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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
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, 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
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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 (EVLSTM), 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), EVLSTM 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 EVI STM (inset). Component details can be found in Appen

Pacifica Foot	Freedom Innovations	FS2000-8A27-RU