Amputee Advanced Donning Device

Design Matrices

BME 400, Lab 306

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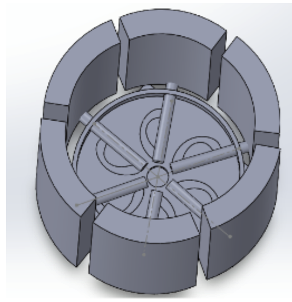
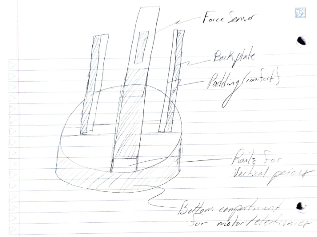
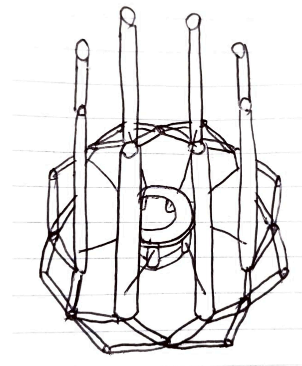
<u>Design Matrix:</u>

Designs		 Design 1: Expanding Pulley Mechanism		 Design 2: Expanding Rail System		 Design 3: Hoberman Design	
Rank	Criteria (Weight)	Score (_/5)	Weighted Score	Score (_/5)	Weighted Score	Score (_/5)	Weighted Score
1	Ease of Donning (25)	3	15	4	20	3	15
2	User Comfort (20)	5	20	2	8	3	12
3	Safety (20)	4	16	5	20	4	16
4	Ease of Fabrication (15)	3	9	2	6	1	3
5	Durability (15)	4	12	3	9	3	9
6	Cost (5)	4	4	2	2	3	3
Total:	**100**	***76***	/100	***65***	/100	***58***	/100

Criteria:

Ease of Donning (25):

Ease of donning is ranked as the most important criterion because it is the primary goal of the project. If the device does not meet this criterion, it will not function as intended. The device must be able to close to a diameter that facilitates the application of the shrinker sock while still being capable of expanding to the maximum diameter required by the user. Therefore, a high score in this category indicates that the device can close to a relatively small diameter, allowing the user to apply the shrinker sock without excessive strain, while still opening as needed. A low score indicates that the device is unable to effectively close or expand to an appropriate diameter.

User Comfort (20):

User comfort is ranked as the second-highest criterion, tied with safety, because the user will interact with the device multiple times each day. It is imperative that the device is comfortable to use so that the user is willing to use it consistently. If this is not achieved, the user may feel that the device is not worth the effort and discomfort associated with daily use, defeating the purpose of the project. Therefore, a high score in this category indicates that the device provides a level of comfort suitable for everyday use. A low score indicates that the device does not achieve the desired level of comfort.

Safety (20):

Safety is ranked as the second-highest criterion, tied with user comfort, because a device that does not keep the user safe is not worth using. This device will be used in a home setting by individuals who may not be familiar with standard safety protocols for electrical medical devices. As such, the device must minimize the risk of harm to the user, regardless of whether it is used properly. Therefore, a high score in this category indicates that the device introduces minimal risk of harm to the user. A low score indicates that the device does not adequately safeguard the user from harm or that the risk of harm is unacceptable high if the device is used improperly.

Ease of Fabrication (15):

Ease of fabrication is ranked as the third-highest criterion because the device must be practical to fabricate and easy to manufacture if additional donning devices are needed for more patients. The device may incorporate various components, materials, and mechanical features; therefore, a simpler design reduces the likelihood of manufacturing issues, simplifies design modifications, and makes repairs or replacements easier. A high score in this category indicates that the device is relatively easy to fabricate, while a low score indicates that the device is more difficult to manufacture.

Durability (15):

Durability is ranked as the third-highest criterion and is tied with ease of fabrication because the device must be strong enough to withstand 30 to 40 N of force exerted by a shrinker sock on a daily basis throughout the user's recovery period, which may last several months. The device's mechanism must be capable of withstanding these stresses while remaining functional for the duration of recovery. A high score in this category indicates a durable device that can withstand long-term use with a low likelihood of failure. A low score indicates a greater likelihood of breaking or becoming nonfunctional over time.

Cost (5):

Cost evaluates the expense associated with fabricating each design. This criterion is weighted the lowest because all of the designs have similar levels of complexity and are expected to remain within the available budget. The overall cost will ultimately be determined by the material selection, which will be evaluated separately in the material matrix.

Evaluation of Designs

Expanding Pulley Mechanism

The Expanding Pulley Mechanism earned an overall score of 76/100. It scored ⅗ for ease of donning because, although it can expand a shrinker sock, the mechanism may become unstable if the device is too long. Additionally, the internal pistons must generate enough force to overcome the resistance of the shrinker sock, which can be challenging given their size. The device scored 5/5 for user comfort because it is easy for the user to operate and understand during daily use. It received a 4/5 for safety, as the primary safety concern is the potential for pinching while the device is closing. The device scored 3/5 for ease of fabrication because it consists of multiple components and requires assembly of the pulley mechanism. It earned a ⅘ in durability because the more delicate components are enclosed and protected, while the extending rods that hold the shrinker sock are strong and can be easily replaced if damaged. Lastly, the device scored 4/5 for cost because it requires relatively few components, uses a simple mechanism, and can largely be manufactured through 3D printing with machined reinforcements, resulting in a reasonable low production cost.

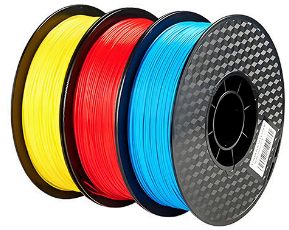
Expanding Rail System

The Expanding Rail System earned an overall score of 65/100. It scored 4/5 for ease of donning because it would likely be capable of contracting to a very small diameter while still expanding to the maximum required diameter. This would make application of the shrinker sock easy for the user. The device scored 2/5 for user comfort because it operates as two separate parts. The lower portion contains most of the electronic and mechanical components, while the portion, to which the shrinker sock is applied, moves independently. This configuration may be unwieldy for users, particularly those who are elderly or suffer from arthritis. The design scored 5/5 for safety due to the inclusion of electrical fail-safes. Force sensors would detect excessive force being applied through any of the vertical components and automatically stop the device before injury could occur. For ease of fabrication, the Expanding Rail System scored 2/5 because the rail system would be fairly complex, making fabrication much more difficult than the other designs. In terms of durability, the design scored 3/5 because, if fabricated properly, the device would be able to function as intended multiple times every day. However, the nature of the design might introduce some maintenance problems with heavy use. Lastly, the design scored 2/5 in cost because of the more complex fabrication process leading to a higher estimated price.

Hoberman Design

The Hoberman Design, which is based on the Hoberman mechanism, received an overall score of 58/100. It scored 3/5 for ease of donning because, while the mechanism can expand a shrinker sock, it does so using only eight points of contact. As a result, not all portions of the shrinker sock would reach the target diameter of 25.4 cm (10 in). Additionally, the Hoberman ring must be sufficiently large to achieve the required expansion. For user comfort, the design scored 3/5 because some users may find the mechanism difficult to understand and operate, which could reduce their confidence and comfort during use. Furthermore, handling and supporting the device may be challenging, contributing to user discomfort. The device scored 4/5 for safety because, although it is generally safe, users could accidentally pinch their fingers within the Hoberman ring while the mechanism is expanding. The Hoberman Design scored 1/5 for ease of fabrication because it consists of a complex assembly with nine unique components and more than 100 individual parts. This level of complexity makes the device difficult to fabricate, manufacture, and assemble. The design earned a 3/5 for durability because several components are relatively thin and vulnerable to damage if not handled carefully. This increases the likelihood of failure before the user's recovery period is complete. Finally, the device scored ⅘ for cost because many of the components are small and can be produced inexpensively through 3D printing, while the larger aluminum components can be machined at a relatively low cost.

Material Matrix:

Materials		 Material 1: Aluminum Alloy [1]		 Material 2: PLA [2]		 Material 3: Nylon [3]	
Rank	Criteria (Weight)	Score (_/5)	Weighted Score	Score (_/5)	Weighted Score	Score (_/5)	Weighted Score
1	Biocompatibil-ity (30)	5	30	5	30	4	24
2	Durability (25)	4	20	1	5	5	25
3	Weight (20)	3	12	4	16	5	20
4	Ease of Fabrication (15)	4	12	5	15	5	15
5	Cost (10)	5	10	5	10	2	4
Total:	**100**	***84***	/100	***76***	/100	***88***	/100

Criteria

Biocompatibility (30):

Biocompatibility is ranked as the most important criterion because a lack of biocompatibility would prevent the device from being used in post-surgical applications. The selected material must be biocompatible while still meeting durability requirements. This consideration is especially important in a clinical setting, where the device will be used repeatedly throughout the day with different patients and sanitized between uses.

Durability (25):

Durability is ranked as the second most important criterion due to issues with structural failure in the previous prototype. The final design is expected to have a minimum service life of one year with minimal maintenance. Ensuring durability will increase longevity and overall performance of the device. Therefore, the selected material must possess sufficient strength to resist bending or breaking under the stresses encountered during normal use. It should also demonstrate resistance to wear and impact that may be encountered in a clinical environment.

Weight (20):

Weight is ranked as the third most important criterion because patients must be able to independently put on their shrinker socks using the device. The selected material must be as lightweight as possible while still meeting strength requirements. This will improve user comfort and reduce physical strain, particularly in a clinical setting where the device will be used repeatedly throughout the day. Reducing the weight of the device also increases patient safety by minimizing the risk of injury if the device is dropped or mishandled.

Ease of Fabrication (15):

Ease of fabrication has been given a lower ranking because the other criteria are more critical to the success of the project. The design should utilize minimally complex fabrication techniques that can be performed in the UW Madison TEAMLab. A sizable portion of the fabrication process will also involve 3D-printed components that can be produced using the resources available in the lab spaces. The fabrication process should be straightforward, and the selected material must be compatible with the available tools and manufacturing processes to ensure safe and accurate construction of the prototype.

Cost (10):

Cost is assigned a lower weighting because performance characteristics such as biocompatibility and durability are of greater importance for this project. As only a single prototype will be manufactured, material cost does not significantly affect the overall design. Furthermore, the client has provided a flexible budget, allowing material selection to be guided primarily by functionality rather than price constraints. However, cost is still considered to ensure responsible purchasing decisions and to maintain the potential for future scalability if additional units are produced.

Evaluation of Materials

Aluminum Alloy:

Aluminum alloy received a total score of 84/100. For biocompatibility, aluminum alloy received a score of 5/5 due to its established use in the medical device industry. Aluminum alloys are used in implants, surgical instruments, prosthetics, diagnostic equipment, and other medical applications. As a result, their interactions with the human body have been extensively studied, providing substantial evidence of their biocompatibility [4]. The other criterion in which aluminum alloy received a 5/5 was cost. The average cost of aluminum across different grades ranges from approximately $2.50 to $6.50 per kilogram, remaining well within the flexible budget [5].

Aluminum alloy received a 4/5 for both durability and ease of fabrication. When properly manufactured, the mechanical properties of certain aluminum alloys can approach those of stainless steel and titanium, providing the strength necessary to withstand the compressive forces exerted by the shrinker sock throughout the device's service life. Additionally, aluminum alloys are highly machinable, allowing for precise manufacturing of complex geometries and components with specific dimensional tolerances. Lastly, aluminum alloy received a 3/5 for weight compared to the other materials evaluated. Aluminum alloys are relatively lightweight compared to other metals, although they are heavier than materials such as polylactic acid and nylon [4].

Polylactic Acid (PLA):

PLA received a 5/5 for biocompatibility, ease of fabrication, and cost. For biocompatibility, PLA was rated highly because it is commonly used in consumer products such as children's toys and wearable accessories. Its inert nature results in low toxicity and minimal skin irritation, while allowing it to remain stable under typical environmental conditions [6]. PLA is also one of the most widely used materials for 3D printing and costs approximately $0.02 per gram when used at the Grainger Engineering Design Innovation lab [7].

Additionally, PLA received a 4/5 for weight. Standard PLA has a density of approximately 1.24 g/cm^3, making components printed from PLA relatively lightweight [8]. However, PLA scored poorly in durability, receiving a 1/5. PLA was used in the previous prototype but proved too flimsy to withstand the compressive forces exerted by the shrinker sock. As a result, its limited mechanical strength presents a disadvantage for this application, leading to a total score of 76/100.

Nylon:

Nylon resulted in a total score of 88/100. For biocompatibility, nylon received a 4/5 due to its established use in medical devices, sutures, prosthetics, and other healthcare applications. Certain medical-grade nylons, such as nylon-6 and nylon-6,6, have demonstrated suitable compatibility with the human body when properly manufactured and processed. However, nylon may absorb moisture, and its biocompatibility can vary depending on the specific grade, additives, and manufacturing method, preventing it from receiving a perfect score [9].

The criteria in which nylon received a 5/5 were durability, weight, and ease of fabrication. Nylon has excellent durability because it possesses high tensile strength, impact resistance, and abrasion resistance. These properties allow it to withstand the repeated loading and compressive forces exerted by the shrinker sock throughout the device's service life. Nylon also received a 5/5 for weight because it is a lightweight material compared to metals such as aluminum alloy and stainless steel, while still providing sufficient strength for the intended application [10]. Additionally, nylon is relatively easy to fabricate using processes like 3D printing compared to other 3D print materials. These manufacturing methods allow nylon components to be produced with complex geometries and specific dimensional tolerances, making it well suited for customized medical devices [11].

Lastly, nylon received a 2/5 for cost compared to the other materials evaluated. Although standard nylon is generally affordable, medical-grade nylon and nylon suitable for 3D printing can be considerably more expensive because of the required material certifications, processing conditions, and quality-control requirements. Therefore, nylon remains a practical material but was ranked lower in cost relative to less expensive alternatives [12].

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