Outcome of Three Dimensional Printed Functional Prostheses for Children with Upper Limb Deficiency in Nepal

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ABSTRACT

Background

Children with congenital and traumatic upper limb amputation are undervalued in a low and middle-income country (LMIC) like Nepal. The use of a prosthetic hand can give them a feeling of self-reliance to perform their daily activities. However, prosthesis require periodic maintenance and replacement which could be a financial burden to some families. The e-Nable community has designed and developed three dimension printed prosthetic hands for children under 19 years old, and distributed them free of cost.

Objective

To explore the functionality of the three dimension printed prosthetic hands using semi-structured questionnaires and assess a series of daily tasks after three months prosthetic use.

Method

This descriptive cross-sectional study was conducted from July 2019 to June 2020, after receiving an ethical clearance from the Nepal Health Research Council (Registration number: 582/2019). Seventy six children (5-18 years old) who met the inclusion criteria were enrolled in this study. Data were collected using semi-structured questionnaires, and observational methods to identify the benefits and drawbacks of the three dimensional prosthetic hands. Mean, standard deviation, and percentage were used to interpret the data.

Result

All participants could only lift light objects such as tray, tennis ball or a bottle of water. They had difficulty with those task that required complex movement and with lifting heavy objects. Moreover, only 47(61.8%) participants were completely satisfied with the prosthetic hand and the major reasons for dissatisfaction were tear of the rubber band or cord, and broken parts.

Conclusion

Participant were able to complete certain tasks using the e-Nable community three dimensional printed prosthetic hands.

KEY WORDS

Children in low and middle-income country, Upper limb deficiency, Three dimensional functional prostheses

INTRODUCTION

Prostheses are artificial devices to replace the missing part or organ of a body, thereby their function should be easy, spontaneous, and appropriate for daily tasks. There are different types of upper limb prostheses like passive prostheses, body-powered, and electric powered prostheses. Passive prostheses are usually used for cosmetic purposes having no functional properties. Body powered device requires extensive fitting procedure including a complex system of cables and harnesses with a lower cost as compared to myoelectric prostheses, which need substantial schooling. Currently, the most cost-effective option for the pediatric population is a passive prosthetic hook.[1] Although they are functional, these devices have a high rejection rate due to an unacceptable cosmetic appearance.[2] Along with the cosmetic and functional property, the size and weight of the prostheses are also important physical characteristics.

While futuristic devices are being designed and tested, they are not commonly used by the participants, due to their high cost and complexity.[3] In LMIC, the access of children with amputation to prosthetic devices is very limited. The prosthetic hands printed by e-Nable Nepal were distributed free of cost to the children, tapering the financial burden to the recipients family. Even though these prosthetic hands are simple, cost-effective, body-powered, and reproducible it must be appropriate for the environment and lifestyle found in the LMIC. Therefore, this paper aims to provide the outcome of 3D-printed upper limb prostheses with their benefits and drawbacks and to accredit their improvement based on the demands of prostheses users.

METHODS

This was a descriptive cross-sectional study conducted from 15th July 2019 to 30th June 2020 in e-Nable Nepal, Sinamangal, Kathmandu, and KIST Medical College and Teaching Hospital, Gwarko, Lalitpur. Ethical clearance was taken from the Nepal Health Research Council (Registration number: 582/2019). The total of 76 participant ranging from five to 18 years who had upper limb differences with a remaining limb length of more than three inches below the elbow and more than one inch below the wrist were included in the study. They also required the power of the elbow or wrist to be at least more than 4 out of 5.[4] The cause of amputation may be congenital or as a result of an accident, civil war, electric shock/burn, or some disease conditions.

Exclusion criteria involved children with partial finger amputation, club hand, insensate, infected hand, recipient allergic to Polylactic acid (PLA), and Polyethylene terephthalate glycol (PETG). The participants who either provided inadequate information or incomplete questionnaire were also excluded from the study.

As the children quickly damage and outgrow the prostheses they have to be replaced regularly. This frequent change in the prostheses can bring a financial burden to the family in LMIC like Nepal. Therefore, the light weighted e-Nable community designed functional prostheses were and are still distributed to children free of cost by e-Nable Nepal as a social responsibility.

Information to the participants was given through social media platforms (including Facebook, and Twitter), television, and radio. The needy participants were asked to contact our office at e-Nable Nepal, Sinamangal, Kathmandu, or KIST Medical College and Teaching Hospital, Gwarko, Lalitpur, using our phone number or through social medias. Convenience sampling was done to select the participants and the data were collected through semi-structured questionnaires and observational methods. The survey questionnaire assessed demographic information, including age, sex, address, and education level followed by clinical information such as side involvement, level of amputation (below the elbow or below the wrist), and etiology of amputation like the congenital, victim of civil war, accident, electrocution (fire) and diseases like a tumor, infection, gangrene, others. All the participants were also asked if they had used a prosthesis before or not.

First of all, the participants were shown an audiovisual clip of the e-Nable designed hand with its various uses, followed by the demonstration conducted by our members. Once the recipients got the basic idea about the prosthetic hands they were taught about application as to how these hands function. The simple mechanism of forward bending or flexion of the wrist or elbow made all the digits bend and create a basic grasping motion, and unbending (extension) of the wrist or elbow let the hand move back into the open position.[5]

Written consents of the parents and children (if possible) were taken. The proforma which included demographic details and a semi-structured questionnaire were filled in. This was then followed by measuring the length and circumference (in cm) of the arm, forearm, and hand of both the sound and residual limbs of the recipients. The length of the arm was measured from the tip of the acromion process to the lateral epicondyle of the humerus. The forearm was measured from the tip of the lateral epicondyle to the radial styloid process. Similarly, the hand was measured from the anterior wrist crease to the tip of the middle finger or the distal-most part. Likewise, the circumference was measured at the site of maximum girth or 3 inches distal to the tip of the acromion process for arm and 3 inches distal to the tip of lateral epicondyle of the humerus for forearm. These measurements were entered into the associated Computer-aided design (CAD) file to scale the device. The sterolithography (STL) file generated in the CAD file was changed into a gcode file using cura or slic3r. The design was then printed in Prusa MK3 and creality ender 3D printer using colorful plastic filaments

(PLA and PETG) layer by layer. By this method, two types of prosthetic hands such as unlimbited arm V2.1 (elbow powered) and phoenix hand V2 (wrist powered) were fabricated. Accordingly, these contrived materials like the forearm and cuff were molded by thermoforming using hot water or a hot gun. Finally, these parts (forearm, cuff, palm, and fingers) as shown in figure 1 were manually assembled using pins, rubber bands, cords (fishing line), screws, velcros, and padding foam into functioning prosthesis.[5]

Figure 1. Showing different parts of the prosthesis.

Fabricating and assembling the device took around five days after which the recipients were called upon for trial fitting. At this time the parents and recipients were taught as to how to use them, which included putting the residual limb properly in the padded prosthetic hand, and tightening them with multiple Velcro. They had to begin with the basic movements of flexing and extending the wrist/elbow to carry out gripping and releasing movements of fingers respectively. They were also taught to pick up coins, push buttons, turn pages, open jar lid, cut food, pour glass jug, pour carton, lift tray, open and close zipper, turn the door handle, rotate screw and key, at the same time holding objects like a tennis ball, pin pong ball, bottle of water, cup, and soup can were also demonstrated and tutored. Taking care of prosthetic hand like washing it with normal soap water, and basic maintenance like changing the rubber band and cord (fishing line) were also exhibited. Finally, a detail of safety guidelines which included avoiding its use in extreme temperatures and near fire and chemicals were also advised. Prostheses were then handed over once the recipients got knowledge and confidence about it as shown in figure 2.

Figure 1. A boy with an amputation below the elbow wearing a new functional prosthesis.

From the date of delivery, the recipients were followed up at the end of three months with the semi-structured questionnaire as in the proforma which included duration of prosthesis use per day in hours with its durability, acceptability, and patient satisfaction. Along with that, the recipients were observed performing certain tasks and holding certain objects within 30 seconds wearing the 3D printed prosthetic hand as given in (Tables 1 and 2).[6]

In our study, we used Standardized testing, such as the Southampton Hand Assessment Procedure (SHAP) which assesses the effectiveness of upper limb prostheses, as the tasks were based on one or more prehensile patterns and included objects common in activities of daily living (ADL).[6]

All the data were collected in the Statistical Package of Social Sciences (SPSS v16) and analyzed using mean, standard deviation, and percentages. Tables and charts were used to present the data.

Table 1. The result of the daily tasks test observed by using Southampton Hand Assessment Procedure (SHAP)

Task	At three month	
	Yes n (%)	No n (%)
Pick up coin	32(42.1)	44(57.9)
Push-button	59(77.6)	17(22.4)
Cut food	0	76(100)
Turn page	25(32.9)	51(67.1)
Open jar lid	31(40.8)	45(59.2)
Pour glass jug	3(3.9)	73(96.1)
Pour carton	0	76(100)
Lift heavy object	0	76(100)
Lift light object	76(100)	0
Lift tray	76(100)	0
Rotate key	0	76(100)
Open/ close zipper	22(28.9)	54(71.1)
Rotate screw	0	76(100)
Turn door handle	22(28.9)	54(71.1)

Table 2. Observed result of size and shape testing based on holding objects using Southampton Hand Assessment Procedure (SHAP)

Object to hold	At three month	
	Yes n (%)	No n (%)
Tennis ball	76(100)	0
Ping pong ball	43(56.6)	33(43.4)
Bottle of water	76(100)	0
Cup	46(60.5)	30(39.5)
Soup can	2(2.6)	74(97.4)

RESULTS

Out of 76 participants, 36 (47.4%) were male and 40 (52.6%) were female. The minimum age of participants was five years and the maximum 18 years with a mean age of

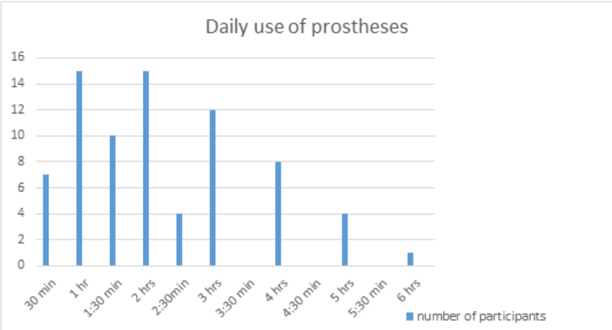

Figure 3. **Daily use of prostheses**

11.4 (±3.8) years. All the participants were going to school in different grades. The amputation of the left upper limb 49 (64.5%) was more than the right upper limb 27 (35.5%). Participants with the amputation below the elbow were significantly higher than the amputation below the wrist 61 (80.3%) and 15 (19.7%) respectively. The socio-economic condition of our participants was of lower or lower middle class. The major causes of upper limb deficiency were congenital in 43 (56.6%) participants followed by war injury in14 (18.4%), accident in 14 (18.4%), burn/electric shock in 3 (3.9%), and disease condition in 2 (2.6%) participants. The majority of the participants did not use prosthesis previously 67 (88.2%), however, only 9 (11.8%) participants had used some kind of prosthesis previously.

At the end of the third month, 47 (61.8%) participants reported that they were satisfied with the prosthetic hand. There were no complaints regarding the prostheses among 27 (35.5%) participants, whereas 30 (39.5%) participants had their rubber torn, 12 (15.8%) had their cord (fishing line) torn and 7 (9.2%) had their prostheses broken during the first three months of their use of prostheses.

DISCUSSION

The upper extremity is a highly complex structure, its deficiency may result from congenital cause or amputation. Amputation being one of the ancient surgical treatment dating back to the 16th century, Ambroise Pare was the first one to design relatively sophisticated prostheses.[7] A study carried out by Ghosh et al. showed an increase in the number of people with limb amputation as a result of an increase in transportation methods, development of mechanical civilization, and prolongation of life.[8] The author also highlighted peripheral vascular disease and trauma to be the major cause of amputation in developed and developing countries like India respectively.[8] But regarding the pediatric populace, there has been an increase in the number of children born with a congenital upper limb deficiency or acquired traumatic amputation in the last two decades.[1]

Executing daily chores with a missing limb is undoubtedly very challenging. For a person who has had his or her upper limb lost, it is highly desirable to replace this loss with a device that is not only identical in appearance but also closely mimicking its capabilities. Children's prosthetic needs are complex due to their small size, constant growth, and psychosocial development.[1] Durability may not be a major issue in pediatric prostheses because they need periodic replacement as the limb size increases even in a once snuggly fitted prosthesis. This may lead a financial burden to the family, since they have to keep on changing them as the children grow older.

Upper limb deficiency is a condition in which a part of the upper limb is missing as a result of a congenital limb deficiency or as a result of an amputation. A prosthesis should meet the basic user demands to increase its usability. These demands can be summarized as cosmesis, comfort, control and function.[9] The process of creating reliable prosthetic devices to amputed hand has remained a challenge to researchers in the hope of making it easier without causing the bearer any additional pain or discomfort. Three dimension printing technology is one of the solutions to manufacture hand prostheses for children with upper limb differences who need frequent repairs and upgrades substantially at a more affordable price.[10]

It is estimated that, in the United States, more than 32,500 children suffer from a major pediatric amputation, and the Centers for Disease Control and Prevention estimates about 1,500 children were born with upper limb reductions in the United States each year.[11,12] Worldwide estimates for upper limb reductions range from 4-5/10,000 to 1/100 live births.[13] Unfortunately, the reliable data regarding children with upper limb amputation in Nepal is not available. In our study, we found the birth defect as the reason for upper limb deficiency i.e. congenital in 43(56.6%), and amputation in the remaining 33 (43.3%) participants, which was comparable to a study conducted by Bethge et al.[13] This high number of congenital cause of upper limb reduction as compared to traumatic amputation is quite alarming and must be taken seriously to find any medical reasons behind it. The acceptability of the prosthesis would be better if it was used immediately after the amputation in traumatic cases (sooner the better) and after five years of age, if it was a congenital case (younger the age better the adaptability). Because children below the age of five years could not use it functionally.

Based on the information of (Tables 1 and 2) all the participants 76 (100%) could lift light objects and tray as it involved simple flexion of fingers which was possible with this device. Some other tasks like pushing buttons were successfully carried out by 59 (77.6%) participants because it did not require gripping motion and much force. Even though fingertip grip on the prosthetic hand provided friction to turn pages, only 25 (32.9%) participants could turn the pages randomly without being able to turn the desired page or one page at a time. Picking up a coin and opening a jar lid was difficult, as only 32 (42.1%) and 31 (40.8%) participants could perform it respectively because the index finger and thumb of the prosthetic device were used to rotate rather than the entire hand. Only a few i.e 22 (28.9%) participants were able to use zipper by grabbing it with index finger and thumb. The door handle with a lever could be opened by 22 (28.9%) participants just by pushing or pulling method. None of the participants could rotate the key, screw, and lift a heavy object, pour carton, and cut food because all these tasks required a firm grip and rotational movement which was not possible with these prostheses.

Holding a tennis ball and bottle of water was ideal shape and weight for all the 76(100%) participant's prosthetic hand to grasp. A very few could only hold a soup can whereas holding a ping pong ball and cup had a mixed result because of its smaller size and shape. All of the above results were comparable with a study conducted by Dally et al. suggesting that a prosthetic hand could restore some of the functions of a missing limb but it could not be used for heavy work and rotational movement.[6] To successfully accomplish any tasks that require grasping an object, the user should grip it by touching it with all the fingers including the thumb. The prosthetic hand is designed in such a way that all of the fingers bend together when the hand closes, causing every finger to move in line with the rest. Because each object has a unique shape, it is not likely that every finger will be able to touch the object as the hand grasps. This is one of the reason for a weaker grip where the recipient could pick up the cup but were unable to tip the cup in order to take a sip.

In our study, only 9 (11.8%) of the total participants had used cosmetic type of prostheses whereas e-Nable designed prostheses having the functional advantage of carrying out daily activities, motivated them. In our work, the average duration of application of the prostheses was one to two hours per day as shown in figure 3, but in a Norwegian survey on 224 adult participants revealed the fact that they wore prostheses for more than eight hours a day. In this case, wear does not necessarily relate to its use.[14] As our study group comprised of children, they could carry out only a certain number of tasks using this device which also made the duration of wear shorter. Suggesting that the less number of activities carried out using this device may be one of the reasons for shorter duration of its wear. Therefore, the use of 3D-printed upper limb prostheses among the children could be increased if they demonstrate greater functionality and a more anthropomorphic appearance.

In our study, the reason for dissatisfaction among the teens was the lack of cosmetic design. Even though the younger children accepted this e-Nable designed prosthetic hand, they seem to be more destructive as compared to the teens. Hence, tear of the rubber band in 30 (39.5%) participants followed by cord (fishing line) tear in 12 (15.8%) recipients and broken parts in 7 (9.2%) were the major reason for dissatisfaction in 29 (38.2%) participants and also a ground for abandonment of the prostheses at the end of third month, which is in accordance with the study done by Davids et al.[2] However, the benefit of 3D-printing machine is that, if the device breaks, it is easy to replace the parts. But in our context, it was not possible because most of the recipients were out of the Kathmandu valley, from geographically remote parts of the country. Their periodic visit to health care providers for adjustment or replacement often made them reluctant to wear prostheses.

The advantage with the 3D printing machines is their design freedom, therefore high complex geometries can be made, and the product can be customized in a short period without the need for adjusting the production machine. It also has some disadvantages such as it is hard to predict the mechanical property and hence cannot be used in extremes of temperatures, the size of the prostheses to be made depends upon the size of the printer.[14] There are some other components in the prostheses like the rubber band, cord, screws that can get torn or unfastened easily, and need replacement and readjustment frequently. With respect to the durability of the parts no test has been carried out to predict the life cycle of the printed parts.[9] None of the publications has mentioned as how long a prosthetic hand could be worn without requiring its repairment, rather they have stated that the broken parts can be easily replaced using a 3D-printing machine.[9]

While 3D printed prostheses were thought to be cheap, most of our participants could not afford them when asked about their manufacturing cost, as most of them were from lower socio-economic background which was in consonant with a study done by Kate et al.[9] His study states that, even though the material cost was cheap, the development, including designing, assembling, and fitting has made the total price hike as compared to the injection molding parts. But in our study, all the prostheses were given free of cost.

The study was limited in terms of its small sample size and short duration of the study.

CONCLUSION

The task that the children performed using this prosthetic device were light and simple (lift light object, lift tray, hold tennis ball, hold a bottle of water). Children being more playful and destructive has questioned the durability of the device. Even though replacing the torn rubber band and cord (fishing line) were made possible by the recipient's family, restoration of the broken part of the prostheses was not feasible as the 3D Printing machine and technical resources was limited to our center. The study also concluded that the main reason of teens' dissatisfaction toward the prostheses was that they lack cosmetic appeal.

Therefore, there is a critical need for practical, easy to replace, customized, aesthetically appealing, affordable, durable, and lightweight prosthetic devices for children. Developing awareness programs for early prosthetic fitting and rehabilitation can result in easy acceptability and prevent the child with amputated limb from becoming a burden to the family and society.

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