Facilitating Locking Pin Alignment in Transtibial Amputees

via Auto-Retracting Tethered Pin

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Abstract

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Transtibial amputees have a variety of suspension systems available to them. One of the more common systems uses a locking pin to create a mechanical connection to their prosthesis. For those using a locking pin, it is common for the user to partially doff while seated in order to release pressures created by the socket on the residual limb. When attempting to re-don, there can be difficulty aligning and inserting the pin into the lock, requiring multiple attempts or for the user to stand with a not yet connected prosthesis. This can be an issue and possibly a fall risk for a new user or someone who has poor proprioception. By introducing an auto-retracting tether between the socket and pin, a constant connection is created. The retraction guides the pin into the lock without fail and allows for ease of donning while seated. In this investigation, a prototype design is modelled and built. Transtibial amputee participants are fitted with the system and provide feedback to further develop the system. Feedback was overall positive with a majority saying they would personally use the system. This improved functionality is designed to promote the frequency of partial doffing which may positively impact limb health.

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John, for his wealth of knowledge and constant guidance.

Dr. Sanders, for providing me the opportunity to work on such a rewarding challenge.

DEDICATION

This work is dedicate to my wife, Michelle,

for her unwavering support and encouragement

throughout all my endeavors.

CHAPTER 1: INTRODUCTION

1.1 Background

Transtibial amputees have many options for prosthetic solutions. There are feet designed to aid in balance, articulating motorized feet designed to mimic the natural motion of the ankle, even non-anthropomorphic feet which are mechanically advantageous over the human foot [1]. There are suspension systems that use mechanical connections, vacuum pressure, suction, and even Velcro. Despite all these innovations, there is still no perfect solution and the difficulty of coupling to the human body persists.

Of the suspensions mentioned above the most common are locking pin (mechanical), and vacuum. Vacuum suspension is achieved using a special liner and external sleeve. The residual limb with the liner is inserted into the socket and the sealing sleeve is placed such that it overlaps the lip of the proximal socket. A vacuum pump, typically distal to the socket evacuates the sealed space between the liner and socket wall. More advanced vacuum systems, like Össur's Unity, uses the Seal-In liner, a ribbed liner which eliminates the need for the sleeve. The locking pin suspension is much simpler. A rigid pin is affixed to the distal end of the liner and the distal socket has a shuttle lock. The pin is inserted into the lock and a mechanical connection is made.

With most suspension systems, especially with locking pin, limb volume decreases throughout the day. The suspension force created by the pin is localized to the distal end of the liner, which causes a squeezing of the liner proximally. This squeezing pulls volume out of the proximal limb and traps it distally [2]. This effect is often referred to as "milking." As the day progresses, and volume decreases, socket fit deteriorates. The loose fit allows for high shear forces between the limb and prosthesis which can lead to skin damage. Vacuum suspension has been shown to actually benefit limb health. In comparing vacuum and suction conditions, Board et al. found that vacuum suspension can actually increase limb volume [3]. They believe this is due to either a reduction in lost volume during stance, or an increase in recovered volume during swing, or both. Despite the obvious benefits of vacuum suspension, the locking pin is often preferred. Gholizadeh et al. compared user satisfaction of the Seal-In X5 and Dermo liner (pin liner) [4]. Despite reporting better fit and greatly reduced pain, overall satisfaction was significantly higher for the pin. This result was almost entirely due to the difficulty of donning and doffing with the Seal-In liner.

Since the pin is preferred despite its shortcomings, many users take measures to improve their comfort. One such measure is partial doffing. While seated, the prosthesis creates a torque against the residual limb, resulting in pressure and discomfort in the posterior-proximal leg. To relieve this pressure, the user will release the pin and partially remove the residual limb from the socket. While the limb does recover volume, problems arise by partial doffing. Since the prosthesis is no longer attached it is possible for it to fall over. An anecdote shared by one participant during this study exemplifies this issue. He partially doffed during a public event and his prosthesis fell over. He had no choice but to fully remove his pants in order to re-don. While seated, when a user wants to re-don, the pin and residual limb are at an angle relative to the shuttle lock. This misalignment can become troublesome as the pin may miss the shuttle lock and the user would need to keep attempting to align the pin. Often users will not attempt to engage the pin while seating and will instead stand, then engage the lock. This can be particularly difficult and can be a fall risk for a user with a new amputation who is still learning about their prosthesis, or one with poor balance or proprioception due to illness or other complications, e.g. diabetes or peripheral neuropathy.

1.2 Available Solutions

There are a multitude of available suspension systems for transtibial amputees which may aid in partial doffing, but none of which are specifically designed for such. There are products from well-known companies, such as Össur, as well as lesser-known options like the K.I.S.S. and HOLO systems.

Össur provides many suspension systems, one of which is in part similar to the proposed solution to be described later. The Össur Icelock 300 series seen in Figure 1.1 uses a lanyard attached to the distal liner that runs through the bottom of the socket, then is pulled externally towards the proximal end of the socket in order to pull the residual limb fully into the socket.

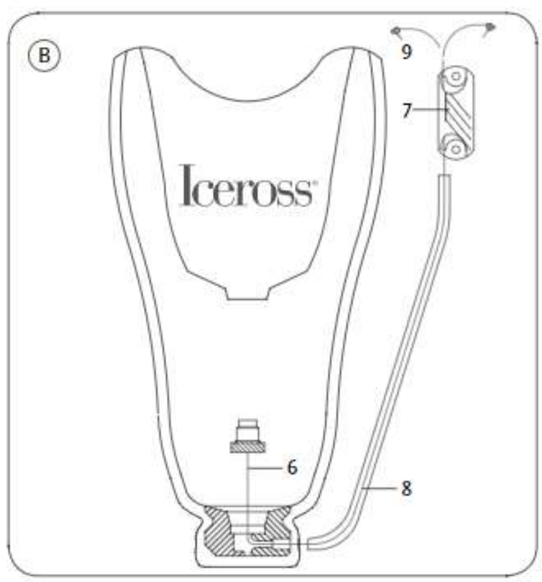


Figure 1.1: Össur Icelock 300. Image taken from ossur.com

The lanyard is then clipped to a cleat in order to secure it. This is a good solution for guiding the end of the limb correctly into the bottom of the socket, but it fails to provide an easy partial doffing/donning experience. The way it is designed, the lanyard is only secured while the prosthesis is fully donned, thus if a user were to partially doff, the experience is no different than with a standard locking pin. As a further complication, if the user is wearing pants, he/she would need to roll their pant leg up in order to draw the lanyard proximally towards the cleat. The lanyard is also not as rigid as a locking pin and thus could cause greater pistoning. This option also requires a socket only compatible with the lanyard system and the cleat requires holes to be drilled in the proximal socket to be attached.

Össur also provides the common vacuum and suction suspension systems. Although these suspensions likely best reach the end goal of regulating limb volume and fluid flow, it has been shown that amputees tend to prefer the simplicity of the locking pin [2]. Partial doffing is impractical with these systems; most require a sealing sleeve be worn externally around the rim of the socket, which again would be impossible to manipulate while wearing pants, and very time consuming otherwise. Össur has made the Seal-In sleeveless liner, which removes the need for the sealing sleeve, but often fail as a reliable suspension due to leaking. Like the lanyard, this requires specific components that are only compatible with Össur vacuum systems.

Figure 1.2: Össur Seal-In Liner. Image taken from ossur.com

Another solution, much like the Icelock 300, is the Keep It Simple Suspension (K.I.S.S.), which replaces the lanyard with a strip of Velcro.

Figure 1.3: K.I.S.S suspension. Image taken from kiss-suspension.com

The Velcro strip is run in the same fashion as the Icelock 300. Since the entire strap is covered in Velcro, the K.I.S.S. is capable of partial attachment unlike the Icelock 300, which would allow for continued attachment during partial doffing. However, like the previous systems, manipulation would be impossible with pants, and is still complex otherwise.

Another Velcro-based solution is the HOLO (Hook and Loop) system, seen in Figure 1.4. The HOLO is donned/doffed by simply rolling the lateral/medial Velcro bands until the prosthesis is fully coupled. Then a secondary securing band is wrapped around the socket. The issue of partial donning with pants persists. The HOLO was also evaluated via the prosthesis evaluation questionnaire (PEQ) and directly compared to other common suspension systems, of most interest the locking pin. Overall satisfaction was slightly lower for the HOLO system compared to locking pin, and most were dissatisfied with the sound of the HOLO [5].

Figure 1.4: H.O.L.O Suspension system. Image taken from [5]

This thesis outlines the development and initial evaluation of a novel locking pin suspension system to be used by transtibial amputees. A system that aims to address the shortcomings of currently available solutions, a system that will provide amputees with an easy to operate and secure suspension that allows for simple and secure partial donning and doffing while the user is seated.

The new system builds upon the normal locking pin suspension system by adding two major components: a modified locking pin with integrated quick release, and an auto-retracting, auto-locking tether reel. The system will henceforth be referred to as the Retractable Tethered Pin (RTP) suspension system. The RTP system is designed specifically to aid in partial donning/doffing while seated. It is also designed to be quickly and easily integrated into the user's current locking pin system. The tether provides constant connection to the prosthesis and guides the locking pin directly into the shuttle lock without fail. Unlike the previously mentioned systems the tether reel does not require direct manipulation. It functions by simply pulling with the residual limb with varied force relative to the socket in order to activate the auto-retracting mechanism.

CHAPTER 2: DESIGN PROCESS

The design process for the RTP was carried out in three main segments. First a set of design criteria was established. Next the RTP went through an iterative conceptual design phase via Autodesk Inventor CAD modelling. Once a general concept was chosen, that design was prototyped first with 3D printed parts using an Objet30 Pro, then chosen parts were sent out for fabrication.

2.1 Design Criteria

The RTP has to be capable of being integrated with a user's current shuttle lock (Össur Icelock 700). This will ensure a user will be able to still use their current socket, reducing the time to deployment of the new system, as well as maintaining a sense of familiarity with their prosthesis. Obviously adding components onto a current system will add weight and volume, but minimizing weight and creating a compact, unobtrusive design are of high importance. Since the RTP will be used frequently on a daily basis, it is of utmost importance that the operation be simple, intuitive, and reliable. Further usability criterion was added during the first phase of user evaluation; one participant was a multiple-amputee and thus one-handed operation is a design requirement for the RTP. A very high strength of retraction is necessary in order for the pin to be pulled into the bottom of the socket but safety of the user as well as their prosthesis is a top priority, so a mechanism to regulate that strength is necessary.

2.2 Conceptual Design Phase

The RTP is comprised of two components: the auto-retracting tether reel and the connection of the tether to the pin. The connection of the pin is dependent on the reel mechanism, so both were designed in parallel.

2.2.1 Auto-retracting tether reel

Once it was determined that a tethered system was to be implemented as a solution to re-donning after partial doffing, it was decided that in order to improve upon the user experience of current solutions like the Icelock 300, the tether retraction had to be automatic. Inspiration for such a mechanism was initially drawn from tape measures and badge reels, specifically the use of constant force, or flat spiral springs to create the retraction force. A high retraction force is required for proper function. The force is approximately equal to the weight of the prosthesis. This creates an approximate equilibrium wherein the prosthesis will stay partially doffed and not continually try to retract as well as strongly guide the pin through the shuttle lock. If a simple constant force spring was to be used there would be continual tension in the tether which translates to a continual traction force on the residual limb from the gel liner. This "milking" effect has negative effects on limb health [6]. This is already a common issue with locking pins during gait, so it was necessary to eliminate this compounding effect.

In order to reduce the milking effect, a braking element was introduced. A brake would clamp the tether preventing continual retraction while partially doffed and creating slack in the line. Based on rope ascension devices, a small cam was placed along the length of the tether. The camming device would be housed within the pylon itself; see Figure 2.1. The cam (purple) would be loaded with a torsion spring such that it would be constantly pinching the tether (thin green) against the housing (red). The change in radius of the cam acts as a one way catch; the tether can be extended freely without resistance, but the retraction force will only increase the camming action. In order to retract the tether, the cam can be manually released (rotating the blue knob) either fully if the user wants a strong pull in order to don, or partially for a weak pull in order to simply retract the tether after doffing.

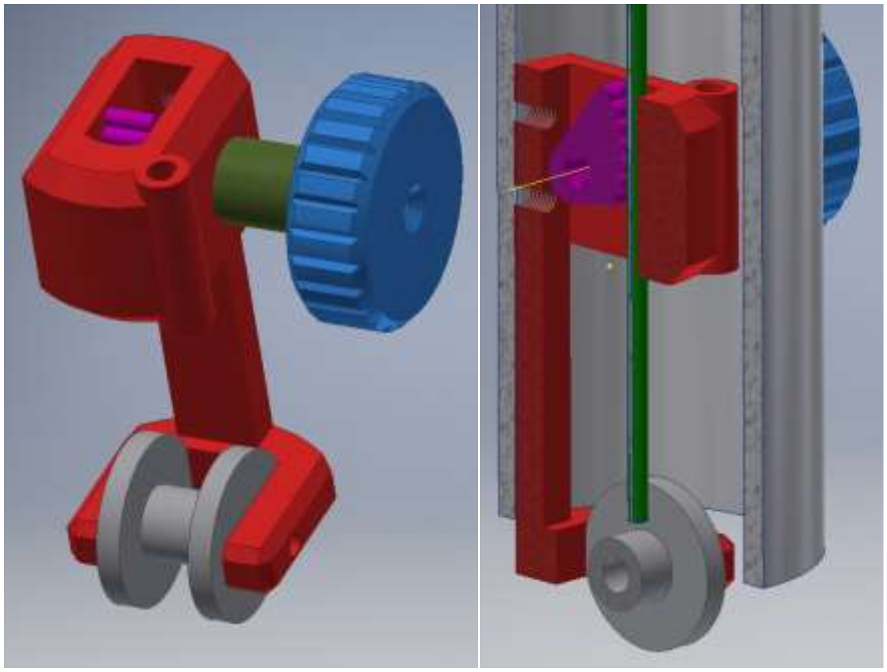


Figure 2.1: Camming tether lock

Upon further evaluation, this design was deemed too complex. The direct manual control, i.e. rotation knob, was too distal and would be hard to manipulate, so it was determined that the control had to be more proximal. This required that the rotational motion of the cam be translated to a linear actuation. This translation and the tight dimensions of the pylon would require the machining of custom gears. It was also decided that control of the tether retraction should be more direct, i.e. control of the tether is achieved via manipulating the tether itself. With the cam brake, in order for the user to retract, he/she would need to hold open the cam the entire time while re-donning.

The next and final iteration of the reel design took inspiration from car seatbelts. Attached to the spool of most seatbelts is a small arm with teeth on the end. Attached to the housing of said spool is a ring of oppositely facing teeth. The arm is attached in such a way that at high rotational acceleration it swings free by centrifugal force and catches on the ring of teeth, thus locking the seatbelt in place.

Referencing Figure 2.2, as the spool (central ring) rotates counterclockwise, even at high speed the attached arm will never catch on the teeth of the outer ring. However, once rotated clockwise, the arm falls against the ring and catches in the groove of a tooth, locking in place. Generally the arm is weakly spring-loaded such that it holds it clear of the teeth during a slow clockwise rotation.

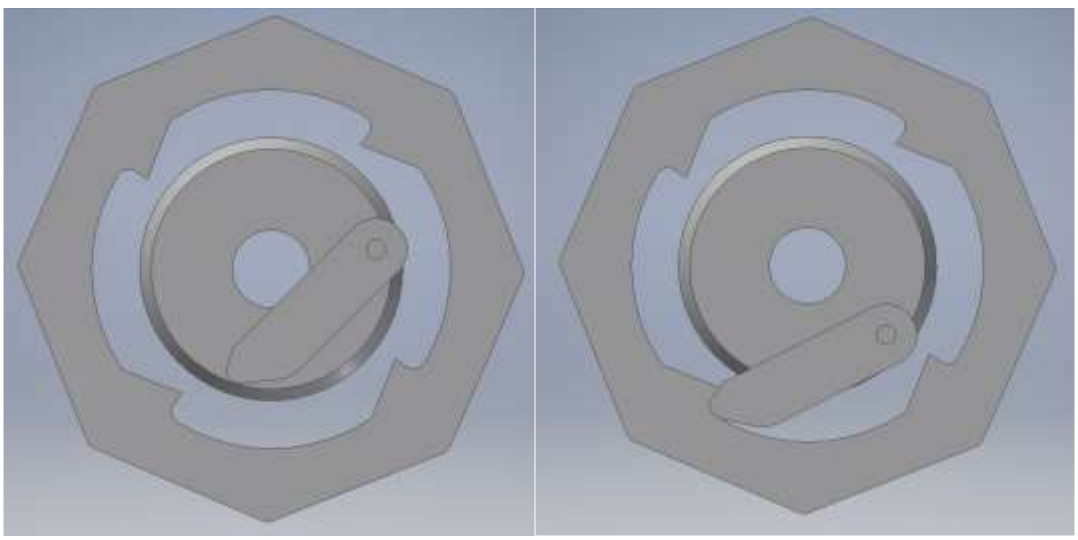
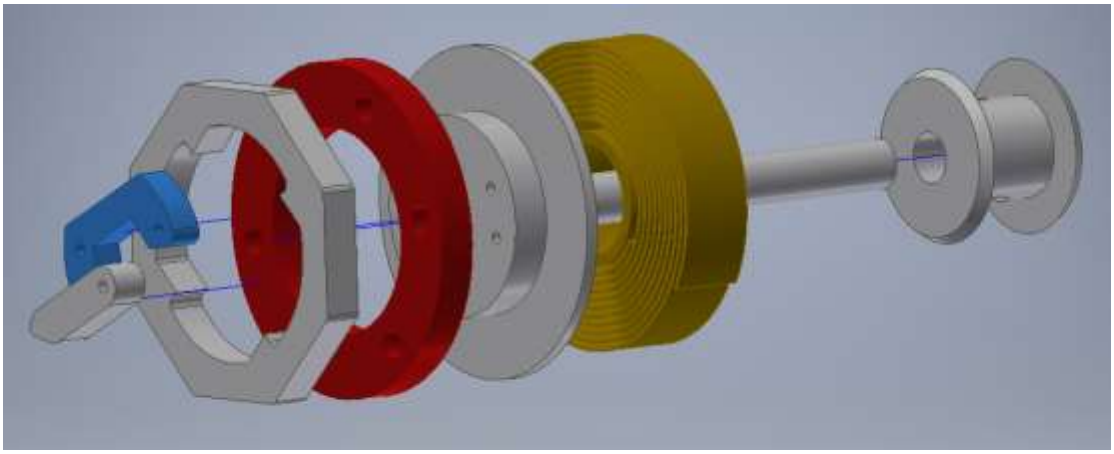


Figure 2.2: Seatbelt locking mechanism

By simply reversing the direction of the teeth relative to the spooling direction, the opposite effect can be achieved, i.e. extension causes no interfacing of the teeth, but fast retraction locks the system in place. This is the desired effect for the RTP. Figure 2.3 illustrates the mechanics of the RTP retractor.



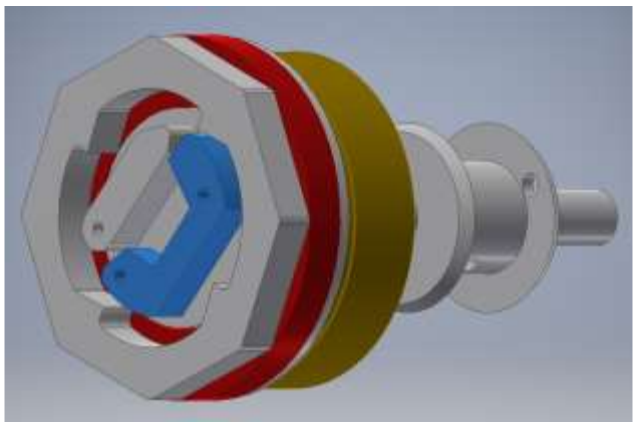


Figure 2.3: Top: exploded view of retractor. From left to right: arm, spacer (blue), tooth ring, thrust bearing (red), mounting rod, spiral spring, tether spool. Bottom: assembled view of retractor.

In order to prevent the need for gearing, all the rotational components, e.g. spool, spring, brake, are kept on the same axis of rotation. The system is best described in planes. The first plane is the locking mechanism where the arm and spacer sit within the radius of the tooth ring. During rotation, the blue spacer keeps the arm in place, and is an attachment point for the mechanism that keeps free of the teeth during slow rotation in either direction. The spacer and arm are loose and press fitted onto dowel pins extending from the base of the mounting rod which is the central axis and attachment/coupling unit for all the mechanisms. The next plane is the thrust bearing (red) which interfaces with the tooth ring and largest radius of the mounting rod. This radius also acts to separate the lock from the spiral spring which is the next plane. Finally some distance from the spring is the tether spool. During extension, the system translates the spool rotation to spring potential energy and during retraction, spring energy into adequate rotational acceleration to swing the arm into the tooth ring. Since the spool had to be relatively small in order to fit within the pylon, to provide adequate excursion of the tether, the spring coil had to be relatively large and thus would not fit within the pylon as seen in Figure 2.4. A three-piece external housing was added to not only contain the system, but to anchor it to the pylon.

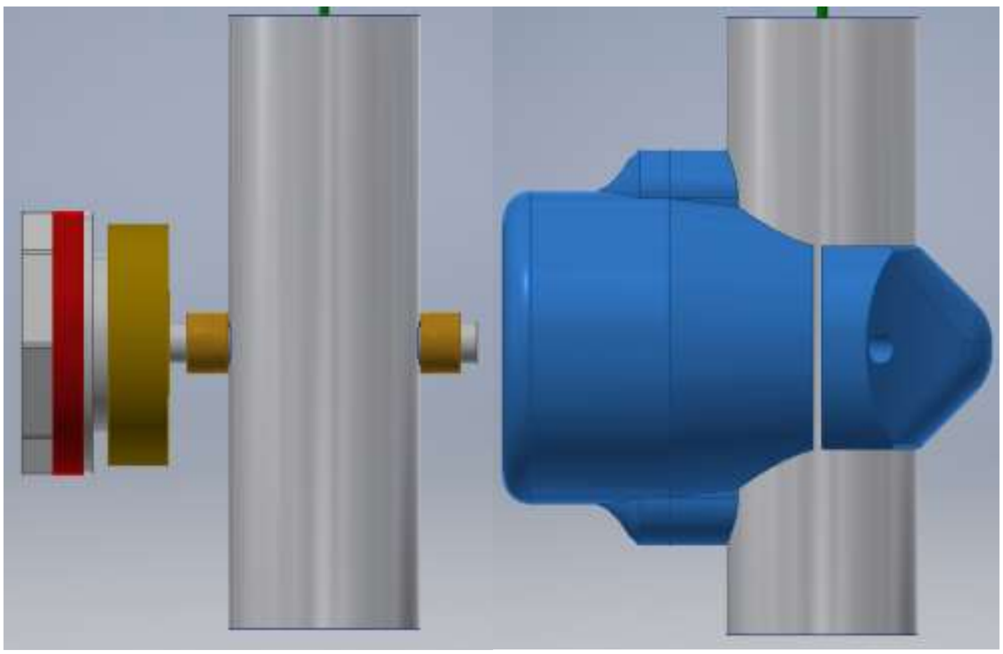


Figure 2.4: Left: Retractor attached to pylon. Right: Retractor housing attached to pylon

This new design, although more obtrusive, greatly simplifies the user experience. To partially doff, simply pull the prosthesis free from the residual limb, then quickly create slack in the line to engage the brake. The prosthesis is now loosely tethered to the limb. To re-don, slightly extend the tether to disengage the arm, and the balanced force of the spring will slowly guide the pin directly into the shuttle lock. Once mastered, the whole process can be done hands-free by anchoring the prosthesis with the other foot.

2.2.2 Quick-Release Pin

Regular locking pins are threaded into the distal liner. Since with the RTP there is a persistent connection between the socket and the liner and thus the user, it is necessary for the pin to be quickly detached, and a threaded attachment is unacceptable. Previously mentioned, a requirement for the design was that the new system would be able to integrate with the user's current socket and shuttle lock. This introduces an issue in the options for a quick release connection. Referencing Figure 2.5, at the distal end of the liner (tan) is an umbrella (orange) which is the threaded connection for the pin. To don, the pin is inserted through the shuttle lock (dark gray). The umbrella nests into a funneled nylon disk (light grey). As can be seen there is little room for alteration of the pin. To further complicate the issue, the quick connection has to be above the flared ring of the pin in order to prevent the pin from being pulled fully through the lock and lost in the pylon. Thus the quick connect mechanism essentially has to be within the threading of the pin.

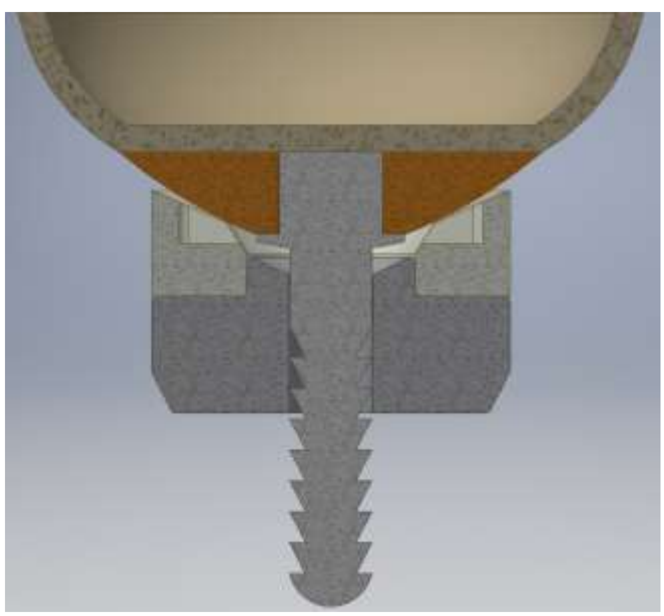


Figure 2.5: Cross-sectional view of standard locking pin inserted into shuttle lock

Different types of threaded to quick-release adapters were developed. First a BNC type twist adapter was modelled.

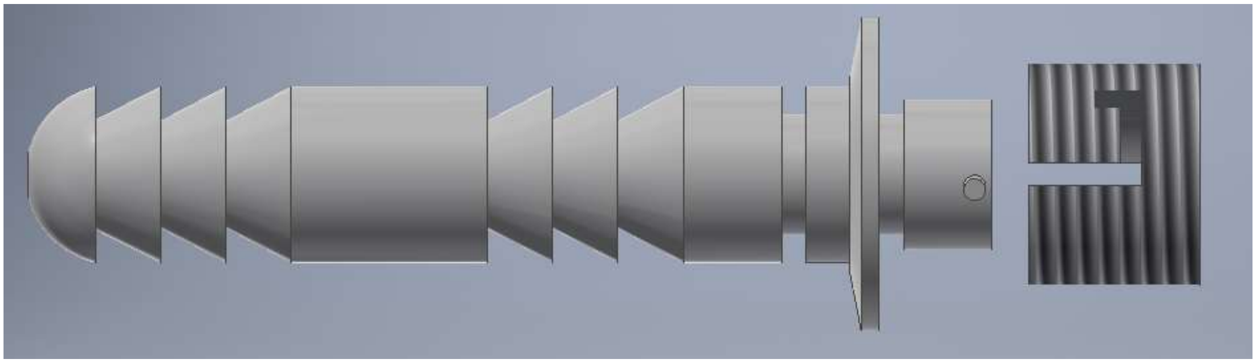


Figure 2.6: Twisting quick release pin

In this design the flare of the pin is a separate part and is spring loaded. The threaded adapter is inserted into the umbrella and the pin is slid into the adapter's slots and twisted. The spring loaded flare acts as a counter force to lock the pin in place. This design was determined to be too complex and potentially insecure; if the pin was impacted while trying to insert into the shuttle lock, it could potentially unlock.

The second adapter type was based on the ball bearing lock used with socket wrenches.

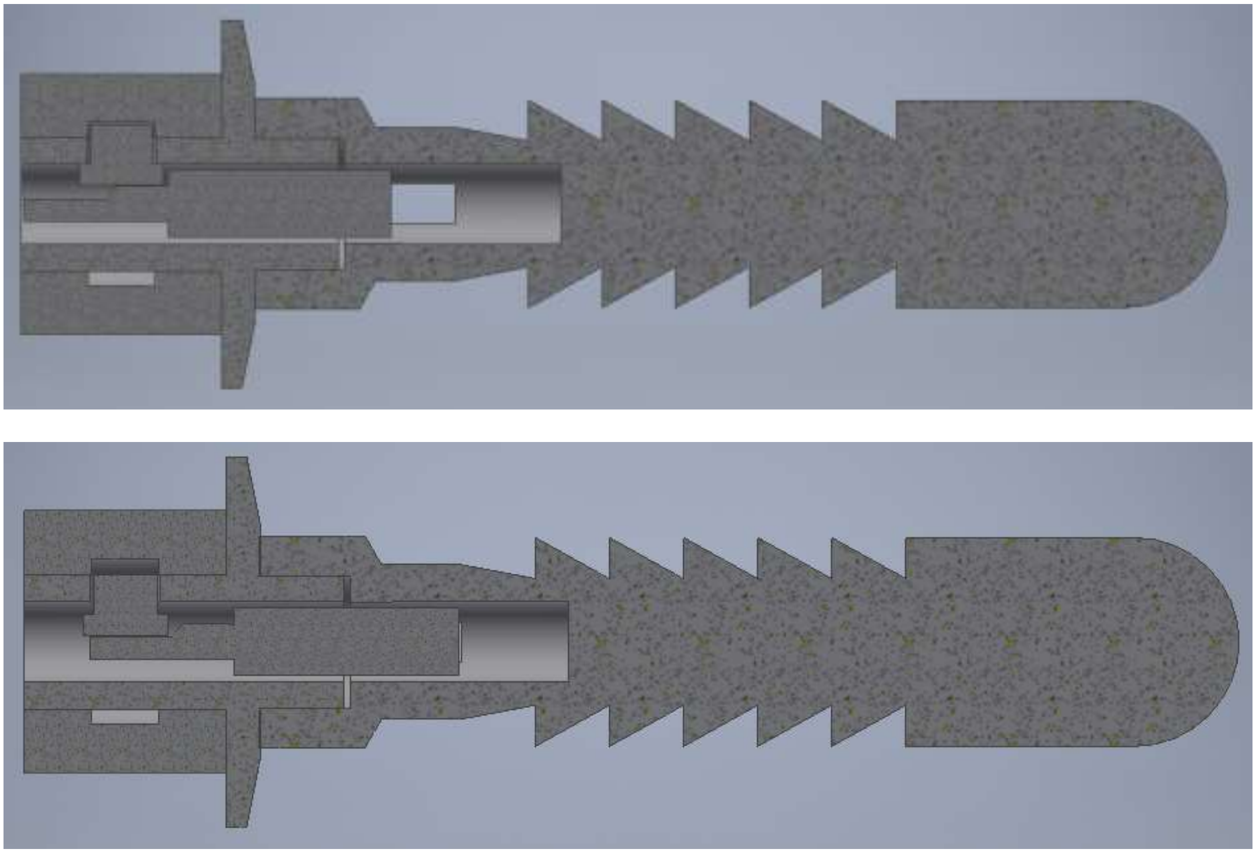


Figure 2.7: Cross-sectional view of ball bearing lock pin. Top: locked position. Bottom: unlocked position.

The premise of the design is a stepped spring loaded plunger pushes a ball bearing, or in this case, a lipped cylinder, up and down. The threaded adapter has a sharp ring cut out of the inside, where the cylinder fits tightly and prevents axial motion. To disengage, the plunger is actuated and the cylinder falls free, allowing the pin to be smoothly removed. Conceptually this design worked very well; it created a strong interface between the pin and umbrella and was contained within the same dimensions as a standard pin. However, the parts, particularly the plunger would be extremely small, fragile, and difficult to machine. Assembly would also be near impossible.

Once the “seatbelt” retractor was designed, it was decided that since it automatically locks the tether during unintended retraction, a quick connection above the flare was not entirely necessary. It would almost need to be intentional for the tether to fall into the pylon.

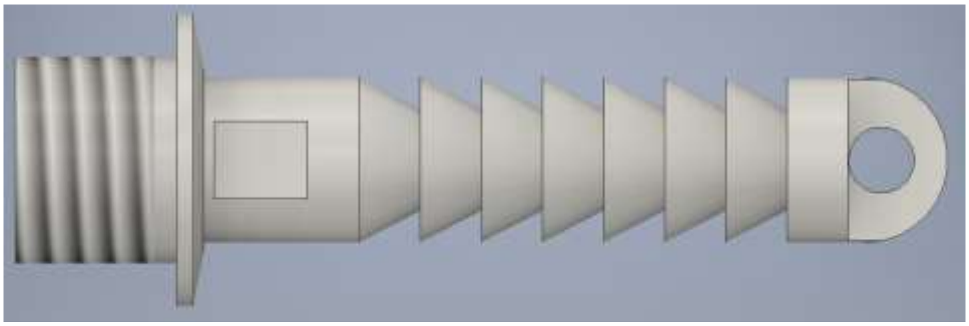


Figure 2.8: Loop quick release pin

A very simplified final design is essentially a standard locking pin with a loop on the end. The tether is simply clipped onto the end of the pin. This design maintains the structural integrity of a standard pin as it is one solid part. It also can function as a standard pin, in the event the tether is severed or lost within the pylon; if the previous designs were to fail, the prosthesis would be rendered unusable.

2.3 Prototyping

Once designs were finalized, prototyping began. There were three main stages of the prototyping process: A rough build using mostly off the shelf parts, followed by multiple iterations of 3D printed models, then finalized parts were sent out for fabrication.

A crude initial prototype was constructed using a Gear Keeper RT3-0093 Locking Scuba Console Retractor. This specific model of Gear Keeper has a retraction strength of 24 oz, and an 80-lb breaking strength for the cable. The goal of this prototype was to simply evaluate the efficacy of a retracting pin. As such, a quick release mechanism for the pin attachment was not included in this prototype. Instead, a nearly standard pin was fabricated with a narrow hole through its length. The tether was simply threaded through the hole and knotted at the back end.

Figure 2.9: First prototype tether pin

This prototype was used to determine the necessary spring force to balance the weight of the prosthesis. Luckily, the spring within the Gear Keeper was nearly perfect and no further evaluation was necessary. User evaluation was also a goal for this stage of prototyping. Three transtibial amputees were brought in and fitted with the Gear Keeper and custom pin. Due to its size, the Gear Keeper had to be external to the pylon, and thus the tether had to be routed from the socket, down the pylon, and out a hole cut into the pylon. In order to increase bend radius as well as prevent wear on the tether, printed inserts were installed around the hole of the pylon.

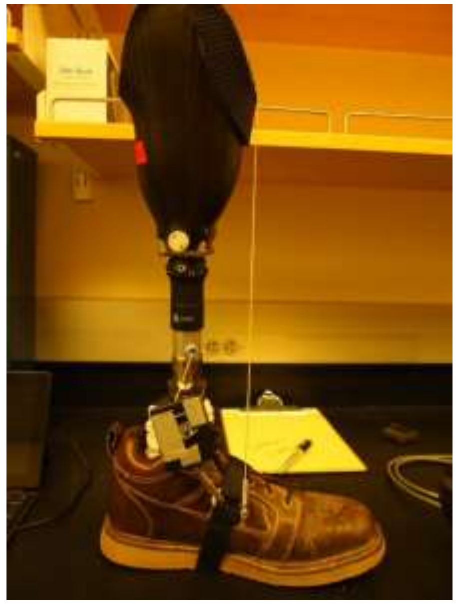


Figure 2.10: Gear Keeper prototype fully assembled

The participants were asked to use the system, i.e. partially doff and don while seated, and their feedback was recorded. The users found the tether helpful so further development of the RTP continued.

The housing shown in Figure 2.4 was not the initial design. Multiple iterations of fully 3D printed designs were evaluated and can be seen in Figure 2.11.

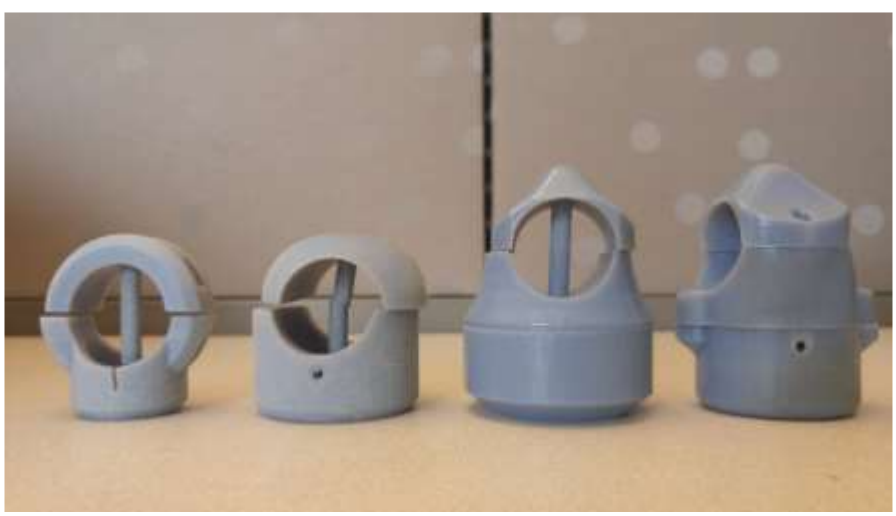


Figure 2.11: Iterative progression of housing design. Revisions increase from left to right.

A first prototype (leftmost in Figure 2.11) was made to be as unobtrusive as possible. However, its diminutive size greatly restricted the space for the spiral spring and no commercially available spring of equivalent strength to the one found in the Gear Keeper could be found. Also, the tooth ring had significantly more teeth and was integrated into the bottom of the housing. This was determined to be too expensive to have fabricated so the tooth ring was reduced to four teeth and was designed to be press-fit into the bottom of the housing.

The second prototype (2^{nd} from left in Figure 2.11) was enlarged to accommodate the spring that had been removed from the Gear Keeper for further use. This model was partially functional. It housed all the major components described in the previous section, the spring could be wound, and the arm would engage with the teeth as the spring released. As described previously, typically a spring is used to keep the arm free of the teeth during slow rotation. However, again due to the small size of the system, a small/weak enough spring could not be found, and an alternative solution was necessary. Since the chosen components were to be fabricated from mild steel, a strategically placed magnet could create a weak enough containing force. The spacer was originally integrated with the mounting rod, but with magnetic control in mind, the spacer was made modular so various geometries could be made in order to best determine the necessary distance from the magnet and arm. Although mostly operational, the 2^{nd} prototype was far from smoothly operational.

The next iteration introduced multiple load bearing components, specifically two bushings and a thrust bearing, which are seen in Figure 2.4 as the two smaller gold components and larger red component, respectively. The housing was also separated into three parts in order to separate the bushing from the spring. A cutout ring within the lower third of the housing was added for a retaining clip which would hold the mounting rod flare against the thrust bearing. This iteration functioned as completely as the last, but was significantly smoother. A full mockup of the RTP system was made with this iteration, but when the tether was extended, the force required caused the mounting rod to fail almost immediately; the 3D printed material was just too weak for a full evaluation of the system. However, confidence was high enough that the major components were sent out for fabrication.

The arm, tooth ring, mounting rod, and tether spool were the only parts fabricated. In order to keep weight and cost low, and allow further refinement, the housing and magnet mount/spacer were kept as printed parts. Such further refinement can be seen in Figure 2.11 on the far right where the overall diameter is reduced. With the metal parts, the magnetic containment concept could be tested. Multiple spacers were printed and matched with various shape and strength magnets until a suitable pair was found that was strong enough to contain the arm but weak enough to free it at high revolutions. A new tether was also added. FMS Spectra Line is designed for spear gun reels. As such, it has a very high strength to diameter ratio, and is extremely durable. With this line and the metal parts, the RTP was fully functional from first assembly.

Figure 2.12: Left: RTP fully assembled on pylon stock. Right: Cross-section render of fully assembled system with socket and shuttle lock.

CHAPTER THREE: EVALUATION

After IRB approval from the Human Subjects Division, amputee volunteers were asked to evaluate the RTP in a controlled lab setting. Three participants consented to visiting up to 10 times to give feedback on the design. To qualify for the study the participants had to be at least 18 years of age. They had to have unilateral transtibial amputation that occurred a minimum of 18 months prior to the study. They had to currently use or have significant experience with a locking pin suspension and use a foot that requires a pylon. The pylon also had to be long enough to accommodate the RTP housing. User evaluation was conducted in two phases corresponding to the two main prototyping stages: Gear Keeper and "seatbelt."

3.1 First Phase: Gear Keeper

Participants were first asked to visit for an initial evaluation of the concept. This was achieved with the Gear Keeper based prototype. The participants were asked to focus on evaluating the concept of a tethered pin rather than the crude implementation with the Gear Keeper. Figure 3.1 shows participant B donning his standard locking pin socket with the Gear Keeper system.

Figure 3.13: Participant B evaluating the Gear Keeper prototype

While seated, participants were asked to repeatedly partially doff and re-don to get a feel for the tether assist. Participants were encouraged to give verbal feedback while using the system. Once all parties were satisfied, the participant was refitted with their original locking pin and pylon and given an abridged PEQ. Results from three participants can be seen in Table 3.1.

Table 3.1: Abridged PEQ Results for Gear Keeper. Scaling goes from 0 to 100. A higher score represents a more positive response.

	Participant Code		
Question	A	B	C
Overall how would you compare this suspension system to your normal system?	97	54	68
Rate the weight of this prosthesis relative to your current prosthesis	98	74	44
Rate the ease of putting on this prosthesis relative to your current prosthesis	61	52	64
Rate the ease of taking off this prosthesis relative to your current prosthesis	63	60	75
If you regularly partially doff while seated, rate the ease of partially doffing this prosthesis relative to your current prosthesis	100	21	71
If you regularly partially doff while seated, rate the ease of re-donning this prosthesis relative to your current prosthesis	100	25	74

Feedback was somewhat mixed. Verbal feedback was all fairly positive. Most participants found the tether to be helpful and could see the benefits with a more refined design. However, PEQ results were varied. Although one said he would personally not use the system, all three saw merit in the concept. Those with poor proprioception may not be able to feel when the pin is properly engaged with the lock; with the tether there is confidence that the pin will always be properly engaged. This same confidence can be beneficial to new users who may have good proprioception, but still do not know what proper engagement feels like. Without knowledge of future designs, all three requested a quick release mechanism and control of tether retraction; features that were planned to be implemented in the next iteration.

3.1 Second Phase: Seatbelt

Following from the design feedback of the first phase, once the final prototype was fabricated, the same participants were asked back for further evaluation.

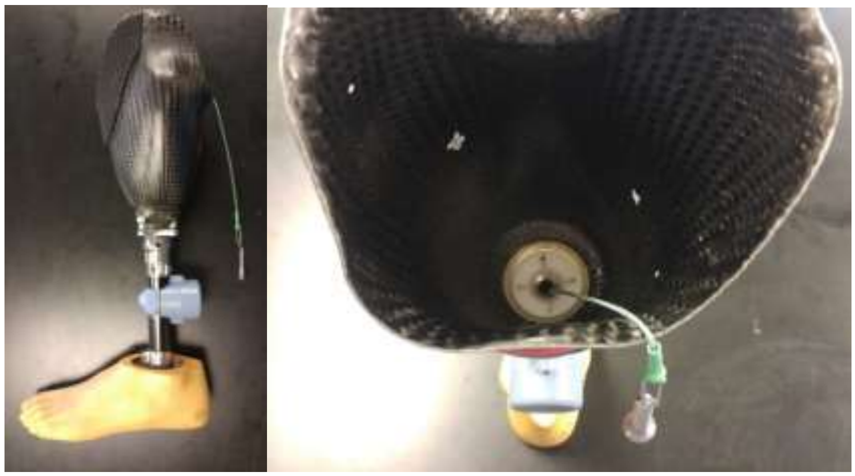


Figure 3.14: Left: RTP fully assembled with socket. Right: View into socket showing path of tether into shuttle lock.

Visits followed a similar protocol as the previous phase: participants were asked to repeatedly partially doff and re-don and make use of the tether lock and quick release. They were asked to fill out another PEQ. Results seen in Table 3.2.

*Table 3.2: Abridged PEQ results for RTP. *Participant A filled out a different version of the PEQ that did not include this question.*

	Participant Code			
Question	A	B	C	D
Overall how would you compare this suspension system to your normal system?	*NA	51	85	50
Rate the weight of this prosthesis relative to your current prosthesis	90	53	32	72
Rate the ease of putting on this prosthesis relative to your current prosthesis	72	37	25	46
Rate the ease of taking off this prosthesis relative to your current prosthesis	25	50	48	46
If you regularly partially doff while seated, rate the ease of partially doffing this prosthesis relative to your current prosthesis	27	95	94	80
If you regularly partially doff while seated, rate the ease of re-donning this prosthesis relative to your current prosthesis	28	85	88	80

Again results were varied as well as inconsistent from the previous design. Participant A, for example, found the more refined system harder to use. Unfortunately, it is likely that all these participants are too able-bodied to truly benefit from the RTP. The RTP scored low on weight, which is to be expected. Weight could be reduced by using aluminum instead of steel for most of the fabricated parts. Operation of the braking mechanism was not initially intuitive, but once the participants were instructed how to operate it, they all quickly were able to control it easily. The participants all seemed to struggle with the clip for the loop pin and someone with poor manual dexterity would likely find it too difficult to operate. A better solution should be found. Although it was explained that it would be very difficult for the tether to be lost into the pylon during retraction, it was still a unanimous concern. As a temporary solution, a printed peripheral device, seen in Figure 3.3, was made that, when fully doffed, the user can clip the tether to it and it would be too large to fall through the shuttle lock and is easily retrieved from the bottom of the socket.

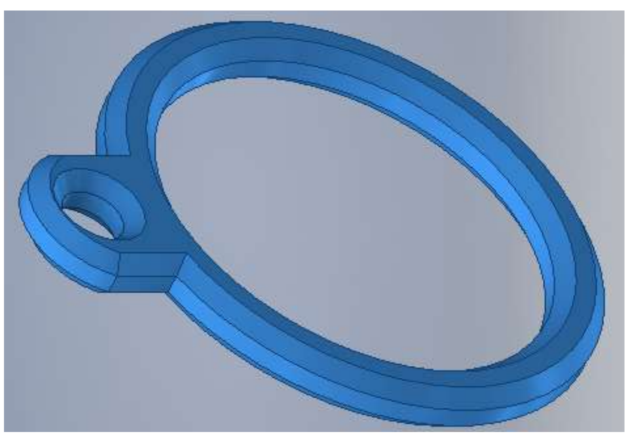


Figure 3.15: Tether stopper

CHAPTER FOUR: CONCLUSION

A novel suspension system based on standard locking pins was developed in order to improve the user experience of transtibial amputees who regularly partially doff. By incorporating an automatic retractable tether between the socket and the pin, a high confidence level that the pin will engage securely can be maintained by those with poor proprioception or those with recent amputations. The hope in this design is to not only provide a better experience, but to promote the frequency of partial doffing which can improve overall limb health by reducing pressures on the residual limb and allowing for fluid volume recovery.

The novel system, dubbed the RTP, was iteratively designed using Autodesk Inventor. Once a final design consisting of a spring tensioned spool, centrifugal gear catch, and quick release pin was created, amputee volunteers were asked to evaluate multiple prototypes. The first prototype evaluated used an off-the-shelf retractor as a proof-of-concept and was met with high praise for its ingenuity. Three users evaluated the initial prototype and were asked to score it relative to their current locking pin suspension using a modified PEQ. For partial doffing one user gave a maximum score of 100, while another gave a minimum score of 21, the mean score was 64.14 (s = 32.66). For re-donning, a maximum score of 100 was again given, and the minimum score received was 25. The mean score was 66.27 (s = 31.08) for re-donning. This initial prototype confirmed the feasibility of an auto-retracting tether as a means for improving re-donning. A final prototype was evaluated by four users and the majority found it helpful in partial doffing and re-donning. For partial doffing, the maximum score received was 95, and the minimum was 27. The mean PEQ score was 72.0 (s = 27.76) for partial doffing. For re-donning, a maximum score of 88.1 was given, a minimum of 28, and a mean of 67.03 (s = 24.58) for re-donning.

Conceptually, this design proved to be successful; based on PEQ results, the RTP is effective in improving the ease of partial doffing and re-donning. In practice, it not only guided the pin into the shuttle lock without fail, it allowed users to do so without having to stand which completely removes a potential fall hazard. The auto-locking feature also performed admirably. Although it occasionally locked too easily, it never failed to engage which is extremely important for the safety and health of the user. Unfortunately, the RTP has yet to exit the prototyping stage. With further work, the RTP could be improved in its function as well as form, and could be implemented to positively affect the lives of transtibial amputees.

4.1 Future Work

There is still much that can be done with this project. There are many further design refinements possible and more in-depth user evaluation would be beneficial. Also, the real objective of this design has yet to be evaluated: improvement of limb health.

4.1.1 Design Refinement

As a first measure, the printed housing should be replaced with a stronger material. One iteration of the final design was made with thinner walls. The screw head seen on the bottom third of the housing in Figure 2.12 is an anchor point for the spiral spring. With the thinned housing, the force of the spring actually shattered the housing, seen in Figure 4.1.

Figure 4.1: Fatigue failure of housing due to weak 3D printer material.

The parts were printed using Veroblue RGD840, which has a flexural strength of 60-70 MPa and modulus of 1900-2500 MPa. If the parts were printed instead with RGD525 (flexural strength: 110-130 MPa, modulus: 3100-3500), a thinner wall could be achieved. Alternatively the housing could be machined from a low weight and corrosion resistant metal like aluminum.

The housing also requires at least 2.5" of pylon clearance in order to be attached. Properly redesigned, the spool could be added around the circumference of the spring housing, creating a more advantageous ratio of spring to tether excursion, i.e. less spring rotation creates more tether extension. This spool/spring combination could then be mounted with its axis of rotation perpendicular (rather than the current parallel design) directly to the distal end of the socket. An example of a similar form factor would be the LimbLogic Electronic Vacuum Pump seen in Figure 4.2. A possible puck design is also seen in Figure 4.2.

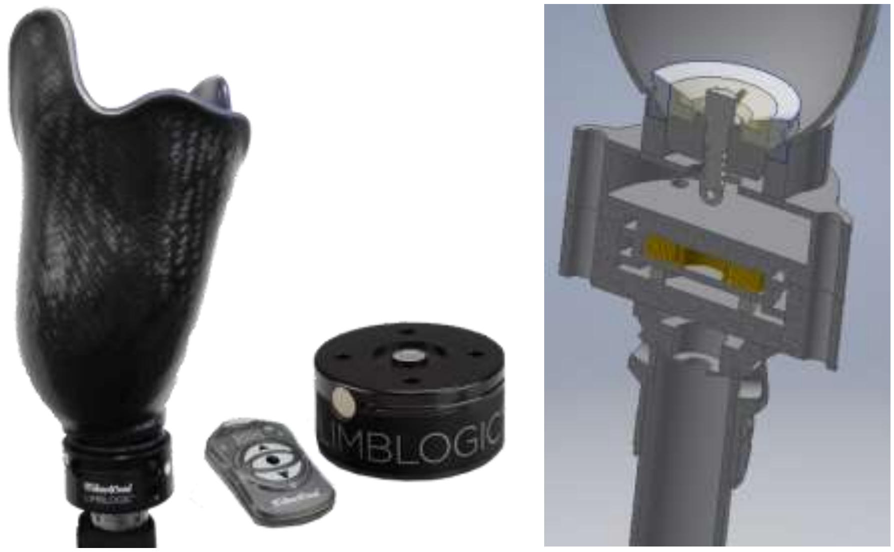


Figure 4.2: Left: LimbLogic Electronic Vacuum Pump. Image taken from orthopaedie-schmieg.de. Right: render of possible RTP puck design.

Such a design would greatly reduce the pylon length requirement and create a more anthropomorphic look for the system. It would in fact remove the necessity of a pylon, and open availability of the RTP to those using a nonstandard foot, e.g. Össur Cheetah foot. Also, having the tooth lock in the transverse plane would maintain a constant centrifugal force independent of arm angle. Since the current design is in the coronal plane, if the arm locks in the bottommost tooth, gravity makes it harder for the magnet to retract the arm and disengage. Unfortunately, such a design is beyond the available timescale for this project as it would require many custom machined parts and unlike the current design, this puck RTP would be load-bearing and would require FEA to ensure the safety of the user.

4.1.2 Further user evaluation

A second phase of user evaluation was planned as part of this study, however time constraints did not allow for such. In this more clinical phase, a larger group of participants currently using locking pins would come in for an initial visit. They would each first fill out a PEQ evaluating their current prosthesis. Then they would be fitted with their own RTP and sent home and asked to use their new system exclusively. After appropriate time for the users to acclimate to the RTP (3-4 weeks), they would return for a second visit. During this visit they would fill out another PEQ evaluating the RTP system. These two PEQ's could then be compared to see, what improvements, if any the RTP system provided.

4.1.3 Limb health study

As initially stated, the real purpose of the RTP is to hopefully promote an increased frequency of partial doffing, which should reduce pressures at the posterior residual limb and thus improve limb health. In combination with the above evaluation study, the users' sockets could be fitted with sensing devices. One device could be used to track frequency of partial doffing throughout the day. Such devices have already been used successfully to track full doffs throughout the day. Redfield et al. used two accelerometers, one attached to the socket and one strapped to the participant's thigh [7]. By tracking the relative position of the two accelerometers, they were able to classify certain events as doffs. Sanders et al 2006 describes a similarly effective device that uses a photoelectric sensor placed at the distal end of the socket [8]. The large scale measurements of the former device combined with the small scale measurements of the latter sensor could surely be used to capture partial doffs. Another device could be used to track the volume changes of the residual limb. Sanders et al. used bioimpedence measurements to track limb volume changes over time [9]. Collecting data with a large set of participants and over the aforementioned three to four week acclimation period, would provide ample data for analysis. By first collecting data with their standard pin, a baseline of frequency of partial doffs and limb volume could be established. Then the protocol would be repeated with the RTP. The frequency of partial doffs could be compared between the two systems to see if the RTP is effective at promoting partial doffing. Both data sets could also be used in conjunction to correlate limb volume fluctuations with partial doffing. With this analysis the benefit to limb health of the RTP system could be quantitatively shown.

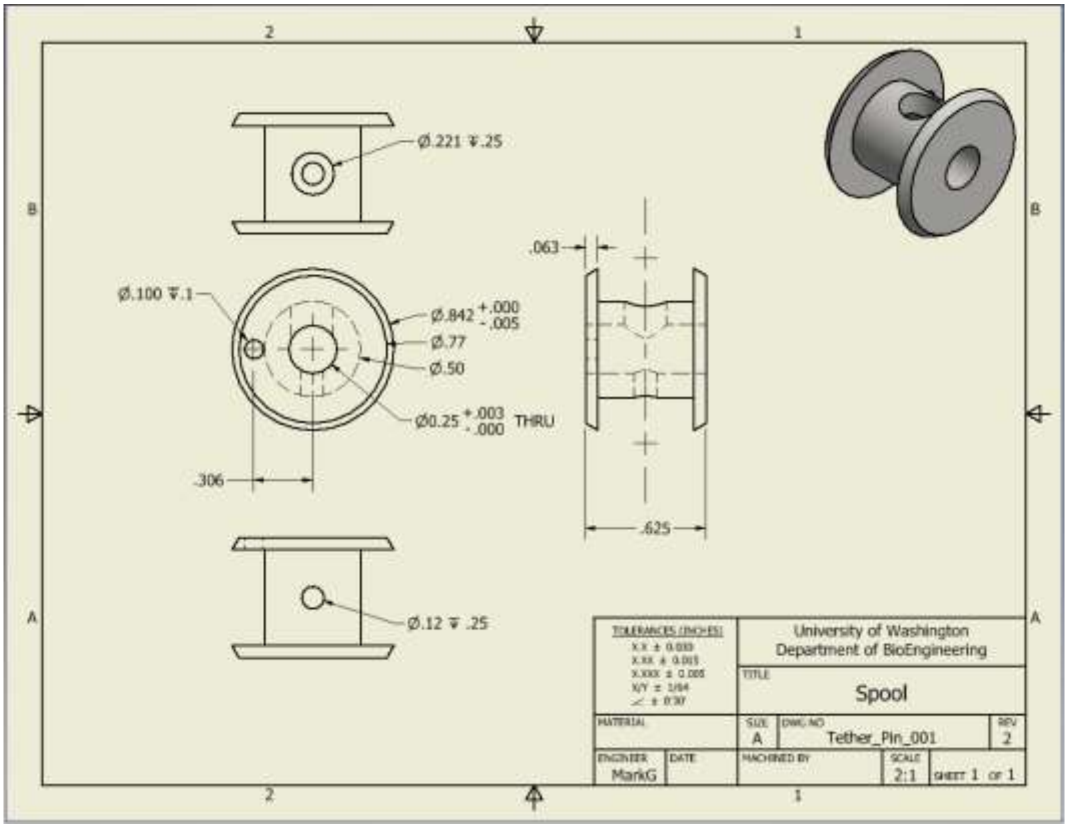
REFERENCES

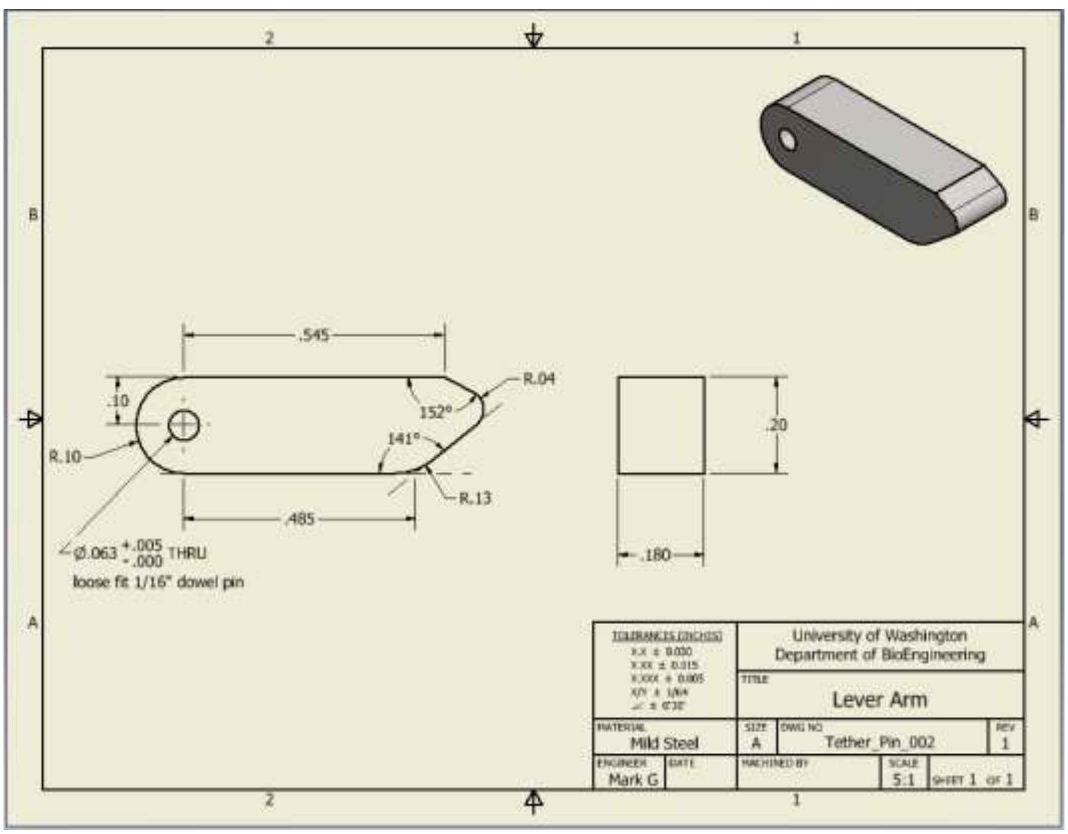
1. G. Brüggemann, A. Arampatzis, F. Emrich, “Biomechanical and metabolic analysis of long sprint running of the double transtibial amputee athlete O. Pistorius using Cheetah sprint prostheses,” December 2007.
2. G.M. Street, “Vacuum Suspension and its Effects on the Limb,” *Orthopädie Technik Quarterly*, vol. IV, 2006.
3. W.J. Board, G.M. Street, C. Caspers, “A comparison of trans-tibial amputee suction and vacuum socket conditions,” *Prosthetics and Orthotics International,* vol. 25, pp. 202-209, 2001.
4. H. Gholizadeh, N. Osman, A. Eshraghi, S. Ali, S. Sævarsson, W. Abas, G. Pirouzi, “Transtibial prosthetic suspension: Less pistoning versus easy donning and doffing,” *Journal of Rehabilitation Research & Development,* vol. 49, no. 9, pp. 1321-1330, 2012.
5. H. Gholizadeh, N. Osman, A. Eshraghi, S. Ali, N. Arifin, W. Abas, “Evaluation of new suspension system for limb prosthetics,” *BioMedical Engineering OnLine,* vol. 13, no.1, 2014.
6. T. Beil, G. Street, “Comparison of interface pressures with pin and suction suspension systems,” *Journal of Rehabilitation Research & Development*, vol. 41, no. 6A, pp. 821-828, November/December 2004.
7. M. Redfield, J. Cagle, B. Hafner, J. Sanders, “Classifying prosthetic use via accelerometry in persons with transtibial amputations,” *Journal of Rehabilitation Research & Development,* vol. 50, no. 9, pp. 1201-1212, 2013.
8. J. Sanders, A. Karchin, J. Fergason, E. Sorenson, “A noncontact sensor for measurement of distal residual-limb position during walking.” *Journal of Rehabilitation Research & Development*, vol. 43, no. 4, pp. 509-516, July/August 2006.
9. J. Sanders, E. Rogers, D. Abrahamson, “Assessment of residual-limb volume change using bioimpedence,” *Journal of Rehabilitation Research & Development*, vol. 44, no. 4, pp. 525-536, 2007.

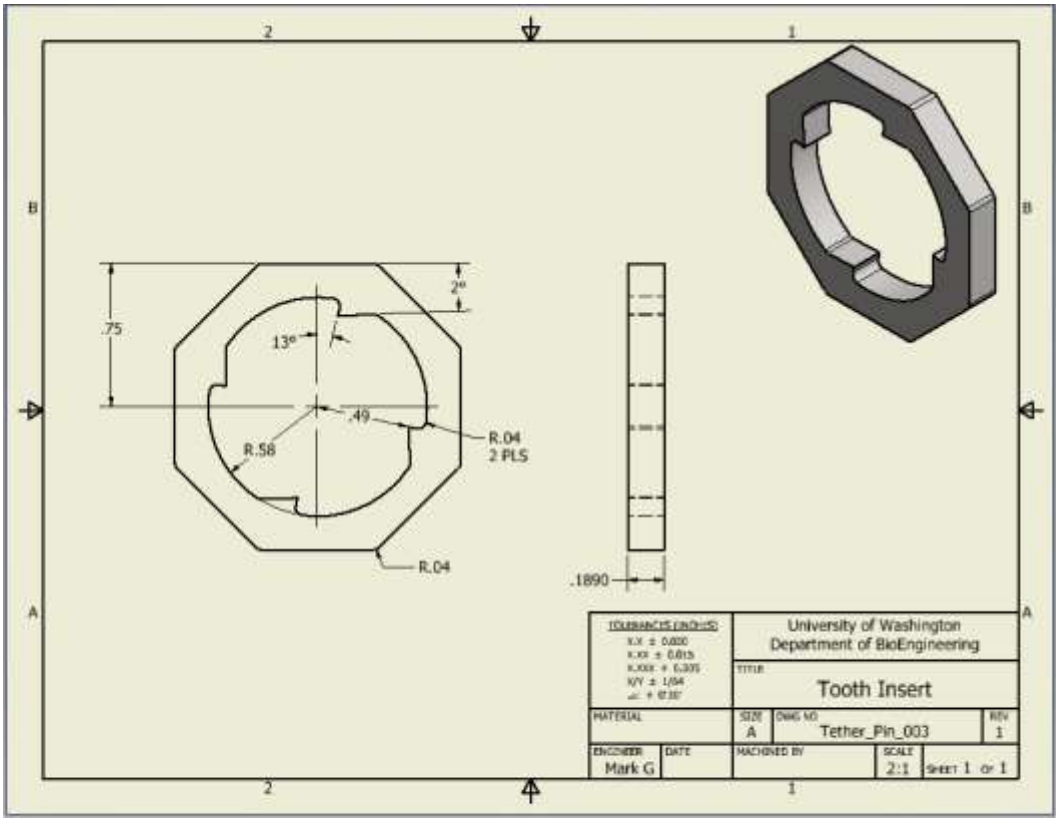
Appendix A: PEQ open ended results for Phase 2

	Participant Code			
Question	A	B	C	D
Describe how you feel about the tension of the tether. Is it too strong? Too weak?	Just right for doffing. It would be better if the tension could be stronger donning	just right	tension is good	I would judge it as right. Strong enough to feel it engage but not too much as to make it difficult to use.
Describe how you feel about the quick release of the pin. Is it easy to operate? Does it feel secure? How would you change it?	stronger material needed	it takes getting used to, but viable	Secure - yes. Somewhat small and difficult to see	I would make it easier to engage. Something on the lines of a carabiner: requiring less finger dexterity or strength to hook up
Describe how you feel about the tether lock. Is it easy to operate? How would you change it?	I would add something to prevent tether being lost in prosthetic	one button for in and one for out	lock is good I have control of it	After a few times, I found it easy to operate, with the advice of the designer re. holding the prosthetic foot down and engaging w/o use of hands
If this system was commercially available, would you be interested?	Yes!	yes	Not at this stage of life (70). If overweight or unable to lift my leg or reach the floor this	possibly
what other feedback would you like to provide	Tether needs to be longer and needs to be made from more durable material. Great idea!	N/A	Even if the tether was lost or damaged the system would still work as the older pin types. This is good.	I do feel this device would definitely be of benefit to prosthetic users of a more advanced age or less manual dexterity

Appendix B: Drawings of machined parts



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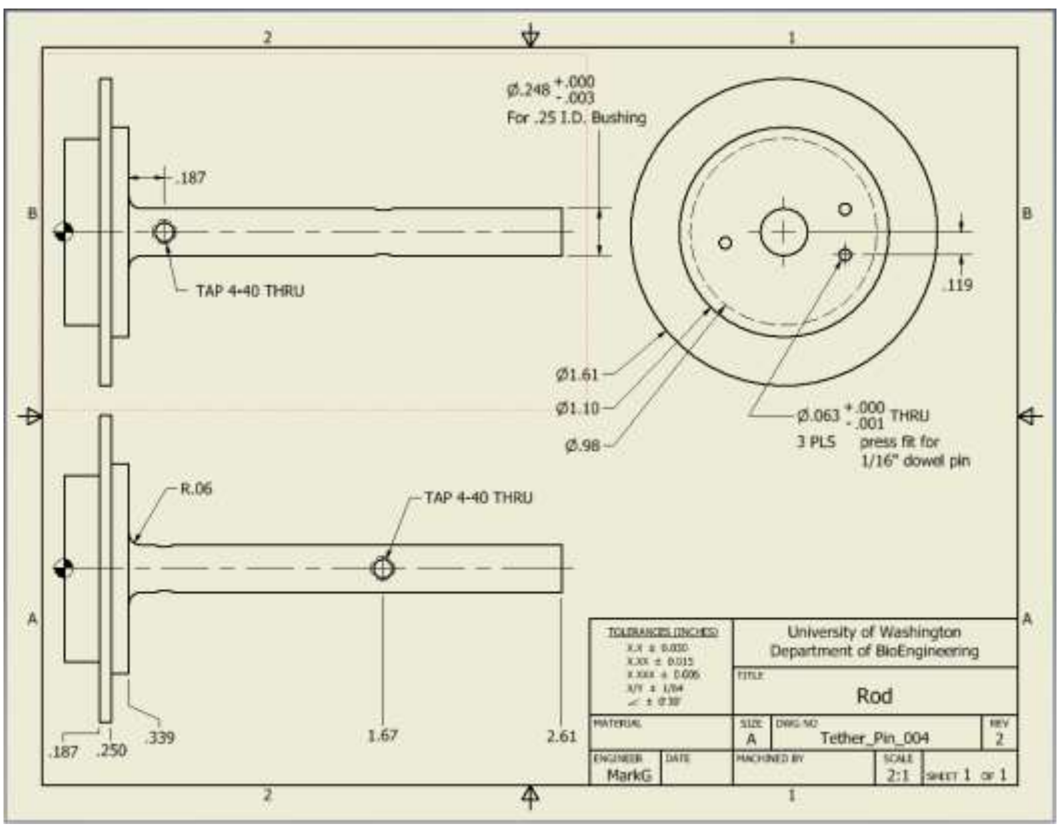
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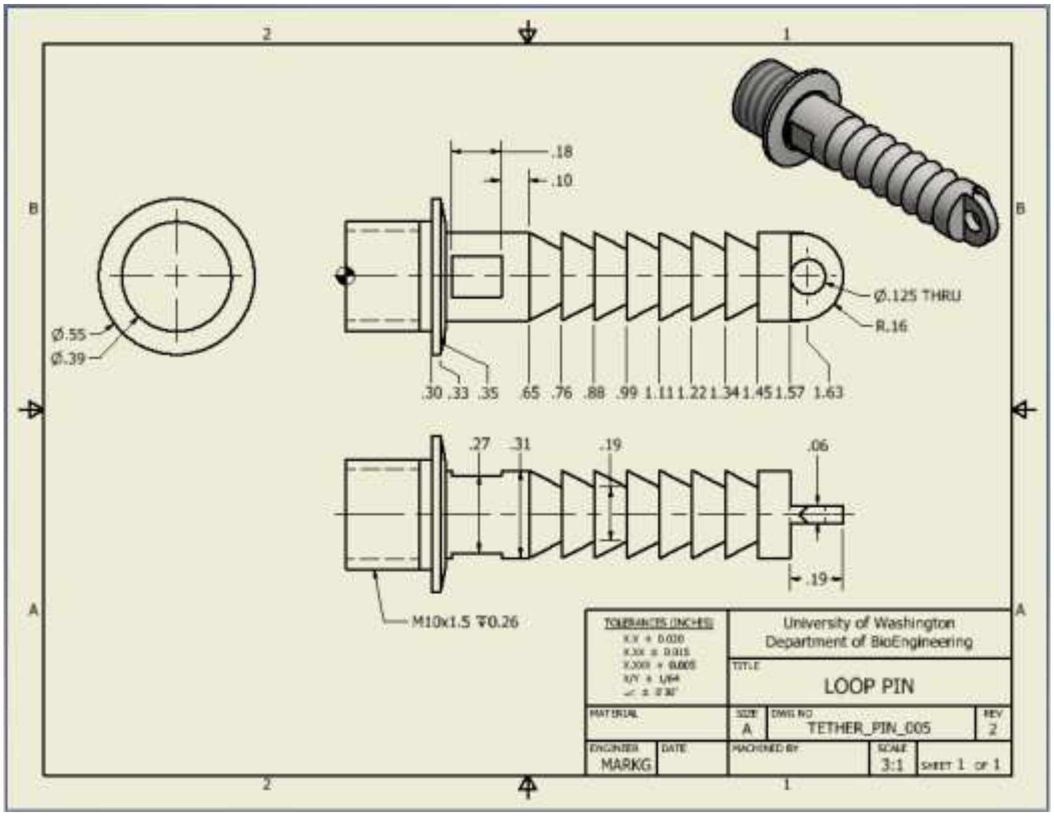
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