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Development and Usability of an Adjustable Prosthesis for Aquatic Therapy

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ABSTRACT

Introduction: During aquatic therapy, without a prosthesis, individuals with lower-limb difference are limited in navigating stairs or ladders, performing gait training, balance, and strengthening exercises. A noncustom prosthesis for individuals with transtibial limb difference in aquatic therapy, consisting of interchangeable sockets and pylons, does not exist. Dilatancy has not been applied within a socket to provide an accommodative shape for multiple users.

Objectives: This study explores the development and usability of an adjustable prosthesis, utilizing dilatancy, for aquatic therapy.

Study Design: The design of this study is developmental.

Methods: Participants underwent an informed written consent process (IRB STU00219525). Three individuals (1 male, 55 years; and 2 female, 47 and 22 years) with unilateral transtibial amputations were recruited. A set of interchangeable adjustable sockets and pylons were developed. Utilizing dilatant properties, small particles under vacuum were assessed for their ability to provide a rigid, lightweight, and remoldable pouch within the socket. Participants trialed the prosthesis during two fittings and three aquatic therapy sessions. Upon completion, participants and treating therapists completed the System Usability Scale. Survey results were converted to a 100-point scale. Time to don the prosthesis was recorded, and socket comfort scores at the final session were averaged.

Results: The System Usability Scale indicated that the prosthesis was usable for aquatic therapy. Participant scores were 97.5, 95, and 87.5, and therapist's scores were 92.5 and 85 of a total possible 100. Average socket comfort scores were 10, 9, and 7.6/10. Times to don the prosthesis were 5:45, 5:32, and 4:10 (minutes:seconds).

Conclusions: This system functioned successfully as a noncustom prosthesis for multiple users in aquatic therapy from the participant and therapists' perspective.

Clinical Relevance: The novelty of this system is utilizing a prosthesis for multiple users, improving the rehabilitation capabilities during aquatic therapy. (*J Prosthet Orthot.* 2024;00:00–00)

Key Indexing Terms: aquatic therapy, adjustable prosthesis, limb loss, amputation, hydrokinetic therapy, dilatancy

Aquatic therapy (AT) is a beneficial rehabilitation intervention well studied in poststroke, chronic back pain, Parkinson's disease, and other neurological and musculoskeletal disorders.[1–9] The physical properties of water, including density, hydrostatic pressure, buoyancy, viscosity, and thermodynamics, are related to the biological effects of AT.[10] Buoyancy of water offloads body weight, with immersion at waist level offloading approximately 48% of body weight and 76% at the chest,

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increasing with greater depth.[10,11] AT can facilitate greater confidence in trying new therapeutic exercises and reducing pain, allowing progression toward goals unachievable on land.

Many individuals with lower-limb loss or difference (LLD) participate in AT as an alternative or addition to land-based therapy; however, the therapeutic benefits for this population are not well studied. Individuals with LLD may be limited by pain, phantom pain, decreased flexibility, strength, and weight bearing tolerance. AT can reduce joint stress, improve flexibility and strength, and provide a safe environment for initial gait training. One study comparing aquatic and land therapies for 16 individuals with LLD concluded AT improved balance and exercise adaptation to a greater extent than land therapies.[12]

Typically, individuals with LLD do not use a prosthesis in AT. A daily prosthesis is not often waterproof, and a secondary prosthesis may not be covered by insurance. Furthermore, individuals with recent amputation may not have a definitive prosthesis at the time of AT involvement. Additionally, entering and exiting the pool using stairs or ladders cannot be safely performed without a prosthesis. Unilateral weight bearing leads to unbalanced standing posture, and dual limb exercises, including gait training, are not possible.

The principle of dilatancy has been used in prosthetic and wheelchair impressions by placing particles under vacuum pressure, creating a rigid shape.[13,14] Dilatancy could be useful in designing an adjustable prosthesis for AT, facilitating an adjustable rigid inner socket.

An adjustable, noncustom prosthesis for individuals with transtibial limb difference (TTLD) is expected to improve accessibility to therapeutic activities in AT and be considered a useful rehabilitation tool from both the patient and therapists' perspective. The concept of this design is to create a system of interchangeable sockets and pylons, which can be fit by a physical therapist (PT) for use in AT.

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METHODS

STUDY DESIGN AND PARTICIPANT RECRUITMENT

An adjustable prosthesis system was developed and tested on three individuals during two fitting and three AT sessions (Table 1). Participants were recruited from Shirley Ryan AbilityLab following recommendation from a clinical prosthetist or PT for meeting inclusion criteria and appropriate to test a prototype system. Inclusion criteria were 18–89 years of age, unilateral TTLD, K2–K4 level, ability to wear a prosthesis, and active in AT, recently completed within 6 months, or determined a good candidate for AT by a therapist. Exclusion criteria included comorbidities which would interfere with the study design, pregnancy, contraindications for AT, and inability to walk without an assistive device for 2 minutes. Written consent of participants was obtained prior to study involvement. All participants were active in PT at consent, and two had completed at least one clinical AT session prior to consent.

Two members of the PT department (W.G. and M.H.) provided initial insight on desired features of the prosthesis and administered AT, alternating sessions due to availability. At the conclusion of the study, their feedback was obtained after consent.

Table 1. Participant demographics at time of study enrollment

									Adjustable Prosthesis Sizing			
ID	Age (Years)	Gender	Height (m)	Body Mass (kg)	Cause of Amp.	Amp. Laterality	Years Since Amp	K-Level	Suspension	Socket and Pouch	Pylon	Distal End Pad	Pretibial Pads or Gel Spots
1	47	Female	1.69	63	Dysv	Right	3.5	3	Locking	M	Tall 11, mm extended	3 cm	Pretibial pads
2	55	Male	1.8	95.5	Dysv	Left	2	3	Locking	S	Tall, max height	2 cm	None
3	22	Female	1.67	95.2	Blood clot	Right	<1	3	Suction	L	Short, min height	3 cm	Gel spot

Amp., amputation; Dysv, dysvascular; S, small; M, medium; L, large.

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DILATANCY

To identify the optimal material for the adjustable dilatancy design, particles were filled into neoprene pouches, placed inside a plastic bag, and vacuum was pulled to allow ranking of rigidity under vacuum. Additionally, a consistent volume of the materials was weighed for ranking. Materials tested included the following: nonexpanded polystyrene (NEPS), expanded polystyrene (EPS), buckwheat hulls, silica sand, and vermiculite. Materials were selected with the following reasoning: EPS and buckwheat are commonly used in bean bag chairs, NEPS due to its small, uniform shape, and silica sand and vermiculite for their availability in prosthetic environments. A neoprene pouch was filled with the optimal material and used to cover the residual limb (RL).

SOCKET DESIGN AND FABRICATION

Prosthetic socket design and componentry were chosen to allow independent PT donning with minimal need for adjustments. The socket (3 sizes) consisted of thermoformed Vivak with a four-hole plate at the distal end and a one-way valve. An Alps Skin Reliever Liner served as the interface between the RL and dilatancy pouch. This was reflected outward onto the socket, creating a closed system for the pouch. Inside the socket was a custom-fabricated 1-mm double layer neoprene pouch (3 sizes) filled with 2- to 3-mm diameter EPS. The socket was suspended to the RL with an Alps Super Stretch Sleeve. Distal to the socket, an Xtend by Lindhe four-hole plate quick-change adapter facilitated swapping sockets to adjustable pylons. The combinations included attachment directly to the prosthetic foot, or pylon to foot, using Össur adjustable height pylons, short and tall. The height ranges from mid-patellar tendon (MPT) to floor accommodated were 35.4 cm to 51.9 cm. The Niagara by Empire Medical, a universal 26-cm Hydex plastic foot, was used with a 1.2-cm heel wedge and rubber treading adhered to the plantar surface. Socket alignment included 5° extension, 0° adduction/abduction, and no inset/outset. In the transverse plane, the foot was rotated to the appropriate toe out when setting pylon height. Socket sizing was guided by average anthropomorphic lower-leg lengths and typical transtibial amputation lengths.[15,16] The expected MPT circumferences to be accommodated were 20–44 cm and RL lengths 8–23 cm (Figure 1).

The rigid socket shape was relatively cylindrical with mild anterior triangulation. Additional Velcro pretibial pads were used for loading the RL as needed. Gel spots were used under the liner for relief as needed.

To don the prosthesis, an Alps Skin Reliever Liner was first applied to the RL, and over this, the neoprene pouch with EPS was donned. EPS was shifted around the RL, covering bony prominences as needed. Distal end pads with EPS accommodated height from MTP to distal end of the socket, with appropriate fit determined with the patella sitting just proximal to the anterior trimline. The socket was donned and then the liner was reflected to the outside of the socket, sealing the pouch from the RL. The suspension sleeve was reflected proximally onto the thigh. Vacutec 800 EV2 Aspirator pump was attached to the one-way valve, and 203–254 mm Hg vacuum was applied (Figure 2), which is below the typical levels used in elevated vacuum (EV) prosthetic applications.[17]

FITTING AND THERAPY VISITS

Participants attended two fitting visits with prosthetic team members (A.A. and S.H.-L.) for the development of the prosthesis and appropriate sizing; standard clinical practice principles of static and dynamic alignment were applied with a goal of successful therapeutic use in AT. Sizing was recorded and replicated for all AT visits. The sizing consisted of socket and corresponding dilatancy pouch size, pylon length, distal end pouches used, and any necessary gel spots and/or pretibial pads. Two PTs were trained to don the prosthesis. Each participant completed three 30-minute AT sessions led by a PT, completing exercises, gait training, and swimming. During initial AT sessions, prosthetists assisted the therapist in prosthesis donning. At each participant's third session, the PT independently donned it.

OUTCOMES

The primary outcome was the System Usability Scale (SUS), administered to participants at the conclusion of their third

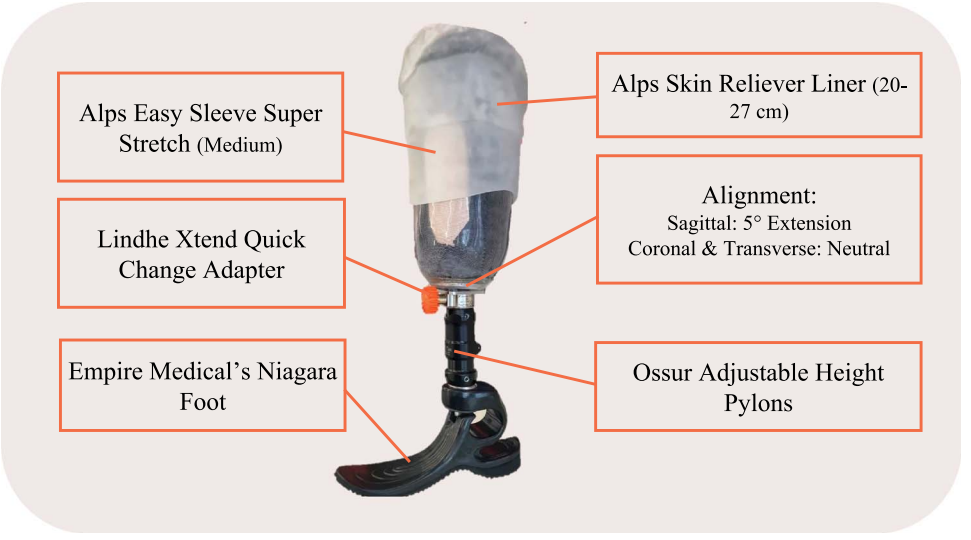


Figure 1. Componentry used in the adjustable prosthesis.

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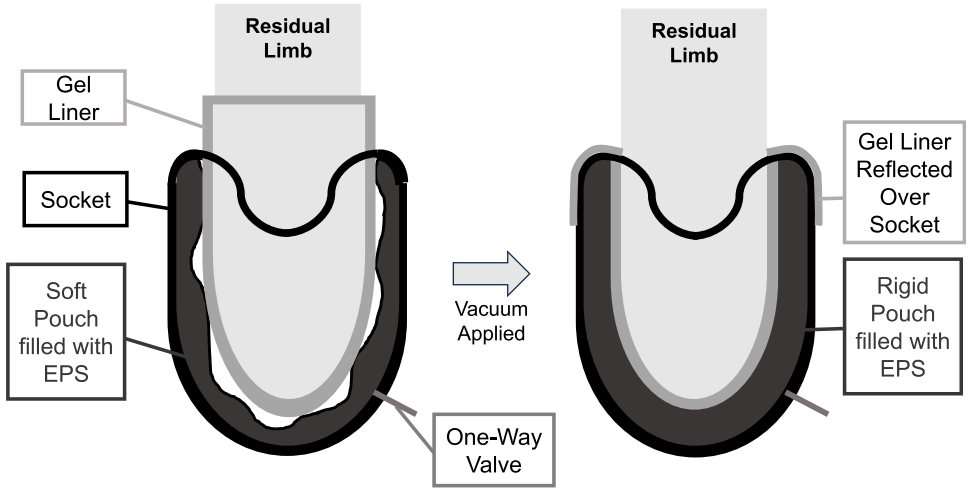


Figure 2. Process for creating a rigid, custom shape within a noncustom prosthetic socket utilizing dilatancy.

AT session.[18] The two PTs also completed the SUS at the end of the participant sessions. The SUS is a 10-item questionnaire assessing usability of a variety of items from the consumer's perspective. This survey is not specific to prosthetic devices, but universally used with strong validation. Survey results were converted to a 100-point scale.[19,20]

Secondary outcomes included socket comfort scores (SCSs) and timed prosthesis donning by the therapist at the third AT session. SCS is a 0–10 ranking of comfort in increasing order.[21] Each participant's SCSs from the third AT session at donning, during AT, and after AT were averaged.

RESULTS

DILATANCY MATERIALS

EPS displayed an optimal combination of rigidity and weight and was selected for use in the dilatancy pouches. Other materials were rejected for a variety of reasons: vermiculite demonstrated high rigidity and low weight; however, it was excluded due to the potential for asbestos contamination; silica sand was difficult to disperse around the RL; NEPS pulled through seams of the sewn pouch; and buckwheat hulls were not comfortable within the pouch (Table 2).

Table 2. Ranking rigidity under vacuum and weight of materials

Material	Rigidity	Weight
Sand	1	8
Vermiculite	2	2
Expanded polystyrene	3	1
20% Sand/80% vermiculite	4	4
50% Sand/50% NEPS	5	7
20% Sand/80% NEPS	6	6
NEPS	7	5
Buckwheat hulls	8	3

Ranking of 1–8, where 1 is most rigid and lightest.
NEPS, nonexpanded polystyrene.

OUTCOMES

Participant's SUS scores were 97.5, 95, and 87.5 of the total 100 possible points. Therapist's scores were 92.5 and 85. Average SCSs during the third session were 10, 9, and 7.6/10 (Table 3). Recorded times for the therapist to don the prosthesis were 5:32, 5:45, and 4:10 (minutes:seconds).

DISCUSSION

The Veterans Administration Clinical Practice Guidelines (CPGs) recommend that appropriate equipment and assistive technology be provided during the perioperative stage of amputation and emphasize importance of early mobility training after amputation, including weight bearing through the RL.[22] An adjustable prosthesis for AT could assist in meeting both CPG recommendations for individuals with TTLD. This study was the initial work developing and assessing the usability of an adjustable prosthesis to allow early gait training in AT, enhancing the rehabilitation benefit for individuals with LLD.

DILATANCY

Dilatancy properties of EPS offered an adjustable socket with total contact for multiple individuals. The inner shape conformed and hardened to the RL, offloading the distal tibia and translating

Table 3. Socket comfort score before, during, and after the third aquatic therapy session for each participant

ID	Pre	During	Post
1	7	9	7
2	10	10	10
3	8	10	9

Ranking from 0–10, with 10 being the most comfortable.

forces to the prosthesis for actuation. It was determined that material to fill the dilatancy pouch should be lightweight and rigid under vacuum for socket comfort and control. EPS provided an optimal combination of these characteristics. Similar strategies with EPS are used for custom wheelchair impressions.

FITTING SESSIONS

Fitting sessions provided feedback on the design and guided sizing recommendations. Participants noted improved comfort when vacuum was applied to the pouch in standing, rather than seated or offloading the RL. The greatest comfort was achieved with 203–254 mm Hg vacuum. Participants reported 127 mm Hg did not provide enough relief to the distal RL, and higher levels near 381 mm Hg resulted in the socket feeling tight. This vacuum technique is different from traditional EV applications. Rather than applying vacuum to the entire system, pulling the RL toward the inner socket walls as in EV, this system only applied vacuum to the dilatancy pouch. Due to this, lower levels of vacuum resulted in appropriate socket comfort and fit. Initial socket triangulation provided appropriate offloading of the distal tibia for two participants, whereas the third required additional pretibial pads added via Velcro. One participant required a gel spot placed over a sensitive area, which relieved discomfort.

Prosthetic alignment goals for the system included a safe and stable gait for both left and right use. Neutral coronal alignment resulted in stable gait, with minor varus or valgus at mid-stance on land, eliminated in the water. Participants denied discomfort resulting from this deviation. The socket was initially set in standard bench alignment of 5° sagittal flexion, resulting in excessive knee flexion at initial contact. For all three participants, 5° of extension eliminated this deviation and improved participant comfort.

It was expected that the distal end pads would accommodate the difference between RL length and socket length. This was not found to be consistent, most likely due to the large amount of variation in the placement of the EPS within the pouch based on limb shape. More EPS located at the distal end required fewer distal pads. For all three participants, fewer distal pads were required than expected. Participant's distal end pad sizing was consistent in each AT session, without issue. The sizing of distal end pads will require further investigation to create a sizing guide.

The initial concept for this prosthesis was to not require the input of a prosthetist for sizing selection or fitting; however, it is expected that an evaluation by a prosthetist will be required prior to a therapist donning. It is expected that this will improve the participant's socket comfort, reduce time required by the PT, and verify appropriateness of the device.

AT SESSIONS

Both therapists facilitating AT sessions frequently treat individuals who use prostheses. One therapist led four AT sessions, and the other led five sessions. With the prosthesis donned, participants entered the pool via stairs or a ladder, then engaged in gait training, strengthening and balance exercises, and swimming, with the RL weight bearing, stabilizing, or as a longer lever for strength activities (Figure 3). Occasionally, hydro-tone fins were attached to the prosthesis for added resistance.

Resisted side steps induced minor discomfort for one participant at the medial proximal socket trim line. It is speculated that discomfort occurred due to the pouch shifting during donning of the prosthesis or insufficient pouch height at the femoral condyles. This could be addressed in the next iteration by increasing the pouch height. Additionally, one participant experienced slight movement

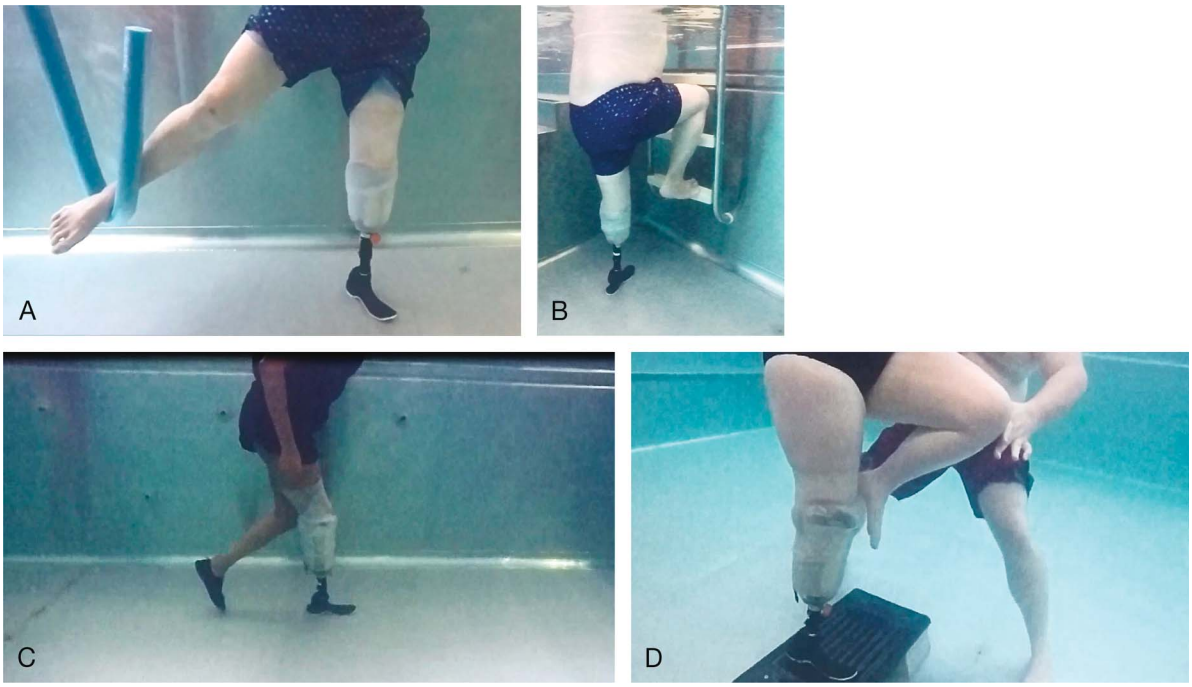


Figure 3. Photos of the prosthesis during AT. A, Single leg balance on prosthesis with resisted contralateral adduction. B, Ladder to exit pool. C, Single-leg lunge jumps. D, Step-up on prosthesis with contralateral knee drive.

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of the prosthesis on the RL while swimming breaststroke. This distraction may be due to the force on the prosthesis while swimming and shifting of proximal thigh tissues when kicking, magnified by the high elasticity of the suspension sleeve. All participants experienced minor amounts of water entering through the proximal aspect of the suspension sleeve; however, the motion or water in the sleeve did not impact suspension, comfort, or function.

SUS

The participants and the therapists completed the SUS as they are both "users" from a unique perspective. Participant feedback demonstrates clinical interest from a patient perspective, whereas therapist feedback will guide the potential use in AT, as a PT will be required for fitting and using the system. Participant SUS scores of 97.5, 95, and 87.5 and PT scores of 92.5 and 85 demonstrate a usable system with the grading of "A+" or greater than passable for usability based on recommended scoring (Appendix A, http://links.lww.com/JPO/A148).[19,23,24] Compared with over 5000 SUS scores assessing a variety of systems, our results fall into the 96–100 percentile range, demonstrating users are more likely to recommend this to others.[23,24] Questions that assess the likelihood of using the system frequently and confidence using the system resulted in participants selecting maximum values. All participants deducted a point when evaluating their required technical support to use the system, and one participant deducted a point when assessing the ease of use of the system. Our goal is for the prosthesis to be easily adjusted by the therapist; it is not intended for the participant to independently don the prosthesis. Due to this, the participant responses are acceptable. An important element is the learnability of the system from the therapist perspective. Both therapists reported that they "strongly disagree" with needing support from a technical person to use the system. These responses reflect that after initial training in the system, therapists may be able to operate it independently for AT sessions.

SCS

During the fitting sessions, reported SCSs were lower than scores reported at the final AT session. This is attributed to the optional additional removable pretibial pads and gel spots. It is important to note that two participants had slightly lower SCSs on land (7–8/10) than in the water (9–10/10). This is expected as body weight is offloaded with water immersion. The lowest SCS reported while in the pool was 9/10, demonstrating a high degree of comfort during all therapy activities in the pool, even when loading forces were increased during jumping and resistance training.

TIME TO DON

Donning time is expected to be reduced with therapist repetition. Times of 5:32 and 5:45 (minutes:seconds) were recorded by separate therapists at the final AT session for two participants. At the last participant's final AT session, the therapist had gained greater experience donning the prosthesis by this time, and 4:10 (minutes:seconds) was recorded. Additionally, 60–90 seconds were included for allowing the vacuum pump to pull air from the system. This can likely be reduced, as extra time was allotted for beginning trials. An additional time intensive step was reflecting the sleeve onto the thigh. This could be simplified with assistance from the participants but was not allowed for consistency between participants. Additionally, alternative sleeve designs could be considered.

LIMITATIONS, ATTEMPTED MITIGATIONS, AND FUTURE RESEARCH

Participants represented a sample of prosthetic users, and the design should be further assessed by a population with greater variability in age, K-levels, RL presentation, and time since amputation. It is important to note the relatively narrow RL size variance tested, with circumferences at MPT measuring 32–40 cm and RL length 14–16 cm.

PTs conducting AT in this study also completed the SUS to evaluate the feasibility of this design in a clinical setting, which may induce bias. However, this prototype was not used outside of the study, and it was important to record the therapist's initial perspective on the system. Reviews from alternative PTs will be obtained in the future.

This was an initial feasibility and usability study, and future iterations have the possibility for improvement. A new pylon should be designed with the ability to adjust height without a tool. Additionally, the pylon should include greater adjustment to ensure the prosthesis can accommodate most individuals. A new prosthetic foot should be considered with a greater weight rating. A battery vacuum pump that can be set to a specific vacuum level should be considered for safety in the pool setting. For socket and pouch sizing, an initial sizing chart was developed with the limited testing performed in this study. This should be further investigated to ensure accuracy of sizing. The therapy team also expressed interest and need for a system for individuals with bilateral TTLD. The cost of a unilateral TTLD kit was approximately $4000. Although this is expected to change with future iterations, it is an important consideration when comparing cost to traditional custom prosthetic fabrication and componentry.

CONCLUSIONS

This system functioned successfully as a noncustom prosthesis for multiple users in AT and was determined as useful from both the participant and therapists' perspectives. Applying vacuum to EPS, within a neoprene pouch, created a rigid interface that was successfully used on multiple RLs, allowing a therapist to conduct gait training, bilateral balance training, and other dual limb activities not typically accessible to individuals with LLD in AT.

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