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Retracting Locking-Pin Mechanism That Allows Partial Prosthetic Socket Doffing during Sitting

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INTRODUCTION

Residual limb volume loss over the day is a source of socket fit problems for people using transtibial prostheses.¹ Research studies have shown that prosthesis users may gain fluid volume during walking, but lose fluid volume during sitting.² Pin suspension systems may accentuate limb fluid volume loss during sitting. With the distal end of the residual limb held in place by the pin, the posterior proximal residual limb tissues in the popliteal area are stretched tightly over the posterior brim of the socket, focusing stress that may reduce limb fluid volume and cause soft-tissue damage. If the foot is flat on the floor, anterior distal pressures may increase.

Intermittent doffing may reduce fluid volume loss and mitigate socket fit problems.³ In a study on 16 people with transtibial amputation, a 30-minute doff performed after activity significantly increased limb fluid volume compared with not doffing.

While doffing a prosthesis with locking-pin suspension during sitting either partially or completely may reduce socket fit problems caused by fluid volume loss, re-donning the prosthesis can often be difficult. Typically, donning requires the user has access to the socket (i.e., the user must remove pants or other lower-limb garments). Further, the user may have difficulty aligning the locking pin with the shuttle lock since it is not visible during donning. A mechanism that conveniently allows partial doffing and facilitates easy re-donning may help prosthesis users to implement intermittent doffing practices and overcome discomfort and fluid volume loss during sitting.

Several systems have been designed to facilitate re-donning, with most of them using a fabric pull cord that passes through a hole in the distal end of the socket.⁴ The user draws the cord to pull in and seat the liner. One system (Lanyard Plunger Pin, Bulldog Tools Incorporated, Lewisburg, Ohio) is simply a cord affixed to a locking pin. Other systems eliminate the locking pin and shuttle lock and instead attach the cord to the liner using a threaded fastener⁵ (Icelock 300, Össur, Reykjavik, Iceland; Keep It Simple Suspension,⁶ KISS Technologies, Baltimore, Maryland; Hook and Loop System,⁷ HOLO). The cord is pulled proximally by the user and held against the socket to maintain tension in the cord. One system uses a ratcheting mechanism that allows tension to be incrementally applied to the cord.⁵ The primary limitations of all of these systems are that users must have direct access to the socket to operate them, and users must have sufficient dexterity, balance, and strength to pull the cord taut. Further, systems without locking mechanisms would be expected to have weaker socket connections and thus be less secure during active gait than systems that include them.

The purpose of this research was to develop and test a suspension system that allowed partial or complete doffing but did not require access to the socket, nor require the user to pull a cord taught during donning. A retractable tethered pin system was developed to operate with a normal shuttle lock suspension. Initial tests with prosthesis users were conducted.

METHODS/DESIGN

The Retractable Tethered Pin (RTP) system developed in this research was made up of a mechanism, cord, clip, and pin. The tethered cord was a polyethylene fiber material of diameter 1.9mm (Spectra® braid, LINE-SP19, Spearvit, Marco Island, Florida). The retracting mechanism included a locking arm, magnet and mount, ratchet ring, thrust bearing, spring, spool, shaft, and housing (Figure 1). The housing and mount were 3D printed parts (RGD840, Objet, Stratasys, Eden Prairie, Minnesota), the magnet a purchased product (Neodymium Disc Magnet (¼ “diameter, 1/16” thickness), Grade N52, K&J Magnetics, Incorporated, Pipersville, Pennsylvania) and the spring taken out of a commercial scuba retractor (RT3-0093, Gear Keeper, Ventura, California). The spring had a constant retraction force of 6.7N. All other components of the retracting mechanism were machined from aluminum except the locking arm, which was steel. The clip was an angler’s power clip (Tactical Anglers, Amityville, New York), and the loop pin was made of stainless steel. The mass of the RTP was 202.5g.

When assembled, the tethered cord extended from the retracting mechanism mounted in the pylon through the shuttle lock to the clip that fastened to the bottom of the loop pin (Figures 2, 3). The system was designed so that when the loop pin was inserted into the shuttle lock, it functioned as normal; i.e., the tether had no effect on suspension or prosthesis function (Figure 1a). When the user sat and disengaged the locking pin by pushing the release on the shuttle lock, the tether operated similarly to a seat-belt retraction mechanism. It applied tension but lengthened as long as displacement was executed slowly, thus allowing the user to pull the limb and liner partially or fully out of the socket. Once the tether was extended to a desired length, the user applied a quick impulsive load to the tether, causing the mechanism to lock and no longer retract (Figure 1b, 1c). The tether then remained at the

desired length, allowing the user to move with no tension on the tether. When ready to don the socket, the user slowly extended the tether to disengage the ratchet. This action engaged retraction and drew in the tether towards the mechanism in the pylon. As the tether was connected to the distal end of the pin, retraction automatically aligned the pin with the hole in the shuttle lock. The system thus eased donning by actively pulling the pin into the shuttle lock.

An evaluation study was conducted to test performance of the RTP system. Participants with transtibial limb loss who had a unilateral amputation a minimum of 18 months prior were considered for inclusion. Participants were required to be a minimum of 18 years of age, be at a functional classification level (K-level) of 2 or higher, and currently use a locking-pin suspension system (i.e., a liner with a pin and a shuttle lock that allowed a tether to pass through to the pylon). Participants' as-prescribed prostheses also needed to have a pylon long enough to accommodate the RTP housing (at least 6.35cm). A University of Washington Institutional Review Board (IRB) approved the testing protocol, and written informed consent was obtained before any test procedures were initiated.

After entering the lab and sitting for 10 minutes, participants doffed their prosthesis. The participant's locking pin was replaced with the loop pin, and the participant's pylon was replaced with a pylon that included the ratcheting mechanism, taking care to maintain the participant's normal socket alignment.

Participants were instructed by the researcher how to use the RTP. They were then asked to repeatedly partially doff and re-don their prosthesis while seated in the laboratory. Participants were encouraged to provide verbal feedback to the investigators while using the system. They were also advised how to modify their use of the RTP if problems occurred. After finishing the evaluation, participants were asked to rate the RTP relative to their existing prosthetic suspension system. Participants responded to questions about overall satisfaction, donning, doffing, partial donning, and partial doffing using a visual analog scale (VAS). Participants also answered open-ended questions about the tether, pin, lock, and interest in using the RTP system.

RESULTS

Four transtibial prosthesis users, ranging in age from 52 to 72 years, participated in this study. All were K3 or K4 ambulators, had their amputation at least 6 years prior, and used a patellar-tendon-bearing socket in their as-prescribed prosthesis (Table 1).

Evaluation results varied among participants; three had mixed comments (#1-#3), and one had only negative comments (#4) about the RTP system. Interestingly, even though the system added weight relative to each participant's as-prescribed prosthesis, it felt lighter to two of the four participants. Partial doffing and donning with the RTP was much improved over the as-prescribed prosthesis for three of the four participants, though initial donning and final doffing the prosthesis was more difficult than with the regular prosthesis for all participants (Figure 4). Responses to open-ended questions indicated that participants were generally positive about the level of tension in the tether and their ease of operating the

locking mechanism (Table 2). However, they felt that connecting and disconnecting the pin from the tether, which was required during initial donning and final doffing, was difficult. Two of the four participants were concerned about losing the tether through the hole in the shuttle lock, even though this was not possible due to the physical dimensions of the clip. Participants also seemed startled by how quickly the pin retracted when it was free of the liner.

DISCUSSION

Part of the impetus for this research stems from recent findings that doffing a prosthesis temporarily during the day facilitates limb fluid volume recovery and retention in people with limb loss.⁸ It is possible that partial doffing will facilitate the same effect. Partial doffing would be more convenient than full doffing for prosthesis users, as it would not require users to remove the entire socket but instead just withdraw the residual limb enough to promote fluid volume recovery. The developed mechanism contributed to this effort by facilitating pin alignment and reinsertion into the shuttle lock.

Participants liked that the RTP system pulled their limb into the socket. One potential reason two of the four participants commented that the prosthesis felt lighter than their normal prosthesis, even though it was actually heavier, was because of the active retraction force. In some cases, the retracting mechanism partially lifted the prosthesis off the ground towards the residual limb during donning. As such, users did not need to forcefully drive their residual limb into the socket to engage and lock the pin.

Participants struggled to line up the tether clip with the hole in the locking pin. The dexterity and effort required to clip or unclip the pin was likely why participants rated the system as more difficult to don and doff than their regular prosthesis. A single action snap-on/snap-off connector would likely be more effective and should be considered in future RTP designs.

Additional improvements to the RTP system would enhance performance. Modifying the design so that the spool was around the circumference of the spring housing would create a more advantageous ratio of spring-to-tether excursion; i.e., less spring rotation would create more tether extension. The axis of rotation could extend parallel to the pylon rather than perpendicular to it as in the current design, reducing the required clearance. Reducing required clearance would allow the RTP to be fit to people with longer residual limbs. These features should be considered in future design revisions and subsequently tested with prosthesis users. The RTP system has the potential to improve the long-term limb health of people with transtibial amputation.

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Figure 1. Retracting mechanism

Top: Assembly view of the retracting mechanism. Bottom: (a) Active retraction: There is high tension on the cord, and the mechanism spins slowly. (b) About to lock: There is little to no tension on the cord and the mechanism spins so rapidly that the centripetal acceleration of the locking arm overcomes the holding force of the magnet. (c) Locked: The locking arm catches the ratchet ring and stops rotation, locking the mechanism.

Figure 2. Components of the system

Left: Cross-sectional view of the pin, tether cord, and retraction mechanism assembled in a prosthesis. Right: Loop pin.

Figure 3.
Retractable locking-pin system assembled in a prosthetic socket.

QUESTION	
A.	Overall how would you compare this suspension system to your normal system?
B.	Rate the weight of this prosthesis relative to your current prosthesis
C.	Rate the ease of putting on (donning) this prosthesis relative to your current prosthesis
D.	Rate the ease of taking off (doffing) this prosthesis relative to your current prosthesis
E.	If you regularly partially doff while seated, rate the ease of partially doffing this prosthesis relative to your current prosthesis
F.	If you regularly partially doff while seated, rate the ease of re-donning this prosthesis relative to your current prosthesis

Figure 4.
Visual Analog Scale questions and results.

TABLE 1

Participant characteristics.

Participant	Gender	Age (years)	Time since amputation (years)	Mass (kg)	Height (cm)	Activity level (K-level)	Liner
#1	M	52	26	102	183	K-4	Willow Wood Alpha Max
#2	M	70	42	88	185	K-3	Willow Wood Alpha Silicone Select
#3	M	61	8	97	185	K-3	ALPS Uniform
#4	F	72	6	61	155	K-3	Iceross Dermo

TABLE 2

Participant responses to open-ended questions.

QUESTION	PARTICIPANT			
	#1	#2	#3	#4
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	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	Too strong
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	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	For me, it's harder to operate
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	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 without use of the hands	It's hard to get a hold on it to pull on it
If this system was commercially available, would you be interested?	Yes!	Not at this stage of life (70). If overweight or unable to lift my leg or reach the floor this would work. This tether system has a place	Possibly	Not at this time
What other feedback would you like to provide?	Tether needs to be longer and needs to be made from more durable material. Great idea!	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	I struggle with strength in my hands so it's hard to grab hold of the line