Contract Book

ProSkin

Creating an ideal prosthetic fit for lower-limb amputees

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EN.520.657 Design of Biomedical instruments and Systems

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Abstract

ProSkin is a novel smart prosthetic liner that improves the fit between the prosthetic socket and residual limb for transfemoral, or above-the-knee, amputees who experience everyday physical and emotional discomfort. Current solutions either require manual liner adjustment, which burdens the patient with costly and untimely prosthetic replacements. The novelty of this product involves a continuous and automatic mechanism: microarray channels of air pockets embedded within a form-fitting liner that inflates and deflates in response to fluctuations in pressure at the liner socket. This design ensures there is a precise fit at all times. The use of ProSkin will ensure that amputees can use their prosthetics safely and comfortably with peace of mind.

Introduction

In the United States, there are about 2.1 million limb amputees and 150,000 new people each year with lower limb loss [1]. Among lower limb amputees, up to 82% experience discomfort in their usage of prosthetics everyday [2]. This discomfort is primarily due to the slippage at the interface between the prosthetic liner and the socket, which is caused by the rotational torque and shear force stresses while walking. Furthermore, having a comfortable and secure linkage between the prosthetic socket and the residual limb is critical for successful rehabilitation and daily living [3].

Correct transverse rotational control of the socket on the residual limb is critical for transfemoral amputees because the prosthetic does not have the same functionality or adaptability as actual human feet. This is because there is accumulation of shear stress at the residual limb interface, which is prominent when turning while walking in everyday activities [4]. Moreover, torque forces from the long axis of the prosthesis are transmitted as shear force stresses at the limb-socket interface, which leads to excessive transverse plane rotation contributing to shear stress [5]. As a result, excessive transverse plane rotation can be caused by uncontrolled torque forces, which stems from a poor suspension system. Therefore, it is crucial that the transverse plane rotation at the interface between the limb and the socket is kept within a manageable threshold. To address this unmet clinical need, ProSkin aims to keep the prosthetic interface at an optimal fit with the liner to allow enough flexibility and rotation to enable proper gait for the users, but not excessive enough to cause other unforeseen secondary issues.

Field Survey

Customer Needs

We have conducted preliminary interviews with transfemoral amputees and prosthetic users, Christopher Shallal, a graduate from Johns Hopkins University, and Patti Graham, a book seller based in California, to gain personal insight on their prosthetic usage. They have voiced their concerns about the risk of slippage, which contributes to the increase in their mental burden, anxiety, and risk of burnout of readjusting prosthetics. In particular, they ran into additional problems during the COVID-19 pandemic when attempting to seek out adjustments for their prosthetics. Patti expressed that she was not able to get adequate in-person care due to the restrictions put on the number of visits to clinics. She then stated that there is a need to provide amputees with stable, functioning liners to begin with in order to minimize their visits to clinics due to issues with prosthetics. As we are in an uncertain time in 2021, we do not know how long the pandemic will last, so the need is greater than ever before for a solution to decrease unnecessary clinic visits. Through our preliminary customer discovery with two of the prosthetic users, we were able to confirm the clinical need and problems that are commonly experienced by transfemoral amputees. With more customer discovery and stakeholder interviews, we hope to further solidify and confirm our clinical need, and more importantly, we are motivated to deliver a comfortable, accessible liner to 82% of the lower limb amputees who experience discomfort in their usage of prosthetics on a daily basis [2].

Market Analysis

Across the globe, the World Health Organization estimates that there are 40 million amputees [6]. In the U.S. alone, approximately 2.1 million people live with limb loss, and of those, about 65% have a lower limb amputation [2]. Every year, about 150,000 patients per year experience lower extremity amputations in the U.S. [3]. This drives the market growth rate as more amputees are being rehabilitated with prostheses.

In 2018, the prosthetic liner market had a market size of $246.5 million globally, and of that, the U.S. had a market size of $115.1 million. In terms of anticipated growth, the compound annual growth rate is 5.1% [7]. Of the current prosthetic liner materials popular on the market, silicone leads and is followed by thermoelastomers. The customers targeted prosthetic users, hospitals which consist of clinicians and physical therapists, and prosthetic and rehabilitation clinics. Notably, the majority of end use market shares belong to hospitals.

SWOT Analysis

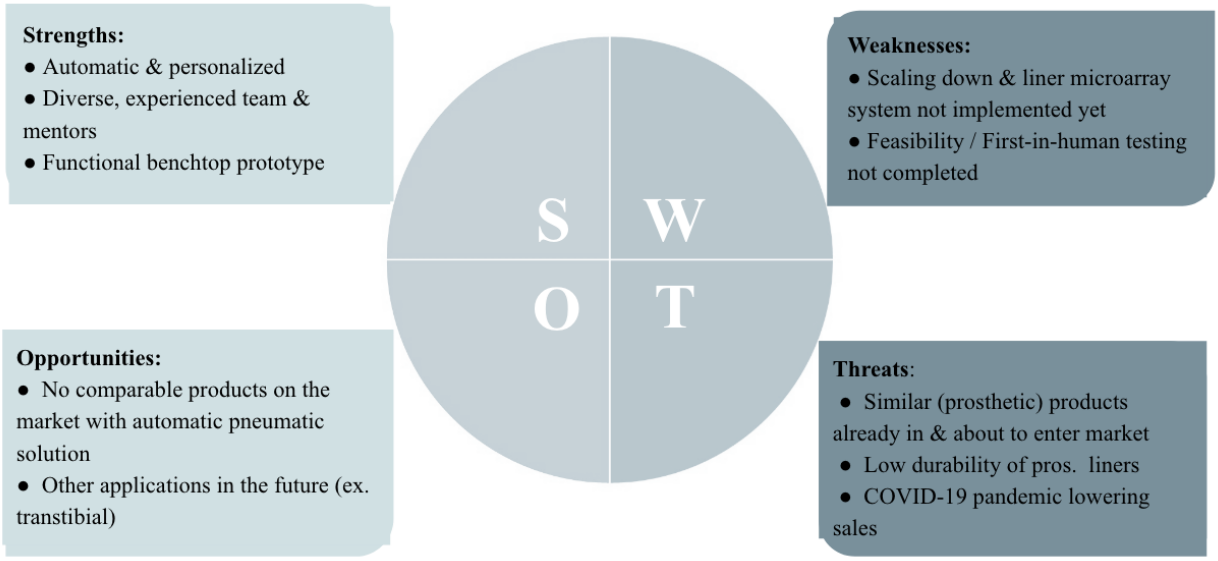


Figure 1. Identification of strengths, weaknesses, opportunities, and threats [8], otherwise known as SWOT

As shown in Figure 1 above, some highlights include that we have a strong, diverse, and experienced team, including members who are either founders or current members of medical technology ventures. Moreover, we are supported by advisors and mentors from FastForward U and Maryland's Student Entrepreneurship Network (Innov8MD). We demonstrated our proof-of-concept, functional benchtop prototype, and we aim to iterate our design such that it can be incorporated within a liner. Although there is no liner quite like ours in the market, we acknowledge that there are other forms of competitors, whether they be manual adjustment sockets or liners that serve a similar purpose. We believe our edge over these competitors will be ease-of-use, accessibility, and accuracy. One threat that we face is the COVID-19 pandemic, of which the end is uncertain. It has lowered sales of prosthetic liners, but we hope that our innovation which will decrease the need to visit clinics will turn the trend around.

Patent Survey

Competitor Analysis

In order to address the clinical need of an optimal healthy fit between the socket and residual limb, there have been several attempts both in the field of adjustable sockets and prosthetic liners.

RevoFit from Click Medical [9] and Connect TF from Ossur [10] are examples of adjustable sockets on the market available for transfemoral amputees. First, RevoFit, as shown in the Figure 2a, is a socket design that includes strategically-placed panels, as well as laces and dials that enable amputees to manually adjust the fit of their sockets throughout the day. This in turn gives the individual more control over the fit and comfort. Another example of an adjustable socket on the market is Ossur's Connect TF product, which is shown in Figure 2b. This adjustable socket has an on/off tensioning handle, and it also needs to be custom-fitted by a certified prosthetist and adjusted throughout the socket lifetime for height, angle, and circumference.

Figure 2. Examples of adjustable sockets on the market for transfemoral amputees.

(a) Click Medical's RevoFit

(b) Ossur's Connect TF

Moreover, another class of suspension techniques used in sockets includes vacuum pumps. VASS (Vacuum Assisted Socket System) can be cited as a recent example as shown in Figure 3 [11]. The VASS creates a seal between the residual limb and the socket by mechanically pumping air out of the system with each step. The actual vacuum pump is placed below the socket and there is also a separate electric pump component to maintain desired socket pressure.

Figure 3. Example of a socket with a vacuum pump suspension system on the market, VASS.

Adjustable and vacuum sockets do have their merits; however, in comparison to our liner product, adjustable sockets are much bulkier and involve constant manual adjustment, which puts an enormous burden on the user. Therefore, it is important to note that modifications to the prosthetic sockets have limitations compared to prosthetic liners. While the sockets provide support to the residual limb as a whole, the prosthetic liner is in direct contact with the residual limb in contrast to the socket. As a result, there is a limit on how much the socket and the limb can act as a unit without modifying the liner.

In the field of liners, we found that while there are generally little modifications being made on them to provide more comfort for the prosthetic users. An example of a liner with a seal component on the market is the Iceross Seal-In liner as shown in Figure 4 [12]. Instead of a single seal, this liner incorporates a series of five seals that is intended to enhance rotation control and minimize pistoning.

Figure 4. An example of a prosthetic liner with seal elements, the Iceross Seal-In liner. Five seal-in elements can be observed (in white).

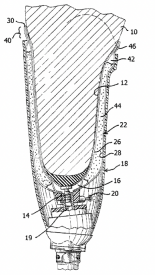
While this liner achieves the goal of reducing twisting in the socket with the improved suspension system, our product differs in that the suspension system is responsive to changes in the residual limb. More specifically, their product is static while our product is dynamic, and adjusts accordingly to the user's residual limb.

Intellectual Property Search

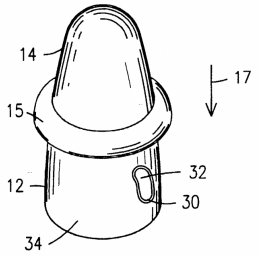
There has been extensive research on developing a liner that is capable of adjusting itself based on the pressure changes occurring at the interface. Current commercial solutions are based on manual lacing or clamping systems. But there is no proper solution developed yet, in which the fit is adjusted automatically and continuously depending on the activity of the user.

Our research showed that there are devices proposed in the U.S. Patent App. Pub. 2015/9017420 entitled “Inflatable Interface for Use Between a Limb Liner and a Limb Prosthesis” that used air bladders as shown in Figure 5a. Moreover, the U.S. Patent App. Pub. 1995/5387245 entitled “Inflatable Prosthesis Liner”, as displayed in Figure 5b, is also based on the inflatable air bladders within the liner. Nevertheless, these two systems are static systems that require manual adjustments, which can be stressful for the user.

Figure 5. Examples of previous liners and liners systems that use air bladders



(a) U.S. Patent App. Pub. 2015/9017420: Inflatable Interface for Use Between a Limb Liner and a Limb Prosthesis

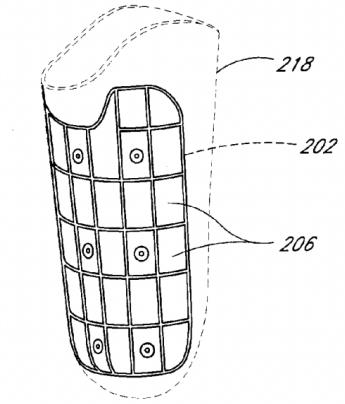


(b) U.S. Patent App. Pub. 1995/5387245: Inflatable Prosthesis Liner

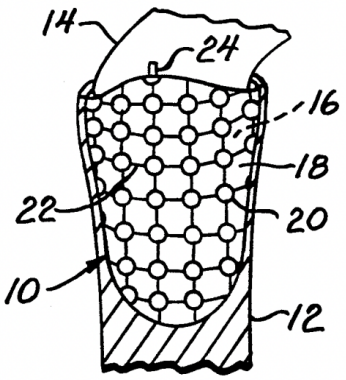
The U.S. Patent App.Pub. 2010/7655049 entitled “Socket Insert Having a Bladder System”, as presented in Figure 6a below, uses socket inserts to cover the gaps and thus relieve pressure at the interface of the residual limb and socket. However, the bladders used are fluid cells located at specific points of the socket, so in the spots where there are no cells, there is a chance for slippage. With regards to fluid channels, they can be prone to leakage and can increase the weight of the socket, leading to issues with load bearing and balance. Additionally, fluid is a limited resource unlike an electronic device which can be used by powering.

U.S. Patent App. Pub. 1992/5156629 entitled “Pneumatic Prosthetic Insert", as exhibited as Figure 6b below, developed a polymerics insert that has air pockets embedded into it which inflate by using an air valve thus providing proper fit and comfort. However, this invention does not have any means of sensing the pressure changes that occur at the stump and the socket interface. The lack of pressure sensors can make this device incapable of addressing the problems with filling the voids or air fillings that develop while the person walks. Moreover, being an insert that itself is not a part of the prosthetic or socket, the user is bound to carry it wherever he goes, which could be a burden. The patent claims about feasibility of bulk manufacturing of the inserts, but because it is an insert, it is disadvantageous as it may not be suitable for different sizes of sockets. So, it cannot be an effective solution for everyone.

Figure 6. Examples of patented socket inserts



(a) U.S. Patent App. Pub. 2010/7655049: Socket Insert Having a Bladder System



(b) U.S. Patent App. Pub. 1992/5156629: Pneumatic Prosthetic Insert

The U.S. Patent App. Pub. 2013/0218296 entitled "Adjustable Prosthetic Socket and Suspension System", as shown as Figure 7 below, focuses mainly on addressing the problems with volume changes of the residual limb. This invention includes a socket which comes with an inbuilt liner with a sealed gap between them. If the user wants more space, the liner is pushed towards the socket walls. Now when there is a need for tight fit, the liner inflates by the use of fluid running through the sealed space; this allows the liner to pull away from the socket wall and grab the residual limb. This method fails to address the issues associated with regional filling of the spaces as the inflation/deflation mechanism is not specific to any particular region. Moreover, the use of fluid increases the weight of the system, making it difficult for the user to use it for many hours.

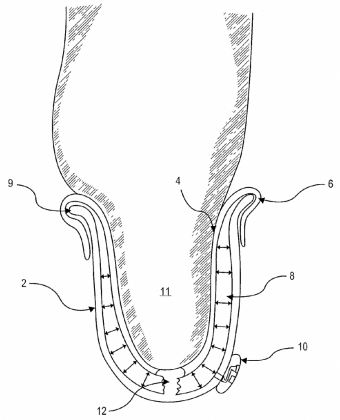


Figure 7. U.S. Patent App. Pub. 2013/0218296: Adjustable Prosthetic Socket and Suspension System

Elevator Pitch

Hi! We're team Proskin, and we're creating a prosthetic liner to create an ideal interface for lower-limb amputees!

A few years back, I was walking towards the airport gate before my flight. When I reached the gate, I was shocked to see a Hopkins friend --from North Carolina, sitting at this gate in Georgia.
I greeted him with "Chris, hi! Look who's here."
'Oh heyy', he said in his slow southern drawl, 'didn't expect to see you here.'
Immediately, I questioned him, 'Don't you live in North Carolina, what brings you here?'
In response, he said, 'Yeah, I came here for a doctor's appointment for my prosthetic legs. Had to get them readjusted. Also, I'm currently looking into a new pair."
Taking a moment to digest this, I added, "'Oh, wow, I can't believe you'd have to travel this far out of your way to look into these services."
Hearing this, he kinda just shrugged, and we later delved into more talk about back-to-school topics.

Although it was a short-lived conversation, it permanently etched itself into my mind. Here is my friend who is so used to doing extraordinary feats to attain a normal lifestyle, something that I take for granted as an able-bodied person. It pained me to realize how people with disabilities have to go the literal extra mile, taking away from their precious time.

With the support of this class, we have felt motivated to co-found a start-up named Proskin, so we can produce better prosthetic fit for lower-limb amputees. We would have the potential to positively impact 40 million amputees around the world and 2.1 million in the U.S. [1,6]. In current literature, for those who are lower limb amputees in the U.S., it is established that up to 82% experience discomfort between the prosthetic socket and limb [2]. We uncovered that this is due to insufficient suspension, causing uneasiness and even skin lesions.

Currently, the solution is to change the liner or the prosthetic itself as the size of the residual limb changes over time. However, this requires manual readjustment, which is correlated with an increasing number of visits to the doctor. So, there is an unmet need for an automated liner system that dynamically responds to changes in the remaining limb. And that is why, our team of inventors is developing an automated smart prosthetic silicone liner which inflates and deflates in response to pressure fluctuations. In our current stage of development, we have a benchtop proof-of-concept which renders an automatic inflation/deflation mechanism using a two-by-two array of pressure sensors.

Through our collected efforts, in our journey to creating a better prosthetic fit for lower-limb amputees, our team has performed the research and have spoken to many-- from personal stories on the prosthetic user experience to advice on how to optimally design the liner interface. By embracing the opportunity of this class, we hope to expand nationally and, later down the road, globally to expand the reach of this automated liner system. Ultimately, we want to encourage lower limb amputees to spend less time worrying about their prosthesis and more time pursuing what makes them happy.

Product Design

Technical Aspects

The product consists of a light flexible thin sheet of an array of pressure sensors embedded within the prosthetic liner. An array arrangement of fluid, encompassing but not limited to air or water, pockets are weaved throughout the liner in another thin layer sandwiched within the liner. After the user wears the liner and turns on the adjustment mechanism, the fit is automatically set, the pressure between the liner and socket is obtained, and a range is created to a percentage above and below this threshold. By detecting pressure changes caused by slippage while walking, the sensors read into a controller, such as a microcontroller, which then powers a motor (e.g. air pump) to inflate the appropriate pockets located at the area of slippage to bring the pressure between socket and liner within threshold range, thereby maintaining the fit of the socket. If the pressure goes above the threshold range, indicating the limb is too compressed, a control element, such as a solenoid valve, controlled by the controller will allow the pockets to deflate.

Control elements control the flow of fluid, allowing an open passageway when the motor is running and turned off. If the pocket needs to be deflated from excess pressure at the liner socket interface, the control element will close the main passageway, and open a different flow from the pockets into the surrounding atmosphere, allowing the pockets to deflate and therefore decreasing the pressure.

Experiments

Our team has constructed a benchtop prototype to demonstrate the feasibility of an automatic mechanism that can inflate and deflate. The prototype consists of two air pumps, two solenoid air valves, transistors, resistors, a breadboard, microcontroller, piezoresistive fabric, and an airbag.

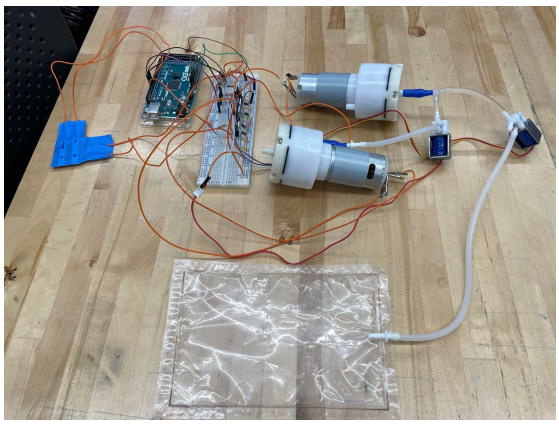


Figure 8. Benchtop Prototype

We represent the interface of the residual pressing against the limb liner as a finger pressing the piezoresistive fabric, or blue tape. This blue tape consists of a 2 x 2 array of tactile sensors that can identify pressure changes in 4 locations. This is analogous to the pressure changes along the whole liner

as the amputee walks. The workflow of this setup consists of the sensor array sending a signal to the microcontroller; the microcontroller interprets and sends a signal to the air pump; and the air pump then modulates the airbag. The airbag symbolizes the air pockets, placed in the liner, that would balance pressure changes to provide stability and avoid the limb from slipping off the liner.

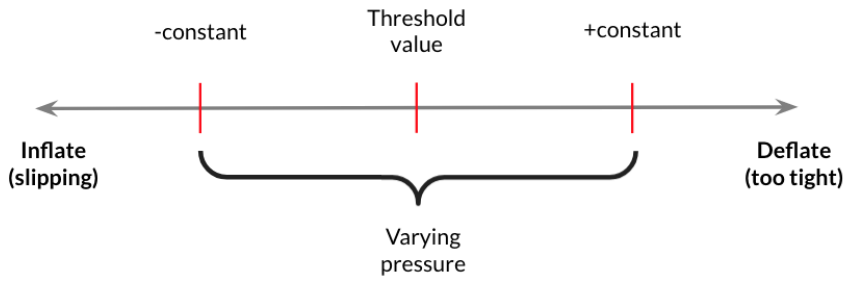


Figure 9. Airbag Dynamics

When a finger is pressed against the blue tape, the airbag inflates. The air fills in the gap and maintains an optimal fit. When there is a good fit, so there is neither too much nor too little pressure, the bag stays still. However, when the finger is released from the blue tape, the airbag deflates automatically. Even while using off-the-shelf benchtop materials, this prototype has a fast response speed (<5 sec). When moving forward, with these preliminary results in mind, we plan to optimize our design into a form fitting liner with miniaturized parts.

Bill of Materials

Expenses Related to the Prototype Building

Part	Manufacturer	Features	Quantity	Price/Unit	Price
Mini Solenoid Valve	uxcell	Type: 2 Position 3 Way Normally Open	4	$16.89	$67.56
Logic Element for Pneumatics	Crouzet	Logic functions: OR, AND, YES, NO	4	$28.33	$113.32
Micro Vacuum Pump	Vikye	DC 12 Volts	2	$20.39	$40.78
				TOTAL	**$221.66**

Table 1. Materials Purchased in Class

Regulatory Strategy

We expect a Class 1 classification for our liner. We have looked at FDA databases and found that similar products were classified as Class 1. We do not expect there to be any substantial risk in wearing the liner, but we may potentially submit a 513(g) request to the FDA to receive a formal device determination and classification, so that we can craft our regulatory strategy accordingly from the get-go. We anticipate our clinical and other business strategies to fall in line with the overall regulatory strategy. In the case our device is classified as class 2, due to the introduction of the automatic array system, we expect to file for 510(k) clearance. However, we are prepared for either case, as we have devices in the market that can act as substantial equivalence. Regardless, we plan on taking advantage of the extensive mentor network through FastForward U to receive advice from regulatory experts to best craft our regulatory strategy. Later on, we will recruit a formal regulatory consultant to hone our strategy.

Moreover, we will proactively uphold regulatory standards that the FDA advises upon. We will implement Quality Systems under 21 CFR 820 and ISO 13485. These standards will be used to establish and maintain procedures to control the design of the device to ensure that specified design requirements are met. As we continue to develop our prototype, we will take into consideration and apply CFR 820.30 Design Controls. A design plan will be written to establish the overall design goals, specifications, input and output objectives, project schedule, studies to be performed, and when formal design reviews shall be held. We will detail our preliminary product specification for our device and continue to update our user manual depending on feedback and results. We believe in a thorough and rigorous development process to ensure the highest standard of device and to protect against any potential regulatory hurdles in the future.

Business Strategy

Business Model

Based on our market research and product specifications, the wholesale business model is the most suitable because consumers trust recommendations from entities such as hospitals and these entities understand medical devices better than the general public.

As we are an early-stage start-up, we acknowledge that it is not easy to get the customers' trust from the get-go. Consumers can be emotionally driven during decision-making processes and rely on that when selecting the brands they prefer. In order to positively sway the customer, we will market our product to entities such as hospitals, rehabilitation (rehab) centers, and doctors, so they can recommend it to their patients. With their influence, our end-goal target consumers, or amputee patients, would be exposed to our product and be more willing to embrace it. As a result, in our business model, there is a greater emphasis on business partners such as hospitals and rehab centers than there is on consumers. Additionally, with the backing of a JHU course, FastForward U, and Innov8MD, we can guarantee product quality. The business partners, who are more knowledgeable than the general public about medical devices, can understand the innovation and in turn, see the value in it improving lower limb amputee lives. So, it would be much easier to initially sell our products to the business partners than it would to consumers.

The benefits of the wholesale business model include the ease of connecting people from different businesses via social media and the reduction of costs via bulk purchases. With respect to social media, this model can encourage people from different businesses to work in synergy to maintain the relationship and get the deal going for more years. Although we initially reach out to consumers via business partners such as rehab centers and doctors, we can plan to veer toward marketing directly to consumers via online marketplaces like Amazon and eBay. This would occur much later down the line, once the product generates significant interest from lower limb amputees and has vast social reach. With regards to reducing manufacturing costs, it is notable that business partners tend to buy in bulk. This would enable the bulk manufacturing of raw material, which would significantly reduce the costs of both raw materials and manufacturing.

The costs of developing each unit, assuming we are manufacturing in bulk, would be approximately $200. Including the manufacturing costs, it would come upto $250. Based on our research on various competitors and their pricing of sockets with similar capabilities as our liner, we plan to sell it for $750. The usual margin for medical devices is around 20%, so the other businesses we sell to would sell it at this margin. This sums up to be $840 and is the final price to the consumer.

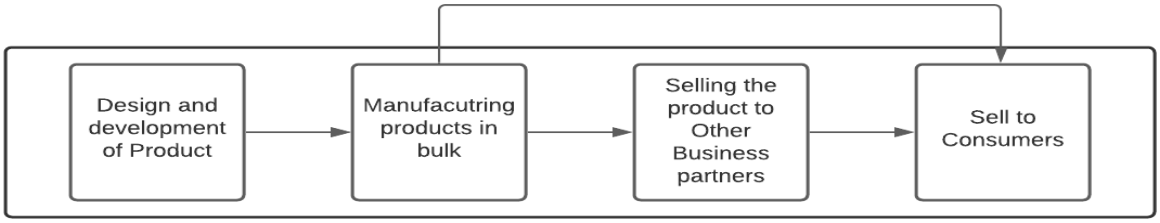


Figure 10. Business Plan Structure

As shown in Figure 7, once the product is designed and developed by our research and design (R&D) engineers, it is then passed on to the manufacturers to get manufactured in bulk. Once our devices are ready, these are transported to the various businesses, who then sell them to the customers.

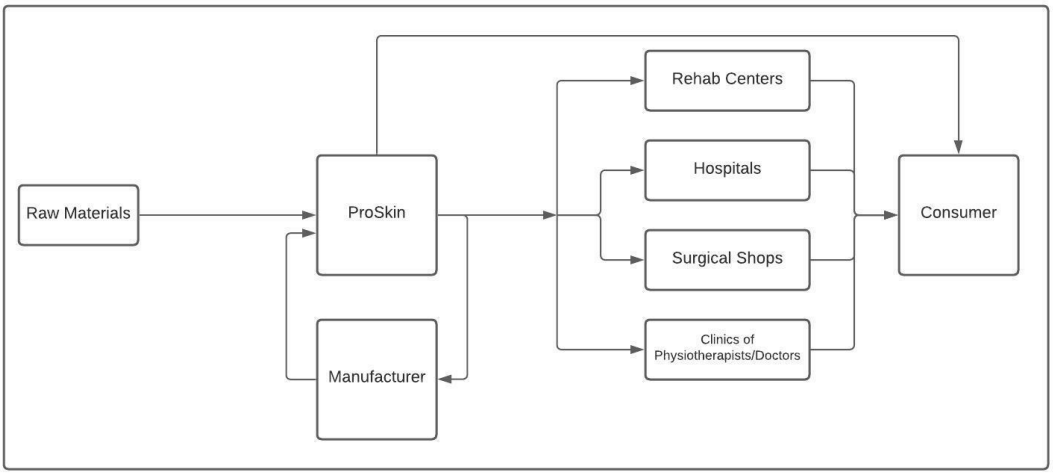


Figure 11. Scheme of Operation

Figure 8 shows how our company develops the product and targets our consumer base, a process that is summarized in four stages. In the first stage, raw materials are procured. In the next stage, the materials are developed by Proskin and are manufactured at the appropriate facilities. After manufacturing, the product moves to locations such as rehab centers, hospitals, surgical stores, and physiotherapy clinics. Finally, these entities recommend our products to consumers who are lower limb amputees.

Financial Plan

Line Graph of Expected Net Revenue (in Millions of USD) vs. Year

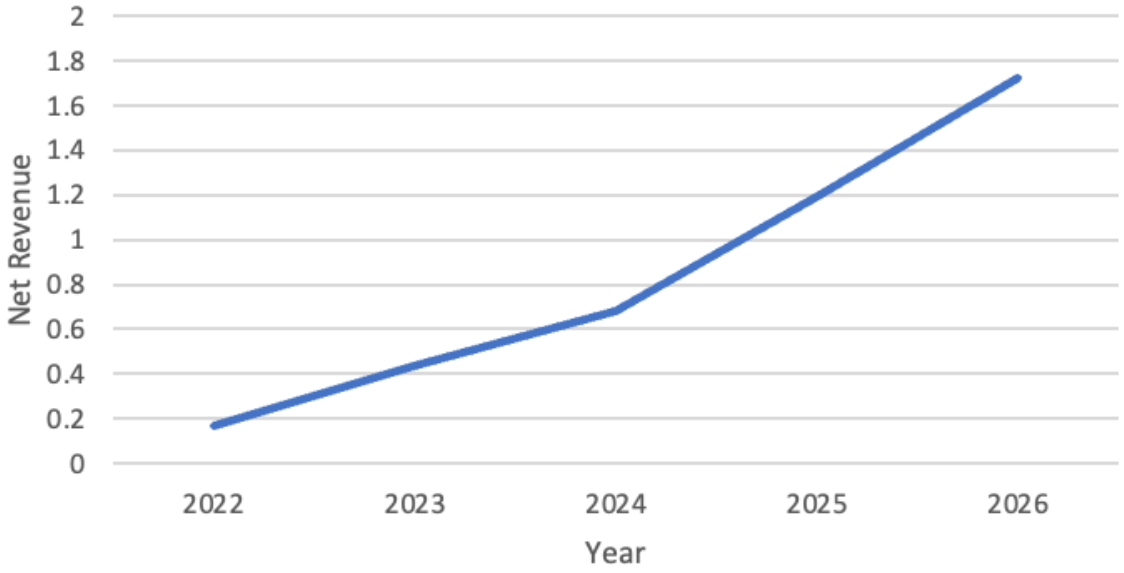


Figure 12. Graph shows the growth of net revenue each year from 2022 to 2026

The following assumptions are calculated based on two key statistics, the first being that there are currently 2.1 millions amputees in the U.S. and the other being that 150,000 people experience lower limb amputations every year in the U.S [1].

Based on this reasoning, we expect to sell 1,000 units in the first year. That is analogous to selling units to 1,000 of the 150,000 new lower limb amputees in 2022, which is just 0.66% of our objective customer base. We are confident that we can sell this small number of units in 2022 and continue to grow the number of units-sold-per-year every year in the period 2022-2026.

Financial Summary for 5-Year Period

Financial Sheet	Year 1	Year 2	Year 3	Year 4	Year 5
Development					
Units	1000	1500	2000	3000	4000
Components/Raw Materials	$200,000	$300,000	$400,000	$600,000	$800,000
Manufacturing costs	$50,000	$50,000	$45,000	$45,000	$40,000
Salaries & Business Expenses					
R&D Engineer	$100,000	$120,000	$120,000	$140,000	$140,000
Software Engineer	$80,000	$90,000	$100,000	$110,000	$120,000

Marketing agents	$60,000	$65,000	$70,000	$75,000	$80,000
Office space	$30,000	$30,000	$35,000	$35,000	$40,000
Travel & Transportation	$20,000	$25,000	$30,000	$35,000	$40,000
Legal and Advertisement					
Regulations	$30,000	$1,000	$1,000	$1,000	$1,000
Promotions	$10,000	$10,000	$15,000	$15,000	$20,000
Totals					
Total Expenses	$580,000	$691,000	$816,000	$1,194,000	$1,281,000
Gross Revenue	$750,000	$1,125,000	$1,500,000	$2,250,000	$3,000,000
Profit	$170,000	$434,000	$684,000	$1,194,000	$1,719,000

Table 2. Full Financial Plan for the next 5 years

The table below shows the number of orders, net revenue and gross revenue over the course of a 5-year period.

Total Orders vs Gross vs Net Revenue Chart, Each Year for a Period of 5 Years

Year	Orders	Gross Revenue	Net Revenue
2022	1000	$750,000	$210,000
2023	1500	$1,125,000	$494,000
2024	2000	$1,500,000	$767,000
2025	3000	$2,250,000	$1,314,000
2026	4000	$3,000,000	$1,879,000

Table 3. Total Orders for the time period 2022 to 2026

Funding and Exit Strategy

Initial pre-seed funding will be sought after through non-dilutive government or institutional grants and awards. We will take advantage of our unique position within the FastForwardU system, an entrepreneurial hub for Johns Hopkins University students, and apply for the SPARK Accelerator

program to build upon early venture basics, such as market research and customer discovery. We will also apply for grants through NIH/NSF SBIR/STTR Phase 1 programs where we will pursue research and development, as well as conduct early feasibility tests of our device in user groups. Our early stage funding will help us develop a functional prototype to test with the initial user population, as we start developing IP, reimbursement, and regulatory strategies.

As we successfully develop our commercialization plan and connect with business mentors, we will reach out to angels and venture capitals. Each successful round of funding will validate our work and prove that our team is capable of delivering our value proposition to all stakeholders involved. Eventually, we hope to get acquired by a larger, more established medical device company who may be interested in our device. We have identified Ossur, Scheck & Siress, and Ottobock as potential acquirers in the future, and our go-to exit strategy. We plan on establishing a connection with these industry players and closely follow their R&D and business directions to best identify which group most closely aligns with our goals and product.

Market Strategy

Although currently we are in the prototyping stage as an early medical device startup, we have developed a future-looking marketing strategy in hopes of optimizing the commercialization of our device and gaining wide market adoption as soon as possible. To align with our overall business strategy, we will develop a two-part strategy where we first market to hospitals and doctors, who are our initial buyers, then reach the customers directly after garnering interest. To clinics and practitioners, we will demonstrate our product's value by conducting user interviews and publishing feasibility studies, and collecting real-world evidence. Our evidence will center on health-care outcomes, as well as cost-savings for the clinics. We will trial our device to practitioners with their customers and incorporate user feedback into our future iterations to deliver a user-tested device. We will present our device at conferences and symposiums, such as the International Society for Prosthetics and Orthotics (ISPO) and Orthopedic Medicine for Primary Care, so that we can reach key-opinion leaders who can potentially champion our device and its usefulness.

Also, we will have a social media marketing plan that is tailored to each sub-market (age, gender, activity level, etc.). We will have an accessible and professional website where we work with brand ambassadors, such as previous and current paralympic athletes with transfemoral amputations or veterans, to demonstrate our device's effectiveness and raise interest. Outside of the direct function of the liner, we will incorporate a larger message of giving back a normal lifestyle and optimizing the mind-body health of users. This will be achieved by partnering with other prosthetic and orthotic organizations, the Paralympic Games marketing team, the Veterans Affairs, and general health and exercise-oriented organizations who share a similar mission with our team. Our marketing will include educational materials in the form of specific exercises that can be optimally performed with our liner, as well as suggestions for healthy diets and lifestyle choices.

Reimbursement Strategy

It is important to consider the consumer's ability to purchase medical products. The capacity of insurance to cover the cost can play a role in consumer accessibility across socioeconomic statuses. As a way to support the customers, Centers for Medicare and Medicaid Services have a standardized coding system called Healthcare Common Procedure Coding System (HCPCS). It has Levels I and II, with Level I corresponding to Current Procedural Terminology (CPT) Codes and Level II corresponding to products, supplies, and services that are not included in the CPT [13].

Looking into the HCPCS codes, we found that our invention falls under Level II in "L" codes, which stands for "Orthotic and Prosthetic Procedures, Device." The code that best aligns with our invention is the L5679, which is known as the "Addition to Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold Or Prefabricated, Socket Insert, Silicone Gel, Elastomeric or Equal, Not for Use with Locking Mechanism."

HCPCS Codes and Their Short Descriptions

HCPCS Code	Short Description
L5679	Sock Insert w/o lock mech
L8410	Sheath Above Knee
L8417	Pros Sheath/Sock W Gel Cushion
L8460	Shrinker Above Knee
L8480	Pros Sock Single Ply Ak

Table 4. HCPCS codes that are relevant to our invention

Biographies

Dheeraj Dhanvee Kairamkonda, B.S. is a graduate student at Johns Hopkins University, studying Biomedical Engineering with a focus in Imaging and Medical Devices. Through his internship at Heamac Healthcare, a medical device start-up, he has gained insights into developing a product & product life cycle and learned various business aspects of medical devices. Moreover, his internship at Apollo Hospitals has opened him up to various medical devices and gained a broader perspective on the medical device industry. This knowledge over a wide range of devices would help him develop a solution based on an identified clinical need. These attributes support ProSkin to thrive as a successful startup.

Yoseph Kim, B.S. is a graduate, and past undergraduate student at Johns Hopkins University, studying Biomedical Engineering (BME) with a focus in Imaging and Medical Devices. His experiences and knowledge gained from rigorous course loads in both the BME and Business minor programs will prepare him well to make ProSkin successful. Yoseph is currently working as the Chief Operating Officer (COO) of Optosurgical, an early-stage medical device startup and oversees the day-to-day administrative and operational functions. He will translate his working experience and skills to this team to ensure a smooth, calculated plan to commercialization.

Paroma Mukhopadhyay, B.S. is a graduate student at Johns Hopkins University, studying Biomedical Engineering (BME) with a focus in Imaging and Medical Devices. She has extensive experiences in prototype testing and entrepreneurship experiences in working with a BME design team to create a device to make efficient patient repositioning from supine to lithotomy position in high risk surgeries. Moreover, she played a critical role as a founding member of a global health design project where she developed a low-cost blood sample analyzer to quickly diagnose malaria in Uganda. All of her experiences and background in BME will positively contribute to the success of our venture ProSkin.

Eugene Oh, B.S. is a graduate student at Johns Hopkins University, studying Biomedical Engineering (BME) with a focus in Imaging and Medical Devices. She possesses valuable skill sets in engineering and entrepreneurship through her experiences working with two med-tech startup companies. As a clinical development engineer in her student-led venture Relavo, she helped plan usability studies and aided in prototyping with a focus on ergonomics. Eugene is also currently working in a med-tech startup company Optosurgical where she helps develop an imaging tool and validate it in both pre-clinical and clinical studies. She continues to play a pivotal role as Optosurgical's Interim CEO by connecting with med-tech industry experts and raising funds through grants and pitch competitions. She hopes to directly apply her expertise in innovation and entrepreneurship to further grow ProSkin as a venture.

Recruitment Strategy

Our team consists of a strong group of biomedical engineers who have abundant experiences in both engineering and entrepreneurship through working in medical device ventures. While we possess strong expertise and skill sets in biomedical engineering to make great progress in prototyping for our product, we acknowledge that there are additional areas of expertise that we need to further grow our venture and make it successful in the long run.

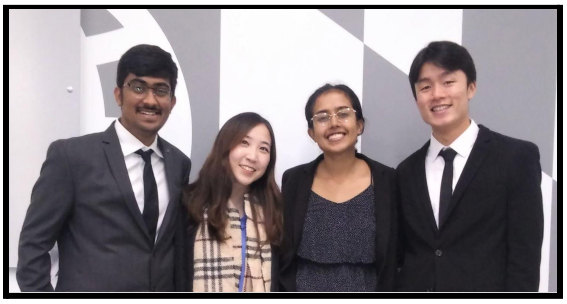


Figure 13. Proskin Team Group Picture from Class Demo Day, 12/01/2021

Moving forward, we would like to recruit a software engineer who can aid in the technical aspects to create a more intricate and sophisticated microcontroller code to control our novel, automatic mechanism in the airbags. Additionally, we would like to pair up with clinical collaborators such as physical therapists in rehabilitation clinics by taking advantage of our unique connections with the Johns Hopkins University and the Johns Hopkins Hospital. Most importantly, we plan to recruit two experts in business and marketing administration. We would like to carefully search for personnel who have a nuanced understanding of the medical device industry, including product, branding, and market development. These experts, preferably with their extensive experiences with medical device industries, will provide invaluable insights and make progress for the advancement of ProSkin's commercialization strategy as well as our business, reimbursement, and financial strategies.

Patent

DYNAMIC & AUTOMATIC PROSTHETIC LINER TO IMPROVE FIT AT THE LINER-SOCKET INTERFACE

Inventors: **Dheeraj Kairamkonda**, Baltimore, MD (US); **Yoseph Kim**, Baltimore, MD (US); **Paroma Mukhopadhyay**, Baltimore, MD (US); **Eugene Oh**, Baltimore, MD (US)

Assignee: **ProSkin**

Appl. No.: **1881711**

Filed: **December 10, 2021**

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Abstract

We propose a novel smart prosthetic liner, ProSkin, which aims to improve the fit between the prosthetic socket and residual limb for transfemoral amputees. The novelty of this product involves a continuous and automatic mechanism: array channels of fluid pockets embedded within a liner that inflate and deflate in response to fluctuations in pressure at the liner socket interface to keep rotational torque within a manageable threshold for the user, and therefore reducing slippage and maintaining healthy skin. In an ideal embodiment, the use of ProSkin will ensure that amputees can use their prosthetics safely and comfortably with peace of mind.

9 Claims, 5 Drawing Sheets

FIELD OF THE INVENTION

[0001] The present invention relates to prosthetic liners for transfemoral amputees that automatically adjusts to continuously improve the socket-limb interface fit, comfortability, and skin health for the user.

BACKGROUND

[0002] Slippage at the prosthetic liner and socket interface due to rotational torque while walking is a common problem among transfemoral amputees. There are about 2.1 million limb amputees in the U.S. and 150,000 new people each year with lower limb loss in the U.S. Among the prosthetic users, up to 82% experience discomfort everyday. Among this population, discomfort and skin injury due to shear force stresses at the residual limb and prosthetic socket interface are known problems. Furthermore, having a comfortable and secure linkage between the prosthetic socket and the residual limb is critical for successful rehabilitation and daily living.

[0003] Correct transverse rotational control of the socket on the residual limb is critical for both the stance and swing phases of walking. In the swing phase, transverse plane gait deviations can happen because of poor suspension. In the stance phase, when the body moves over the foot, the ankle and foot absorb the forces resulting from needing to maintain contact with the ground. Due to the fact that the prosthetic does not have the same functionality or adaptability as actual human feet, there is accumulation of shear stress at the residual limb interface. This is especially prominent when turning while walking, which is usually an everyday occurance. Thus, it is important that transverse plane rotation at the interface is kept within a manageable threshold: enough flexibility and rotation to allow proper gait, but not excessive enough to cause other unforeseen secondary issues. In addition, because torque forces from the long axis of the prosthesis are transmitted as shear force stresses at the limb-socket interface, excessive transverse plane rotation is one of the major contributing factors to shear stress. As a result, excessive transverse plane rotation can be caused by excessive torque forces, which stems from a poor suspension system.

[0004] The residual limb volume changes due to various reasons and this may lead to transverse plane rotation displacement. As time passes due to physical and physiological reasons the stump may lose or gain weight and muscle mass. Hence there is a mismatch and gaps at the interface resulting in poor fit at the socket-residual limb interface. This creates unwanted transverse rotation which involves slippage, and displacement of the socket. These unwanted factors all contribute to poor skin health and necessitates frequent visits to the clinic to replace the prosthetic or adjust the liner/sock layers.

[0005] The prior art has not yet developed a liner that adjusts itself as per the pressure changes that happen during the gait cycle. However, there were devices that incorporated air bladders that are inflatable within the liner they are U.S. Patent App. Pub. 2015/9017420 entitled Inflatable Interface for Use Between a Limb Liner and a Limb Prosthesis, and U.S. Patent App. Pub. 1995/5387245 entitled Inflatable Prosthesis Liner. They are static systems that require the user to manually adjust them, and these adjustments are subjective to every individual. Hence, these could be a point of stress and anxiety to the patient. Additionally, instead of adjusting dynamically according to pressure fluctuations, the adjustments are made after the user experiences a certain level of discomfort that may further increase the burden on the user.

[0006] The prior art as demonstrated in the U.S. Patent App.Pub. 2010/7655049 entitled Socket Insert Having a Bladder System uses socket inserts to mitigate the potential gaps to relieve pressure automatically at the interface of the stump and socket. But the bladder in this device employs fluid cells instead of air which are

located at specific locations of the socket. Thus, there is a possibility for slippage in the regions where there are no bladders. Further, the fluid filled cells are prone to leakage may put the user at risk as it is a limited resource that is enclosed within a container. The use of fluids would add on weight to the system which may lead to problems with balance and extra load to the user. U.S. Patent App. Pub. 2013/0218296 entitled Adjustable Prosthetic Socket and Suspension System uses fluid within the liner to adjust for the volume changes between the limb and socket is not adapted for use during the gait cycle. U.S. Patent App. Pub. 1992/5156629 entitled Pneumatic Prosthetic Insert similarly proposed a socket insert that uses air, however it failed to enable regional inflation control.

[0007] There is a need to have a new type of liner that dynamically responds to abnormal fluctuations in pressure at the socket-limb interface. It is also important to detect the abnormal fluctuations even before it leads to physical pain and discomfort to the user. Further, the need is to have an inflatable interface that can precisely inflate the gaps produced at the interface that might be caused due to the transverse rotational slippage at the prosthetic-limb interface. Ultimately, there is a need to have a liner that can sufficiently maintain the suspension without causing any adverse effects on the residual limb. This invention meets all the needs as described below.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 depicts the anterior view of the liner and its components.

FIG. 2 depicts the side view of the liner and its components.

FIG. 3 shows the pressure array system.

FIG. 4 shows the electronics and circuit system.

FIG. 5 shows the different possible modes of the inflation/deflation mechanism.

SUMMARY OF THE INVENTION

The present invention is a device that addresses slippage at the liner socket interface due to shear stresses and external rotational torque while walking for transfemoral amputees that prior art has failed to address, described as follows.

The invention consists of a light, flexible thin sheet of an array of pressure sensors embedded within the prosthetic liner. An array arrangement of fluid, encompassing but not limited to air or water, pockets are weaved throughout the liner in another thin layer within the liner. After the user puts on the liner and turns on the adjustment mechanism, the fit is automatically set and the pressure between the liner and socket is obtained and a range is created to a percentage above and below this threshold. By detecting pressure changes caused by slippage while walking, the sensors read into a controller, such as a microcontroller, which then powers a motor (e.g. air pump) to inflate the appropriate pockets located at the area of slippage to bring the pressure between socket and liner within threshold range, thereby maintaining the fit of the socket. If the pressure goes above the threshold range, indicating the limb is too compressed, a control element, such as a solenoid valve, controlled by the controller will allow the pockets to deflate.

Control elements control the flow of fluid, allowing an open passageway when the motor is running and turned off. If the pocket needs to be deflated from excess pressure at the liner socket interface, the control element will close the main passageway, and open a different flow from the pockets into the surrounding atmosphere, allowing the pockets to deflate and therefore decreasing the pressure.

DETAILED DESCRIPTION OF THE DRAWING

In the following section, possible preferred embodiments of the invention will be described with reference to the figures. Our

invention is a novel prosthetic liner that aims to minimize transverse rotational displacement while maintaining optimal fit between the residual limb for transfemoral amputees, through an automatic inflation and deflation system of microarray air pockets.

The words and phrases pressure, force, rotational torque, and shear stresses are all meant to indicate the readings from the sensor within the liner.

In an embodiment, referring to **FIG. 1,** a front transparent view of a prosthetic liner **170** is shown. The liner houses all the major parts of the device which will be explained in the following section. **FIG. 2** shows a side cross section of the liner, which consists of the outer layer silicone, polyurethane, or other comparable liner material **210,** the pressure array sheet **220,** and microarray air pockets **200**. Referring to **FIG. 4**, the electronics **400** is made up of a single-board microcontroller and a flexible printed circuit board (PCB) or breadboard with resistors, transistors, diodes, and wires attached. The microcontroller controls the valve **130** and motor **140** through a basic transistor-diode circuit **400**. A battery **210** powers the electronics **100.** The wires connect a solenoid valve **130** and air pump motor **140** to the microcontroller **100** for the control of each air pocket. A simple on/off switch **110** is conveniently located near the top of the liner. Tubes **120** connect the solenoid valve **130** to the motor **140** and microarray system of air pockets **160.** An array of pressure sensors **150** is located throughout the liner to detect changes in pressure between the liner and socket interface.

In this preferred embodiment, the pressure sensor array consists of 4 pressure sensor reading points **330**, as shown in **FIG. 3**. A piezo resistive fabric **340** that is integrated with copper tape **320** is employed, and each intersection of the tape acts as a pressure sensor **330.** This arrangement ensures having a broad range of sensors using simple fabric and tape. This system also has the advantage that it is lightweight and surrounds the whole residual limb. This has an advantage that pressure applied by the limb at every location is detected thus helping the air filled array **160** to inflate and deflate accordingly and decreasing the slippage thus increasing the stability. Analog **300** and digital **310** pins connect to the microcontroller **400.** The circuit and system is easily scaled up, simply by adding more copper wire **320** intersections to create more pressure reading points **330** increasing specificity and accuracy. The circuit is completed as a voltage divider with resistors **360** and being connected to ground **350.**

In an embodiment, **FIG. 4** explains the control mechanism for automatic inflation and deflation based on a threshold detected pressure. The automatic mechanism is split up into three regions: Region 1, in which the air pockets will inflate **400** if there is slippage detected and the pressure sensors read values below the threshold value minus a constant **430**; Region 2, in which the air pockets keep inflated **410** if the pressure sensors read values in between the threshold plus or minus the constant value; and Region 3, in which the air pockets deflate **420** if the pressure sensors detect too much pressure, which means an overly tight fit, and the pressure sensors read values over the threshold plus a constant **450**.

The embodiments described above are intended to be exemplary and do not limit the full scope of the present invention as set forth in the following claims.

CLAIMS

We claim:

1. A novel liner and mechanism that can detect the pressure at the residual limb-socket interface and inflate/deflate embedded array fluid pockets

correspondingly within the liner improving fit, comprising of:

a. A pressure sensor array
b. Batteries
c. Controller
d. Control elements
e. Array of fluid pockets
f. Motors
g. Electronics

2. A device as defined in claim 1, wherein a pressure sensor array, including but not limited to a copper tape and piezoresistive fabric system, detects the pressure at the liner and socket interface.
3. A pressure sensor array as defined in claim 2, wherein the sensor array is placed strategically around the residual limb to capture the small changes in pressure specifically and precisely.
4. A device as defined in claim 1, wherein the device controls the inflation and deflation of the fluid pockets according to the pressure readings from the pressure sensor array from claim 2.
5. A device as defined in claim 1, wherein motors, including but not limited to pneumatic pumps, are placed within the liner, and which include both inflation and deflation capabilities.
6. A mechanism as defined in claim 4, in which the motors inflate the fluid pockets when slipping is detected, and deflate the pockets when the pressure crosses the upper limits of the threshold.
7. A mechanism as defined in claim 4, in which a control system controls the flow of fluid from the motors to the fluid pockets and to the atmosphere according to the pressure detected at the socket liner interface.
8. A device as defined in claim 1, wherein a controller controls the actuation mechanism.
9. A device as defined in claim 1, in which the electronics that are powered by a portable battery, which is rechargeable or replaceable, comprises but is not limited to wires, resistors, transistors, breadboards, and diodes.

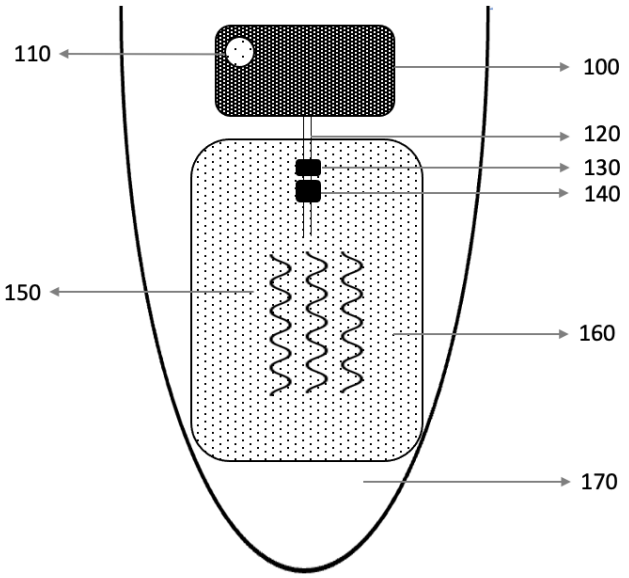

Figure 1

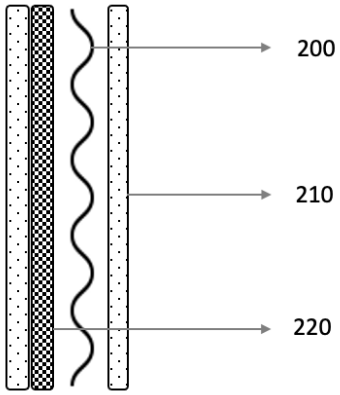

Figure 2

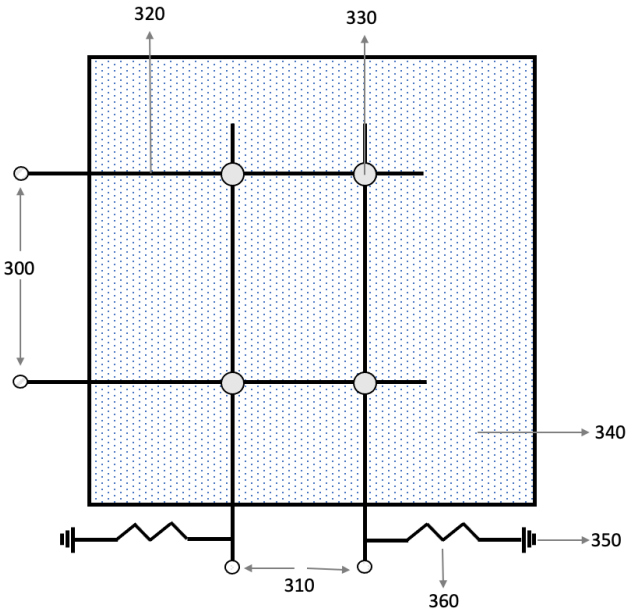

Figure 3

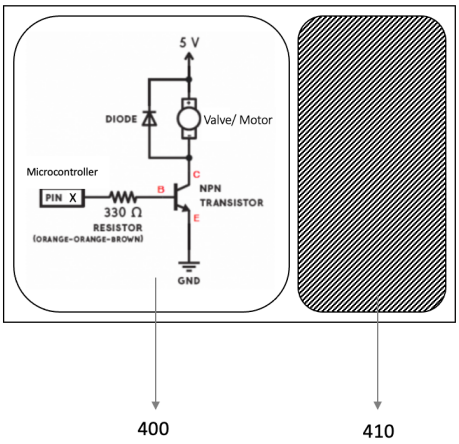

Figure 4

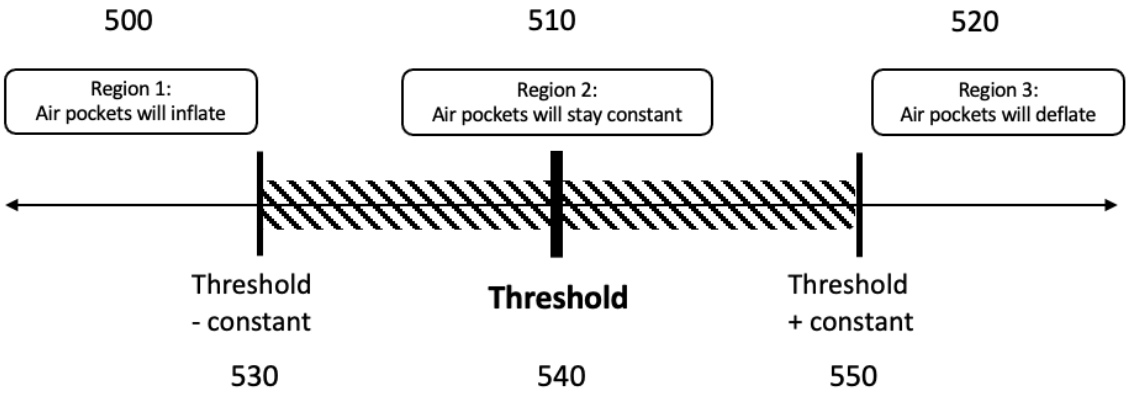
500
510
520
Region 1:
Air pockets will inflate
Region 2:
Air pockets will stay constant
Region 3:
Air pockets will deflate
Threshold
- constant
Threshold
Threshold
+ constant
530
540
550

Figure 5

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