

Lower Limb Amputation & Prostheses

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Course Overview

This course includes a review of current literature relating to pathophysiology of conditions leading to amputation, diagnostic techniques, surgical procedures, and lower limb prosthetic components.

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Course Rationale

- The purpose of this course is to present contemporary knowledge about lower extremity amputations and prosthetics to rehabilitation professionals so that they may use this information to maximize functional outcomes. Areas of focus include causative conditions, assessment, surgical interventions, and post-operative prosthetic options.

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Goals and Objectives

1. Detail the pathophysiology of conditions leading to amputations of the lower limb.
2. Define the levels of lower limb amputation.
3. Identify diagnostic procedures utilized to determine tissue viability.
4. Detail lower limb amputation surgical procedures.
5. Define functional classification levels for expected mobility.
6. Outline the primary components of the lower limb prostheses.
7. Compare and contrast the mechanisms of lower limb prosthetic suspension.
8. Identify the primary characteristics of prosthetic knee units.
9. Detail the benefits of foot and ankle prosthetic designs.
10. List examples of specialty lower limb prostheses.

4

Disclaimer

- Application of concepts presented in this webinar is at the discretion of the individual participant in accordance with federal, state, and professional regulations.

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Course Outline and Schedule

Topic	Time
Epidemiology of Lower Limb Amputations	0:00-0:05
Causes of Amputation	0:06-0:10
Diabetes	0:11-0:15
Critical Limb Ischemia	0:16-0:25
Determining Level of Amputation	0:26-0:30
Surgical Procedures	0:31-0:35
Partial Foot Amputation	0:36-0:40
Syme Amputation	0:41-0:45
Transfemoral Amputation	0:46-0:50
Interactive Discussion of Clinical Applications	0:51-1:00
Knee Disarticulation	1:01-1:05
Transfemoral Amputation	1:06-1:10
General Surgical Considerations	1:11-1:15
Complications and Phantom Limb Pain	1:16-1:25
Medicare Functional Classification Levels	1:26-1:35
Sockets and Suspension	1:36-1:40
Transfemoral and Transtibial	1:41-1:50
Interactive Discussion of Clinical Applications	1:51-2:00
Microprocessor Knee	2:01-2:05
Prosthetic Feet	2:06-2:15
Rehabilitation Outcome Measures	2:16-2:20
Specialty Prostheses	2:21-2:25
Emerging Techniques and Components	2:26-2:30
Socket Sensors	2:31-2:35
Osseointegration	2:36-2:40
Agonist/Antagonist Myoneural Interface	2:41-2:45
Gait Analysis Innovations	2:46-2:50
Interactive Discussion of Clinical Applications	2:51-3:00

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Historical Perspective

- Technology advances have contributed to developments in prosthetic design to enhance quality of life.

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Causes of Lower Limb Loss

- Amputation is a difficult decision made to improve health, function, and quality of life.

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Non-traumatic Lower Limb Amputation

- Incidence trends suggest opportunities for public education on healthy life-style.

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Diabetes Mellitus

- Poor healing associated with diabetes contributes to ulcer failure to heal with infections common and increased amputation risk.
- Nutritional support should be a component of management to ensure food consumption is adequate for metabolic needs during healing.

Xin, Y., Zhang, H., Ye, T., Ge, S., Zhao, R., & Zhu, H. (2017). The geriatric nutritional risk index independently predicts mortality in diabetic foot ulcers patients undergoing amputations. *Journal of diabetes research*, 2017.

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Ulcer Assessment

- Probe-to-bone test, procalcitonin (PCT) levels and MRI guide diagnosis of soft tissue versus osteomyelitis to aid clinical decision making for appropriate management.

Lam, K., van Assen, S. A., Nguyen, T., La Fontaine, J., & Lavery, L. A. (2016). Diagnostic accuracy of probe to bone to detect osteomyelitis in the diabetic foot: a systematic review. *Clinical Infectious Diseases*, 63(7), 944-948.

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Critical Limb Ischemia (CLI) 13

- Peripheral arterial disease (PAD) involves progressive atherosclerosis of the arteries in the limb leading to claudication, and skin lesions.
- CLI presents as nocturnal and at rest pain, ulcers, and gangrene.

Fontaine classification

- Stage III-IV

Rutherford classification

- Grade 4-6

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PAD Assessment 14

- Ankle-Brachial Index (ABI) is a diagnostic sensitive index for assessing perfusion.

Ankle
systolic
blood
pressure

÷

Brachial
systolic
blood
pressure

=

≤ 0.9 PAD presence

0.69 – 0.41 Moderate PAD

< 0.4 Significant PAD

- Walking Impairment Questionnaire (WIQ) measures self-reported walking distance, speed, and stair climbing.
- 6-Minute Walk Test documentation should include total walking and claudication onset time or distance.

Jain, A., Liu, K., Ferrucci, L., Criqui, M. H., Tian, L., Guralnik, J. M., ... McDermott, M. M. (2012). The Walking Impairment Questionnaire stair-climbing score predicts mortality in men and women with peripheral arterial disease. *Journal of vascular surgery*, 55(6), 1662–73.e2.

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PAD Management 15

- Surgical or catheter based endovascular revascularization restores arterial blood flow to the lower extremity.

Therapeutic
Angiogenesis

Endovascular
Intervention

Open Bypass

Minor
Amputation

Major
Amputation

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Therapeutic Angiogenesis 16

- Facilitating the formation of new capillaries and collateralization of existing vessels can replace occluded arteries ensuring adequate oxygen supply to ischemic tissues.

Medications

Stem cells

Gene
Therapy

Benedek, T., Kovács, I., & Benedek, I. (2017). Therapeutic Angiogenesis for Severely Ischemic Limbs—from Bench to Bedside in Acute Vascular Care. *Journal of Cardiovascular Emergencies*, 3(4), 160-171.

Shou, J. J., Lin, P. Y., Sung, F. H., Chen, Y. C., Liu, S., Chen, Y. L., ... Yin, H. K. (2014). Levels and values of lipoprotein-associated phospholipase A2, galectin-3, RhoA/ROCK, and endothelial progenitor cells in critical limb ischemia: pharmacotherapeutic role of clostrazol and clopidogrel combination therapy. *Journal of translational medicine*, 12, 101.

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Stem Cell Angiogenesis 17

- Safe harvesting, delivery and efficacy are being established for this promising therapy to reduce amputation risk and improve wound healing.

Trial	Cells	Outcome
TACT	Intramuscular bone marrow cells	Improved leg pain, reduced ulcer size, increased pain-free walking distance.
PROVASA	Intra-arterial bone marrow cells	Improved ulcer healing, pain, but not significant change in ABI

Benedek, T., Kovács, I., & Benedek, I. (2017). Therapeutic Angiogenesis for Severely Ischemic Limbs—from Bench to Bedside in Acute Vascular Care. *Journal of Cardiovascular Emergencies*, 3(4), 160-171.

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PAD Surgical Failure Risk Factors 18

- Compared to timing of revascularization on surgery, comorbidities are more influential on wound healing and limb loss.

Smoking

End stage renal disease

Hyperlipidemia

Diabetes

BMI ≥ 30

Congestive heart failure

Shi, E., Jex, M., Patel, S., & Garg, J. (2019). Outcomes of Wound Healing and Limb Loss After Transmetatarsal Amputation in the Presence of Peripheral Vascular Disease. *The Journal of Foot and Ankle Surgery*, 58(1), 47-51.11

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Determining Lower Extremity Amputation Level

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- Physicians consider multiple factors when making the decision to amputate a limb.

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Wound, Ischemia, foot Infection Classification (WIFI)

20

- To predict 1-year amputation risk in individuals with PAD, a classification system has been developed based on the major risk factors leading to lower limb amputation.

Mills Sr, J. L., Conte, M. S., Armstrong, D. G., Pomposelli, F. B., Schanzer, A., Sidawy, A. N., ... & Society for Vascular Surgery Lower Extremity Guidelines Committee. (2014). The society for vascular surgery lower extremity threatened limb classification system: risk stratification based on wound, ischemia, and foot infection (WIFI). *Journal of vascular surgery*, 59(1), 220-234.

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Transcutaneous Oxygen (TcPO2)

21

- Hemodynamic indicators of oxygenation released from the tissues in the lower extremity can support physician decision making.

Arsenault, K. A., Al-Ozabi, A., Devereaux, P. J., Thorlund, K., Tittley, J. G., & Whitedock, R. P. (2012). The use of transcutaneous oximetry to predict healing complications of lower limb amputations: a systematic review and meta-analysis. *European Journal of vascular and Endovascular surgery*, 43(3), 329-336.

Zingg M, Lacraz A, Robert-Ebadi H, Kressmann B, Glauser F, Walbel F, et al. (2019). Transcutaneous Oxygen Pressure Values Often Fail to Predict Stump Failures after Foot or Limb Amputation in Chronically Ischemic Patients. *Clin Surg*, 4: 2366.

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Limb Salvage

22

- Reconstructive techniques attempt to avoid amputation and preserve an individual's limb that has experienced severe trauma.

Schiavo, G. R., Sessa, S., Piccoli, A., & Maccauro, G. (2015). Primary amputation vs limb salvage in mangled extremity: a systematic review of the current scoring system. *BMC musculoskeletal disorders*, 16(1), 372.

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Mangled Extremity Severity Score (MESS)

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- Most commonly utilized tool to predict success of limb salvage surgery.

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Levels of Amputation

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Surgical Technique for Muscles 25

- When determining closure, the surgeon considers proper muscle balance and creating a stable soft tissue envelope.

Tenodesis
Tendon to
periosteum

Myoplasty
Antagonists
sewn
together

Myodesis
Muscle to
periosteum

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Partial Foot Amputation 26

Transmetatarsal
 • Midsection of metatarsals

Lisfranc
 • Tarsometatarsal joint

Chopart
 • Talonavicular and calcaneocuboid joints

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Partial Foot Muscle Relocation 27

- Elimination of foot musculature attachments can contribute to the development of equinovarus deformity.
- Altering tendon mechanical advantage can reduce the risk of contracture development.

Allow dorsiflexion	Achilles lengthening
Retain eversion	Preservation of peroneus brevis
Promote dorsiflexion in sagittal plane	Tibialis anterior or Extensor digitorum longus tendon transfer

Consider This

Sukur, E., Altar, A., Uyar, A. C., Citelek, O., Kochal, A., Turker, M., & Topcu, H. N. (2018). Vacuum-assisted closure versus moist dressings in the treatment of diabetic wound ulcers after partial foot amputation: A retrospective analysis in 65 patients. *Journal of Orthopaedic Surgery*, 26(3), 2309499018799769.

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Transmetatarsal Amputation Gait 28

- Maximizing foot length can minimize altered weight bearing on the residual limb that leads to increased re-amputation risk.

Shorter plantarflexion moment

↓

Achilles loss of elasticity

↓

Loss of rigid lever

↓

Increased plantar surface pressures

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Syme Amputation 29

- Ankle disarticulation is performed with tenodesis of achilles to posterior tibia and anchoring of heel pad to anterior tibia.

↓
Benefits

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Syme Outcomes 30

- Adults present with more complications and require re-amputation more frequently than children.

Pediatric	Adult
Calcaneus reformation	Residual limb pain
Heel pad migration	Ulceration and Infection
Skin problems	Skin problems

Morrison, S. G., Thomson, P., Lenz, U., & Dorman, L. T. (2019). Syme Amputation: Function, Satisfaction, and Prostheses. *Journal of Pediatric Orthopedics*.
Braskama, R., Dijkstra, P. U., & Geertzen, J. H. (2018). Syme Amputation: A Systematic Review. *Foot & ankle international*, 39(3), 284-291.

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Transtibial Surgical Procedure 31

- The optimal length of the residual limb can be calculated based on height for adults.
- At minimum, the tibia shaft should be equal to the tibial plateau width.
- The fibula should be 1-2 cm shorter than the tibia.
- The Burgess procedure utilizes a long posterior muscle flap for closure.

Pasquina, P. F., Bryant, P. R., Huang, M. E., Roberts, T. L., Nelson, V. S., & Flood, K. M. (2006). Advances in amputee care. Archives of Physical Medicine and Rehabilitation, 87(3), 34-43. Copyright Jodi Gootkin 2020

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Transtibial Osteomyoplasty (Ertl Procedure) 32

- An osteoperiosteal or fibular graft is placed between the distal ends of the amputated tibia and fibula.
- With healing, a bony strut is created allowing end-bearing on the residual limb.

www.ertlreconstruction.com/about/procedure/ Copyright Jodi Gootkin 2020

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Ertl vs. Burgess Procedure 33

- The Transtibial Amputation Outcomes Study (TAOS) is currently in progress to evaluate surgical technique functional outcomes and complication rate.

Burgess	Ertl
Lower complication rate	Better prosthetic fit
Wounds from "bottom out"	Longer surgical time

Bosse, M. J., Marshad, S., Reider, L., Ertl, W., Toledano, J., Firoozabadi, R., ... & MacKenzie, E. J. (2017). Transtibial amputation outcomes study (TAOS): comparing transtibial amputation with and without a tibiofibular synostosis (Ertl) procedure. Journal of orthopaedic trauma, 31, 563-569. Copyright Jodi Gootkin 2020

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Transtibial Surgical Technique Outcomes 34

Population	Outcome
18 – 65 y.o. Very active prosthetic ambulators	Curb: Ertl limb work similar to intact limb Sit-to-stand: Ertl quicker performance
Retrospective Young Active duty military	Similar functional outcomes on long-term follow-up

Ferris, A. E. (2016). Biomechanical Assessment of Ertl and Burgess Transtibial Amputation Techniques. University of North Colorado. Dissertation.
Shawen, L. P. S. B., Forzberg, C. J. A., Kork, L. K. L., Hsu, L. J. R., Gwinn, C. D. E., & Potter, M. P. B. K. (2013). Comparison of functional outcomes following bridge synostosis with non-bone-bridging transtibial combat-related amputations. JBJS, 95(10), 888-893. Copyright Jodi Gootkin 2020

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Knee Disarticulation 35

- This level amputation may be beneficial for non-ambulatory patients by providing increased sitting comfort and eliminating the risk of knee flexion contracture.
- Sectioning through the knee joint requires an intact gastrocnemius for a posterior flap.
- The patellar tendon is sutured into the cruciate ligaments.

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Knee Disarticulation Outcomes 36

- Retaining femur length provides a longer lever arm, permits end-bearing, and improved suspension but leads to an off-set prosthetic knee component.

Etiology	Outcome
Infection, thrombosis, trauma	Diabetes and infection reduced ambulation. Greater ambulation in trauma cohort.

Albino, F., Seidel, R., Brown, B. J., Crono, C., & Atzinger, C. (2014). Through knee amputation: technique modifications and surgical outcomes. Archives of plastic surgery, 41(5), 562. Copyright Jodi Gootkin 2020

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Transfemoral Surgical Procedure 37

- The Ertl osteomyopathic technique places bone grafting as an end-cap on amputated femur.
- The Gritti-Stokes procedure involves femur transection at the level of the adductor tubercle with patella arthrodesis.

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Transfemoral Muscle Relocation Adduction 38

- To minimize lateralization of the femur with prosthetic gait, the adductor myodesis is secured over the distal end of the femur with the hip in slight adduction.

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Transfemoral Muscle Relocation Extension 39

- Through myodesis to the femur or myoplasty to each other, the quadriceps and hamstrings are secured with appropriate balancing to allow hip ROM.
- Failure to attach the iliotibial band to the femur may contribute to hip flexion contracture.

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Surgery General Considerations 40

- Several general considerations are required for all patients regardless of the level of amputation and specific surgical technique employed.

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Anesthesia Outcomes 41

- Type of anesthesia does not appear to influence outcomes for patients with advanced age and impaired functional status.

Population	Outcomes
≥ 75 y.o. and pre-op partial/total functional dependence	No difference in wound or pulmonary complications, CVA, UTI or MI
≥65 y.o.	No difference in pulmonary or cardiac complications, or mortality

Moreira, C. C., Farber, A., Kalish, J. A., Estami, M. H., Didato, S., Rybin, D., ... & Siracuse, J. J. (2016). The effect of anesthesia type on major Lower Limb amputation in functionally impaired elderly patients. *Journal of vascular surgery*, 63(3), 696-701.
Bigli, B., Halliçoglu, M., Edipoglu, E., Cetingok, H., Pektas, Y., & Bigli, M. G. (2017). The type of anesthesia technique does not have an impact on 30-day mortality in geriatric patients undergoing Lower Limb amputation. *International Surgery*, 102(3-4), 178-183.

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Post-operative Dressing 42

- Several types of dressing are available to provide wound protection and edema control.

Kwah, L. K., Webb, M. T., Goh, L., & Harvey, L. A. (2019). Rigid dressings versus soft dressings for transtibial amputations. *Cochrane Database of Systematic Reviews*, (6).

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Negative Pressure Wound Therapy (NPWT) 43

- The goal is to promote healing and reduce post operative wound complications.

Open Surgical Site NPWT

- Serial debridement
- Promotes granulation
- Reduced infections

Closed Incision iNPWT

- Reduce incision tension
- Reduce edema
- Reduce seroma formation
- Increase blood flow

Consider This

Zayen, N. E., Weiss, J. M., Schutz, S. A., Jordan, S. W., & Valerio, L. L. (2019). Incisional Negative Pressure Wound Therapy: An Effective Tool for Major Limb Amputation and Amputation Revision Site Closure. *Advances in wound care*, 8(8), 368-373.
Georgiev, C. P., Nielsen, C. T., Nappolitano, G. M., Larsen, B. M., Fick, M. J., Brander, D. C., ... & Pabian, P. (2019). Does closed incision negative wound pressure therapy in non-traumatic major lower-extremity amputations improve survival rates?. *International wound journal*.

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Surgical Drain 44

- Some physicians elect to utilize a drain in the initial days following surgery.

+

Minimize dead space
Reduce hematoma formation

+

Increased infection risk

Coulston, J. E., Tuff, V., Twine, C. P., Chester, J. F., Eyers, P. S., & Stewart, A. H. R. (2012). Surgical factors in the prevention of infection following major Lower Limb amputation. *European Journal of Vascular and Endovascular Surgery*, 43(5), 556-560.

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Revision Surgery 45

- Residual limb pain during prosthetic use can result from unequal bone length, scarring, neuroma, or excessive soft tissue that may require surgical revision.

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Neuroma 46

- Multiple surgical techniques have been proposed to inhibit or treat neuromas that create pain and limit prosthetic use.

Collagen wrap

Nerve coaption

Embed in bone or soft tissue

Targeted muscle reinnervation (TMR)

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Targeted Muscle Reinnervation 47

- To minimize neuroma formation, nerves that are resected from the amputated portion of the limb are relocated to nearby muscles.
- Surgical planning utilizes anatomical "road maps" to determine locations of motor nerve targets.

Superficial peroneal to EDL or Peroneus longus

Deep peroneal to Tibialis anterior

Tibial to Soleus or FDL

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Phantom Limb Pain 48

- There are multiple theories to explain pain associated with the portion of the limb that is no longer present.

Historical
Psychogenic theory

Peripheral mechanism
Neuroma hyperactivity

Central neuronal mechanism
Neurosignature
Spinal cord sensitization
Cortical reorganization

Subedi, B., & Grossberg, G. T. (2011). Phantom limb pain: mechanisms and treatment approaches. *Pain research and treatment*, 2011, 864605.

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Phantom Exercise

49

- Active movements of the sound limb are performed while mental imagery replicates movement of the phantom limb to modulate pain.

Kulinkoğlu, B., Erbağcı, F., & Alkan, A. (2019). A comparison of the effects of mirror therapy and phantom exercises on phantom limb pain. Turkish journal of medical sciences, 49(1), 101-109.
Collins, K. L., Russell, M. G., Schumacher, P. J., Robinson-Freeman, K. E., O'Connor, E. C., Gibney, K. D., ... & Tsao, J. W. (2018). A review of current theories and treatments for phantom limb pain. The Journal of clinical investigation, 128(6), 2168-2176.

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Mirror Therapy

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- Use of a reflected image of the intact limb moving provides visual feedback replacing the amputated limb has been successful in diminishing phantom limb pain.

```

graph LR
    A[Positive feedback to motor cortex] --> B[Reversal of neural reorganization]
    B --> C[Diminish visual responsiveness of sensorimotor cortex]
    
```

Chen, A. W. Y., Bigler, E., Griffin, S., Ekl, V., Weeks, S., Hussey-Anderson, L., ... & Baker, C. I. (2019). Visual responsiveness in sensorimotor cortex is increased following amputation and reduced after mirror therapy. NeuroImage Clinical, 101882.
Chen, B. L., Wei, R., Charrow, A. P., Hagle, A., Howard, R., Paquiza, F. F., ... & Tsao, J. W. (2007). Mirror therapy for phantom limb pain. New England Journal of Medicine, 357(21), 2206-2207.

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Virtual Reality

51

- Participants view virtual images of two intact limbs and at the same time perform motions with their sound and residual limbs.
- Visualizing the phantom limb in motion on the avatar is an enhancement of mirror therapy.

Ambron, E., Miller, A., Kuchenbecker, K. J., Buxbaum, L. J., & Colett, H. (2018). Immersive low-cost virtual reality treatment for phantom limb pain: Evidence from two cases. Frontiers in neurology, 9, 67.
Rutledge, T., Vlezer, D., Depp, C., McQuaid, J. R., Wong, G., Jones, R. C. W., ... & Giap, H. (2019). A Virtual Reality Intervention for the Treatment of Phantom Limb Pain: Development and Feasibility Results. Pain Medicine.

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Post-operative Mobility

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- Higher level of independence with activities of daily living (ADLs) is associated with higher survival rates, prosthetic use, and good walking ability.

```

graph TD
    Influences((Influences)) --- Age{{Age}}
    Influences --- Pain{{Pain}}
    Influences --- Strength{{Strength and balance}}
    Influences --- Comorbidity{{Comorbidity}}
    Influences --- Cognition{{Cognition}}
    Influences --- Emotional{{Emotional distress}}
    
```

Madsen, U. R., Bååth, C., Berthelsen, C. B., & Hommel, A. (2018). A prospective study of short-term functional outcome after oesophageal major lower limb amputation. International journal of orthopaedic and trauma nursing, 28, 22-29.

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Psychological Considerations

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- Cognitively and emotionally individuals experience and array of complicated thoughts and feelings.

```

graph TD
    subgraph Losing_Control [Losing Control]
        A[Overwhelmed and facing dependency] --- B[Allow patient to express themselves]
    end
    subgraph Digesting_Shock [Digesting the Shock]
        C[Detecting the amputate body and life-changing decision] --- D[Demonstrate empathy]
    end
    subgraph Regaining_Control [Regaining Control]
        E[Managing consequences and building hope and self-motivation] --- F[Support independence]
    end
    A --> C
    C --> E
    
```

Madsen, U. R., Hommel, A., Bååth, C., & Berthelsen, C. B. (2016). Pendulating—A grounded theory explaining patients' behavior shortly after having a leg amputated due to vascular disease. International journal of qualitative studies on health and well-being, 11(1), 32739.

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Self-efficacy

54

- An individual's confidence in their ability to perform specific life activities can positively contribute to successful rehabilitation.

```

graph TD
    A[Minimize medical set-backs] --> B[Teach adaptive skills]
    B --> C[Encourage return to activity]
    C --> D[Gradual forward progress]
    D --> E[Positive self-efficacy]
    
```

Wise, J., White, A., Sinner, D. J., & Ferguson, J. R. (2017). A unique application of negative pressure wound therapy used to facilitate patient engagement in the amputation recovery process.

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Prosthetic Components

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- For insurance to cover prosthetic components, medical necessity is demonstrated based on the individual's current status, expected functional potential, and desire to ambulate.

```

    graph TD
      Socket[Socket] --> Suspension[Suspension]
      Socket --> Knee[Knee]
      Suspension --> Knee
      Knee --> Ankle[Ankle]
      Ankle --> Foot[Foot]
  
```

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Medicare Functional Classification Levels (MFCL)

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- K0** Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.
- K1** Has the ability or potential to use prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- K2** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
- K3** 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.
- K4** 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. **Consider This**

<https://www.cms.gov/Regulatory-and-Compliance-Policies/Transparencies/Informational/2018/07/20180711-1P-Census-Document.pdf>

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Not Medically Necessary

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- Trends from third party insurance providers appear aligned in what is not covered by insurance.
 - Prosthesis for K-0 functional level
 - Consumable supplies for device care
 - Components not required for participation in normal activities of daily living.

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Determining MFCL

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- Errors in classification may limit functional mobility, patient satisfaction, and quality of life.
- There is no "gold standard" instrument.

Specialized Measures

Amputee Mobility Predictor (AMP)

General Measures

6-minute walk (6MWT)
 Timed Up and Go (TUG)
 Climbing Stairs Questionnaire
 Short Form Health Survey 12 (SF-12)

Subjective
 Clinician experience
 Personal Opinion

Balk EM, Gazda A, Markosman G, et al. Lower Limb Prosthesis: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long-Term Outcomes [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2018 Sep. (Comparative Effectiveness Review, No. 213.)

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Amputee Mobility Predictor (AMP)

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- Developed to measure the individual's functional performance and predict their potential ability to utilize a prosthesis.
- Scored tasks with and without the prosthesis are designed to correlate with K-levels.

AMPnoPRO • 0-38 AMPPRO • 0-42

Galley RS, Roach KE, Applegrae EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. Arch Phys Med Rehabil. 2002;83(5):613-627.
 Rays, M. A., Galley, R. S., Gaurnard, L. A., Gaurnard, M., Knapp-Wood, J., McDonough, K., & Palmisano, T. (2013). Amputee mobility predictor: bilateral: a performance-based measure of mobility for people with bilateral lower-limb loss. Journal of Rehabilitation Research & Development, 50(7)

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Socket and Suspension

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- Socket Design**
 - Shape creating load bearing pressures on residual limb
- Residual Limb Interface**
 - Materials between residual limb and socket
- Suspension**
 - Mechanism to maintain prosthesis on residual limb

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Socket and Suspension Considerations 61

- Pressure distribution in the socket facilitates load transfer under static and dynamic conditions with minimal movement at the limb-prosthesis interface.

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Transfemoral Socket Design 62

- Increased adduction angle of the femur improves prosthetic control and balance.

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High-Fidelity (HiFi) System 63

- Indirect skeletal anchoring occurs through tissue compression and release method.
- Gait vibrations are transmitted into the skeletal system allowing increased proprioceptor activity.

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Proprioception 64

- Prosthetic components increasing awareness of limb position contribute to accuracy of interpreting the relationship between the prosthetic foot and the ground.

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Transfemoral Suspension 65

- Suspension systems hold the prosthesis in place providing a connection that promotes stability with activity while minimizing skin breakdown.

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Vacuum Assisted Suspension (VAS) Devices 66

- Sleeve applied to the residual limb creates a seal around the edge of the socket.
- A mechanical or electrical pump removes excess air to create a secure fit.

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VAS Benefits

67

- When other socket systems are not successful in ensuring fit or skin breakdown is a concern the vacuum suction may be an alternative.

Controls volume fluctuation
Reduces forces on residual limb
Improved proprioception
Suspension without vascular restriction
Improved tissue oxygenation

Increased socket weight
Require maintenance

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Transfemoral VAS Models

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- Manufacturers incorporate mechanical or electrical systems to generate the suspension.
 - eVAC®
 - LimbLogic®
 - Vacuum-Assisted Socket System (VASS®)

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Transtibial Socket Design

69

- The current recommendation to maximize comfort and function is total surface bearing.

Patellar Tendon Bearing (PTB)

- Pressure tolerant and intolerant regions

Total Surface Bearing (TSB)

- Equal surface loading on tissues

Stevens, P. M., DePalma, R. R., & Wurdeman, S. R. (2019). Transtibial Socket Design, Interface, and Suspension: A Clinical Practice Guideline. *JPO: Journal of Prosthetics and Orthotics*, 31(3), 172-178.

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Transtibial Interface and Suspension

70

- Anatomic**
 - Socket contours to femoral condyles
 - Socks accommodate limb volume changes
- Locking Liner**
 - Elastic liner with distal locking mechanism
- Suction**
 - External sleeve and valve create suction
- Vacuum Assisted Suspension**
 - Pump creates suction seal

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Locking Suspension

71

- The current recommendation, assuming user ability, is a viscoelastic interface.
- Multiple locking mechanisms are available.

Stevens, P. M., DePalma, R. R., & Wurdeman, S. R. (2019). Transtibial Socket Design, Interface, and Suspension: A Clinical Practice Guideline. *JPO: Journal of Prosthetics and Orthotics*, 31(3), 172-178.

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Pistoning

72

- Excessive motion causes force absorption in the soft tissues instead of transmission to the foot for loading and energy return in gait propulsion.

Vacuum Assisted Suspension (VAS) • Least pistoning

Suction Suspension

Pin and lock Suspension

Supracondylar Cuff or Sleeve • Compromised suspension

Consider This

Stevens, P. M., DePalma, R. R., & Wurdeman, S. R. (2019). Transtibial Socket Design, Interface, and Suspension: A Clinical Practice Guideline. *JPO: Journal of Prosthetics and Orthotics*, 31(3), 172-178.

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Infinite Socket ® 73

- For the transfemoral socket, carbon fiber struts attached to a flexible pressure management strap allow the individual control comfort and stability.
- The transtibial socket includes adjustable air bladders and adjustable closure system.

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Socket and Suspension Outcomes 74

Socket	Outcome
Ischial containment vs. HiFi	HiFi improved gait velocity, prosthetic motion, center of mass deviation, and perceived disability.
All types of transtibial sockets and suspension	<ul style="list-style-type: none"> • Suction decreased gait asymmetry and distal pain but more difficult donning. • Pin-lock preferred for comfort and function • PTB with Pelite high durability and low cost

Klenow, T. D., Kahle, J. T., Fedel, F. J., Rupp, J., & Highsmith, M. J. (2017). Comparative Efficacy of Transfemoral Prosthetic Interfaces: Analysis of Gait and Perceived Disability. *JPO: Journal of Prosthetics and Orthotics*, 29(3), 130-136.
Gholzadeh, H., Osman, N. A., Eshraghi, A., Ali, S., & Razak, N. A. (2014). Transtibial prosthesis suspension systems: systematic review of literature. *Clinical biomechanics*, 29(1), 87-97.

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74

Knee Component 75

- Based on the individual's activity level, the knee provides varying amounts of stability or motion.

- Exoskeletal single axis manual lock or friction control
- Endoskeletal friction swing and stance control
- Single axis, constant friction knee
- Fluid or pneumatic
- Microprocessor controlled
- Endoskeletal knee-shin system
- High activity knee control

https://www.cms.gov/medicare-coverage-database/details/lod...
datahub/CCDR/33783Control?item=13&ControlSelected=14073&Control=1408&=13&DocType=2&bc=AAQAAQAAAAA&...
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Microprocessor Knee 76

- Dynamic variation to step cadence is achieved through variable resistance swing and stance phase control that simulates natural knee adaptations.

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Microprocessor Knee Benefits 77

- Insurance may require additional justification for medical necessity including cardiovascular, functional, and cognitive requirements for coverage.

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Microprocessor Knee Models 78

- Manufacturers include a variety of control options to maximize function.
 - Endolite Orion®
 - Endolite Intelligent Prosthesis®
 - Endolite SmartIP®
 - Genium and X2®
 - Otto-Bock C-Leg®
 - Ossur RheoKnee®

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Endoskeletal Knee-Shin System 79

- In addition to the microprocessor controlled knee, the prosthesis includes a powered and programmable knee flexion and extension assist control motor.
 - Ossur Power Knee

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Endoskeletal Knee-Shin System Coverage 80

- According to criteria outlined in the Centers for Medicare and Medicaid Services Local Coverage Determination, the following individuals may benefit from the use of a power knee-ankle device:
 - the individual has a microprocessor (swing and stance phase type (L5856) controlled (electronic) knee
 - is K3 functional level only
 - has a weight greater than 110 lbs and less than 275 lbs
 - has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone
 - is able to make use of a product that requires daily charging
 - is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

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Knee Component Outcomes 81

- Controlling flexion without sacrificing stability, the microprocessor knee appears to improve efficiency and contribute to safety.

Outcome
Compared to fluid knee for active walkers: Microprocessor increased speed, comfort, and symmetry
Compared to fluid for young high-functioning: Microprocessor decreased falls, increased uneven surface walking speed.
Microprocessor for limited community ambulators: increased balance and reduced falls
Genium vs. C-leg: Genium step-over-step ascent, increased prosthetic peak knee flexion, increase swing duration

Stevens, P. M., & Wurdeman, S. R. (2019). Prosthetic Knee Selection for Individuals with Unilateral Transfemoral Amputation: A Clinical Practice Guideline. *Journal of Prosthetics and Orthotics*, 31(1), 2-8.
Lara, D. J., Wernke, M. W., Carey, S. L., Kahle, J. T., Miro, R. M., & Highsmith, M. J. (2017). Crossover study of amputee stair ascent and descent biomechanics using Genium and C-Leg prostheses with comparison to non-amputee control. *Gait & posture*, 58, 103-107.
Paella, S. A., F., Kanesberg, A., & Benici, A. B. (2018). Enhancements of a prosthetic knee with a microprocessor-controlled gait phase switch reduces falls and improves balance confidence and gait speed in community ambulators with unilateral transfemoral amputation. *Prosthetics and Orthotics International*, 42(2), 228.

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81

Powered Lower Limb Prosthesis 82

- Combined microprocessor motor powered knee and ankle systems fabricated into one prosthesis support higher level mobility.
 - LiNX®
 - Symbionic® Leg 3

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Prosthetic Foot 83

https://www.cms.gov/medicare-coverage-database/details/foot-details.aspx?LCDId=33787&Contriid=140&Ver=17&ContrVer=2&Cntrcr=Selected=14072&Cntrcr=140&=12&DocType=2&bc=AAgAAA QAAAA& Copyright Jodi Gootkin 2020

83

Energy Storage and Return Foot (ESAR) and Dynamic Response Foot (DRF) 84

- Engineering of the prosthetic foot allows mechanical energy to be stored during late stance which is released to assist propulsion during push-off.
- Decreased ground reaction force in the sound limb during stance reduces stress and risk of overuse injury to the sound limb and low back.

Stevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic Foot Selection for Individuals with Lower-Limb Amputation: A Clinical Practice Guideline. *Journal of Prosthetics and Orthotics*, 30(4), 175.

Consider This

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Microprocessor Controlled Ankle and Foot 85

- Through sensor technology, the microprocessor identifies sloping gradients.
- The ankle angle is adjusted to the terrain to promote gait symmetry.

Adjusts ankle angle during swing

Alters power for cadence

Identifies sloping gradients

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Microprocessor Ankle and Foot Models 86

- Some models additionally contain a motor to allow powered push-off with gait.
 - BiOM® Foot
 - EmPOWER® Ankle
 - Elan Foot®
 - Kinnex®
 - Meridium Foot®
 - Proprio Foot®
 - Raize®
 - Triton Smart Ankle®

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Weighted Walking 87

- When carrying heavy loads, the prosthetic ankle-foot system must provide support while in addition to good function for mobility during unweighted activities.
- For K4 level activity, a compliant forefoot keel appears to enhance late-stance energy return contributing to reduced physiologic metabolic cost.

Koshler-McNicholas, S. R., Nickel, E. A., Barrons, K., Blaharski, K. E., Dellamano, C. A., Ray, S. F., ... & Hansen, A. H. (2018). Mechanical and dynamic characterization of prosthetic feet for high activity users during weighted and unweighted walking. *PLoS one*, 13(9), e0220884.

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Foot Outcomes 88

- Single-axis foot is recommended for single speed ambulators requiring stability due to weakness and poor balance.

Outcome
ESAR greater prosthetic stability and propulsion than flex keel
Better stair negotiation and gait efficiency than SACH
ESAR less fatigue than single and multi axis
ESAR longer sound side step length than SACH
ESAR higher walking speed

InStevens, P. M., Rheinstein, J., & Wurdeman, S. R. (2018). Prosthetic Foot Selection for Individuals with Lower-Limb Amputation: A Clinical Practice Guideline. *Journal of Prosthetics and Orthotics*, 30(4), 175.

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Amputee Rehabilitation Outcome Measures 89

Patient Reported
<ul style="list-style-type: none"> Amputee Activity Survey Prosthesis Evaluation Questionnaire (PEQ) Prosthetic Profile of the Amputee (PPA) Locomotor Capabilities Index (LCI) Orthotic Prosthetic User's Survey (OPUS) Trinity Amputation and Prosthesis Experience Scale (TAPES)
Performance
<ul style="list-style-type: none"> Timed Up and Go (TUG) Six Minute Walk Test (6MWT) Amputee Mobility Predictor (AMPPRO and AMPnoPRO) Comprehensive High-Activity Mobility Predictor (CHAMP)
Biomechanical
<ul style="list-style-type: none"> Symmetry in External Work Measure (SEW)

Agrawal, V. (2016). Clinical Outcome Measures for Rehabilitation of Amputees – A review. *Physical Medicine and Rehabilitation International*, 3(2), 1080.

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Patient Reported Outcome Measures (PROM) 90

Amputee Activity Survey (AAS)
<ul style="list-style-type: none"> Prosthesis/assistive device use, employment, gait habits, social activity
Locomotor Capabilities Index (LCI)
<ul style="list-style-type: none"> Skill with prosthesis on different surfaces, level of independence
Orthotic Prosthetic User's Survey (OPUS)
<ul style="list-style-type: none"> Lower limb function, quality of life, satisfaction with prosthesis
Prosthesis Evaluation Questionnaire (PEQ)
<ul style="list-style-type: none"> Prosthesis function, mobility, psychosocial experience, well-being
Prosthetic Profile of the Amputee (PPA)
<ul style="list-style-type: none"> Prosthetic use, prosthetic capabilities, environment, leisure
Trinity Amputation and Prosthesis Experience Scale (TAPES)
<ul style="list-style-type: none"> Physical and psychological aspect of adjustment to prosthetic limb

Bull, E.H., Gazak, A., Marikazian, G., et al. Lower Limb Prostheses: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long-Term Outcomes [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2018 Sep. (Comparative Effectiveness Review, No. 213.) Available from: <https://www.ncbi.nlm.nih.gov/books/NBK531523/>

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Self Selected Gate Velocity (SSGV) 91

- When ambulating with a prosthesis, several kinematic variables are associated with walking speed an individual uses.

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Specialty Prostheses 92

- To allow high level of work and sport participation manufacturers have developed prosthesis with specific components to address the individual's needs.

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Heel Height 93

- The user adjusted heel height allows the wearer to accommodate to different types of shoes.
- Training considerations for control over center of gravity and shifted biomechanics.

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Waterproof Limbs 94

- Submergible devices are available for showering, swimming, and recreational purposes.
 - Amphibian Water Leg®
 - Endolite Aqualimb®
 - Genium® X3
 - Kinnex Foot®
 - Ottock Aqualine® System
 - Plie® 3

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94

Running Specific Feet 95

- The absence of a heel sacrifices stability in low to moderate impact activities for enhanced running.
- Biomechanical analysis demonstrates equivalent mediolateral foot displacement in non-amputee and Paralympic sprinters.

Arellano, C. J., McDermott, W. J., Kram, R., & Grabowski, A. M. (2015). Effect of running speed and leg prostheses on mediolateral foot placement and its variability. *PLoS one*, 10(1), e0115637. Image: <https://www.af.mil/News/Article-Display/Article/1270904/rescue-airman-amputee-wins-battle-to-serve-in-af/>

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Rock Climbing Prosthesis 96

- The front toe region of the traditional prosthesis is too flexible for stability with climbing.

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Emerging Techniques and Components 97

- Government, private, and individual researchers continue to innovate to enhance the lives of individuals with lower limb loss.
- Beyond prevention of limb loss, minimizing complications, and prosthetic components, well-being and general health are explored to enhance quality of life.

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Stochastic Resonance 98

- Sub-threshold vibration sensors located in the prosthetic socket may enhance peripheral sensation sufficiently to result in improved postural stability and locomotor function.

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Distributed Sensing 99

- Built in sensors on the prosthetic liner will monitor moisture, temperature, pressure, and shear stress.

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Dynamic Socket 100

- Multidirectional sensors detect volume change and shift fluid from the internal bladders to adjust pressure on the residual limb.

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Evaporative Cooling System 101

- Activity can cause a dramatic increase in skin temperature within the prosthesis causing discomfort and perspiration accumulation.
- Embedded skin temperature sensors and an evaporative cooling system may ameliorate these problems.


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Osseointegration 102

- A titanium implant in the residual limb allows direct skeletal attachment of the prosthesis eliminating the need for a socket.


Stem implantation




Transcutaneous component insertion




6 weeks – 6 months healing



Full weight bearing






Folke, J. P. M., Lejendekers, R. A., & Mann, H. (2017). Osseointegrated prosthesis for patients with an amputation: Multidisciplinary team approach in the Netherlands.


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Osseointegration Benefits 103



- Improved comfort
- Elimination of poor socket fit
- Osseoperception
- Improved energy transfer
- Enhanced prosthetic control
- Accommodates short limbs



- Infection risk
- Skin irritation

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Osseointegration Training Prosthesis 104

- The short training prosthesis is made in knee-length to reduce the length of the lever arm and allow early controlled axial weight bearing.
- Combined with a general exercise program bone mineralization is stimulated by loading the bone-implant unit in additional directions other than axial.

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104

Variable Stiffness Prosthetic Ankle 105

- A powered device that can vary sagittal plane stiffness using a pneumatic actuator to simulate anterior compartment muscles.
- A linear spring simulates contraction of the posterior muscles.

Shepherd, M. K., Azocar, A. F., Major, M. J., & Rouse, E. J. (2018). Amputee perception of prosthetic ankle stiffness during locomotion. *Journal of neuroengineering and rehabilitation*, 15(1), 99.

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Prosthetic Foot Emulator 106

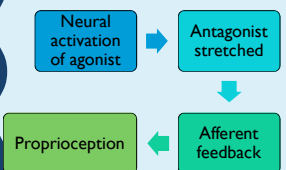
- The robotic prosthetic foot can be adjusted to simulate a variety of commercially available foot options to allow the individual to “try on” different options prior to prescription.

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Ewing Amputation 107

- During the below knee amputation, muscles previously inserting distal to the ankle are mechanically connected to each other in pairs.
- Dynamic muscle relationships are preserved between.
 - Tibialis anterior to lateral gastroc
 - Peroneus longus to tibialis posterior



```

    graph TD
      A[Neural activation of agonist] --> B[Antagonist stretched]
      B --> C[Afferent feedback]
      C --> D[Proprioception]
      
```



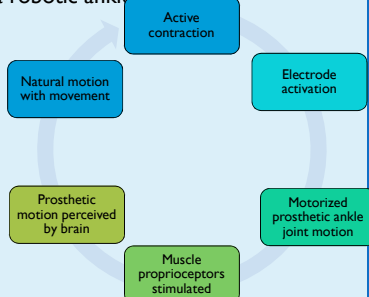
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Agonist Antagonist Myoneural Interface (AMI) 108

- AMI is the name of the process that allows patients with the Ewing amputation to receive proprioceptive feedback from a robotic ankle.



```

    graph TD
      A[Active contraction] --> B[Electrode activation]
      B --> C[Motorized prosthetic ankle joint motion]
      C --> D[Muscle proprioceptors stimulated]
      D --> E[Prosthetic motion perceived by brain]
      E --> F[Natural motion with movement]
      F --> A
      
```

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Mobile Gait Analysis System

109

- Combined communication from a shoe attachment with force sensors and inertial measurement units (IMU) on the trunk and lower extremities collect data on gait to provide information to promote gait symmetry during rehabilitation.

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Smartphone Apps

110

- ReLoad plays music during gait. When the sensors detect gait deviations, the music becomes out of tune providing instant feedback for correction.
- GaitRite uses the smartphone's built in accelerometer to record gait movements during dual-task activities outside the clinical assessment environment.

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Computer Assisted Rehabilitation Environment (CAREN)

111

- Immersive virtual reality environments allow patients to experience challenging scenarios in a safe, controlled manner.

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3D Printing

112

- 3D printing technology is expanding to include lower extremity prosthetics that are biomechanically functional, sockets, couplers, and artistic embellishment.

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Conclusion

113

- Innovations in surgical procedures, prosthetic component design, and socket-limb interface are focused on restoration of tissue structure, functional mobility, and maximum quality of life.

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1. The Wifl scale (assessing wound size, infection, and foot ischemia) is utilized to predict amputation risk by in patients with which diagnosis?

- A. Crush Injury
- B. Congenital Limb Deformity
- C. Malignancy
- D. Peripheral Arterial Disease

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2. What TcPO₂ level is associated with impaired wound healing?

- A. > 70 mmHg
- B. > 50 mmHg
- C. < 40 mmHg
- D. < 30 mmHg

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116

3. Transfer of which tendons during a partial foot amputation reduces the risk of developing equinovarus?

- A. Gastrocnemius and Soleus
- B. Peroneus Longus and Brevis
- C. Flexor Hallucis Longus and Tibialis Posterior
- D. Tibialis Anterior and Extensor Digitorum Longus

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117

4. Which of the following is NOT a benefit of Negative Pressure Wound Therapy to facilitate healing of the residual limb?

- A. Increased incision tension
- B. Enhanced granulation
- C. Increased blood flow
- D. Reduced seroma

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118

5. What Medicare Functional Classification Level (MFCL) would be assigned to a patient anticipated to achieve household ambulation with a prosthesis on level surfaces at a fixed cadence?

- A. K0
- B. K1
- C. K2
- D. K3

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119

6. Which suspension mechanism is most effective at minimizing pistoning?

- A. Vacuum Assisted Suspension
- B. Suction Suspension
- C. Supracondylar Cuff
- D. Pin and Lock

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120

7. Which type of knee component incorporates a stumble recovery mechanism that senses instability and stiffens the knee allowing the individual to regain their balance?

- A. Single axis constant friction
- B. Non-microprocessor controlled
- C. Microprocessor controlled
- D. Fluid controlled

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121

8. An energy storage and return prosthetic foot enhances prosthetic limb propulsion at what phase of the gait cycle?

- Heel Strike
- Push-Off
- Mid-Swing
- Terminal Swing

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122

9. Osseointegration eliminates the need for which component of the traditional prosthesis?

- Ankle assembly
- Knee mechanism
- Pylon
- Socket

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123

10. What is unique about the Ewing amputation surgical technique?

- A longer residual limb is created
- The dynamic muscle relationship is preserved
- General anesthesia is not required
- Skin grafting is minimal

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124

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Lower Limb Amputation & Protheses Resources

Geriatric Nutritional Risk Index

<https://www.mdcalc.com/nutritional-risk-index-nri>

Walking Impairment Questionnaire

<https://www.sciencedirect.com/science/article/pii/S0741521403003124>

Wound, Ischemia, foot Infection Classification (WIFI) App

<https://apps.apple.com/us/app/svs-ipg/id1014644425>

Mangled Extremity Severity Score (MESS)

<https://www.mdcalc.com/mangled-extremity-severity-score-mess-score#targetText=The%20Mangled%20Extremity%20Severity%20Score,setting%20of%20lower%20extremity%20trauma.>

Medicare Functional Classification Levels (MFCL)

https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LLP_Consensus_Document.pdf

Agency for Healthcare Research and Quality: Lower Limb Protheses: Measurement Instruments, Comparison of Component Effects by Subgroups, and Long Term Outcomes

https://www.ncbi.nlm.nih.gov/books/NBK531523/pdf/Bookshelf_NBK531523.pdf

Amputee Mobility Predictor (AMP)

<https://www.sralab.org/rehabilitation-measures/amputee-mobility-predictor-0>

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VA Center for Limb Loss and MoBility (CLiMB)

<https://www.amputation.research.va.gov/index.asp>

National Institutes of Health 3D Print Exchange

<https://3dprint.nih.gov/>

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