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Design for Manufacturing and Assembly of Direct Socket and Suspension System for Transtibial Prostheses

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ABSTRACT: Prosthetic users always look for two key attributes while donning prosthesis that is comfort and the confidence of secure suspension. If the socket doesn't fit right, is uncomfortable or doesn't feel secure, the other components of the prosthesis will not matter because you're probably not going to wear it. Type of Suspension system also plays a vital role while fabrication on socket because it undergoes normal stress and pressure during different stages of gait. The positive impact of advanced technologies and innovative clinical techniques makes this a good time to be a prosthetic user. But as you learn about new materials and components, it's important to keep in mind that situation differs with different users hence makes any prosthetic user always a unique one. Based on the environment in which we live, daily activities we perform shows an impact of what type of suspension system we are utilizing. But most common and preferable suspension used across globe by prosthetic users irrespective of working conditions is Shuttle Lock Suspension System. Here, in this paper we are going to look after the design methodology of double socket with shuttle lock pin suspension system and how we can easily fabricate it with non-traditional manufacturing technique.

KEYWORDS: Prosthetics, suspension system, Design concepts, Shuttle Lock mechanism, ABS

I. INTRODUCTION

After amputation, you want a prosthetic leg system that allows you to resume the activities that are important to you as an individual. The more active you want to be, the more attention you should give to suspension, the method of connecting a prosthesis to your residual limb. You want your suspension system to Match your activity level and keep your limb in good health, ensure your comfort and provide security with every step. Before knowing which type of suspension, you require you should be aware of the types of forces acting upon a residual limb. Various forces are at work in a prosthetic socket, the shell that encases your residual limb. Different suspension systems have varying control over two forces that can cause pressure points or sores on your limb:

Rotation: The socket twisting against your limb occurs during stance phase of your gait (when you are putting weight on your foot). The shape of the socket and the right suspension system will combine to minimize rotation forces.

Shear: Pulling on your skin as your limb moves in and out of the socket (pistoning)—occurs during the swing-through phase of gait (when you are in the midst of taking a step and your foot is off the ground). The liner material and the right suspension system will control shear forces.

Proprioception means awareness of the movement and position of the body and its parts. In a healthy leg, sensory nerves in muscles and tendons tell the brain where your knee and ankle and toes are and whether they are flexing or wiggling. Your suspension system determines the level of proprioception you can have with your prosthesis. The

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suspension system that gives you the most secure connection between the socket and your limb offers the highest level of proprioception. That awareness translates to performance and confidence.

II. COMPARISON OF DIFFERENT SUSPENSION SYSTEMS

Each suspension system has strengths and weaknesses. Here are some of the factors to think about, and how the systems compare:

Activity level. Shuttle-lock systems, best suited for older amputees and patients with reduced mobility, are mainly for amputees with a mobility or activity level of 1 or 2. Suction can be used for all activity levels. Vacuum is appropriate for activity levels 2 to 4, including the most active amputees.

Comfort. Vacuum and suction both require a total-surface-bearing socket, which distributes even pressure on your residual limb throughout every square inch of the socket's surface area. That pressure relief alone makes these suspension systems more comfortable. The superior connection with vacuum, allowing minimal movement of the limb in the socket, makes it the most comfortable. Suction ranks second in linkage. Shuttle-lock systems offer the least control of forces and allow the most movement and rubbing in the socket, the cause of calluses, blisters and sores.

Performance. Vacuum offers the highest performance for maximum confidence and prosthetic control, which promotes a smoother, more symmetrical gait that uses less energy. Shuttle-lock systems fulfil the needs of users with a low activity level, but users with a high activity level probably would notice a lack of control and security.

Proprioception. Because a pump can generate five times the air-pressure differential of suction, vacuum scores highest here. Some patients say the sense of control is almost like having their leg back. Shuttle-lock systems have the lowest level of proprioception.

Limb health. Vacuum excels at limb health. Vacuum actually increases hydration and blood flow, so open wounds can heal even while you continue wearing the prosthesis. In addition, vacuum helps regulate volume changes in your leg as tissues shrink or expand during the day. As a result, your limb retains its size and shape all day, which helps to maintain a consistent fit.

In contrast, other suspension systems constrict blood vessels, causing leg volume to drop an average of 10 to 14 percent as fluids are squeezed out of your leg throughout the day. A prosthesis that fits tightly in the morning will loosen as the day progresses. Too much movement within a socket can cause pain, blistering and sores. Movement in and out of the socket can lead to repetitive impact forces as the socket slides during while you're lifting your leg to take a step and pounds it back onto your limb when you put weight on your foot again.

Convenience. Shuttle-lock systems are the easiest to put on and take off. However, users of these systems may need to add or remove prosthetic socks up to three or four times a day to compensate for changes in leg volume.

With vacuum and suction, your daily routine includes rolling on a liner and shorter prosthetic sock; sliding into the socket; rubbing lotion on your leg at the top of the liner to prevent dragging on the skin; and rolling up the sleeve attached to the socket's perimeter to create a seal with the liner.

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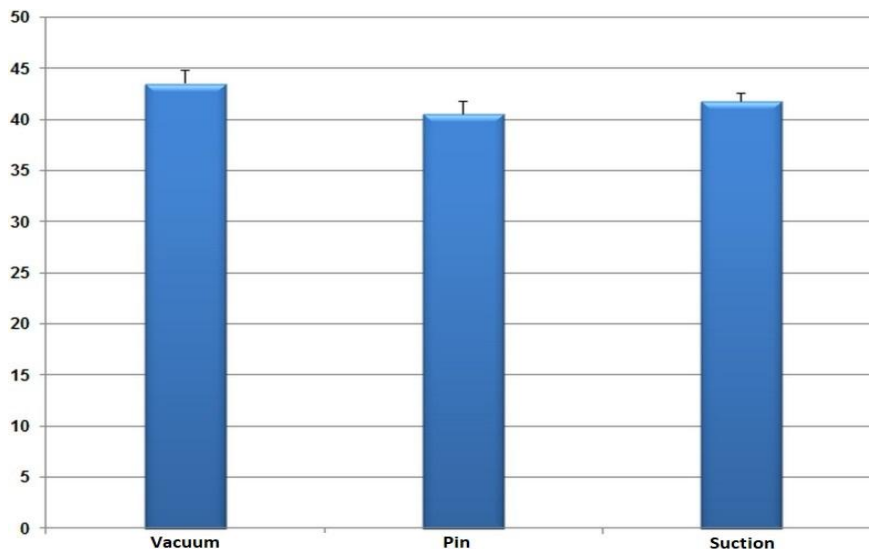


Fig.1: Failure Rate of Different Suspensions available in market

III. DESIGN GOALS

1. The socket will be able to function under a vertical ground reaction force of 1.2 times the patient's body weight. We aim account for a patient weight of 100 kg.
2. The socket must withstand repetitive loading in order to ensure that it can function under cyclic loading coming from an amputee's gait cycle.
3. The socket must allow adequate tissue perfusion through the course of 8 hours. Therefore, the socket must allow enough blood circulation for the user over this period of time based on the average amount of time we propose the person would be walking on a daily basis.
4. In many developing countries of the Asia-Pacific region, information on methods of producing assistive devices is not easily accessible to users or to agencies and organizations which could produce those devices. This supplement contains a selection of technical details pertaining to prostheses and orthoses, wheelchairs, other devices for people with mobility difficulties (e.g., crutches and handgrips), and hearing aids. The selection indicates that small-scale workshops which have the basic tools and skills could go a long way towards helping to meet the need for appropriate devices, especially in rural communities.

IV. DESIGN METHODOLOGY

The overall design for this suspension system was treated as an investigation of feasibility. After performing the necessary background research and studying the available products on the market, it was determined that constructing an entire prosthetic leg was not necessary. A socket/suspension system would be much more realistic to design any limited timeframe of this project. Additionally, the market for a suspension system is substantially larger than that of complete prosthesis. The process for designing this new product focused first on what needs of the user would be. Those needs were assessed through research and confirmed with a professional. Next, products on the market are carefully evaluated for their function and key attributes.

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In order to build upon current ideas, areas of potential innovation were discussed. Mechanical ideas included novel actuation methods such as hydraulics and pneumatics or linear motors, spring storage techniques. Shuttle lock with integrated adapter for injection moulding. Ultimately, it was decided that the main unique novelty of this design which would be the pressure application and snug fitted. None of the current prosthetic legs on the Indian market included a shuttle lock system. Additionally, on the controls side, it was determined that including a visual force feedback to the user through variable click sounds would be innovative. Finally, an overall theme of cost reduction would put this suspension system into a much broader market. A set of design requirements was formulated and adhered to for the remainder of the project. The design process began with brainstorming followed by rough pencil sketches and finally detailed computer aided design work using Solidworks CAD software. As the mechanical design progressed, most mechanical components were sourced and integrated into the design. The design was continually updated with new iterations each day until it was optimized enough for manufacturing purposes. When doing detailed design work, a “product” mindset was adhered to. This meant that the quality of the finished product, in addition to the manufacturability, would be of equal importance. For example, when possible, multiple of the same components should be used as opposed to individual separate components. Similarly, reducing the overall number of parts and components would be hugely beneficial. Understanding and thinking about how each custom component would be manufactured was accounted for during the detailed design process.

4.1 Mechanical Design Of Socket Preparation

Detailed mechanical design was accomplished through the use of rough hand drawn sketches and Solidworks CAD software. Backup data and part files were kept throughout the design process and can be made available upon request. Individual parts were carefully modelled with as much detailed information and accurate dimensions as possible. When working with such limited space and small components, accuracy was a priority.

4.1.1. Shell Design

Different amputees will have different residual limb portion based on the standard provided by Alpha Duo liner with uniform profile sizing guide appropriate Medium Plus size was selected because it is the standard size for average human residual limb and to produce the mould which will have a integrated injection system to inject Silicone Inside it, to develop a liner which will be a essential system for human machine integration.

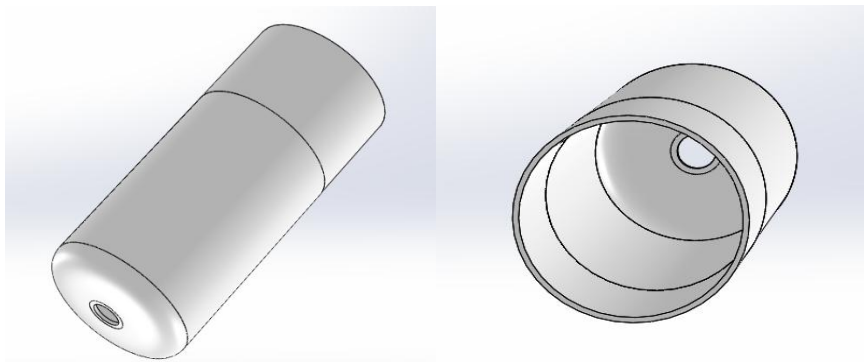


Fig.2: Shell Mould designed in Solidworks

Mass of the material is 96 grams
Material – Polypropylene
Volume = 93996.23 cubic millimetres
Surface area = 94809.04 square millimetres
Centre of mass: (millimetres)
X = -0.02; Y = -0.01; Z = 73.70

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4.1.2 Coupling System

The coupling system one of the integral part of the socket-liner interface because it contains the adapter for the injection system which will be used for the guide ways for the silicone with shore hardness value of 10 to flow inside the shell to produce the desired thickness of the liner and relevant ports for the lock pin mechanism. Desired port of the pin which will connect the silicone liner to the double socket suspension system should always taken into the consideration. Therefore, accurate dimensions and precision will be taken into the consideration while designing the coupling mechanism.

4.1.2.1. Parts in Coupling System

These images (Fig.3) show the results of detailed CAD work and design iteration and refinement

A) Silicone Liner Adapter

Silicone adapter is one of the two part coupling system between liner and socket. When the silicone is filled in the shell the bottom portion mimics the structure of the residual limb and gives the advantage of adding the pin for the shuttle lock mechanism.

Silicone adapter is made of the same silicone material or different material with variable thickness to give the padded and cushioning feel to the amputee while donning the liner.

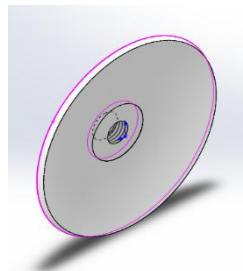


Fig.3: Silicone Adapter

B) Suction Coupling

This device is the other portion of the other portion of the two part coupling system. It is made up of Aluminium 1060-H14 for sustaining high compression loads as well as shear load during gait cycle. This portion extrudes from the inner socket portion which enables user to insert the shuttle lock housing directly after the injection of silicone is done.

Due to Aluminium 1060 -H14, the mass of the component is very low that is therefore, 32 grams increasing the portability index for the user.

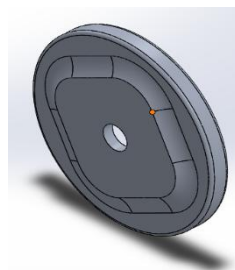


Fig.4: Suction Coupling

C) Holding and Locking Pin

This device is basically a bolt and nut but with circular teeth. During injection process there can be leakage of the synthetic fibre for the socket system and to make a suspension system integrated to the socket itself there should be an accurate gap or tolerance for the socket material because during the assembly of the shuttle lock housing the tolerance plays a vital role while putting up the socket system.

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The other use of locking pin is that it has the injection hole which enables us to inject the silicone inside the shell with ease.

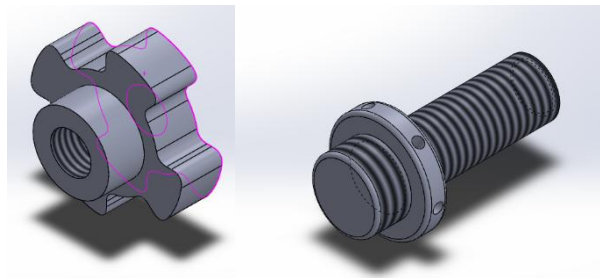


Fig.5:Holding and locking Pin

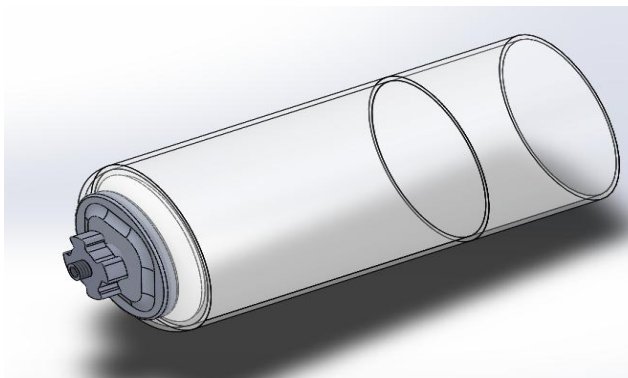


Fig.6: Assembly of Coupling System

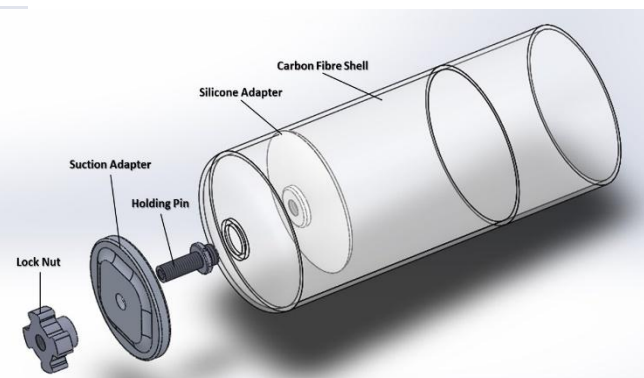


Fig.7: Exploded view of Coupling System

4.2 Mechanical Design of Shuttle Lock Suspension

The advantages of shuttle locks include the following:

- A) They produce an audible “click” when a patient engages the pin lock. This is a strong advantage for patients that desire the confidence of knowing that they are locked securely in the pin lock.
- B) No key is required to help the patient wind down fully into the lock.
- C) Widest variety among pin locks to choose from.

Criteria for Choosing a Lock Before choosing a pin lock, the practitioner should consider the following:

- 1) The patient’s weight: Most pin locks have weight limitations. Some manufacturers, however, have assigned no weight limitations to specific pin lock models in their inventory because they consider those pin locks to be non-weight bearing components. Several pin locks, most notably those manufactured by Prosthetic Design, Inc., have more than one weight limitation depending on the specific activity level of the patient. Therefore, we have taken a consideration of 100kg weight of the patient.
- 2) The patient’s activity level: Active patients place more stress upon a pin lock; therefore, it is important that the practitioner choose a pin lock with good wear characteristics when selecting components for an active patient. If the patient is involved in sports, the practitioner may want to consider a pin lock that is both light and durable in order to keep the prosthesis as light as possible, but able to withstand the demands placed on it by athletics.
- 3) Patient’s hobbies and/or occupation: If the patient is active in harsh environments where the pin lock may be exposed to water, mud, chemicals, and/or other caustic elements, the practitioner should choose a lock with the ability to withstand these destructive elements, yet still function properly. Also, if the patient is involved in activities where accidentally engaging the push button is a risk factor, such as riding a motorcycle, it may be wise to purchase a pin lock with a pull button or a locking push button.

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4) The patient's age: When fitting a child with a pin lock a practitioner should bear in mind that there are a handful of pin locks designed for paediatrics. These locks are smaller in circumference and conform well to the small distal end of a child's residual limb. Adolescents, teenagers, and adults have an abundance of pin locks to be fitted with since most pin locks are designed for full-grown adults. While many geriatric patients are extremely active, practitioners should choose a light pin lock for elderly patients that are inactive and have weak musculature. Elderly patients with poor vision will specifically benefit from a shuttle lock because of the audible feedback produced when the rastered pin engages the pin lock. This will reassure them that they are safely locked into the socket. Based on all the criteria we have designed a shuttle lock system which is most affordable, easy to use and can withstand stress levels up to a threshold intensity.

4.2.1. Parts in Locking System

These images show the results of detailed CAD work and design iteration and refinement

A) Pin

The shuttle lock pin a device which enables the amputee to fit his residual into the silicone liner which will have the pin attached under the residual limb. This pin has pyramid structured extrusion which snugly fits into the socket.

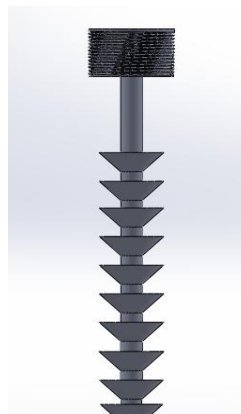


Fig.8:Shuttle Pin

B) Housing

The outer body in which all mechanism gets assemble into is known as housing. It also as jig for the liner hence guides and constrains the who assembly.

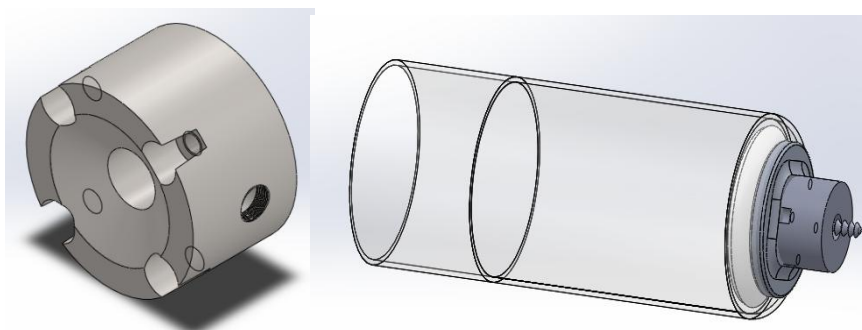


Fig.9:The Housing and housing assembly with adapter

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The housing is made up of plain carbon steel because it does not react with the atmosphere readily and can increase the life of endurance and durability of the lock.

C) Clutch

Clutch system is the amalgam of all small components such as spring adapter, springs and a wedge-shaped pin which is used to lock the system during intake of liner and it is also used to unlock the system when the prosthesis is not in use.

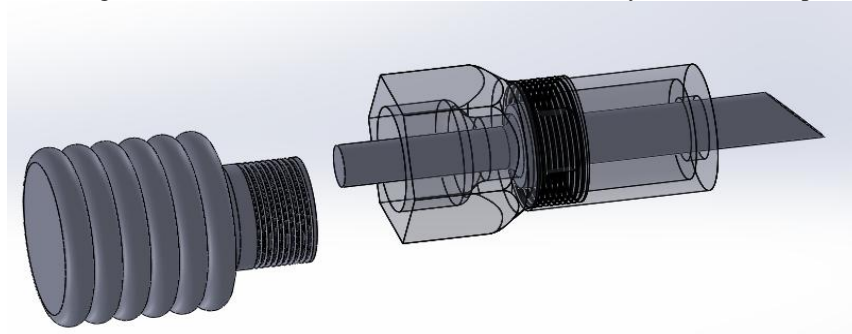


Fig.10:Clutch Mechanism

D) Hex Nut and Plunger

Hex nut is the dimensional constrain for the pin with enables the user to use spring action to release the potential energy stored in the springs when the shuttle pin locks. Plunger is the device which is used to release the energy stored in the spring by user.

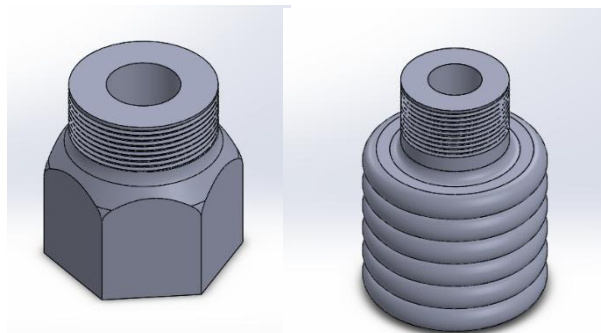


Fig.11: Hex Nut and Plunger

All the components are designed according to the proper dimensional analysis and can easily be 3D Printed with the metal 3D Printer.

The material used for whole locking system is plain carbon steel.

Note- The Springs are not given in the system but are illustrated in the Fig.15

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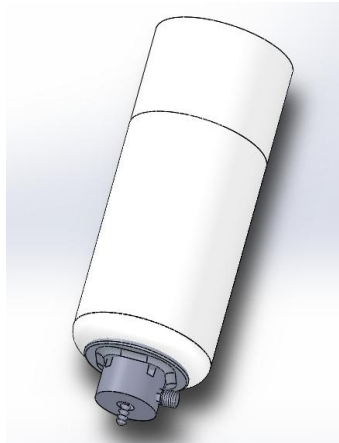
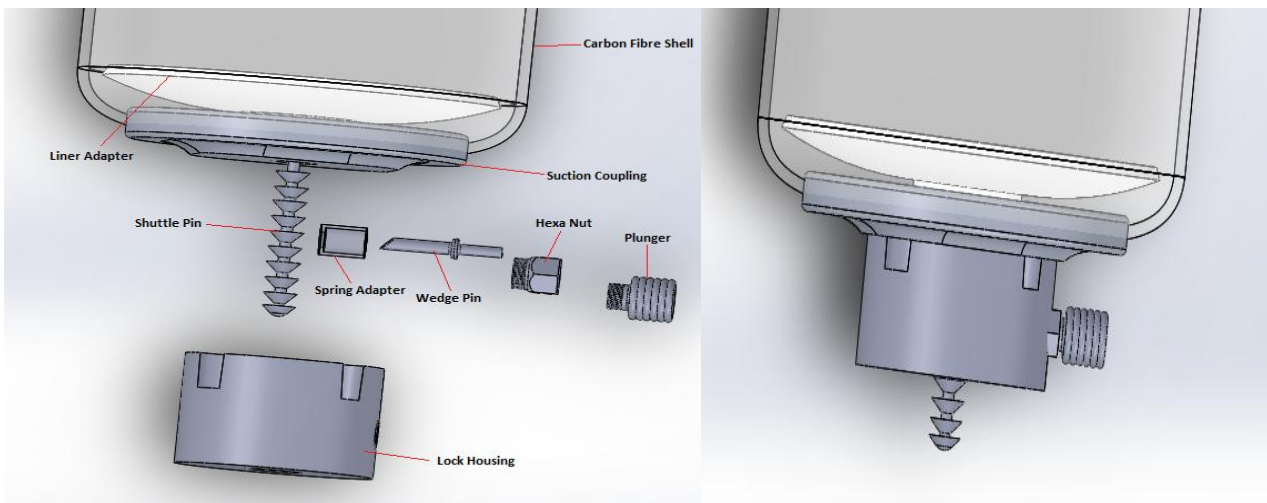


Fig.12: Assembly of Shuttle Lock System



Exploded View of Shuttle Lock System

Fig.14: Shuttle Lock Zoomed Preview

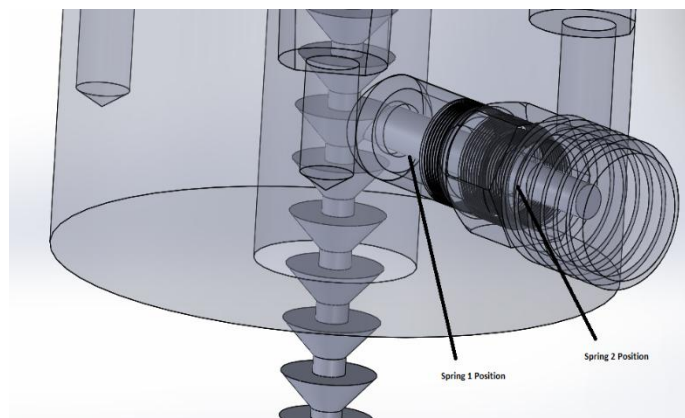


Fig.15: Spring Assembly

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V. CONCLUSION

A complete mechanical design of a suspension system was developed in a short time frame. It was proven to have increased functionality over currently available products. The use of a shuttle lock allowed for proper damping during the gait cycle. The carefully thought out use of universal components allowed for a tight packaging of the complete system while keeping costs to a minimum. The ease of manufacturing of the components for one system was proven by having outside companies actually produce the parts needed. It is clear that there are going to soon be many more prosthetic suspension options as more companies decide to enter the market and produce competitive systems. With the commonly available hobby and remote-control industry components developed today, there is less need to seek out the absolute top of the line precision industrial components. In a large company there is a standard way of designing and creating new systems, and that mostly involves using the highest level of components possible because the designers are not directly paying for the research and development, nor do that care much about the final cost of a high-end item. When an individual design a new system, not working for a company, they are able to challenge traditional design and manufacturing methods to produce an equivalent product more quickly and easily.

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