

Remote Fitting Procedures for Upper Limb 3D Printed Prostheses

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Abstract

Objective: The objective of the current investigation was twofold: i) described a remote fitting procedure for upper limb 3D printed prostheses and ii) assess patient satisfaction and comfort with 3D printed prostheses fitted remotely.

Design: A qualitative study using content and score analysis to describe patient satisfaction after 4 weeks of using an upper limb 3D printed prosthesis fitted remotely. The novel remote fitting procedure is described in detail.

Subjects: Six children (three girls and three boys, 6 to 16 years of age) and 2 adults (males of 25 and 59 years of age) with congenital (n=7) and acquired (n=1) upper limb loss participated in this study.

Results: The research participants reported a score of 3.92 ± 0.50 (closer to the statement “quite satisfied”) for the device satisfaction section of the QUEST questionnaire (Table 2). This acceptable level of satisfaction of our research participant reported in the QUEST was confirmed by the agreement scores of the OPUS items related to prosthetic fitting (My prosthesis fits well = 4.13 ± 0.50) and comfort (My prosthesis is comfortable throughout the day = 3.57 ± 0.98). Furthermore, the comfort level rating in the general prosthetic survey resulted in a score of 3.75 ± 0.70 (closer to the statement “the prosthetic device feels comfortable”) confirming the results of the QUEST and OPUS.

Conclusions: The ability to fit an upper-limb prosthesis remotely, represents a promising methodology to fit upper-limb 3D printed prostheses for patients from developing countries or rural areas. The increasing availability of smartphones and other digital devices makes it possible to obtain photographs from patients located in rural areas that have little or no access to trained technicians. These photographs along with the cost-effective desktop 3D printers allows for the

1 extraction of the anthropometric measurements required for the development of a 3D printed upper
2 limb prosthesis remotely.

3

4 **Keywords:** Computer-aided design—computer-aided manufacturing, rapid prototyping, upper-
5 limb prosthetics, prosthetic design, patient satisfaction

6

1 Introduction

2 The Centers for Disease Control and Prevention (CDC) estimates that about 1,500 babies are born
3 with upper-limb reductions every year in the U.S.^{1, 2} In other parts of the world, such as Australia,
4 Finland, and Canada reports indicate that 3.4 to 5.3 of 10,000 live-born children suffer upper-limb
5 anomalies.³ However, in the United States there are many more unreported cases due to the lack
6 of a mandatory reporting system of birth defects and child amputees. Children with congenital
7 unilateral reductions are most frequently seen in pediatric amputation clinics. Only 1 in 9,400
8 children and adults are considered for prosthetic fitting due to the complexity of the reduction and
9 fitting procedures, as well as the lack of interest of the child in using a prosthesis.³⁻⁵ Even with the
10 great advances in prosthetic technology, a large number of individuals with upper limb reductions
11 still express dissatisfaction with the available technology.^{4, 6, 7} Factors that contribute to this
12 discontent include late age of fitting, high complexity of the devices and fitting procedures, as well
13 as high costs of devices and repairs.^{4, 8, 9} In addition, 35% to 58% of children with access to
14 prostheses reject them due to excessive weight, lack of functional use, discomfort, and low visual
15 appeal of the device.^{4, 8-10} Recent technological advances in computer-aided design (CAD)
16 programs and additive manufacturing (i.e., 3D printing)¹¹, offer the unique possibility of fitting,
17 designing, and manufacturing low-cost and customized upper-limb 3D printed prostheses
18 remotely.^{11, 12} However, there is currently only one paper describing the remote fitting procedures
19 for upper limb 3D printed prosthesis. Zuniga et al.,¹² compared several upper limb anthropometric
20 and range of motion measures taken directly from photographs from a sample of 9 children with
21 unilateral partial hand reductions. The authors found no significant mean difference between the
22 measures taken directly over the arms and those taken from photographs, suggesting the potential
23 development of remote fitting procedures for upper limb 3D printed prostheses. However, as

reported by Diment, et al.,¹³ there is a need to assess the efficacy and effectiveness, as well as the clinical outcomes for remote fitting procedures of upper limb 3D printed prostheses.

Despite great efforts by nonprofit organizations, such as LN-4, E-nable, and others, a number of individuals with upper limb deficiencies from developing countries are still not being fitted with any type of prosthesis. There is a critical need for practical, customized, aesthetically appealing, low-cost upper limb prostheses that can be fitted remotely. Thus, the purpose of the current investigation is to described a remote fitting procedure for upper limb 3D printed prostheses and assess patient satisfaction and comfort with 3D printed prostheses fitted remotely. We hypothesized that there will be an acceptable level of patient satisfaction and comfort after 4 weeks of using an upper limb 3D printed prosthesis fitted remotely. Our hypothesis is based on a previous investigation¹² that found no significant mean difference between the measures taken directly over the arms and those taken from photographs, suggesting the potential development of remote fitting procedures for upper limb 3D printed prostheses.

Methods

A qualitative study using content and score analysis was used to describe patient satisfaction after 4 weeks of using an upper limb 3D printed prosthesis fitted remotely. Research participants provided photographs following a template provided by our research team (Fig. 1A, B, C, D). Several anthropometric measurements were extracted from the photographs to determine lengths and widths of different segments of the upper limbs. For the wrist-driven 3D printed partial hand prosthesis, additional photographs of wrist extension and flexion were requested to quantify active range of motion. The anthropometric measurements extracted from photographs were used to scale and modify the CAD model of each upper limb prosthesis using a methodology previously

validated by our research team.¹¹ After the prosthesis was manufactured it was sent to the research participants via The United States Postal Service with detailed instructions of prosthetic use and care. After 4 weeks of use, the research participants or family members of pediatric patients were asked to complete several surveys and questionnaires.

Study Population

Six children (three girls and three boys, 6 to 16 years of age) and 2 adults (males of 25 and 59 years of age) with congenital (n=7) and acquired (n=1) upper limb loss participated in this study. All participants were remotely fitted with a wrist-driven 3D printed partial hand prosthesis (n=6) and an elbow-driven 3D printed trans-radial prosthesis (n=2; Table 1).

Table 1 here

Inclusion criteria for all participants included individuals from 6 to 80 years of age with unilateral upper-limb reductions involving the hand and forearm, and range of motion for the wrist and elbow joints greater than 20 degrees.

Exclusion criteria included 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 study participants were informed about the study and parents or guardians signed a parental permission form. For children ages 6 to 10 years, an assent was explained by the corresponding author and signed by the children and their parents. For adults a consent form was explained and signed. The study was approved by the University of Nebraska Medical Center Institutional Review Board.

Two weeks after receiving their pictures, research participants were provided with a 3D printed prosthesis. Detailed safety guidelines were given to the parents regarding the use and care

of the prosthesis. After 4 weeks of using the 3D printed prostheses, participants completed a series of surveys including the Orthotics Prosthetics Users' Survey (OPUS), Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST 2.0), and a general survey developed by our research team. The general survey was developed to estimate the impact of prosthetic devices on elements related to quality of life, daily usage, and types of activities performed. This survey has not been statistically validated, but provides useful information related to daily usage.

Procedures

Remote Prosthetic Fitting Procedures

Anthropometric Measurements: Several range of motion and anthropometric measures were extracted from the template photographs using the image editing tool available in Autodesk Fusion 360 (Fusion 360, Autodesk, Inc., San Rafael, CA, USA). To measure wrist range of motion, participants were requested to actively and maximally extend (Fig. 1A) and flex (Fig. 1B) at the wrist joint. The range of motion measurements for the partial hands included; range of motion of the wrists extension (Fig. 1A1 and A2) and flexion (Fig. 1B1 and B2).

Figure 1 here

The anthropometric measurements for the partial hands included; hand length (tip of the middle finger to center of the wrist joint for the non-affected and affected hands, Fig. 1C1 and C5), palm width (widest region of the palm above the base of the thumb, Fig. 1C2 and C6), forearm length (center of the wrist joint to center of the elbow joint, Fig. 1C3 and C7) and forearm width at three-fourths (width of the forearm at proximal three-fourths of the length of the forearm proximal to the wrist, Fig. 1C4 and C8). In addition, several reference lines were drawn over the

participant's non-affected and affected hands connecting the wrist and elbow joints (Fig. 1C and D, red lines).

Range of motion measurements for the elbow joint were not required for patients with congenital or acquired trans-radial reductions, due to the infrequency of a reduced range of motion at the elbow joint in individuals with trans-radial reductions. Anthropometric measurements of the elbow-driven 3D printed trans-radial prostheses included; hand length (tip of the middle finger to center of the wrist joint; Figure 1D1), palm width (widest region of the palm above the base of the thumb, Fig. 1D2), forearm length (center of the wrist joint to center of the elbow joint of the non-affected and affected arms, Fig. 1D3 and D7), forearm width at three-fourths (width of the forearm at proximal three-fourths of the length of the forearm proximal to the wrist joint of the non-affected and affected arms, Fig. 1D4 and D8), arm lengths (Fig. 1D5 and D9) and arm widths (Fig. 1D6 and D10).

All measurements extracted from the photographs of the affected and non-affected arms were used to fit and scale all 3D printed prostheses (Fig. 2). The measurements from the non-affected hand were used to approach limb symmetry. The main aspects of our digital fitting procedures consisted of properly scaling the digital design of the prosthesis to the dimensions of: 1) the patient's residual limb for generating an appropriately sized socket, and 2) the non-affected limb to approximate limbs length and overall symmetry. Our parametric prosthetic design allows standardization of the size of certain structures, such as the wrist mechanism of the 3D printed trans-radial prosthesis and forearm section of the 3D printed partial hand prosthesis. Finally, the remote fitting procedures were inspected by a certified prosthetist by superimposing the prosthetic design over a 2D image (Fig. 2). This superimposition was also used for patient and their clinician approval. The prosthetic socket was integrated on the inner side of the palm for the partial hand

prosthesis and forearm compartment for the arm prosthesis. A neoprene mitten with a thermoplastic shell was manually constructed and secured to the palm of the partial hand prosthesis. For the elbow-driven trans-radial prosthesis, adhesive foam padding was used as needed to improve fitting and comfort of the integrated forearm socket.

After the digital fitting had been performed by a technician under the supervision and approval of a clinical team, the design was exported as a stereolithographic file and 3D printed using desktop and semi-industrial 3D printers.

Figure 2 here

3D-Printed Partial Hand Prosthesis Characteristics

A modified version of the 3D-printed transitional hand prosthesis named Cyborg Beast¹¹ (Fig. 3) was used in the study. The new version named Cyborg Beast 2, was designed using the modeling software Autodesk Fusion 360 (Fusion 360, Autodesk, Inc., San Rafael, CA, USA) and manufactured in the 3D Printed Prosthetic Orthotic & Assistive Devices Laboratory located in the Biomechanics Research Building of the University of Nebraska at Omaha. The 3D printers used for the manufacturing process included a combination of desktop and industrial 3D printers (Ultimaker 2, Ultimaker B.V., Geldermalsen, The Netherlands and Uprint SE Plus by Stratasys, Minnesota, USA).

The plastic pins to secure all the various components of the prosthesis, fingers, thumb, palm, socket, forearm brace, and leveraging structure were made of polylactic acid which has properties similar to thermoplastic that facilitate post manufacturing adjustments. 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° 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) was used to regulate 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 individual limb size and aesthetic requirements, such as colors and specific designs (Fig. 3).

Figure 3 here

3D-Printed Arm Prosthesis Characteristics

The hand had 5 fingers with 2 degrees of freedom (Fig. 4). The finger and thumb were oriented in opposition to facilitate cylindrical grasp and tip pinch. Silicone finger pads were added to provide increased friction for grasping activities. A rotation mechanism placed in the wrist allowed for full pronation and supination, and a pivot system with internal components allowed for wrist rotation without twisting the line activating the flexion of the fingers. The rotation mechanism of the wrist consisted of an inner circular disc/shaft with a center opening (Fig. 4B). A circle of embedded magnets with matching polarity was placed around the disc. A bi-valve circular sleeve with embedded magnets 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 fixed in various positions by the attraction of the magnets. The magnets were sealed in a protective sleeve for safety. Elbow flexion and extension could be performed using a simple hinge mechanism. A BOA dial tensioner system allowed for the regulation of the tension of the cables controlling the finger flexion. A Velcro strap secured the prosthesis to the arm and harnessing was not needed for suspension.

Figure 4 here

3D Printing Specifications

The 3D printed prostheses were manufactured using desktop and industrial 3D printers (Ultimaker 2, Ultimaker B.V., Geldermalsen, The Netherlands and Uprint SE Plus by Stratasys, Minnesota, USA). The materials used for printing the prosthetic hand were Raptor polylactic acid. 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-.25 mm layer height, and 1mm shell thickness. Rafts and supports were used to 3D print the palm and other delicate components. Production time ranged from 4 to 10 hours to 3D print and fully assemble the prostheses.

Prosthesis Use, Fitting, and Satisfaction Surveys

Prosthesis use was assessed using the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0)¹⁴ which includes items related to assistive device satisfaction, wear, and use. Prosthesis use was also assessed with the Orthotics Prosthetics Users Survey (OPUS) which includes items related to weight, comfort, ease of use and function.¹⁵ The QUEST 2.0 is a standardized self-report questionnaire that is designed to evaluate how satisfied patients are with their assistive devices and the related services they experienced. The survey consisted of 12 satisfaction items (dimensions, weight, adjustments, safety, durability, easy to use, comfort, effectiveness, service delivery, repairs, professional services, follow-up services) where each item receives a rating from 1 to 5, with 1 being ‘not satisfied at all’ and 5 being ‘very satisfied’. The QUEST questionnaire also includes a ranking of importance for the 12 satisfaction items. Patients

or parents were asked to select 3 items that they consider to be the most important to them (Figure 5).

The OPUS is a self-report questionnaire consisting of several items related to satisfaction and function with the prosthetic device and services.¹⁵ The OPUS module for upper extremity functional status, which measure the person's perceived ability to perform activities involving the extremities; client satisfaction with device; and client satisfaction with services was used to assess different satisfaction and function items. To assess general aspect of prosthetic use, patients and parents were asked to complete general survey developed by our research team to include the type of activities performed as well as the estimated daily use of the prosthesis.

Data Analysis

Descriptive statistics (Mean \pm Standard Deviation) were calculated and summarized.

Results

The characteristics of the research participants and reported prosthesis use are summarized in table 1. The descriptive information for the QUEST questionnaire (device and service satisfaction) are summarized in Table 2 and patient importance ratings for the satisfaction items are illustrated in Figure 5. The OPUS satisfaction items are summarized in Table 3 and 4. The results of the general prosthetic survey developed by our research team are described in Table 5.

Table 1 to 5 here

Figure 5 here

Discussion

The main findings reported in the present study suggest that there is an acceptable level of patient satisfaction with the 3D printed prostheses fitted remotely. The research participants

reported a score of 3.92 ± 0.50 (closer to the statement “quite satisfied”) for the device satisfaction section of the QUEST questionnaire (Table 2). This acceptable level of satisfaction of our research participant reported in the QUEST was confirmed by the agreement scores of the OPUS items related to prosthetic fitting (My prosthesis fits well = 4.13 ± 0.50) and comfort (My prosthesis is comfortable throughout the day = 3.57 ± 0.98). Furthermore, the comfort level rating in the general prosthetic survey resulted in a score of 3.75 ± 0.70 (closer to the statement “the prosthetic device feels comfortable”) confirming the results of the QUEST and OPUS.

There is limited literature describing remote fitting procedures for upper limb 3D printed prosthesis.¹¹ Zuniga et al.,¹¹ described a remote fitting methodology for 3D printed upper limb prostheses and compared anthropometric measurements taken directly over the patients upper limb from measurements taken from photographs. The authors found no significant mean difference between the measures taken directly over the arms and those taken from photographs in a sample of nine children with partial hand reductions. Furthermore, a recent systematic review by Diment, et al.,¹³ indicated the efficacy or effectiveness of upper limb 3D printed prostheses has not been properly assessed. The authors¹³ emphasized the need to assess clinical outcomes for remote fitting procedures of upper limb 3D printed prostheses. However, there are no studies examining the patient satisfaction with remote prosthetic fitting and only a few studies that have addressed patient satisfaction with standard prostheses and fitting. A previous investigation by Routhier et al.,¹⁶ examined the satisfaction level of 10 pediatric research subjects (7 girls and 3 boys from 2.5 to 16.0 years of age) with partial hand or below the wrist amputations ($n = 3$), as well as trans-radial ($n = 6$) and trans-humeral amputations ($n = 1$). All research subjects were fitted with myoelectric prostheses using the VASI ($n = 9$) and Steeper ($n = 1$) electric hands as terminal devices.¹⁶ The standard fitting procedures were performed at the Quebec Rehabilitation Institute in Canada and

the clinical team used an early version of the QUEST questionnaire to assess patient satisfaction. In general, the study found that 60% of the participants were satisfied with the prosthesis. Specifically, the authors reported that 6 participants were “very satisfied or satisfied”, 3 participants were “somewhat satisfied” or “rather unsatisfied” and 1 participant was “not satisfied at all”.¹⁶

In the present investigation, we found that for the device subscale of the QUEST only 37.5% of the participants were satisfied with the device fitted remotely. Specifically, 3 participants were “satisfied” (scores = 4.63, 4.5, and 4.5) and 5 participants were “more or less satisfied” (3.5, 3.88, 3.63, 3.25, and 3.75). However, the category that is most relevant for prosthetic fitting, comfort, 50% of the subjects were satisfied with the device fitted remotely. Specifically, two participants were “very satisfied”, two participants were “quite satisfied”, and 4 participants were “more or less satisfied” with the overall comfort of the prosthesis fitted remotely. These findings are similar to those reported by Routhier et al.,¹⁶ where the authors reported 50% satisfaction with the comfort of an upper-limb myoelectric prosthesis fitted using standard procedures at the Quebec Rehabilitation Institute. It should be noted, however, that obtaining a 50% satisfaction of comfort using a myoelectric prosthesis is significantly more difficult than for body-powered prosthesis due to the extra weight of the electronic components of myoelectric devices.

A previous investigation by Ghoseiri & Bahramian¹⁷ evaluated the user satisfaction with orthotic and prosthetic devices and services using the OPUS in a sample of 293 patients. Using standard fitting procedures, patients using lower limb orthoses (n=178), spinal orthoses (n=36), upper limb orthoses (n=40), lower limb orthoses (n=34) and upper limb prostheses or partial hands (n=5) completed the OPUS survey. Overall, the authors¹⁷ found that patients were unsatisfied with their devices with only 17% satisfaction rate. These results are much lower than those found by

1 Bosmans et al.¹⁸ and Routhier et al.¹⁶ reporting 78% and 80% satisfaction with prostheses and
 2 orthoses using similar fitting procedures. As suggested by Ghoseiri & Bahramian¹⁷ the type of
 3 reduction, deformity, injury and overall morphology of the residual limb may affect the results of
 4 satisfaction and comfort with their prostheses or orthoses. Similarly, in the current investigation,
 5 five of the eight research participants had partial hand reductions with different anatomical and
 6 morphological features of the affected limb (Table 1). Thus, the challenges of fitting partial hand
 7 prostheses for individuals with different anatomical and morphological reductions may have
 8 prevented our research participants from been fully satisfied with the comfort of the prosthesis
 9 (Tables 2 and 3). The overall acceptable level of patient satisfaction with the 3D printed prostheses
 10 fitted remotely, however, was likely due to a combination of the versatility of fitting these devices
 11 using an editable digital file and the thermoforming properties of the 3D printing filament that
 12 allows post-processing adjustments of the sockets. Furthermore, for two of the research
 13 participants with partial hand reductions (Subject 5 and 6) a custom neoprene socket was
 14 developed to improve comfort. The three research participants with trans-radial reductions had
 15 similar residual morphology of the residual limb allowing for the integration of the socket inside
 16 of the forearm compartment. The 3D printed arm prosthesis was scaled to approximate the non-
 17 affected arm of the patient for symmetry purposes. The patients and their supervising clinician
 18 were instructed to use adhesive foam padding as needed to improve fitting and comfort of the
 19 forearm socket.

20 In the current study, the satisfaction items of the OPUS agreement scores ranged from 3.67
 21 ± 1.03 (My prosthesis is durable) to 4.57 ± 0.92 (The weight of my prosthesis is manageable; Table
 22 3). Patients tended to agree with the statement “My prosthesis fits well” (4.14 ± 0.53 Table 3).
 23 Furthermore, the prosthetic function module of the OPUS indicated that the majority of the

research participants found that “drinking from a paper cup” (4.00 ± 1.20) and “putting on and taking off the prosthesis” (4.5 ± 0.84) was easy (Table 4). For other functional items, such as “dial a touch tone phone” (3.0 ± 2.0) or “stir in a bowl” (3.50 ± 1.52) the research participants reported that the activity was slightly difficult (Table 4).

Among the many challenges experienced by adult and pediatric prosthetic users, as well as their families, is the distance from the patient residence and the rehabilitation center.¹⁶ Previous investigations and reports^{19, 20} indicated that a number of children and adults with upper limb loss from developing countries and rural areas have many challenges accessing prosthetic services. These challenges are due to many factors, such as the lack of trained technicians able to provide these services and a local shortage of the necessary componentry for the production of upper limb prostheses.^{19, 20} The remote fitting procedures presented in the current investigation can be helpful by allowing health care professionals from developed countries to remotely fit and manufacture the devices and send them to the medical team supervising the patient. The remote fitting procedures described in the present study require minimal anthropometric measurements of the upper limbs for proper scaling and fitting. Most fitting procedures required for prosthetic hands include wrap casting using plaster bandages placed over the affected limb.²¹ More recently, 3D scanning has also been used for the development of different types of prosthetic sockets for upper-limb and lower-limb prostheses.²²⁻²⁴ Casting procedures require the physical presence of the individual needing the prosthetic hand and the health care professional in the same physical location, which may not be possible for patients living in rural or isolated areas. 3D scanning procedures require sophisticated equipment and technical knowledge to perform the measurements. Furthermore, both techniques require the patient to visit the health care facilities for proper fitting procedures. The results from the present investigation describe a novel and simple

remote fitting procedure for 3D-printed upper-limb prosthesis for children and adults with upper-limb loss. The proposed distance-fitting procedures have the potential of making 3D printed prostheses accessible to a large number of individuals in rural or isolated areas. These procedures, however, must be performed with caution, since inaccurate scaling or significant errors in the measurements could affect the function and fitting of the 3D printed prosthesis.

The potential limitations of the present investigation include the individual differences of our research participants at multiple levels including age, gender, daily prosthetic use and etiology of the upper limb reduction, as well as the different anatomical and morphological features of the affected limb (trans-radial versus partial hands; Table 1). This inter-subject variability and the qualitative nature of self-reported questionnaires and surveys may have affected the satisfaction and function scores presented in the current investigation. Furthermore, family members of the four youngest research participants (6 to 10 years of age) helped respond to the questions of the surveys; therefore, some of the responses may not be accurate. For this reason, we asked all of our research participants to complete three different surveys (i.e., QUEST, OPUS, and a general prosthetic survey) to confirm their responses.

In conclusion, the ability to fit an upper-limb prosthesis remotely, represents a promising methodology to fit upper-limb 3D printed prostheses for patients from developing countries or rural areas. The increasing availability of smartphones and other digital devices makes it possible to obtain photographs from patients located in rural areas that have little or no access to trained technicians. These photographs along with the cost-effective desktop 3D printers allows for the extraction of the anthropometric measurements required for the development of a 3D printed upper limb prosthesis remotely.

Clinical Messages

- Only 1 in 9,400 children and adults are considered for prosthetic fitting due to the complexity of the reduction and fitting procedures.
- 35% to 58% of children with access to prostheses reject them due to excessive weight, lack of functional use, discomfort, and low visual appeal of the device
- 3D printing technology offers the unique possibility of fitting, designing, and manufacturing low-cost and customized upper-limb 3D printed prostheses remotely.
- There is an acceptable level of patient satisfaction with the 3D printed prostheses fitted remotely.
- The ability to fit an upper-limb prosthesis remotely, represents a promising methodology to fit upper-limb 3D printed prostheses for patients from developing countries or rural areas.

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Dr. Jorge M. Zuniga, Jean Peck, and Rakesh Srivastava lead the research team that designed the 3D printed prostheses and other devices discussed in this article. The rest of the researchers declare no competing interests.

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1 **Table 1: Characteristics of research participants (n=9)**

ID	Gender	Age (Years)	Reported Prosthesis Use	Amputation Level	Affected Side	Ability to Pinch
1	M	59	6+ hours per day	*Trans-Radial	Right	No
2	M	25	6+ hours per day	Partial Hand	Right	No
3	M	14	Between 1-2 hours per day	Partial Hand	Right	No
4	M	10	10 minutes, 5 times per week	Partial Hand	Left	No
5	M	6	Only when needed	Trans-Radial	Left	No
6	F	16	1 hour per day	Partial Hand	Left	Some
7	F	8	Only when needed	Trans-Radial	Left	No
8	F	6	10 minutes, 5 times per week	Partial Hand	Right	No

2 *Amputation acquired at age 58. All other research participant presented congenital reductions.

3

4

Table 2. Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) Ratings.

Items	Mean \pm SD	Minimum Score	Maximum Score
How satisfied are you with:			
Dimensions (size, height, length, width)	4.13 \pm 0.99	2	5
Weight	4.50 \pm 0.76	2	5
Adjustments (fixing, fastening)	4.13 \pm 0.83	3	5
Safety (secure)	4.38 \pm 0.52	4	5
Durability (endurance, resistance to wear)	3.13 \pm 0.83	2	4
Ease of Use	4.13 \pm 0.64	3	5
Comfort	3.75 \pm 0.89	3	5
Effectiveness (the degree to which your device meets your needs)	3.50 \pm 1.31	2	5
Device Satisfaction	3.95 \pm 0.85	2	5
Services			
How satisfied are you with:	Mean \pm SD	Minimum Score	Maximum Score
Service Delivery	4.25 \pm 0.89	3	5
Repairs and Servicing	4.25 \pm 0.89	3	5
Professional Services	4.75 \pm 0.46	4	5
Follow-up Service	4.75 \pm 0.46	4	5
Service Satisfaction	4.50 \pm 0.67	3	5
Total Satisfaction	4.10 \pm 0.49		

1 = not satisfied at all, 2 = not very satisfied, 3 = more or less satisfied, 4 = quite satisfied, 5 = very satisfied.

1

Table 3. Orthotics Prosthetics Users Survey (OPUS) Frequency Distribution.

OPUS Module 5: Satisfaction Items	Raw Scores						Raw Score Mean \pm SD
	5	4	3	2	1	0	
My prosthesis fits well.	1	6	1	0	0	0	4.14 \pm 0.53
The weight of my prosthesis is manageable.	5	1	2	0	0	0	4.57 \pm 0.92
My prosthesis is comfortable throughout the day.	1	3	1	1	0	2	3.67 \pm 1.03
It is easy to put on my prosthesis.	4	2	1	1	0	0	4.43 \pm 1.13
My prosthesis looks good.	2	6	0	0	0	0	4.29 \pm 0.46
My prosthesis is durable.	1	3	1	1	0	2	3.67 \pm 1.03

5 = Strongly Agree, 4 = Agree, 3 = Neither Agree nor Disagree, 2 = Disagree, 1 = Strongly Disagree, 0 = Don't Know. Mean values calculated excluding 0 = Don't Know raw scores.

2

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Table 4. Orthotics Prosthetics User Survey (OPUS) Frequency Distribution.

OPUS Module 5: Functional Items	Raw Scores						Raw Score Mean \pm SD
	5	4	3	2	1	0	
Drink from a paper cup	4	1	2	1	0	0	4.00 \pm 1.20
Use fork or spoon	2	2	1	2	0	1	3.57 \pm 1.27
Pour from a 12 oz. can	4	0	1	1	1	1	3.71 \pm 1.70
Dial a touch tone phone	2	0	1	0	2	1	3.0 \pm 2.0
Stir in a bowl	2	1	2	0	1	0	3.50 \pm 1.52
Put on and take off prosthesis	4	1	1	0	0	0	4.5 \pm 0.84

5 = Very Easy, 4 = Easy, 3 = Slightly Difficult, 2 = Very Difficult, 1 = Cannot Perform Activity,
0 = Not Applicable. Mean values calculated excluding 0 = Not Applicable raw scores.

2

Table 5. General Prosthetic Survey.

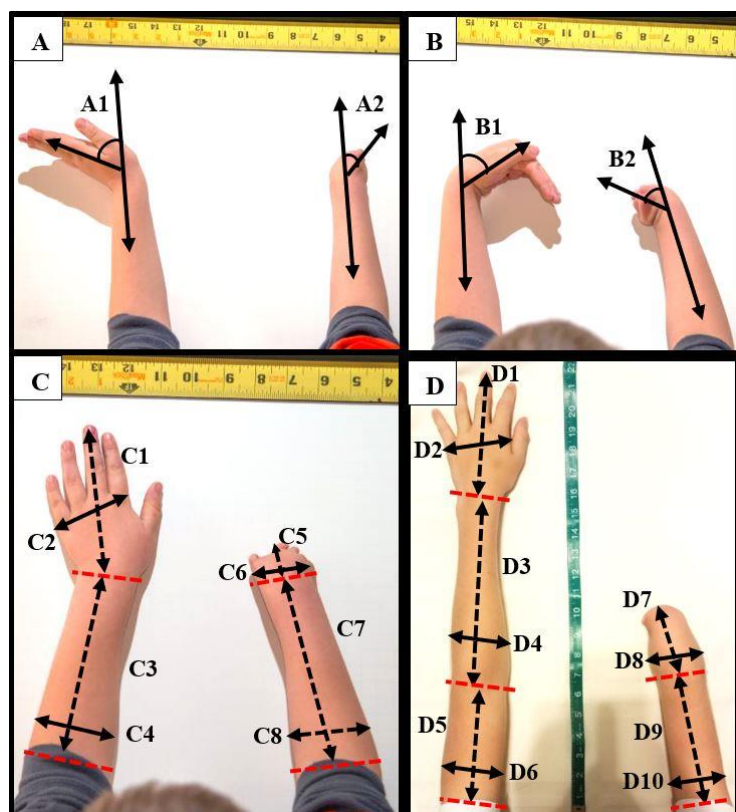
ID	In what type of activities do you use your prosthetic device?	Is your current prosthesis improving your quality of life?	Is your current prosthesis improving your self-esteem?	Has your prosthesis malfunctioned or break?	Please rate the comfort of your prosthetic device on a scale from 1 to 5*
1	Activities at home, Activities at school/work, Just for fun	Yes	Yes	Yes	4
2	Activities at home, Activities at school/work	No	No	Yes	4
3	Play, Activities at home, Activities at school/work, Just for fun	Somewhat	Yes	Yes	3
4	Activities at school/work	Somewhat	Somewhat	Yes	4
5	Activities at school/work, Activities at home	Somewhat	Somewhat	Yes	5
6	Activities at home, Other	Yes	Somewhat	No	3
7	Sports, Activities at home	No	No	No	3
8	Activities at home	Somewhat	Somewhat	No	4
Mean \pm SD					3.75 \pm 0.70

1 *5 = completely comfortable, 4 = comfortable, 3 = somehow comfortable, 2 = not very

2 comfortable, 1 = completely uncomfortable, 0 = Don't Know.

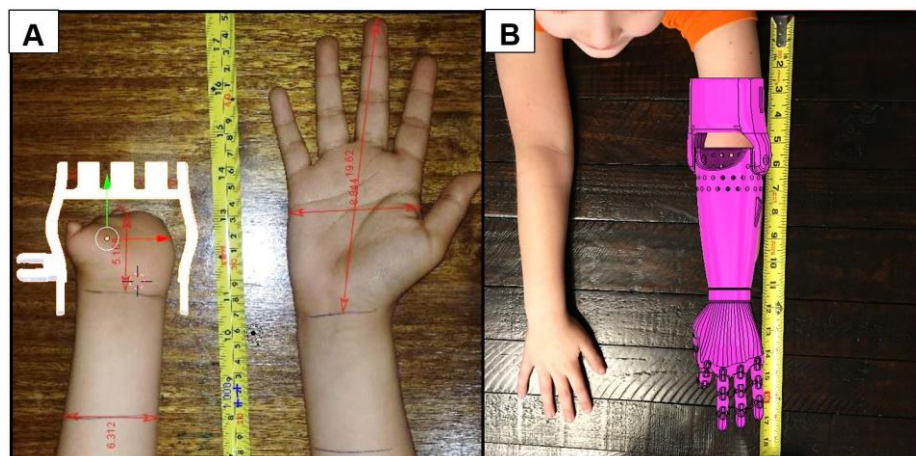
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1 **Figures**2 **Figure 1**

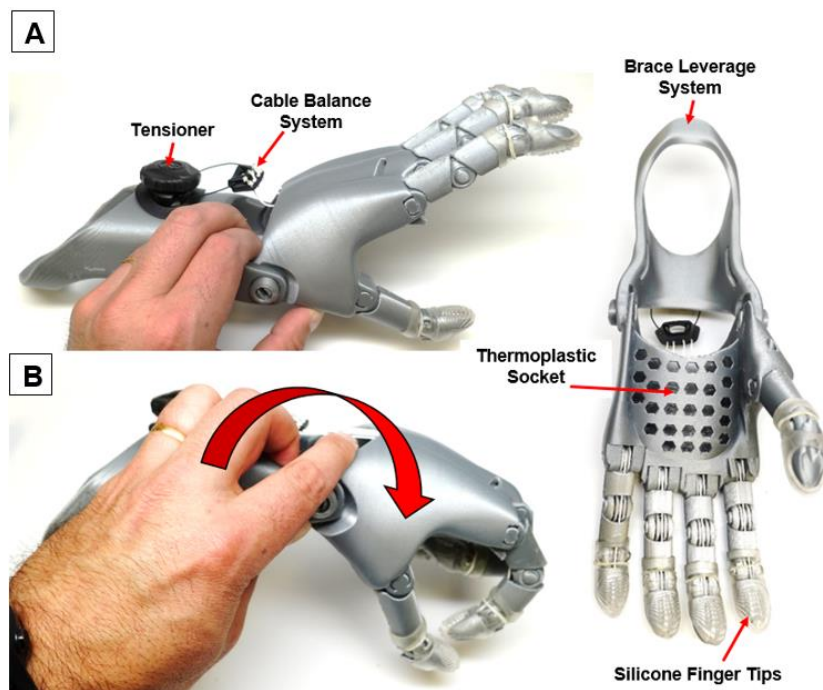
1 **Figure 2**

2



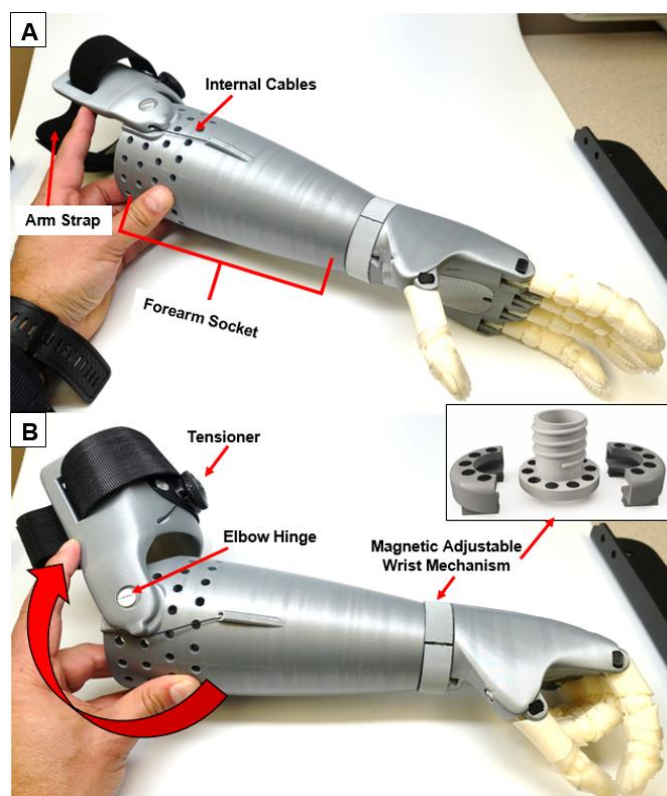
1 **Figure 3**

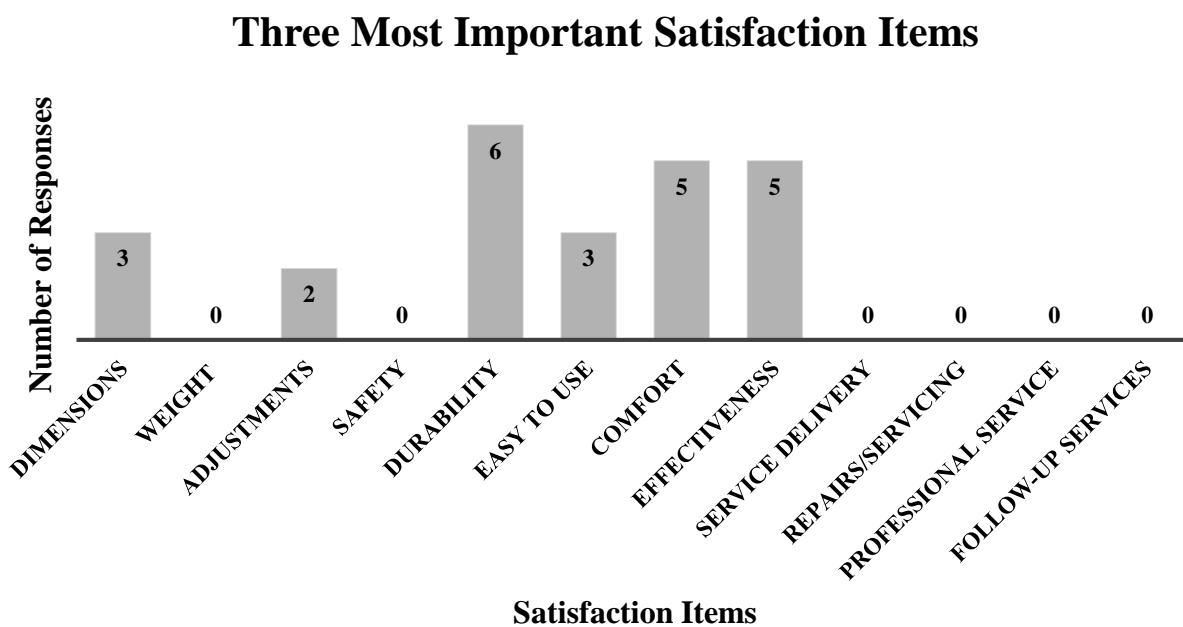
2



1 **Figure 4**

2



1 **Figure 5**

2

1 Figure legends

2

Figure 2. Template photographs for remote fitting procedures of 3D printed partial hand prosthesis (A, B, and C) and arm prosthesis (D). Dashed red lines indicate measurements boundaries over wrist and elbow joints. A: Wrist extension (A1: non-affected, A2 affected), B: Wrist flexion (B1: non-affected, B2: affected), and C: Top view of hands and forearms (C1: Non-affected hand length, C2: Non-affected hand width, C3: Non-affected forearm length, C4: Non-affected forearm width, C5: Affected partial hand length, C6: Affected partial hand width, C7: Affected forearm length, C8: Affected forearm width). D: Top view of the entire arms (D1: Non-affected hand length, D2: Non-affected hand width, D3: Non-affected forearm length, D4: Non-affected forearm width, D5: Non-affected upper arm length, D6: Non-affected upper arm width, D7: Affected forearm length, D8: Affected forearm width, D9: Affected upper arm length, D10: Affected upper arm width).

Figure 1. Illustration of a photograph imported as a plane and overlaid under the palm section scaled at 140% for a 16 year old research participant (A). Overlay of a 3D printed arm prostheses model scaled at 99% for a 7-year old child with a trans-radial reduction in the left arm (B).

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

Figure 4. The 3D Printed arm prostheses. A. The trans-radial arm prosthesis in the open position. Elastic cords placed inside the dorsal aspect of the fingers provide passive finger extension. B. Finger flexion was 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.