DAYTON ARTIFICIAL LIMB
Lower Extremity Specialists

Successful Incorporation of Engineers into Patient Care: A Case Report

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Abstract

A patient who has lost a limb due to a rare condition presents a challenge to prosthetists because current technologies and methods may not apply to his or her specific disorder. One way to address the challenge is to incorporate research and development engineers into the clinical problem solving process. Unfortunately, little documentation of this kind of collaboration has been performed in the prosthetics field. This article presents the case of a patient with proximal femoral focal deficiency (PFFD) that was experiencing functional limitations common to patients with the malformation. His prosthetist suspected that he could benefit from a prosthesis that included an elevated vacuum (EV) socket system, but EV has not been successfully implemented with PFFD patients because it is extremely difficult to maintain a proximal seal for the vacuum. The prosthetist approached a local prosthetic research and development firm with the problem. After 18 months of continuous collaboration and testing, a final design was developed to manage the patient's condition that utilized EV. This case suggests that collaboration with engineers can be useful to the solution of unique clinical problems.

I. Introduction

In the prosthetics industry, patients with rare conditions pose a challenge to practitioners. Innovation can be accomplished through communication with engineers who can lend technical knowledge and development experience to clinical challenges that arise with unique patients. It is the most direct form of user-based development to create a tool that addresses a specific need of a patient, and a multiple disciplinary team approach has been successful in addressing complex health issues in other fields[1-4]. However, very few prosthetics and orthotics facilities engage engineers in the patient care

process, and where cooperation between clinicians and engineers has occurred, inadequate documentation of the design process renders the results unusable to the rest of the industry. Reporting the development process of new technologies in literature is vital to evidence-based practice, because each publication informs and improves the design[5]. This report documents the process and results of collaboration between a clinical practice and a research and development facility to manage a patient with proximal femoral focal deficiency (PFFD).

PFFD is a malformation characterized by a deficient acetabulum and short femoral shaft that is flexed, abducted, and externally rotated[6]. The malformation is rare, occurring once in 52,000 live births[6]. Commonly, amputation is required to treat severe cases of PFFD. After amputation, some kind of transfemoral-type prosthesis is usually prescribed [6].

Even with proven surgical treatments, PFFD patients commonly exhibit significant gait abnormalities on both the affected and sound sides. On the affected side, there is usually a pause in hip extension during mid-stance, an absence of toe off power generation and a constantly abducted femur. The sound side usually displays increased power generation of the hip during stance phase, mid-stance vaulting at the ankle to assist with ground clearance of the prosthetic limb, and lateral trunk bending toward the sound side during toe off[6]. Further complicating the patient's gait is the fact that the malformations of the femur and acetabulum joint cause increased vertical movement in the prosthetic socket compared to other transfemoral amputees[6]. The resulting increased forces on the intact limb and altered body mechanics can cause osteoarthritis, back pain and other musculoskeletal problems if left untreated.

The elevated vacuum (EV) prosthesis is a promising technology for the management of PFFD, but no record of its implementation with patients affected by PFFD has been found. EV systems maximize surface contact between the socket wall and the liner, enabling high frictional forces that improve fit and suspension[7]. Decreased vertical movement inside the socket can contribute to more efficient gait, which could lessen the negative secondary effects of a PFFD patient's use of the prosthesis. Furthermore, EV has the potential to normalize patient gait. A recent study showed that EV prostheses enabled better stance phase and step length symmetry when compared with PTB designs in transtibial amputees[8]. However, recent research shows that morphological changes in the hip anatomy during gait hinder the achievement of a proper proximal seal[10], a seal which is crucial for the maintenance of the vacuum environment in the socket. Therefore, developing alternative methods for sealing is the primary challenge to success with EV transfemoral prostheses and PFFD patients in particular.

II. Case Presentation

The patient in this case is a 51 year old male with PFFD of his left limb. His malformation is considered a Class D on the Aitken scale, the most severe malformation characterized by the absence of both the acetabulum and femoral head. The patient's femoral shaft is extremely short, and its proximal end is pointed. He is a patient at Dayton Artificial Limb in Dayton, Ohio. Until age five, the patient's condition was treated non-surgically with an orthotic/prosthesis that lengthened his limb. At age five, he underwent a Boyd amputation, and he has since been treated clinically as a transfemoral amputee. His amputation did not include knee arthrodesis. The patient utilized a series of non-vacuum prostheses for 44 years, with the most recent an ischial-bearing ramus containment socket with Silesian belt suspension (IBRCSB) prosthesis (Fig. 1). With that prosthesis, the patient required no assistive devices to ambulate and was classified as a K3 ambulator. The patient neither drinks alcohol nor smokes, and he is being treated for high blood pressure. He works as a clerk in the county auditor's office and lives with his family in a single story home. The patient has been bowling three games a week for 25 years.

Figure 1. Patient wearing an Ischial Bearing Ramus Containment socket with Silesian Belt and cosmetic cover.

At age 48, the patient complained to his treating physiatrist of muscle fatigue. After examination, weak hip flexors were identified as the cause of the patient's inefficient gait. Also of noted significance was the manner in which he was currently fit which was a partial suction socket with a single ply sock fit. Additionally, the patient experienced hip instability because the knee was not surgically fused, and this along with the general instability in the socket contributed to the fatigue. The physiatrist recommended that he reduce his activity and prescribed treatment by a physical therapist for strength exercises. The patient's prosthetist suspected that the patient's gait would continue to worsen as a result of the PFFD and socket instability issues and eventually lead to further complications. While EV could possibly improve the patient's gait via improved socket fit and stability, it was not possible for PFFD patients given current technologies. In response, the prosthetist contacted a local prosthetic development facility for assistance in creating a custom EV prosthesis for the patient.

III. Treatment

Throughout the treatment process, four unique socket designs and various sealing methods were designed and tested with the patient in the order shown below (Fig. 2). They were: the double wall socket, the laminated ramus containment socket with sealing sleeve, the proximal and internal seals, and the sealing sheath.

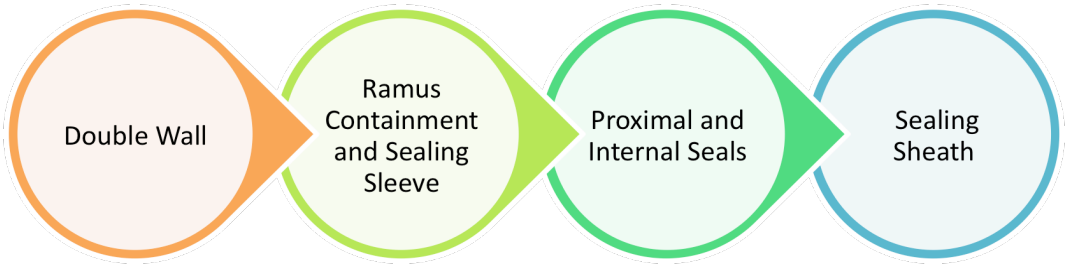

Figure 2. Schematic of designs considered

In June 2008, the process of fitting the patient with an EV socket system began. The preferred method of fitting at the time was a double wall system design in which the inner socket was the sealed portion interfacing with the patient's residuum. The design was originally developed for transfemoral amputees, and it allowed the seal to be moved further down the residuum where fewer morphological changes occur during gait. The inner socket was then anchored to an outer portion which served only as a frame for support and as a means of attaching the knee frame, foot and other distal components of the prosthesis. A thermoplastic double wall test socket with a lanyard anchoring system was

fabricated and fit to the patient (Fig. 3). Sub-atmospheric pressure was created between a custom polyurethane liner (Otto Bock, Minneapolis, MN) and inner socket while the outer socket provided stability. The seal in this design was to be maintained by means of a sealing sleeve (Otto Bock, Minneapolis, MN). This sleeve is commonly used by transtibial amputees, and it creates a seal against the liner proximal to the inner socket brim. A mechanical pump (Otto Bock, Minneapolis, MN) was the vacuum source for this prosthesis.

Figure 3. The double wall socket design (anterior view). The sealing sleeve was placed over the proximal edge of the inner socket, sealing the inner socket where tissue fluctuations are minimal during ambulation.

The patient was pleased with the resulting small improvements in his gait, and he was able to perform daily activities like mowing the lawn and washing his car with less fatigue than with IBRCSB prosthesis. Although the patient theoretically benefitted from even force distribution in the socket, the rigid inner socket was insecurely attached to the outer socket by a Velcro lanyard. This issue along with the small incremental contact discrepancies between the inner socket and outer frame prevented adequate proprioception. The patient reported poor linkage to the rest of his prosthesis, describing it as a loose, heavy feeling in his limb. Additionally, the vacuum pressure fluctuated as the patient ambulated, which could also have contributed to the heavy feeling.

Ideally, a single wall socket would improve the patient's proprioception and control of the prosthesis by eliminating the movement between the inner and outer sockets, so a single-wall laminated ramus containment socket featuring an EV attachment plate and air transfer manifold (Prosthetic Design, Dayton, OH) was designed and fabricated. Along with the attachment plate and manifold, the prosthesis included a custom silicone cushion liner fabricated to mate with the attachment plate, theoretically preventing a void in the distal region of the socket (Prosthetic Design, Dayton, OH). The method for sealing the socket system at this time was similar to the approach used in transtibial fittings where the seal is above the socket, occurring at the interface between the silicone cushion liner and sealing sleeve which is also attached to the socket where it forms the distal seal. The socket brim was lowered as to allow sufficient sealing surface area (2-3" of liner to sealing sleeve contact) above the socket.

Throughout his initial fitting, the patient experienced fluctuating vacuum pressure during ambulation due to voids created by the physical changes of the proximal residuum. When the patient sat on a hard surface, a hole developed in the soft thermoplastic elastomer (TPE) sealing sleeve, rendering it ineffective. Additionally, because the single wall socket had a higher proximal brim than the inner socket used in the double wall design, there was limited space for the sealing sleeve proximal to the socket brim, especially on the medial side. The limited sealing surface available above the medial socket brim was responsible for a majority of the vacuum seal issues.

It was also noted that the patient reported a general instability in the prosthetic socket which translated into an inconsistent gait and increased use of his intact musculature in an attempt to normalize his gait pattern. This was found to be a direct result of lowering the anterolateral socket wall in an attempt to gain more surface area for means of sealing the socket system. Anatomically, the natural knee joint on the affected side was destabilized by lowering the socket wall in this area. It was determined at this point that one of the engineering criteria for the socket was a high anterolateral wall as well as high posterior wall to provide a counter force. This force couple would serve to stabilize the natural, un-fused knee joint that was responsible for socket destabilization seen in this embodiment of the socket design.

Since the transtibial-style sealing method was ineffective in this case, the search continued for a method to seal the socket system. The next method employed was to reflect the top of the silicone cushion liner over the brim of the socket and to then use a TPE sealing sleeve attached to the socket to interface with the reflected liner, as recommended by one liner manufacturer[11] (Fig. 4).

Figure 4. Single wall socket design (anterior view) with liner reflected over proximal brim (left) and sealing sleeve rolled up over the reflected liner to maintain the vacuum seal (right).

However, a reliable seal was not achieved with this design because upon sitting, air entered the space between the limb and the liner. So while vacuum was maintained, the patient was able to slide the socket and liner off his limb. Once again, sitting on a hard surface presented the opportunity for a hole to develop in the soft silicone cushion liner at the point of the posterior socket brim. This would disturb the vacuum seal and thus negatively affect socket fit. Clearly, neither a sealing sleeve nor liner reflection method would work with this patient.

The third design was proposed by the engineering team in September 2008. It incorporated a silicone bladder/seal filled with air that was attached to the proximal brim of the patient's socket. The theorized function of the seal was that it would adapt to the intermittent changes in the proximal tissue during ambulation and when the patient was sitting. When it proved to be an inadequate seal, once again due to the extreme morphological changes in his upper thigh tissue, the engineers created a second internal seal. This additional D-shaped ring was adapted from a window seal and was adhered to the inner wall down inside the socket (Fig. 5).

Figure 5. The proximal and internal seals design (medial view).

However, the thick D-shaped seal caused the patient discomfort because it contacted a high pressure area on the residual limb. The seal also continually failed during ambulation. As the patient shifted his weight onto his sound side, the proximal tissue on the prosthetic side would deform and break the seal. Finally, the engineers moved past the design because of concerns with the durability of the adhesion between the socket and seal material as well as the unreliability of its sealing capability in this application. The information gained through this "failure" made it clear to the engineering team that a thinner flange-shaped seal attached to a sheath or the liner itself was needed. The thinner flange design would decrease the bulk of the seal and allow for increased seal quality as vacuum was applied below the seal.

The fourth and final design was implemented in January 2010 (details in Appendix i). The proximal bladder and D-ring internal seals on the socket were replaced by an independent sealing sheath (Evolution Industries, Orlando, FL) (Fig. 6). This component provided the same type of internal seal as afforded by the D-ring but by attaching the seal to the flexible sheath, its durability and reliability were greatly improved. A seal and sheath combination was chosen as opposed to a seal and liner solution

due to the flexibility of allowing the prosthetist to choose the location of the seal to maximize limb surface area under vacuum.

Figure 6. Patient's residuum in custom silicone cushion liner (left) and patient's residuum in custom silicone cushion liner and locking sheath (right).

Other considerations were made to solve some of the D-ring's issues: the patient was casted for the socket while wearing the sheath, and the lower durometer silicone of the sheath allowed it to deform easily against the socket wall. Both of these changes reduced the pressure on the sensitive areas of the patient's residuum. Furthermore, by moving the internal seal two inches distal to the medial socket wall of the socket, the changes in the proximal tissue did not affect the quality of seal and vacuum level obtained. He was able to maintain consistent vacuum levels throughout the gait cycle and during various activities including sitting.

Innovations in the patient's socket and components followed those in the sealing technology. To increase the patient's anterior-posterior stability, the final laminated socket included higher-than-normal anterolateral, and posterior socket walls (Fig. 7). In particular, these modifications stabilized the patient's proximal tissue and knee joint by countering the patient's naturally abducted femur. A release valve (Ossur, Foothill Ranch, CA) was laminated into the socket to assist donning and doffing by allowing air transfer through the socket wall. The attachment plate and air manifold were excluded from this design in order to level the prosthetic knee center with that of his sound side. Removal of these components allowed the engineers to bring the knee center up an additional 18mm to help

closer match the level of the sound side knee. The patient's mechanical vacuum pump was therefore connected to the socket directly through a slight socket connector (Otto Bock, Minneapolis, MN).

Figure 7. Anterior (left) and lateral (right) views of the patient wearing final EV prosthesis.

During ambulation in the clinic in January 2010, the patient described a sensation of "pins and needles" which was identified by the prosthetist as paresthesia. Upon further investigation, the prosthetist noted that the paresthesia was felt when vacuum pressure reached 10 in-Hg and higher. Following several attempts to remedy the issue via socket volume changes, the prosthetist contacted the engineers and asked about a possible means of controlling vacuum pressure in a system utilizing a mechanical pump. In response, the engineering team developed a vacuum pressure regulation valve (Fig. 8).

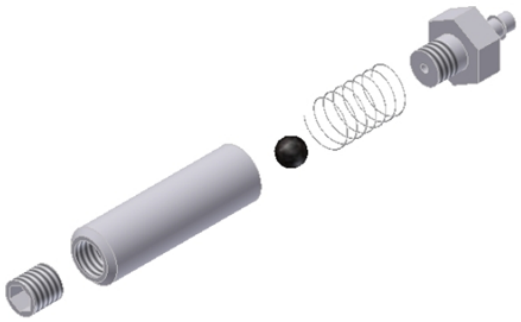

Figure 8. Schematic of the pressure regulation valve.

With the regulation valve, the prosthetist controlled the vacuum pressure within the patient's socket by adjusting the compression of an internal spring. The pressure was regulated to 8 in-Hg, which prevented the onset of the patient's paresthesia.

For the first six months with the final design, the patient elected not to wear the EV prosthesis to work because it lacked a cosmetic cover. After receiving the cosmesis the patient was able to incorporate it into his activities of daily living including bowling. Following incorporation into his daily routine, the patient reports a significant reduction in the muscle pain and fatigue he was experiencing with his old prosthesis. One of the key benefits of the new prosthesis that he enjoys the most is the lack of using the Selisian belt for suspension and rotation control. The patient reports that he is looking forward to continued use of the new EV prosthesis.

IV. Assessment

The efficacy of the collaboration between the engineers and clinicians was judged by the effect of the final design on the patient's self-reported fatigue level. A successful cooperation would result in the patient displaying a more efficient, symmetrical gait and improved functional ability and expressing less fatigue.

IV. Outcome

The patient was able to increase his activity after receiving the final EV prosthesis. At the time of reporting, the patient has been wearing the final prosthesis that included the interior sealing sheath and regulation valve for six months. He wears it during evenings and on weekends, especially during strenuous activities such as mowing the lawn, household cleaning tasks, running errands, and bowling. These activities combine for approximately 54 hours of EV prosthesis use a week. The patient reports minimal fatigue and his gait symmetry is much improved. Specifically, after six months of use with the

final prosthesis the patient reports that he was walking better and likes the way his shoulders stay level as he walked. This can be directly related to the lateral trunk bending towards the sound side used to compensate for lack of power generation in the affected side limb. Since the socket is linked to him better, he is able to use more of his existing residual limb muscle power to advance or swing the prosthesis through during prosthetic swing phase. The increased linkage and suspension quality afforded by the EV socket system decreases the gait inefficiencies inherent with the old prosthesis.

V. Discussion and Conclusions

This case is representative of the challenges facing practitioners and patients with rare conditions. The initial problems facing this patient, fatigue and muscle strain, are common to patients with PFFD but the prosthetic industry's standards were insufficient to manage them[2]. Instead of reducing activity level, this patient was actually able to improve his functional capability thanks to the unconventional incorporation of development engineers in his treatment.

The final prosthesis developed by the research and development engineers was effective for several reasons. First, the higher socket wall and larger radius of the posterior brim provided better support of the pelvis during weight bearing because they counter the pelvic dip and abducted femur that characterize PFFD stance[12]. After six months of use, the patient displayed almost none of the lateral trunk bending during toe off, further contributing to gait efficiency. Furthermore, the stability and control that the patient reported with the final EV prosthesis has been suggested in previous research to be caused by improved proprioception[8]. It also explains why the double wall design failed to alleviate the patient's fatigue, since the design limited proprioception. The flexible, internal seal afforded by the sealing sheath, release valve, and regulation valve enabled the use of EV with this unique patient. With EV, the patient saw increased gait efficiency, less vertical movement in the socket, and decreased strain on hip muscles. In this case, innovation directly allowed the patient to maintain his active lifestyle.

There were limitations to this study. Time and resources available to both the clinician and the engineering team constrained the scope of their collaboration. Additionally, no formal functional measures were implemented that could have quantified the patient's progress with each successive iteration of the EV prosthesis, so self-reports and qualitative judgments were used to assess the quality of the design developed by the team. In an increasingly evidence-based field, more reports need to be written to document the value of collaboration between product developers and clinicians.

For this patient, the common treatment methods failed likely because of his age, unique malformation and unusual surgical management. Incorporating research and development engineering into this patient's treatment had several advantages. The treating prosthetist worked with the engineers to

apply the design process to patient care. The team moved through alternative designs until a solution was found, dealt with a challenge in the patient's treatment, and eventually developed a way for the patient to benefit from advanced technology. Furthermore, the engineering firm was able to develop several new products which include a silicone liner with distal connector geometry, sealing sheath (Aura) and the vacuum pressure regulation valve, which they continue to test and will eventually make commercially available. This case shows that a team approach involving both prosthetists and engineers can bring significant benefits to a patient's quality of life.

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 Final EV Prosthesis

Component	Manufacturer	Part #
Laminated Ramus Containment Socket	Prosthetic Design	Custom
Rheo® Knee	Ossur	RKN120007
Harmony® P2 (locked torsion, increased compression/shock)	Otto Bock	4R144
Double Ended Pyramid Receiver	Prosthetic Design	DEPR-1
Ti 3 Prong Lamination Adaptor	Ti Med	A-551-3
Axion® Foot	Otto Bock	1E56
SealMate™ Liner	Prosthetic Design	SM-CUSTOM
Aura™ Locking Shealth	Evolution Industries	SSN-4-20-10
Icelock Expulsion Valve	Ossur	L-551002
Regulation Valve	Prosthetic Design	EV-BV1
Alternative Slight Socket Connector	Otto Bock	2R117