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Disclosures

Doctors Twichell and Murdock have reported no relationships with proprietary entities producing health care goods or services.

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Transfemoral Amputation and Prosthetic Prescription:

What Every Physiatrist Needs to Know

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Clinical Vignette

JH is a 26-year-old man with no significant past medical history who presented to the emergency department after a motor vehicle accident. During the accident his right lower limb was crushed, and due to the severity of his injury, he underwent an emergent right transfemoral amputation. His other injuries were minor, including multiple abrasions and lacerations from debris. His operative pain was managed via a nerve block, which was removed on postoperative day one. He initially had no complaints of phantom pain; however, after a few days he reported tingling and burning in his right foot. Otherwise, his hospital course was uncomplicated, and he was discharged home with family.

Prior to his amputation, JH was a very active man, employed as a warehouse worker whose job entailed driving machinery using hand held controls. His injury was not work-related. He enjoyed running marathons, hiking outdoors, and cycling. He lives with his wife in a three-story house with a first-floor setup. Functionally, he was independent with all daily activities. JH is ready to learn how to use a prosthesis and is asking what he can expect in terms of functional outcomes, including returning to work.

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Definition of the Problem

In 2012, the prevalence of limb loss in the United States was 1.9 million patients.¹ It is estimated that the annual incidence of new lower limb amputation in the United States will rise to 58,000 before 2030. The main etiologies of limb loss are dysvascular disease, including diabetes, accounting for 54 percent; trauma at 45 percent; and cancer at less than 2 percent. Males are at a significantly higher risk for trauma-related amputation, and the risk for traumatic amputation in all genders increases with age.

A study from the National Trauma Databank found that the most common mechanism resulting in limb amputation was blunt trauma after motor vehicle accidents involving motorcyclists or pedestrians.² Other causes of traumatic amputations include natural disasters, such as earthquakes, or man-made disasters, such as the Boston Marathon bombing. Separate from epidemiologic studies involving the civilian population, traumatic amputations from military conflicts have dramatically increased.³ During combat, 93 percent of amputations were primarily caused by explosion. In all causes of combat-related amputations, 75 percent of amputations were performed on the lower limbs.

Residual Limb Complications Impacting Prosthetic Rehabilitation

Complications in the residual limb can negatively affect outcome in transfemoral prosthetic rehabilitation. The differential diagnoses of residual limb complications are listed in Table 1.

TABLE 1:

Residual Limb Complications

Skin			
 Socket related skin conditions: 			
— Verrucous Hyperplasia			
— Contact Dermatitis			
— Epidermoid Cysts			
Infection			
Joint			
Hip Flexion Contractures			
Iliotibial Band Syndrome			
Trochanteric Bursitis			
Bone			
Heterotopic Ossification			
Avascular Necrosis			
Fracture			
Nerve/Muscle			
Neuroma			
 Radiculopathy 			
Myonecrosis			
Muscle Imbalance			
Pain			
Phantom Limb Pain			
Residual Limb Pain			
Infection			

Skin Complications

Skin hygiene is very important to prevent bacterial and fungal infections, eczema, or epidermoid cysts. If contact dermatitis is suspected, identification and removal of the allergen responsible are of utmost importance. Dermatitis in this population can arise from the plastics and resins in the cushion liner, or the agents used in the manufacturing of the socket. If contact dermatitis occurs due to the cushion liner, a barrier sock worn on the residual limb underneath the liner can be useful, although suspension from socket contact may be slightly less snug.



FIGURE 1: Verrucous hyperplasia.

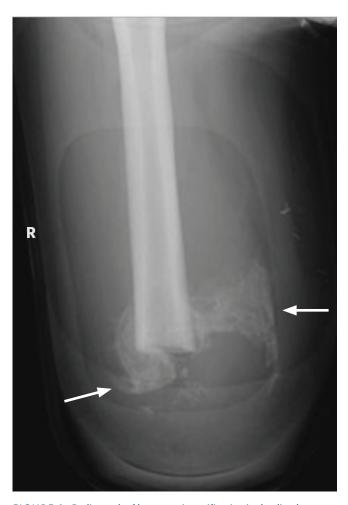


FIGURE 2: Radiograph of heterotopic ossification in the distal femur (arrows).

Verrucous hyperplasia (see Figure 1) is a warty condition of the distal portion of the residual limb. It is thought to be related to a poorly fitting prosthesis that has proximal constriction and distal venous engorgement, termed "choke syndrome." In a study by Dudek et al., prosthetic fit was noted as the major reason contributing to the development of all distal skin problems, including verrucous hyperplasia.⁴ There also may be a superimposed bacterial or fungal infection. Treatment involves recasting the socket to ensure total socket contact, especially distally, without proximal constriction.

Epidermoid cysts are the most common type of skin cysts. They are dome-shaped lesions that project into the dermis and produce keratin. Cysts may appear after months or years, and typically occur in the inguinal folds and adductor region of the thigh. They are caused by excessive pressure over the sweat glands from improper loading in the socket. Incision and drainage may be performed for temporary relief; however, chronic cysts may be minimized or even eliminated by proper fit and alignment of the prosthesis to avoid regions of high pressure.⁵

Musculoskeletal Complications

Heterotopic ossification (HO) is another potentially painful condition affecting transfemoral amputees. In HO, trabecular bone forms in soft tissues and protrudes outside of the periosteum with its own vascular supply (see Figure 2). A forthcoming large, cross-sectional study from researchers at UPMC has shown a 23 percent incidence of HO in civilian lower limb amputees. This abnormal bone growth was seen equally in both traumatic injuries and dysvascular patients.



FIGURE 3: Offset plate (marked with white arrow).

Additionally, patients with HO reported a 60 percent rate of residual limb pain. (Matsumoto, submitted for publication 2013).

Joint contractures and arthritis may pose special complications. Severe limitations in hip range of motion limit the abductors and extensors from generating maximal torque. Hip extension and abduction strength is highly correlated with improved walking in individuals with lower limb amputation.⁶ A transfemoral socket can only accommodate up to 20 degrees of hip flexion contracture, and physical therapy programs for preamputation training should focus on improving and maintaining hip range of motion, as well as strengthening the hip extensors and abductors. For hip flexion contractures of less than 20 degrees, an offset plate can be added between the socket and knee unit to keep the center of mass underneath the prosthetic foot while accommodating flexed posture (see Figure 3).

Phantom Limb Pain

Phantom limb pain (PLP), defined as painful sensations such as itching, aching, or burning in the nonexistent limb, is experienced by 60 to 80 percent of patients.⁷ PLP usually will begin immediately after surgery, although there are some studies that suggest PLP decreases over time. PLP is typically described by short, intermittent episodes of pain that can occur several times a day.⁸

PLP is a result of biochemical and structural changes that cause amplification of nociceptive signals in severed axons, dorsal root ganglion cells, and the spinal cord. In the residual limb, neuromas form at the site where the nerve was transected. The sensitivity of these peripheral nerve fibers can be triggered by factors such as local inflammation, socket-contact pressure, or even stress.⁹

Other studies have shown that the motor cortex undergoes neuroplastic changes following amputation. The areas that previously controlled the amputated limb become integrated into neighboring regions in the motor cortex. However, the primary sensory areas typically continue to produce phantom sensation and, at times, phantom pain.

In a study by Maclver et al., functional MRI was used to compare a group of individuals with upper extremity amputation and PLP. Functional MRI demonstrated a

correlation between reorganization within the primary motor cortex and the intensity of PLP.¹⁰ Additional studies have shown that various interventions, including prosthetic wear, visual imagery, and particular movement sequences of nonamputated and phantom limbs, may contribute to motor reorganization and modulation of PLP, although further studies are ongoing.

There is no clear consensus for optimal treatment of PLP. Treatment options include desensitization techniques, mirror therapy, medications, mechanical interventions, and more invasive procedures, often requiring surgery for implantation of pain-modulating devices.

Desensitization

Desensitization is performed by rubbing, tapping, or massaging the residual limb to decrease the perception of non-nociceptive stimuli as painful. Desensitization can begin once dressings have been removed, and it is important to perform appropriate hand hygiene prior to massaging the residual limb. Gentle friction massage also will help reduce scar formation and allow skin to glide on top of the bone.

Mirror Therapy

Mirror therapy may be an effective treatment for modulating PLP. A mirror is placed between the amputated limb and the intact contralateral limb in the parasagittal plane. The patient visualizes moving the phantom limb while simultaneously moving the intact limb, as observed in the mirror. Upon completion of this treatment in one study, there was increased activation of the prefrontal cortex, supporting the theory of cortical reorganization after lower extremity amputation.¹¹

Medications

Pharmacologic agents commonly used to modulate phantom limb pain are similar to those used to treat other neuropathic pain conditions, and include anticonvulsants, opioids, NSAIDs, amitriptyline, and calcitonin. There is, however, no consensus in the literature regarding optimal treatment regimens.

Amitriptyline has been studied in several randomized trials. Bone et al. demonstrated a statistically significant decrease in the intensity of PLP in patients receiving amitriptyline.¹² A randomized controlled crossover study of amitriptyline versus an active placebo conducted by Robinson et al. in 2004 did not find a significant improvement in PLP after controlling for initial level of pain.¹³ Two additional studies (Smith et al. 2005 and Nikolajsen et al. 2006) showed no improvement in PLP with amitripyline.¹⁴⁻¹⁵ The typical dose of amitriptyline ranges from 10mg to 150mg nightly.

Neuromodulators, such as gabapentin and pregabalin, have also been used for the treatment of PLP. Gabapentin, however, is the most studied for PLP. In a study comparing gabapentin versus placebo for phantom limb pain, Smith et al. found that half of the patients reported a meaningful decrease in their pain while on gabapentin.¹⁴ The dose of gabapentin was started at 300mg/day and titrated up to the maximum dose of 3600mg/day as needed. No randomized studies using pregabalin for treatment of phantom limb pain have been published. Pregabalin doses range from 50mg to a maximum of 600mg daily, divided two to three times a day. Intranasal calcitonin may be beneficial for patients who develop PLP within seven days of amputation.¹⁶ However, another study by Eichenberger et al. found that it does not seem to have much effect on chronic phantom limb pain.¹⁷ For chronic PLP, the same study utilized ketamine infusions with significant reduction in chronic PLP.

Mechanical Interventions

According to a Cochrane Database Review in 2010, there are no adequate randomized controlled trials evaluating the efficacy of transcutaneous electrical nerve stimulation (TENS) on phantom limb pain. One older study suggests that TENS may produce benefits, such as shorter healing times and decreased rates of reamputation, but there was no change in amount of pain medications required to achieve analgesia.¹⁸

Invasive Procedures

For patients who are refractory to the above interventions, more invasive approaches may provide benefit. In a small pilot study by Viswanathan et al., four patients with phantom limb pain underwent the placement of spinal cord stimulators. Postoperatively, all four described a decrease in their pain by more than 80 percent. Reported complications included an allergic reaction to the generator in one patient, and a wound infection in a subsequent patient. Three out of four patients would elect to undergo the procedure again, and one patient was neutral.¹⁹

Katayama et al. reported long term phantom pain control in six of 19 patients after placement of spinal cord stimulators. For patients who did not achieve adequate pain control, deep brain stimulators were implanted in the ventral caudal thalamic nucleus, and six out of 10 patients then reported significant reduction of pain.²⁰

For nerve pain due to neuromas, a recent study used targeted muscle reinnervation to possibly prevent neuroma formation.²¹ In rabbits, the nerve developed a more normal appearance after it was connected to a specific muscle target. While the purpose of the nerve transfer was to operate an upper extremity myoelectric prosthesis, this study implies that targeted muscle reinnervation also may be useful to treat symptomatic neuroma in lower extremity amputees.

Because there is no consensus in the literature about optimal PLP treatment, we recommend a patient-specific treatment algorithm including physical, psychological, and pharmacological interventions (see Figure 4), similar to the Department of Defense Guidelines.²²

Prosthetic Prescription

Generally, patients with transtibial amputation have more favorable outcomes compared to transfemoral patients, in terms of prosthetic usage and distance walked.²³ Much of this difference is explained by loss of the knee joint and medical comorbidities associated with dysvascular transfemoral amputations. However, as technology improves, this functional difference is narrowing.²⁴ With an emphasis on reducing health care expenditures, there is increasing scrutiny on prosthetic prescription, and physician documentation is vital to ensure that optimal components are provided. The more technologically advanced the components, the higher the cost of the prosthesis. Therefore, insurance

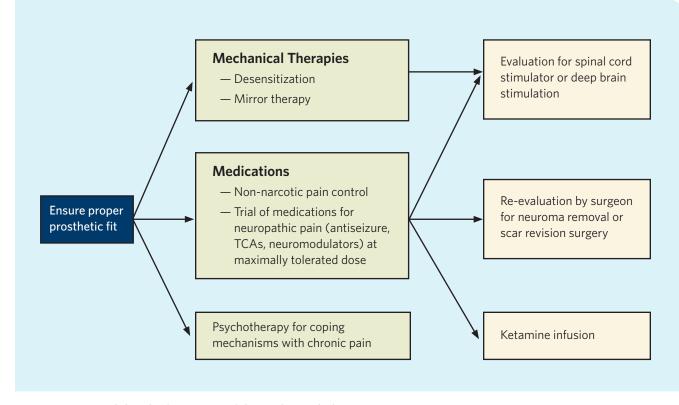


FIGURE 4: Proposed algorithm for treatment of chronic phantom limb pain.

companies may limit coverage of more expensive and advanced components to patients who were highly functional prior to their injury. High-quality, randomized controlled studies to guide prosthetic component selection are lacking.

Centers for Medicare and Medicaid Services (CMS) has developed activity categories for patients with lower extremity amputations as a way to document and establish medical necessity for a prosthetic device. When a patient is categorized into a functional level, certain components are available to maximize function. This classification works to avoid abuse by restricting advanced and costly technology in lower-functioning patients. Therefore, it is imperative that the physician not only record the patient's current functional status, but also the functional status that can be expected once the patient is utilizing an appropriate prosthesis. Moreover, prosthetic companies are required to have this documentation from the physician for Medicare beneficiaries in order to bill for the artificial limb. Thus, a physiatric note that encompasses these domains is essential to help patients receive the most optimal components. A simple note from the primary care physician stating "New prosthesis" will not allow the prosthetic company to bill for its services.

Medicare Functional Classification Levels

In 1995, CMS developed a system of modifiers to describe patients with lower limb amputations

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TABLE 2: Medicare Functional Classification Levels

Modifier	Code Description	Suggested Knee Component
ко	The patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance the quality of life or mobility.	• No prosthesis
К1	The patient has the ability or potential to use a prosthesis for transfers or ambulation, on level surfaces at fixed cadence for limited household ambulation.	Manual lockSingle axis with stance control
К2	The patient has the ability or potential for ambulation, with the ability to traverse low-level environmental barriers, such as curbs, stairs, or uneven surfaces for limited community ambulation.	Single axis with stance controlPolycentric knee
КЗ	The patient has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational therapeutic or exercise activity that demands prosthetic utilization beyond simple locomotion.	 Passive mechanical single axis or polycentric with hydraulic stance and swing phase control Microprocessor knee unit to control stance and swing phase
K4	The patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.	 Advanced microprocessor designed for running Passive mechanical single axis or polycentric hydraulic

(see Table 2). This is known as the Medicare Functional Classification Level (MFCL), and describes a patient's functional status as it relates to the projected outcomes.²⁵ Most third-party payers will provide microprocessor knee units for K3 and K4 patients.²⁶ Some argue that active K2 patients would benefit from a microprocessor knee unit.

Assessment

The physical examination should support the need for more expensive prosthetic components, if clinically indicated. In our clinic, balance and functional ability are documented prior to providing a prosthesis, in order to assess the patient's current functional state. Four separate activities are tested:

- 1. Can the patient independently sit upright for a minimum of 60 seconds?
- 2. Can the patient reach forward greater than 12 inches in a sitting position?
- 3. How much assistance does the patient require to perform sit-to-stand transfers?
- 4. Can the patient balance unipedally for a minimum of 30 seconds?

Combined with a thorough pre-injury mobility history, the patient's balance and current functional level can be assessed to justify the appropriate prosthesis.

Choosing a Prosthesis

To view a slide presentation featuring examples of knee and ankle units, please visit this issue of *Rehab Grand Rounds* at UPMCPhysicianResources.com/Rehab.

Knee Units for K3 to K4 patients

Microprocessor units sense changes in cadence and adjust resistance to match the speed of the residual limb with each step, providing real-time adjustment for each step. Limitations of microprocessor knee units are added weight, a battery that requires daily charging, and higher cost. Also, these units cannot handle extreme weather conditions, such as submersion in water. Examples would include the Ottobock C-leg® and Genium®, the Össur Rheo[®], the Endolite Orion[®], and the Freedom Plié[®]. In a study by Hafner et al., transfemoral patients had improved stair descent, hill descent, and decreased frequency of falls with a microprocessor unit compared to a passive mechanical knee.²⁷ Another study found that for K3 or K4 patients, there was a significant increase in physical activity when wearing a microprocessor knee versus a mechanical fluid control knee.²⁸

Passive hydraulic units use varying resistance of air or fluid to provide variable cadence and resistance; however, the speed does not change as quickly as with microprocessor units. Advantages of a hydraulic unit include the ability to withstand higher forces and weight, as well as variable weather conditions. This device may be more appropriate for a patient who performs frequent outdoor activity in all weather conditions, or carries heavy objects. The hydraulic system also provides a controlled resistance to knee flexion, which can help slow a patient's fall. Examples of passive hydraulic knee units include the Ossur Mauch S and S[®], the Seattle Select 657[®], and the Ottobock 3R80.

Foot and Ankle Units

The powered ankle actually propels the patient forward at toe-off, while the microprocessor ankle allows dorsiflexion and plantarflexion strategically during ambulation. Advantages include increased foot clearance during swing phase, which is beneficial for inclines, and active plantarflexion, which can provide more powerful propulsion. Studies in individuals with transtibial amputation revealed 10 percent faster self-selected walking speed over loose gravel when compared to an energy-storing foot.²⁹ Disadvantages include heavier weight, increased cost, need for batteries and charging, and a larger pylon length to contain the ankle unit. Examples of advanced prosthetic ankles include the BiOM[®] and the Endolite élan[®].

Ankle units are also available with passive hydraulic mechanisms without microprocessor control to match cadence; however, they lack the ability to power plantarflexion or to immediately sense when the foot should go into dorsiflexion/plantarflexion. Examples of hydraulic ankle systems include the Freedom Innovations Kinterra[™], the Endolite Echelon[®], and the Fillauer Motion Foot[™]. These units may add weight to the prosthesis. In order to make the prosthesis lighter and more effective, many studies have shown that energy-storing feet are superior to the conventional solid ankle cushioned heel (SACH) feet. Energy-storing materials, such as carbon fiber, are used to provide ground reactive force to aid in forward propulsion. In a study by Graham et al., oxygen consumption was decreased in transfemoral amputees at average walking speed when wearing an energy-storing foot as compared to a SACH foot.³⁰ An earlier study by Graham et al. also found that transfemoral amputees had significantly faster selfselected walking speed when wearing an energy-storing foot compared to a SACH foot.³¹ Examples of carbon fiber energy-storing feet include the Ottobock C-Walk[®], the Össur Flex-Foot®, the Freedom Innovations Highlander[®], and the College Park Soleus[™].

Energy-storing feet are available in split-keel versions as well. The split keel allows for some ankle motion, which mimics ankle inversion and eversion. This offers increased reaction and stability over uneven surfaces. Examples include the Seattle Energy, Freedom Innovations Sierra[®], and the Endolite Elite[®]. The Freedom Innovations Thrive[™] also has an additional upper keel, which can support increased loading when carrying heavy objects.

Energy-storing feet also may include multiaxial ankle joints, which can allow for medial and lateral motion that is useful in uneven terrain. Examples include the Seattle Catalyst Triumph, Freedom Innovations Renegade[®], College Park Trustep[®], and the Fillauer Ibex[™].

Clinical Outcome

Based on his history and physical examination, JH is expected to become a K3 or K4 ambulator once he completes prosthetic training. He requires a device that will allow him to walk with variable cadence and traverse uneven terrain. He is active, and a good candidate for a microprocessor knee unit. He will benefit from a carbon fiber energy-storing foot with multi-axial properties to navigate uneven terrain in the community.

Once his prosthesis was fabricated, JH was admitted to the UPMC Rehabilitation Institute to undergo prosthetic training for more than three hours of therapy per day, daily prosthetic adjustments, and physician/nursing management of pain and skin healing. His wear time was gradually increased, with frequent monitoring of his residual limb for any signs of skin irritation or breakdown. To evaluate his residual limb pain, right femoral x-ray was negative for HO formation, and physical exam was negative for a palpable neuroma. He was instructed on tactile desensitization and performed daily scar massage. He was started on gabapentin 300mg at bedtime for his phantom limb pain. The medication was titrated up to 600mg three times a day, which provided relief of his burning pain.

He began ambulating with a wheeled walker, and had progressed to independent status without assistive devices by the time of discharge.

One year later, JH reports that he is wearing his prosthesis daily and has been able to return to work full-time. He also has started to train for marathons using a specialized passive hydraulic knee unit that is designed for running, combined with a specialized running blade foot.

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