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Sand & Swim Leg

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Sand and Swim Prosthetic

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I. Introduction

There are currently limited options that allow below-the-knee (BTK) amputees to transition from land to water effectively and allows for easier participation in water activities. We have designed the Sand and Swim Leg to be an affordable alternative to other swim legs and devices on the market. Our design is a waterproof and sand proof weight-bearing attachment to the socket of a BTK amputee.

Most swim legs currently on the market are thousands of dollars and have a limited functionality. Because of this, BTK amputees only have the option of buying an expensive swim prosthesis or deciding to swim with only their residual limb, which can make swimming a more difficult task. By creating the Sand and Swim Leg, we provide a more accessible and useful option for BTK amputees who wish to participate in water activities.

II. User Needs

To create a working idea of how the Sand and Swim Leg would address the issues discussed above, a list of user needs was developed from interviews with stakeholders, discussions with prosthetists, and background research. The main priorities found in the user needs stage were functionality, durability, comfort, and safety. The needs of the user encompassed the goal of this project, which was to create a functional weight-bearing swim leg for BTK amputees. Careful consideration went into all the properties deemed necessary for the end product to be considered successful. The compilation of all user needs may be found in Appendix B.

III. Design Inputs

To ensure the Sand and Swim Leg met all user needs, the needs were translated into engineering requirements. The engineering requirements gave specific and measurable values to achieve regarding the device design. These requirements focused on creating a device with performance characteristics, safety, and cost and resources in mind. The full list of engineering requirements can be found in Appendix B.

A quality function deployment (QFD) matrix was created to assess how the user needs correlated to the engineering requirements, as shown in Appendix C. The QFD also shows how the engineering requirements relate to each other, how competitive products compare to the Sand and Swim Leg, and target values for the device design to meet.

A preliminary risk assessment was performed on the conceptual device design using a failure mode and effects analysis (FMEA), as shown in Appendix F. The FMEA was updated through the remainder of the project to mitigate as many risks as possible.

To mitigate risks during the testing phase, we included the following standards as design inputs for consideration: ASTM D695 – Standard Test

Methods for Compressive Properties of Rigid Plastics, ASTM D638 – Standard Test Methods for Tensile Properties of Rigid Plastics, and ASTM D790 – Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.

IV. Design Process

To produce an initial design, a concept map was created to decide which components would be part of the final design. From there, sketches of ideas were created, until we had refined which specific components we would include.

When designing the device, we created a decision matrix to decide on which materials to make each component from. The results of the down selection can be found in Appendix D. A part design matrix, seen in Appendix E, was also created to ensure the user needs and engineering requirements would be met by our device.

The Sand and Swim Leg was designed to be undamaged by UV rays, salt water, fresh water, and sand and weigh less than 8 pounds total. The device was also designed to not fracture under intended use and have proper traction on the foot to ensure the user's safety.

V. Design Outputs

After completing the design process, we needed to make sure the prototype met all engineering requirements, and that all risks were mitigated.

As seen in Appendix C, a parts design matrix was used to determine how to ensure each component of our project would meet the engineering requirements listed in Appendix B. The combined pylon and pyramid piece was constructed using Rigid 10K resin and was 3D printed. The foot component was composed of a Nomex honeycomb and aluminum plate core, surrounded by carbon fiber sheets and epoxy. The fin was constructed using Shore 80A resin and 3D printed. The device was assembled using 316L stainless steel screws. All materials used can be found in the bill of materials, as seen in Appendix H.

Shown below in Figure 1 is the SolidWorks assembly of the pylon/pyramid, the fin, and the foot components of our project.

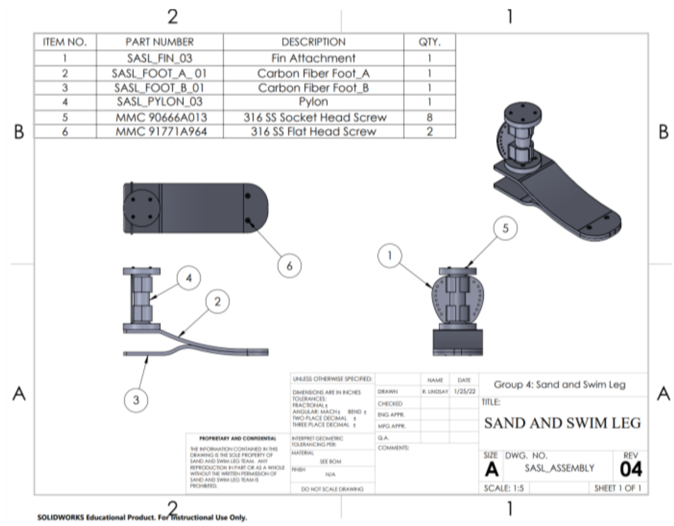

Figure 1: SolidWorks Assembly of Sand and Swim Leg

VI. Design Verification

Materials testing is an imperative part of the design process. To ensure the materials used in the design of the Sand and Swim Leg met the device specifications, Instron testing machines were used for tensile, compression, three-point bending, and friction tests. In the first round of prototyping, we were planning on using Grey Pro, a material with lower tensile and compressive strength as compared to Rigid 10K resin. The testing showed that the material passed the engineering requirements, however, was not as strong as we would have liked. The stress-strain curves for the Grey Pro are shown below in order of compression, tension, and three-point bending (Figures 3-5).

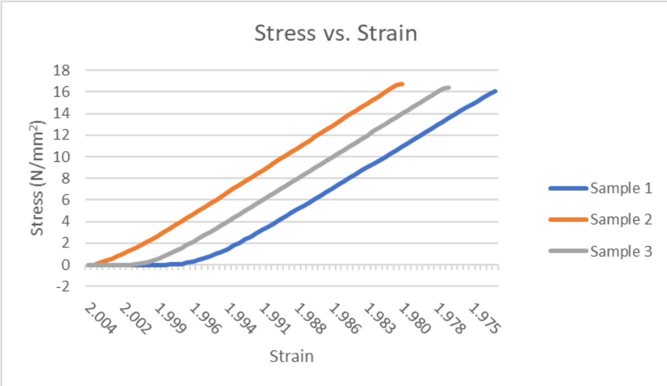

Figure 2: Compression Stress-Strain Curve for Grey Pro

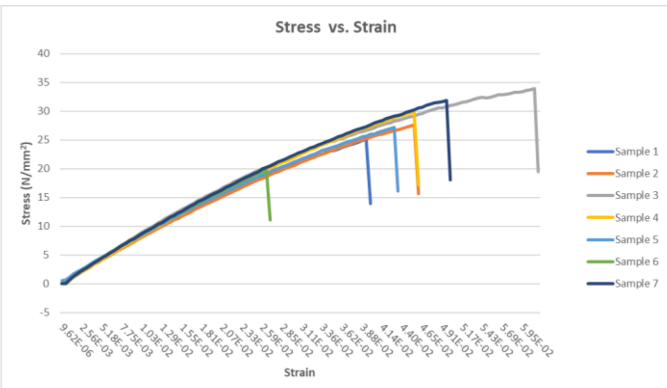

Figure 3: Tensile Stress-Strain Curve for Grey Pro

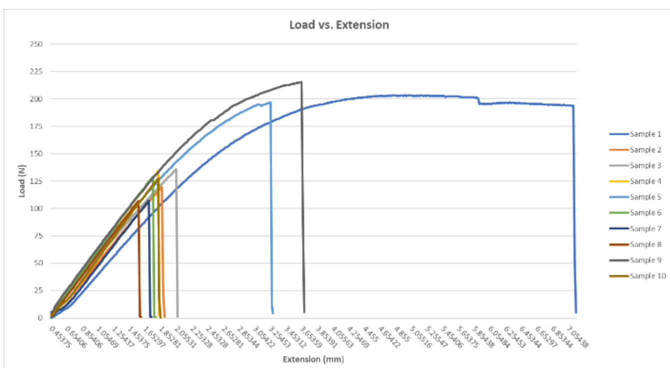

Figure 4: Three-Point Bending Stress-Strain Curve for Grey Pro

The tests shown above, along with the friction test for the material used on the bottom of the carbon fiber foot, a water displacement test, and a wind tunnel drag test, all showed that the materials used passed our engineering requirements. Because Rigid 10K resin is stronger than Grey Pro, this shows that the Rigid 10K resin is an adequate material to use for building the pyramid/pylon component.

VII. Medical Device

The final prototype, as shown below in Figure 5, is a weight-bearing waterproof attachment to a pre-existing BTK socket. The bottom of the pylon/pyramid screws into the carbon fiber foot using 316L stainless steel screws. The top of the pylon/pyramid component is where a BTK amputee would screw the device onto their own socket. The flexible resin fin clips onto the pylon/pyramid component as shown.

Figure 5: Carbon Fiber Foot, Pylon/Pyramid, and Fin

After verification and validation, the prototype was found to meet device specifications.

VIII. Validation Testing

For validation, we created methods for each customer requirement. The customer requirements can be seen in Appendix B, and to validate these, we used a combination of inspection, visual confirmation testing, and a questionnaire. The questionnaire is intended for stakeholders of the device and will be given to BTK amputees as well as prosthetists to confirm the Sand and Swim Leg meets or exceeds expectations. Inspection was used for evaluating natural swimming wearing the device and being easy to clean off. All validation tests performed have passed.

IX. Risk Mitigation Process

One of the key elements in the design process is risk assessment. Risk assessment provides a way to ensure no unacceptable risks are overlooked. For the Sand and Swim Leg, the main risk factors would be if the device were to break while in use. Some risks are more severe than others. If the pylon/pyramid breaks, the user will lose balance and fall. A less severe risk is the fin detaching from the pylon/pyramid. Both are considered risks that must be mitigated; however, one failure would be much more catastrophic than the other. To analyze all risks in this way, a design failure mode and effects analysis (dFMEA) was created. The Risk Summary Table outlines each risk and can be found in Appendix F.

Overall, the benefits of this device outweigh the residual risk. After the risks were mitigated, each received a ranking of low risk, and the device would greatly improve quality of life for BTK amputees who wish to participate in water activities.

X. Marketing and Manufacturing Considerations

The current market for swim legs for BTK amputees is very limited, and what little is out there is very expensive. Our project is a much cheaper alternative, and also stands out by being a weight-bearing leg. The Sand and Swim Leg cost under $1000 to make, whereas competitors' prostheses cost anywhere from $3000-$5000. The $1000 to build the Sand and Swim Leg also includes the resin tanks for the Shore 80A and the Rigid 10K, which would only be a one-time expense. Creating more devices in the future would cost $600 or less, making the production cost for every device after the first would be around $400 per device. Doubling this to account for labor costs, doubling again to account for company overhead, and adding a 60% margin for sale price, this comes out to $2560, which is still hundreds of dollars cheaper than current competitive products.

XI. Summary Feasibility Discussion

The Sand and Swim Leg did satisfy the user needs once completed. The device is strong enough to be weight-bearing, has a good traction, is waterproof, and improves swimming capabilities. While the created device does meet the user requirements, it is still considered a prototype, as the product is made to be highly personalized from customer to customer. Without having a person's specific measurements for their residual limb, the height of the device and the size of the foot is an approximation. The resulting prototype, however, is still fully functional.

XII. Discussion, Lessons Learned, and Conclusions

Overall, the Sand and Swim Leg turned out to be very successful. We had help from many different sources for testing, designing, and creating the prototype. There were several setbacks along the way, but this only improved the final product. Up until the end of the Design Output stage, we had planned to use a 3D printed material called Grey Pro. We had no capabilities to test in shear or torsion, but the tensile, flexure, and compression testing done on the material met the engineering requirements. After learning that Grey Pro is not nearly as strong in shear or torsion, however, the pylon/pyramid printing material was changed to Rigid 10K resin. This resin is stronger than the Grey Pro and exceeds our needs. Also, when printing the pylon/pyramid component, the orientation of the print made the part print and cure incorrectly. We adjusted the design to fit the capabilities of the printer, and the second print was successful.

To stay on top of the workload, weekly team meetings were set, and monthly meetings were held with Dr. Nguyen, our project mentor. Dr. Nguyen was a major help in pushing past difficulties and helped the design process run smoothly.

XIII. Future Work

Looking toward the future, the Sand and Swim Leg design could be used to create customized swim legs for BTK amputees. There are still improvements that could be made and more testing to be done, but the prototype has proven to be a viable option for a swim leg. To reduce risk further, the model could be adjusted to fit the induvial user’s needs.

XIV. Individual Roles and Responsibilities

Throughout the past two semesters, each member of the group has put in a significant amount of effort and time into this project. Allison Testa has made major contributions in connections to prosthetists, created the pylon/pyramid structure in SolidWorks, and has aided in the completion of all documentation. Allison has also done background research for competitive projects, helped with material testing, and has helped in all reports and gate review presentations. Chloe Davidson has focused on report writing, material testing, and has also helped with documentation along the way. Chloe wrote most of the honors final report and has also aided in data analysis and gate reviews. Jessica Galford has led the group in material data analysis, helped with report writing, and has also contributed to the documentation of the process. Jessica has kept the files organized, has helped with gate review presentations, and has also been a key component in communications with our mentor and professors. Reagan Lindsay has done all meeting documentation, is the main communicator to stakeholders, and has helped with design process documentation. Reagan has also done simulations on our SolidWorks parts, created most of the validation methods, and has helped with gate review presentations. Victoria McLaughlin has delegated most tasks, helped with documentation and testing, and designed the fin and foot parts of our project. Victoria also aided in process documentation and gate reviews and has been the lead in the carbon fiber layup process for the foot. Overall, each team member has contributed a significant amount of time and effort to this project.

XV. Professional and Ethical Responsibilities

The Sand and Swim leg has considered the impact it will have in many different areas of consideration. This design provides a way for BTK amputees to swim with a weight bearing leg without worrying about ruining their everyday use leg. The Sand and Swim leg is also more cost effective and makes swimming more accessible for many BTK amputees.

XVI. Acknowledgements

We would like to acknowledge and thank our design professor, Dr. Keszenheimer as well as our mentor, Dr. Nguyen for their continued support and help. We would also like to thank Steve Patterson, Dr. Noble, Dr. Garafolo, Eric Pfiffner, Pamela Schram, George “Bud” Weisgarber, Gene Yeager, Alex Betancourt, Abbey Calderone, and all who have helped along the way.

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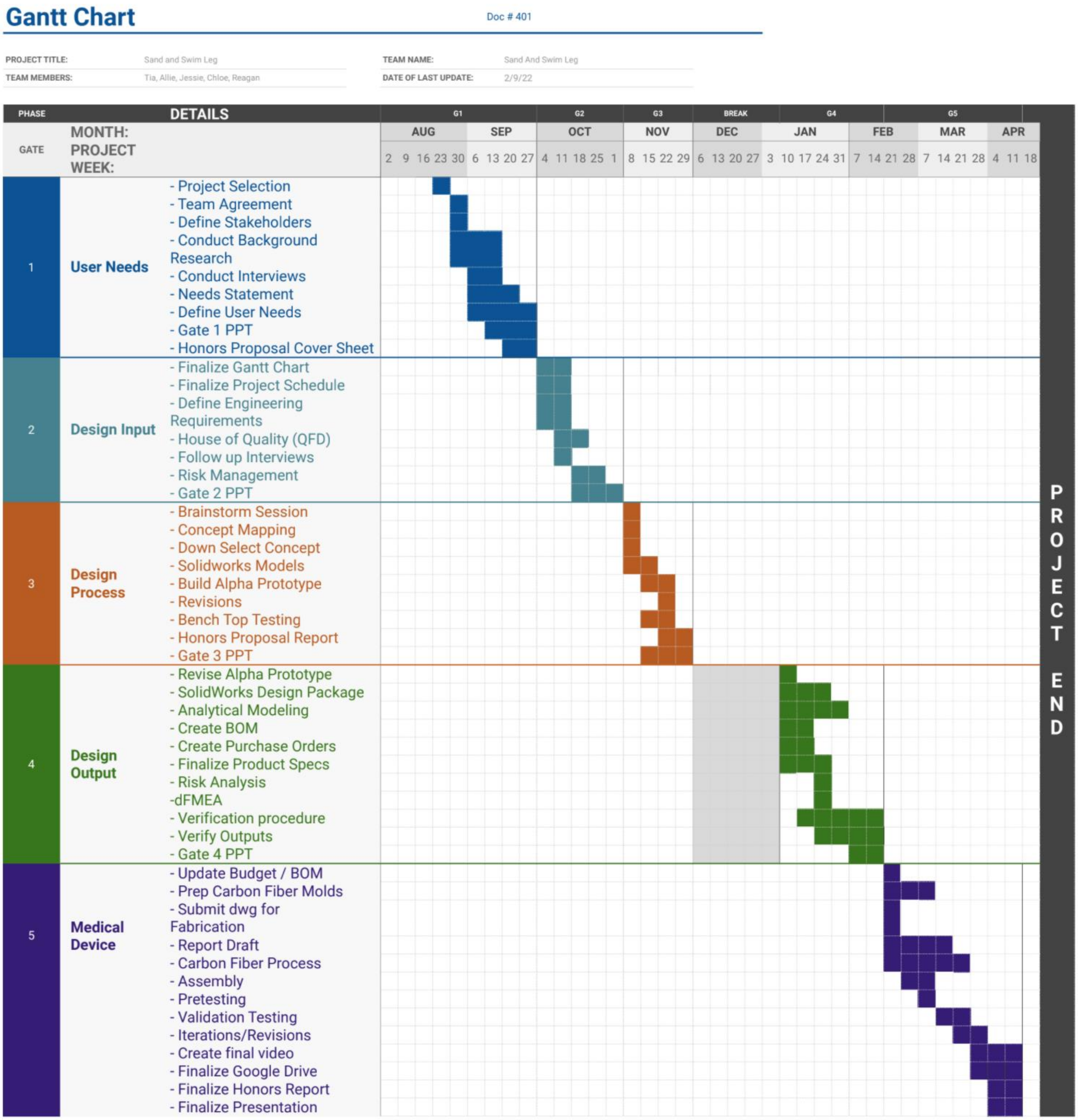
Appendix

Appendix A

Gantt Chart:



Appendix B

User Needs:

1. Materials are not damaged by use in water or on sand Device should enhance straight-line swimming
2. Materials shall be corrosion resistant
3. Prosthesis shall not rotate, or detach while in use
4. Device shall be able to hold up person's body weight while walking on various terrain
5. The device should not sink when used in the water
6. A non-skid tread shall be present on the bottom of the foot
7. Water resistance should be adjustable for the user
8. Price shall be comparable to current market costs
9. User should be able to maintain stability when traversing uneven/unstable terrain such as sand or boats
10. Device should be clean after rinsing with water

Engineering Requirements:

1.0 User/Patient/Clinical Performance Characteristics

1.1 Improved Straight-Line Swimming Ability

1.1.1. The device shall enhance the function of the amputated leg while swimming

1.1.2. The device should float

1.1.3. The fin shall have low drag in fluid

1.1.4. The device shall have no water time limitation

2.0 Safety

2.1. Mechanical

2.1.1. The device shall withstand average male weight with a safety factor

2.1.2. The device shall have a non-slip rubberized material on the bottom surface

2.1.3. The device shall have no easily corroded metal components

2.1.4. The device shall weigh between three and ten pounds

2.1.5. The device shall be able to be disinfected

3.0 Cost & Resources

3.1. Affordability

3.1.1. The total cost of the device shall be less than or equal to $3,000

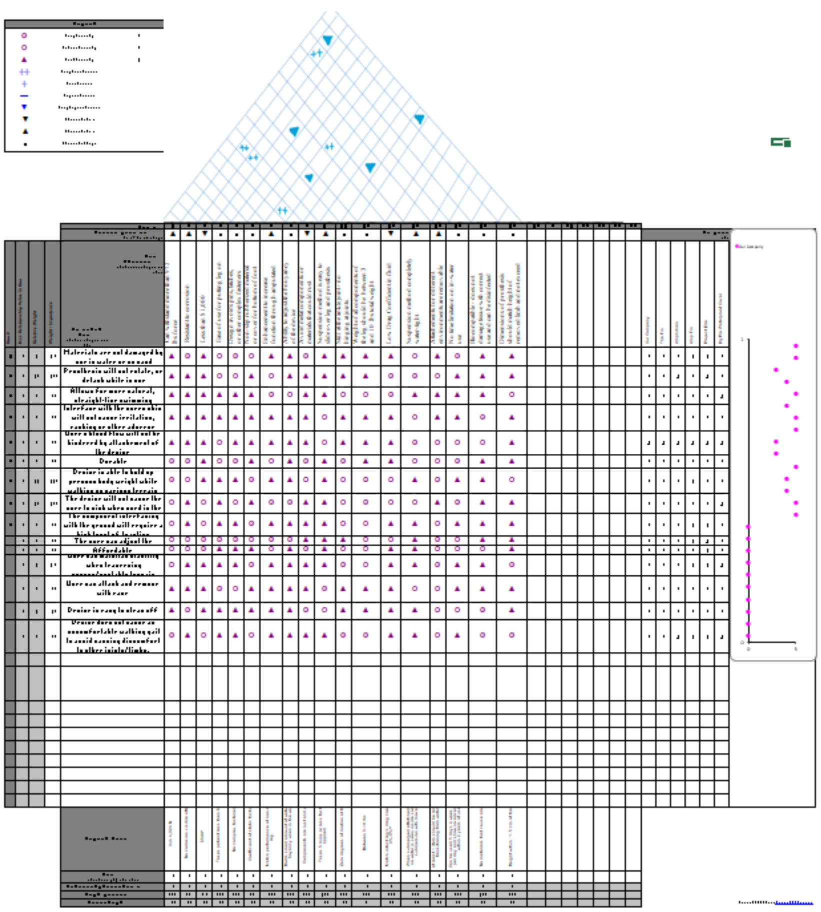
Target Values:

Target or Limit Value	min 4,324 N	No corrosion visible after 7 days	$500*	Takes patient less than 8 mins to apply	No complex fasteners	Coefficient of static friction 0.5 or more	Match performance of non-amputed leg	Holds small amount of water weight to adjust boyancy when in the water	Components are rust and wear resistant
Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	6	4	8	2	3	5	7	9	4
Max Relationship Value in Column	9	9	9	9	9	9	9	9	9
Weight / Importance	346.0	290.0	204.0	236.0	322.0	330.0	296.0	226.0	322.0
Relative Weight	6.6	5.5	3.9	4.5	6.2	6.3	5.7	4.3	6.2

Takes 5 mins or less for the sleeve to be applied	Zero degrees of motion at the ankle joint	Between 3-10 lbs	Match intact leg's drag coefficent within 3%-5%**	When submerged attatched to a stump, no water is seen inside socket after 1 min of submersion with movement	At least 1 item should be removable when transitioning from water to land	Can be used 5 days a week for at least 2 hrs per day and show no adverse wear within 2 years of use	No materials that cause adverse reactions	Height within +/- 5 cm of the missing limb length
3	3	5	9	5	3	4	2	6
9	9	9	9	9	9	9	9	9
172.0	342.0	366.0	272.0	328.0	376.0	378.0	196.0	232.0
3.3	6.5	7.0	5.2	6.3	7.2	7.2	3.7	4.4

Appendix C

QFD:



Full QFD (Customer Requirements, Engineering Requirements, Target Values, Competitive Product Analysis, and Correlations)

Competitive Product Analysis:

Customer Requirements:	Sand and Swim Leg	The Fin	Amphibian	Amp Fin	Project Elle	DryPro Waterproof Cover
Not damaged by water or sand	5	5	4	1	1	3
Will not rotate or detach in use	5	5	4	5	5	4
Allows for natural swimming	3	4	3	5	5	1
Will not cause irritation	4	4	4	4	4	3
Will not hinder blood flow	5	5	5	5	5	5
Durable	4	4	4	5	4	4
Devices holds body weight	5	5	4	1	2	5
Will not cause sinking	5	5	5	5	5	3
High traction level	4	4	5	1	1	2
Adjustable for environment	3	2	2	1	1	2
Affordable	5	3	5	2	1	5
Will provide stability	4	4	4	1	1	4
Easy attachment and removal	4	4	5	5	5	4
Easy to clean	5	5	4	5	5	5
Allows natural walking motion	5	5	5	1	1	3

Where 1 = Worst, 5 = Best

Appendix D

Decision Matrix:

Pylon		
PVC	3D Printed Single	3D Printed w/ Pyramid
11	**9**	**12**
Foot		
Prosthetic Foot	Carbon Fiber Blade	3D Printed Model
5	**12**	**10**
Fin		
Polymer, Clipped	Polymer, Velcro	Rigid, Slot
13	**11**	**8**

Feasibility Rankings for Each Component

Appendix E

Part Design Matrix:

Relationships Key

Relationships	
Strong	
Moderate	
Weak	

Pyramid

Pyramid					
	Specifications				
Engineering Requirements	Material	Strength	Durability	Weight	Connection
Compression Force					
Resistant to corrosion					
Price					
Ease of use					
Fasteners					
Traction					
Swimming enhancements					
User friendly suspension					
Ankle mobility					
Weight					
Drag					
Water tight					
Attachments					
Time limitation					
Biocompatible					
Symmetry					
Target Values	Fracture > than 1500 lbs; Solvent Resistant	Fracture > than 1500 lbs	No fracture after 10k cycles of loading/unloading	< 2 lbs	316L screws/bolts

Pylon

Pylon								
	Specifications							
Engineering Requirements	Material	Height	Diameter	Thickness	Strength	Durability	Connection	Weight
Compression Force								
Resistant to corrosion								
Price								
Ease of use								
Fasteners								
Traction								
Swimming enhancements								
User friendly suspension								
Ankle mobility								
Weight								
Drag								
Water tight								
Attachments								
Time limitation								
Biocompatible								
Symmetry								
Target Values	Fracture > than 1500 lbs; Solvent resistant	Within 5% error of symmetry to non-amputated leg	Outer - 1.25 in. Inner - 1 in.	.25 in.	Fracture > than 1500 lbs	> 10,000 cyclic loading cycles; Solvent resistant	Rigid	< 2 lbs

Foot

Foot					
	Specifications				
Engineering Requirements	Material	Surface Area	Connection	Friction	Weight
Compression Force					
Resistant to corrosion					
Price					
Ease of use					
Fasteners					
Traction					
Swimming enhancements					
User friendly suspension					
Ankle mobility					
Weight					
Drag					
Water tight					
Attachments					
Time limitation					
Biocompatible					
Symmetry					
Target Values	Carbon Fiber	100 cm^2	Rigid	Coefficient of static friction 0.5 or more	< 2 lbs

Fin

Fin							
	Specifications						
Engineering Requirements	Material	Surface Area	Connection	Thickness	Width	Hardness/Flexibility	Weight
Compression Force							
Resistant to corrosion							
Price							
Ease of use							
Fasteners							
Traction							
Swimming enhancements							
User friendly suspension							
Ankle mobility							
Weight							
Drag							
Water tight							
Attachments							
Time limitation							
Biocompatible							
Symmetry							
Target Values	Solvent Resistant;	< 100 cm^2	Rigid	0.25 in.	Within 5% of avg male calf	Shore Hardness Value < 80A	< 1 lb

Appendix F

Risk Summary Table:

Risk Summary Table					
Name of Risk	Summary of Risk	Mitigation	Risk Level Before Mitigation	Risk Level After Mitigation	RPN
Carbon fiber foot breaks or deforms	User will fall leading to potential injury	Proper material testing	Medium	Low	12
Pyramid/Pylon connection to the socket is too difficult to attach	Connection fails and prosthetic detaches from socket; User falls and gets potentially injured	Research a wide variety of connection options	Medium	Low	12
Pyramid/Pylon connection to the socket fails	Connection fails and prosthetic detaches from socket; User falls and gets potentially injured	Work with prosthetists to set alignment	Medium	Low	12
Carbon fiber foot is too heavy	Difficult and unbalanced swimming	Proper material research	Medium	Low	8
Pyramid/Pylon cannot bear load while walking	User will fall leading to potential injury	Proper material testing	Medium	Low	8
Pyramid/Pylon cannot withstand shear forces	User will fall leading to potential injury	Proper material testing	Medium	Low	8
Carbon fiber foot is unable to grip/maintian solid contact with the ground	User will slip and fall leading to potential injury	Friction testing	High	Low	6
Carbon fiber foot interferes with motion of other leg	Difficult and unbalanced swimming	Work with prosthetists to set alignment	Medium	Low	6

Pyramid/Pylon is too heavy	Difficult and unbalanced swimming	Take measurements multiple times and average, work with prosthetist to get professional measurements	Medium	Low	6
Fin is not durable	Material degrades over time and device becomes ineffective	Research material and interactions	Low	Low	4
Fin interfaces with the water improperly	Difficulty swimming	Proper flexibility of material or holes in fin	Medium	Low	3
Carbon fiber foot is not compatible with water	Device corrodes or degrades and then fractures	Proper material testing	Medium	Low	2
Pyramid/Pylon interferes with motion of other leg	Difficult and unbalanced swimming; difficulty walking	Ensure pylon/pyramid doesn't portrude past the socket	Medium	Low	2
Pylon/Pyramid is not compatible with water	Material degrades over time and device becomes unusable	Diligent material research and testing	Low	Low	2
Fin interferes with motion of other leg	Difficult and unbalanced swimming; difficulty walking	Approximately match size of intact foot, ensure fin does not protrude much outside the calf	Medium	Low	2
Fin material is not compatible with water	Material degrades over time and device becomes unusableble	Diligent material research and testing	Low	Low	2
Fin is difficult to attach	Difficult and unbalanced swimming, cannot attach device	Research and use of inclusive and simplistic fasteners, use as little of them as possible	Low	Low	2
Fin connection fails	Device detaches from pylon, causes difficulty swimming	Research fastener options, make sure they will stay attached during swimming	Medium	Low	2

Appendix G

Validation Matrix:

Customer Requirement No.	Customer Requirement	Validation Method	Validation Name	Validation Procedure No.
1	Materials are not damaged by use in water or on sand	Inspection	Water Inspection	1.0
2	Prosthesis will not rotate, or detach while in use	Inspection	Rotation Inspection	2.0
3	Allows for more natural, straight-line swimming	Test	Pool Test	3.0
4	Interface with the users skin will not cause irritation, rashing or other adverse reactions by the device	Questionnaire	N/A	N/A
5	User's blood flow will not be hindered by attachement of the device	Questionnaire	N/A	N/A
6	Durable	Questionnaire	N/A	N/A
7	Device is able to hold up persons body weight while walking on various terrain	Questionnaire	N/A	4.0
8	The device will not cause the user to sink when used in the water	Test	Weight Test	4.0
9	The component interfacing with the ground will require a high level of traction	Questionnaire	N/A	N/A
10	The user can adjust the device functionality depending on the environment	Questionnaire	N/A	N/A
11	Affordable	Questionnaire	N/A	N/A
12	User can maintian stability when traversing uneven/unstable terrain	Questionnaire	N/A	N/A
13	User can attach and remove with ease	Questionnaire	N/A	N/A
14	Device is easy to clean off	Inspection	Clean Test	5.0
15	Device does not cause an uncomfortable walking gait to avoid causing discomfort to other joints/limbs.	Questionnaire	N/A	N/A

Appendix H

Bill of Materials:

Item Number	Part Number	Quantity	Name	Material	Procurement Type	Vendor/Source	Price Each	Typical Lead Time
1	1-001	1	Carbon Fiber Heel	Carbon Fiber	MTS	Soller Composites	$68	1 week
2	1-002	1	Carbon Fiber Top	Carbon Fiber	MTS	Soller Composites	$68	1 week
3	1-003	2	Honeycomb Core	Nomex	MTS	Design Center	-	1 week
4	1-004	2	Aluminum Block Toe	Aluminum	MTS	Design Center	-	1 week
5	1-005	1	Aluminum Block Heel	Aluminum	MTS	Design Center	-	1 week
6	4-001	1	3D printed Pylon	Rigid 10K	MTS	Formlab	$498	3 days
7	4-002	1	3D Printed Fin	80A Resin	MTS	Formlab	$350	1 week
8	4-003	10	Super Corrosion Resistant 316 Stainless Steel Socket Head Screw	316 Stainless Steel	OTS	McMaster-Carr	$8.17	2 weeks