

How RevoFit[®] Technology Improves Prosthesis Function and the Delivery of Care to People with Amputations

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Introduction to People with Amputations

In 2005 there were approximately 1.6 million people living with limb loss. This number is projected to reach 3.6 million by 2050.¹ Limb loss includes a wide variety of presentations spanning upper and lower limb deficiencies. There are multiple diagnoses that can result in an amputation, including diabetes, vascular disease, cancer, and trauma. A well-fitting socket is one of the most crucial elements needed for a patient's successful rehabilitation and long-term health outcomes. Achieving and maintaining appropriate prosthetic socket fit is a complex and challenging process that requires the engagement of the prosthetic user and the Certified Prosthetist.

Socket Fit & Volume Fluctuation

The socket has long been described by prosthetic users as the most important consideration in their satisfaction with their prosthesis. The purpose of the socket is to transfer loads under both static and dynamic conditions onto the limb and provide structural integrity to the prosthesis where it interfaces with the residual limb. Pressure distribution within the socket is an essential element to the fit and function of the prosthesis. Ill-fitting sockets can lead to dermatologic concerns, injury to the limb, increased fall risk, and decreased prosthetic utilization^{4,2}. The functional comfort of a prosthesis is dependent upon a number of interrelated factors including socket type, fit, interface materials, and suspension approaches.

The fluctuation of residual limb volume commonly exacerbates socket fit issues. The amount of daily volume fluctuation varies greatly among individual amputees and is a function of socket fit, activity level, ambient conditions, body composition, dietary habits, and hormonal cycles.⁴ Diurnal residual limb volume change is a significant clinical challenge. Volume reduction creates a loose socket fit. Without appropriate accommodation, a loose socket fit can create excessive pressure over bony prominences. Limb volume expansion can increase tissue pressures in the residual limb and cause blood flow occlusion, restricting venous return and creating a buildup of cell waste products in the limb. Both conditions can lead to soft tissue injury.⁵ Poor volume management can result in a variety of secondary adverse effects of prosthetic use, including ulcers, verrucous hyperplasia, and osteomyelitis.⁵

Given the great deal of complexity in managing appropriate socket fit for patients with amputations, a better solution is warranted. One such improvement can be achieved by integrating a RevoFit system into a prosthetic socket. The RevoFit system is a user-adjustable residual limb volume management system that is added to a custom prosthetic socket. This novel system allows people with amputations to make small adjustments to their socket volume as needed throughout the day to ensure appropriate socket fit for maximum function, skin integrity and a reduced risk of falling.

A socket that fits poorly on a patient's limb is an unstable base for weight bearing (standing, walking, etc). RevoFit addresses both volume loss and volume gain by allowing the user to mechanically change the volume of the socket depending on the patient's current limb size. The user can decrease the socket volume if the socket becomes loose or if they are doing an activity that requires a more secure fit (walking, cooking). The user can also increase the socket volume to accommodate for water retention or limb volume gain. In addition, expansion of the socket volume while seated, or at rest, has been proven to increase fluid exchange and increase the overall limb health of the beneficiary.⁹⁻¹²

I. Product Description

The RevoFit system allows the prosthetic user to instantly adjust the fit of their prosthetic socket to accommodate for limb volume decrease, limb volume increase, and activity level changes throughout the day to maintain appropriate socket fit. The RevoFit system consists of a heavy duty tensioning dial (with 7:1 mechanical advantage), lamination collar,

lamination dummy, Teflon tubing, nylon sheath, heavy duty lace, wire lace feeder and reel tool. This technology can be used when added to the design, fabrication, and fitting of a custom fabricated prosthetic socket.

The primary benefits of the RevoFit system are:

- User-controlled socket adjustability
- Accommodation for both limb volume reduction and limb volume expansion
- No disruption of ADLs when socket adjustments are required
- Increased safety
- Improved limb health and mobility
- One socket can fit a wider range of limb volumes
- Earlier prosthetic fitting post-surgery
- Ability to adjust prosthetic socket in targeted, specific areas
- Accommodation for limb sensitivity



Exploded Reel components



Full reel assembly

RevoFit System installed in sockets:



II. RevoFit Function

The RevoFit Kit, when added to a custom fabricated prosthetic socket, functions differently than existing volume management systems. RevoFit allows the patient to turn a dial to instantly expand or compressing the volume of their prosthetic socket in 1mm lace increments as needed throughout the day.

The dial actuates a reel that is equipped with a 7:1 mechanical advantage. The mechanical advantage multiplies the user input force x7 as they turn the dial, which allows them to adjust the socket volume, even if they have missing appendages, dexterity problems, or strength issues. The mechanical advantage of the reel also allows for compression or

expansion of the socket even while the prosthesis is weighted by the user, thereby allowing them to make volume adjustments while wearing the prosthesis.

Expanding the socket decreases friction between the limb and the socket walls, which ultimately improves limb health and circulation.^{9, 11-13} Expanding the socket also permits easier donning, doffing and proper limb positioning within the socket for beneficiaries with limited dexterity. Seated donning and doffing is also achievable with the RevoFit. In traditional sockets, the limb is properly positioned by pushing the limb into place or by standing up to force the limb to the bottom of the socket, which increases friction and shear forces on the limb.

Compressing the socket effectively tightens the socket when limb volume loss or an increase in activity occurs. Tightening the socket provides a more secure fit, improving stability while standing and walking. Both expansion and compression of the socket are functionally and operationally different from existing therapies because they are controlled by the beneficiary, on-demand, without removal of the socket or interruption of their ADLs.

3 Steps to managing socket volume with RevoFit

Pause your activity



Turn Dial to correct fit



Resume your activity



III. Application across K-Levels

The RevoFit system is appropriate for patients across the spectrum of functional levels (K-levels), **as the benefits are not solely activity dependent but are applicable across many patient presentations and limb shapes.** K-levels are designations from K0-K4 assigned to a patient by a physician based on their potential functional abilities.

K1: The primary goal of this population is to ambulate short distances in their homes, often with an assistive device. The prosthesis is also crucial for transfers, standing, and ADLs. The mobility pattern of K1 patients tends to involve short bouts of standing and walking along with longer periods of rest and sitting. This population may have challenges donning and doffing their devices. The easy adjustability of the RevoFit facilitates the transitions between activities and helps to ensure a more secure socket fit for safer ambulation and other weight bearing activities such as ADLs. With socket expansion capabilities, these patients are able to expand the socket during seated activities, which decreases inner socket pressures to allow for increased fluid exchange and increased blood flow within the limb, also making the prosthesis tolerable for longer periods of time.⁹ Incorporating the RevoFit system for this patient population facilitates easier donning and doffing due to the simple mechanism to expand and compress the socket.

K2: Community ambulators include patients who use their prostheses to traverse barriers in their environment such as curbs, stairs, and uneven surfaces (grass, gravel, uneven sidewalks, etc). These patients experience volume fluctuation as well as the need to increase or decrease socket volume based on seated vs. standing, walking activities, terrain and ADLs. Additional compression reduces internal limb movement, which provides stability and a lower fall risk when navigating low environmental barriers. Reducing fall risk subsequently reduces the likelihood of injury due to poor fit. Similar to K1 patients, expanding the socket during seated activities can improve limb health.



K3: This population in particular is engaged in more strenuous activities that surpass single speed walking, such as walking at a variable cadence, hiking, gardening, mowing the lawn, and recreational athletic activities. These more strenuous activities can often lead to sweat accumulating between the residual limb and liner, which can compromise fit. By using RevoFit, patients can control socket compression to achieve a secure fit no matter what activities they are engaged in, ultimately increasing safety and reducing fall risk. K3 ambulators also experience volume fluctuation and limb sensitivities, both conditions that the RevoFit can address with user-controlled adjustability and targeted compression and expansion. Some

RevoFit users expand the socket to allow for muscles to expand and function during more strenuous activities.

K4: K4 patients participate in a wider range of activities that can include running and other high impact sports. Many K4 users report adjusting their volume up to 10 times an hour, depending on their activity level. The RevoFit system can provide desired compression and expansion capabilities in order to have a proper fit as their activity level changes and as their limb changes in volume⁴⁰. Socket expansion also allows for improved fluid exchange when at rest and improved limb health overall. Improved socket fit also improves socket stability, and subsequently a reduced fall risk when engaging in these high impact and high stress activities typical of a K4 ambulator.



IV. RevoFit Indications for Use

RevoFit is appropriate for a wide variety of patients: both upper and lower limb amputations, across all functional levels, and new and mature amputees.¹⁴ Upper limb amputations include transradial, elbow disarticulation, transhumeral, and shoulder disarticulation levels. Lower limb amputations include partial foot, Symes, transtibial, knee disarticulation, transfemoral, and hip disarticulation levels.

1. Volume Fluctuation & Dramatic Volume Changes

New Amputees: Newly amputated limbs commonly undergo reduction in size, shape, and volume.¹⁴ This progression occurs in two phases: 1) rapid, acute shrinkage immediately following amputation and 2) progressive stabilization of volume one year post amputation. These changes are dependent on individual lifestyle, activity level, and weight. Moreover, amputees experience daily volume fluctuations influenced by multiple factors, including diet, environment, and weather conditions. These fluctuations often require an iterative process involving numerous trips to the prosthetist for socket adjustments. Poor fit can lead to prosthetic abandonment. It has been shown that limb volume decreases 17% to 35% over the first 160 days post amputation, 7% to 10% in the 12-month post-op period and approximately 2% on a daily basis thereafter, thus requiring immense patient-provider coordination.¹⁴ In addition, chronic volume change may continue for up to 12 to 18 months post amputation due to tissue atrophy and indefinite diurnal volume fluctuations.¹⁴ RevoFit allows the patient to adjust their socket fit to the current volume of their residual limb to maintain proper socket fit across the wide range of volumes a patient may experience within a day or longer time period.

Dialysis Patients: Dialysis patients experience dramatic limb volume fluctuations between and after dialysis treatments. Gross, global volume adjustment of the socket is required to maintain proper socket fit and mobility during these volume fluctuations. Traditional sockets, especially those that use socks, must often be shaped around the patient's largest volume, which creates significant fit challenges when the patient is at their smallest volume. A poor global fit leads to increased risk of wounds forming on a residual limb, which increases the risk of infections and possible re-amputation. Adding RevoFit for patients with the above presentation and similar can help to manage the dramatic volume changes pre- and post-dialysis through the significant compression and expansion of adjustable areas.¹⁸

Cancer Patients: Patients who have undergone amputation due to cancer often return to their pre-diagnosis activity level once fully recovered. Cancer medications are known to cause limb volume fluctuations. Using a RevoFit system for this patient population can help minimize disruptions caused by prosthetic fit by allowing the patient to adjust their socket fit to the current volume of their residual limb.

Diabetes or Vascular Disease Amputees: In the US, diabetes mellitus is "present in 82% of all vascular-related lower extremity amputations".¹⁹ Patients with amputations who also have vascular disease already experience compromised circulation in their residual limbs. It is imperative that these prostheses do not further restrict circulation. RevoFit allows the amputee to easily expand their device when they are seated or at rest. This expansion can decrease inner socket pressures to allow for increased fluid exchange and increased blood flow within the limb, thereby increasing overall limb health.²⁰ Maintaining skin integrity for these patients in particular is of utmost importance, as wounds on the residual limb can lead

to re-amputation at a higher level, effectively restarting a patient's rehabilitation journey at a more challenging level of amputation.

2. Atypically Shaped & Sensitive Limbs

Traumatic Amputation: Due to the nature of the injury, patients who have experienced a traumatic amputation may have more scar tissue compared to a patient who has an amputation due to vascular disease. These limbs may be restricted in how much a surgeon can optimally shape the limb, and as such, socket fit may be more challenging. Residual limbs in this category tend to not be as cylindrical in shape and may be more conical or atypically shaped, which makes it more challenging to evenly distribute socket pressures for an appropriate fit. RevoFit allows the prosthetist to create sockets that dynamically load or unload pressures in targeted locations on the limb, thus avoiding sensitive areas.



RevoFit is uniquely configured to reduce levering, also referred to as bell clapping. Bell clapping is a painful prosthetic complication in which the distal portion of the socket is loose and the proximal portion fits snugly, causing the residual limb to clap against the sides of the socket like a bell. RevoFit allows for targeted compression that can reposition the bony anatomy or accommodate for excess volume in the distal end of the limb, thereby reducing bell clapping and limb pain.

Congenital Limb Deficiencies: Patients with congenital limb deficiencies may have atypically shaped limbs that are not cylindrical or uniform, which makes socket fit and donning challenging. RevoFit's ability to expand the socket allows for easier donning. Once donned, RevoFit allows for substantial compression of the socket to apply appropriate pressure to the limb along the socket contours. In addition, there may be areas of sensitivity due to the shape of the limb that can be accommodated by the fine-tuned offloading provided by the RevoFit system which the patient can operate independently.



Mature Amputees: Many mature amputees have atrophied limbs, which often have more exposed bony prominences or areas of sensitivity. This can lead to socket fit challenges due to the lack of targeted adjustability and compression zones in traditional sockets, as it may be difficult to accommodate for these limb sensitivities. RevoFit allows for targeted compression and expansion zones to offload pressure sensitive areas and load pressure tolerant areas.

3. Improved Socket Functionality



Upper Limb Prosthetic Patients: Patients with upper limb amputations often rely on a prosthetic control strategy that uses electrodes to read myoelectric muscle signals. Consistent and continuous skin contact is necessary to allow these electrodes to function. The RevoFit system allows for compression of areas where electrodes are present, facilitating consistent and reliable use of the prosthesis. Myoelectric components such as elbows, wrists, and hands tend to be heavier due to their complex functionality, which increases the weight of the prosthesis and effectively the forces on the residual limb. The prosthetic socket must "work harder" to suspend on the residual limb and counter the weight of these components. As such, the improved control via compression from the RevoFit system can help to distribute forces along the residual limb.

Patients with transhumeral amputations tend to have fleshy limbs, and the compression and control afforded by the RevoFit system allows for an improved socket fit, allowing more delicate manipulation of objects with a prosthetic hand. Patients with upper limb amputations may also have bulbous residual limbs, which can be difficult to don and doff when the volume of the socket cannot be expanded. The RevoFit system allows for

expansion of the socket, followed by snug compression once the limb is seated, to achieve improved control of the prosthesis.

Pediatric Patients: Pediatric patients change very quickly as they grow, both in presentation and functional requirements. These rapid changes can create challenges when using a traditional socket that is relatively fixed in volume and shape. Creating adjustable socket areas accommodates changes in limb size and minor changes in shape which allows a socket to fit better and serve the patient longer. The RevoFit system can effectively extend the lifetime of a prosthetic socket, reducing visits to the prosthetist and reduced costs to both insurers and patients.

V. RevoFit's Benefits

Introduction

One solution to accommodate volume is by including a RevoFit system in the prosthetic socket design. A prosthetic socket outfitted with RevoFit is designed for proper limb support and can also adjust over the areas that experience volume loss or gain. Because RevoFit allows parts of the prosthetic frame to compress inward and expand outward, it does not have a fixed volume like a traditional prosthetic socket. Thus, the RevoFit system can accommodate for changes in a person's residual limb volume. The RevoFit system is integrated into the custom fabricated prosthetic socket frame to allow the user to manage their volume by turning the control dial one way to tighten the fit of their device or the other way to loosen the fit of their device. The prosthetist pre-determines areas where socket adjustability will benefit the patient as they gain or lose volume in their limb. They then determine a design for the integration of the RevoFit system into the socket such that those areas are able to be contracted or expanded as needed. The Prosthetist controls the overall amount of compression or expansion the device will have, and the patient is then able to adjust within that range by turning the dial.



User-controlled socket adjustability

The numerous benefits of the RevoFit system are described below:

- User-controlled socket adjustability (at home, no appointment necessary)
- Accommodation for both limb volume reduction and limb volume expansion
- Users experience no disruption of ADLs when socket adjustments are required
- Increased safety
- Improved limb health and mobility
- One socket can fit a wider range of limb volumes, allowing for earlier prosthetic fitting
- Ability to adjust prosthetic socket in targeted, specific areas
- Accommodation for limb sensitivity

RevoFit allows for both limb volume reduction and limb volume expansion.

Both traditional sockets and EV sockets are entirely rigid in structure - the frame cannot change shape to accommodate for limb volume increases or decreases. The RevoFit socket frame is also structurally rigid for proper limb support. However, it is simultaneously able to compress or expand over the areas of the limb that have changed volume, while leaving parts of the limb that have not changed undisturbed. In a transtibial socket, the RevoFit system is able to accommodate multiple adjustable areas that provide compression and expansion in precise locations as compared to a

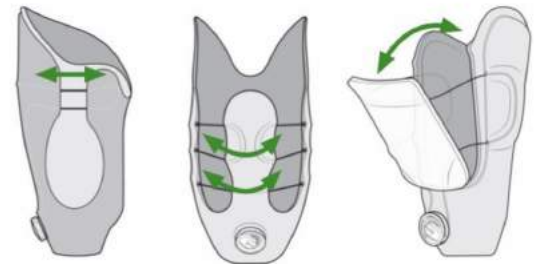
traditional socket that does not have this type of adjustability. In a transfemoral socket, adding a RevoFit system presents an opportunity for patient-specific, customized adjustability.

What is also unique about the RevoFit is the ability for the user to increase their socket volume in specific areas of the device, which is impossible with traditional socket technologies. Similarly, traditional sockets cannot be expanded to allow for donning bulbous, PFFD, or atypically shaped limbs. RevoFit allows for socket expansion to facilitate custom donning and doffing needs regardless of limb shape, dimensions or size.

Traditional Socket



RevoFit Adjustable Sockets



Users experience no disruption of ADLs when socket adjustments are required

It is important to note that this benefit is tremendously positive for the well-being and mental health of prosthetic users. Many RevoFit users have experienced a profound transformation by having access to user-controlled adjustability that minimally interferes with their ADLs. RevoFit users report being able to pursue activities they initially thought were not possible, without having to stop to adjust their prosthesis.



"I don't have to take my leg off and be forcibly reminded of what has happened."

-Patrick Marziale, 3 year RevoFit user, Active Duty Military

Increased Safety

Because the RevoFit system allows for significant expansion of socket volume, prosthetic users can more easily don the prosthesis in a seated position. Some traditional socket designs require that the prosthetic user don the device in a semi-standing or weight bearing position to allow the limb to become fully seated in the socket, which can increase the likelihood of a fall. Expanding the socket volume with the RevoFit system, being able to seat the limb fully, and then increase compression with the RevoFit allows for a more secure fit before weight bearing and standing activities.

In the case of an emergency such as a flood or other natural disaster, the RevoFit system allows for rapid donning of the prosthetic device. Being able to don a prosthetic device quickly in the case of an emergency allows the prosthetic user to be more mobile and get to safety more easily. In an emergency situation where a patient's prosthesis is stuck or

they need to remove their device quickly, the RevoFit system also allows for rapid doffing.

Patient testimonials:

"I can go anywhere without loading my pockets with socks and worrying about finding a place to sit down and remove my socket."

-Prosthetic RevoFit User

"Now that I have my adjustable socket, with the dial (RevoFit), I am able to tighten and loosen my leg anytime I want without stopping what I'm doing, which has allowed me to get back to being very active."

-Bob Beachamp (CSM Retired Army), Prosthetic RevoFit User

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