Pilot Study Investigating the Use of 3D Printing in Designing Upper-Extremity Prosthetics for Children: A Progress Report

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Abstract

The availability and cost-effectiveness of functional prototypes and designs has increased considerably over the last decade because of 3D printing. The growing field of biomedical engineering is expanding on 3D-printing technology to make low-cost, upper-extremity prosthetics. This pilot study reports on the potential use of 3D printing for low-cost, upper-extremity prosthetics, specifically prosthetic hands for children. We start by characterizing existing open-source, 3D-printed upper-extremity prosthetics to determine their mechanical strength, statically and dynamically. Based on outcomes from these early tests, we optimize the existing designs to develop a new prosthetic. The prosthetic design, fabricated in The University of New Mexico Orthopaedic Biomechanics & Biomaterials Laboratory, will consist of 3D-printed parts optimized for function, adjustability, and cost effectiveness. The design will be clinically and mechanically tested to assure optimization of all outcome measures. Our goal is that the optimized 3D-printed, upper-extremity prosthetic can be used as an alternative option to the current available prosthetics, superior function, greater adjustability, and adequate strength, all at a lower cost.

Introduction

The incidence of congenital limb deficiency is between 5% and 10% per 10,000 live births, with a 3:1 ratio of upper to lower limbs. There is also an increase in children sustaining injuries requiring amputation.[1] In New Mexico, more than 307,000 children from low-income families are covered through Medicaid and an additional 22,000 are uninsured.[2] Children in these categories are limited by Medicaid guidelines for the type of prosthetic they can receive (usually non-functional or claw-type) and limited on the ability to receive a replacement of their prosthesis in the event of outgrowth, damage, loss, or theft. Furthermore, more than half of the non-elderly population of New Mexico resides in a rural part of the state without easy access to a prosthetic for refitting, replacement, or adjustments.[3] These statistics support the need for improved pediatric prosthetics that allow for hand functionality equivalent to that of expensive myoelectric prosthetics, at a price less than hook-type or purely cosmetic options.

Additionally, these prosthetics should allow for adjustability or low-cost replacement as the child grows. With the invention of 3D printing, the availability and cost-effectiveness of functional prototypes and designs has increased notably in the past decade. Its popularity has evolved from a simple rapid prototyping technology to a technology capable of serving as a fabrication tool for end-products. This evolution became possible as the cost of hardware and software decreased and as the potential for 3D-printed materials became more diverse. In the construction industry, 3D printing of cement has enabled low-cost housing options in developing countries.[4] In the automotive industry, 3D printing of carbon fiber filament has enabled fabrication of vehicle bodies and interior components.[5] In the medical field, 3D-printed biological materials enable advancements in tissue engineering.[6] More recently, 3D-printed prosthetic upper-extremity devices have been introduced as low-cost alternatives to traditional prosthetics.[7] Using open-source designs, an inexpensive 3D printer, and a few materials, individuals can create prosthetics in-house.

The application of 3D printing for prosthetic design may have a considerable global impact. Currently available prosthetics for pediatric populations can be expensive and un-adaptable as the children grow. Purely cosmetic hands cost $5000 on average.[8] Functional claw-type hands can average $10,000. A low-cost, functional, myoelectric hand can start at $20,000. These costs are problematic for families in low-income communities around the world, particularly when the child may outgrow the device at an accelerated pace. There is a crucial need for low-cost, adaptable, patient-specific, fully functional, and comfortable 3D-printed prosthetic hands for children.

Although designs of 3D-printed prosthetics are easily accessible from the internet, most have not been optimized for activities of daily living. None have been mechanically characterized to assess the feasibility of offering this option in a clinical setting. We report on the progress of our pilot study regarding potential use of 3D printing in creating upper-extremity prosthetics for children.

Methods

The methods outlined were performed in The University of New Mexico Orthopaedic Biomechanics & Biomaterials Laboratory (UNM OBBL). The proposed pilot study has five aims. 1) We begin with a currently available, open-source 3D-printed hand known as the Cyborg Beast (e-NABLE) (Figure 1A).[6] We mechanically test this prosthetic to characterize each component's strength until failure (bulk material and joint locations). 2) Using data collected from aim 1, we modify the design of the existing prosthetic to optimize each component to withstand loads that may be introduced by young users. 3) The resulting design from aim 2 will be mechanically and clinically tested to prove feasibility for clinical use. 4) We will investigate modification of the Kyriakopoulos open-source design (Open Bionics, Bristol, United Kingdom) as a 3D-printed prosthetic option. This "hand" is currently made as a robotic manipulator for low-load manipulations by robotic arms. We wish to adapt this system as a prosthetic medical-device option. 5) Simultaneously, we will be investigating the Cyborg Beast and Kyriakopoulos systems for use with myoelectric interfaces to enable electronic actuation.

Progress

The pilot study introduced in this article was recently initiated. This section provides a brief description of the progress made toward each of the five aims.

Aim 1: Mechanical Testing of Cyborg Beast

The Cyborg Beast was printed in our laboratory (Figure 1B) using an Ultimaker 2+ Extended 3D printer (Ultimaker North America, Cambridge, MD). All 3D-printed parts were made from acrylonitrile-butadiene-styrene (ABS) polymer filament and joined together with aluminum bolts and nuts as suggested by e-NABLE. The cables, which are meant to simulate tendon loading on the fingers, were made from high tensile-strength fishing wire and high-strength suture. The finger attachments, gauntlet, palm, and pin connections are being tested in a uniaxial tensile loading condition to evaluate failure strength (Figure 2). Components will be loaded at a rate of 1 mm/s until failure, defined as the point of yield on the stress-strain curve. The whole hand will also be tested under cyclic loading conditions to simulate long-term use.

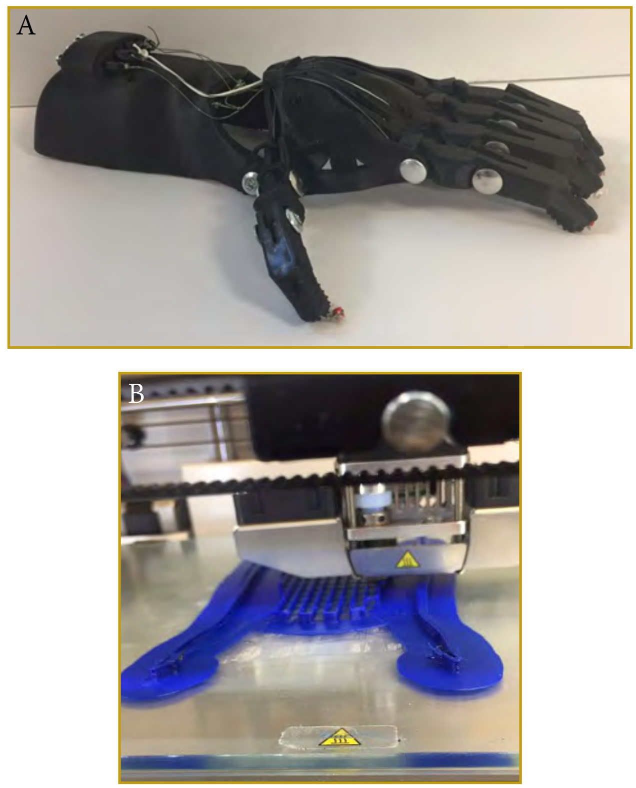

Figure 1. (A) 3D-printed Cyborg Beast prosthetic hand by e-NABLE, printed in our laboratory. (B) Cyborg Beast during printing with the Ultimaker 2+ Extended printer using blue acrylonitrile-butadiene-styrene polymer.

Figure 2. 3D-printed distal phalange undergoing uniaxial tensile testing to evaluate failure strength at the proximal interphalangeal joint of the prosthetic.

Aim 2: Optimization of the Cyborg Beast Model

Although the mechanical testing is underway, some areas of improvement have been discussed with clinicians. We have begun implementing the suggestions in the new design: "tendon" cable-system protection and thumb reposition.

The cable system lies over the top of the prosthetic device and is susceptible to early failure owing to wear induced by sharp edges. We have replaced the fishing wire and suture with flexible braided Kevlar to minimize the potential for cable failure. Additionally, the exposed cables are seen as a likely area for failure or loosening if acted upon by an external force. The first iteration of re-design includes a housing over the top surface of the prosthetic to protect the cables from external factors. The current design can be seen in Figure 3.

The thumb position in the Cyborg Beast model is at a fixed angle (about 80°) relative to the fingers. This is likely to allow for the thumb to perform an opposition function where it should cross over the palm of the hand. In a human hand, the carpometacarpal joint of the thumb is shaped like a saddle, which allows opposition at a variety of angles. Additionally, the average resting position of the thumb is about 45° from the fingers to allow for pinching and gripping activities. In the first iteration of the re-design, we implemented a feature that would allow for manual positioning of the angle of the thumb relative to the fingers (Figure 3). Further iterations of the re-design will focus on reducing stress concentrations and reinforcing weak areas in the prosthetic.

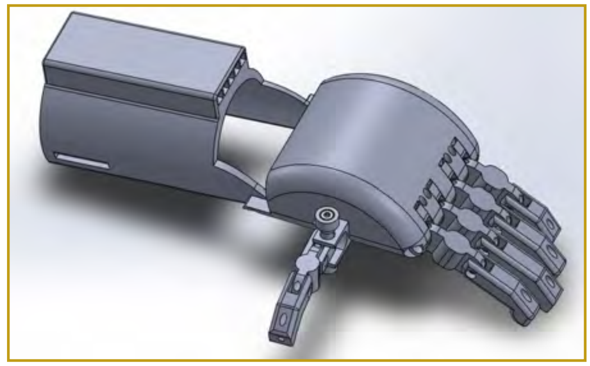

Figure 3. First iteration of the Cyborg Beast re-design, which protects the exposed "tendon" cables from early failure. Notably, there is a greater level of coverage of the cables as compared to Figure 1. Additionally, the thumb is modified to allow for manual repositioning of the angle of the thumb relative to the fingers to allow for better opposition as preferred by the user.

Aim 3: Mechanical Testing of Optimized Cyborg Beast Model

Because optimization of the Cyborg Beast model has not yet been completed, we have not started mechanical testing of this model. The hand will undergo joint failure testing, cyclic loading of the entire prosthetic, and component load to failure testing. If mechanical testing of the optimized model does not show improvement or shows little improvement from the original, additional modifications will be completed and testing will continue in an iterative fashion.

Aim 4: Kyriakopoulos Open-Source to 3D Printed Prosthetic

The open-source Kyriakopoulos model has been 3D printed and assembled based on the computer aided-design outlined on the OpenBionics.org website (Figures 4A and 4B). This open-source design includes a whiffle tree configuration within the palm to allow for sharing of forces between finger cables and the use of only one motor for finger actuation. This aspect is optimal for reduction of cost and ideal for incorporation into the design created in aim 2. The open-source design also includes an elegant design of the thumb mechanism, which allows for 144 hand positions. The thumb mechanism will be incorporated into the design in aim 2. Lastly, the hand will be modified such that 1) the prosthetic can be coupled to a forearm cuff for situations in which the residual limb does not include the radial carpal joint and 2) the palm of the device will allow for carpals and partial finger placement for situations in which the residual limb includes the radial carpal joint.

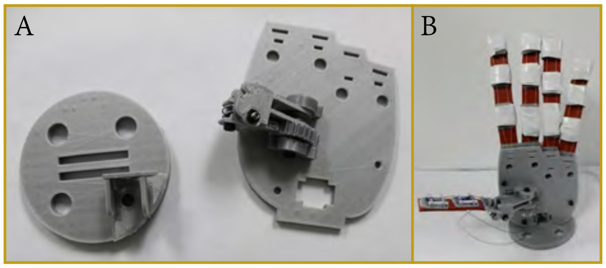

Figure 4. (A) 3D-printed components of the Kyriakopoulos Open-Source hand model. (B) Fully assembled Kyriakopoulos model for preliminary analysis.

Aim 5: Myoelectric Interface

We chose to investigate the use of the MyoWare™ electromyography (EMG) sensor (AT-04-001, Advanced Technologies, Merrimack, New Hampshire) for actuation of the modified Cyborg Beast and Kyriakopoulos prosthetic models. The MyoWare sensor is powered and controlled by an Arduino MEGA microcontroller (Arduino, New York, New York) and snaps directly to electrodes that are adhered to the skin above the muscle from which signal will be obtained (Figure 5). Raw EMG data signals processed with Arduino code will allow for the user to trigger the motor that controls finger and thumb actuation. The MyoWare system is compact and can be easily incorporated into the designs created in aims 2 and 4.

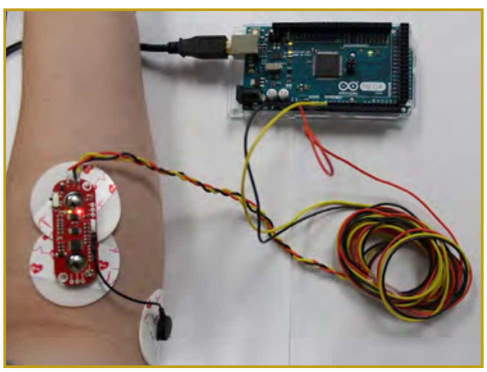

Figure 5. Myoware sensor attached to an arm and connected to an Arduino MEGA microcontroller.

Future Goals

Once we have completed aims 1 through 5, we will proceed with an investigative study to evaluate comfort, adaptability, dexterity, and wear of the prosthetic with children participants. Clinical testing will commence only after approval by our institutional review board. In this study, a mold of the residual limb of the patient will be created during a visit with a physician. The inner surface of the mold will be scanned using a NextEngine 3D scanner (NextEngine, Santa Monica, CA) to serve as a negative mold for creation of the prosthetic. We will combine the negative mold with an existing model of the prosthetic, such that the final design will perfectly contour the residual limb of the patient. The patient will be asked to wear the device and perform a series of simple tasks with parental or guardian supervision. Qualitative and quantitative outcome measures such as comfort, adaptability, strength, and dexterity will be obtained from these tasks.

Discussion

The current prosthetic designs available on the market range from hooks to robotically actuated prosthetics.[7-11] Regardless of prosthetic type, the cost of the device is high. These prices can become burdensome for parents of children who replace their prosthetic because of growth or damage during activities of daily living. Although open-source 3D-printed prosthetic designs have recently become available and notably help reduce cost, none of these current options have been mechanically tested to ensure functionality during normal use. Additionally, these models have not been evaluated to ensure physiologic motions similar to that of the native hand. We hypothesize that the modified designs created in our laboratory will allow for a low-cost, patient-specific, and mechanically robust prosthetic with functionality similar to that of the native hand.

Using 3D printing as a manufacturing technique to this end, reduces cost of customization, creation of new designs, and reproduction of the prosthetic when compared to traditional manufacturing. It also allows for the prosthetic to be easily reproduced in a larger size as the child grows. This allows for the parents to purchase a new prosthetic as their child grows, equivalent to the cost of filling up a car with gas. Another advantage is that it reduces casting, molding, and manufacturing times and processes when compared to those of traditional prosthetics because an exact fit can be obtained from computed tomography or magnetic resonance imaging scans of the residual limb. The exact fit also allows for continued adjustment over multiple iterations of the prosthetic as the child grows and replaces the prosthetic. Furthermore, it allows for stability and improved functionality of the prosthetic.

It is widely known that upper-extremity prosthetics tend to be relegated to a drawer and not used by patients owing to prosthetic complexity and lack of functionality. We pursue this research effort to create a simple, functional prosthetic for use by children. The prosthetic will be lighter, easy to use, less-expensive, and more functional to use compared to traditional prosthetic devices.

Funding

The authors were awarded a grant from the Carrie Tingley Hospital Foundation.

Conflict of Interest

The authors report no conflicts of interest.

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