Development of a Modular Below-Elbow Prosthesis with Bidirectional Signaling for Children

Grant Proposal

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I. Author Note

I would like to give a special thanks to Dr. Kevin Crowthers, Ph.D. and Mr. Pavel Loven for their advice, time, and support throughout the journey of this research project. Without their help, none of this would have been possible.

II. Executive Summary

Today, many prosthetic options are too expensive for the majority of individuals to obtain, causing a lowered quality of life for millions of amputees around the world. For children with a limb difference, it is even harder to obtain functional prostheses, as the child outgrows the limb too quickly, thus, new prostheses are needed every 12-18 months. In order to combat the price barrier surrounding advanced prostheses, a modular myoelectric prosthesis model was created. The movement control of the myoelectric was implemented through an Arduino-microcontroller and powered by servo motors and photoelectric sensors by way of electrical signals emitted from muscles. The modular prototypes were developed with many different 3D-printed materials, infill levels, Arduino code, and movement mechanic designs, then tested on five specific criteria: functionality, modularity, durability, comfort, and cost effectiveness. Due to its modularity, the prosthesis will be more accessible to children who cannot afford to buy new ones. Additionally, bidirectional signaling between the prosthesis and the user was a major focus of this project so that the user would be able to feel simple sensations with the prosthesis. A cheaper, 3D-printed, and modular below-elbow myoelectric prosthesis will allow children to grow up with and utilize prostheses to a greater extent. The best prototype according to the criteria was selected via an engineering design matrix. Testing showed that the prototype performed at 42% the functionality of a human arm. Future work will be geared toward implementing permanent electrode sensors and continuing to improve upon the criteria.

Keywords: sensory feedback, 3D printed, durability, comfort, cost-effective, myoelectric

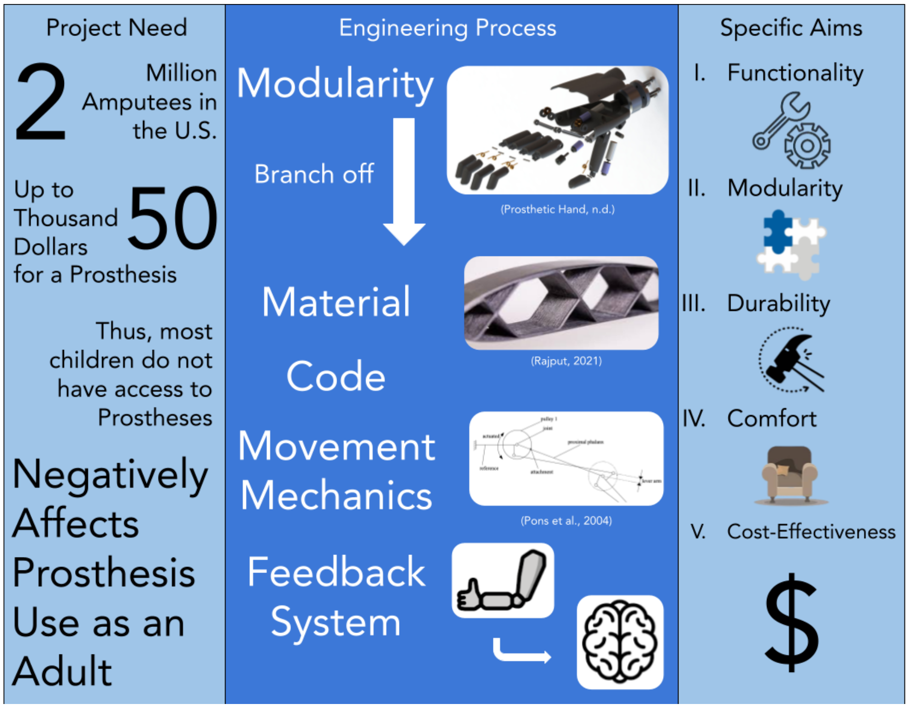


Figure 1: Graphical Abstract (Made by T. Tran in Google Drawings, 2022).

III. Development of a Modular Below-Elbow Prosthesis with Bidirectional Signaling for Children

Current prosthetic (Appendix A) options are too expensive, causing a lowered quality of life for millions of amputees around the world. This problem is more exacerbated for children, as the child outgrows the limb too quickly and needs a new prosthesis each year. The absence of prostheses during childhood can cause detrimental effects to the user's prosthesis use later in life because having not used the prosthetics during their youth, in their adulthood, these children are not used to operating daily life activities with a prosthesis (Huizing et al., 2010). The older the children get, the harder it will become for them to adapt to using a prosthesis. To solve this problem, a 3D printed prosthesis focusing on bidirectional signaling, comfort, durability, and modularity will be created. Computer aided design (CAD) and various materials, movement mechanisms, and microelectrodes will be tested on Backyard Brains neuroscience tools to achieve this. Hopefully, a cheaper, more widely accessible, and effective prosthesis can be created for children.

Prosthesis Types

There are currently many different types of prostheses, all utilizing different technologies or mechanics and targeting different patient groups. The most prevalent prosthesis types are passive, body powered, myoelectric, and hybrid (Smail et al., 2021). Passive prostheses are simply for aesthetics, have no functional ability, and are made of mostly silicone, plastic, and paint. Passive prostheses are also the cheapest type of prosthesis (Smail et al., 2021).

Next, body powered prostheses have functional use, but no electrical parts to them. Usually fitted with a shoulder harness and hook, body powered prostheses are the simplest and cheapest type of functional prosthesis (Smail et al., 2021). Having been created more recently, myoelectric prostheses are more advanced than body powered ones and require an external power source, usually a rechargeable battery. Utilizing electrodes connected to muscles on the residual limb, myoelectrics take input (EMG signals) and move the prosthetic limb with motors. Because of the batteries, electrodes, and motors, myoelectrics are on the pricier side (Smail et al., 2021).

There are three main ways to map out the mechanical control of a myoelectric prosthesis: sequential control (SeqCon), direct control (DirCon), and mapped control (MapCon) (Zhu et al., 2022). SeqCon utilizes “modes” within the prosthesis. When the user contracts a certain muscle, the prosthesis will move. When the user contracts a different muscle, the microprocessor will switch modes. Now, the original muscle contracted will control a different operation. DirCon maps out prosthesis movements to specific muscle contractions (via the microprocessor). Contraction of muscle x will control movement x and contraction of muscle y will control movement y. MapCon is similar to DirCon, but instead, the mappings are inverted. Contraction of muscle x will control movement y and contraction of muscle y will control movement x. The most common movements which myoelectrics mimic are open-close (Opn-Cls), pronation-supination (Pro-Sup), extend-flex (Ext-Flx), and radial-ulnar (Rad-Uln) movements (Zhu et al., 2022). SeqCon, compared to both DirCon and MapCon, is inferior because it is not as effective in multiple degree of function (DoF) situations (Zhu et al., 2022). This is why only DirCon and MapCon myoelectric control will be focused on.

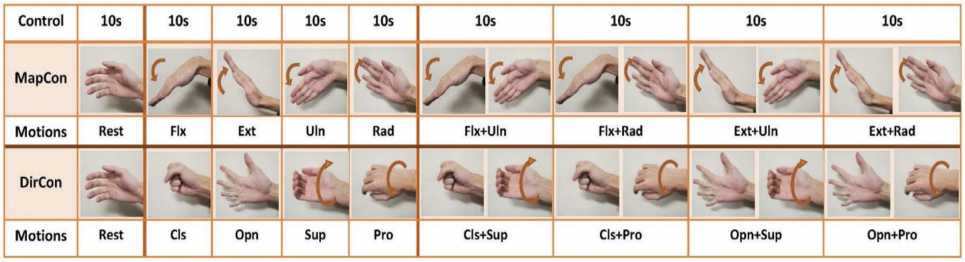


Figure 2: MapCon and DirCon. Common myoelectric movements with MapCon and DirCon control (Zhu et al., 2022).

Lastly, hybrid prostheses are a combination of myoelectric and body powered prostheses. Hybrid prostheses have the harness of a body powered prosthesis with the electric motors and electrodes of a myoelectric. Because of this, a hybrid prosthesis’s price might range from a little more than a body powered prosthesis to more expensive than a myoelectric (Smail et al., 2021). Bidirectional signaling can also be incorporated into myoelectrics.

Sensors can be implemented into a myoelectric so that the user can receive sensations. The myoelectric discussed in this proposal will incorporate this functionality as well.

Prosthesis Materials

The main materials used to create prostheses are: silicone, carbon fiber, polymers, aluminum, and titanium (Mota, 2017). Silicone is mostly used for the liner of the prosthesis, separating the skin of the residual limb from the prosthesis. Carbon fiber can be used for many parts of the prosthesis such as the fingers/hand as well as the socket for the residual limb. Its main advantages are that it is light and durable. However, carbon fiber is expensive and hard to 3D print. Polymers are used in the same fashion as carbon fiber as a cheaper alternative. Polymers are weaker, less durable, and heavier compared to carbon fiber. Aluminum and titanium are used in creating some of the joints in a prosthesis. A high stress part, joints have to be made of strong materials, such as aluminum and titanium. Aluminum and titanium are used more in body powered prostheses because they are supported by shoulder harnesses and can handle the added weight. Hooks are usually made from those metals as well.

Prosthesis Modularity

Today, few are pursuing modular prosthetics in the sense that the prosthesis will physically grow with a child. With 3D printing, a shape-changing prosthesis will be created. Modular parts of the prosthesis will be added on by a prosthetist (a healthcare professional who fits prostheses) without needing to change the design. A dynamically changing prosthesis made utilizing pressure sensors, an airbag, and a pump, similar to a shape-changing cast, was also considered as an option (Shoshan & Shamaev, 2015). As an arm grows, it will create more pressure against the prosthesis. The pump will then change the airbag (underneath the prosthesis) size to accommodate. This airbag concept has been prototyped, however, it only expands and contracts with four pump systems for extra support when the prosthesis is in use (Sang et al., 2014). This design will be expanded on to create a shape-changing prosthesis for growing children. Currently, for competitor analysis, the closest thing resembling the modularity being sought is hand attachments for prostheses and modularly designed prostheses software (Johannes, 2011). For example, consider a fin attachment for a prosthesis so that the user can

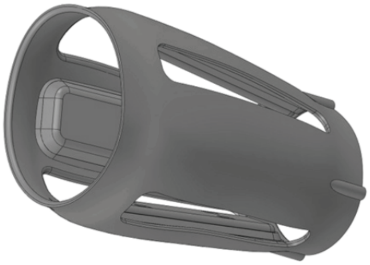


Figure 3: Novel socket design. Airbag and pump powered shape-changing prosthetic socket (Sang et al., 2014).

Figure 4: Prosthetic Fin Attachment. Designed to attach to prosthesis for swimming (Freestyle Swimming Device, n.d.).

swim or an algorithm on a microprocessor that can be used for different prostheses. Therefore, there is essentially nothing in the field which can be compared to the modular design pursued in this project.

Prosthesis Comfort

Currently, a high percentage of amputees who receive prostheses abandon them permanently (Smail et al., 2021). This wastes the user's money and lowers their quality of life. The main cause of this is that prostheses are not comfortable to use or wear, due to irritation or pain. The main issues users find with their prostheses is that they are too heavy, hot after an extended period of use, rigid, and bulky (Smail et al., 2021). In addition, users abandoned prostheses without sensory feedback, listing the lack of sensation as the cause (Smail et al., 2021). Users who abandon prostheses feel like it is not a part of them and they could function better without it.

Backyard Brains's "The Claw"

Backyard Brains is a company that creates neuroscience tools that utilize the human nervous system to control computers. One of their products, "The Claw," will be used as the subject model in experimentation. The product comes with electrodes, an Arduino (microcontroller computer), and a plastic claw which can be controlled by the user (The Claw, n.d.). When the electrodes sense muscle contraction, they relay the EMG signal (electromyography signals, or electrical signals the brain sends to muscles to control them) to the Arduino. The Arduino, coded in C++, then takes that signal to control a servo motor which rotates to move the plastic claw.

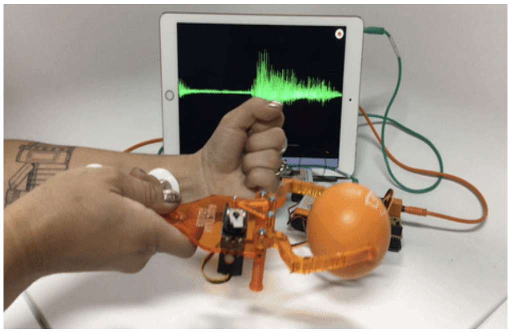


Figure 5: The Claw from Backyard Brains. Arduino also connected to tablet to visualize the strength of the EMG signals (The Claw, n.d.).

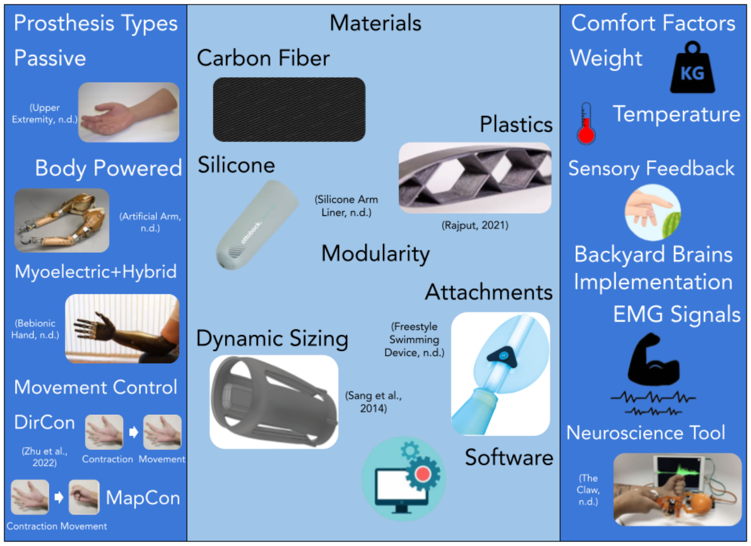


Figure 6: Graphical Background (Made by T. Tran in Google Drawings, 2022).

IV. Relevance and Aims

There are over two million amputees in the United States, and many cannot afford prostheses (Zhu et al., 2022). This is especially an issue for children since they grow out of prostheses quickly (Huizing et al., 2010). The price of body powered prostheses range from $4,000 to $50,000, while the price of the externally-powered prostheses cost from $25,000 to $50,000 (Cabibihan et al., 2018). Modern prostheses are so expensive because each one must be personalized. Each situation is different, so there is no way to generalize the traditional silicone casting process, which is time consuming. Because of this, most children amputees do not grow up using a prosthesis, decreasing the likelihood of prosthesis use as an adult (Huizing et al., 2010). To combat this, a modular prosthetic design can be developed to grow with children. Using a modular design for childhood prostheses can increase overall comfort and accumulate children to use prostheses for the rest of their lives.

The objective is to create a cheaper, 3D-printed, and modular below-elbow myoelectric prosthesis for children to allow them to grow up with and utilize prostheses better. Bidirectional signaling between the prosthesis and the user will be a priority of the project, so that the user will be able to feel simple sensations. The expected outcome will be a prototype of a 3D-printed, bidirectionally signaling, and modular myoelectric prosthesis which can utilize DirCon and MapCon movement control. The five specific aims for this project are as follows.

Specific Aim 1: Functionality

The first and most important specific aim is functionality. A prosthesis lacking functionality has no use. Elaborated more in the methodology section, the three main trials for functionality are stacking wooden blocks, hanging clothespins, and twisting a round doorknob with the prosthesis prototype.

Specific Aim 2: Modularity

The second specific aim is modularity. Modularity will allow the prosthesis to grow up with children. As the residual limb grows, so too will the prosthesis. A few ways modularity can be achieved are: plastic 3D-printed pieces that link to one other, airbags and an air pump to adjust the size of the prosthesis, or a combination of the two.

Specific Aim 3: Durability

The third specific aim is durability. If the prosthesis is not durable, the user has to adjust their life to the prosthesis when it should be the other way around. This could ultimately lead to prosthesis abandonment, lowering the user's quality of life. Different types of 3D-printing filaments and infill levels will be tested.

Specific Aim 4: Comfort

Comfort is the fourth specific aim. A leading reason for prosthetic abandonment is comfort. The prosthesis cannot be too heavy, rigid, hot, or bulky. The material used and the mechanical design for the prosthesis will determine these factors. Again, many types of 3D-printing filaments and infill levels will be tested.

Specific Aim 5: Cost-effectiveness

The last specific aim for this project is cost-effectiveness. Emphasized throughout this proposal, cost is one of the main hindrances of prostheses being widely available for both adults and children. The budget for this project is 2000 USD, a fraction of the cost of current prostheses, the majority of which is not anticipated to be used.

V. Project Description

Methodology

Prototypes of the prosthesis will be attached to “The Claw” to be tested. The Arduino code will also be modified to control the prototype. The testing will be similar to “Myoelectric Control Performance of Two Degree of Freedom Hand-Wrist Prosthesis by Able-Bodied and Limb-Absent Subjects” (Zhu et al., 2022). The Arduino/Backyard Brain apparatus will be used to test each prototype. The Arduino code will be adjusted as needed. For the prototype, different materials, movement mechanics, and modular approaches will be tested. The prototype will then be compared to the baseline performances of “The Claw” and of a normal human arm. Each of the five specific aims will be tested for.

Functionality Methodology

Test one will be a timed block stacking trial. The independent variable (IV) will be one of the following: material, Arduino code, movement mechanics, or modularity design. The dependent variable (DV) is the time it takes to stack the blocks. The controls will be each of the possible IVs which were not selected for the specific trial.

The second trial will be putting clothespins on a pole, given a two minute timer. The number of clothespins placed will be measured. The IV will be one of the following: material, Arduino code, movement mechanics, or modularity design. The DV is the number of clothespins hung. The controls will be each of the possible IVs which were not selected for the specific trial.

The third trial will be opening and closing a door with a circular doorknob. This trial will test the DoF functionality of the prosthesis as it takes multiple muscle groups to twist the knob. The number of times the door is opened and closed will be measured over a two minute interval. The IV will be one of the following: material, Arduino code, movement mechanics, or modularity design. The DV is the number of times the door was opened and closed. The controls will be each of the possible IVs which were not selected. There will be three iterations of each prototype done for three each of the trials.

Justification and Feasibility.

The functionality tests are relevant because they test different types of motor skills that a human arm would have. As mentioned before, these three trials have been inspired by “Myoelectric Control Performance of Two Degree of Freedom Hand-Wrist Prosthesis by Able-Bodied and Limb-Absent Subjects” (Zhu et al., 2022). Their data from their version of the block trial is shown in figure 7. The graph shows that DirCon participants were able to stack around 15 blocks per minute on average.

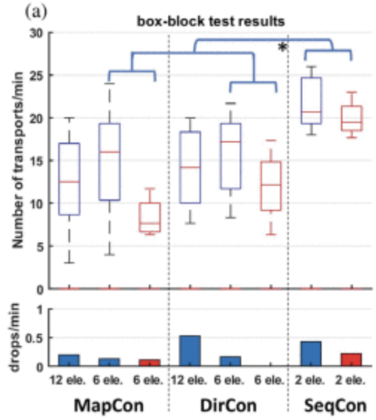


Figure 7: Block Trial Data (Zhu et al., 2022).

Summary of Preliminary Data.

Below, in figures 8 and 9, is the preliminary data from the Backyard Brains baseline on all three trials, all utilizing DirCon. As the trials continued, the time to stack 10 blocks steadily decreased, giving a comparable 20 blocks per minute on the third attempt of the block trial. The same pattern was also seen for the door trial and the clothespins trial. Comparing this data to Zhu et al.’s data, it is quite promising.

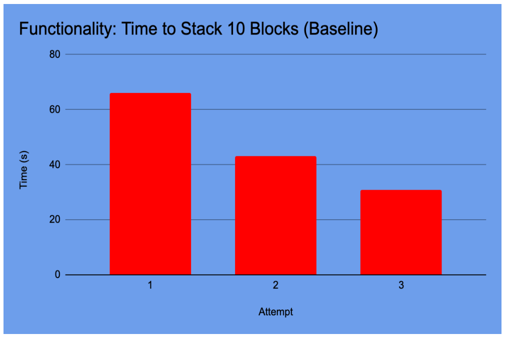


Figure 8: Functionality Graph 1. Baseline of the Backyard Brains system (Made by T. Tran in Google Sheets, 2022).

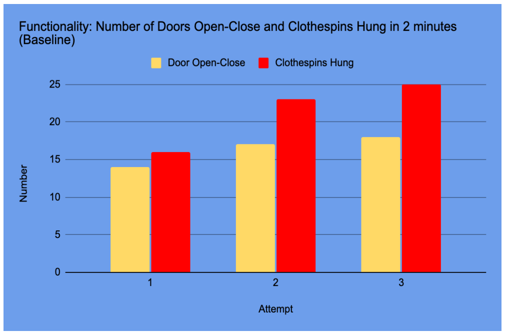


Figure 9: Functionality Graph 2. Baseline of the Backyard Brains system (Made by T. Tran in Google Sheets, 2022).

Expected Outcomes.

Maximizing the results from these trials, a functional prosthesis with movements similar to that of a human hand will be developed. The data from the trials will be used to help create the next prototypes.

Potential Pitfalls and Alternative Strategies.

Although these three trials are good at determining the motor function of a prosthesis (multiple DoF), they may not fare well in determining sustained motor function. It is hard to keep a constant EMG signal from the user to the Arduino, thus it is hard to keep the motor function for an extended period. An alternative strategy could be to add an alternate mode which keeps the prosthesis constantly flexed.

Modularity Methodology

To determine the modularity in a prosthesis prototype, the model must be able to grow while keeping functionality. To test this, the functionality trials should be run again at each size which the prosthesis can be.

Justification and Feasibility.

Testing modularity in this fashion is relevant because it shows whether or not the prosthesis prototype can work for the child at each different size/age which the child needs the prosthesis for.

Expected Outcomes.

If the prosthesis has proper functionality at all levels of the modularity, then a fully functioning modular prosthesis can be expected to be developed. Failed attempts for modularity will be used to aid in creating the next prototype until a desirable modular form is achieved.

Potential Pitfalls and Alternative Strategies.

Although the modular prosthesis might be functional at all size levels, it might not perform the best at all size levels. For the smaller sizes, the weight might be too much to bear for a child. In that case, functionality might have to be reduced for comfort (weight) until the residual limb grows large enough.

Durability Methodology

To test how durable the prosthesis is, two different material tests must be conducted. More specifically, a stress analysis on the software SolidWorks and an everyday degradation test. Various 3D printing materials will go through this testing; different polymers, materials, and infill (hollowness) levels will be tested.

Justification and Feasibility.

The two tests of stress testing and degradation testing are relevant because those two forces are the most likely to be put upon the prosthesis during use. If those two tests are satisfied by a prosthesis model, then that model will be durable when it is put through the usual forces of everyday use.

Expected Outcomes.

If the prosthesis prototype is durable in regards to the two tests, then a robust and durable prosthesis can be expected to be developed. The failed attempts for durability will be used to aid in creating the next prototype until a desired durableness level is achieved.

Potential Pitfalls and Alternative Strategies.

Although the prototype might be durable daily aspects of use, it might not be able to handle high force stress. Especially with children, these types of instances are more common. To address this, a more robust and durable model could be made, but with a tradeoff of comfort for the child.

Comfort Methodology

To determine the comfort for each prototype, two tests will be conducted: rigidity and weight. Rigidity and weight are two leading contributors to prosthesis abandonment and if reduced, the prosthesis would become more comfortable. Each prototype will be weighed and the number of rigid points and edges will be counted.

Justification and Feasibility.

Weighing the prosthesis is the only way to get a quantifiable value for how heavy the prosthesis will be when worn by the user and is therefore justifiable. Because rigidity is not necessarily a quantifiable value, the number of points and edges is one of the best ways to portray this feature as a number.

Expected Outcomes.

If the prosthesis prototype passes the weight and rigidity tests, then a comfortable prosthesis can be expected to be developed. The user should be able to wear it for extended periods without discomfort. The failed attempts will be used to create the next prototype until a desired comfort level is achieved.

Potential Pitfalls and Alternative Strategies.

Although weight and rigidity are good factors for determining comfort level, comfort cannot be totally quantified in a value because every user has different standards for comfort. Thus, comfort level will vary and should be adjustable after the creation of the prosthesis by way of modularity.

Cost-effectiveness Methodology

To determine the cost effectiveness of each prosthesis prototype, the cost of all of the parts of the prototype will be aggregated.

Justification and Feasibility.

Quantifying the cost of each prototype is justifiable because lowering the cost of the final prototype would allow more children to access this product. The hardest part of this section would be to calculate the cost of the filament used to 3D print the prototype.

Expected Outcomes.

If the prosthesis prototype is cost-effective, then more amputees will have access to it. The failed attempts for cost-effectiveness will be used to create the next prototype until a desired cost is achieved.

Potential Pitfalls and Alternative Strategies.

Although the aggregate cost of all of the prototype's cost might be correct, current levels of inflation and supply chain issues the world is facing might significantly change the cost in the future. Thus, cost effectiveness might need to be recalculated as time passes.

Process of Product Design

In designing the product, the first part to figure out is the modularity of the design. From there, branches can be made off of the modularity ideas. Material can be changed, the Arduino code can be changed, the feedback sensors can be changed, and the movement mechanics can be changed. This creates the possibility for many different prototypes. Each prototype will be tested, and one, via an engineering design matrix (Appendix B), will be chosen as the final prototype. During the design process, a 3D printer will be utilized to print most of the parts of the prosthetic prototypes.

For the Arduino system, there will be two systems of input and output running through the same Arduino. The first system is composed of input from the EMG electrodes (adhered to the user's skin inside of the prosthesis socket) to the servo motors that control the movement of the prosthetic arm. The second system is composed of photoelectric sensors (which detect change in light intensity) on the tips of the prosthetic fingers which trigger vibration motors on the inside of the prosthetic socket. In this way, the user will receive sensory input. Note, along with the photoelectric sensors, infrared sensors will also be tested as well.

Materials

The materials list is as follows. Backyard Brain's The Claw (software C++), Arduino kit (with various sensors, motors, and cables), Arduino power shield, Solidworks CAD modeling software, able-bodied human subject, clothespins, door with round doorknob, wooden blocks (the size of a Jenga piece), 3D printer (software

Solidworks) with filament (different polymer types and carbon fiber), silicone liners, aluminum/titanium/copper wire, resistors, 9V batteries, photoelectric sensors, EMG sensors, vibration motors, servo motors, and transistors.

Procedure

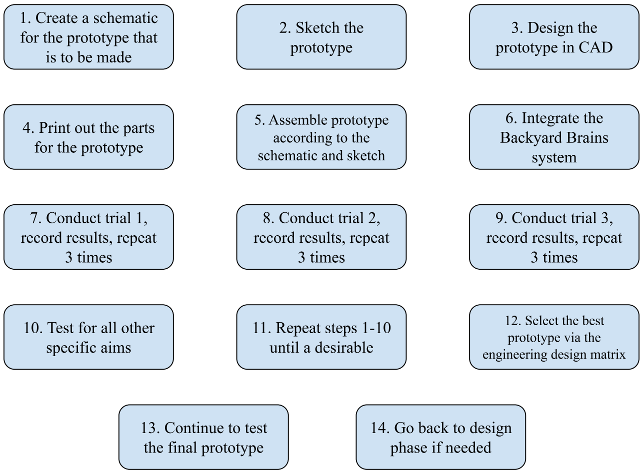


Figure 10: Procedure infographic for prosthesis prototyping and testing (Made by T. Tran in Google Drawings, 2022).

Innovation

The main innovation in this project that has not been found predominantly in the field yet is the modularity of the prostheses. No other prosthesis accommodates for growing children in this way. Modularity, in conjunction with the bidirectional functionality of the prosthesis allows children to grow up with prostheses at a cheaper cost with the functionality of a myoelectric.

Resources

For the methodology of this project, some of provided resources are: the preloaded C++ code that came with Backyard Brain's "Claw," some preliminary testing Arduino attachments (sensors and motors) and shields (which give more ports to the Arduino), 3D printers and filament provided by the Massachusetts Academy of Math and Science at WPI, and logistics help from Mr. Pavel Loven.

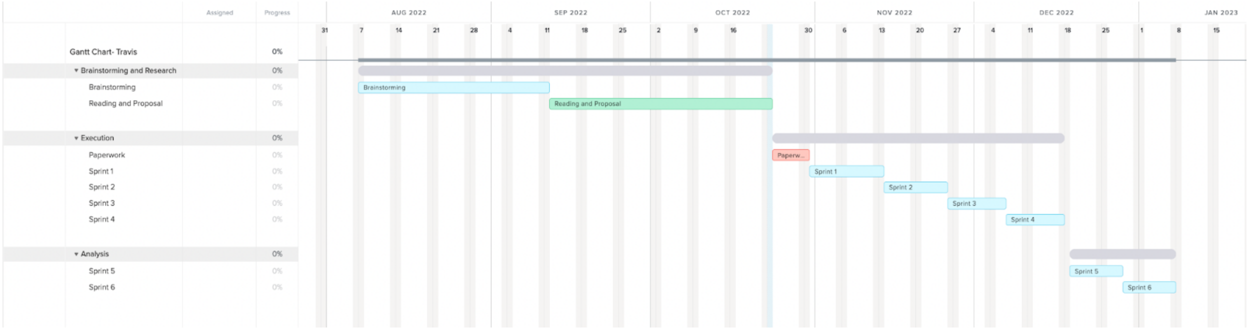
Ethics

There is little to no risk of harm when using The Claw from Backyard Brains in testing. There is not enough voltage to do any harm to the human testing the prosthesis. Some precautionary practices are to clean the area where the electrode will be placed on the skin and make sure the area is dry. It should be made sure that there is smooth contact between the electrode and the skin of the user.

VI. Budget and Timeline

The maximum budget for this project is around 2000 USD. As of now, 300 USD have been spent buying the Backyard Brains Claw and Arduino parts.

A hyperlink for the timeline of this project (a Gantt chart from TeamGantt) is below: https://app.teamgantt.com/projects/gantt?ids=3244289.



	Assigned	Progress
Gantt Chart- Travis		0%
▾ Brainstorming and Research		0%
Brainstorming		0%
Reading and Proposal		0%
▾ Execution		0%
Paperwork		0%
Sprint 1		0%
Sprint 2		0%
Sprint 3		0%
Sprint 4		0%
▾ Analysis		0%
Sprint 5		0%
Sprint 6		0%

Figure 11: An image of the timeline of the project, in the form of a Gantt chart, made by T. Tran in TeamGantt.

VII. Appendices

Appendix A: Prosthesis Terminology

The term "prosthetics" refers to the field of research and expertise in designing and building artificial limbs. The term can also be used as an adjective (e.g. prosthetic limbs). The term "prosthesis" is the most accurate term for an artificial device that is built to replace a missing body part. The plural of prosthesis is prostheses (Amputee Coalition, n.d.).

Appendix B: Engineering Design Matrix

Engineering Design Matrix

Criteria (Rank)	Example	Design A	Design B	Design C	…
Safety - how safe the user feels when using the prosthesis; how well the user trusts the prosthesis (10)	9				
Functionality - determined from functionality methodology (9)	7				
Modularity - determined from modularity methodology (9)	5				
Comfort - determined from comfort methodology (7)	10				
Durability - determined from durability methodology (7)	3				
Cost-effectiveness - determined from cost-effectiveness methodology (6)	6				
Control - how well the user can manipulate the prosthesis	9				

to do desired actions (8)					
Sensory Feedback - how well the prosthesis conveys the sense of touch to the user (8)	3				
Total (Max 640)	421				

Each criteria is given a 1-10 score, then multiplied by the rank and aggregate the results to calculate the final score. Max final score is 640. This table will be used to determine the best prototype/design.

- Safety (10) - in any trials, products, or experiments involving humans, safety is always the number one priority.
- Functionality (9) - Being one of the most important specific aims of this project, the functionality of the prosthesis determines to the user if they can use the device or not. If they cannot use the product, then the product is a failure.
- Modularity (9) - Modularity is one of the features that makes this prosthesis design unique and separate from the rest of the field. If the prosthesis is not modular, then it is just like all of the other competition in the field. The project will then be considered incomplete.
- Confort (7) - Comfort is one of the leading factors in prosthesis abandonment, so if the prosthesis is not comfortable for the user then it will be deemed unusable.
- Durability (7) - If the prosthesis is not durable, especially considering the target group of children, then the product will be rendered unusable for most of the time and cost the user extra money.
- Cost-effectiveness (6) - The price of prostheses is what keeps them from being available to a large proportion of the global amputee population, especially children. Being one of the specific aims of this project, price plays a factor, but is not as important as the others in this prototyping stage.
- Control (8) - If the user cannot control the prosthesis, they would most likely abandon it. Going hand in hand with functionality, the prosthesis must be controllable.
- Sensory Feedback (8) - Sensory feedback, in conjunction with control and functionality, plays an important role in the abandonment of prostheses. The prosthesis must have sensory feedback, no matter what kind.

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