Using Elevated Vacuum to Improve Functional Outcomes: A Case Report

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Abstract

Elevated vacuum (EV) is a promising technology in the field of prosthetics. It has been scientifically shown to increase the quality of contact between the residual limb and prosthetic socket, resulting in benefits to fit, suspension, and function of a prosthesis. However, very little research has been done on its effect on patient function. This unique case report was written to document the effect on one patient's function of transitioning from a patella tendon-bearing (PTB) socket with ischial weight-bearing thigh cuff (IWBTC) to prosthesis with an EV socket system. The patient underwent a transtibial amputation as a result of an avulsive trauma and used the PTB socket and thigh cuff for 16 years. In an effort to correct the patient's gait and improve his ability to perform the necessary tasks of his occupation, farming, the patient began using an EV prosthesis. He was interviewed and his functional status was evaluated one week, one month and one year after receiving the prosthesis. After one week the patient showed improvement in skin condition and expressed increased confidence in difficult locomotor tasks. At one month he was no longer experiencing pain in his sound side knee and his gait symmetry had improved dramatically. After one year the patient showed further improvement in gait and balance as well as the ability to wear the prosthesis comfortably for 24 hours at a time when necessary for his occupation. The transition from a PTB with IWBTC prosthesis to an EV system dramatically improved this patient's functional outcome and overall satisfaction.

Keywords: lower-limb, prosthetics, function, outcomes, vacuum, sub-atmospheric

I. Introduction

It is the goal of all prosthetic interventions to maximize patient function. Research has shown that physical mobility is the only independent factor that significantly affects quality of life in amputees when compared with non-disabled persons[1]. While they theoretically have the highest probability of achieving normal functioning[2], patients who have undergone amputation due to an avulsive trauma generally have secondary injuries that complicate their recoveries. For transtibial amputees, injuries typically include extensive damage to the patellar tendons and hamstring group. It is possible to accommodate for the resulting gait deficiencies with a patella tendon weight bearing (PTB) socket connected to an ischial weight-bearing thigh cuff (IWBTC) with external knee joints and check strap (Figure 1). In this type of prosthesis, the external knee joints and check strap combine to prevent knee hyperextension in the PTB socket, accommodating the hamstring group weakness. The forces responsible for hyperextension on the residuum are countered by the check strap[3].

Figure 1. Patella tendon weight bearing socket with ischial weight-bearing thigh cuff

Alternatively, there is an emerging technology that shows promise as a replacement for traditional prosthesis designs: elevated vacuum (EV). Also known as sub-atmospheric, EV prostheses consist of an elastomeric liner, total surface bearing socket, mechanical or electronic vacuum pump, and a sealing sleeve. Designs can also include an elevated vacuum locking system (EVLS™), a safety feature which provides suspension should the vacuum seal be breached. EV systems have been found to distribute forces evenly over the residuum, so there is an exceptionally high suspension force without the high pressure areas seen in patella tendon bearing sockets[4]. EV systems also maximize surface contact between the socket wall and the liner, enabling high frictional forces that augment suspension and fit. This phenomenon was recently proven in a study of traumatic transtibial amputees where those wearing EV prostheses demonstrated significantly less vertical movement of the tibia during gait[4]. For a highly-active transtibial amputee, intimate socket fit and effective force distribution are integral to the performance of daily activities, as they are imperative to suspension, comfort, proprioception, function, and limb health. Furthermore, a recent study found that skin problems on the residual limb are uncommon with vacuum system users[5]. Finally, EV was shown to enable better stance phase and step length symmetry when compared with PTB designs in transtibial amputees[6]. Clearly, EV has the potential to greatly increase patient functional achievement.

Despite the possibilities of EV, the lack of research into its effects on patient function limits the evidence for its use. This fact is highlighted by Van der Linde et al.'s literature review which found a lack of unbiased information about the effects of different components, including sockets, on patient functional status[7]. The vast majority of clinical studies that do exist on the topic have used standardized gait assessment protocols with limited ecological validity, making them inappropriate to use in making a prosthetic prescription[7]. No published reports were found documenting EV technology's long-term effect on patient function. Very little unbiased, valid research has been found comparing PTB sockets and EV sockets. Therefore, the purpose of this report is to show the long-term functional development of one patient during his transition from a transtibial prosthesis featuring PTB socket, with IWBTC, external knee joints, and check strap to an EV system.

II. Case Presentation

The subject in this case is a patient at Dayton Artificial Limb Clinic in Dayton, Ohio. He is a highly active 40 year old male with a left amputation at the transtibial level. His amputation is the result of an avulsive traumatic accident in 1992, in which the patient's limb was caught in a grain augur. The injury caused extensive patellar tendon and hamstring group damage. At the time of reporting in May 2010, the patient was 165 centimeters tall and weighed 108 kilograms. He did not smoke and consumed two alcoholic drinks a week. He had not been diagnosed with any other physical health conditions.

Shortly after his amputation, the patient was fit with a PTB socket connected to an IWBTC with external knee joints and a check strap. He was classified a functional level K3 and participated in three months of physical therapy and prosthetic training. He wore this prosthesis for sixteen years, with routine fittings and replacements. He required no assistive devices and walked approximately four miles a day on varied terrain as required by his profession as a farmer.

Throughout the prosthetic process, the patient reported discomfort around the fibula head, mid-patellar tendon, and at the proximal brim of the IWBTC. The fibula head and mid-patellar tendon area pain were managed with pads and socks. He also exhibited minor but persistent circumduction and gait asymmetry. He began experiencing more difficulties with his prosthesis in January 2010. Specifically, the patient complained of pain and stiffness in his sound side knee joint that were likely due to the gait asymmetry, and his limb displayed contact dermatitis. These factors resulted in occasional disuse of the prosthesis. He expressed a lack of confidence in daily activities like getting down from a tractor, climbing a ladder and walking on uneven ground.

III. Treatment

The patient's residuum was manually examined in May 2010 at a routine fitting, and his limb displayed increased range of motion and muscle mass since he began using his PTB with IWBTC prosthesis. In a gait evaluation, the patient demonstrated increased proprioception that allowed for better control of knee hyperextension, and increased anterior-posterior and medial-lateral stability secondary to increased muscular compensation. Furthermore, the patient reported a desire to wear a less cumbersome prosthesis that would allow him more freedom of movement. Based on the patient's increased stability and interest in a new prosthesis, the treating physician ordered an EV prosthesis for the patient. The transition to an EV system was also made in order to simplify the prosthetic use and management for both the patient and the clinician. A total surface bearing socket can be fabricated at a central fabrication facility in a matter of hours, compared with the week required to create a custom laminated PTB socket with IWBTC.

The EV prosthesis included a total surface bearing socket (Prosthetic Design, Dayton OH), silicone liner (Prosthetic Design, Dayton OH), Harmony HD mechanical pump (Otto Bock, Minneapolis MN), EVLS™ suspension (Prosthetic Design, Dayton Ohio), Derma ProFlex sealing sleeve (Otto Bock, Minneapolis MN), and Pacifica foot (Freedom Innovations, Irvine CA) (Figure 2).

Figure 2. The EV prosthesis with detail of EVLS™ (inset). Component details can be found in Appendix i.

IV. Assessment

To measure the effectiveness of the EV prosthesis in increasing the patient's functional capabilities, he was administered three assessments one week, one month, and one year after he received the EV prosthesis (Table 1).

Table 1. Evaluation Schedule

Time Using EV	Assessments
1 week	Qualitative Interview, LCI5, IADL
1 month	Qualitative Interview, LCI5, IADL, AMPPro
1 year	Qualitative Interview, LCI5, IADL, AMPPro

The first assessment was a qualitative interview with questions about residual limb health, sound limb health and daily activities. Also performed was the Locomotor Capabilities Index 5 (LCI5), a measure of a lower limb amputee's capabilities with a prosthesis. It consists of 14 basic and advanced activities on a five-point ordinal scale. It has demonstrated good internal consistency, test-retest reliability and construction validity[8]. The third assessment was the Instrumental Activities of Daily Living (IADL) index, which is a valid assessment found to have utility for a wide range of patient types including amputees[9]. Finally, a research assistant administered the Amputee Mobility Predictor (AMPPro), a highly reliable instrument designed to objectively measure function in amputee subjects so that clinicians can implement the most appropriate components to achieve an optimal gait[10].

V. Outcome

During the initial fitting session in May 2010, the patient was able to ambulate without aid within five minutes of donning the EV prosthesis (Figure 3). He reported that he liked the stability that it provided around his knee as he walked.

Figure 3. The patient wearing the EV prosthesis

One week later, the patient came in for a final fitting and delivery of the EV prosthesis. He reported that initially, blisters developed on the distal end of the residuum as a result of inconsistencies in his donning technique. The sores healed within two days of continued use of the EV prosthesis. At his one week appointment, the patient reported in the interview that he wore this EV prosthesis for ten hours a day with adequate knee joint stability and was feeling more confident with the prosthesis. His residual limb was in excellent condition, with no discoloration, irritation or redness. The patient scored a perfect 56 on the LCI5 and a perfect eight on the IADL index.

One month into use of the EV prosthesis, the patient was again administered the interview and functional assessments. He reported better linkage between the residuum and prosthesis and was not experiencing any pain in his sound side knee joint. Gait evaluation by the physical therapist revealed better weight distribution and symmetry. The patient stated that he wore the prosthesis for 16 hours a day and walked approximately six miles every day. The patient again received perfect scores on the LCI5 and IADL, demonstrating the significant ceiling effects of those assessments. The patient completed the AMPPro. He scored 44 out of 47 possible points, classifying him as a K4 ambulator. He was unable to stand on his prosthesis side foot unsupported, stand with his eyes closed for 30 seconds or to smoothly vary cadence during the gait tasks. His score indicated the ceiling effects of the AMPPro, but no other proven quantitative measure existed at the time of reporting so data collection continued with this assessment.

After one year of use, the patient's functional status was evaluated. In the interview, he reported satisfaction with the EV prosthesis and stated that during the planting season, he was routinely required to wear it for 24 hours a day. He described that he was able to confidently get up and down from his combine, climb ladders and walk over uneven ground in the fields. He displayed remarkably symmetrical gait as he ambulated around the examination room. His residual limb appeared healthy, with hair-regrowth evident over the entire surface. He again received perfect scores on the LCI5 and IADL. He scored a 46 on the AMPPro, missing one point for being unable to stand unassisted on his prosthetic foot.

VI. Discussion and Conclusions

This patient maintained a high activity level when using the PTB with IWBTC prosthesis, but he was experiencing common negative secondary effects of using that type of prosthesis, namely gait abnormalities, skin irritation at high pressure areas, and joint pain. These effects resulted in noticeable functional deficiencies expressed in his lack of confidence in more challenging locomotor tasks. Therefore, the clinician's goal was to reduce the negative secondary effects and enable the patient to improve his functional status. Most importantly, it was hoped that the patient would benefit from the gait normalizing effect that had been seen with other transtibial EV patients. This would reduce the stress on his sound side knee. Less vertical movement in the socket could also eliminate the contact dermatitis that he experienced with the PTB with IWBTC prosthesis.

The interview and functional assessments allowed the patient's prosthetist to track his development as he became accustomed to the EV prosthesis. His responses and scores indicated that the EV prosthesis did in fact have positive effects. Qualitatively, the patient expressed confidence and stability within one week of transitioning from the PTB with IWBTC. This result was unexpected, as it was assumed that the patient would need more time to build up hamstring strength necessary for stability. However, the patient's assertion is consistent with Beil's study of transtibial vacuum users and is likely due to the high suspension forces possible with vacuum systems[4]. While the clinical assessment tools were largely unsuited to his high functional level, the improved balance task performances suggest that he saw increased proprioception with the prosthesis. This also could have contributed to his confidence during locomotor tasks.

In addition to balance, his gait normalized throughout the process. He displayed new abilities to vary cadence and display step length symmetry in the first year of use, consistent with his improved score on the gait tasks of AMPPro. Most likely, these developments were enabled by both the increased range of motion possible without the IWBTC and the increased linkage between the residual limb and the socket. In turn, the pain and swelling in his sound side knee was not present after one month of EV prosthesis use, since he was able to distribute his weight evenly between his sound leg and the prosthesis.

Significantly, all skin issues were resolved within one week of switching to the EV prosthesis, and his residuum remained healthy even under extreme use conditions. This progress can also be explained by the high suspension forces which kept his limb from moving vertically in the socket[4]. Again, improved skin health is common in amputees using EV[5] and suggests that very little movement of the limb against the socket takes place during ambulation.

With his EV system, the patient was able to walk more, wear his prosthesis longer, climb ladders, jump down from a tractor and traverse uneven ground on a regular basis. For this patient, the transition from a PTB with IWBTC system to an EV system dramatically improved his functional outcome and overall satisfaction with the prosthesis.

Additional work is needed in the use of vacuum in the prosthetic industry. Case reports comprise an important step to justifying the efficacy of vacuum systems, and more are needed that include qualitative data provided by the prosthetist and physical therapist and quantitative data provided by standard functional assessments. Furthermore, this patient's outstanding results on the three functional assessments were unexpected. The LCI5 and the AMPPro are considered difficult measures appropriate for high activity amputees, so further research needs to be performed in the area of quantitative gait and balance assessment of amputees. Finally, additional clinical studies are needed that document the functional development of large numbers of patients as they use EV systems, because they would benefit the industry as a whole by identifying technologies that directly improve patient outcomes.

VI. Consent

Written informed consent was obtained from the patient for publication of this case report and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

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Appendix i. Details of Patient's Prostheses

Patella Tendon-Bearing with Ischial Weight-Bearing Thigh Cuff Prosthesis

Component	Manufacturer	Part #
Iceross Original w/o Cover (locking)	Ossur	I-010428
PTB Socket	Custom Fabrication	N/A
IWBTC	Custom Fabrication	N/A
Knee Joint Bars / Med. Duty	Otto Bock	7U2-L/R
Titanium Reinforced Extreme Lock	Prosthetic Design, Inc.	X-TI-PLUS
Titanium Pyramid	Prosthetic Design, Inc.	PYR
Renegade MX Sandal Foot	Freedom Innovations	RS1-M1-0727-SL

Elevated Vacuum Prosthesis with EVLS™

Component	Manufacturer	Part #
Custom SealMate™ Liner	Prosthetic Design, Inc. / Evolution Industries	CUSTOM LINER
TT CAD/CAM Socket	Prosthetic Design, Inc.	BK-4
EVLS™ Kit	Prosthetic Design, Inc.	EVLS-CAUC
Titanium Pyramid	Prosthetic Design, Inc.	PYR
Ti Rotating Pyramid Receiver	Otto Bock	4R51
Derma ProFlex Sleeve	Otto Bock	453A3=3
Harmony HD Pump	Otto Bock	4R150
Pacifica Foot	Freedom Innovations	FS2000-8A27-RU