

Lower Limb Amputation & Prostheses

Goals and Objectives

Course Description

"Lower Limb Amputation & Prostheses" is an online recorded video of a previously presented live CE webinar for occupational therapists and occupational therapy assistants that examines common amputations and prostheses of the lower extremity. This course includes a review of current literature relating to pathophysiology of conditions leading to amputation, surgical procedures, and lower limb prosthetics.

Course Rationale

The purpose of this course is to present contemporary foundational knowledge about lower extremity amputations and prosthetics to occupational therapy professionals. Areas of focus include causative amputation conditions, surgical interventions, and post-operative prosthetics.

Course Goals and Objectives

Upon completion of this course, participants will be able to:

1. Identify 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. List and differentiate lower limb amputation surgical procedures.
5. Identify the primary components of the lower limb prostheses.
6. Recognize the mechanisms of lower limb prosthetic suspension.
7. Identify the primary characteristics of prosthetic knee units.
8. Identify the benefits of foot and ankle prosthetic designs.
9. Identify examples of specialty lower limb prostheses.

Course Provider – Innovative Educational Services

Provider Contact Information – information@cheapceus.com

Course Instructor – Jodi Gootkin, PT, Med, CEAS

Financial/Non-financial Disclosure - Neither the Provider nor the instructor have any financial or non-financial conflict of interest related to the presentation of this CE program.

Target Audience – Occupational Therapists, Occupational Therapy Assistants

OT Scope of Practice – Foundational Knowledge

Course Educational Level – This course is applicable for introductory learners.

Course Prerequisites – None

Instructional Method – Distance Learning – Independent; Asynchronous online video-based home study

Location - Cheapceus.com

Date – Continuously available on-demand

PD Activity Completion Requirements / Criteria for Issuance of CE Credits – Completion of viewing of 1 hour recorded video, and a score of 70% correct or greater on the course post-test.

Continuing Education Credits – Three (3) contact hours / .3 AOTA CEUs

Course Fee - \$34.95

Registration Information – No pre-registration required; available on-demand at Cheapceus.com

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Lower Limb Amputation & Prostheses

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Course Overview

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- “Lower Limb Amputation & Prostheses” examines common amputations of the lower extremity. 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

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- 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

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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.

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Course Outline and Schedule

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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 Transfemoral	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
Ossointegration	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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- After watching the video go to www.cheapceus.com
- Complete the post test with score of at least 70%
 - May be retaken multiple times
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- Print certificate
- **Course review and summary for post test at the end of the webinar.**



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Historical Perspective

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

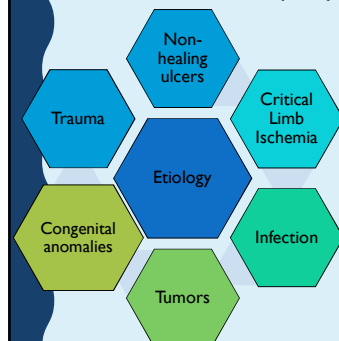
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Causes of Lower Limb Loss

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



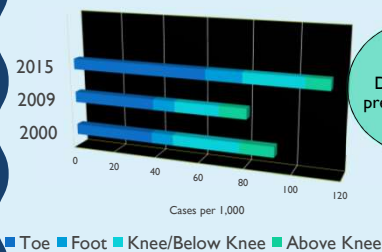
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Non-traumatic Lower Limb Amputation

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



Geiss, L. S., Li, Y., Hora, I., Albright, A., Rolka, D., & Gregg, E. W. (2019). Resurgence of diabetes-related nontraumatic lower-extremity amputation in the young and middle-aged adult US population. *Diabetes care*, 42(1), 50-54.

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Diabetes Mellitus

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- 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.

Xie, Y., Zhang, H., Ye, T., Ge, S., Zhuo, 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

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- 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 Asten, 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)

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- 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

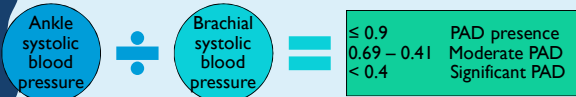
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PAD Assessment

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



- 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.

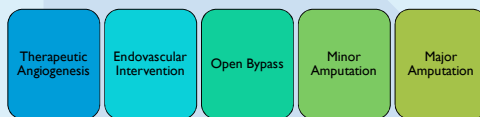
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PAD Management

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



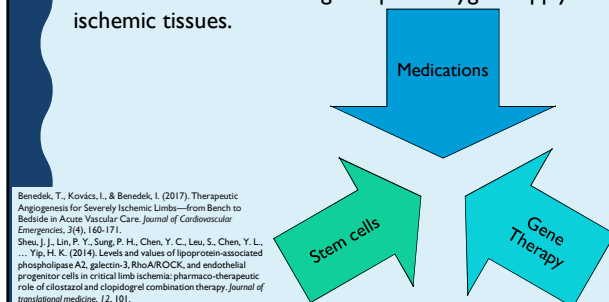
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Therapeutic Angiogenesis

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



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.

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

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Stem Cell Angiogenesis

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- 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.

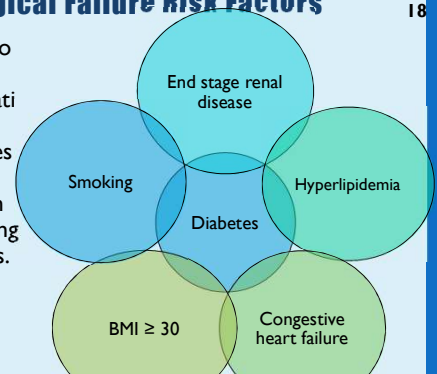
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PAD Surgical Failure Risk Factors

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



Shi, E., Jex, M., Patel, S., & Garg, J. (2019). Outcomes of Wound Healing and Limb Loss After Transcatheter 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

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

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Wound, Ischemia, foot Infection Classification (WIFI)

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.

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Transcutaneous Oxygen (TcPO₂)

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

- >50 mmHg
- Normal
- <40 mmHg
- Impaired healing
- <30 mmHg
- Critical limb ischemia

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Limb Salvage

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

- MESS { Mangled Extremity Severity Score, Amputation Threshold: >7
- LSI { Limb Salvage Index, Amputation Threshold: >6
- PSI { Predictive Salvage Index, Amputation Threshold: >8
- NISSA { Nerve Injury, Ischemia, Soft Tissue, Skeletal, Shock, Age score, Amputation Threshold: >11

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Mangled Extremity Severity Score (MESS)

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

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- 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

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Transmetatarsal
• Midsection of metatarsals

Lisfranc
• Tarsometatarsal joint

Chopart
• Talonavicular and calcaneocuboid joints

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Partial Foot Muscle Relocation

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- 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

Sukur, E., Akar, A., Uyar, A. C., Cicek, O., Kochat, 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

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- 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

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

Proprioception

End weight bearing

Tibia epiphysis intact

↓

Benefits

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Syme Outcomes

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- 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., Lenze, U., & Donnan, L. T. (2019). Syme Amputation: Function, Satisfaction, and Prostheses. *Journal of pediatric orthopedics*.
Brakama, 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

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- 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.



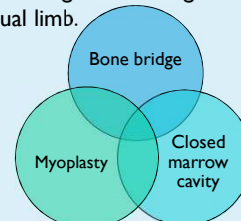
Pasquina, P. F., Bryant, P. R., Huang, M. E., Roberts, T. L., Nelson, V. S., & Flood, K. M. (2006). Advances in amputee care. *Archives of Physical Medicine and Rehabilitation*, 87(3), 34-43. Copyright Jodi Gootkin

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Transtibial Osteomyoplasty (Ertl Procedure)

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- 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/

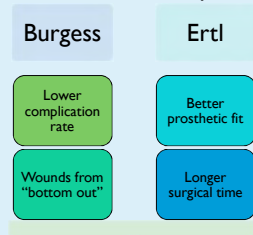
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Ertl vs. Burgess Procedure

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



Bosse, M. J., Morshed, 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

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Transtibial Surgical Technique Outcomes

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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., Forsberg, C. J. A., Kirk, 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. *JBS*, 95(10), 888-893. Copyright Jodi Gootkin

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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

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- 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., Crone, C., & Atsinger, C. (2014). Through knee amputation: technique modifications and surgical outcomes. *Archives of plastic surgery*, 41(5), 562. Copyright Jodi Gootkin

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Transfemoral Surgical Procedure

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- 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

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- 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

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- 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.

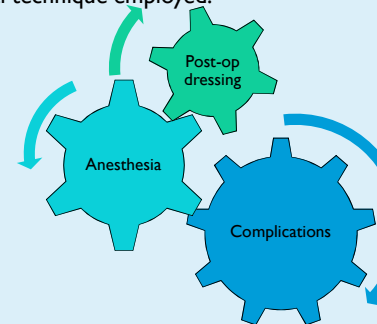
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Surgery General Considerations

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- 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

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- 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., Kallish, J. A., Eskami, M. H., Didato, S., Rybin, D., ... & Syracuse, 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.
 Bilgili, B., Haliloglu, M., Edipoğlu, E., Çelengok, H., Pektaş, Y., & Bilgili, 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.

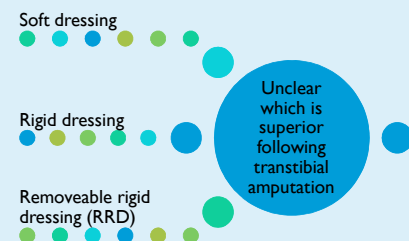
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Post-operative Dressing

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- 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., West, J. M., Schulz, 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), 368-372.
Stumpert, C. P., Nielsen, C. T., Napolitano, G. M., Larsen, B. M., Riss, M. J., Brander, D. C., ... & Palsen, 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., Evers, 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

Sabedi, 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., Erbahar, F., & Altan, 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, H. 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.

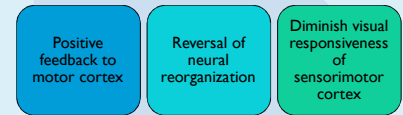
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Mirror Therapy

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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.



Chan, A. W. Y., Bilger, E., Griffin, S., Ellis, 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*, 191-192.
Chan, B. L., Witt, R., Chertow, A. P., Hogue, A., Howard, R., Pappas, P. 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

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- 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., & Coslett, H. (2018). Immersive low-cost virtual reality treatment for phantom limb pain: Evidence from two cases. *Frontiers in neurology*, 9, 67.
Rutledge, T., Velez, 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*.

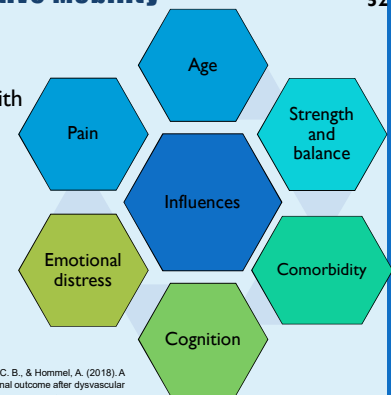
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Post-operative Mobility

52

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



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

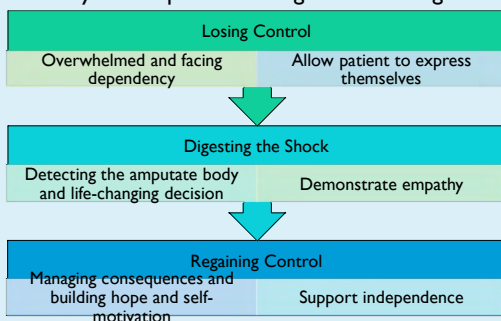
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Psychological Considerations

53

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



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), 327-39.

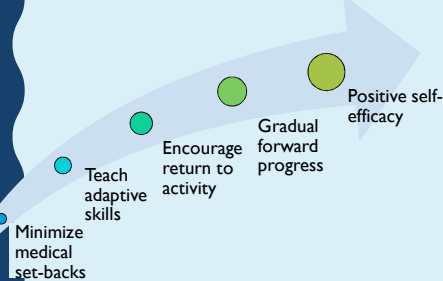
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Self-efficacy

54

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



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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55

-
- ```

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

```

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56

- 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.
  - 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.
  - 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.
  - 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.
  - 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/Medicare/Coverage/DeterminationProcess/downloads/LIP\\_Consensus\\_Document.pdf](https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/LIP_Consensus_Document.pdf)

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57

- 58

- Balk EM, Gazula A, Markozannes 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.)

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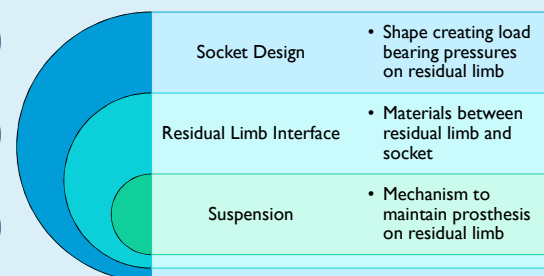
59

- 
- AMPNoPRO  
• 0-38
- AMPPRO  
• 0-42

Gayle RS, Roach KE, Applegate 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.

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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.

A central blue circle labeled 'Pressure Distribution' is surrounded by five other circles: 'Comfort' (top), 'Skin Integrity' (top-right), 'Limb health' (bottom-right), 'Performance' (bottom-left), and 'Convenience' (top-left). These are connected by a circular path. A separate green circle labeled 'Convenience' is also shown, with a line connecting it to the 'Pressure Distribution' circle.

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### Transfemoral Socket Design 62

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

Two boxes are shown. The left box is labeled 'Quadrilateral and Ischial Containment' and contains the text 'Selective loading pressure tolerant'. The right box is labeled 'HiFi' and contains the text 'Sub-ischial compression and relief zones'.

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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.

A central blue circle labeled 'HiFi' is connected to three boxes: 'Brimless' (left), 'Alternate pressure and relief' (top), and 'Osseoperception' (right). Arrows point from each of these boxes to the 'HiFi' circle.

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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.

A seesaw diagram. On the left side, a large blue arrow points down, and the text 'Reduced Compensatory steppage', 'Circumduction', and 'Energy expenditure' is written below it. On the right side, a large blue arrow points up, and the text 'Increased Walking velocity, balance, and confidence' is written above it.

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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.

Two boxes are shown. The left box is labeled 'Mechanical' and contains the text 'Belt, strap, or sleeve'. The right box is labeled 'Suction' and contains the text 'Pin and Lock', 'Passive negative pressure', and 'Active vacuum assisted'.

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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

68

- 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"> <li>• Suction decreased gait asymmetry and distal pain but more difficult donning.</li> <li>• Pin-lock preferred for comfort and function</li> <li>• PTB with Pelite high durability and low cost</li> </ul> |

Klenow, T. D., Kahle, J. T., Fedel, F. J., Ropp, J. 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.  
Gholizadeh, 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.

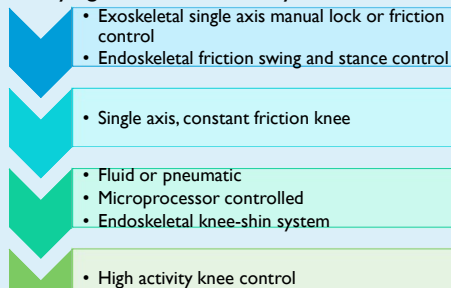
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## Knee Component

75

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



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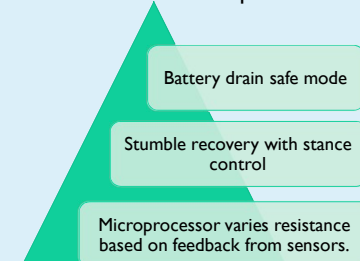
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## Microprocessor Knee

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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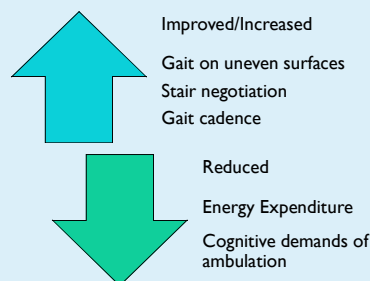
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## Microprocessor Knee Benefits

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- 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. *JPO: Journal of Prosthetics and Orthotics*, 31(1), 2-8.  
Lara, D. J., Wernke, M. W., Conry, S. L., Kahle, J. T., Mitro, 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.  
Squella, S. A. F., Kannenberg, A., & Benetti, A. B. (2018). Enhancement 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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## 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

Solid Ankle Cushioned Heel (SACH)  
Single Axis Foot

Flexible-heel foot  
Multiaxial ankle/foot

Microprocessor controlled ankle foot system  
Energy Storing And Return (ESAR)  
Dynamic Response Foot (DRF)  
Flex foot system  
Flex-walk system  
Shank foot system with vertical loading pylon

Microprocessor foot or ankle with power assist

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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.

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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.

Koehler-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), e0202884.

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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                                       |

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

Highsmith, M. J., Kahle, J. T., Mero, R. M., Orenduff, M. S., Lewandowski, A. L., Ormrod, J. J., ... & Ertl, J. P. (2016). Prosthetic interventions for people with transtibial amputation: Systematic review and meta-analysis of high-quality prospective literature and systematic reviews. *Journal of Rehabilitation Research & Development*, 53(2).

Geertzen, J., van der Linde, H., Rosenbrand, K., Conrad, M., Deckers, J., Koning, J., ... & Schrier, E. (2015). Dutch evidence-based guidelines for amputation and prosthetics of the lower extremity: amputation surgery and postoperative management. Part 1. Prosthetics and orthotics international, 39(5), 351-360.

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## Amputee Rehabilitation Outcome Measures

89

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

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

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

Balk, E.H., Gazula, A., Markozannes, 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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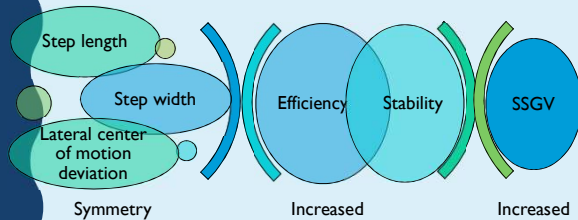
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## Self Selected Gate Velocity (SSGV)

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



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## Specialty Prostheses

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- 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

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- 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®
  - Ottoock Aqualine® System
  - Plie® 3

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## 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/1290904/rescue-airman-amputee-wins-battle-to-serve-in-af/>

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## Rock Climbing Prosthesis

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

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## Emerging Techniques and Components

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- 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

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- 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

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- 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

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- 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



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

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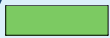
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### Osseointegration Benefits

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- 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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### 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

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- 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.

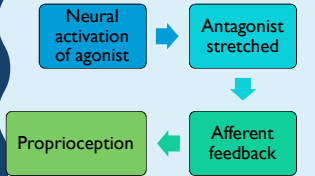
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### Ewing Amputation

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- 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



Consider This

Cities, T. R., Herr, H. M., Srinivasan, S. S., Zorzos, A. N., & Carty, M. J. (2018). The Ewing Amputation: The First Human Implementation of the Agonist-Antagonist Myoneural Interface. *Plastic and Reconstructive Surgery-Global Open*, 6(11), e1987.

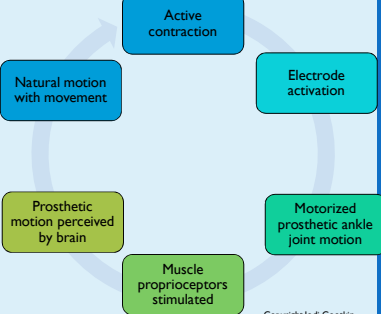
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### Agonist Antagonist Myoneural Interface (AMI)

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



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### Mobile Gait Analysis System

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- 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

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- 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)

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

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### 3D Printing

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

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### Conclusion

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- 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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### 114

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 TcPO<sub>2</sub> level is associated with impaired wound healing?

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

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

- A. Heel Strike
- B. Push-Off
- C. Mid-Swing
- D. Terminal Swing

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

- A. Ankle assembly
- B. Knee mechanism
- C. Pylon
- D. Socket

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

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

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