

Design for Transtibial Modifiable Socket for Immediate Postoperative Prosthesis

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ABSTRACT

Amputations are long-standing surgical procedures that have been performed for centuries; however, very little attention and urgency have been given to immediate restoration of movement and return to a normal lifestyle. In many cases, the time between amputation and prosthetic fitting can pause recovery and development of new routines. To increase recovery, immediate postoperative prostheses (IPOP) have been developed yet these are under-utilized because of concerns for wound healing and complications with vascular diseases. Subsequently, we designed a transtibial IPOP that utilizes an ergonomic modifiable socket that allows for examination, wound care, and in situ edema control. Additionally, the IPOP facilitates early weight bearing and protects the amputated limb from external trauma postoperatively. Our purpose is to introduce this technology and describe how its unique design will serve to provide potential benefits and positive effects on patients who have undergone amputations.

Keywords: Leg, Amputation, Amputation Stumps, Artificial Limbs

INTRODUCTION

Patient care and rehabilitation after amputation presents considerable social, psychological, and economic challenges. As of 2005, an estimated 1.6 million Americans were living with the loss of a limb, at an estimated cost of \$350,000 to \$500,000 for treatment, rehabilitation, prosthetics, and follow-up

care.¹⁻³ Individual limb loss is expected to double by 2050, with more than 185,000 lower limb amputations performed annually.^{1,4,5} Furthermore, amputation most commonly involves the lower extremities. The age-adjusted incidence rate is 2.6 in 10,000 individuals and continues to rise.⁶ Main causes of lower limb amputation include vascular complications (83%), trauma (12%), malignancy (3%), infection (2%), and congenital limb defects (0.2%). Notably, diabetes remains the single greatest cause of lower limb amputation with 68% of procedures performed as a result of diabetic complications.⁷⁻¹⁰ { 2005 #21}

Postoperatively, patients typically undergo three periods of adjustment before receiving a final prosthetic: wound care and rehabilitation, immediate recovery phase, and limb stabilization. Wound care and rehabilitation occur after the amputation and may extend several months after hospital discharge. The aim of rehabilitation is to restore functional independence by promoting ambulation and use of a prosthetic limb, yet the fitting of conventional prosthetics is iterative and labor intensive owing to changes in volume, shape, composition, sensitivity, and scarring of residual limb soft tissues. Changes may also occur day-to-day due to temperature, activity, hydration, or swelling.¹¹ Additional changes may occur after several months because of muscular atrophy and soft tissue remodeling.¹¹ After complete healing of the surgical site, the immediate recovery phase begins, 3 to 6 months postoperatively, during which most patients are fitted with a temporary

prosthetic.¹² During this period, considerable changes in residual limb volume and shape necessitate continual prosthetic adjustments. Due to lack of muscle use, joint contractures may also occur and require treatment and physical therapy. Finally, limb stabilization occurs between preliminary prosthesis and final prosthetic fitting, in which relatively frequent prosthetic adjustments occur. Around 1 year postoperatively, patients can be fitted with a definitive prosthetic.¹³

Lower limb amputations not only affect a patient's ability to walk, but they also influence the patient's psyche, body image, and quality of life. Patients are physically unable to participate in valued life activities with current treatment methods such as gauze and elastic wrap,¹⁴⁻¹⁶ rigid plaster dressings,^{17,18} and prefabricated pneumatic postoperative prostheses.¹⁹⁻²¹ This may lead to lowered confidence in prosthetic use and reduced social activity. Such behavior can result in a lack of engagement by the patient, the development of new routines, and a slower recovery process.

In the 1950s, immediate postoperative prostheses (IPOPs) were introduced to increase patient recovery and prosthetic acceptance. IPOPs are placed on patients' residual limbs in the operating room, are used instead of a rigid removable dressing, and allow for early ambulation and shorter rehabilitation. Traditional IPOPs are placed over (or comprise) plaster that attaches to and protects the limb, whereas current technology allows IPOPs to be secured using various strapping methods and composite materials (ie, soft inner gel liners with rigid outer plastic).

Although studies prove their benefit,^{19,22,23} IPOPs are currently only prescribed in about 5% of cases owing to concerns of monitoring wound health, edema and swelling changes, and unfamiliarity with the technology.²⁴⁻²⁷ To overcome these limitations, we developed a transtibial IPOP that utilizes a fully adjustable ergonomic design. It is easily removable for examination and wound care, allows for in situ edema control, facilitates early weight bearing, and protects the amputated limb from external trauma immediately after amputation.

DESIGN

The transtibial modifiable socket is designed to replace rigid removable dressing, traditional IPOPs, and temporary prosthetic devices currently used in the first year after amputation. Six advancements over previous technology have been implemented:

1. The modifiable socket protects the residual limb while remaining accessible for inspection and wound care.²⁴
2. The design uses a woven biaxial mesh sock to provide uniform compression on the residual limb for shaping, edema control, and day-to-day variations in limb swelling.^{28,29}
3. The socket has an open architecture so that the wound receives proper air circulation, can be inspected, and potentially drained.

4. The socket is continually modifiable through ratcheting components that adjust pressure on anatomically safe contact points,³⁰ all while avoiding loading placed on the surgical site.
5. To transfer load from the residual limb, this design has an upper leg support attached to the socket with a locking knee joint.
6. The locking knee joint helps stabilize patients during early recovery or ambulation while simultaneously helping to restore range of motion and prevent knee flexion contractures by applying an adjustable angular deflection.³⁰

PROSTHETIC SOCKET

To adjust the overall fit of the socket, the front and rear supports connect at the base of the socket (Figures 1A and 1B, Figures 2A and 2B) while remaining adjustable to accommodate larger or swollen limbs. Once the socket is in place, the ratcheting tensioner around the upper section of the socket is tightened, which pulls the front and rear supports together and secures the socket to the patient's residual limb. Because the socket is adjustable, it can be premanufactured in a set of standard sizes (ie, small, medium, large, extra-large), and still gives the patient a secure and comfortable fit. The adjustment system also helps control loading on the residual limb. The front support loads the mid-patellar ligament and tendon, tibial flares, and medial (primary) and lateral (secondary) flares of the tibial condyles (Figure 2C). The rear support loads the knee and popliteal areas (Figure 2D),³⁰ whereas the tensioning system can be used by physicians and prosthetists to adjust the pressure distribution on these load-bearing sites. During use of the socket, an air gap exists between the proximal end of the amputated limb and base of the plate, with the intention of preventing impact and discomfort to the surgical site. Finally, the socket base is designed to accept any commercially available pylon by utilizing the industry-standard attachment screw pattern for a prosthetic leg or blade (Figure 1A). This feature allows individual users to customize the device.

BIAxIAL SOCK

The inner sock surrounds the residual limb, suspending it inside the socket (Figures 1A and 1B). Similar to compressive sportswear fabrics, the use of a biaxial weave in the sock provides circumferential compression, which controls edema in the healing limb while remaining flexible and adjustable when donning or doffing.^{28,29,31} The sock is fitted by rolling the sleeve over the end of the residual limb and wound dressings before donning of the socket, thereby minimizing application time and contact with the incision site. The excess material is folded over the top of the socket and attached to an adjustment mechanism on the outside surface. The amount of circumferential pressure produced by the sock is controlled by the amount of tension applied to the end of the sock by the

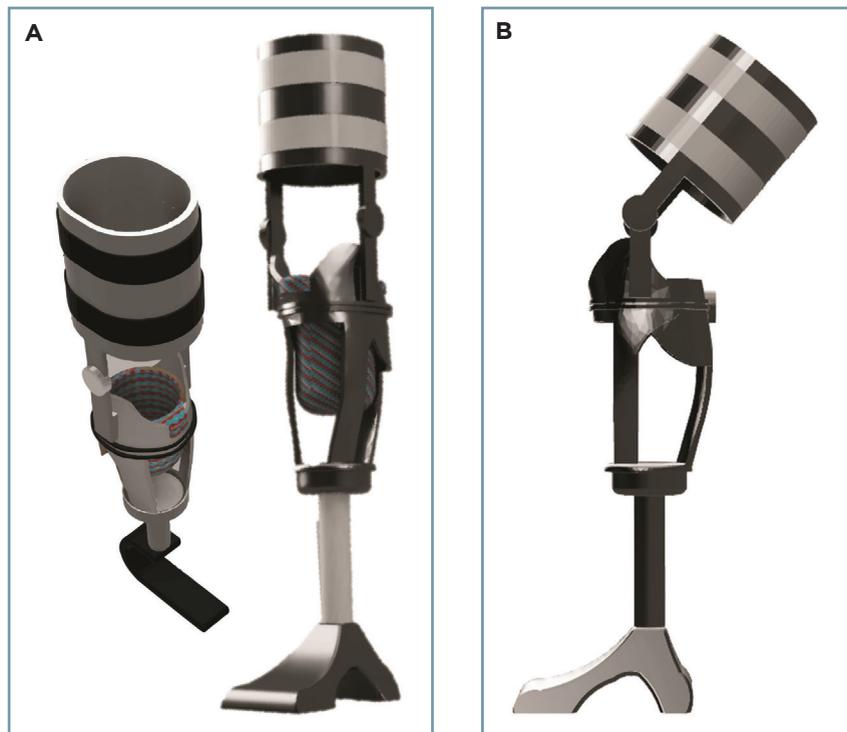


Figure 1. Computer-aided model of immediate postoperative prosthesis socket. A) Foot assembly that includes socket, support sock, knee brace, and above-knee supports. B) Side view with sock removed, showing knee flexion and bending.

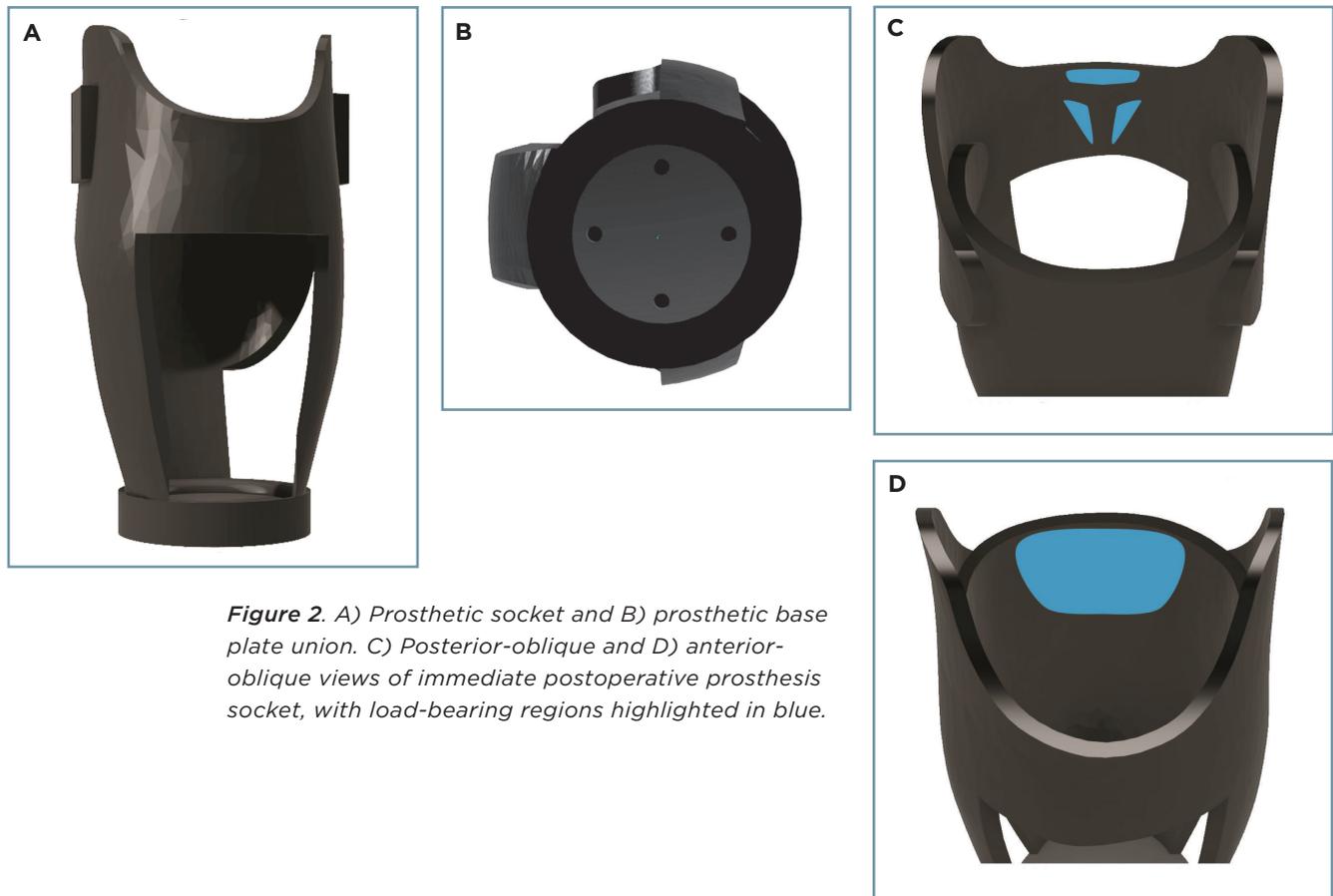


Figure 2. A) Prosthetic socket and B) prosthetic base plate union. C) Posterior-oblique and D) anterior-oblique views of immediate postoperative prosthesis socket, with load-bearing regions highlighted in blue.

residual limb. This is done after the user's weight is fully counter-balanced by the socket.

Load Transfer Above the Knee

To transfer load away from the end of the residual limb, the socket is connected to a thigh support using a hinged knee brace made of lightweight metal and carbon fiber (Figures 1A and 1B). The thigh strap comprises a compressible padding surrounded by a washable fabric and adjustable straps that can be tightened or loosened to apply load on the upper limb, which allows for a comfortable fit. The upper limb support also helps prevent pistoning and holds the socket onto the residual limb, which would normally be accomplished using vacuum suction or non-breathable liners in the standard socket design.³² Additionally, users can lock the knee joint that connects the socket to the upper brace. This limits the knee's range of motion to control for muscle contractures and stabilizes the patient during early ambulation; furthermore, it unlocks the knee to allow for motion during gait retraining.

Pain and Patient Compliance

To ensure the greatest possibility of patient compliance, the transtibial modifiable socket was designed with emphasis placed on reduction of pain and ease of use. The segmented components, biaxial sock liner, socket, and knee brace are intended to be donned in sequential order, with the ability to independently adjust each component for comfort and fit. It has been noted that overall patient adoption and recovery are dependent on comfort of the socket and ability to accommodate changes in limb volume and remodeling. As such, the overall design of the transtibial modifiable socket aims to achieve the greatest adjustability and comfort while allowing for a universal fabrication technique and availability for patients immediately after amputation. As such, considerable patient feedback and discovery of the comfort factors will be undertaken to determine optimal final design parameters of the device for the desired user experience.

CONCLUSION

We have outlined a design of a modifiable socket for use as an IPOP among patients with transtibial amputations. The design utilizes an adjustable socket that suspends the residual limb by applying loads to anatomical loading sites below the knee and above the knee brace, which reduces end-loading on the recently amputated limb.³⁰ This allows for immediate adoption by preventing contact with the suture site. The design also implements a compressive sock that suspends the residual limb, provides edema control, and accommodates shape changes of the limb over time. Additionally, the device provides an open air design, which allows for limb inspection and breathability missing from current socket liners. Meanwhile, the surrounding socket serves as a rigid removable dressing that helps prevent strikes and falls that could result in damage to the amputation site. Finally, the adjustable

nature of this device allows for pre-fabrication and availability of the socket for use immediately after amputation. This differs from the current sockets that do not allow for custom fitting for days to weeks postoperatively, followed by regular modification and adjustments with changes in limb size and shape.

Overall, the design of this device allows for wound protection while remaining accessible during the immediate recovery phase after amputation. However, the modular and adjustable design should allow for continuous use of the device up to and possibly through the final prosthesis stage.³³ This new universal design should result in early adoption by the patient, with the options of earlier ambulation and faster transition to rehabilitation and recovery.

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