Shuttle Lock Suspension Supplemented with Suction for a Person with Transfemoral Amputation: A Case Report

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ABSTRACT

Traditional suction suspension is well documented for fitting amputees with transfemoral amputation. Volume fluctuation and shape change in the transfemoral residual limb can impact the quality of linkage obtained with this type of suspension. Poor linkage can have a negative impact on activity level, confidence, and overall ability of the transfemoral amputee to use the prosthesis. The purpose of this case report was to document the change in the ability to ambulate for persons with transfemoral amputation as they transition from a prosthesis with traditional suction to one with shuttle lock suspension supplemented with suction (passive vacuum [PV]). A 59-year-old male subject with a unilateral transfemoral amputation experienced a decline in participation activity level and decreased confidence while using a prosthesis with suction suspension and ischial containment (IC) socket design. The Amputee Mobility Predictor with prosthesis (AMPpro) was administered while he used the suction-only prosthesis and after 5, 9, and 12 months with a prosthesis featuring shuttle lock suspension combined with PV along with a total surface bearing (TSB) socket interface (SI). His AMPpro scores increased 5 points in the first 5 months with the PV prosthesis and improved slightly in the final 7 months of testing. Performance in reaching, transfers, and static balance tasks improved, allowing the subject to transition from an activity level K2 to activity level K3. The subject's improved capability can likely be attributed to the combination of the prosthesis with the PV SI along with physical therapy. (J Prosthet Orthot. *2013;25:188-192.)*

BACKGROUND

The link between functional capability and quality of life for persons with amputation is well established. Most persons with amputation are presented with challenges to mobility, especially those with transfemoral amputation. Persons with transfemoral amputation typically experience greater difficulty performing activities of daily living than those with transtibial amputation.[1,2] For example, it has been shown that persons with transfemoral amputation expend 40% to 67% more energy than those with transtibial amputation during ambulation with a prosthesis.[3] Persons with transfemoral amputation also experience a number of other challenges that can reduce activity level and quality of life including skin irritation, inability to walk over uneven surfaces, and contralateral limb pain.[4]

Limb loss affects approximately 1.9 million people in the United States, of whom 400,000 have amputation above the knee. Amputation associated with dysvascular conditions accounted for most (82%) cases of limb loss and increased[5] at a rate of 27% from 1988 to 1996. Predictors for functional success with a prosthesis have been well documented and include good muscle strength and balance, more distal amputation level, amputation caused by trauma as opposed to compromised vascularity, and general lack of other comorbidities.[1,2,6] However, most persons with transfemoral amputation do not meet that description. To overcome these challenges and improve the functional capability of persons with transfemoral amputation, advances in componentry, socket interface (SI) improvement, training, and physical therapy are necessitated. For instance, the functional benefits of different types of prosthetic knees have been proven in persons with transfemoral amputation of a dysvascular nature, especially for those who have microprocessor-controlled stance. A study was conducted in which a 53-year-old man with peripheral vascular disease completed the Activities-specific Balance Confidence (ABC) test, the Berg Balance Assessment, and the Timed Up and Go (TUG) functional mobility test with a prosthesis featuring a

traditional geometrically stabilized knee joint. Three weeks later, the subject completed the same testing with a microprocessor-controlled knee joint, in which he demonstrated improved scores in all three assessments. Furthermore, the subject returned to participation in previous recreational activities including bowling and jogging.[7] One possible mechanism responsible for an increase in activity level for persons using a microprocessor-controlled knee is an improvement in gait through increased confidence and improved balance. In this case, the subject's gait improved by placing more reliance on the prosthetic limb when using the microprocessor-controlled knee.[5] The same can be said for prosthetic feet that allow for greater control and mobility through increased ground compliance.[3]

Another important component having a profound effect on the ability to use a prosthesis is the SI, which is the style of socket in terms of modification to the limb model, interface medium (if any), and the method by which it is suspended or linked to the user. There are many different SI designs and several different suspension methods; however, the function of the SI remains the same—to accommodate the unique shape of the residuum and effectively link the prosthesis to the user of the device. Along with proper training and physical therapy, a properly fitted and suspended SI is crucial to maintaining functional level because quality of socket fit was rated as the most important issue among users of lowerlimb prostheses in a 1999 study by Legro et al.[8] One widely used SI is the ischial containment (IC) socket with skin-fit suction as the suspension method. This SI has been shown to reduce energy expenditure by 20% when compared with the older quadrilateral socket design with similar suspension.[9]

Researchers have also reported improved temporospatial gait parameters with the IC socket in similar comparisons.[10] Although this research is encouraging, one of the major deterrents for success when using any SI relying on suction as the primary means of suspension is the decrease in suspension or linkage quality with a change in limb shape or volume. With suction suspension, it is common for the residual limb to experience a decrease in volume, which can result in an illfitting socket that places excessive pressures on the tissue over bony prominences. Conversely, an increase in residual limb volume can result in excessive pressure on the entire surface of the limb, which can occlude blood flow and deny residual limb tissues of nutrients.[11] Both increase and decrease in limb volume contribute to compromised linkage, which can result in loss in functional capability. With suction as the primary means of suspension, this can lead to complete detachment of the prosthetic device from the residual limb. A new type of SI for persons with transfemoral amputation that does not rely on suction as the primary means of suspension and alleviates the negative effects of residual limb volume change would further improve functional capabilities.

The total surface bearing (TSB) socket design has been shown to benefit persons with transtibial amputation over the conventional patellar tendon-bearing socket design,[12] but no such comparison has yet been made between the IC and TSB sockets for persons with transfemoral amputation. One of the differentiating factors between transtibial and transfemoral suction sockets is the ability for persons with transtibial amputation to use a suspension sleeve, which also acts as a sealing sleeve. The nature of the transfemoral amputation does not allow for much anatomy proximal to the socket brim to accomplish a sealed socket in this manner. A supplemental sealing and suspension method would be necessary in this case.

An emerging SI termed passive vacuum locking suspension (PVLS) combines the security of a mechanical pin and lock suspension with the comfort of a TSB suction socket.

Passive vacuum (PV) locking suspension consists of a silicone liner and shuttle lock system used in conjunction with a sealing sheath (one-ply sock) worn on the outside of the liner that creates an airtight seal inside the SI. To don the system, a silicone liner is rolled directly on the subject's limb to provide an intimate fit between the subject's residuum and the prosthesis. A sheath with a silicone seal is placed over the liner before the limb is inserted into the socket. As the prosthesis is donned, the seal on the sheath engages the liner on one side and the inside socket wall on the other side. This creates a sealed system from the most proximal aspect of the seal distally to the connector on the end of the socket. As the seal engages the liner and the socket wall, the shuttle lock pin attached to the bottom of the liner mechanically locks into the suction/vacuum compatible shuttle lock. A one-way valve distal to the socket and lock is used to expel air from the system and keep it from reentering. The shuttle lock functions as a secure primary means of mechanical suspension and a sealing plate to make the distal end of the socket airtight. The

sealing sheath allows air to be expelled from within the socket but does not allow it to reenter the system from the top of the socket. This unidirectional flow of air creates suction within the sealed chamber inside the socket. Passive vacuum locking suspension is essentially suction with a shuttle lock acting as the suspension device. With the added security of the shuttle lock, PVLS may be able to increase patient confidence in the suspension of the device, as well as optimize quality of fit and function. Passive vacuum locking suspension has been used successfully with transtibial amputees for years and can be easily adapted for use with a prosthetic vacuum pump to create an elevated vacuum or vacuum-assisted SI in both transtibial and transfemoral cases. Unfortunately, evidence for its use with transfemoral amputees ismostly limited to clinical anecdotes and subjective observation.

This case report shows the functional development of a subject with a unilateral transfemoral amputation transitioning from a traditional IC-suction SI to a PVLS system with TSB socket and shuttle lock suspension. It was hypothesized that the patient's functional ability would improve because of this prosthetic intervention.

CASE DESCRIPTION AND METHODS

The patient in this report is a 59-year-old man with a left transfemoral amputation as a result of a motorcycle accident 32 years ago. In addition to the amputation, his injuries necessitated a posterior lumbar fusion. He is nondiabetic and is a nonsmoker and regular alcohol drinker. He was 6 ft 1 in tall and weighed 204 lbs at his initial evaluation. At the time the patient agreed to participate in this study, he had been wearing a prosthesis featuring an IC socket with traditional skin-fit suction for 12 months and was being treated for arthritis in his contralateral knee.

The patient commented that his IC prosthesis was causing him pain and noted that his activity level had decreased since his latest prosthetic fitting 1 year earlier. His primary complaint was that the IC socket did not fit appropriately and he often lost suction, causing his residuum to slip inside the socket and lose suspension. He had been using his cane more frequently and had stopped participating in recreational activities that included gardening and fishing. The patient confided that he did not trust his current prosthesis. Specifically, he had fallen several times in the previous 12 months. The falls were reported by the subject to be a direct result of the SI losing suction. The loss of suction caused his knee unit to act erratically, which resulted in disruption of his gait pattern. An evaluation by the referring physiatrist revealed that the subject had developed some poor gait habits likely as a direct result of distrust in the prosthesis. Among the gait deficiencies, the subject was not transferring sufficient weight to the prosthetic side for proper function of the microprocessor knee. The physiatrist ordered an evaluation by a physical therapist to assess further deficiencies and needs. The examination by a licensed physical therapist concluded that the subject was experiencing additional gait deficits caused by his ill-fitting prosthesis, including asymmetrical step length and poor hip extension.

With input from the physical therapist, the treating physiatrist and prosthetist decided to fit the subject with a prosthesis featuring a PVLS SI, a decision that was based on the subject's active lifestyle and need for reliable suspension, fit, and function (Figure 1). Specifically, the Elevated Vacuum Locking Systemi(EVLS) was chosen for its abilities to provide a secure method of suspension should the PV (suction) fail. The EVLS also provides an audible indicator when the plunger pin engages the lock. This is a cue to the subject that he is secured in the socket and that distal end contact will be achieved and maintained until the lock is released.

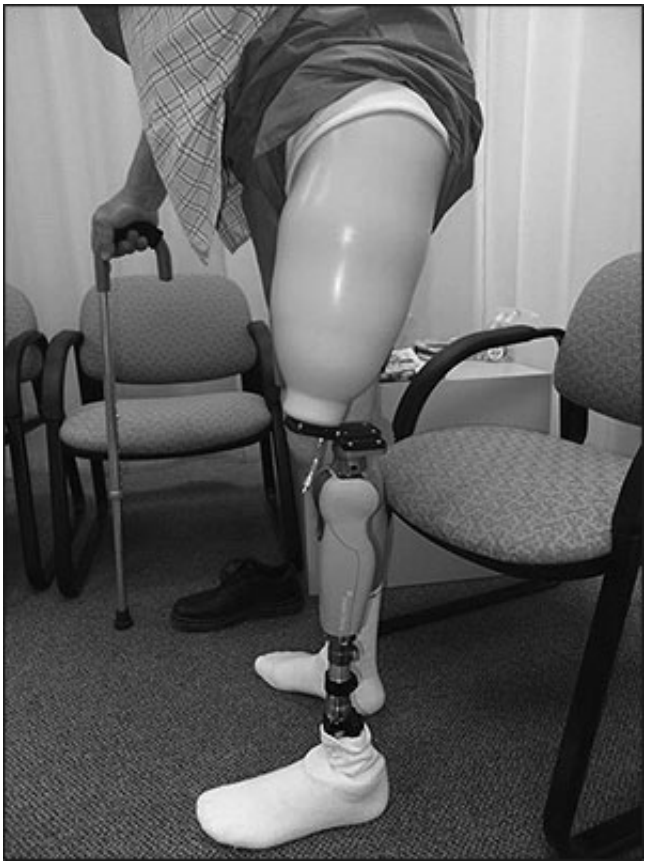

Figure 1. Subject wearing the PVLS prosthesis during the first fitting. All of the subject's prosthetic components are listed in Appendix 1. PVLS, passive vacuum locking suspension.

The subject's progress was quantitatively measured four times: while wearing the IC prosthesis before PVLS fitting, at his initial PVLS fitting, after 4 months of continued PVLS use, and after 12 months of PVLS use.

An effort was made to implement a reliable, ecologically valid assessment to track the subject's functional development through his transition from IC socket with skin-fit suction prosthesis to the one featuring PVLS. The outcome measure used for this study was the Amputee Mobility Predictor with prosthesis (AMPpro). The patient performed tasks such as standing from a seated position, walking up and down stairs, and reaching for an object. Scores were given on the basis of the patient's ability to complete the task regardless of assistive devices used. A 3-point scale (0, 1, and 2) was used for most activities, with the lowest score indicating the poorest performance. The AMPpro test has been proven comparable with the traditional 6-minute walk test and is a valid measure of amputee ability with or without a prosthesis.[13] The test is conventionally used to determine the initial K-level of a patient before prosthetic prescription, but it is possible to show functional improvement using repeated AMP pro tests.[14]

FINDINGS AND OUTCOMES

The patient's scores in the AMPpro increased throughout the rehabilitation process (Table 1).

Months in PV	Suspension	Score (of 47)	K-level
NA	Suction only	31	K2
5	EVLS with suction	36	K2
9	EVLS with suction	37	K3
12	EVLS with suction	38	K3

AMPpro, Amputee Mobility Predictor with prosthesis; PV, passive vacuum; NA, not applicable; EVLS, Elevated Vacuum Locking System.

Table 1. Subject's AMPpro scores

In the IC system, the subject was unable to safely rise from a chair, reach for an object, remain standing after a perturbation, stand with his eyes closed, or smoothly turn around without a walker. Those scores reflected the subject's statement that he was feeling unstable in the IC system.

After 5 months with the PVLS prosthesis, the subject's performance in sit-to-stand, standing balance, and standing balance after perturbation improved. In addition, he no longer required the walker for any task. Instead, he used a straight cane for most activities. He also reported participation in recreational activities. For the first time in several years, the subject was able to walk long distances, climb up and down long flights of stairs, and walk on a dock at his lake house. Other activities he reported were mowing the lawn and carrying firewood. Furthermore, he was no longer taking pain medication every morning. The subject attended 10 physical therapy sessions in the 5 months between receiving the PV prosthesis and the second AMPpro administration. At his physical therapy appointment that day, the subject said, "How much longer do I have to come? I have a garden to put in." He was discharged from physical therapy with detailed home exercise instructions.

After 9 months of use, the subject's stand-to-sit score increased. He reported more participation in recreational activities, including auto repair and camping. He reported no falls and wore the prosthesis approximately 14 hrs a day. The subject's AMPpro scores increased, and he still required the cane for the stability and reaching tasks.

At the final appointment, after 12 months of regular use, the subject had further increased his score but remained unable to perform the single-limb stance or stand with eyes closed without the straight cane. The subject maintained participation in recreational activities and expressed confidence in his stability while wearing the prosthesis. No decreases in function were measured for any task at any appointment.

CONCLUSION

The subject was experiencing significant functional deficiencies while using the IC prosthesis with traditional skin-fit suction. It was hypothesized that his functional ability would increase as a result of wearing the PVLS prosthesis because of the technology's ability to provide better suspension, fit, and function for transtibial patients. In fact, the subject significantly improved in the areas of reaching, transfers, and static balance. It is believed that the subject's functional ability improved because of the intimate fit and the rotational control provided by the TSB suction socket as well as his confidence in the suspension forces and socket environment created by the PVLS.

The subject's increased stability as he used the PVLS prosthesis has been noted in individuals with transtibial amputation wearing elevated vacuum prostheses.[15] It has been theorized that application of negative pressure via an active vacuum pump to a sealed space leads to high static frictional forces that prevent separation of the limb and the liner from the socket wall.[16] Separation of the limb and the liner from the socket wall is analogous to motion of the liner, the limb tissue, and the underlying bone structure inside the SI. Passive vacuum locking suspension is essentially elevated vacuum with the active vacuum pump

replaced by a one-way check valve, which allows air to move out of the socket but not into the socket. Therefore, it is possible that the subject's increased stability could be explained by relatively high suspension forces such as those maintained in an elevated vacuum system.[17] The higher suspension forces achieved with elevated vacuum have been shown to result in less tibial movement within the socket.[18] It is possible that the suspension forces inside the PVLS socket stabilize the limb tissue and the femur enough to provide a significant increase in stability and thus functional ability.

The subject's participation in physical therapy and new prosthetic components other than the PVLS system, including the foot and the knee, could be viewed as contributing factors to the subject's increased functional level. However, the subject's satisfaction with the liner interface between his prosthesis and residual limb is the most important factor to improved functionality.[8] The subject expressed increased satisfaction with the fit of the PVLS system, and his function improved accordingly. In addition, the fact that he was able to improve function long after physical therapy discharge suggests that this subject's progress is not due entirely to physical therapy.

This article is a case report considering only one patient, and it is hindered by the conventional limitations of that research design. A larger study documenting the effects of passive and elevated vacuum on transfemoral amputees is under way. This study examines only functional capability as measured by one assessment, but further research using additional outcome measures such as energy expenditure and socket comfort should be conducted to determine the effect of PVLS on transfemoral amputees.

This report suggests the potential of PVLS to enable a patient to take advantage of his/her prosthesis and participate in activities beyond those required by daily living. Once the fitting process has been completed, the patient is able to ambulate with confidence. Even a patient who has been limited by an inadequate prosthesis can, within months, greatly improve ambulatory ability.

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APPENDIX I

Component	Manufacturer	Part no.
Total surface bearing socket	Prosthetic Design	Custom
Elevated Vacuum Locking System (EVLS)	Prosthetic Design	EVLS-CAUC
Custom SealMate™ Silicone Liner	Prosthetic Design	SM-Custom
AURA™ Seal Sock	Evolution Industries	HSSN-6-16-6
EVLS Slide Valve Manifold	Prosthetic Design	EVLS-MAN-VLV
FLEXCON™	Prosthetic Design	FC15-TD8CFI
Sliding and rotating pyramid receiver	Prosthetic Design	PR-SL-R-TI
Rheo Knee®	Ossur	RKN120007
Height-adjustable tube clamp	Prosthetic Design	TC30-1/2
Standard tube clamp	Freedom Innovations	ACC-00-12500-00
Pylon	TiMed	A300
Vari-Flex® with EVO®	Ossur	VFPE6270

Appendix I

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References:

1. Gauthier-Gagnon C, Grise MC, Potvin D. Predisposing factors related to prosthetic use by people with a transtibial and transfemoral amputation. *J Prosthet Orthot* 1998;10:99-109.
2. Raya MA, Gailey RS, Roach KE. Impairment variables predicting activity limitation in individuals with lower limb amputation. *Prosthet Orthot Int* 2010;31:73-84.
3. Schmalz T, Blumentritt S, Jarasch R. Energy expenditure and biomechanical characteristics of lower limb amputee gait: the influence of prosthetic alignment and different prosthetic components. *Gait Posture* 2002;16:255-263.
4. Hagberg K, Branemark R. Consequences of non-vascular transfemoral amputation: a survey of quality of life, prosthetic use and problems. *Prosthet Orthot Int* 2001;25:186-194.
5. Kaufman K, Levine J, Brey R, et al. Energy expenditure and activity of transfemoral amputees using mechanical and microprocessor-controlled prosthetic knees. *Arch Phys Med Rehabil* 2008;89: 1380-1385.
6. Zidarov D, Swaine B, Gauthier-Gagnon C. Quality of life of persons with lower-limb amputation during rehabilitation and at 3-month follow-up. *Arch Phys Med Rehabil* 2009;90:634-645.
7. Wong C, Wilska J, Stern M. Balance, balance confidence, and falls using nonmicroprocessor and microprocessor knee prostheses: a case study after vascular amputation with 12-month follow-up. *J*

Prosthet Orthot 2012;24:16-18.
8. Legro MW, Reiber G, del Aguila M, et al. Issues of importance reported by persons with lower limb amputations and prostheses. *J Rehabil Res Dev* 1999;36:155-163.
9. Gailey RS, Lawrence D, Burditt C, et al. The CAT-CAM socket and quadrilateral socket: a comparison of energy cost during ambulation. *Prosthet Orthot Int* 1993;17:95-100.
10. Flandry F, Beskin J, Chambers RB, et al. The effect of the CATCAM above-knee prosthesis on functional rehabilitation. *Clin Orthop Relat Res* 1989;239:249-262.
11. Carroll K. Options in sockets and liners. *In Motion Mag* 2009; 19:19-22.
12. Selles RW, Janssens PJ, Jongenengel CD, Bussman JB. A randomized controlled trial comparing functional outcome and cost efficiency of a total surface-bearing socket versus and conventional patellar tendon-bearing socket in transtibial amputees. *Arch Phys Med Rehabil* 2005;86:154-161.
13. Gailey RS, Roach KE, Applegate EB, et al. The Amputee Mobility Predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. *Arch Phys Med Rehabil* 2002;83: 613-627.
14. Resnik L, Borgia M. Reliability of outcome measures for people with lower-limb amputations: distinguishing true change from statistical error. *Phys Ther* 2011;91:555-565.
15. Kannenberg A, Guirao C, Samitier P, Pleguezuelos C. Elevated vacuum socket supsension improves balance and gait performance in elderly dysvascular transtibial amputees. Presented at: American Academy of Orthotists & Prosthetists 38th Academy Annual Meeting and Scientific Symposium. 2012; Atlanta, GA.
16. Street GM. Vacuum suspension and its effects on the limb. *Orthopädie Technik* 2007;2:2-4.
17. Ferraro C. Outcomes study of transtibial amputees using elevated vacuum suspension in comparison with pin suspension. *J Prosthet Orthot* 2011;23:78-81.
18. Wood J, Papaioannou G, Fiedler G, et al. Effect of elevated vacuum sockets on residual limb-socket motion in prolonged strenuous activities. In: Proceedings of the American Academy of Orthotists and Prosthetists; March 16 to 19, 2011; Orlando, FL.

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