Prescription Writing Lower Limb Prosthetics

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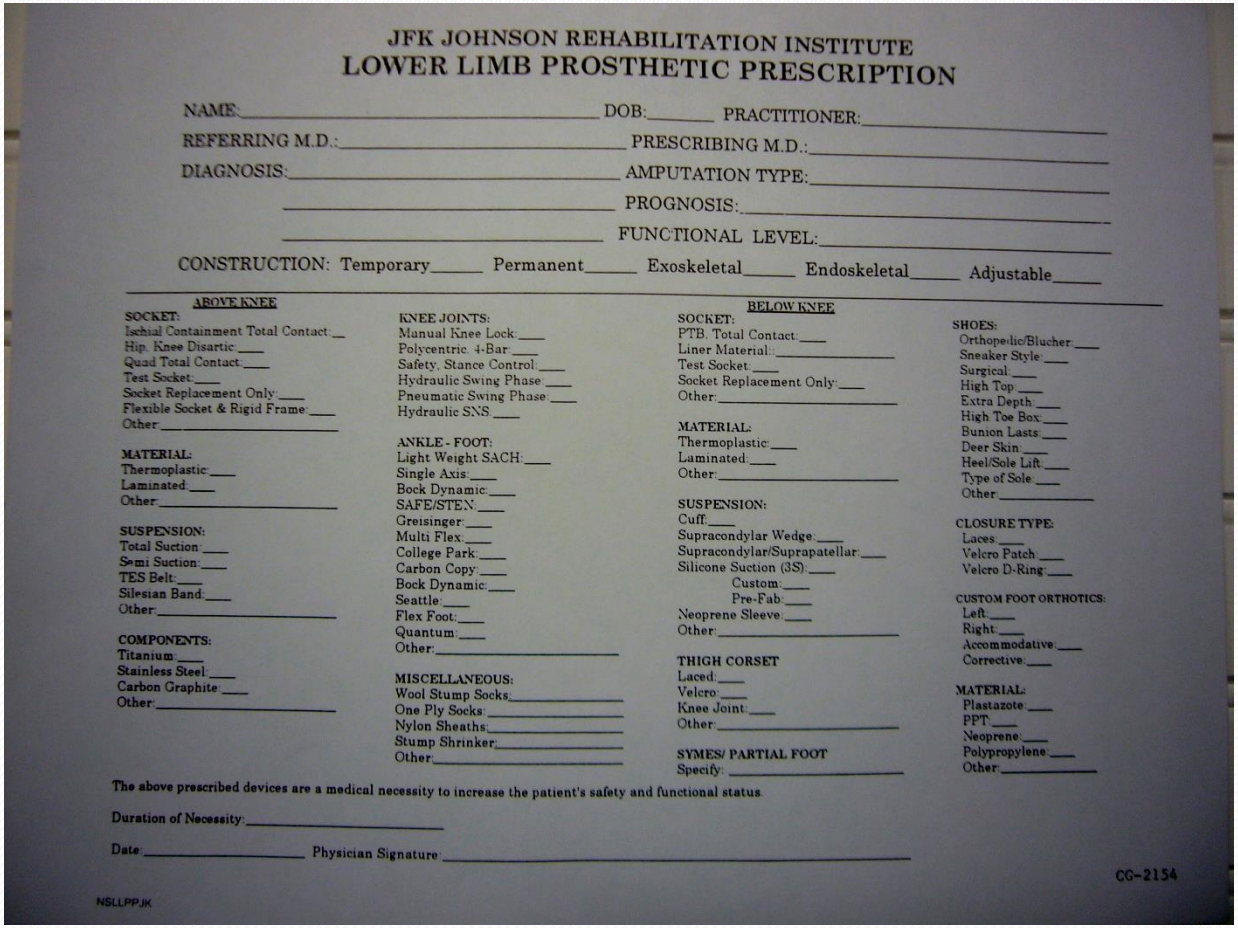
The goal is to generate a treatment plan to rehabilitate the patient and maximize their functional outcome

The treatment plan should include the prosthetic prescription, proper footwear, therapy program, education, and follow-up

The prosthetic prescription should be formulated and agreed to by the physician, prosthetist, and patient (and insurance carrier if needed)

Prosthetic prescription



JFK JOHNSON REHABILITATION INSTITUTE
LOWER LIMB PROSTHETIC PRESCRIPTION

NAME:_____ DOB:_____ PRACTITIONER:_____
REFERRING M.D.:_____ PRESCRIBING M.D.:_____
DIAGNOSIS:_____ AMPUTATION TYPE:_____
_____ PROGNOSIS:_____
_____ FUNCTIONAL LEVEL:_____
CONSTRUCTION: Temporary_____ Permanent_____ Exoskeletal_____ Endoskeletal_____ Adjustable_____

ABOVE KNEE

SOCKET:
Ischial Containment Total Contact:__
Hip. Knee Disartic:___
Quad Total Contact:___
Test Socket:___
Socket Replacement Only:___
Flexible Socket & Rigid Frame:___
Other:_____

MATERIAL:
Thermoplastic:___
Laminated:___
Other:_____

SUSPENSION:
Total Suction:___
Semi Suction:___
TES Belt:___
Silesian Band:___
Other:_____

COMPONENTS:
Titanium:___
Stainless Steel:___
Carbon Graphite:___
Other:_____

KNEE JOINTS:
Manual Knee Lock:___
Polycentric 4-Bar:___
Safety, Stance Control:___
Hydraulic Swing Phase:___
Pneumatic Swing Phase:___
Hydraulic SNS:___

ANKLE - FOOT:
Light Weight SACH:___
Single Axis:___
Bock Dynamic:___
SAFE/STEN:___
Greisinger:___
Multi Flex:___
College Park:___
Carbon Copy:___
Bock Dynamic:___
Seattle:___
Flex Foot:___
Quantum:___
Other:_____

MISCELLANEOUS:
Wool Stump Socks:_____
One Ply Socks:_____
Nylon Sheaths:_____
Stump Shrinker:_____
Other:_____

BELOW KNEE

SOCKET:
PTB. Total Contact:___
Liner Material::_____
Test Socket:___
Socket Replacement Only:___
Other:_____

MATERIAL:
Thermoplastic:___
Laminated:___
Other:_____

SUSPENSION:
Cuff:___
Supracondylar Wedge:___
Supracondylar/Suprapatellar:___
Silicone Suction (3S):___
Custom:___
Pre-Fab:___
Neoprene Sleeve:___
Other:_____

THIGH CORSET
Laced:___
Velcro:___
Knee Joint:___
Other:_____

SYMES/ PARTIAL FOOT
Specify:_____

SHOES:
Orthopedic/Blucher:___
Sneaker Style:___
Surgical:___
High Top:___
Extra Depth:___
High Toe Box:___
Bunion Lasts:___
Deer Skin:___
Heel/Sole Lift:___
Type of Sole:___
Other:_____

CLOSURE TYPE:
Laces:___
Velcro Patch:___
Velcro D-Ring:___

CUSTOM FOOT ORTHOTICS:
Left:___
Right:___
Accommodative:___
Corrective:___

MATERIAL:
Plastazote:___
PPT:___
Neoprene:___
Polypropylene:___
Other:_____

The above prescribed devices are a medical necessity to increase the patient's safety and functional status.

Duration of Necessity:_____

Date:_____ Physician Signature:_____

CG-2154

NSLLPPJK

Key elements of the prosthetic prescription

- Patient name, age, sex, date of birth, identifying info
- All relevant diagnoses (diabetes, PVD, cardiac, dialysis)
- Level of amputation
- Prognosis
- Functional level (Medicare level 0-4)
- Prescribing physician and referring physician/surgeon
- Prosthetic provider
- Details of the prosthesis
- Justification or Letter of Necessity if needed
- Duration of Need

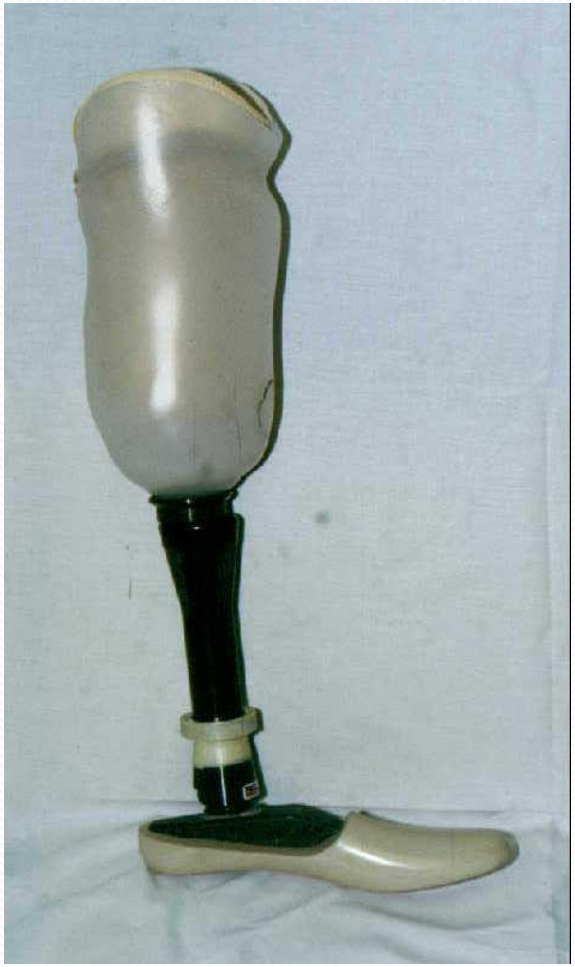
Details of the prosthetic Rx

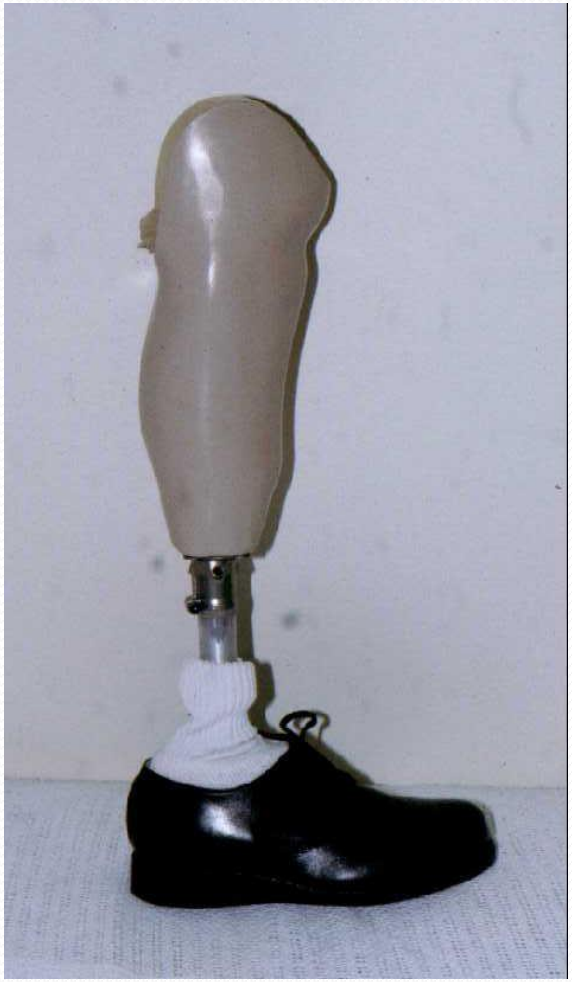
- Preparatory , permanent, specialty (sports, waterproof)
- Overall design and construction (endo vs. exo)
- Socket design including soft interface materials, socket material, suspension mechanism, special features
- Pylon materials
- Knee unit (AK) with control features
- Foot/ankle unit with special features as needed
- Accessories (socks, shrinkers, liners, covers, chargers)
- Proper footwear and custom foot orthotic if appropriate

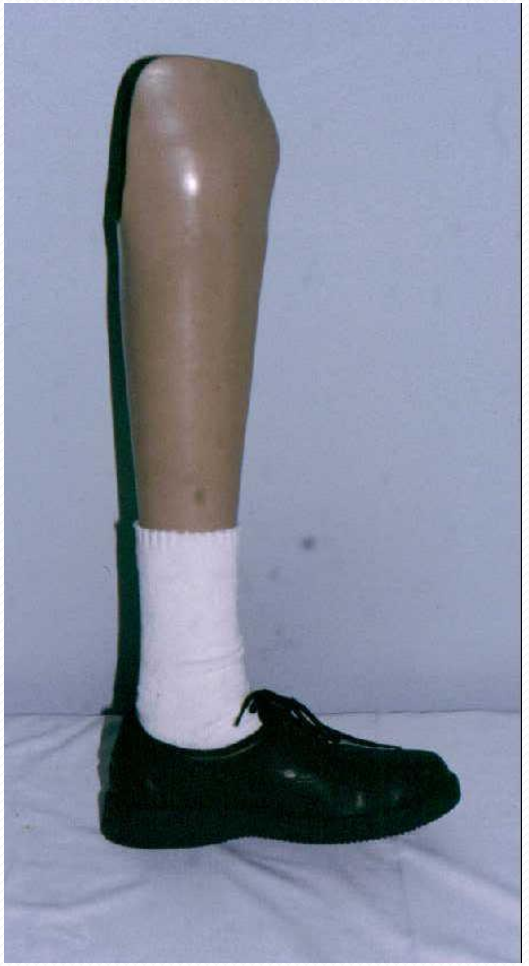
Trans-tibial Prosthesis Design and Options

- Weight-bearing : PTB, total contact, total surface bearing
- Interface material : Gel liner, foam (Pelite/Bocklite), socks, leather/rubber
- Socket materials : Thermoplastic, carbon lamination
- Suspension : Supra-condylar wedge, elastic sleeve, gel liner with pin or strap, vacuum (passive or active)
- Pylon/connector materials : aluminum, titanium, carbon fiber, steel
- Foot/ankle

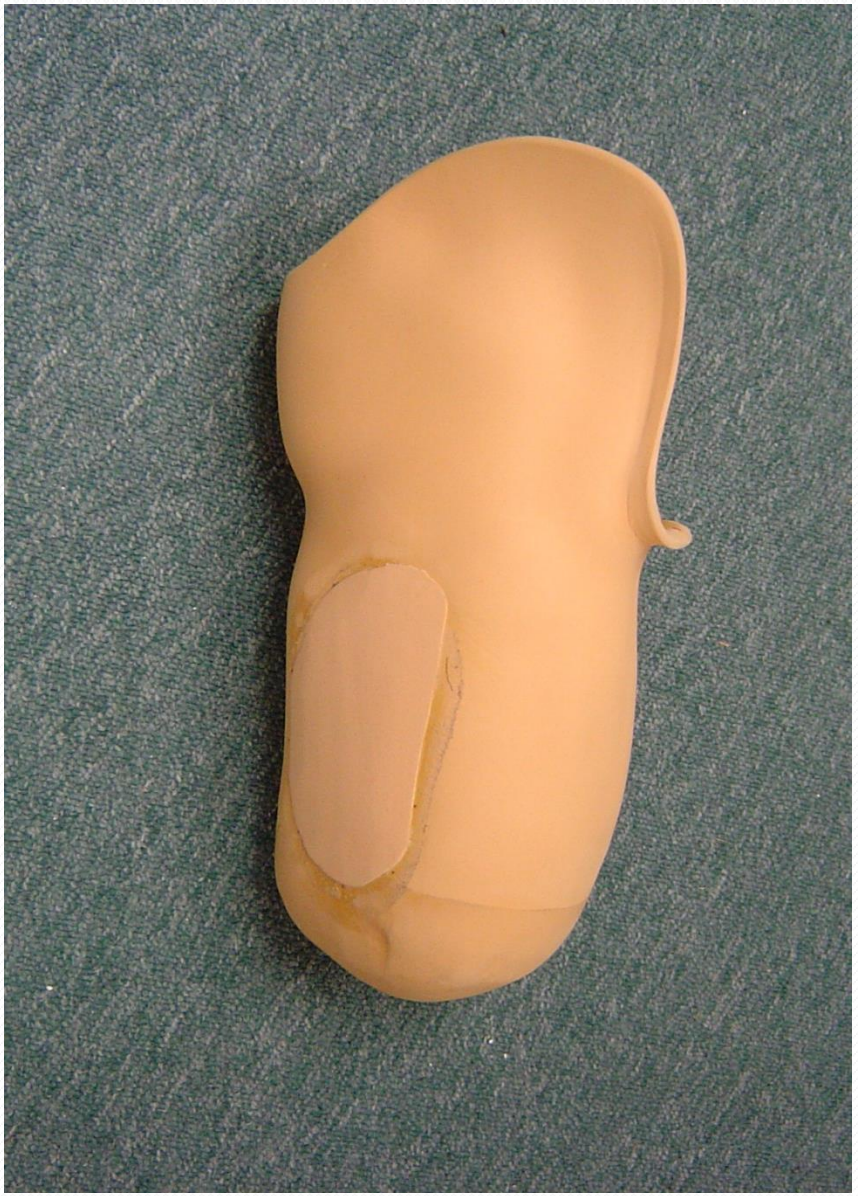
TTA Prostheses
Socket materials and trimlines



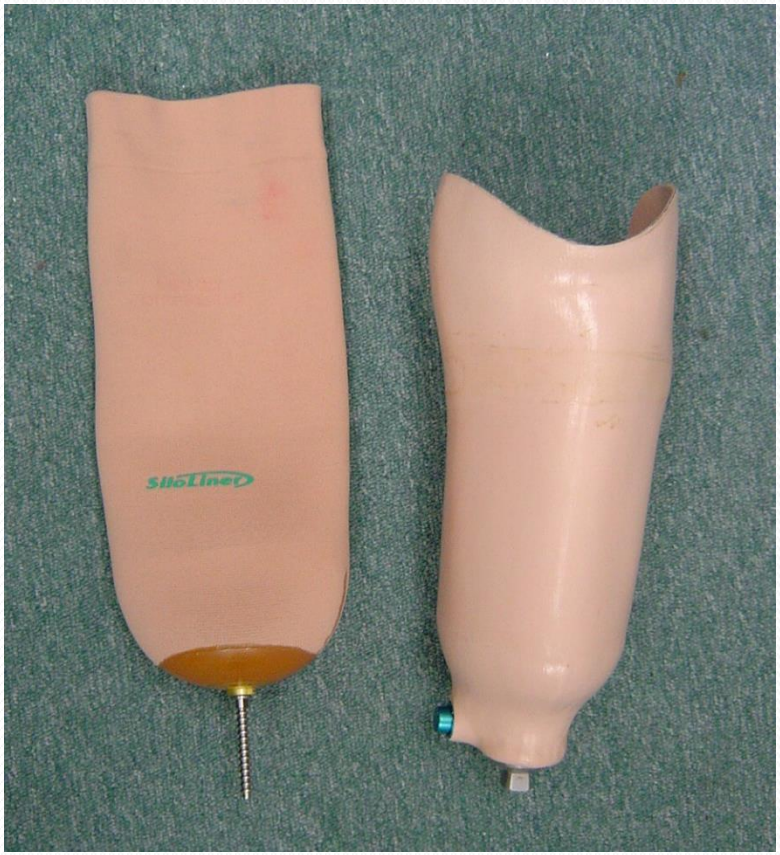




Foam liner in preliminary prosthesis (easy to modify)

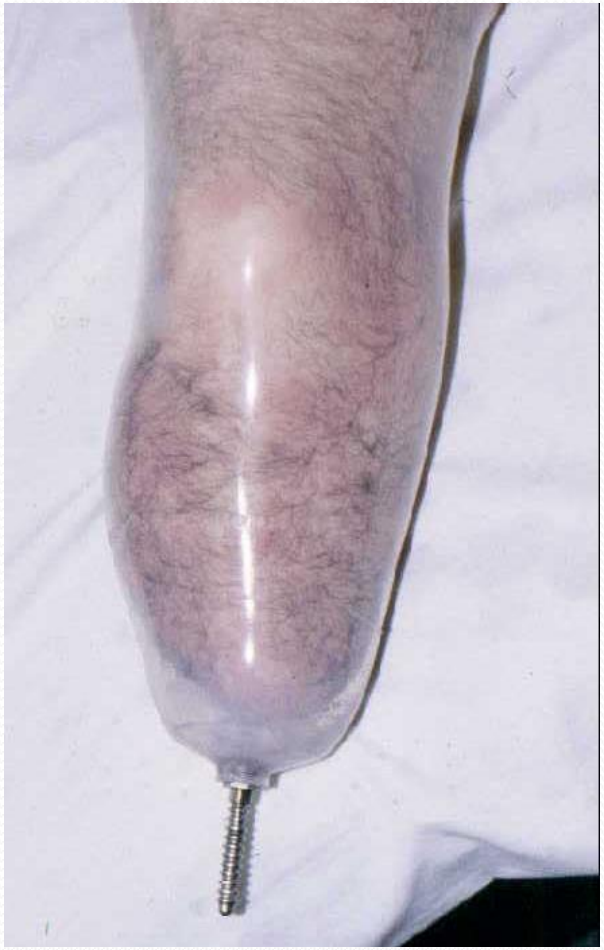


3S or Shuttle lock Socket design



Seal-in liner

Custom Gel Liner with Pin

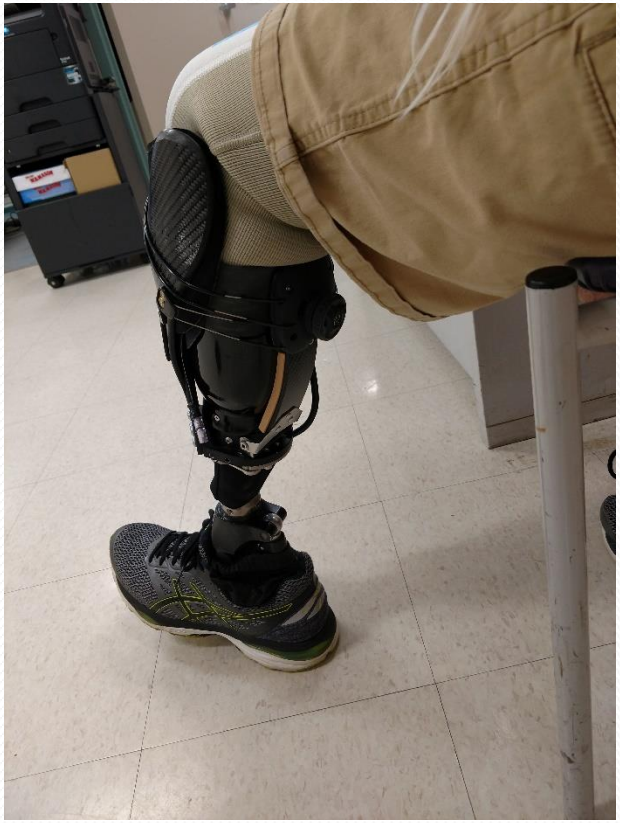


Gel Liners

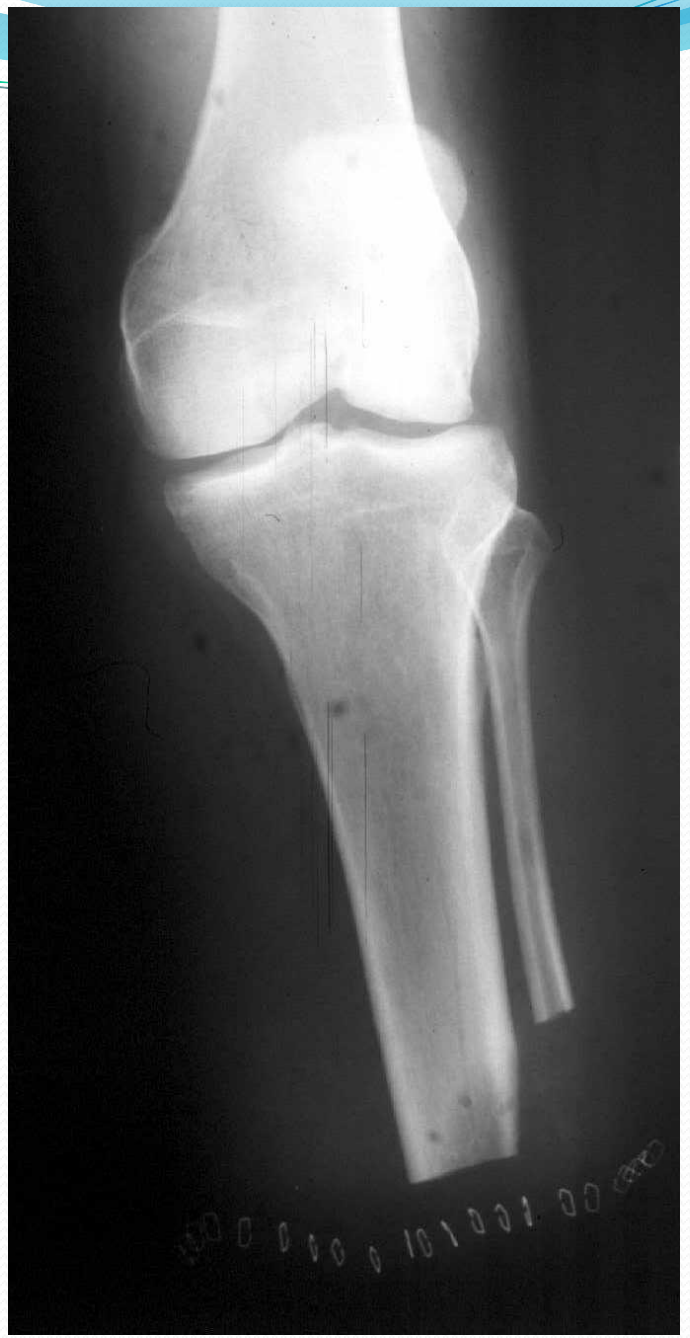
Name	Thickness	Material	Features
Alpha	3, 6, 9 mm	TP Elastomer	Shapes to limb
Ossur Iceross	2.5 prox 7 distal	Silicone	Soft distal pad
TEC	7-9 mm	Urethane	Creep & Flow
Silipos	3, 6, 9 mm	Polymer Gel	Distal matrix
Alps	2, 6 mm	Silicone	Transparent
ESP Aegis	2, 4 mm Preflex 45°	Silicone Mineral Oil	Less bunching behind knee

active vacuum can be mechanical or electronic

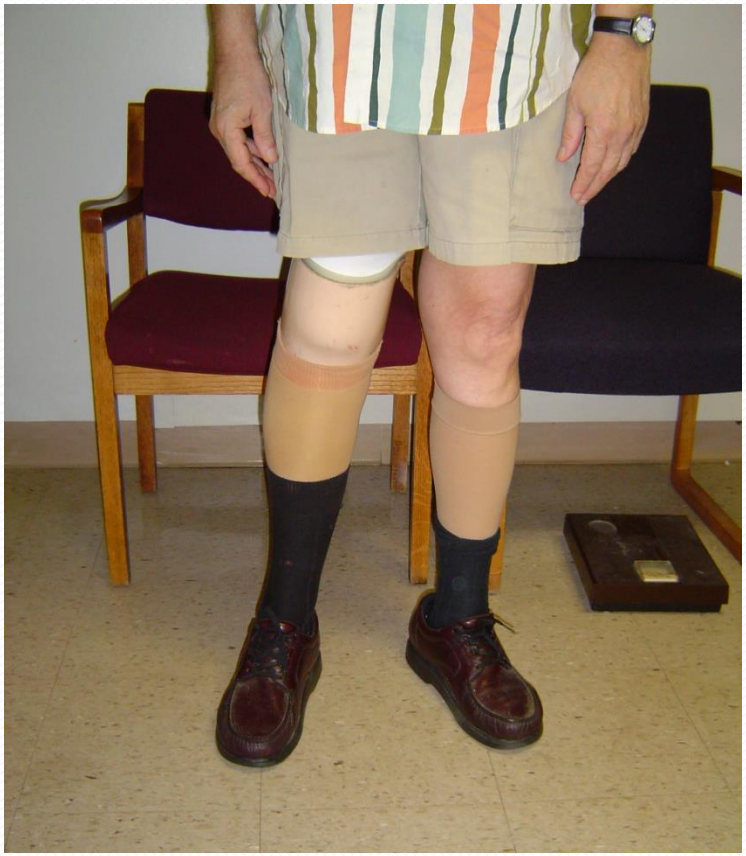
Adjustable sockets

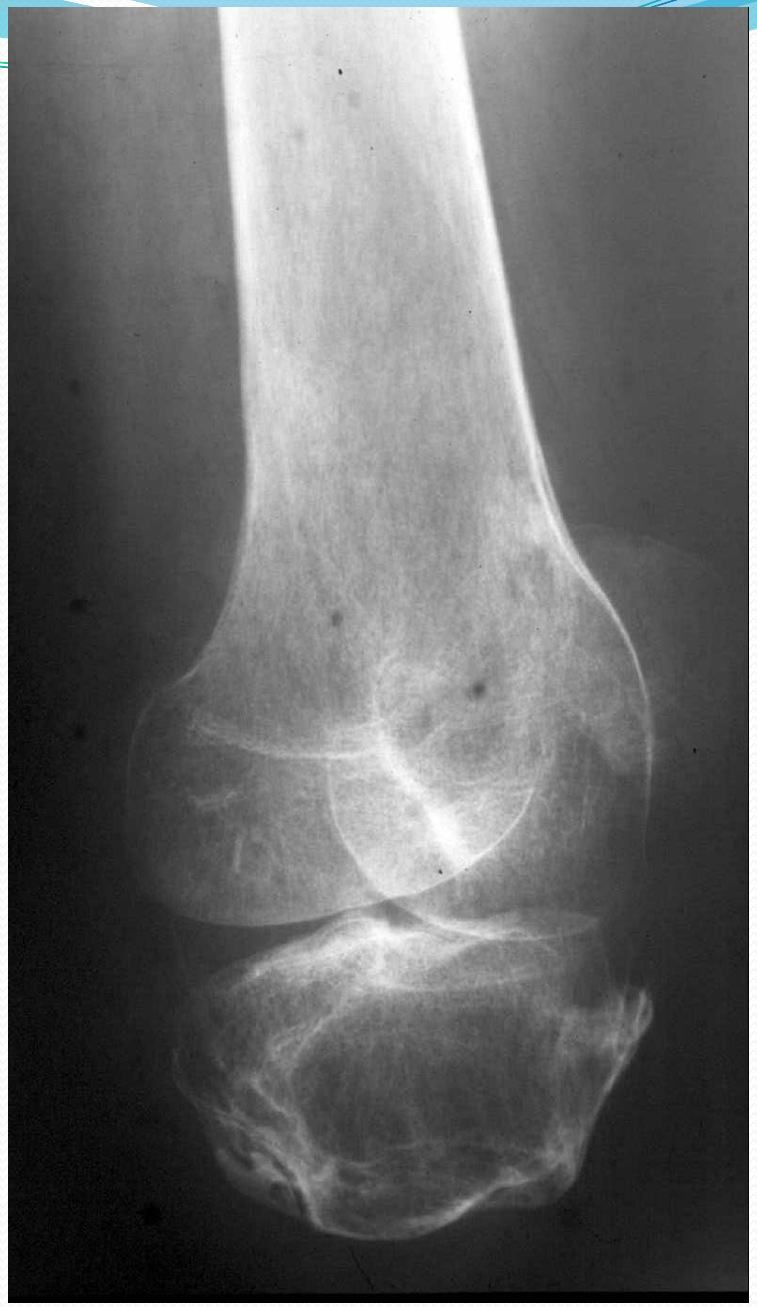


X-ray of Recent TTA

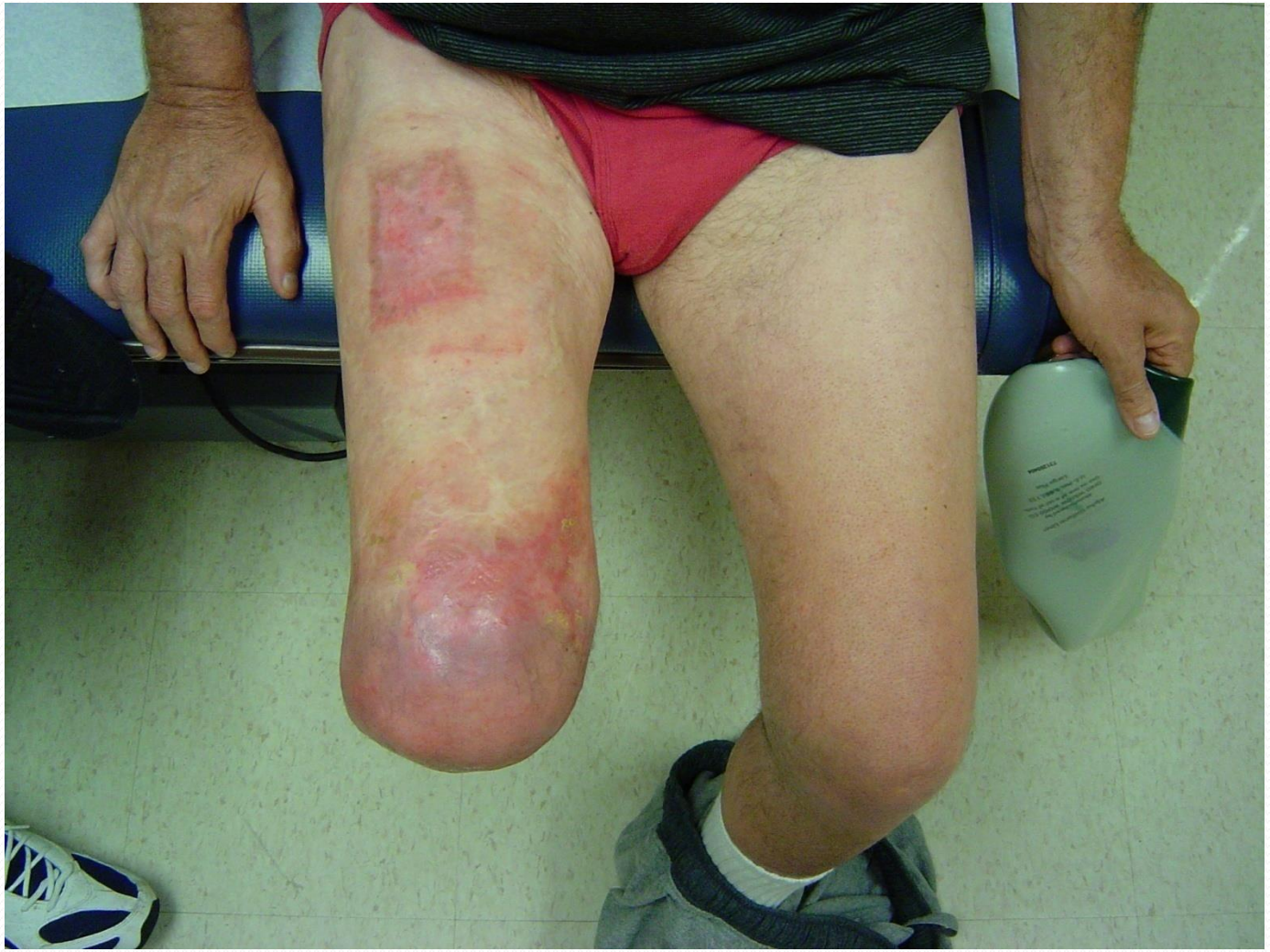


Short TTA

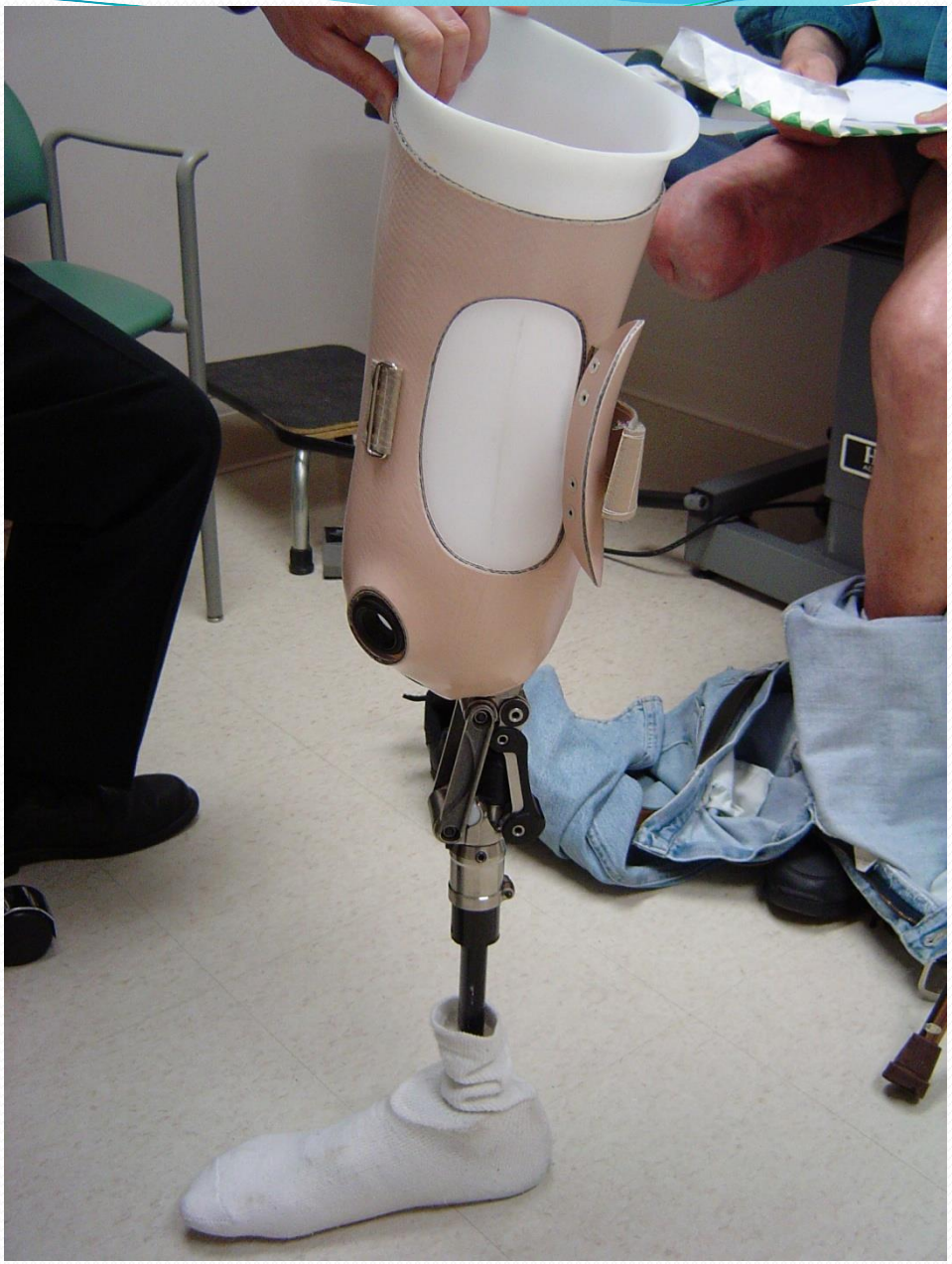




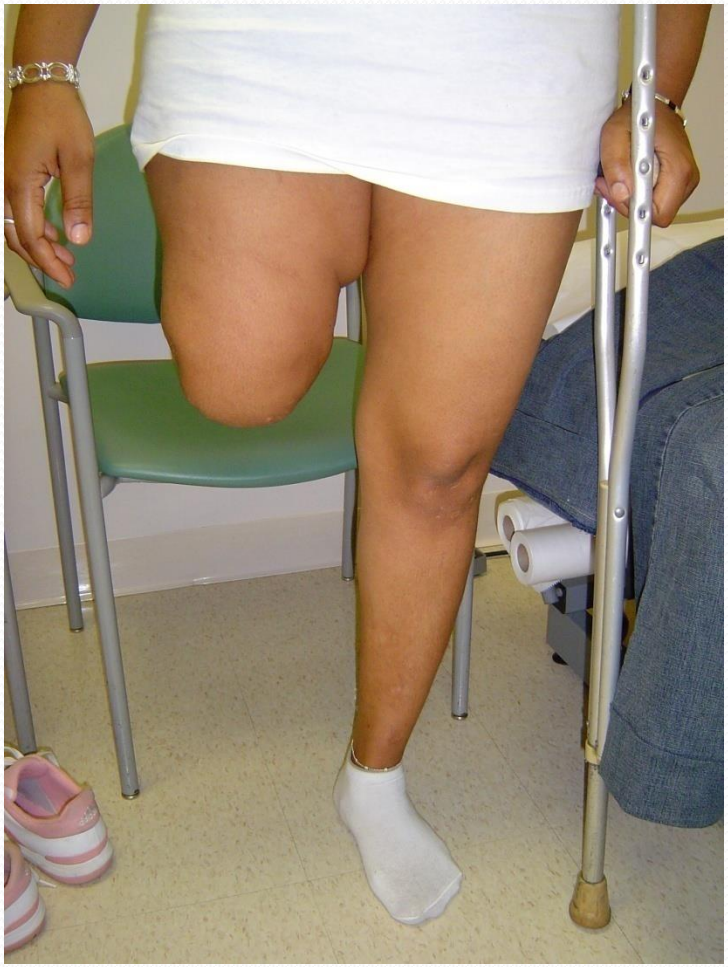
Traumatic knee dis-articulation

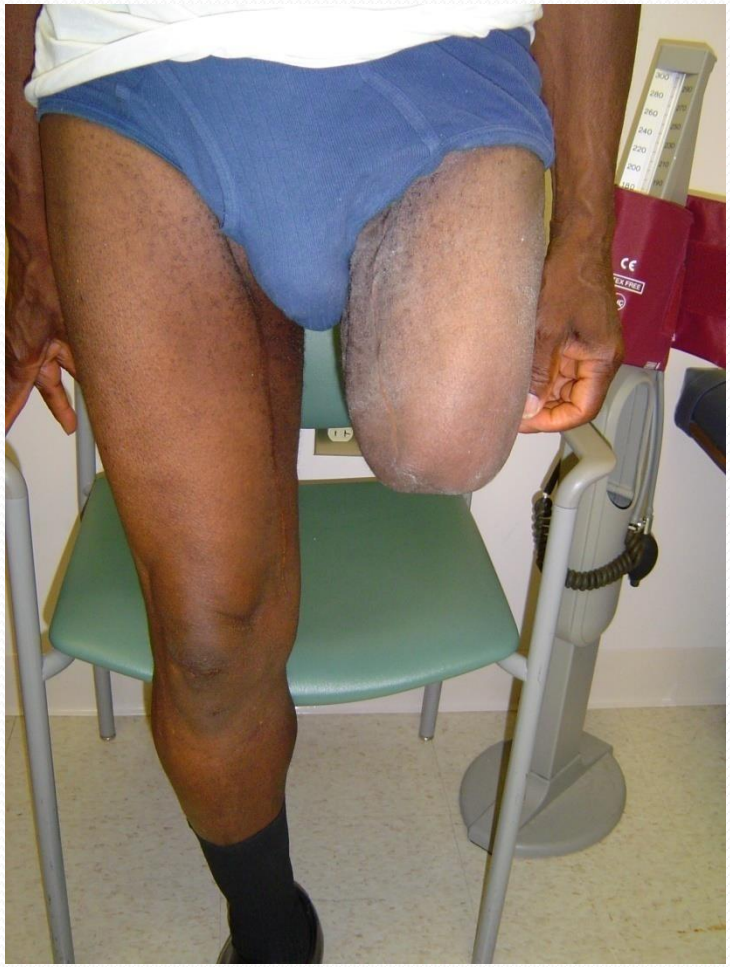


Self-suspending socket design for knee dis-artic

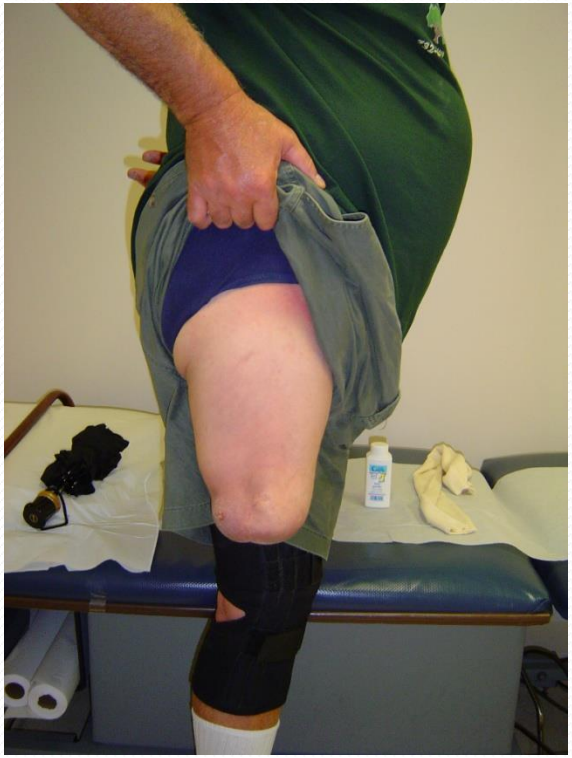


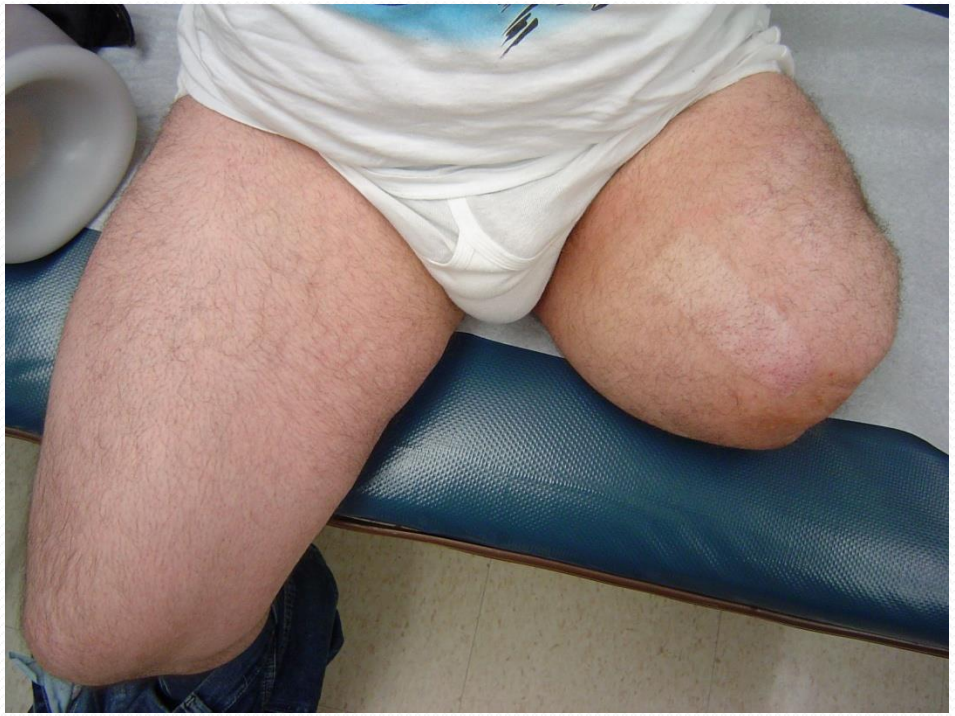
Long trans-femoral amputation





Mid-length trans-femoral amp

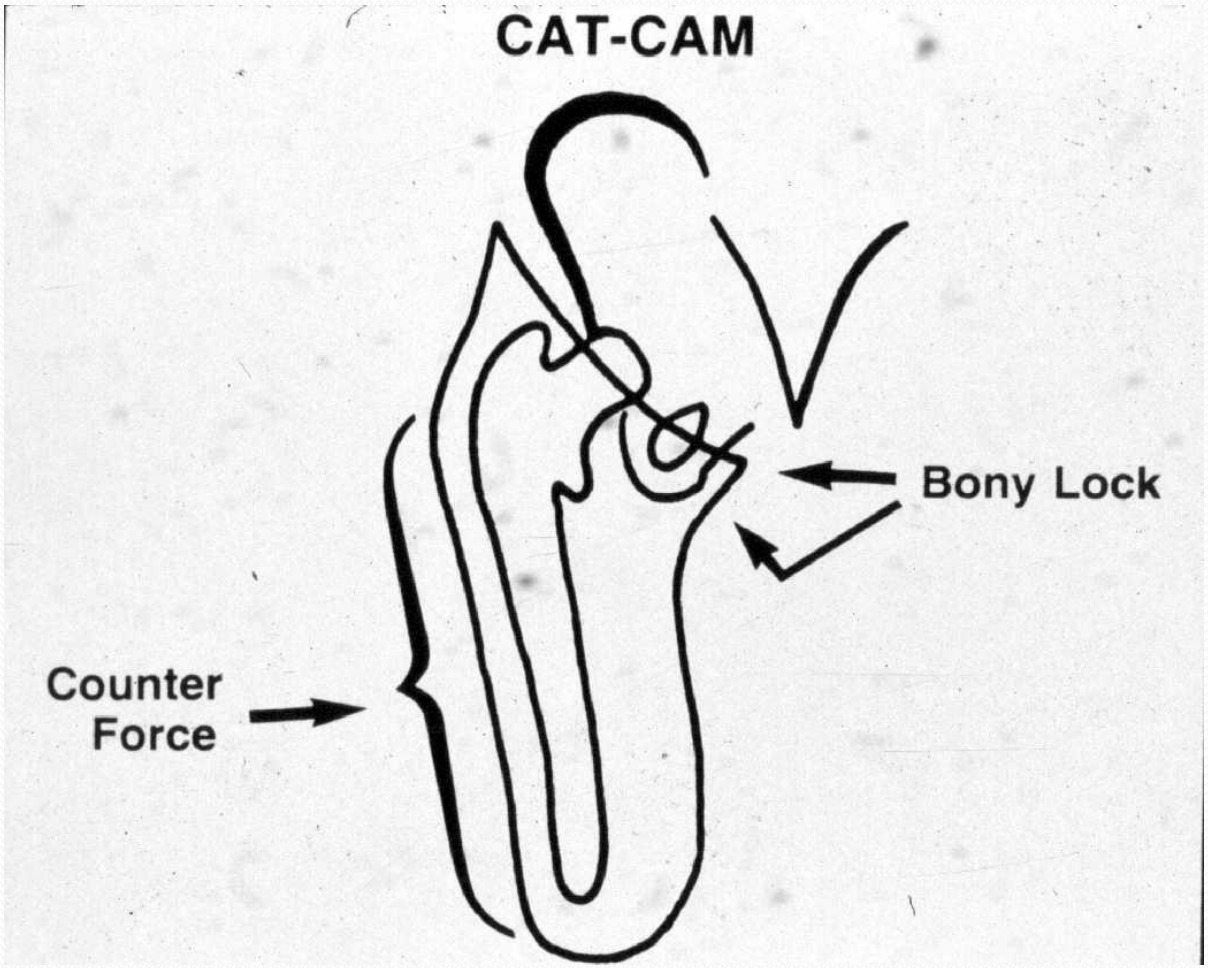




Trans-femoral Prosthesis Design and Options

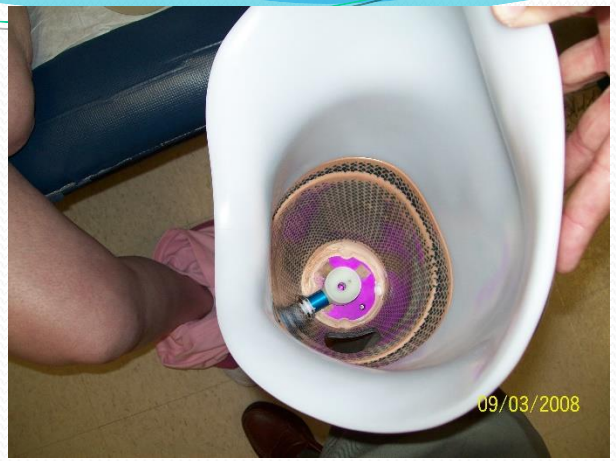
- Weight-bearing : Ischial and gluteal containment, total contact, total surface bearing, Quad socket design
- Interface material : Socks, gel liner, thermoplastic, foam (Pelite/Bocklite),
- Socket materials : Thermoplastic, carbon lamination
- Suspension : Suction, elastic belt, gel liner with pin or strap, vacuum (passive or active), hip joint and belt
- Pylon/connector materials : aluminum, titanium, carbon fiber, steel
- Rotators, quick disconnect (Ferrier coupling)
- Knee and Foot

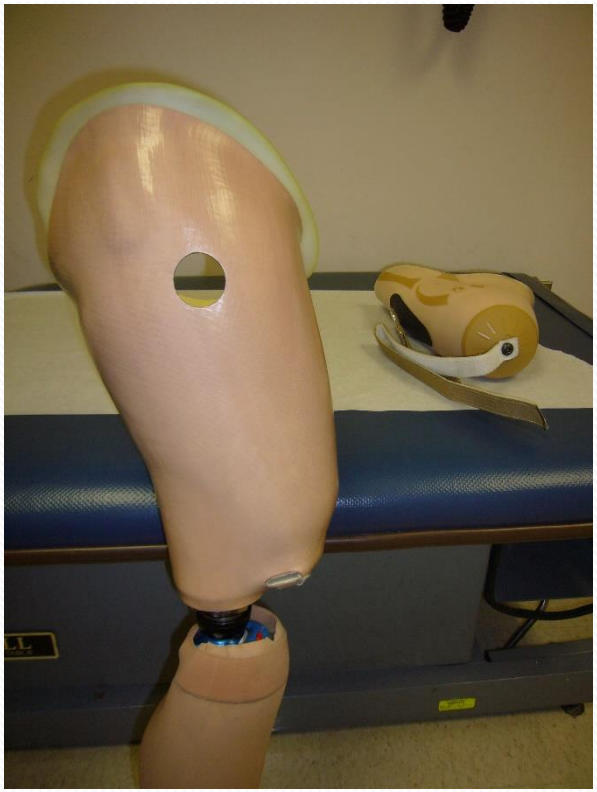
Trans-femoral Sockets
Ischial Containment Feature



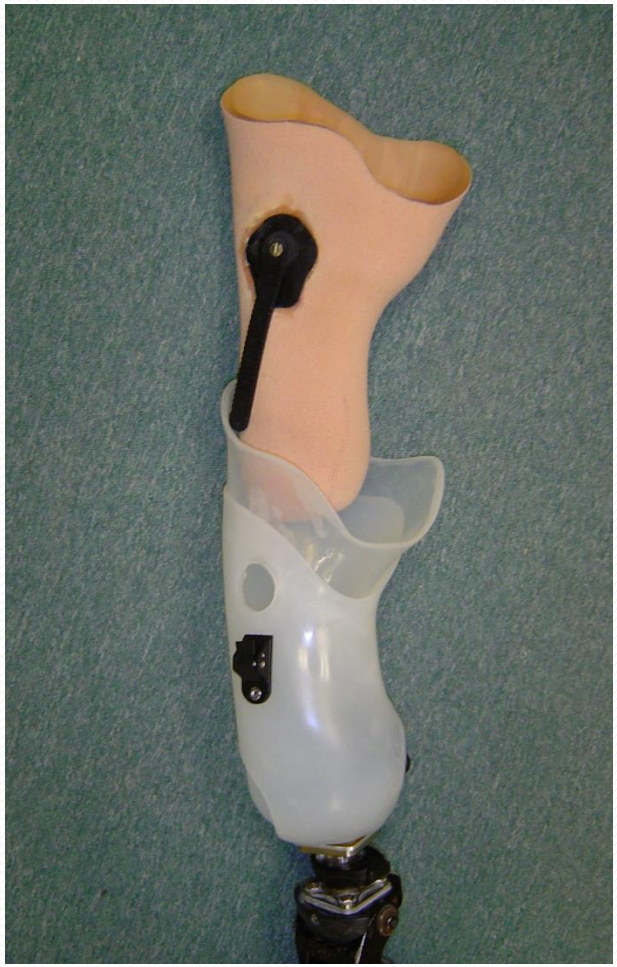
Suction socket design features

Suspension options

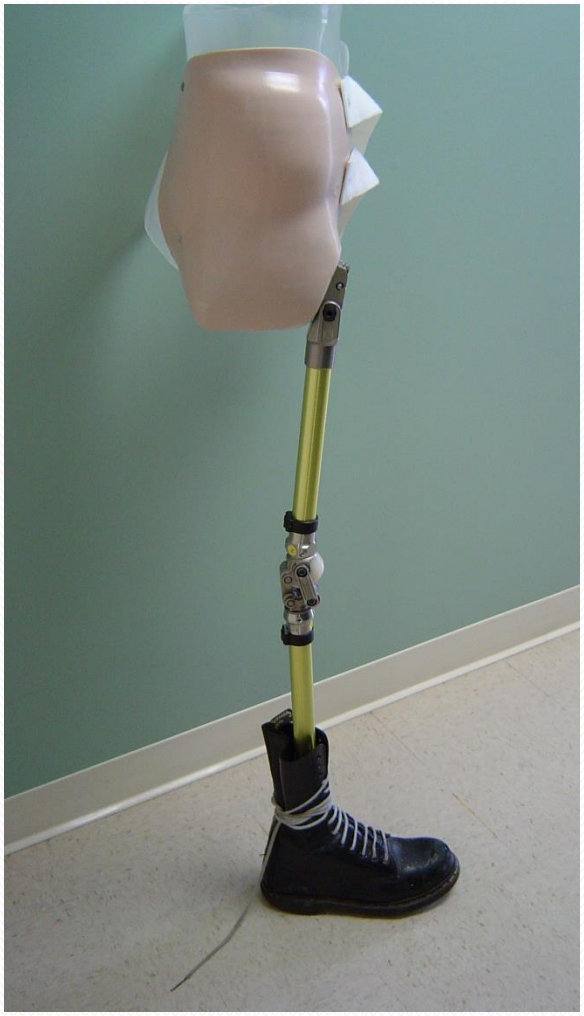




Gel liner with ratchet lock or pin



Hip Dis-artic Prosthesis



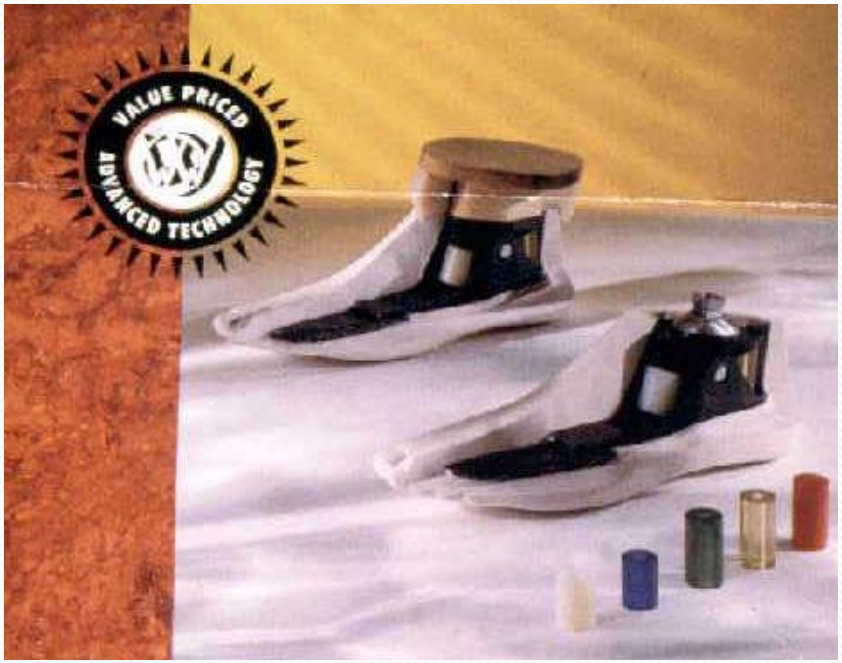
Foot Selection

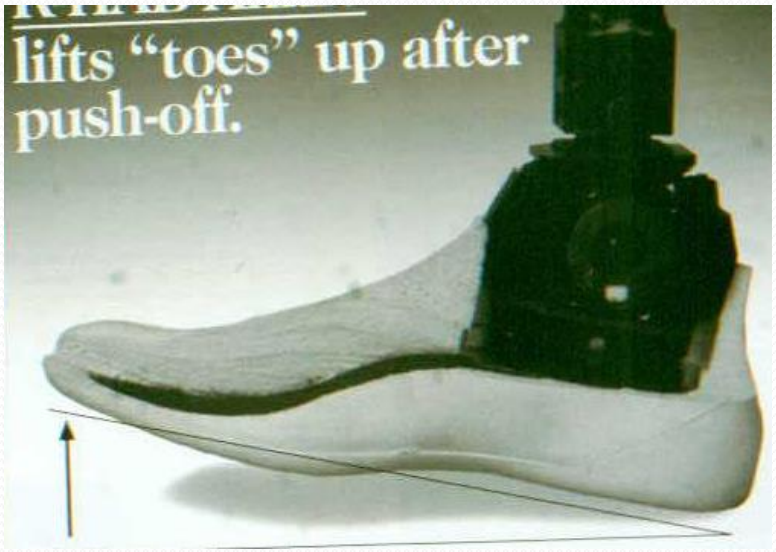
- Movable foot or not
- Single-axis or multi-axis movement
- Dynamic response or not (energy-storing)
- Hybrid/combo feet
- Supplemental ankle joints
- Shock and torque absorbers
- Heel height adjustable
- Cosmetic cover or shell profile

So many choices

No Movement and No Energy SAFE and SACH

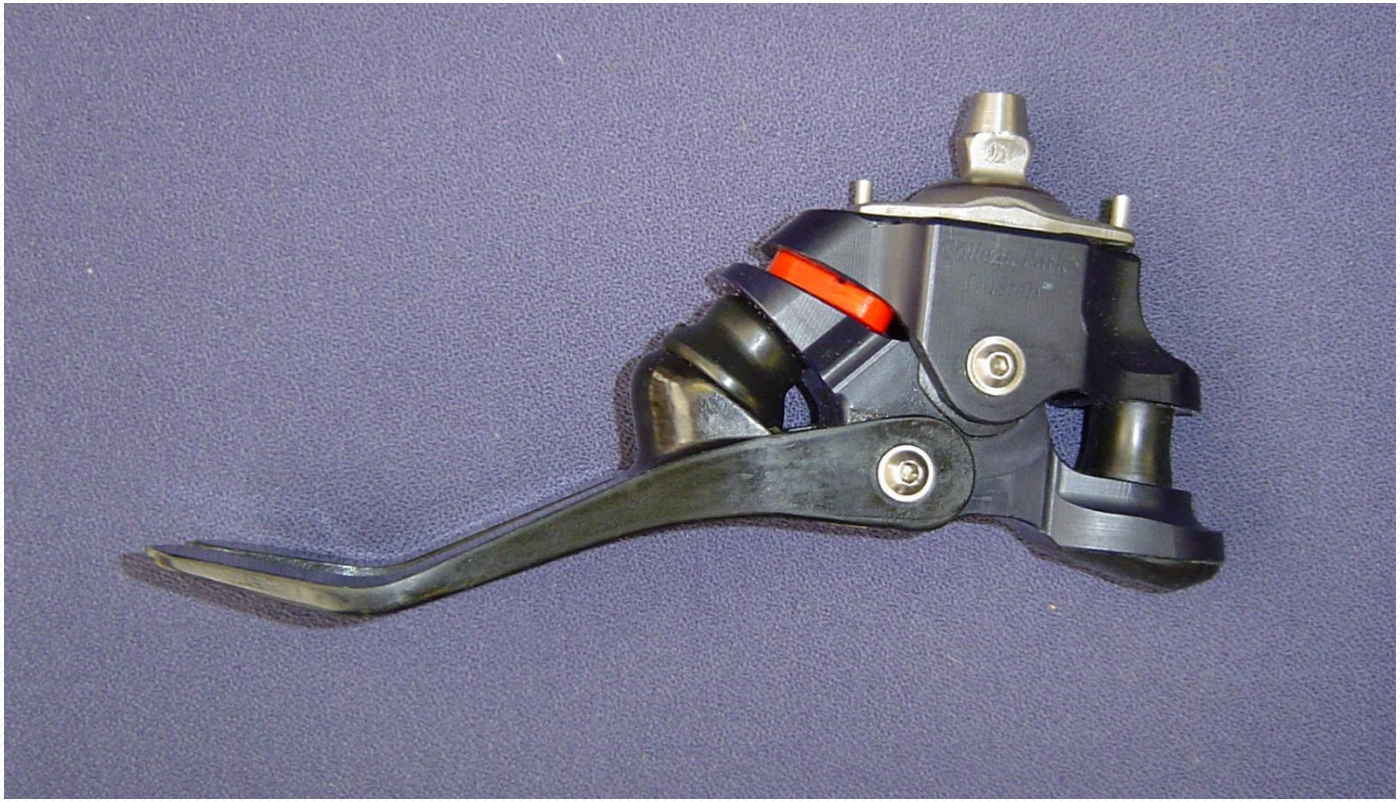
Single Axis Feet
Allow PF at heel strike
Block tibial progression at PS



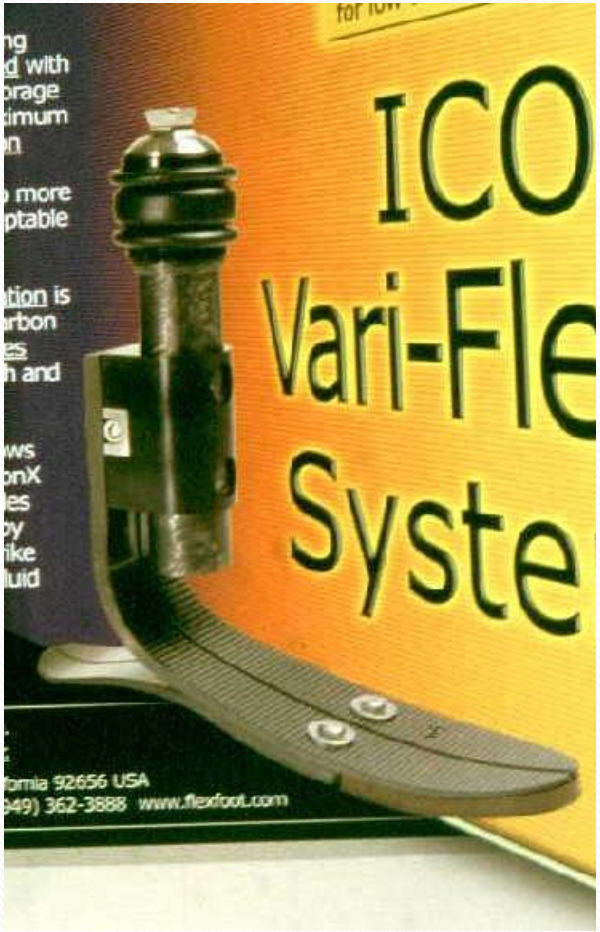


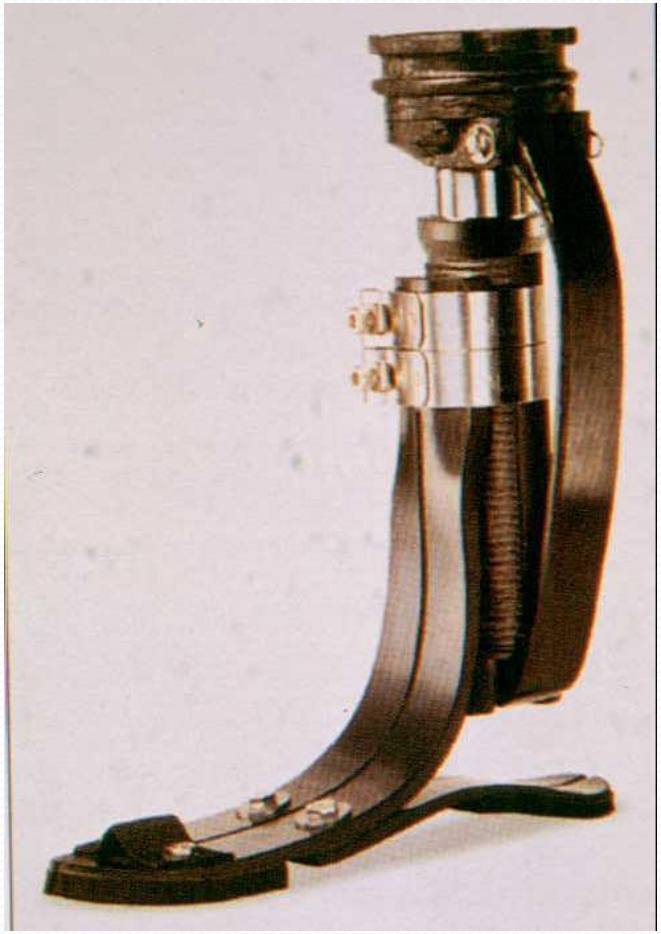
Carbon fiber configurations or fiberglass

Dynamic Response with True Multi-axis Motion

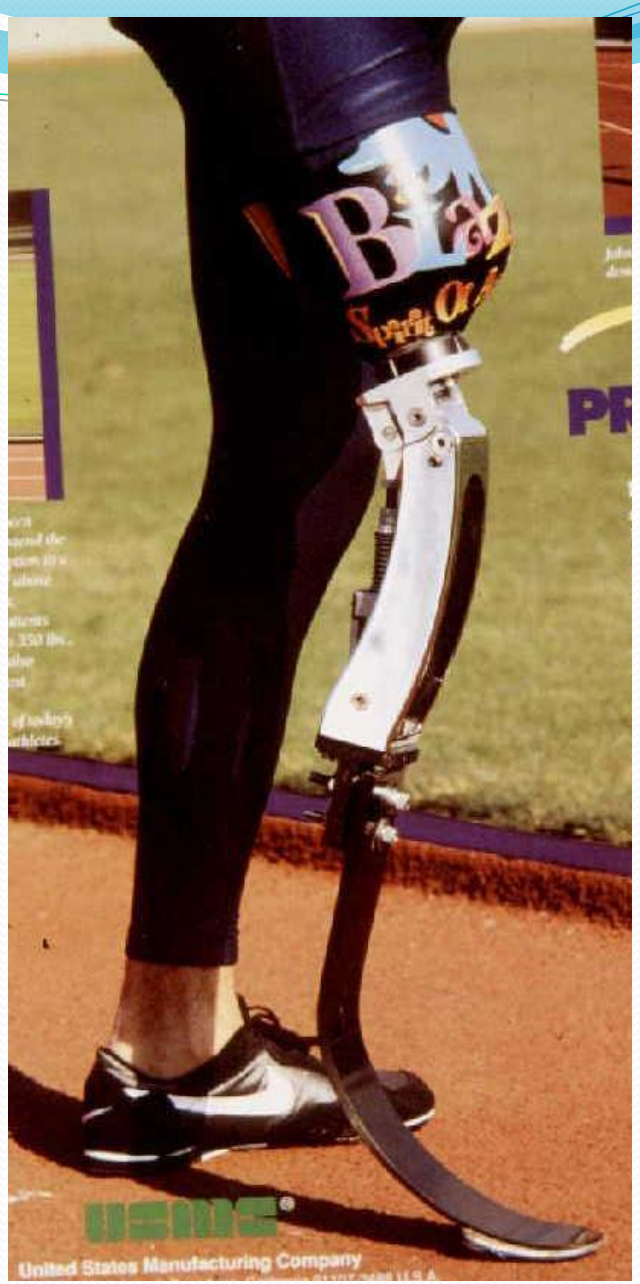


Dynamic Response Feet with Shock Absorbers





Sprinters Foot (no heel)

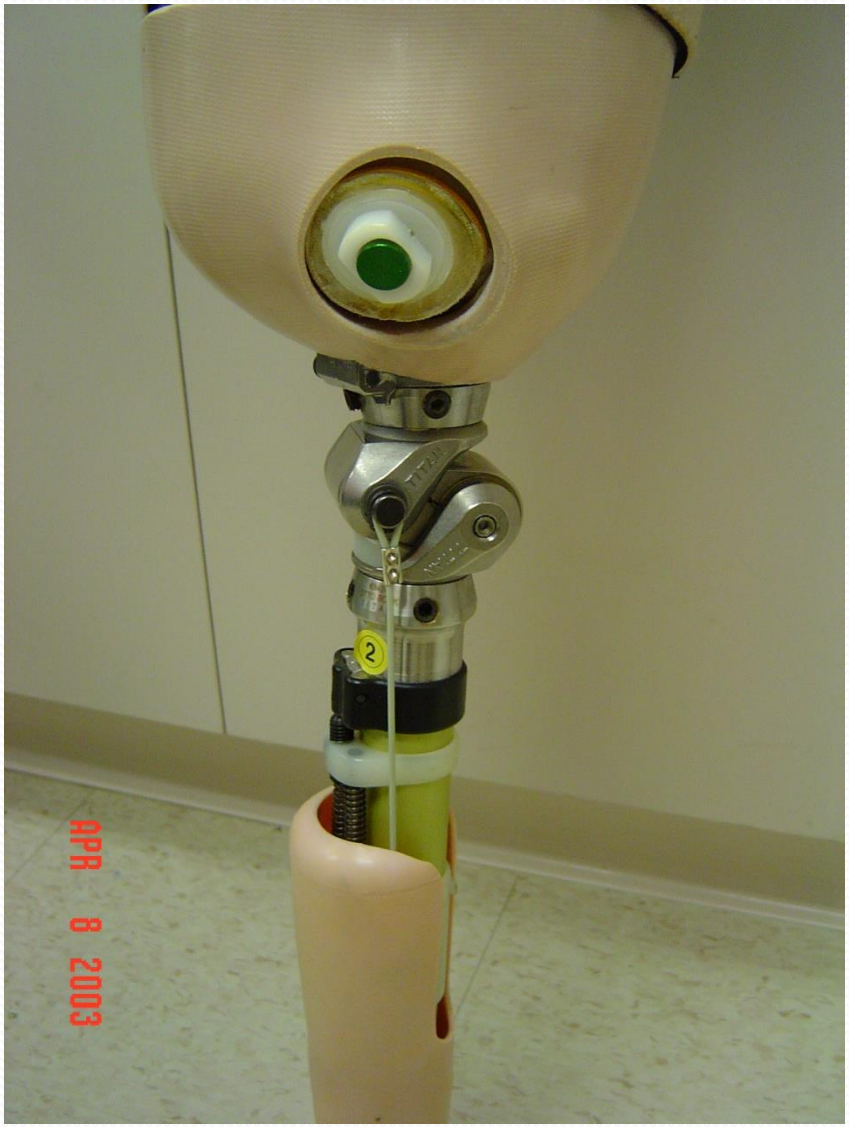


Prosthetic Knees

- Manual lock (simple and safe)
- Stance control (weight activated locking)
- Poly-centric (migrating axis of rotation)
- Pneumatic (variable cadence swing control)
- Hydraulic (swing and stance control)
- Hybrids (polycentric plus hydraulic)
- Micro-processor control hydraulic ($$$)

Again, so many choices

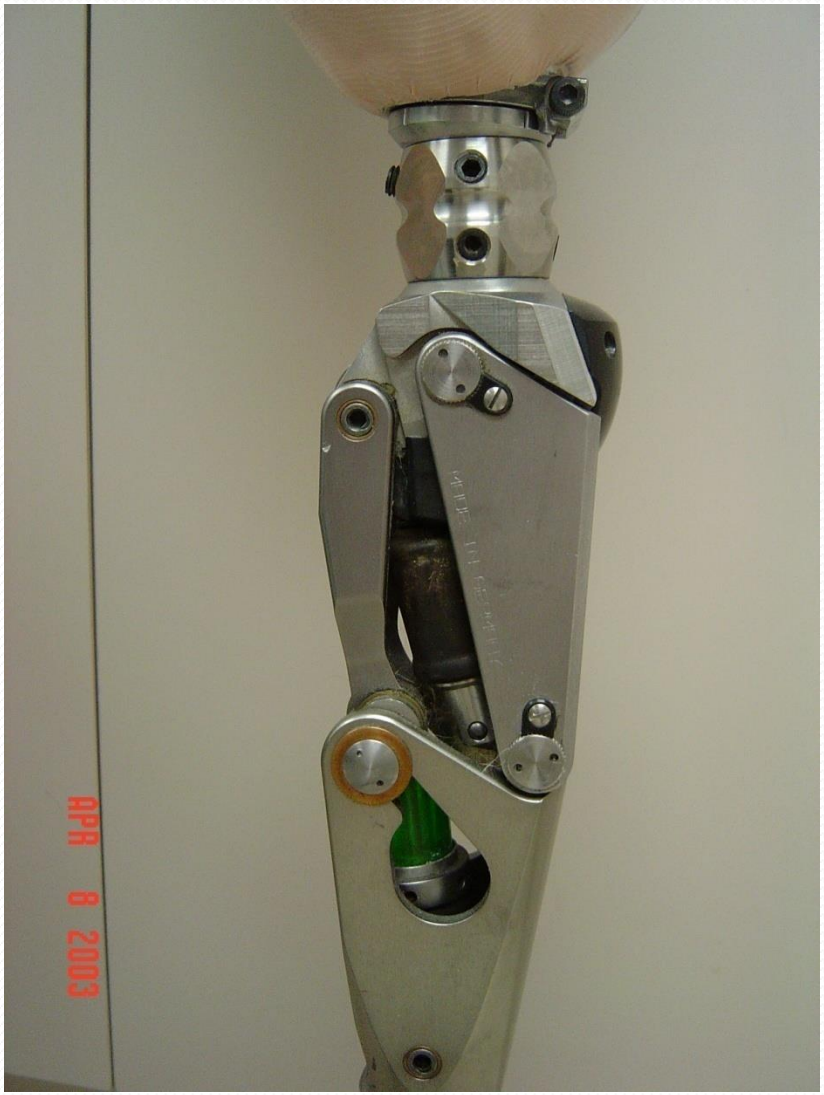
Stance control knee unit with fixed cadence



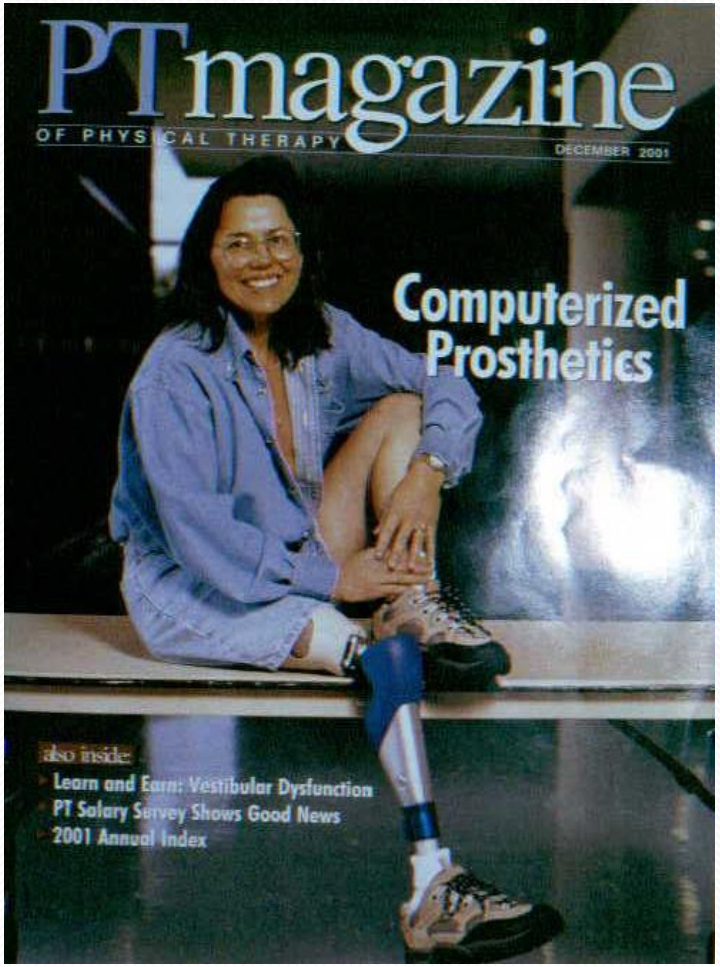
4-bar polycentric for knee dis-artic

Full-size hydraulic knee with swing and stance phase control for variable cadence

6-bar polycentric with hydraulics

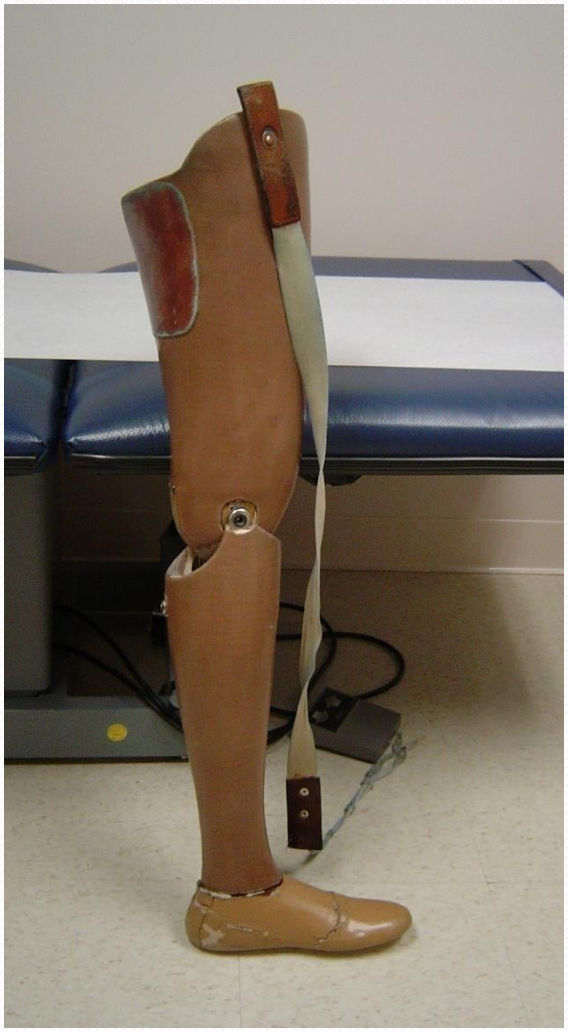


C-Leg with micro-processor control hydraulics

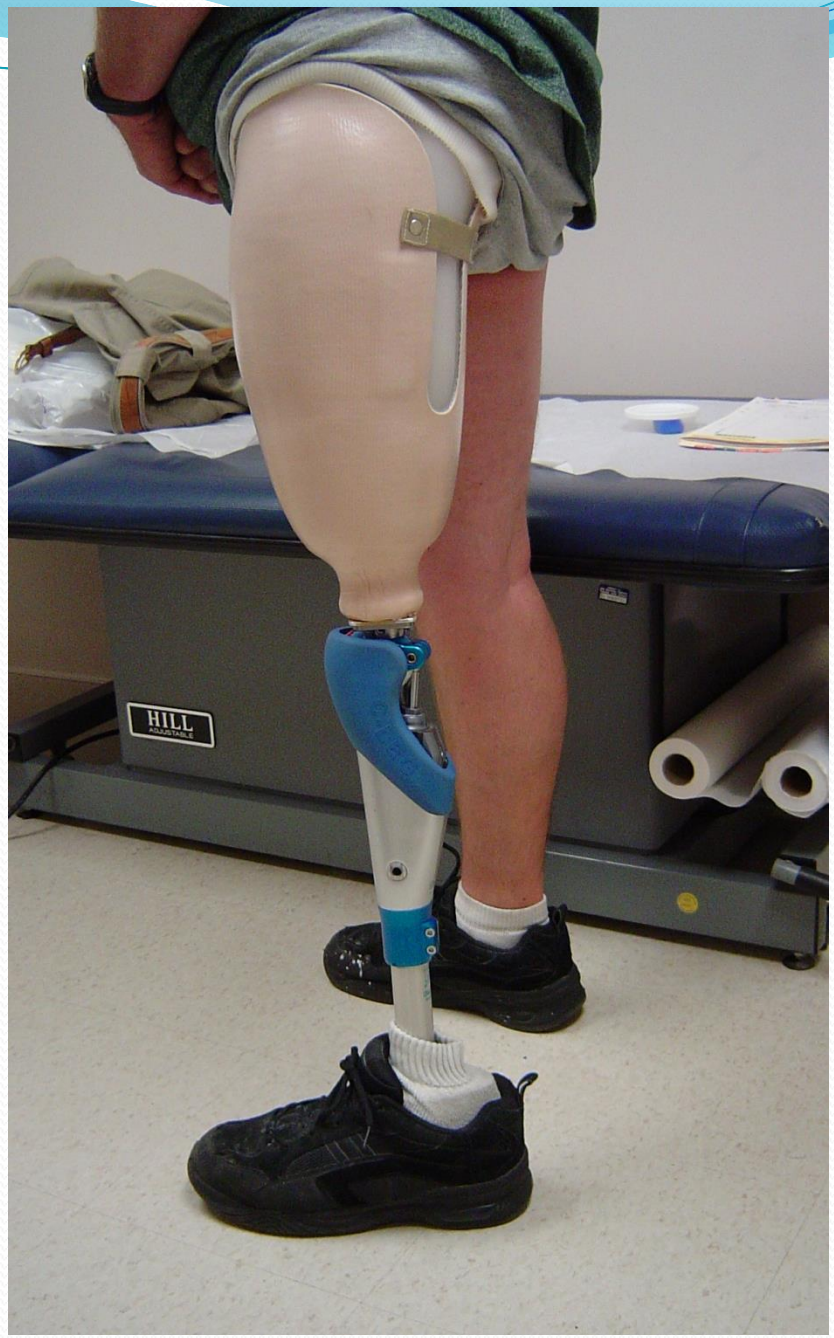


Semi-suction socket with stance control knee and single axis foot

Endo or exo-skeletal design



Suction socket with micro-processor controlled hydraulic knee unit



Decision-Making Process for Prosthetic Components

- Patient medical status
- Previous level of function
- Level of amputation
- Anticipated Medicare Functional Level

Medicare Functional Levels

- Level 0 - Patient is non-ambulatory
- Level 1 - Transfers or limited household
- Level 2 - Limited community ambulator
- Level 3 - Unlimited community ambulator
- Level 4 - High energy activities

Prosthetic Feet

- Level 1: SACH, single-axis feet
- Level 2: Multi-axis feet
- Level 3&4: Energy-storing feet

Prosthetic Knees

- Level 1: Manual lock, stance control
- Level 2: Manual lock, stance control
- Level 3&4: Polycentric, Hydraulic, micro-processor

Ideal Candidate for Micro-Processor Control Knee

- Active adult who ambulates indoors and outdoors on uneven terrain regularly without an assistive device
- High risk adult who cannot tolerate a fall or the consequence of a fall
- Young, healthy adult with bilateral AKA

Conclusions

- Ultimately, the patient's use of the prosthesis and functional outcome depend most on good socket fit and proper training
- Proper selection of prosthetic components is based on the patient's functional needs and limitations

Therapy Prescription (PT/OT)

- Level of amputation , medical diagnoses
- Precautions (cardiac, falls)
- Frequency and duration of treatment
- Treatment:
  1. Prosthetic training, progressive ambulation
  2. Strengthening, conditioning
  3. Stretching, AAROM, back program
  4. ADL review and training
  5. Home exercise and instruction on home use
  6. Driver assessment and training if appropriate

Driver Testing and Training

- In New Jersey cannot use prosthesis to control any pedal in passenger car
- Right foot amputation requires left foot accelerator pedal installed in car
- Testing and training by certified provider is recommended but not required
- Left foot pedal requires prescription from physician, but usually not covered by insurance
- Patient must submit to voluntary road test at DMV and license re-issued with restriction code

Follow-up

- See patient after prosthesis delivered for fit and function of device
- See patient every 4 weeks during therapy training
- See patient 2-3 months after therapy completed and then every 6 months after permanent prosthesis fitted
- Sometimes additional therapy is needed for higher level activities with permanent prosthesis
- Lifetime follow-up for long-term problems and residual limb changes

Thank You

Amputee Mobility Predictor

AMPUTEE MOBILITY PREDICTOR ASSESSMENT TOOL

Initial instructions: Client is seated in a hard chair with arms. The following maneuvers are tested with or without the use of the prosthesis. Advise the person of each task or group of tasks prior to performance. Please avoid unnecessary chatter throughout the test. Safety First, no task should be performed if either the tester or client is uncertain of a safe outcome.

The **Right Limb** is: ❒ PF ❒ TT ❒ KD ❒ TF ❒ HD ❒ intact
The **Left Limb** is: ❒ PF ❒ TT ❒ KD ❒ TF ❒ HD ❒ intact

1. Sitting Balance: Sit forward in a chair with arms folded across chest for 60s.	Cannot sit upright independently for 60s Can sit upright independently for 60s	= 0 = 1	1
2. Sitting reach: Reach forwards and grasp the ruler. (Tester holds ruler 12in beyond extended arms midline to the sternum)	Does not attempt Cannot grasp or requires arm support Reaches forward and successfully grasps item.	= 0 = 1 = 2	2
3. Chair to chair transfer: 2 chairs at 90°. Pt. may choose direction and use their upper limbs.	Cannot do or requires physical assistance Performs independently, but appears unsteady Performs independently, appears to be steady and safe	= 0 = 1 = 2	2
4. Arises from a chair: Ask pt. to fold arms across chest and stand. If unable, use arms or assistive device.	Unable without help (physical assistance) Able, uses arms/assist device to help Able, without using arms	= 0 = 1 = 2	1
5. Attempts to arise from a chair: (stopwatch ready) If attempt in no. 4. was without arms then ignore and allow another attempt without penalty.	Unable without help (physical assistance) Able requires >1 attempt Able to rise one attempt	= 0 = 1 = 2	2
6. Immediate Standing Balance: (**first 5s**) Begin timing immediately.	Unsteady (staggers, moves foot, sways) Steady using walking aid or other support Steady without walker or other support	= 0 = 1 = 2	2
7. Standing Balance (30s): (stopwatch ready) For item no.'s 7 & 8, first attempt is without assistive device. If support is required allow after first attempt	Unsteady Steady but uses walking aid or other support Standing without support	= 0 = 1 = 2	2
8. Single limb standing balance: (stopwatch ready) Time the duration of single limb standing on both the sound and prosthetic limb up to 30s. Grade the quality, not the time. **Eliminate item 8 for AMPnoPRO** Sound side 6.57 seconds Prosthetic side _____ seconds	**Non-prosthetic side** Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s **Prosthetic Side** Unsteady Steady but uses walking aid or other support for 30s Single-limb standing without support for 30s	= 0 = 1 = 2 = 0 = 1 = 2	1 1
9. Standing reach: Reach forward and grasp the ruler. (Tester holds ruler 12in beyond extended arm(s) midline to the sternum)	Does not attempt Cannot grasp or requires arm support on assistive device Reaches forward and successfully grasps item no support	= 0 = 1 = 2	1
10. Nudge test: With feet as close together as possible, examiner pushes lightly on pt.'s sternum with palm of hand 3 times (toes should rise)	Begins to fall Staggers, grabs, catches self ore uses assistive device Steady	= 0 = 1 = 2	2
11. Eyes Closed: (at maximum position #7) If support is required grade as unsteady.	Unsteady or grips assistive device Steady without any use of assistive device	= 0 = 1	1

12. Pick up objects off the floor: Pick up a pencil off the floor placed midline 12in in front of foot.	Unable to pick up object and return to standing Performs with some help (table, chair, walking aid etc) Performs independently (without help)	= 0 = 1 = 2	2
13. Sitting down: Ask pt. to fold arms across chest and sit. If unable, use arm or assistive device.	Unsafe (misjudged distance, falls into chair) Uses arms, assistive device or not a smooth motion Safe, smooth motion	= 0 = 1 = 2	2
14. Initiation of gait: (immediately after told to "go")	Any hesitancy or multiple attempts to start No hesitancy	= 0 = 1	1
15. Step length and height: Walk a measured distance of 12ft twice (up and back). Four scores are required or two scores (a. & b.) for each leg. "Marked deviation" is defined as extreme substitute movements to avoid clearing the floor.	**a. Swing Foot** Does not advance a minimum of 12in Advances a minimum of 12in **b. Foot Clearance** Foot does not completely clear floor without deviation Foot completely clears floor without marked deviation	= 0 = 1 = 0 = 1	Prosthesis: 1 Sound: 1 Prosthesis: 1 Sound: 1
16. Step Continuity	Stopping or discontinuity between steps (stop & go gait) Steps appear continuous	= 0 = 1	1
17. Turning: 180 degree turn when returning to chair.	Unable to turn, requires intervention to prevent falling Greater than three steps but completes task without intervention No more than three continuous steps with or without assistive aid	= 0 = 1 = 2	2
18. Variable cadence: Walk a distance of 12ft fast as possible safely 4 times. (Speeds may vary from slow to fast and fast to slow varying cadence)	Unable to vary cadence in a controlled manner Asymmetrical increase in cadence controlled manner Symmetrical increase in speed in a controlled manner	= 0 = 1 = 2	2
19. Stepping over an obstacle: Place a movable box of 4in in height in the walking path.	Cannot step over the box Catches foot, interrupts stride Steps over without interrupting stride	= 0 = 1 = 2	1
20. Stairs (must have at least 2 steps): Try to go up and down these stairs without holding on to the railing. Don't hesitate to permit pt. to hold on to rail. Safety First, if examiner feels that any risk in involved omit and score as 0.	**Ascending** Unsteady, cannot do One step at a time, or must hold on to railing or device Step over step, does not hold onto the railing or device **Descending** Unsteady, cannot do One step at a time, or must hold on to railing or device Step over step, does not hold onto the railing or device	= 0 = 1 = 2 = 0 = 1 = 2	1 1
21. Assistive device selection: Add points for the use of an assistive device if used for two or more items. If testing without prosthesis use of appropriate assistive device is mandatory.	Bed bound Wheelchair / Parallel Bars Walker Crutches (axillary or forearm) Cane (straight or quad) None	= 0 = 1 = 2 = 3 = 4 = 5	4
	Total Score AMPnoPRO _____ /43 AMPPRO 39 /47		

Abbreviation: PF = partial foot; TT = transtibial; KD = knee disarticulation; TF = transfemoral; HD = hip disarticulation

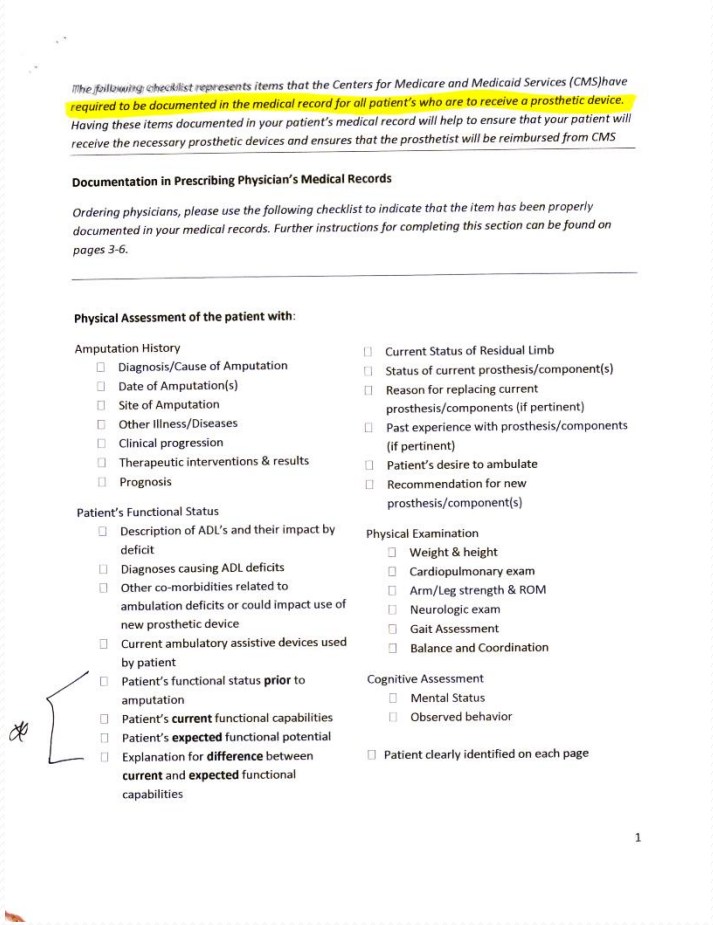
Test: ❒ no prosthesis ❒ with prosthesis **Observer:** [redacted] **Date:** 5-14-14

K LEVEL (converted from AMP score)

AMPnoPRO ❒ K0 (0-8) ❒ K1 (9-20) ❒ K2 (21-28) ❒ K3 (29-36) ❒ K4 (37-43)

AMPPRO ❒ K1 (15-26) ❒ K2 (27-36) ☒ K3 (37-42) ❒ K4 (43-47)

CMS Medicare Guidelines 1



The following checklist represents items that the Centers for Medicare and Medicaid Services (CMS)have required to be documented in the medical record for all patient's who are to receive a prosthetic device. Having these items documented in your patient's medical record will help to ensure that your patient will receive the necessary prosthetic devices and ensures that the prosthetist will be reimbursed from CMS

Documentation in Prescribing Physician's Medical Records

Ordering physicians, please use the following checklist to indicate that the item has been properly documented in your medical records. Further instructions for completing this section can be found on pages 3-6.

Physical Assessment of the patient with:

Amputation History
- ☐ Diagnosis/Cause of Amputation
- ☐ Date of Amputation(s)
- ☐ Site of Amputation
- ☐ Other Illness/Diseases
- ☐ Clinical progression
- ☐ Therapeutic interventions & results
- ☐ Prognosis

Patient's Functional Status
- ☐ Description of ADL's and their impact by deficit
- ☐ Diagnoses causing ADL deficits
- ☐ Other co-morbidities related to ambulation deficits or could impact use of new prosthetic device
- ☐ Current ambulatory assistive devices used by patient
- ☐ Patient's functional status **prior** to amputation
- ☐ Patient's **current** functional capabilities
- ☐ Patient's **expected** functional potential
- ☐ Explanation for **difference** between **current** and **expected** functional capabilities

- ☐ Current Status of Residual Limb
- ☐ Status of current prosthesis/component(s)
- ☐ Reason for replacing current prosthesis/components (if pertinent)
- ☐ Past experience with prosthesis/components (if pertinent)
- ☐ Patient's desire to ambulate
- ☐ Recommendation for new prosthesis/component(s)

Physical Examination
- ☐ Weight & height
- ☐ Cardiopulmonary exam
- ☐ Arm/Leg strength & ROM
- ☐ Neurologic exam
- ☐ Gait Assessment
- ☐ Balance and Coordination

Cognitive Assessment
- ☐ Mental Status
- ☐ Observed behavior

☐ Patient clearly identified on each page

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CMS Medicare Guidelines 2

Signature and Date Requirements

- ☐ Physician signature, printed name and date on each chart note
- ☐ Notes are dated prior to delivery
- ☐ Each chart note includes printed name of physician or signature attestation attached

Detailed Written Order from Doctor with:

- ☐ Start date for order
- ☐ ICD-9 diagnosis code
- ☐ K-level
- ☐ Description of each item provided (Manufacturer, Brand, or Model # may be acceptable)
- ☐ Patient's name on every page

Physicians Signature and Date Requirements:

- ☐ Signed and dated prior to billing
- ☐ Hand written
- ☐ Includes physician's name, credentials, address, and phone #
- ☐ Compliance with state law

Dispensing Prescription Contains:

- ☐ Patient's name
- ☐ Start date for order
- ☐ Description of prescribed item
- ☐ Printed physicians name
- ☐ Physicians signature and date
  If given verbally:
  - ☐ Printed name of person speaking
  - ☐ Signature and date
- ☐ Compliance with state law

Documentation in Prosthetist's Records

Prosthetists please use the following checklist to indicate that the item has bee properly documented in your medical record. A description of each item can be found in pages 6-7.

Functional Assessment

- ☐ Pre-amputation functional capabilities
- ☐ Current functional capabilities
- ☐ Expected functional potential (K-level)
- ☐ Explanation of difference

Current Prosthetic Profile

- ☐ History of prosthesis being replaced
- ☐ Description of labor involved
- ☐ Reason for replacement
- ☐ Patient's desire to ambulate
- ☐ Recommendation for new prosthesis (Manufacturer, brand, model#)
- ☐ Chart note for each visit
- ☐ Patient name on each page
- ☐ Prosthetist printed name, signature & date
- ☐ ABN (if required)
- ☐ Patient Authorization

Proof of Device Delivery

- ☐ Patient's name
- ☐ Quantity
- ☐ Amputation side for each device
- ☐ Brand name, manufacturer, model #
- ☐ Detailed description of each device
- ☐ Serial number (if available)
- ☐ Patient signature and printed name
- ☐ Hand written signature note

CMS Medicare Guidelines 3

Instructions for ordering physicians

Medicare requires that ordering physicians chart notes in the patient's medical records reflect the need for care. The patient's medical record should contain adequate documentation of the patient's medical condition to substantiate the need for the type and quantity of the prescribed items and the frequency of use and/or replacement. This documentation should include the patient's diagnosis, duration of the patient's condition, clinical course (whether worsening or improving), prognosis, nature and extent of functional limitations, therapeutic interventions and their results, past experience with related items, etc. It is recommended that this information be provided to prosthetists **prior** to dispensing the prosthetic device, in order to facilitate the recovery and reimbursement auditing process. It is important that the amputation side be clearly and consistently identified in the patient's medical record. This is especially important for patients with multiple amputations.

Definition of patient medical record

As defined by the Centers for Medicaid and Medicare Services (CMS):
"The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals[1]."

Amputation History

The patient's medical record should include the following:

- Documentation of patient's medical history associated with the amputation, including:
  - Initial diagnosis leading to the amputation procedure
  - Date amputation procedure was performed
  - Part of the body amputated
  - Patients clinical course should be clearly described
  - Therapeutic interventions and their results should be clearly described
  - Prognosis – expected outcomes given patient history
- Description of patient's functional limitations and capabilities experienced on a typical day:
  - Description of patient's ability to perform activities of daily living (ADL's) and how they are impacted by deficit
  - Diagnosis for deficiency in functional status. These should include ICD-9 codes.
  - Co-morbidities either related to functional deficiencies or could potentially impact use of a new prosthesis. ICD-9 codes for comorbidities should be included.

[1] See CMS Manual System Pub. 100-08, Medicare Program Integrity Manual Chapter 5, §5.7

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CMS Medicare Guidelines 4

- Indicate other devices used for ambulation (eg, cane, walker, wheelchair), either prior to amputation or in addition to their prosthesis.
- Description of patient's functional capabilities **prior** to amputation
- Description of patient's **current** functional capabilities. Functional capabilities should correspond to K-level definitions.
- Description of patient's **expected** functional capabilities
- Explanation for the difference in patient's functional capabilities prior to their amputation and current or expected capabilities

NOTE: If prosthetist evaluates patient's functional capability, this must also be documented in the patient's medical record. This evaluation should be dated and the physician should restate patient's functional capability in a separate chart note and indicate agreement/disagreement with prosthetist's assessment and the rationale for this decision.

- Status of current prosthesis/component(s) and reason for replacement (if relevant) should be clearly indicated
- Patient's past experience with related items (previous prostheses/component(s) use) should be noted
- Patient's desire to ambulate should be assessed and documented.
- Recommendation for new prostheses/component(s) should be clearly indicated.
- Patient's medical record should include a recent physical examination that focuses on body systems responsible for patient's ambulatory capabilities or impact their functional ability. This exam should include, but not limited to the following:
  - Weight and height (noting any weight loss or weight gain)
  - Cardiopulmonary examination
  - Musculoskeletal examination
  - Arm and leg strength and range of motion
  - Neurological examination
  - Gait assessment
  - Balance and coordination

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CMS Medicare Guidelines FUNCTIONAL LEVELS

Note : K-levels are defined by Medicare based on an individual's ability or potential to ambulate and navigate their environment. Medicare uses a person's k-level to determine coverage for prosthetic devices as follows:

K-Level	Description	Foot/Ankle components	Knee components
K0	Patient does not have the ability of potential to ambulate or transfer safely without assistance and a prosthesis does not enhance their quality of life or mobility	Not eligible	Not eligible
K1	Patient has ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence – a typical limited or unlimited household ambulatory	External keel, SACH feet or single axis ankle/feet	Single-axis, constant friction knee
K2	Patient has the ability or potential for ambulation with the ability to traverse low-level environmental barriers, such as curbs, stairs, or uneven surfaces – a typical community ambulatory	Flexible-keel feet and multi-axial ankle/feet	Single-axis, constant friction knee
K3	Patient has the ability or potential for ambulation with variable cadence – a typical community ambulatory with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic use beyond simple locomotion	Flex foot and flex-walk systems, energy storing feet, multi-axial ankle/feet, or dynamic response feet	Fluid and pneumatic control knees
K4	Patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels – typical of the prosthetic demands of a child, active adult, or athlete.	Any ankle foot system	Any knee system

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LMN

Letter of Medical Necessity

April 8, 2014

Re: **Santiago Fernandez**

SS# 152-52-3341A

DOB: 08/09/1960

Mr. Fernandez is a 53-year-old, 210 pound, white male who underwent a transfemoral amputation of his right limb in March of 2004, secondary to gunshot wound. He currently ambulates at a K3 level, using his current prosthesis. He has a C-Leg microprocessor knee which was fit in 2007. He has demonstrated the ability to ambulate at various speeds using his prosthesis; however he has been struggling with a poor fitting socket and C-Leg microprocessor knee which is malfunctioning and does not hold a charge. Additionally, he has had significant difficulties with rheumatoid arthritis which cause pain and stiffness in his joints. This has affected the strength and stability of his left knee. The combination of his amputation and rheumatoid arthritis has severely limited his mobility. His reason for requiring a new prosthesis at this time are to correct an ill fitting socket due to limb maturation and weight change, as well as providing a prosthetic knee /foot that will allow safe and stable ambulation.

Mr. Fernandez led an active lifestyle prior the above-knee amputation, and desires to return to the same activity level. His activities include walking for exercise, shopping, working around the house and yard work. His leisure activities include fishing. His activities of daily living will have Mr. Fernandez encountering a multitude of different surfaces and difficult situations which will challenge his stability while using a prosthesis. He will need the sound-side leg to be strong and stable. However, with his limited strength and stability of the left leg, the prosthetic knee will have to act as the stable side so Mr. Fernandez has a "sound side" or stable side which will provide confidence and stability while walking. The sound-side leg problem requires him to use a prosthesis to initiate load-bearing on the right side, while relieving his left lower extremity and his upper body from constant load-bearing. Once he is able to shift weight onto his lower extremities, he will be able to facilitate greater use of his upper extremities during activities of daily living. Since his current knee is not working properly this requires Mr. Fernandez to constantly be aware of what he is currently walking on and what he is about to walk on so that he can alter his muscle activity inside of the socket to prevent inadvertent buckling of the knee. If this occurs, the knee will buckle at a rate established by the metering valves as if he were still in a walking mode rather in a safe mode. Because of this uncertainty, he must err on the safe side and constantly exert excessive muscle activity to keep the knee in a safe mode. This also requires that his walking is always a very conscience act, rather than subconscious, which diverts his attention from the task at hand. This is a real concern as his focus will be on not falling rather than negotiating the terrain

which is in front of him. The potential risk of additional injury is more probable than possible in this circumstance.

Mr. Fernandez is currently using a semi suction socket with a 1 ply sock and a suspension belt. The socket fits poorly due limb maturation and weight gain. He does not have a total contact fit or distal contact on this socket which greatly reduces proprioception and stability of his prosthesis. Due to the poor fitting socket he has bruising along the posterior distal residual limb which requires him to sit down to relieve the discomfort.

Mr. Fernandez is now seeking to be fit for a prosthesis which will address the chronic condition it is essential that any new prosthetic intervention address his need for stability in various terrains and slopes, accommodate his different speeds of ambulation, and do so with minimal additional energy costs. Since the foundation of any prosthesis is the limb-socket interface, this should be addressed first. His activity level will require a prosthetic socket which provides superior suspension, control of the remaining femur, and stability around the pelvis. The suction socket design provides the best suspension while allowing easy donning through the use of lotion to push into the socket expelling the air out of a one way valve. This system gives him the superior suspension, stability, and will reduced fatigue of the left leg. Another beneficial component within the socket is a flexible brim along the outer socket. This will allow him to sit on various seating surfaces and increase the range of motion around the hip joint by lowering the trim lines of the rigid material. To achieve the required intimate fit around the pelvis, distal femur control and protecting the skin within the socket, two test sockets will need to be fit. During the initial fittings, every attempt will be made to make adjustments directly to the test sockets to achieve the desired result. In some instances, this requires additional modifications be made to the initial mold and a subsequent new test socket be fabricated.

To address the limitations outlined with his current microprocessor knee system it will be necessary to utilize a microprocessor-controlled knee. The specific knee is a Freedom innovations Plié 2.0 MPC Knee. The Plié 2.0 MPC Knee is a single-axis prosthetic knee joint system that provides hydraulic control of both the swing and the stance phase of gait. The stance phase control is assisted by sophisticated in-frame sensors that allow the microprocessor to control the resistance necessary to manage stance and determine when to send a message to enable a modification to fluid management system resulting in a change in torque about the knee center necessary for swing in 10 milliseconds. Sophisticated software has been developed and incorporated to allow adjustment for each user's walking style and personal preferences. Both the swing flexion and stance extension adjustments are independently optimized. The hydraulic cylinder is also capable of providing stance flexion for level ground walking as well as stair and ramp descent. Stance extension has been engineered into the hydraulic cylinders capabilities as well. An extension assist is also incorporated into the design to complement the patients' hip extension movement and reduce effort to extend the shank. This ensures optimal stability for increased safety and efficiency when walking on level ground, uneven ground, and descending ramps and stairs, all of which Mr. Fernandez encounters on a daily basis. Finally, a removable lithium ion battery is utilized as the power source for the knee, and each knee will come complete with two batteries and a charger.

The following is a detailed list of codes with further medical necessity rationale for each code:

L5321 – Above knee, molded socket, open end, SACH foot, endoskeletal system. This is the base procedure code and describes only the very basic components to describe a transfemoral prosthesis. The "L" coding system is an add-on system to more fully describe the specific prosthesis required.

L5624 x2 – Addition to lower extremity, test socket, above knee. As previously mentioned, the test socket fitting procedure ensures an optimal fit and function. These sockets are fabricated out of clear thermoplastic, allowing visual inspection of the limb tissues inside of the socket. This is necessary when suction is used for suspension to ensure that the tissue tension is correct. This is determined by tissue coloration as compared to the sound limb. Too much tension and the skin blanches whereas too little tension causes the skin to become reddish or purple in color. In either case, an improper fit will result in tissue damage.

L5631 – Addition to lower extremity, above knee or knee disarticulation, acrylic socket. This not an additional socket, rather it is defining the type of material that the socket is made from as compared to the standard material included in the base code. The acrylic material is far lighter and stronger than the polyester material. Due to the inner and outer socket design, a stronger material is indicated. In addition, to reduce energy consumption, the lighter socket weight will further reduce stress on the patient joints.

L5649 – Addition to lower extremity, ischial containment/narrow M-L socket. Again, this is not another socket, rather it describes the shape of the socket as opposed to the standard quadrilateral design included in the base code. This socket design is necessary to better control the femur by containing the ischial tuberosity. Given the distal musculature is not attached to the bone, it is imperative that the proximal pelvic structure is secured inside of the socket so that the lateral socket wall can help stabilize the distal femur. This design also decreases stress on the tissues of the perineal area. In a quadrilateral socket, the ischial tuberosity sits on top of the socket, relying on firm perineal tissues to stabilize the socket on the limb. Stabilization of the femur is not possible inside of the soft distal tissues.

L5650 – Addition to lower extremity, total contact, above knee or knee disarticulation socket. This is a procedure that is done to establish that distal contact is established inside of the clear test socket. This is necessary when suction is used to prevent a condition called verrucose hyperplasia.

L5651 – Addition to Lower extremity, above knee, flexible inner socket, external frame. This describes the definitive outer-socket design that consists of two parts. The inner portion of the outer socket is made from a flexible thermoplastic material that is housed inside of a rigid frame to make a complete outer socket unit. The flexible material is necessary so that it will conform to a variety of seating surfaces that he is required to sit on. The posterior portion of the inner socket is exposed and will conform to the different seating surfaces. The standard socket configuration is a hard exoskeletal shell that causes tissue impingement. In addition, the proximal brim area will flex during bending to allow increased range of motion.

L5652- Addition to Lower Extremity, Suction Suspension, Above Knee or Knee Disarticulation Socket as described above. The inner socket is held on the residual limb by suction. This is the primary suspension which attaches the prosthesis to the limb. The secondary suspension will hold the limb and inner socket inside the outer frame. Both suspension mechanisms are needed to complete the system.

L5695: Addition to Lower Extremity Prosthesis, Above Knee, Pelvic control, sleeve suspension. These soft goods have the tendency to be damaged during everyday activities. suction system. Suction suspension allows very little pistoning between the residual limb and the socket. During the swing phase of gait, distally directed forces will pull at the prosthesis, making it more inclined to come off. Suction holds the prosthesis on the residual limb with little to no movement off the leg.

L5828 – Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control. This describes the base code of the knee system. The metering valves regulate the rate at which the knee can bend during swing and stance phases of gait. Increased weight on the heel during stance phase will allow him to load the knee and maintain stability with varying degrees of knee flexion. Decreased friction during early swing phase will allow the knee to flex with little effort and delivers an energy efficient, symmetric and more natural gait over a wide range of walking speeds. The increased stability and ease of initial knee flexion will allow him to reduce the stress level on his lower back and allow him to reduce the stress on his sound-side arthritic knee.

L5845 – Addition, endoskeletal knee-shin system, stance flexion feature, adjustable. Stance flexion allows for controlled flexion up to 15 degrees during the initial stance phase of gait. Stance flexion limits the rise of the center of gravity, absorbs the initial impact of heel contact, and reduces energy consumption. This will allow him to walk foot-over-foot down stairs and to walk down hills or ramps without the fear of the knee buckling under him.

L5858 – Addition, endoskeletal knee-shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type. Microprocessor stance phase control optimizes the prosthetic knee to respond to a wide range of cadence changes. Walking slower or faster than the manual setting on a traditional hydraulic knee will compromise the performance and cause him to expend more energy to compensate. The microprocessor can release from the necessary resistance for stance to swing in 10 milliseconds allowing him to adjust his walking speed without making a conscious effort. This allows him to concentrate on the task at hand rather than on his walking speed.

L5848 – Addition to endoskeletal, knee-shin system, hydraulic stance extension, dampening feature, adjustable. This feature describes the portion of gait that occurs directly after terminal stance flexion as the knee begins to move back into full extension. Without an adjustable dampening feature, the knee would abruptly move back into an extended position, jarring the limb and interrupting the gait cycle. This jerky type of gait would cause an increase in energy expenditure.

L5850 - Endoskeletal above knee or hip disarticulation extension assist. A hand pump is utilized to connect to the air chamber and add or remove air pressure within the chamber. As the oil displaced by the shaft, enters the oil reservoir during compression, the air in the chamber is compressed. As a result, the pressure inside the air chamber increases as the knee bends. This increase in pressure acts as an