Abstract

To overcome user dissatisfaction with current prostheses, the Functional Neural Interface (FNI) Lab at Case Western Reserve University integrated sensory feedback into the prostheses of distal arm amputees using an implanted nerve electrode system. Because this current system relies on the velocity-based linear feedback control of myoelectric prostheses rather than the continuous control seen during natural hand posture maintenance, this system has reached a barrier in acquiring quantitative data as they begin in-home trials. To enable quantitative data acquisition for the FNI Lab, the goal of this project was to develop a novel control system that interfaces with commercially-available prostheses to integrate the natural, continuous feedback system present in intact musculature hand control. The system was developed using an embedded software controller that maps incoming electromyography signal amplitudes from forearm muscles to motor actuation, leveraging a feedback loop mechanism to replicate intact muscle control. Outputted pulse width modulation signals will be utilized to allow for prosthetic actuation and hand posture maintenance through continuous muscle activation. The software was trained using human phantom test trials and integrated with an electromyogram (EMG) microcontroller and a servo motor intended to mimic prosthesis behavior. This device is to be implemented into the FNI Lab's project to improve the quantitative characterization of the functionality of their neural-connected sensory prosthesis.

Description of the Problem

Commercially available myoelectric prostheses can result in dissatisfaction among users due to a lack of fine motor control and sensory feedback. These factors lead to a sense of disembodiment between the amputee and their prosthesis, resulting in abandonment of the device altogether. A team of researchers at Case Western Reserve University and the Louis Stokes Cleveland VA Medical Center created a solution to this prevalent problem by successfully designing a neural-connected sensory prosthesis to restore natural neural feedback systems. This solution is currently transitioning to in-home trials.

Characterizing the functionality of this system is integral to the trial; however, disparities between the control systems of current myoelectric prostheses and physiological motor units has constrained their team to qualitative data. Current prostheses operate on a velocity-based control system, where hand posture is maintained by the cessation of active motor drive. This method of control is optimal in the absence of sensory feedback but does not replicate the natural musculature control system. With this, the functionality of the sensory restored hand is difficult to quantitatively compare to intact muscle control functionality because they are fundamentally different.

Neural-connected sensory prostheses are at the frontier of the field, so prosthesis control systems emulating natural muscle control systems are lacking. There exists a need for a force-based control system for prostheses with the requirement of continuous active motor drive for hand posturing, enabling Case Western Reserve University to overcome their barrier to collecting quantitative data.

Project Objective Statement

Our team has addressed this problem by designing, implementing, and validating a force-based controller to be integrated with commercially available myoelectric prostheses. The developed controller will allow for the adaptation of the current linear velocity-based control states of myoelectric prosthesis to continuous force-based, biomimetic control schemes. First, the system will link the sustenance of muscle contraction to the maintenance of hand posture. Second, the force of prosthetic contraction will be controlled by the user through continuous muscle activation limiting unnecessary or excessive hand contraction during object manipulation. With the sensory feedback integrated system of Case Western Reserve University, these two aspects comprise an innovative force-based control system for more biomimetic motor control in amputees, previously unattainable due to the inherent limitations of commercial prostheses. Ultimately, this was accomplished using low-cost commercially available hardware and a novel software control scheme that can be easily implemented in a laboratory environment.

Documentation of the Design

To facilitate the successful design and implementation of the project, a preliminary needs assessment and risk analysis were performed to identify the critical needs and risks of the patient, provider, and system. For the patient, the hardware needed to be minimal, wearable, durable, and easily implementable with commercially available prostheses, as well as easy to use and affordable. For providers and researchers implementing the final system, ease of use was a primary focus for intuitive setup, calibration, manipulation, and research usage. The system needed to seamlessly integrate with current prosthetic systems to allow continuous, real-time, biomimetic muscle control of hand posturing. The risk analysis presented was subsequently performed by rating design considerations around biomedical standards in electrical, biocompatible, and functional safety on a scale of 1-10 to prioritize and address risk concerns where possible. Design documentation throughout this development process was recorded on an available website, which is linked below. The full risk analysis and needs assessments can be found there for consideration:

https://my.vanderbilt.edu/forcebasedprosthesiscontroller/2019/04/safety-design-considerations/

With the needs and risks of the system defined, the design and team were subdivided into four work areas to optimize time usage: EMG acquisition, external hardware integration, software and algorithm development, and motor actuation.

Natural muscle activity, or EMG, acquisition was accomplished via commercially available, low-cost Myoware EMG sensors. These sensors were chosen for their compact pre-integrated circuitry and bandpass filters in an integration-ready package. This aspect reduces the size and maintenance required by patients and researchers, making them more wearable and durable. Two sensors were used to replicate the setup of a commercially available prosthesis. Additionally, pre-existing source code for interfacing with the sensors was used.

The primary external hardware needed was a microcontroller platform able to accept input analog EMG signal from the sensors, process the data, and output control signals. In choosing a microcontroller, the size, memory, processor speed, resolution, output voltage range, and cost

were weighed among several possible choices. The 32 bit 180 MHz ARM Cortex-M4 processor Teensy 3.6 was ultimately chosen as the best fit for the need as it provided speed, processing capability, and a 3.3 V operating voltage at a $30 price point. An external 3V battery was purchased to provide an isolated source of power for the system. To improve wire and hardware management and make the system wearable and durable, a plastic cage was 3D printed to hold the microcontroller and battery. A velcro strap was added to the plastic cage for donning and doffing the system quickly and easily.

The software and algorithm development focused on four elements in series: sampling, digital signal pre-processing, intent interpretation, and PID control. Due to the difficulty of validating an algorithm in real-time, each of these steps was incrementally developed and tested in Matlab using raw data pre-acquired for base validation, implemented and deployed using PlatformIO, and fully validated in real-time using PLX-DAQ. From literature, the average maximum possible frequency of an EMG signal was 300 Hz, so per the Nyquist theorem, a 1000 Hz sampling frequency was chosen as a safe value that avoided signal aliasing while providing high resolution. An interrupt timer was chosen as the method of implementation for sampling. Pre-processing was accomplished through rectifying the signal, applying a 1 Hz Tustin approximation low pass smoothing filter, and outputting 200 ms envelopes every 50 ms for processing. Tustin's method, a discrete bilinear transform, was chosen for smoothing over a moving average filter because of its ease of implementation as a simple I/O equation following mathematical transform to the time domain. Intent interpretation was accomplished by calculating the mean absolute value (MAV) of the 200 ms envelope for each channel, taking the differential between the two channels, and feeding the differential value to a logistics classifier. The logistics classifier is a machine learning piecewise linear function trained using phantom data from team members. The classifier extracts intended percent contraction from the differential value and applies a threshold to ensure the guessed intent is not outside the hardware limitations of the system. To piggyback on the existing control system of a prosthetic hand, a PID controller was implemented. The PID controller translates maintained contraction to maintained hand posture in the prosthetic hand by lowering the input signal of the hand to 0 which results in maintained hand posture in the prosthesis. Further documentation can be found on the project's github page:

https://github.com/christian-stano/Force-Based-Myoelectric-Controller

As a proof of concept, we used a Parallax 900-00008 servo to model force-based control behavior at various contraction levels by mapping the software output to various pulse widths between 700 and 2500 microseconds. These widths correspond to various angles of posturing which are dependent on the force and direction of contraction (flexion v. extension). To adapt with a traditional prosthesis, the PID output can be mapped to output voltages that feed directly into the microcontroller input of a traditional prosthesis, creating a wearable force-based control system for users.

Prototype of the final design

There are two parts to the developed controller prototype: the novel software system and the integrated hardware system for communication with the prosthetic. The hardware is demonstrated by Figures 1 and 2 shown below. The schematic shows the system without the optional LED shields that show the relative contraction level throughout testing. When removed, the system loses the battery from the shields which power the microcontrollers independently, therefore power for the EMG microcontrollers is restored directly from the teensy development board. The system in Figure 2 demonstrates the hardware implementation with LED shields as can be seen on a phantom subject. The Servo motor actuation can also be seen in this image, although it is a tool for proof of concept, rather than an integral portion of the developed prototype.

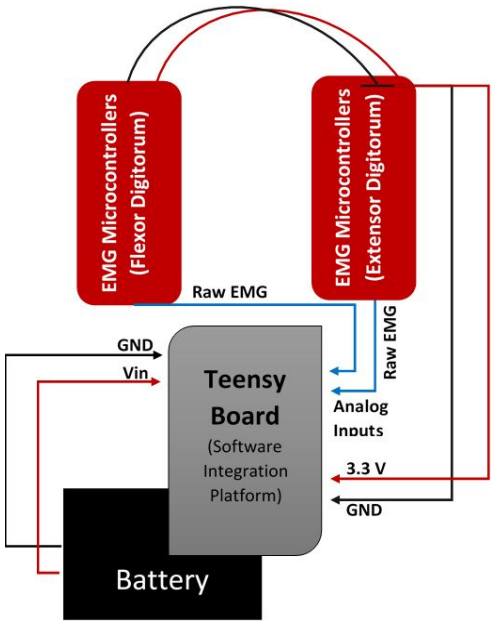

Figure 1: Diagram of hardware used in the system

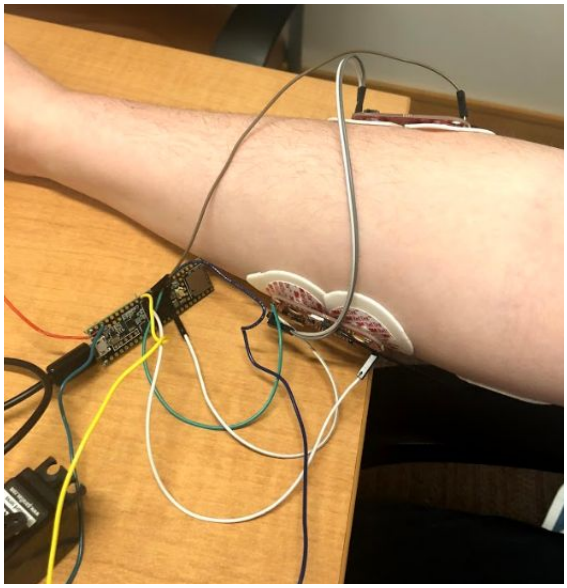

Figure 2: Example of EMG electrode placement and wiring on a test subject

The software was implemented in the Platform IO environment using Teensy adapted Arduino libraries. The scheme for the entirety of the software developed for this process is shown in Figure 3 below. This scheme was validated using a Servo motor that would rotate to the desired hand angle using the EMG controllers. This motor operates under a different control scheme than the natural scheme of the prosthesis, therefore the dashed portion of the software scheme was developed independently for the prosthesis versus the validation scheme. Calibration and preprocessing was visualized through serial communication with the computer, while the effectiveness in the control scheme was monitored using the servo motor position.

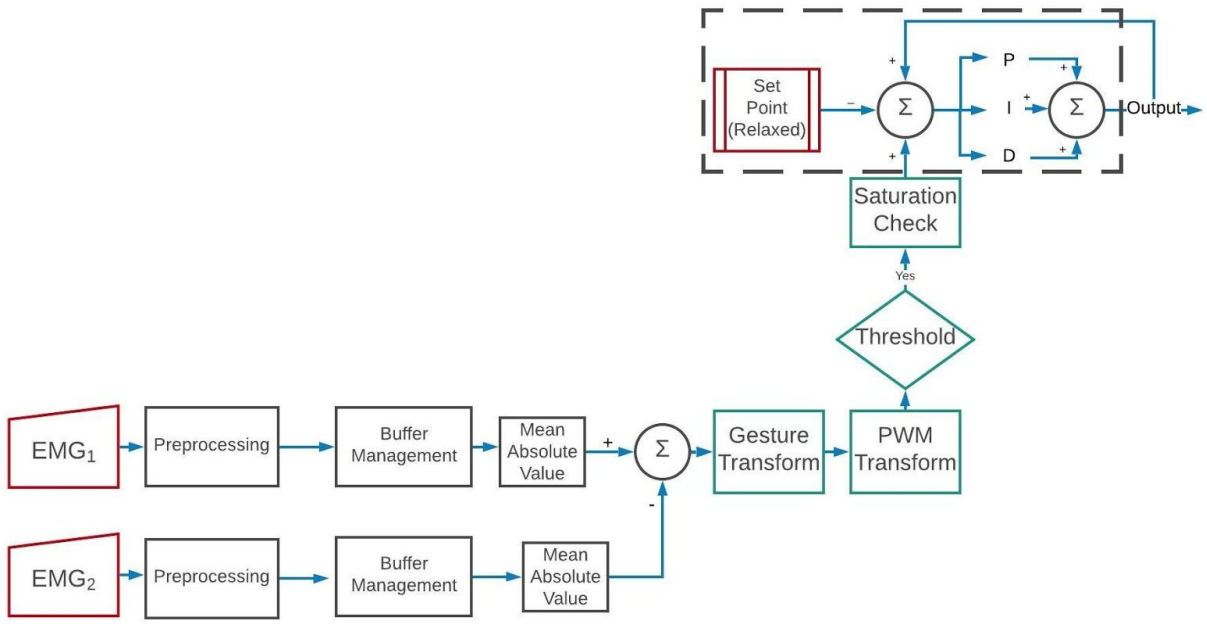

Figure 3: Scheme of software implementation

Proof that the Design is Functional

The validation of the hardware was achieved through independent EMG signal acquisition using the Myoware and Teensy microcontrollers in tandem with the Arduino system. The raw outputs achieved with this hardware configuration can be seen in Figure 4.A with varied flexor and extensor contraction.

Each part of the algorithm was tested in Matlab using static data as a preliminary validation followed by real-time testing using PLX-DAQ to ensure that each component shown in Figure 2 was working as intended. The digital signal pre-processing, including rectification and low pass filter smoothing, on a raw EMG signal of various contraction levels from MVC to 25% contraction is shown in Figure 4.B. It is evident that the pre-processing is able to successfully transform the raw input into distinguishable peaks ranging from MVC (far left peaks) to 25% contraction (far right peaks) for input into the intent interpretation algorithm.

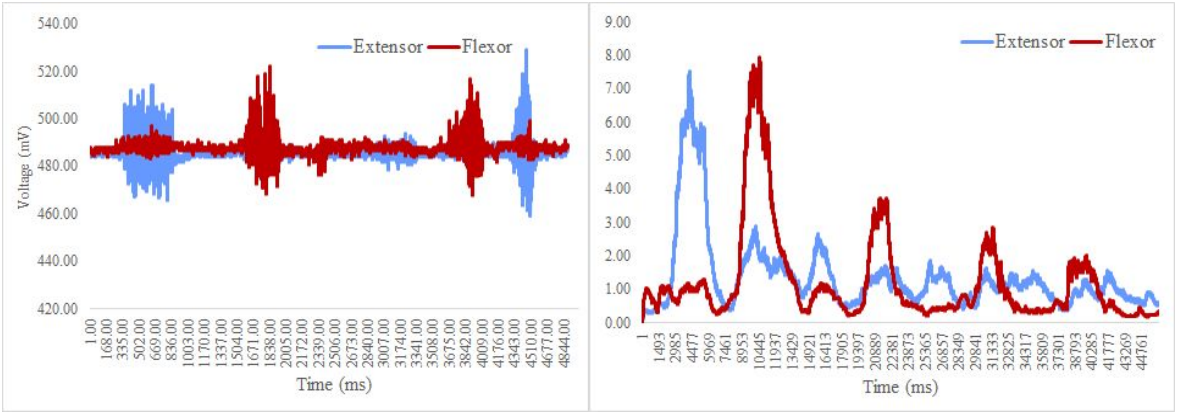

Figure 4: EMG signals acquired from myoware sensor. A) example of signal gathered before processing B) example of pre-processed EMG signal for different levels of contraction from MVC to 25%

An example of the processing component of the algorithm (MAV calculation, differential, gesture classifier, and motor actuation output) robustly, efficiently, and accurately extracting the intent of the user's muscle activity and translating it to pulse widths is shown in Figure 5. Figure 5.A demonstrates the algorithm's ability to accurately calculate and output the MAV of varying levels of contractions (similar to Figure 5.B). Figure 5.B displays the corresponding output of the gesture classifier given the input MAV in Figure 5.A, and Figure 5.C exhibits the pulse widths mapped to the contraction levels outputted by the classifier. Figure 6 shows the algorithm's output in comparison with perceived contraction intent across multiple trials for a subject. The grey bars represent the perceived contraction level, and the red bars indicate the mean recorded algorithm output across trials with standard deviation. From this, it is evident that the algorithm is able to accurately and consistently translate EMG signals to continuous force-based control.

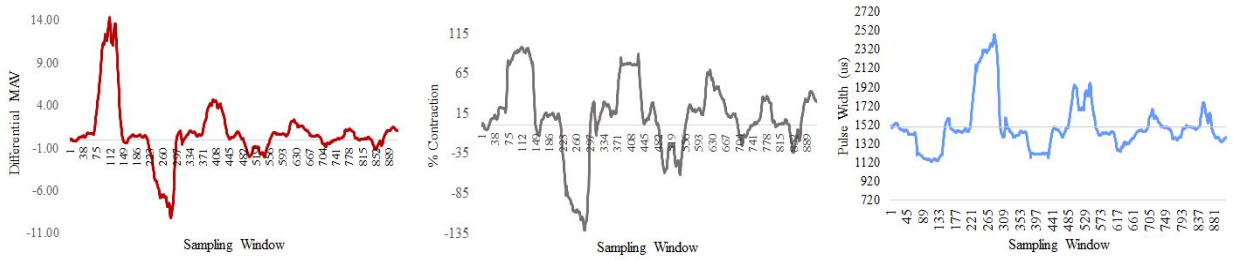

Figure 5: Examples of pulse widths translated from a users muscle activity. A) demonstrates MAV output at varying levels of contractions B) displays gesture classifier output given the input MAV C) shows the mapped pulse widths from the contraction levels outputted by the classifier

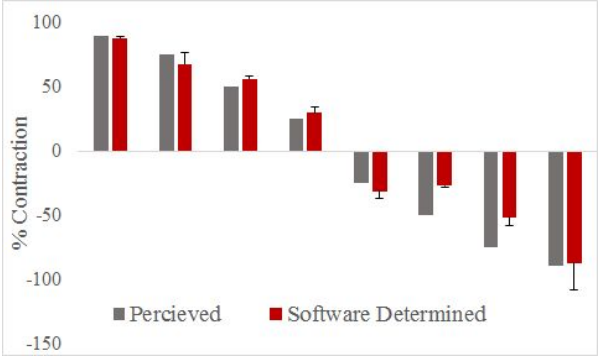

Figure 6: Contraction intent determined by the Software and perceived by the user across multiple test trials

Due to budget constraints, the developed PID software could not be tested with a myoelectric prosthesis. A proof of concept demonstration video showing the effectiveness of our force-based myoelectric control system in accurately controlling and maintaining the posture of a servo:

https://my.vanderbilt.edu/forcebasedprosthesiscontroller/2019/04/servo-actuation-proof-of-concept/

Results of a search for prior art, assessment and patentability

Overview: A preliminary search for prior art yielded a fairly constricted patent landscape for this device. Among the patents found and considered relevant, elements claimed pertained to the mechanical hardware design of the device as well as pattern recognition algorithms using EMG signal. Based on the prior art, it would be difficult for a patent examiner to not consider someone skilled in the art to view our device as nonobvious. Additionally, although previous unattainable, our device builds upon principles that are understood in the mechatronics community, making the patentability of our device unlikely.

However, the marketplace competition for our device is extremely low. Currently, velocity-based myoelectric prostheses are the norm for distal arm amputees, but the functionality of these devices is extremely limited due to the need for visual feedback to accurately manipulate hand movement. Our device's objective is to integrate with a new prosthetic hand system that circumvents this through the integration of the sense of touch. The only currently existing alternate methods to this sensory integrated system with force-based myoelectric control are cable-based feedback systems (which have resulted in widespread dissatisfaction) and other competing sensory restoration systems in research and development.

Search Terms Used: (upper limb prosthesis) AND (force controller); (upper limb prosthesis) AND (force-based controller) AND (pattern recognition); (upper limb prosthesis) AND (force-based controller) AND (hand posture); (continuous myoelectric control) AND (arm prosthesis)

	Patent Number	Analysis
1	US20160331561A1	Claims pertain to the sensory feedback aspect of the prosthesis instead of the controller, so it is not applicable.
2	US20120004736A1	Claims are worded towards a lower extremity prosthesis and pertain to volitional control of the prosthesis during non weight-bearing activities
3	**US20130338540A1**	**Claims surround the use of pattern recognition algorithms to interpret EMG signals and produce an more fluid-like motions than currently available prosthesis controllers.**
4	US7313463B2	The claims present a postural stability controller for a prosthesis or robotic appendage, but are more guided towards development of the linear model than their application to a force-based controller.
5	**US20160074181A1**	**The claims describe a method for mapping an EMG signal to a posture control space of a hand and a subsequent translation of that to a joint angle that is actuated by the prosthetic hand.**

Anticipated regulatory pathway

Because there are a variety of commercially-available powered and mechanical prosthetics, it is believed that this device should not require pre-market approval (PMA). Since this is a joint effort between our team and Case Western, it is understood that they will be responsible for bringing the product or certain components of this project to market. Many similar devices in this space have been approved in the past, so the process should be expedited. As of April 2018, the FDA classifies “external limb prosthetic components” as being Class I devices. These devices include but are not limited to “ankle, foot, hip, knee, and socket components; mechanical or powered hand, hook, wrist unit, elbow joint, and shoulder joint components; and cable and prosthesis suction valves [1].” Although this prosthesis mostly falls under the criteria outlined above, it may require 510(k) approval because it will integrate and relay sensory feedback to the user via electrical stimulation.

Reimbursement

The prosthesis that integrates with our device may be covered by insurance depending on whether or not the company deems the device a “medical necessity” based on references from a doctor or a certified prosthetist [2]. However, it is unlikely that the cost of addition of our device would be considered “medically necessary” since the velocity-based myoelectric prosthesis

systems that we are modifying can theoretically perform the same tasks. Based on this, we do not expect the device to be reimbursable by Medicare or Medicaid. Because of this, our goal is to design this device in such a way that it will not present a significant financial burden to any patient that would prefer a force-based system.

Estimated Manufacturing Costs

Expected costs involved in manufacturing our device currently include the purchase of two Myoware EMG microcontrollers, a Teensy v3.6 development board, 3 AA batteries and corresponding battery pack, disposable EMG electrodes, and optionally, two LED Myoware adapting shields. These will be the highest costing elements in the designed controller with negligible cost being seen from the required wiring. The EMG microcontrollers can be purchased for approximately $37, along with the LED shields for approximately $27 [1, 3]. The battery pack will cost less than $5 and the Teensy development board can be purchased for $30 [4, 5]. The total cost of a controller with the LED shields will be approximately $169, and without the optional shields, it will be approximately $115. The EMG electrodes and batteries will be disposable expenses placed on the user with potential bulk discounts from various sources available to mediate that burden. According to the CAD software, which provides the option to submit your design for print, the 3D printed cage and lid shown could cost approximately $80 if printed by a commercial source, but this is optional. All software packages used are free to the user for implementation and quality assurance following hardware manufacturing.

These units will be made in a small scale environment as they will be implemented in current laboratory experiments. Given this method of manufacturing, single unit development by a small team of competent researchers, there will be no investment in quality assurance. This element will be implemented within the studies being produced with this force-based controller. The total cost for the prosthetic hand with which we are communicating will not be not be accounted for within this project as it will always be provided by the patient.

Potential Market and Impact

The primary end users of this device would be hand and arm amputees (at or below the elbow). Currently, there are approximately 2 million amputees in the U.S., with around 500 amputations occurring each day. Based on data from 2016, the powered prosthetic market size is about $760.9 million dollars and is predicted to grow to $839.2 million by 2025. Of this market, about 33% is for upper body prosthetics [6]. This could yield a $276.9 million dollar market for our force-based myoelectric prosthesis. As of 2014, there were around 25,000 arm amputees in the U.S., many of whom would could qualify as potential customers [7].

Myoelectric prostheses vary in cost, and can range from $9,000 to $40,000. Many advancements are being made in 3D printing and alternative, low-cost fabrication methods, so we could anticipate the price lowering [8]. However, this high cost can be a major barrier to entry for many users since insurance does not consider functional prosthetics to be necessary medical purchases, meaning they will not cover the cost [9]. Since many amputees can still carry out the majority of necessary daily activities with their intact limb, they often desire prosthetics for aesthetic and cosmetic purposes, rather than for their biomimicry and

functionality [8]. This might limit the market size for a functional prosthetic limb, even if this device would have the potential to increase their quality of life.

Based on the cost of materials for this product so far, we could imagine that the entire artificial limb, including our software and hardware additions, would cost around $35,000/unit. Primary customers and distribution channels would include medical device retailers, hospitals, and prosthetists. Ideally, we would want to keep prices under $40,000 to make it more economically viable and medically efficacious in the eyes of our distribution channels. More fundamentally, we would want to keep costs reasonable so that a greater number of people could benefit from a more physiologically-accurate, force-based prosthetic creating a more natural prosthetic experience.

Resources

[1] "MyoWare Muscle Sensor." *Karlsson Robotics*, https://www.kr4.us/myoware-muscle-sensor.html

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[8] Lee, Kyu Ho, et al. "Hand Functions of Myoelectric and 3D-Printed Pressure-Sensored Prosthetics: A Comparative Study." *Annals of Rehabilitation Medicine*, vol. 41, no. 5, 2017, p. 875., doi:10.5535/arm.2017.41.5.875.

[9] "How to Find Out If Your Insurance Will Pay for Prosthesis." *Georgia Prosthetics*, www.georgiaprosthetics.com/how-to-find-out-if-your-insurance-will-pay-for-prothesis/.