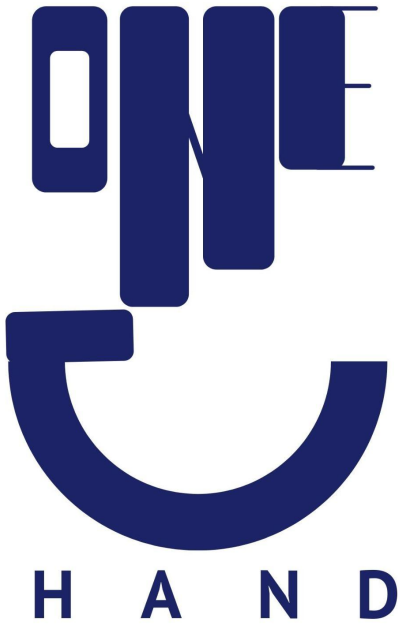


Enabling Amputees to
Live their Best Lives

Table of Contents

Biographies

Jesse Haworth is a graduate student at Johns Hopkins University studying medical robotics. His interests include surgical robotics, prosthetics, and exoskeletons. He has a background as an R&D Engineer working on minimally invasive medical devices and received his Bachelor's degree in biomedical engineering from the University of Iowa.

Heba Sattar is currently a Master's student at Johns Hopkins University, in the biomedical engineering department. Her undergraduate background involves neural engineering and this interest has been carried forward in her graduate career as well. She is interested in the design of wearable technology and compact medical devices for diagnostics and monitoring.

Rasika Thombre is a graduate student at Johns Hopkins University studying biomedical engineering. Her research interests lie in instrumentation and developing therapeutic ultrasound-based techniques. She received her Bachelor's degree in biomedical engineering from the University of Mumbai, India. She has worked as a healthcare consultant conducting market research for greenfield hospitals, designing medical spaces and carrying out technical analysis of medical equipment

Abstract

*Our device aims to improve access to prostheses for all amputees around the world, specifically developing countries. The **OneHand** device does this by reducing the cost of manufacturing the prosthetic device and eliminating the need for a prosthetist. This device comprises flexible paneling and 3 BOA systems that allow a user to independently adjust the fit of their prosthetic. This allows a user to be able to continuously use their prosthetic in a manner that is most comfortable for them, without having to partake in costly prosthetist appointments and manufacturing adjustments*.

Introduction

Out of the 3 million below elbow (transradial) amputees reported worldwide, 80% are reported to be in developing countries where a significant percentage do not even have access to current prosthetic devices [1]. With prosthetic devices costing over several thousand USD, most patients cannot afford it with only 5% of amputees in developing countries having access to prostheses [2]. OneHand was developed to address this need for an adaptable and affordable transradial prosthesis for amputees worldwide.

OneHand is a flexible below elbow prosthetic socket that allows a user to adjust the fit of the prosthesis around the residual limb independently. It has the capability to promote user independence and eliminate costs associated with prosthetist visits and device customization. The flexible panels connected with cabling allow an overall tightening mechanism adaptable to the changes a residual limb undergoes over time.

The socket is the most expensive part of a cosmetic or body-powered prosthetic due to the need of a prosthetist and patient-specific casting required for fitting. Due to the OneHand's design, it can be mass produced and does not require the patient to visit a prosthetist. This will improve the accessibility of prostheses in developing countries and open up a previously untapped market.

Field Survey

To get a better insight into the patient requirements and market demands, a primary survey was conducted by interviewing a prosthetist and a product developer of a prosthetics company. Key takeaways from the interview with the clinician were targeted towards understanding the workflow and the process of getting a prosthesis. It was reported that during the early stage amputees undergo drastic changes of their residual limb due to inflammation. This required the patient to remain without a prosthesis for a period of time till the limb stabilizes. This could take 5-6 months. Furthermore, the process of getting the prosthesis demanded the patient do multiple visits for fitting to the clinics. With every registered change, the device is sent to the manufacturer. This not only causes elevated costs but also significant time delay. It was reported that while body powered prostheses are mostly covered under insurance, myoelectric or sensor driven prostheses have to be paid out of pocket. Regardless, patient drop out has been an issue either due to inconvenience, unaffordability or deeming non-necessity for a prosthesis.

The interview with the product developer was targeted to gauge the demands in the market, competition and regulatory challenges. It was found that 'aesthetic prosthesis' is in demand and at the same time there is no such device in the market that can be suitable for all. Furthermore, to make a device that does not need a practitioner can be very challenging. Special emphasis needs to be given on the choice of material, the sizing that will be offered, and a user-friendly design that enables the amputee to wear and adjust independently. It was

recommended that taking the predicate device track can significantly reduce the cost of regulatory procedures. As well as obtaining approval for the device to be over the counter and prescription free, it requires thorough backing.

The potential of the product and how it can transform the healthcare setting and the market was all discussed and an overall positive feedback was noted.

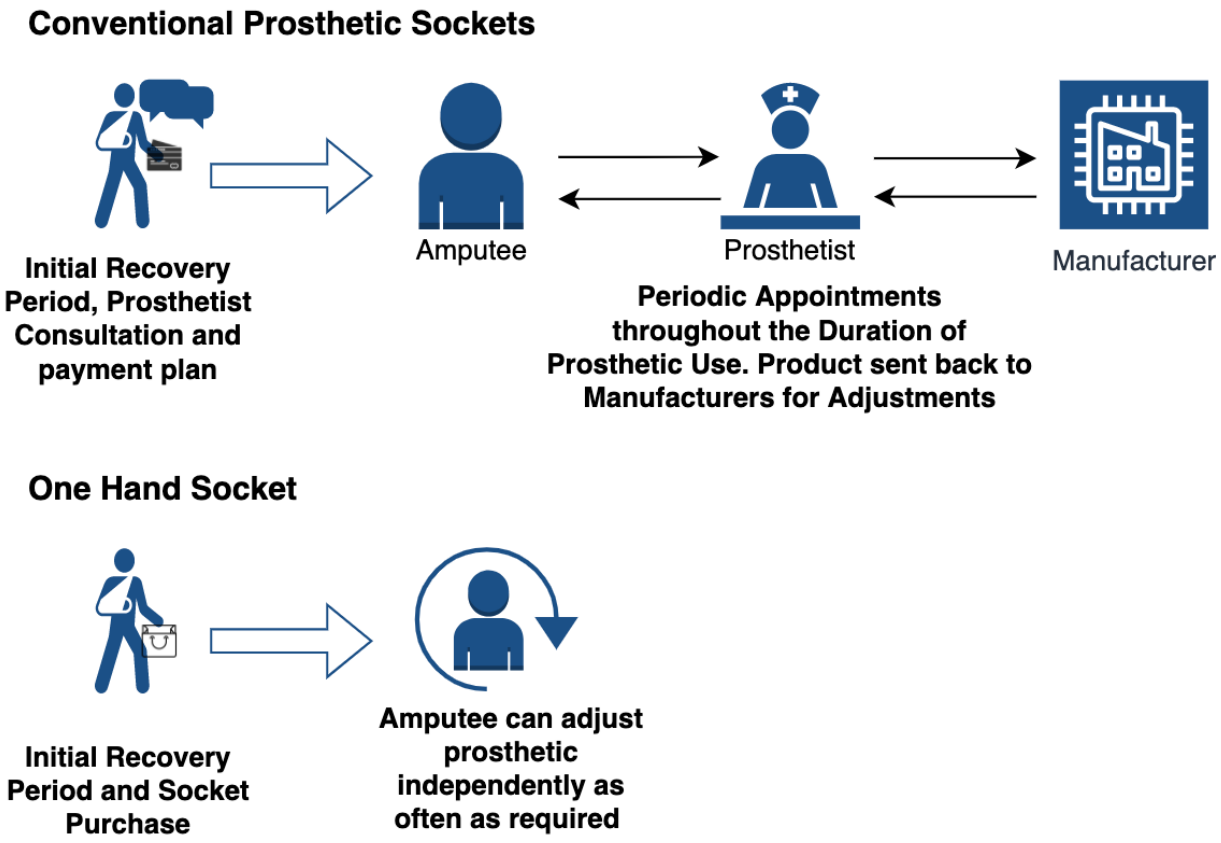


Figure 1: Conventional vs proposed flowchart of getting a prosthesis

Secondary Survey

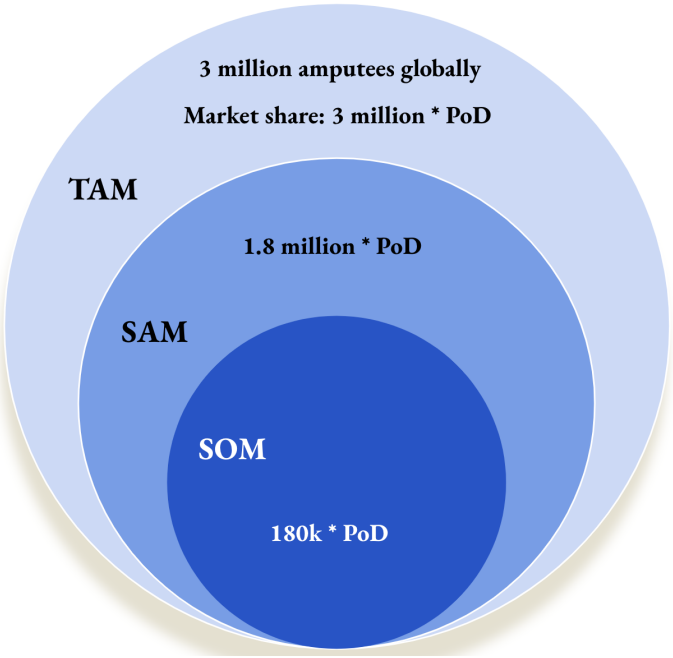


Figure 2: Total Available Market (TAM), Serviceable Available Market (SAM) and Serviceable Obtainable Market (SOM) analysis

Currently, there are over 3 million transradial amputees globally, which defines our total available market. Our sizable addressable market, however, would realistically encompass the amputees who do not have access to prosthetic devices: 60% of the TAM, 1.8 million transradial amputees [9]. We expect to promote our product to and attain 10% of this population, 180,000 amputees.

Competitor Analysis

An evaluative analysis was conducted to assess the immediate competitors in the market for upper limb and specifically transradial prosthesis.

Figure 3: Open Bionics arm

Open Bionics [3]

- Open Bionics offers a customizable transradial arm which is 3D printed based on the patient's requirements.
- The prosthesis offers six grip choices and degrees of freedom and is myoelectric powered prosthesis
- The prosthesis requires user, clinician and manufacturer involvement to get the right size of the prosthesis
- Cost: ~$20,000

Revofit [4]

- Revofit offers a body powered, laterally adjustable based prosthesis
- It consists of an adjustable dial allowing one directional tightening of the prosthesis
- The customized casted arm is designed based on clinician feedback and requires proper fitting
- The prosthesis is priced approximately $7,000-10,000

Figure 4: Revofit arm

Orthopus [5]

- Orthopus offers a range of cosmetic hand/arms available in different sizes
- The prosthesis is to be worn as a sleeve and mainly for aesthetics and offers little to none functional offerings
- Such prosthesis are non-adjustable and one sized prosthesis
- Such a type of sleeve is priced at approximately $500

Figure 5: Orthopus sleeve

Patent Survey

Thorough research to assess direct competitors as well as gauge the patent ability was conducted. The resources employed for the patent assessment were via the Darwin Innovation Index offered by the Johns Hopkins Library. The obtained patents are given as follows:

1. US 6,991,657 B1: Adjustable Prosthesis Socket [6]

- This invention describes a cup-like structure having a lateral cutout, lower closed portion and an open upper portion, a brim, and a lateral wall.
- The brim allows mounting to the residual limb and the lateral wall allows adjustments using hooks, straps and other locking mechanisms

2. US 8,945,237 B2 : ADJUSTABLE PROSTHETIC LIMB SOCKET [7]

- This invention consists of a socket with a rigid support that is shaped to conform to the residual limb. The non-elastic, flexible support attached to the socket allows adjustment to maintain a volumetric fit of the residual limb, wherein the adjustable means provides

an adjustable circumferential force to obtain a volumetric fit.

Regulatory Issues

To follow through with the distribution plans (mentioned later), the following regulatory requirements must be met based on the location of distribution: FDA 510(k) approval, CE mark from a European Union regulatory body, compliance with the International Medical Device Regulators Forum (IMDRF) Global Harmonization Task Force (GHTF) Medical Device Requirements, and any additional requirements an individual country requires. For the FDA regulatory process, this device falls under a class II device and will require a 510(k) submission along with a substantially equivalent device. According to ISO 13485, this product is identified as a Class IIa device and must go through a conformity assessment through a notified body. This paperwork will be used for GHTF approval submissions as well as for any other countries where product distribution will take place that are in harmony with international regulatory requirements.

Design

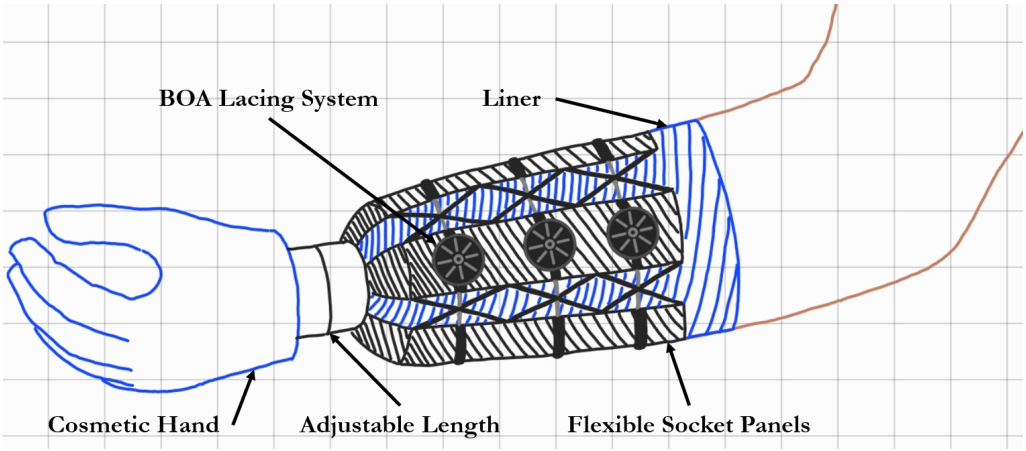


Figure 3: Schematic design of the prototype

The fit of the OneHand Socket around a trans-radial residual limb can be adjusted through three BOA lacing components. Each dial controls the fit of the socket around the circumference of different parts along the residual limb. The implementation of multiple laces along the socket creates a design that is able to create an effective placement for many different types of residual limb forms. When a dial is turned to tighten or loosen the socket, the panels will move closer or farther from each other, respectively, with the criss-cross sections contracting or dilating. The paneling of the socket was designed on Fusion360 and printed with Thermoplastic Polyurethane (TPU), a plastic with greater flexibility than Polylactic Acid (PLA) (more commonly used for 3D printing), to allow for adjustability. Injection molding will be the

preferred manufacturing method for high volume assembly to reduce production time and cost. Specifically, the unit cost of 3D printing the OneHand device is about $200 and is consistent even with larger orders. Injection molding presents a high cost of production for individual orders ($20,000 per unit), but the unit price decreases with bulk orders ($50 per unit) as the main source of the cost is mold generation (the mold can be reused for larger orders).

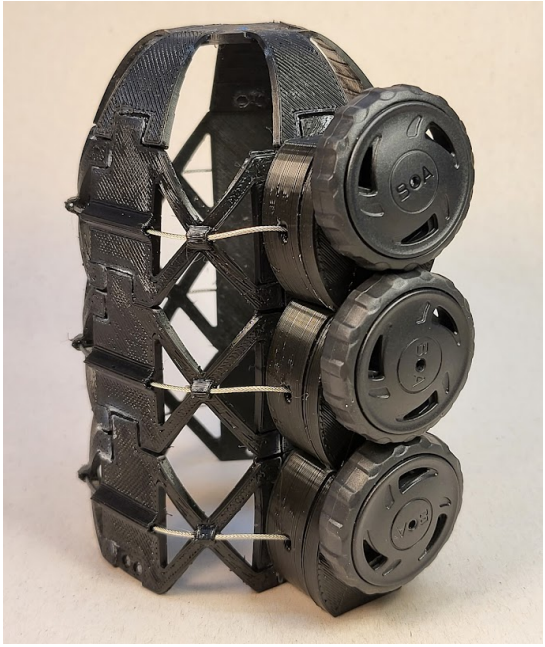


Figure 4: First iteration of the prototype

Bill of Materials

The following bill of materials is required to create one prototype of the OneHand trans-radial socket. It can be followed as a guiding point to develop initial iterations of the product to gain investment and seed funding.

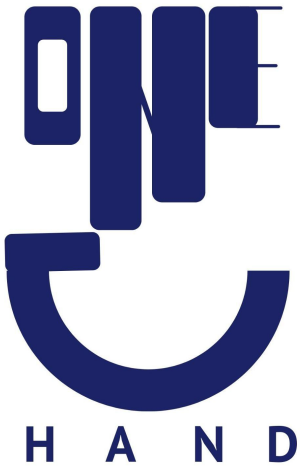
Sr.no	Item	Qty	Unit Cost $	Total cost $
1	Thermoplastic Polyurethane (TPU) fibers for 3D printing	1	11.99	11.99
2	Boa system with cables	3	12.99	38.97
3	Liner	1	12.99	12.99
4	Printing cost	N/A	20	20
5	Labor cost	N/A	80	80

6	Assembly apparatus	N/A	30	30
Total				~200

Table 1:Bill of materials for one prototype

The overall cost of the product is expected to be reduced significantly by resorting to injection molding and mass production.

Branding



“Enabling Amputees to Live their Best Lives”

Figure 5: Logo

Marketing Strategy

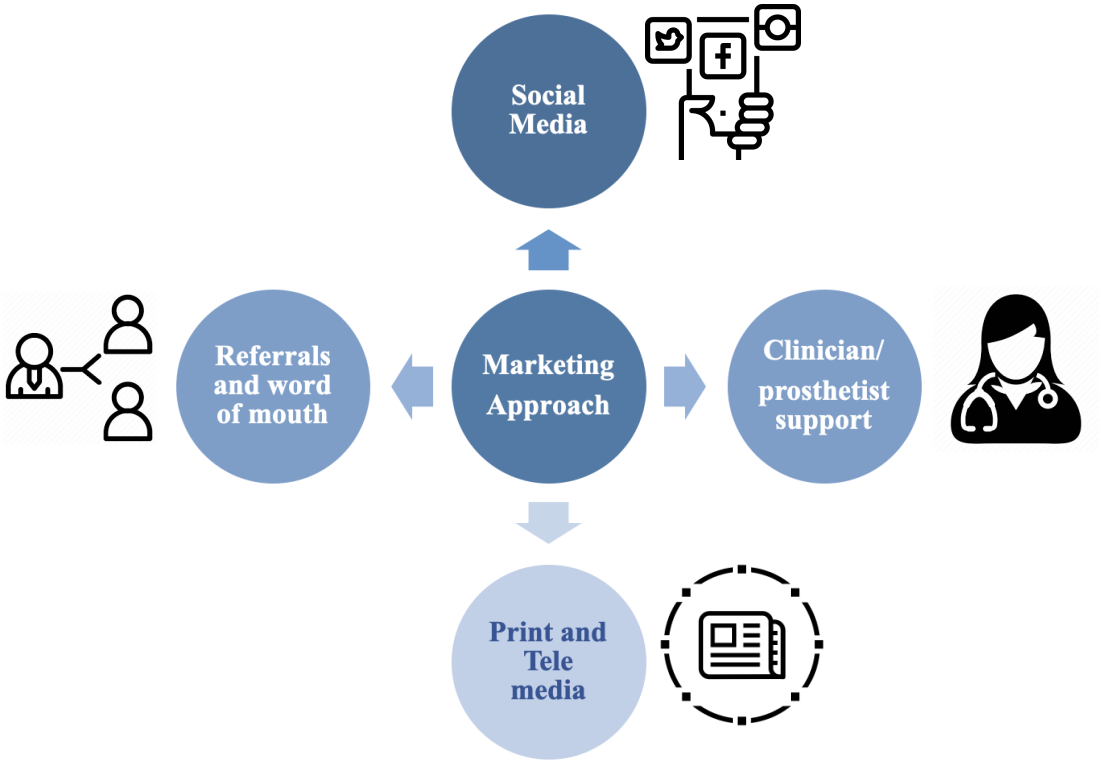


Figure 6: Marketing strategy

As with any new product in the market, the proposed device is also expected to face reservations in immediate acceptance by the patients. The go-to strategy for the product to be known in the market is through traditional print and tele media as well as social media. Informational pamphlets and television advertisements have been the most effective means of communicating with large masses. Furthermore, with increasing use of smartphones, the extent of social media exposure has also increased significantly. Social media tools such as Instagram, Facebook and Youtube can be used to reach a wider population. To acquire the trust of the amputees around the globe, it is preferred to get the product certified and approved by clinicians and prosthetists. This will allow the product to be marketed as 'Prosthetists approved'.

The power of referrals and word of mouth cannot be refuted. Good customer review automatically creates a sense of validation, thus encouraging current customers to spread a good word would help the product gain some traction in the market.

SWOT

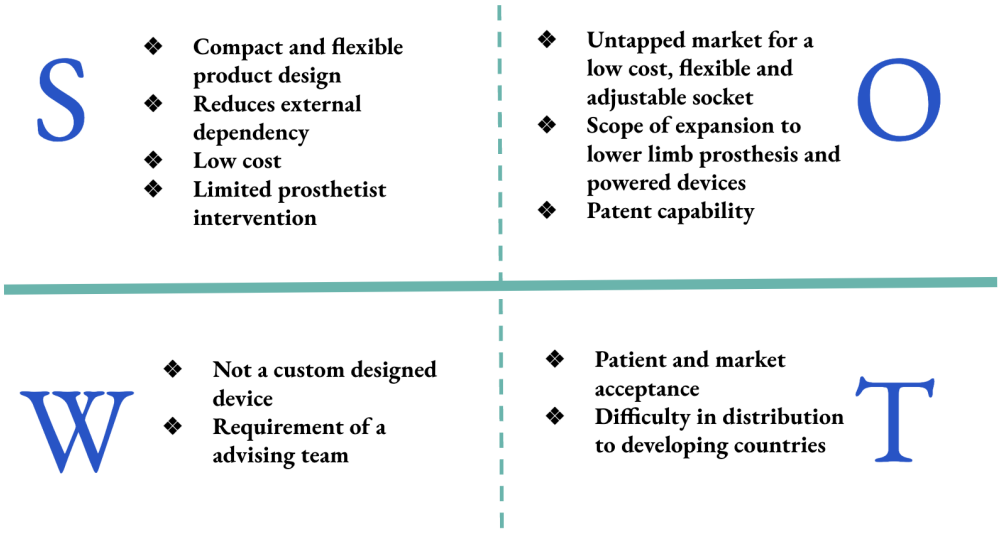


Figure 7:SWOT Analysis

Business Strategy

Figure 8: Business strategy

The proposed business strategy for our product is described in the flowchart above. Although promotion of independence from prosthetists is one of the driving motivations of the product, it is still a huge source of revenue if rightly marketed as a good preliminary or trial device prior to a permanent attachment. Thus, healthcare institutions are one of the big sources of income for this device. The primary selling point would be pharmacies and stores, where the device is available as 'over the counter' and thus target a wide audience. As we intend to make this product cost effective, tie-ups with foundations actively working in war inflicted regions or developing countries will be very beneficial. Collaboration with big companies conducting mandatory corporate social responsibility (CSR) can also be a potential source of income and making the product known.

Financial Plan

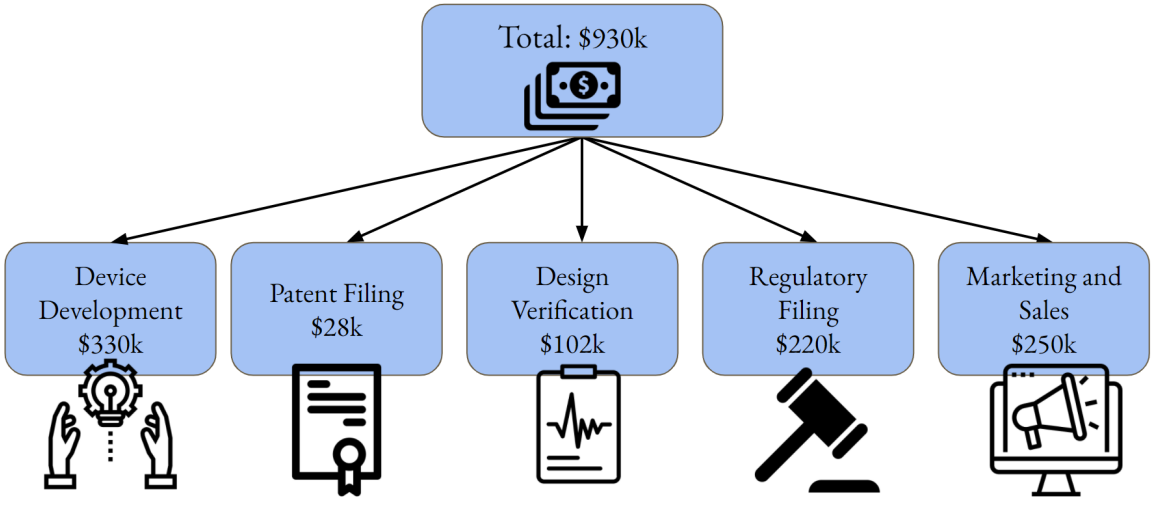


Figure 9: Financial Plan

A two year financial plan was developed estimating the cash outflows for different key tasks to get the device into the market and gain traction. It is projected that a total of $930,000 dollars investment at predefined intervals will be requested to funding sources such as venture capitalist, bank loans or seed funding. The total sum is broken down into four phases. The first phase requiring $330,000 is attributed to device development required in the first six months. This will enable the finalization of the device specifications, method of production i.e injection molding and identifying potential outsourced mass manufacturing. The next phase of six months will be assigned to performing validation, testing and application of patent and related documentation. The funding required for this phase is $130,000. Further to this, regulatory filing would require $220,000 for the procedures mentioned earlier. Lastly, in order to make the product known and ensure market traction, $250,000 is requested.

The cost of production for 1 device employing injection molding technique is estimated to be $50. The product is projected to be sold for 100% profit at $100/device. Thus, aiming at

180,000 units, the total revenue over a period of 10 is $18 million. Thus, the potential profit is $9 million which can be used for payback, reinvestment and expansions.

Reimbursement

Due to the fact that our target population for this product is individuals in regions with lower access to healthcare facilities, we plan on joining the United Nations Global Marketplace. The UN provides resources to regions of need and obtains such products and services through their $20 billion dollar procurement plan (grows by about 10% every year), of which 25% involves healthcare supplies. We intend to join this community, propose our product, build connections with other manufacturers, and potentially gain a contract to provide adjustable transradial prosthetic sockets. Simultaneously, we plan on supplying our product to hospitals, pharmacies and rehabilitation centers so that customers can independently purchase the device, increasing the accessibility of this technology.

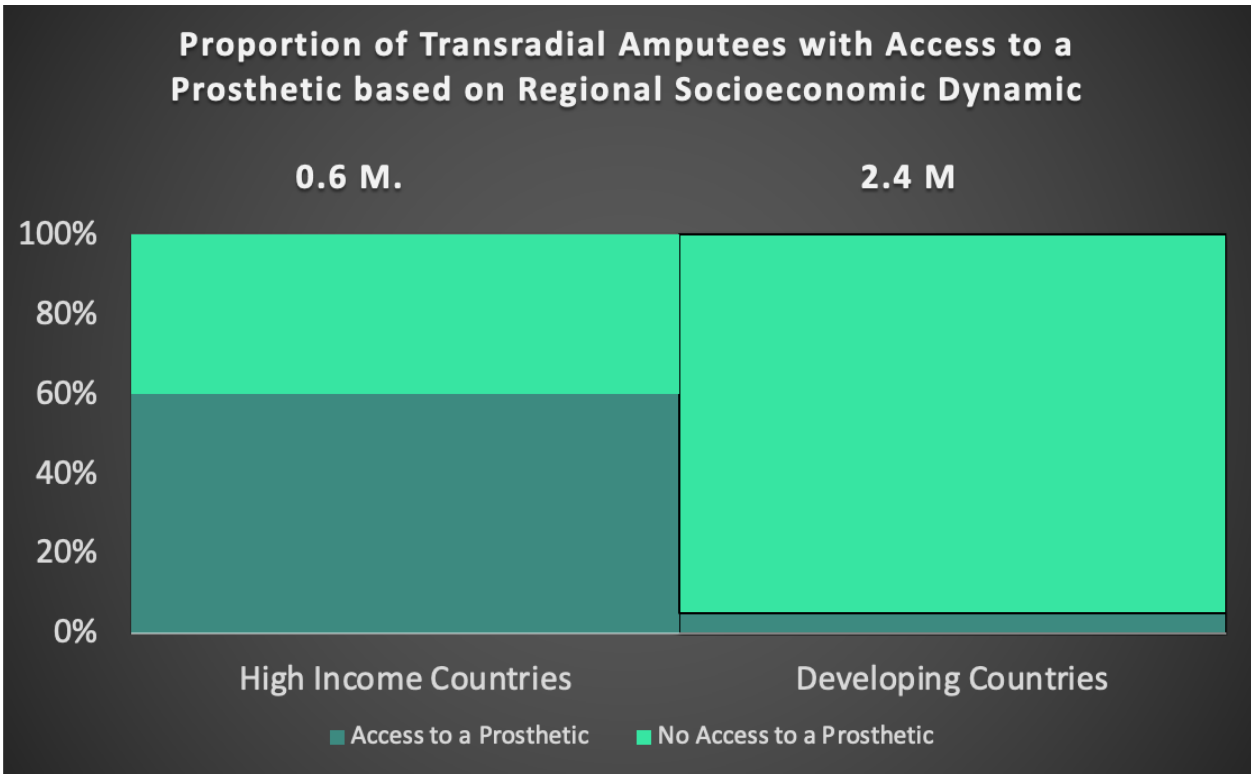


Figure 9: Opportunity for prosthetic socket distribution in developing countries [9, 10]

Ethical Considerations

In the process of manufacturing and bringing the product to the market, at any point, there are certain ethical principles that we intend to follow. These principles can be described as follows:

- Environment consciousness: In an effort to mass manufacture the product, we will take into account environmental concerns and aim to create green manufacturing units.
- Legal production practices: The manufacturing units will ensure that no human rights and working rights are compromised
- Health and safety at workplace: Hazard protection and general requirements will be ensured at all our workplaces
- We aim to implement ethical accounting, fair marketing practices and privacy protections of our customers

Future Steps

After development of the transradial prosthesis socket, this technology can be applied to future products further expanding the mission of the company. With minimal resources, low cost cosmetic prosthesis can be developed for the following types of amputations:

- Transhumeral (above elbow)
- Wrist Disarticulation
- Transfermoral (above knee)
- Knee disarticulation
- Transtibial (below the knee)
- Foot Amputations

These products will bring prosthetic access to all amputees instead of just transradial (below elbow) amputees. Adding these devices to our product offerings would drastically increase the obtainable market size and future company revenue. Future profits can be used to develop technology in more complex product categories. Research in body-powered and EMG prosthetics can be done to reduce the cost of those device categories. Adding low cost body powered and EMG prosthetics to our product offerings further increases the company's future earning potential while bringing access to these technologies to all amputees.

References

[1]Limb Statistics https://u.osu.edu/fitness4all/loss-limb-stats/
[2]https://www.limbsinternational.org/why-limbs.html
[3]Open Bionics https://openbionics.com/faq/
[4]Revofit https://clickmedical.co/revofit/
[5] Orthopus https://orthopus.com/
[6]Google Patents: US 6,991,657 B1: Adjustable Prosthesis Socket
[7]Google Patents: US 8,945,237 B2: ADJUSTABLE PROSTHETIC LIMB SOCKET
[8]ISO 13485:2016 Medical devices quality management systems requirements for regulatory purposes
[9] Diane W. Braza MD, Jennifer N. Yacub Martin MD, in Essentials of Physical Medicine and Rehabilitation (Fourth Edition), 2020.
[10] Limb Statistics https://www.limbsinternational.org/why-limbs.html

Appendix: Patent

United States Patent **Patent Number: 52065705**

Haworth et al. **Date of Patent: December 21, 2021**

FLEXIBLE AND ADJUSTABLE PROSTHETIC SOCKET

Inventors: **Jesse Haworth; Heba Sattar; Rasika Thombre**
Assignee: **OneHand**
Appl. No.: 52065705
Filed: **December 12, 2021**

References Cited
U.S. Patent Documents
BOA® Patent 7,992,261 9,743,714 2011-08-09 Hammerslag

ABSTRACT

This invention is a flexible adjustable socket for amputees, which includes 3D printed panels and cables. The three disc-like, knob tightening systems mounted on different panel arrays allow circumferential tightening at different positions along the residual limb. The socket base can be attached to an extending component and a cosmetic structure (i.e. hand) for functionality and aesthetics.

10 Claims 2 Drawing sheets

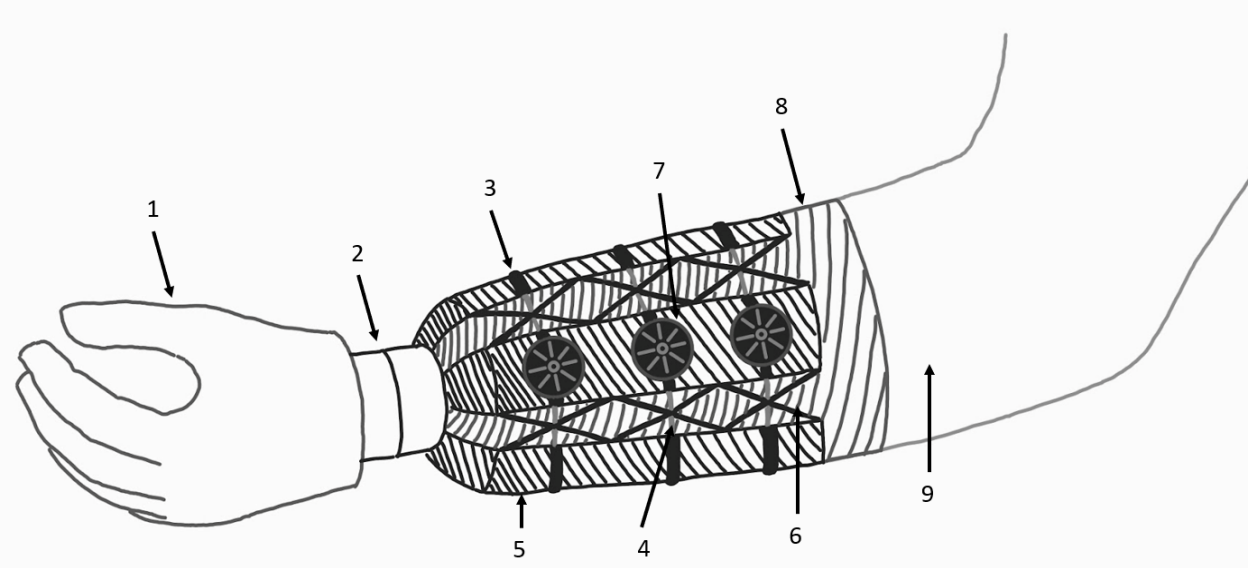


FIG 1

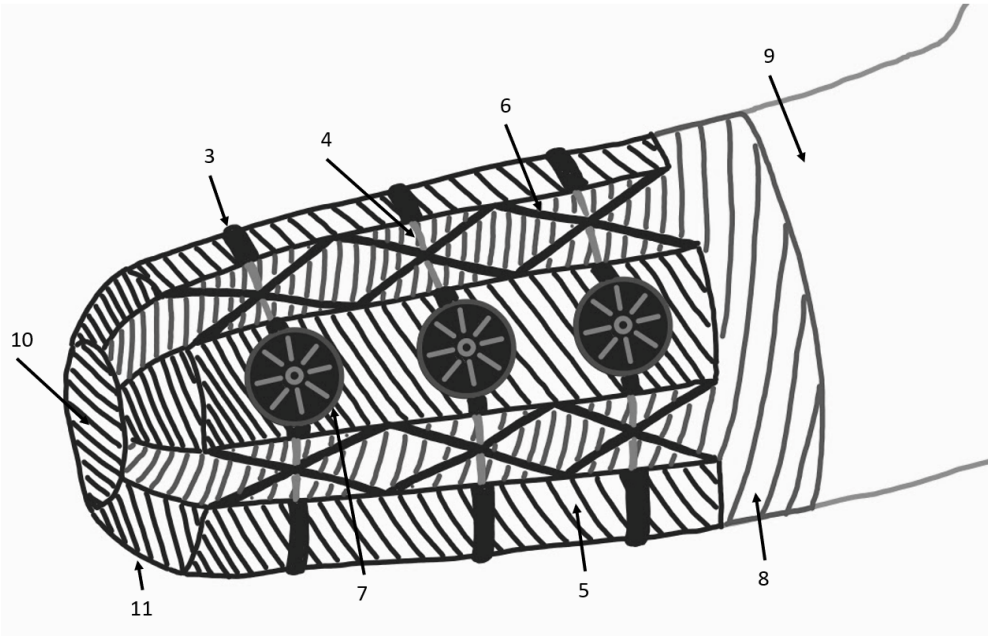


FIG 2

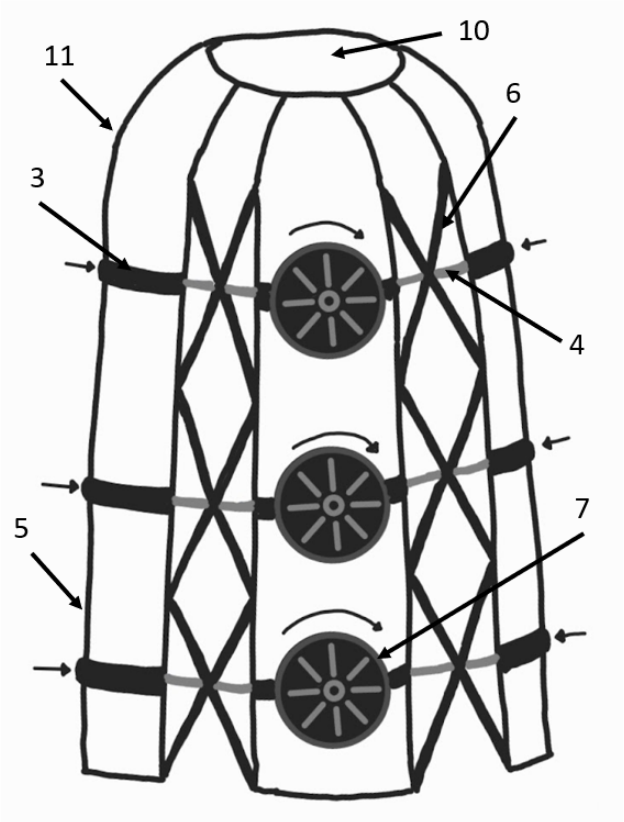


FIG 3

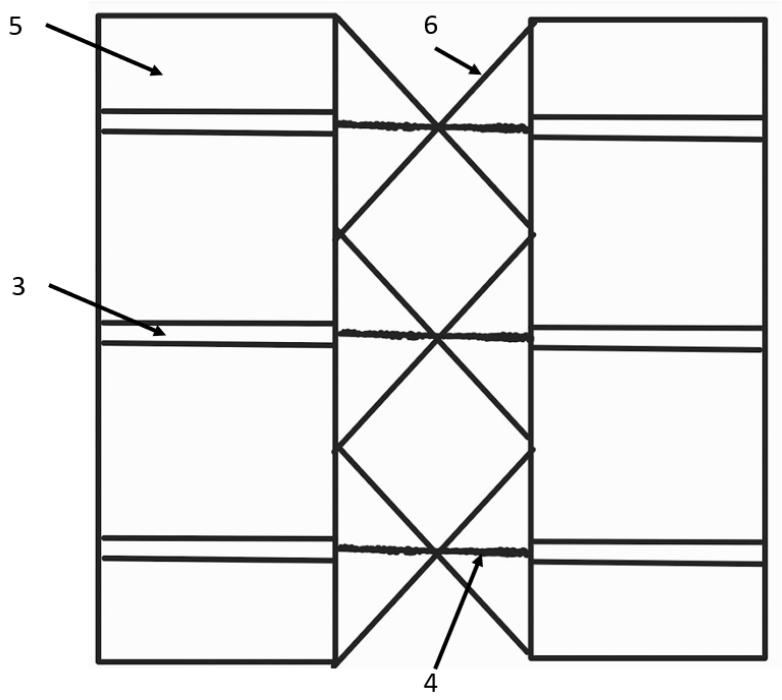


FIG 4

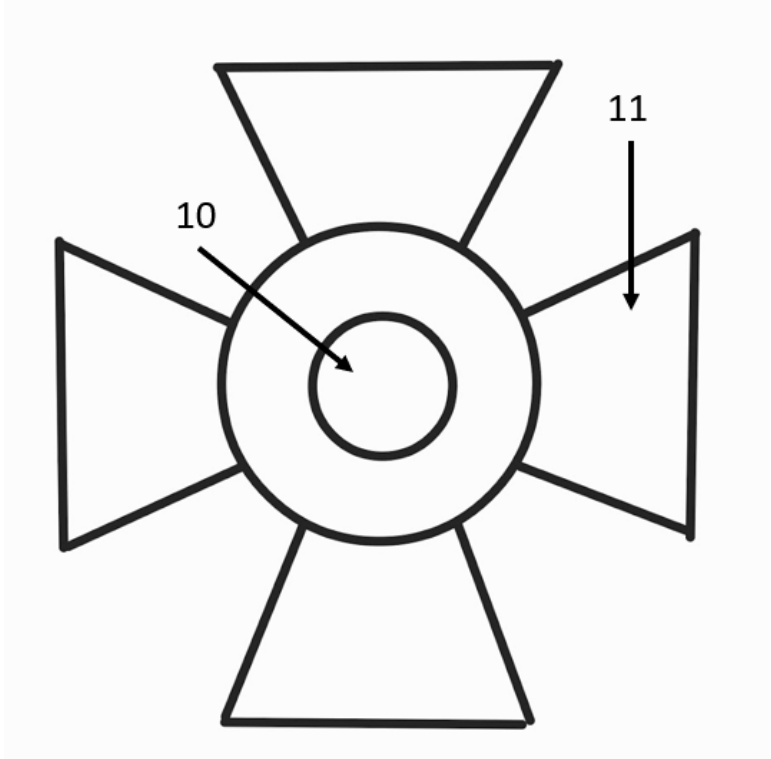


FIG 5

1	Prosthetic Hand
2	Adjustable Length
3	Cable Channels
4	Cabling
5	Flexible Panels
6	Flexible Scaffolding
7	DLacing System
8	Liner
9	Patient's Residual Limb
10	Adjustable Length Mounting Location
11	Flexible Top Panels

BACKGROUND OF THE INVENTION

For those with upper or lower limb amputations a common device to use is a prosthetic limb [1]. Artificial limbs can be used for transradial, transhumeral, transfemoral, and transtibial amputations along with many others. These are used to replicate the visual and functional capabilities of the original limb. One of the main components of any upper or lower limb prosthesis is the socket. This is used to interface the device with the patient's residual limb [9]. Liners [8] are often used for comfort, adherence, and hygienic purposes between the socket and the limb. A casting process is used to shape the socket perfectly to the residual limb to get as comfortable of a fit as possible. This process can be time consuming and requires a specialist to create the mold and fit the device. A casted device is also very difficult to modify if the limb swells or changes shape, which is a common occurrence among amputees. Custom sockets are a large contributing factor to the high cost of a body-powered prosthetic, which prohibits the accessibility of this product for some patients. Other methods to make an adaptable socket include single adjustable panels, straps, or balloon inflation; however, these products still require a prosthetist and present a similar cost as the standard casted socket. This presents the need for an adaptable socket that can adjust to the patient's changing residual limb, does not require a specialist for fitting, and reduces the production cost of the device.

SUMMARY OF THE INVENTION

The invention is an adjustable prosthetic socket for amputees. The adjustable socket includes 3D printed flexible panels, three radial tightening systems, cabling and a liner. The flexible panels are adapted to include a cylindrical hole to allow thin synthetic cables to pass through for tightening. The tightening system is mounted on a housing structure, in which the cables are coiled. As one disk-like system is turned anticlockwise, the cables are wound within the housing, tightening the panels radially.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure **1** shows the socket being used in a full prosthesis with the prosthetic hand (1), extendable length (2), and socket mounted onto a patient's arm.

Figure **2** shows the adaptable socket design, without the hand, placed over a liner (8) that is covering a residual limb.

Figure **3** demonstrates how a clockwise rotation of each knob (7) will retract the cables, which radially tightens the socket by bringing the panels (5) closer together.

Figure **4** shows a section of the panels (5) and scaffolding (6) that allow the socket to expand and contract. The panel distributes the force from the cables and conforms to the residual limb, while the scaffolding (6) in between panels allow the panels to move closer and further to one another allowing for radial expansion and contraction.

Figure **5** shows the top portion of the socket. In the middle is a mounting feature for the prosthetic hand, while each of the flexible side mounts can bend closer or further from the midline of the socket to accommodate larger and smaller limbs.

DESCRIPTION OF PREFERRED EMBODIMENT

To attain an appropriate understanding of the preferred embodiment of this invention, the following description will reference the labels of the accompanying drawings.

Furthermore, the following explanation of preferred embodiment of this invention aims to address and expand on aforementioned descriptions. This is one possible use and does not limit the functionality of the device for other applications and expansions.

The intention covers all modifications, alternate designs and equivalents following the same technique of the disclosure.

FIGs **1-3** depict the first embodiment of a flexible and adjustable prosthetic socket system. This invention was created as the socket of a body-powered prosthetic that can attach onto the trans-radial residual limb of an amputee. It is intended to be used throughout the day for functional performance. Furthermore, the adjustable fitting allows for greater autonomy for the user by requiring less frequent adjustments by a prosthetist over a long period of time as well as short-term adjustments for variations in residual limb swelling throughout the day. The socket will be attached to the liner-covered residual limb.

The socket includes flexible panels **5**, three adjustable disk-like radial lacing components **7**, for maximal adjustment throughout the residual limb. Each dial controls the fit of the socket around the circumference of the arm, at different sections, to account for the variety of residual limb shapes.

Claims:

1) A flexible and adjustable prosthetic socket comprising:
    a. A series of flexible panels used for distributing the force of the cables.
    b. Scaffolding that connects each panel allowing for radial expansion and contraction of the socket.
    c. A series of cables that circumscribe the socket for tightening.
    d. A series of disk-like, knob systems to tighten each cable.
    e. An attachment feature for the prosthetic hand.
2) The flexible and adjustable prosthesis socket as per claim 1, wherein each array of the flexible panels can be adjusted independently using a disk-like system
3) The flexible and adjustable prosthesis socket as per claim 1, wherein the liner worn under the socket allows comfort
4) The flexible and adjustable prosthesis socket as per claim 1, wherein the flexible panels are 3D printed using PLA
5) The flexible and adjustable prosthesis socket as per claim 1, wherein the disk-like system is a knob or similar
6) The flexible and adjustable prosthesis socket as per claim 1, wherein the disk-like system is a BOA® system
7) The flexible and adjustable prosthesis socket as per claim 1, wherein a housing for the BOA® stores the coiled cables
8) The flexible and adjustable prosthesis socket as per claim 1, where the base enables attachment of an extendable rod and cosmetic hand
9) The flexible and adjustable prosthesis socket as per claim 1, will have a larger diameter and length for transhumeral and leg prosthesis
10) The flexible and adjustable prosthesis socket as per claim 1, to have a more number of the horizontal flexible panel arrays for transhumeral and leg prosthesis