Development of a Modular Activity-Specific Upper Limb Prosthesis

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Intended Journal: *Prosthetics and Orthotics International*

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Abstract

Introduction: The use of activity-specific upper-limb prosthesis helps children with upper-limb loss to engage in functional and recreational activities, such as music and sports.[4,5] Therefore, the purpose of this study was to develop a modular activity-specific prosthesis and develop a remote-fitting procedure. We evaluated patient satisfaction after using the device for 8 weeks and evaluated anthropometric and range of motion (ROM) measurements of the residual limb after use of the prosthesis.

Methods: We enrolled 7 children with unilateral trans-radial amputations between 7 and 12 years of age. The modular activity- specific prosthesis was specifically designed for playing musical instruments (cello and violin) and sports (golf and bicycle riding). A survey was performed to evaluate items such as assistive device satisfaction, wear, comfort and use.

Results: Descriptive statistics were performed to calculate the mean and standard deviation of the scores recorded in the patient satisfaction survey. The larger standard deviations showed that the observations were more spread out which represents that the patients were satisfied after using the prosthesis after using it for 8 weeks. A dependent T-test was performed between the anthropometric and ROM measurements after use of the prosthesis.

Conclusion: The main findings of this study were that an effective modular activity-specific prosthesis can be developed at a low-cost. Additionally, remote fitting procedures were developed. The results also showed that participants were satisfied with the devices after 8 weeks of use. Furthermore, we observed that for strength of the affected limb there was a significant main effect for wrist motion. The limitations of this study was that the sample size was small which made it difficult to acquire data based on age and gender.

Introduction

In some parts of the world, such as Australia, Finland, and Canada, reports indicate that 3.4 to 5.3 of 10,000 live-born children suffer upper-limb anomalies.[3] The Centers for Disease Control and Prevention estimates that about 1,500 babies are born with upper-limb reductions every year in the U.S.[1,2] In the United States, however, there are many more unreported cases due to the lack of a mandatory reporting system of birth defects and child amputees. The Centers for Disease Control and Prevention[1] has identified four main challenges experienced by children with limb loss: a) difficulties with normal development such as motor skills, b) needing assistance with daily activities such as self-care, c) limitations with certain movements, sports, or activities, and d) potential emotional and social issues because of physical appearance.

The use of activity-specific upper-limb prostheses can help children with upper-limb loss tackle the issues that were discussed before[4]. These devices help users to engage in functional and recreational activities, such as music and sports.[4,5] The active participation in music and sports activities is fundamental to the normal growth and motor development of children.[6,7] Specifically, participation in music and sports during childhood has a profound effect in brain development associated to improvements in motor skills and overall well-being of the child.[6,7]

The benefits of performing music and sports activities in brain development during childhood is supported by the Neuronal Group Selection Theory (NGST).[18] According to the NGST, the brain is dynamically organized into neuronal networks or neuronal groups. The structure and function of these networks is influenced by the motor development and motor behavior of the child.[5,18,19]

However, the development of activity-specific upper-limb prostheses is challenging due to the child specific activity needs and the increased out-of-pocket cost of these devices due to the lack of insurance coverage.[4,8-10] Even with the great advances in prosthetic technology, up to 58% of children with upper-limb loss reject or abandon their prosthesis due to excessive weight, lack of visual appeal, limited function and complex fitting procedures.[5,7-9] As a result, children with limb loss have a lack of participation in bimanual recreational activities, such music (i.e., cello and violin) and sports (i.e., golf and bicycle riding).[4] Thus, there is a critical need to develop practical and affordable activity-specific upper-limb prostheses for children. 3D printing provides a cost-effective manufacturing method to develop activity-specific, lightweight, customized and visually appealing activity-specific prostheses aimed to increase participation in music and sport activities.[10-17]

The major problem with casting procedures is that they are messy and require the physical presence of the individual needing the prosthesis and the health care professional in the same physical location, which may not be possible for patients living in rural or isolated areas. Similarly, 3D scanning procedures require sophisticated equipment and technical knowledge on site to perform the measurements. Thus, the development of a remote fitting methodology for upper-limb prostheses that can use standard photographs allowing family member to perform the procedure will not only simplified the process, but also will reduce the number of required visits of patients to their clinics.[11] This is a significant shift in the current clinical paradigm.

To our knowledge, there are no known practical methods for the development of remote fitting procedures for activity-specific prostheses. Therefore, the proposed aim intends to develop remote fitting methodology using standard photographs of the upper extremities to extract all the measurements required to develop the activity-specific prosthesis and verify the proper fit by superimposing the CAD model of the device over the upper extremity photograph.

Advancements in computer-aided design (CAD) programs, advance manufacturing, and image editing software offer the possibility of designing, printing, and fitting activity-specific 3D printed prostheses at a very low cost.[13,20] Therefore, the purpose of this study was to develop an activity-specific 3D printed prostheses, develop a remote-fitting procedure for the prosthesis and evaluated patient satisfaction after using the device for 8 weeks. We also evaluated anthropometric and range of motion (ROM) measurements of the residual limb before and after use of the prosthesis.

Methods

Participants:

Inclusion criteria for all participants included boys and girls from 3 to 17 years of age with unilateral carpus upper-limb reductions, missing some or all fingers, and wrist range of motion of the affected wrist greater than 20°. Exclusion criteria included upper extremity injury within the past month and any medical conditions that would contraindicate the use of the transitional pros- thesis, such as skin abrasions and musculoskeletal injuries. Nine children (two girls and seven boys, 6 to 16 years of age) with congenital upper limb deficiencies participated in this study and were fitted with a 3D printed modular activity-specific prosthesis (Table 1). This research was approved by the Institutional Review Board of the University of Nebraska Medical Centre and all participants will give informed consent during the first visit of the entire study.

ID	Gender	Age (years)	Daily Prosthesis Use (hours)	Diagnosis	Ability to Pinch
1	M	7	3	Congenital deficiency right hand	No
2	M	10	2.5	Congenital deficiency right hand	No
3	M	16	1	Congenital deficiency left hand	No
4	M	9	3	Congenital deficiency left hand	No
5	M	8	2.5	Congenital deficiency left hand	No
6	F	6	4	Congenital deficiency left hand	No
7	F	7	2	Congenital deficiency left hand.	No
8	M	7	3	Congenital deficiency right hand	No
9	M	12	3	Congenital deficiency left hand	No
Mean		9.11	2.67		
SD		3.18	0.83		

Table 1. The demographics of the subjects that participated in the study

Design:

For the development of the modular activity-specific device, we used a proprietary high-strength, antimicrobial, recyclable and biocompatible polymers.[16,28] The terminal device of the modular prosthesis was specifically designed to playing musical instruments (cello and violin, Figure 1) and sport activities (golf and bicycle riding). The arm section of the prosthesis was suspended with a flexible support strap (Fig. 1B). The interior of the arm section and prosthetic socket in the distal portion of the forearm has a liner made of proprietary antimicrobial thermoplastic polyurethane (TPU) with elastic and mechanical properties appropriate for skin contact[15]. The distal portion of the prosthesis has a proprietary sliding ball-connector to attach the activity-specific terminal effector.

The CAD models of the prostheses with the integrated socket was designed and scaled using Autodesk Fusion 360 (Fusion 360, Autodesk, Inc., San Rafael, CA, USA). The geometry and overall design of the 3D models have been specifically developed to be printed in small desktop 3D printers. After each component of the prosthesis was 3D printed, post-processing were required depending on the implemented design and print settings. This post-processing stage included the removal of the support and rafts using tools to file and smooth areas exposed to friction, such as the plastic pins, wrist joint, and connectors.

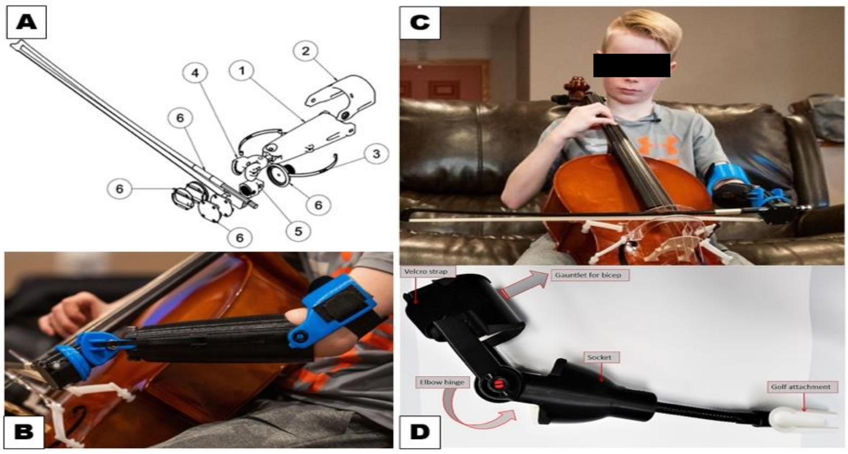

Figure 1. Modular 3D printed prosthesis early prototypes for task-specific activities. A) Modular componentry of prosthesis with cello terminal effector. B) Lateral view of prosthesis with cello terminal effector. C) Frontal view of prosthesis with cello terminal effector. D) Modular prosthesis with golf terminal effector.

Procedure/Conditions:

The developed activity-specific prosthesis were fitted to the subjects. Moreover, guardians were approached to screen the action explicit prosthesis use and record the long periods of day by day use in a log gave by our exploration group during the multi week-time span. Youngsters were urged to utilize the prosthesis during their present music and game exercises including cello, violin, golf, or potentially bike riding. A board-guaranteed prosthetist and an affirmed hand advisor supervised the fitting methodology and directed the acclimation with the gadget and organization of studies. Following two months of utilization, patients and their families were approached to visit the research facility once more (visit 2) to finish the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0)[26] administrated via prepared clinicians. The QUEST 2.0 incorporates things identified with assistive gadget fulfilment, wear, and use. Our team's published data [11,13] demonstrated the feasibility of extracting measurements form photographs to fit a prostheses remotely. The standard fitting procedures currently used by most prosthetic is by wrapping plaster bandages over the affected limb.[29] 3D scanning methods have also been used for the development of different types of prosthetic sockets for upper-limb and lower-limb prostheses.[20,30,31]

For the remote-fitting methodology, the participants of the examination members were solicited to send photos from their upper-appendages 3 weeks before their first research facility visit. In the wake of assembling the action explicit gadget utilizing the separated estimations from the photos, parent and research members visited the lab on two events. During the primary testing (visit 1), direct anthropometric estimations were taken to check the estimations got remotely. Moreover, members were given the prosthesis fitted remotely and our clinicians will assist them with acclimating with the capacity of the gadget.

Our exploration group created layouts and itemized directions for the photos required to play out the remote fitting methodology for action explicit prosthesis. After the formats were created, our examination volunteers (n=9) sent three distinct photos of the upper appendages like our present methodology (Fig. 2). A few anthropometric (lengths and widths) and ROM measures (flexion and expansion of the elbow) were extricated utilizing the picture altering instrument accessible in Autodesk Fusion 360. These removed estimations were utilized to fit the gadgets and get a balanced look. The separated estimations were a contrasted with direct anthropometric estimations taken by a prepared word related specialist utilizing a standard measuring tape and goniometer.

The principle parts of our advanced fitting systems comprised of appropriately scaling the computerized structure of the prosthesis to the components of: 1) the patient's remaining appendage for creating a properly measured attachment, and 2) the non-influenced appendage to encouraging respective length balance and improve generally speaking capacity. The remote fitting methodology were confirmed by superimposing the prosthetic plan over a 2D picture (Fig. 3). The attachment was incorporated in the inward side of the lower arm compartment of the movement explicit prosthesis.

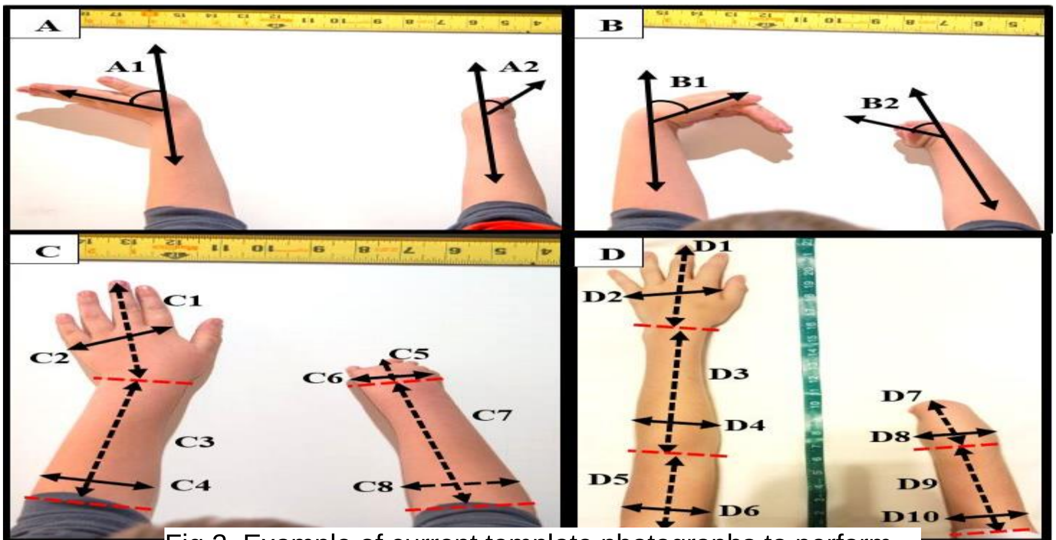

Fig 2. Example of current template photographs to perform the remote fitting procedures.

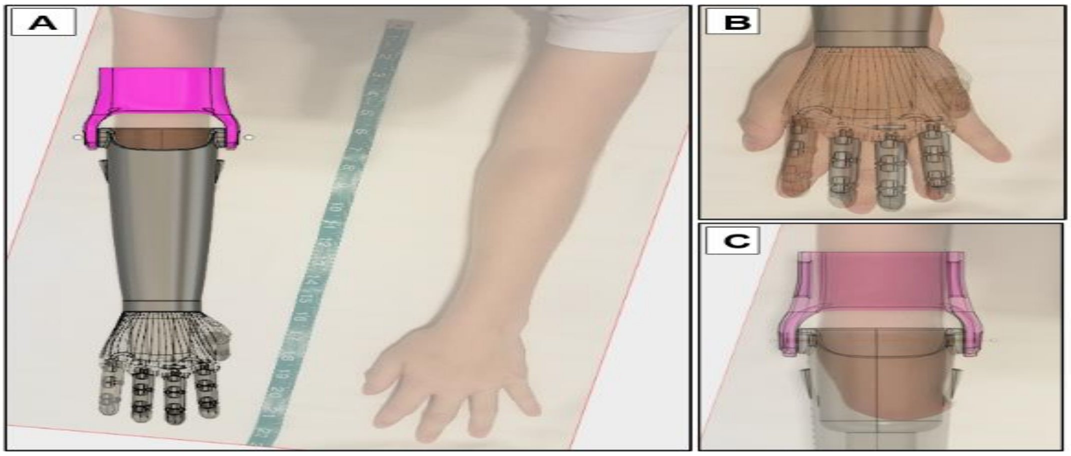

Fig 3. Illustration of our current remote fitting procedures showing the design of the 3D printed arm prostheses s on a photograph of the patient's upper limbs. (A) Illustration of 3D printed arm prostheses scaling. (B) Scaling for the hand section of the 3D printed arm prosthesis. (C) Scaling for the socket and upper arm sections of the 3D printed arm prosthesis.

Statistical Analysis:

This is an observational study using content and score analysis to describe patient satisfaction after remote prosthetic fitting. Descriptive statistics (Mean ± Standard Deviation) was calculated and summarized for the survey (QUEST 2.0).

A dependent T-test was performed between the anthropometric and ROM measurements extracted from photographs with those directly measured by the trained occupational therapist with an alpha level set at $p<0.05$.

Results

The subjects completed a QUEST 2.0 survey that consisted of eight questions which helped in the evaluation of parameters such as satisfaction, comfort and effectiveness. Fig. 1 represent the scores that were recorded from the survey given to the patients. Descriptive statistics were performed to calculate the mean and standard deviation of the scores recorded in the QUEST 2.0 survey as shown in Fig 1. The mean is calculated across the observations and it represents the measure of central tendency. The standard deviation was calculated to measure the spread of the observations. The larger standard deviation represents that the observations are more spread out.

The dependent t-test analysis showed that for strength of the affected limb there was a significant main effect for range of motion as shown in Fig 2 and Fig 3.

All nine families and children participating in this study completed a short survey. After 6 months of using the 3D printed hand prosthesis, children and their families reported using the hand for 2.7 ± 0.83 h a day (Table 1). Furthermore, children reported using the prosthetic hand "just for fun" (n = 8), for "activities at home" (n = 4), to "play" (n = 9), for "school activities" (n = 3), and to perform "sports" (n = 3)

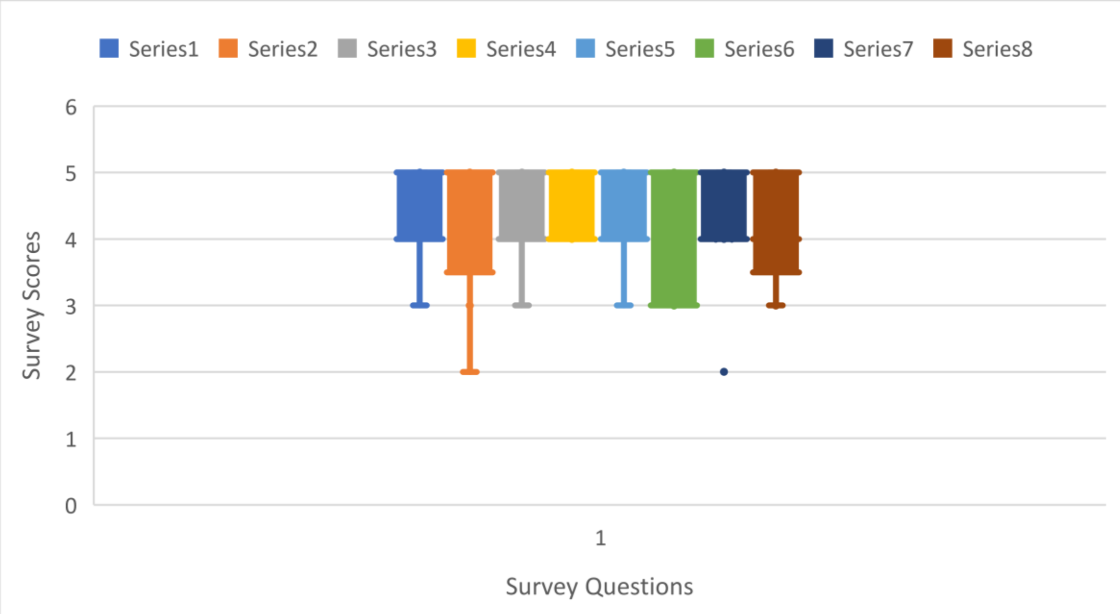

Fig 1. The scores of the QUEST 2.0 survey that the participants completed. The questions are represented by the series here.
Series 1: How satisfied are you with the dimensions (size, height, length, width) of your assistive device?
Series 2: How satisfied are you with the weight of your assistive device?
Series 3: How satisfied are you with the ease in adjusting (fixing, fastening) the parts of your assistive device?
Series 4: How satisfied are you with the safety and security your assistive device?
Series 5: How easy it is to use your assistive device?
Series 6: How comfortable your assistive device is?
Series 7: How effective your assistive device is (the degree to which your device meets your needs)?
Series 8: How satisfied are you with the service delivery program (procedures, length of time) in which you obtained your assistive device?

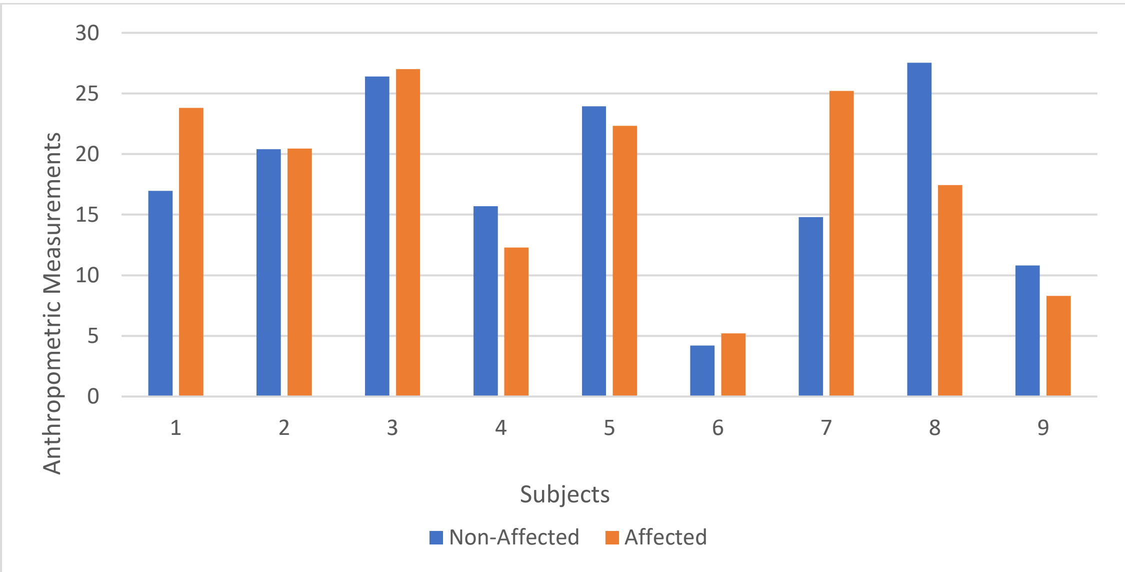

Fig 2. The box plot representing anthropometric measurements of non-affected and affected after the use of the modular activity-specific device

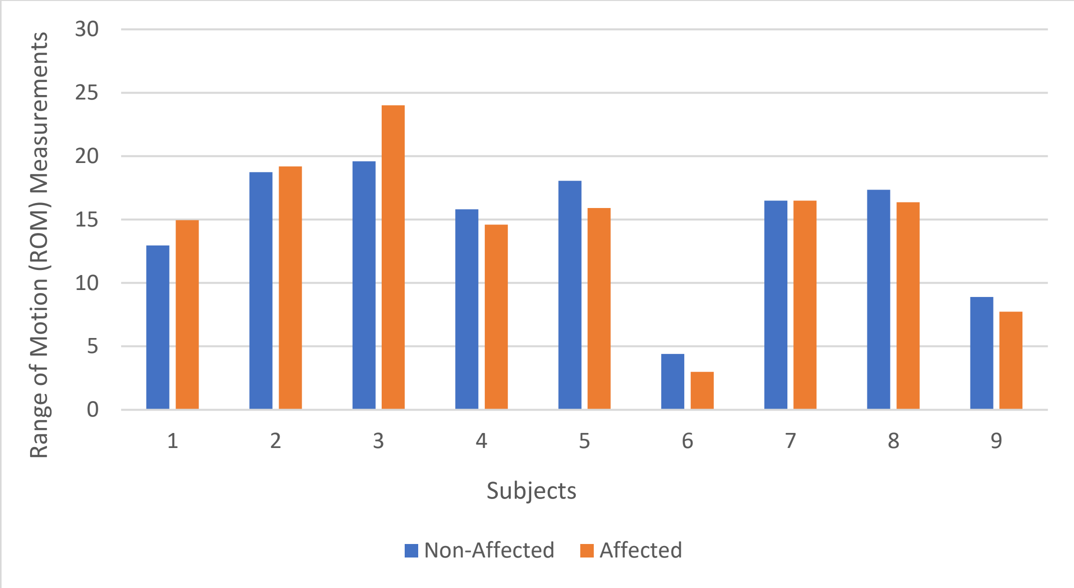

Fig 3. The box plot representing ROM measurements of non-affected and affected after the use of the modular activity-specific device

Discussion

The main findings of this study were that an effective modular activity-specific prosthesis can be developed at a low-cost. Additionally, remote fitting procedures were developed. The results also showed that participants were satisfied with the devices after 8 weeks of use. Furthermore, we observed that for strength of the affected limb there was a significant main effect for wrist motion. This investigation shows that the secluded prosthesis had a practical job in regular day to day existence in efficiency, self-care and recreation. The prosthesis encouraged word related execution, and along these lines reliance on the prosthesis particularly among the individuals who had an awful removal. Among those with inborn decrease insufficiency the practical need was not as solid since they expressed that they could do everything without prosthesis. A few exercises were ideally performed with the leftover appendage, paying little heed to the reason for missing one arm. This was particularly clear in childcare.

The closeness and skin-to-skin contact in care was not cultivated with a prosthesis and dread of squeezing the youngsters accidentally when utilizing the prostheses was constraining. The significance of reasonableness in the stump was additionally an essential for execution in certain exercises. Dietrich et al (2012)[33] report that preparation program with a counterfeit prostheses brought about better useful control.

The potential limitations of the current assessment are related to the nonattendance of an age-composed benchmark gathering, the humble number of children looking into the examination and the quality necessities of the 3D-printed prostheses. The current examination bars an age-facilitated benchmark gathering to study ordinary improvement of solidarity and manual artfulness in age-composed children over the time scope of the assessment. In any case, the contralateral arm will be used as a control, as proposed and depicted in past examinations.[10,13]

A model size of just 9 subjects makes it difficult to amass ask about individuals by age and sexual direction. Another restriction of the current assessment consolidates the characteristic strength goals of interweaved testimony exhibiting process used to make 3D-printed prostheses definite in past examinations[12] could have affected the most ideal use and limit of the prostheses. Besides, it has been as of late point by point that the current materials used for 3D-printed prostheses, for instance, polylactic destructive (PLA), need assistant consistent quality inside seeing suddenness and at high temperatures (>60 Degrees Celsius)[15]. The quick defilement of PLA under these conditions can impact the strength and limit of 3D-printed prostheses. Disregarding the way that strength objectives are factors to consider while using 3D printed prostheses, the sensibility and cost-reasonability address a promising new decision for clinicians and their patients.

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