left hand.	No

ID	Gender	Age	Diagnosis	Ability to pinch
8	M	9	Congenital deficiency left hand.	No
9	M	10	Congenital deficiency right hand.	No
10	M	12	Congenital deficiency left hand.	No
11	M	15	Congenital right trans-radial deficiency.	No

Table 2. Mean (±SD) for function and strength measurements before and after six months of using the 3 D-printed hand prosthesis. (Table view)

	Box and Block test (blocks per min)[a]				Flexors Strength (Kg)[b]			
	Non-affected		Affected		Non-affected		Affected	
ID	Before	After	Before	After	Before	After	Before	After
1	24	25	0	5	10	11.6	8.46	14.6
2	22	26	3	3	11.8	13.46	11.7	13.2
3	26	27	0	3	–	–	–	–
4	36	38	13	19	4.2	10	5.2	7.6
5	36	38	0	9	–	–	–	–
6	50	54	40	47	27.53	33.13	17.43	18.9
7	60	66	0	3	14.8	14.7	25.2	22
8	60	62	13	16	15.7	17.8	12.3	19.46
9	53	53	0	17	24.4	19.4	20.46	22.46
10	69	68	0	9	10.8	10.1	8.3	12.16
11	75	75	0	12	–	–	–	–
M	46.45	48.36	6.27	13.00	14.90	16.27	13.63	16.30
SD	18.67	18.34	12.31	12.70	7.70	7.62	6.83	5.24

[a] The results of the two-way repeated measures ANOVA for function showed a significant two-way interaction for hand × time and significant main effects for time and hand.
[b] No interaction or main effect was found for strength. – No strength data were recorded for subject 3, 5 and 11.

Inclusion criteria were children (boys and girls; 3–17 years of age) with unilateral upper-limb reductions that are missing some or all fingers and range of motion for the wrist and elbow joints greater than 20 degrees.

Exclusion criteria were the presence of an upper extremity injury within the past month and any medical conditions that would contraindicate the use of the transitional prosthesis, such as skin abrasions and musculoskeletal injuries.

All subjects completed a medical history questionnaire. All parents and children were informed about the study and parents signed a parental permission form. For children age 6–10 years of age, an assent was explained by the corresponding author and signed by the children and their parents. Detailed safety guidelines were given to the parents regarding the use and care of the prosthesis. In addition, the families and children participating in this study completed a short survey. The survey was developed to estimate the impact of the prosthetic device on items related to the quality of life, daily usage, and types of activities performed. The survey has not been statistically validated but provides useful information related to daily usage.

Participants were asked to visit the laboratory on three occasions. During the first visit, a 3 D scanning of the upper limbs was performed using a custom-made electronic rotatory mechanism with a consumer-grade optical 3 D scanner (Sense 3 D scanner, 3 D systems Inc. Rock Hill, SC). Anthropometric measurements were also performed to confirm the digital measurements obtained from the scan. After three weeks, research participants and their families returned to the laboratory for the prosthesis fitting and baseline testing. After 24 ± 2.61 weeks of using the prosthesis, participants visited the laboratory for a third time and repeated all assessments performed during the baseline testing. All children participating in the study and their families were encouraged to use the prosthesis for as long as possible during their activities of daily living. The function and strength testing were performed by a trained occupational certified hand therapist. The prosthetic fitting was performed by a certified prosthetic and orthotic professional. The study was approved by both the Creighton University Institutional Review Board and the University of Nebraska Medical Center Institutional Review Board.

Function test

The Box and Block test was used to assess function before and after 24 ± 2.61 weeks of using the 3 D-printed transitional prosthesis (Figure 1). The Box and Block test has been suggested as a measure of unilateral gross dexterity [13,14] and has been previously used to assess upper-limb prosthetic performance and motor learning [15]. Norms have been collected on adults with neuromuscular involvement and in typically developing children [13,14]. The Box and Block test consist in a wooden box with dimensions 53.7 cm by 25.4 cm by 8.5 cm. A partition is placed at the middle of the box creating two containers of 25.4 cm each [13]. The Box and Block test provides quantitative data regarding the gross dexterity of the affected and non-affected upper limbs [13,14].

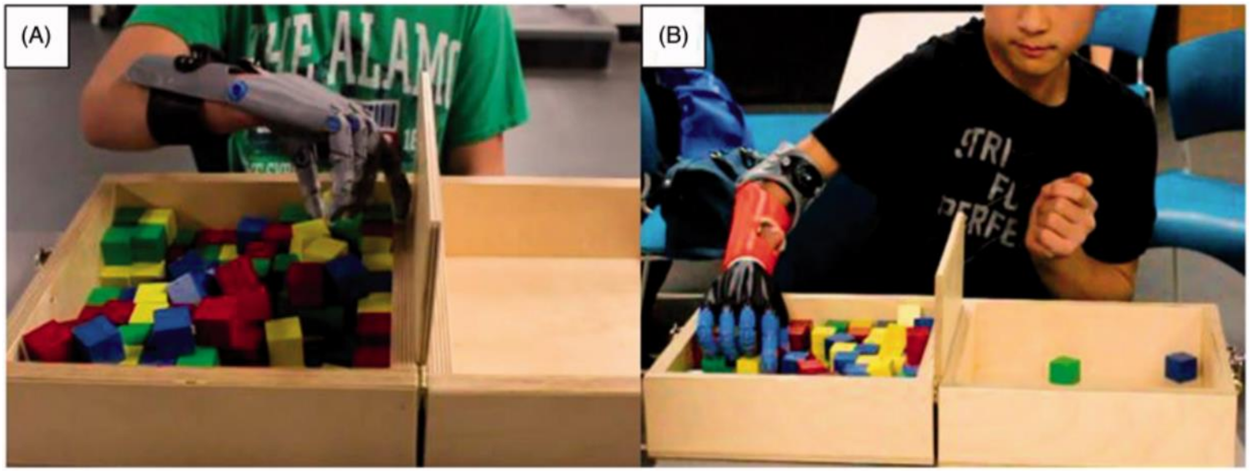

Figure 1. The Box and Block test. (A) A research subject using a 3 D-printed partial hand prosthesis. (B) A research subject using a 3 D-printed arm prosthesis.

After providing instructions, the children were allowed a 15-s familiarization period prior to testing. Immediately before testing began, the child was asked to place the hands on the sides of the box. When testing started, each child was asked to grasp one block at a time, transport the block over the partition and release it into the opposite compartment. This task was performed for one minute in duration. The procedure was then repeated with the other hand. After testing, the blocks were counted. If a child transported two or more blocks at the same time, this was noted and subtracted from the total. No penalty was made if the child transported any blocks across the partition and the blocks bounced from the box to the floor or table.

Strength measurements

Wrist flexion and extension strength were measured for both hands using a strength testing dynamometer (microFET3, Hoggan Health Industries, West Jordan, UT). The researcher stabilized the applicator pad of the dynamometer at the palm of the non-affected hand and at the distal end of the affected hand with the wrist and forearm in neutral position. The subject was asked to push the pad of the dynamometer down towards flexion and extension of the wrist as hard as possible. Each measure was repeated three times for each motion and the average of the three measures was used for the data analysis.

Wrist-driven 3 D-printed transitional partial hand prosthesis characteristics

A modified version of the 3 D-printed transitional hand prosthesis named Cyborg Beast [16] (Figure 2) was used in the study. The new version named Cyborg Beast 2, was designed using the modeling software program Autodesk Fusion 360 (Fusion 360, Autodesk, Inc., San Rafael, CA, USA) and manufactured in the 3 D Printed Prosthetic

Orthotic & Assistive Devices Laboratory located in the Biomechanics Research Building of the University of Nebraska at Omaha. The 3 D printers used for the manufacturing process included a combination of desktop and industrial 3 D printers (Ultimaker 2, Ultimaker B.V., Geldermalsen, the Netherlands and Uprint SE Plus by Stratasys, MN).

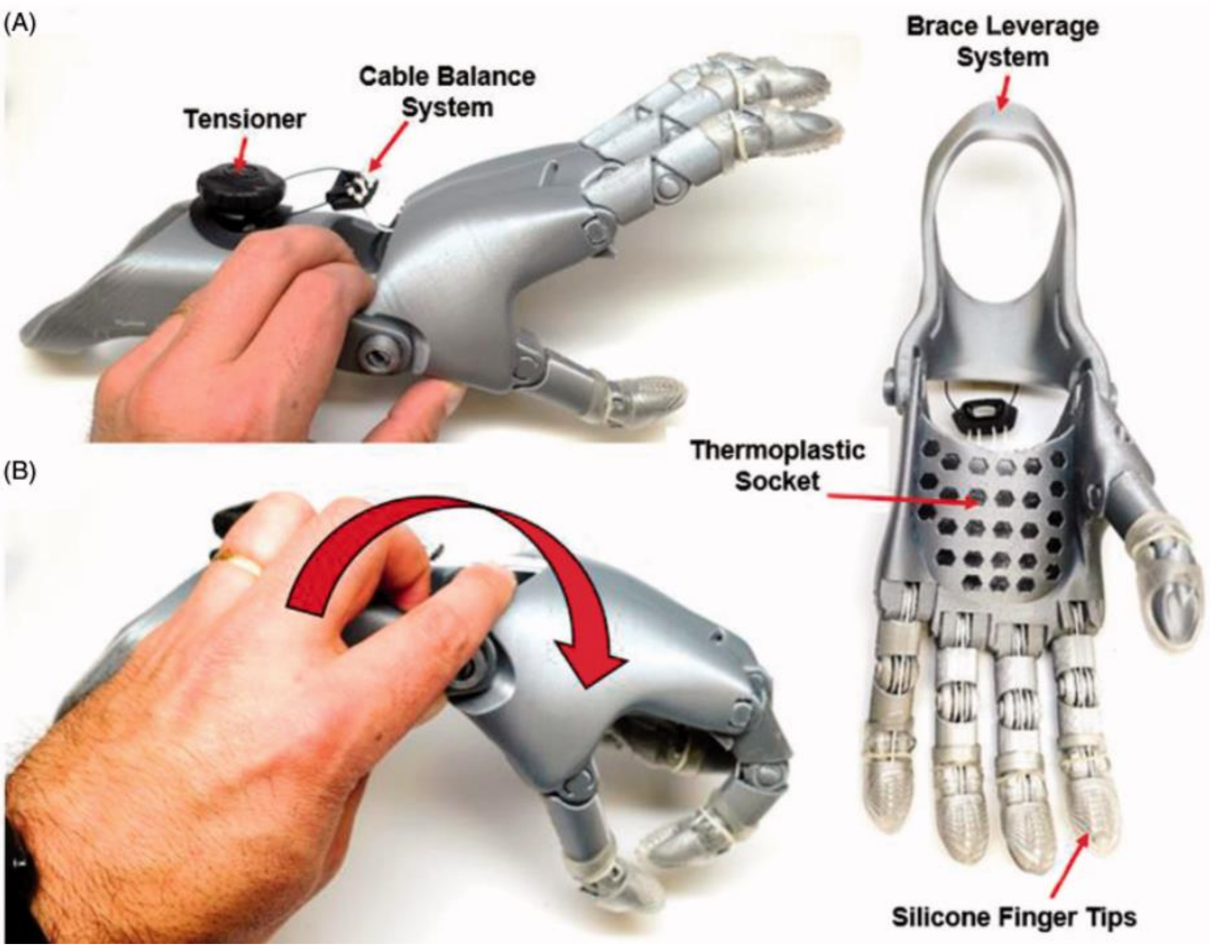

Figure 2. 3 D-printed wrist-driven hand prosthesis. (A) Shows the hand prosthesis in the open position. Elastic cords placed inside the dorsal aspect of the fingers provide passive finger extension. (B) Finger flexion is driven by non-elastic cords along the palmar surface of each finger and is activated through 10–20° wrist flexion. The red arrow shows the direction of wrist flexion to close the fingers and produce a functional grasp.

The plastic pins to secure all the various components of the prosthesis, as well as the fingers and thumb were made of acrylonitrile butadiene styrene manufactured using an industrial 3 D printer. The palm, socket, forearm brace, and leveraging structure were made of polylactic acid which has properties similar to thermoplastic that facilitate post-manufacturing adjustments [17]. Elastic cords placed inside the dorsal aspect of the fingers provided passive finger extension. Finger flexion was driven by non-elastic cords along the palmar surface of each finger and was activated through 20–30 degrees of wrist flexion. The result was a composite fist (flexing the fingers towards the palm) for gross grasp. The finger and thumb were oriented in opposition to facilitate cylindrical grasp and tip pinch. A BOA dial tensioner system (Mid power reel M3, BOA Technology Inc., Denver, Colorado) allowed regulating the tension of the cables controlling the finger flexion. A brace leverage structure was included in the proximal aspect of the forearm to increase torque development and stability. A thermoplastic socket embedded in the palmar aspect of the hand prosthesis was added to facilitate fitting of the device. The hand prosthesis was customized to each child's limb size and aesthetic requirements, such as colors and general fictional character's theme.

Elbow-driven 3 D-printed arm prosthesis characteristics

The hand had five fingers with two degrees of freedom (Figure 3). The finger and thumb were oriented in opposition to facilitate cylindrical grasp and tip pinch. Silicone finger pads were added to increase friction for grasping activities. A rotation mechanism placed on the wrist allowed full pronation and supination. Specifically, a pivot system with internal components allowed rotation of the wrist without twisting the line. The rotation mechanism of the wrist was comprised of an inner circular disc/shaft with a center opening (Figure 3(B)). A circle of embedded magnets with matching polarity was placed around the disc. A bi-valve circular sleeve with embedded magnets was aligned to match the disc magnets was placed over the disc. The magnets were placed with opposing polarity to assure mutual attraction. The disc and sleeve rotated independently and were stabilized in various positions by the attraction of the magnets. The magnets were sealed in a protective sleeve for safety. Elbow flexion and extension can be performed using a simple hinge mechanism. A BOA dial tensioner system allowed the regulation of the tension of the cables controlling the finger flexion. A Velcro strap secured the prosthesis to the arm. No harnessing was needed to suspend the prosthesis.

3 D-printing specifications

The wrist-driven and elbow-driven devices were designed to be manufactured in desktop and industrial 3 D printers (Ultimaker 2, Ultimaker B.V., Geldermalsen, the Netherlands and Uprint SE Plus by Stratasys, MN) with a building platform of at least 28.5 cm ×15.3 cm ×15.5 cm. The materials used for printing the prosthetic hand were polylactic acid and acrylonitrile butadiene styrene. All parts were printed at 40% infill (hexagon pattern for desktop, crosshatch for industrial), 60–100 mm/s print speed, 150–200 mm/s travel speed, 70 °C heated chamber for acrylonitrile butadiene styrene (50 °C heated bed for polylactic acid), 0.15–0.25 mm layer height, and 1 mm shell thickness. Rafts and supports were used to 3 D print the palm and other delicate components.

Figure 3. 3 D-printed elbow-driven prostheses. (A). shows the device in the open position. Elastic cords placed inside the dorsal aspect of the fingers provide passive finger extension. (B). Finger flexion is activated through 10–20° of elbow flexion of the residual functional joint. The red arrow shows the direction of elbow flexion to close the fingers and produce a functional grasp. The wrist can be manually adjusted. No harnessing is required to suspend the prosthesis.

The components of the prosthetic hand included a 1 mm lift nylon cord, a 1.5 mm diameter elastic cord, Velcro, medical-grade firm padded foam, a protective skin sock and a BOA dial tensioner system. The range of the time that took to 3 D print and fully assemble the prosthetic hand design was 4–7 h. The fitting procedure for the prosthetic hand required a few simple anthropometric measures of both limbs to properly scale the prosthesis [10].

Statistical analysis

Two subjects had trans-radial reductions, thus wrist strength measurements were not acquired. In addition, one child was not compliant during strength measurements so strength data was not acquired. The data from these three subjects were not incorporated in the statistical analysis for strength. Data from the wrist and elbow prostheses were combined due to the repeated measures nature of our experiment and since the function of a wrist drive and an elbow driven device should be comparable. Separate two-way repeated measures ANOVAs [2 × 2; hand (affected vs. non-affected)×time (before and after)] were performed to analyze function and strength data. An alpha value of 0.05 was considered statistically significant for all comparisons.

Results

Physical characteristics of the research participants are described in Table 1. Table 2 shows the mean (±SD) for function and strength measurements. There was a significant hand by time interaction for the function [$F(1,10) = 6.42$; $p = .03$, $\eta p^2=0.39$], but not for the wrist flexion strength [$F(1,7) = 0.67$; $p = .44$, $\eta p^2 = 0.02$], or for the wrist extension strength [$F(1,7) = 0.05$; $p = .40$, $\eta p^2 = 0.1$]. There were significant main effects of function for the hand [$F(1,10) = 52.41$; $p = 0.01$, $\eta p^2=0.84$] and the time [$F(1,10) = 37.31$; $p = .01$, $\eta p^2 = 0.79$]. There were significant main effects of strength for time [$F(1,7) = 6.56$; $p = .38$, $\eta p^2 = 0.48$].

All 11 families and children participating in this study completed a short survey. After 24 ± 2.61 weeks of using the prosthetic hand, 10 children reported using the hand for 2 h a day and one reported using the hand for 4 h a day. Furthermore, children reported using the prosthetic hand “just for fun” ($n = 10$), for “activities at home” ($n = 5$), to “play” ($n = 8$), for “school activities” ($n = 5$), and to perform “sports” ($n = 2$).

Discussion

The main finding of the present investigation was that using low-cost 3 D-printed transitional prostheses significantly improved manual gross dexterity after 24 weeks of use (before =6.3 ± 12.3 blocks per minute and after =13.0 ± 12.7 blocks per minute) on children with congenital and acquired upper-limb reductions.

However, changes in strength of the wrist on a subsample of eight children with partial hand reductions while increased were not found to be significant (before =13.63 ± 6.83 kg and after =16.63 ± 5.24 kg). The lack of significant differences may be related to the small sample size and the large variability in force production among children participating in the present study [8] (Table 2).

The use of transitional prosthetic devices to restore and preserve function, strength and joint mobility in individuals with upper limb reductions has been described by previous investigators [6–8]. For example, Bryant et al. [6] developed a transitional terminal device with a purpose to restore opposition and control of grip strength in 12 children between 2 and 11 years of age with congenital aphalangia. Shim et al. [7] reported a case of a 52-year-old woman with thumb and index finger disarticulation who used a transitional hand prosthesis made of low-temperature thermoplastic, designed to increase strength and range of motion of the three remaining fingers. Both studies [6,7] reported increases in strength and range of motion. More recently, Zuniga et al. [8], reported increases in range of motion before (54.60 ± 14.48°) and after (68.40 ± 14.29°) six months of using a 3 D-printed partial hand prosthesis in a sample of five children with partial hand reductions. Changes in function, however, were not reported [8]. The present investigation used a larger sample size ($n = 11$) and a redesigned model of the prostheses with the purpose of increasing function. The new features of the Cyborg Beast 2 design of the wrist-driven and the elbow-driven devices include finger and thumb oriented in opposition to facilitate cylindrical grasp and tip pinching, inclusion of silicone fingertips to improve grasping, embedded thermoplastic socket to improve fitting, and a brace leveraging structure in the wrist-driven device to improve gripping strength (Figures 2 and 3). Furthermore, the present investigation included two children with trans-radial reductions, providing preliminary data of the function of a 3 D printed transitional elbow-driven prosthesis.

The increase in manual gross dexterity as measured by the Box and Block Test suggests that the Cyborg Beast 2 3 D-printed prostheses (wrist-driven and elbow-driven) can be used to improve function in children with traumatic or congenital upper-limb reductions. These findings also suggested that transitional prostheses may play an important role in patient rehabilitation and improving manual gross dexterity [6,7]. The transitional prostheses used in previous investigations [6,7] were constructed manually and were customized to the patients’ needs and particular hand morphology. This manufacturing method is usually time-consuming and labor-intensive [6,7]. However, recent advances in manufacturing technology allow the production of 3 D-printed prostheses from a customized digital file [10], providing a practical option for patients and clinicians interested in these type of devices. Furthermore, these transitional prostheses can also be used to provide crucial information to clinicians to improve prosthetic prescription by providing an early assessment of prosthesis daily use, function, and patient satisfaction before exploring more sophisticated and costly prosthetic options.

The potential limitations of the present investigation are related to the lack of an age-matched control group, the small number of children participating in the study and the durability constraints of the 3 D-printed prostheses. The current study did not include an age-matched control group to assess typical development of strength and manual dexterity in age-matched children over the time span of the study. However, the contralateral arm was used as a control, as suggested and described in previous investigations [8,9]. A sample size of 11 children (5 girls and 6 boys) made it difficult to group research participants by age and gender. For example, the difference in age shown in Table 1 and the resulting inter-subject variability in strength shown in Table 2 may have limited our experimental capabilities in terms of identifying statistical significance in strength. Coincidentally, the youngest participants (subjects 1 to 5 in Table 1) were also female which may complicate potential gender comparisons. In addition, decreased strength values were found for male subjects 7, 9 and 10 during the second visit for the affected (subject 7) and unaffected limbs (subject 9 and 10 in Table 2). Based on previous data collections with pediatric research participants, it can be speculated that the lack of effort and testing errors may have contributed to this unexpected decreased in strength.

Another limitation of the current investigation includes the inherent durability constraints of fused deposition modeling process used to manufacture 3 D-printed prostheses reported in previous investigations [10,17] could have affected the proper use and function of the prostheses. In the present study, four of 11 children (36%) reported breaking or encountered malfunctioning of the 3 D-printed prostheses. Our research team replaced or fixed the prosthesis within two weeks. The main problems reported by the children and families included breaking of the elastic components ($n = 3$) that maintain the hand in the open position and breaking of the finger due to lateral forces ($n = 1$). The malfunction of the elastic components and fingers have been previously reported in three of five children participating in a previous investigation using an older hand prosthesis design (Cyborg Beast) [8]. Furthermore, it has been previously reported that the current materials used for 3 D-printed prostheses, such as polylactic acid, lack structural stability in the presence of moisture and at high temperatures (>60 °C) [10,17]. The rapid degradation of polylactic acid under these conditions can potentially affect the durability and function of 3 D-printed prostheses. Although durability constraints are factors to consider when using 3 D printed prostheses, the practicality and cost-effectiveness represent a promising new option for clinicians and their patients.

Based on the high impact and media attention given to the development of 3 D-printed prostheses as well as findings from previous investigations [8–10] the authors of the current investigation strongly recommend the supervision of a certified prosthetist for the proper implementation and use of these devices. Thus, our research team strongly encouraged to include prosthetists and other health care professionals, such as certified hand therapists in the development, fitting, and testing of 3 D-printed prostheses.

Future investigations should examine the clinical application of 3 D-printed prostheses not only to increase function but as part of the prosthetic rehabilitation process. A detailed review of the technical and clinical considerations for the development of 3 D-printed upper-limb prostheses for children will be helpful in understanding future applications of these particular designs of prostheses.

Acknowledgements

We would like to thank the parents and their children for participating in our study. We also like to thank the students working in the 3 D-printed prosthetic, Orthotic and Assistive Devices Laboratory at the Biomechanics Research Building at the University of Nebraska at Omaha who assisted in data collections.

Disclosure statement

Jorge M. Zuniga, Ph.D. is the designer of the 3 D-printed transitional prostheses Cyborg Beast and his research team (Jean L. Peck, Rakesh Srivastava, James E. Pierce, and Drew R. Dudley) fabricated the prototypes and conducted the data collection. The rest of the researchers declare no conflict of interest.

Funding

This study was partially funded by the National Institutes of Health (P20GM109090–01), the Center for Research in Human Movement Variability at the Biomechanics Research Building at The University of Nebraska at Omaha, the Teacher-Researcher Partnership Program (TRPP) and the University of Nebraska Science Collaboration Initiative.

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