Developing and Testing of Low-cost 3D Printed Prostheses to Restore and Improve Function of Children with Congenital or Traumatic Amputations

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INTRODUCTION

Advancements in computer-aided design (CAD) programs and additive manufacturing (3D printing) offer the possibility of designing and printing customized upper-limb prostheses at a low cost[1,2]. However, there is a lack of specific technical descriptions and clinical evidence supporting the use of 3D printed prostheses. The purpose of this investigation was to provide technical considerations and clinical evidence of the possible benefits and obstacles in the use of upper-limb 3D printed prostheses in pediatric populations. This information is crucial for clinicians interested in exploring the use of 3D printed prostheses for their patients.

METHOD

Technical Considerations: A description of the technical considerations associated with the design, 3D printing processes, and current Food and Drug Administration (FDA)[3] recommendations for testing and characterization for upper-limb 3D printed prostheses are examined.

Clinical Evidence:

Study 1: Five Children (three boys and 2 girls; 12 to 17 years of age, all with congenital digit reductions) form the Instituto Teletón Santiago, Chile, which is one of the main institutions in South America providing rehabilitation to children. Each child was fitted with a 3D printed upper-limb prosthesis. Assessment of the limb function was completed with the modified Bilan Score 400. Testing was completed before delivery of the prosthesis, then at 1 month and 4 months of use. In addition, the Upper Extremity Functional Index (UEFI) was used to evaluate the perceived functionality of upper-limbs before the use of the prosthesis and after 4 months of use. A descriptive analysis of the data was performed by each participant.

Study 2: Five children (two girls and three boys, 3 to 10 years of age) with absent digits (one traumatic and four congenital) participated in this study and were fitted with a 3D printed prosthetic hand. Gross dexterity, anthropometric measurements, active range of motion, and strength measurements were assessed before and after 6 month of using a low-cost 3D printed prosthetic hand. Seven separate two-way repeated measures ANOVAs [2 x 2; hand (affected versus non-affected) x Time (before and after)] were performed to analyze the data. A p-value of ≤ 0.05 was considered statistically significant for all comparisons.

Study 3: Nine children (two girls and seven boys, 3 to 16 years of age) with upper-limb reductions (one with traumatic finger amputations, one with transradial congenital reductions and seven with congenital digit reductions) were fitted with a 3D printed transitional prostheses. Their parents completed a survey at 1 and 3 months asking to quantify the time their child used the prosthesis on a daily basis in addition to the type of activities they performed with the prosthesis.

RESULTS

Technical Considerations: A practical guide to effectively and safely 3D print upper-limb prosthesis is presented. The manufacture of a prosthetic component or orthotic device is only a small part of the creation of a prostheses or orthoses. The components that are included in the completed prosthesis or orthosis must be adjusted and aligned by a properly educated, trained, and certified healthcare professional such as an orthotist or prosthetist.

Clinical Evidence:

Study 1: At 1 month and 4 months of use, the median change for hand function for the unaffected and affected limbs were -11% and -4% and -9% and -2%, respectively. The overall median change percentage for the perception of upper-limb functionality was -62%.

Study 2: There were significant hand × time interactions for the forearm circumference [$F(1,4) = 16.90$; $p = 0.02$], active ROM flexion [$F(1,4) = 12.70$; $p = 0.02$,], and active ROM extension values [$F(1,4) = 8.80$; $p = 0.04$]. There was no significant hand x time interaction, however, for wrist flexion strength [$F(1,4) = 1.48$; $p = 0.29$], and wrist extension strength [$F(1,4) = 0.05$; $p = 0.84$].

Study 3: Nine parents reported that their children used the device 1 to 2 hours a day, 3 reported using it longer than 2 hours and 1 reported using it only when needed. Furthermore, the parent also responded that their children used the device for activities at home (9), just for fun (10), to play (6), for school activities (4), and to perform sports (2). Four children reported malfunctioning and/or breaking of the 3D printed prosthetic device after 3 months of use.

CONCLUSION

The main finding of our studies is that the initial prosthesis design of the Cyborg Beast was not a functional solution for congenital pediatric patients with remnant opposition and pinch function (Study 1), but significantly increased forearm circumference (Before=16.70±1.86 cm and After=17.80±1.48 cm), wrist active ROM flexion (Before=54.60±14.48° and After=68.40±14.29°), and active ROM extension (Before=40.40±37.75° and After=47.00±36.42° cm) after 6 months of use (Study 2) and can be incorporated in several activities at home and in school. However, 44% of our research participants reported durability issues and/or malfunctioning of these devices after 3 months of use.

SIGNIFICANCE

Technical considerations and clinical evidence are crucial for healthcare professional interested in exploring the use of 3D printed prostheses for their patients. Although durability of 3D printed prostheses is a major concern, the practicality and cost effectiveness represents a promising new option for clinicians and their patients. The supervision of a certified prosthetist is crucial for the proper development and use of 3D printed prostheses.

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