Osseointegration

The Latest and the Greatest?

Stephen J. Wallace, MD
Summit Orthopaedics
Lake Oswego, OR

SUMMIT
ORTHOPAEDICS

Financial Disclosures

- I have no relevant financial relationships.

Stephen Wallace, MD (Lake Oswego, OR)
Submitted on: 08/24/2023
Johnson & Johnson: Paid consultant

SUMMIT ORTHOPAEDICS

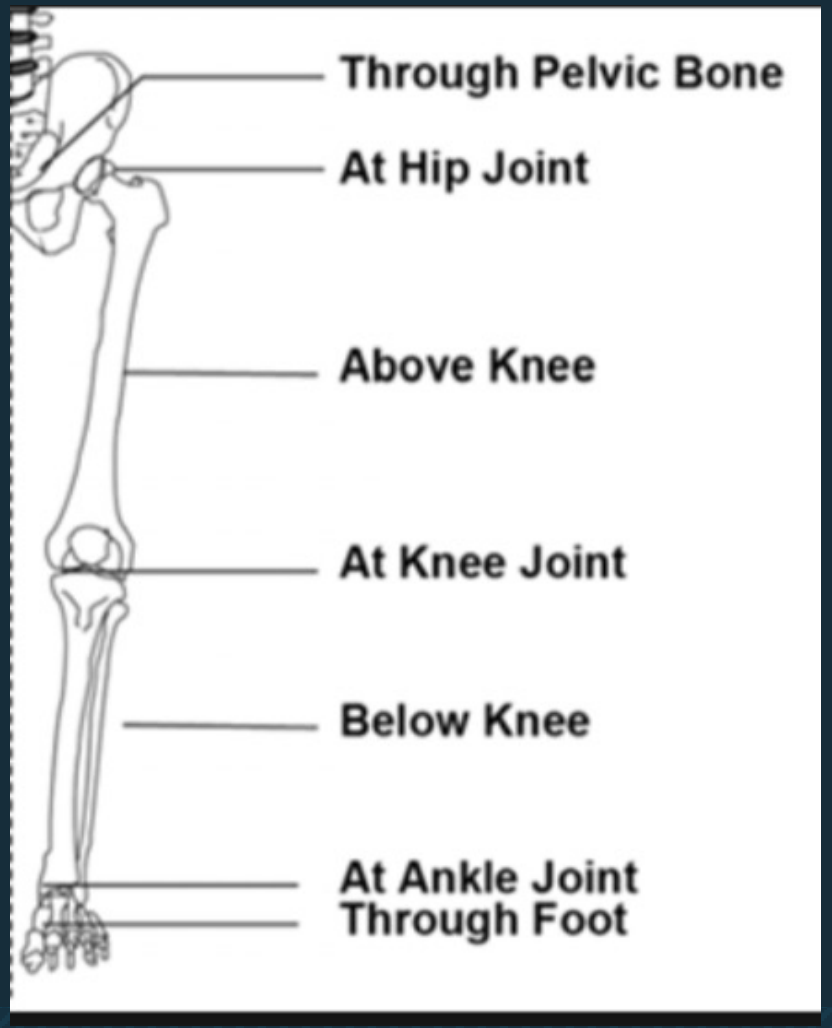
Outline

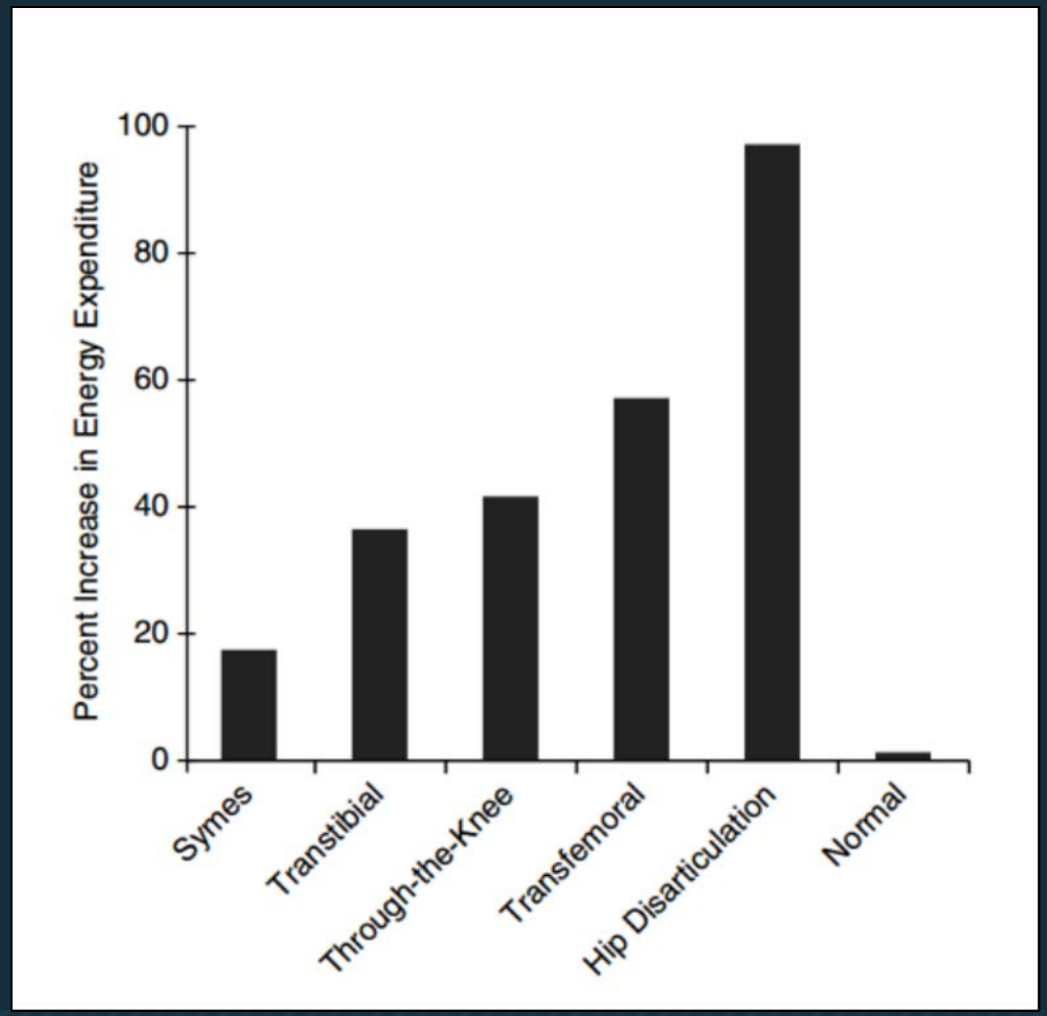
Osseointegration

- What is Osseointegration?
- Problems with Traditional Socket Prothesis
- Functional Outcomes
- Early Experience

SUMMIT ORTHOPAEDICS

As you know…



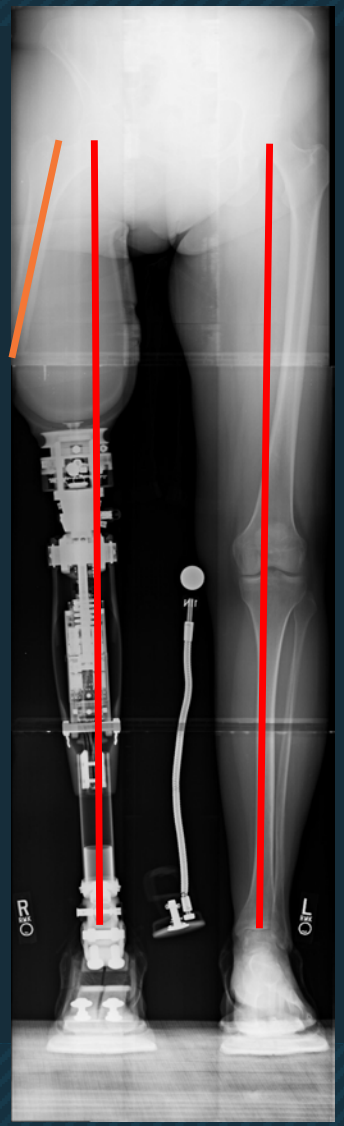


SUMMIT ORTHOPAEDICS

Osseointegration

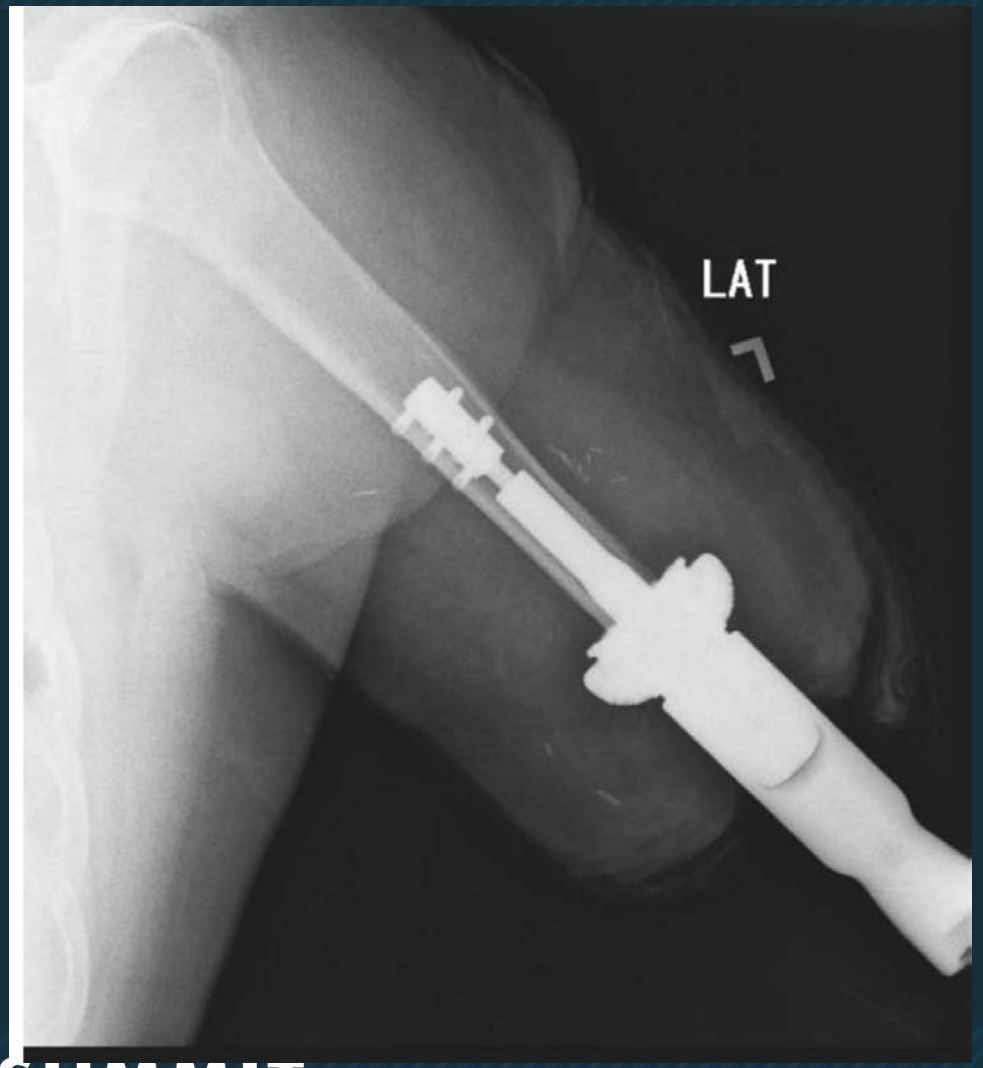
SUMMIT ORTHOPAEDICS

The problem with traditional socket prostheses…



SUMMIT ORTHOPAEDICS

Osseointegration



SUMMIT ORTHOPAEDICS

Osseointegration - Terms

- Transcutaneous Osseointegration for Amputees (TOFA)
- Percutaneously Attached Artificial Limb (PAAL)

- “Intramedullary metal endoprosthesis that passes transcutaneously to connect with a limb exoprosthesis”

- “Direct interface between bone and implant, without intervening tissue”

- Versus socket prosthesis: squeezes residual soft tissue

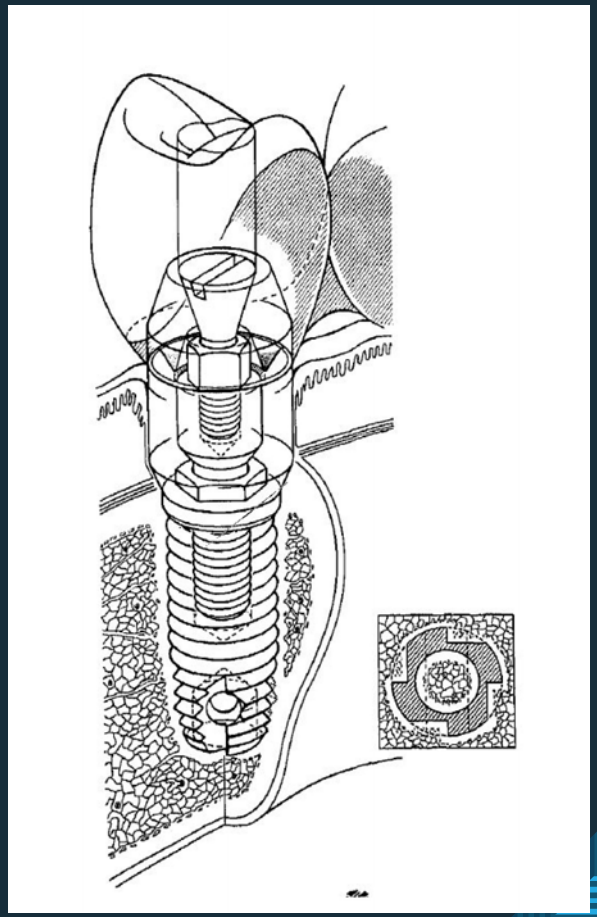
SUMMIT ORTHOPAEDICS

History - First Case

- 1990 – Sweden
  - Rickard Brånemark

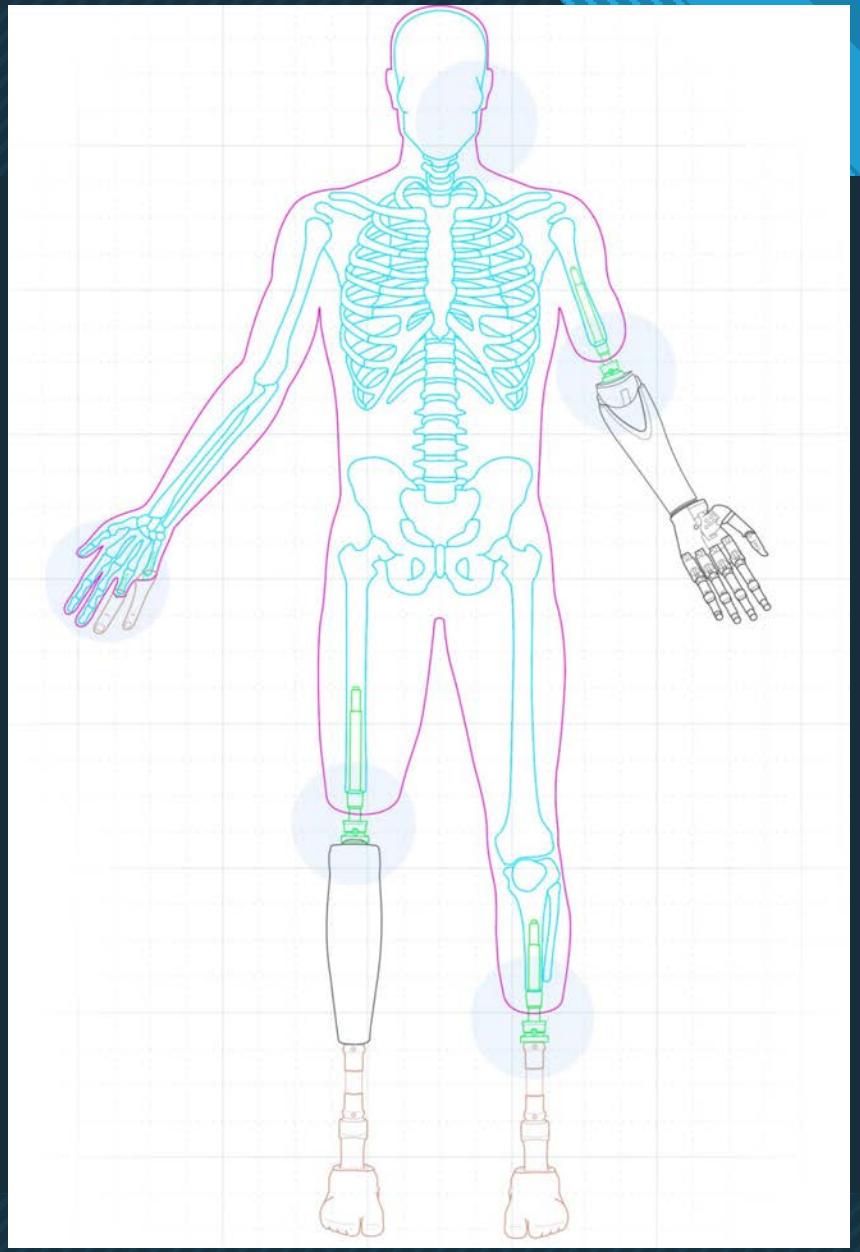
Based on:

- 1965 – Dental Implants
  - Per-Ingvar Brånemark
    - (his father)



Variations

- Location
  - Femur
  - Tibia
  - Humerus
  - Ulna
  - Phalanges



- System
  - **OPRA (1990)**
  - ILP
  - **OPL (2014)**
    OTN (2016)
  - POP
  - Compress
  - ITAP (failed)

SUMMIT ORTHOPAEDICS

Systems

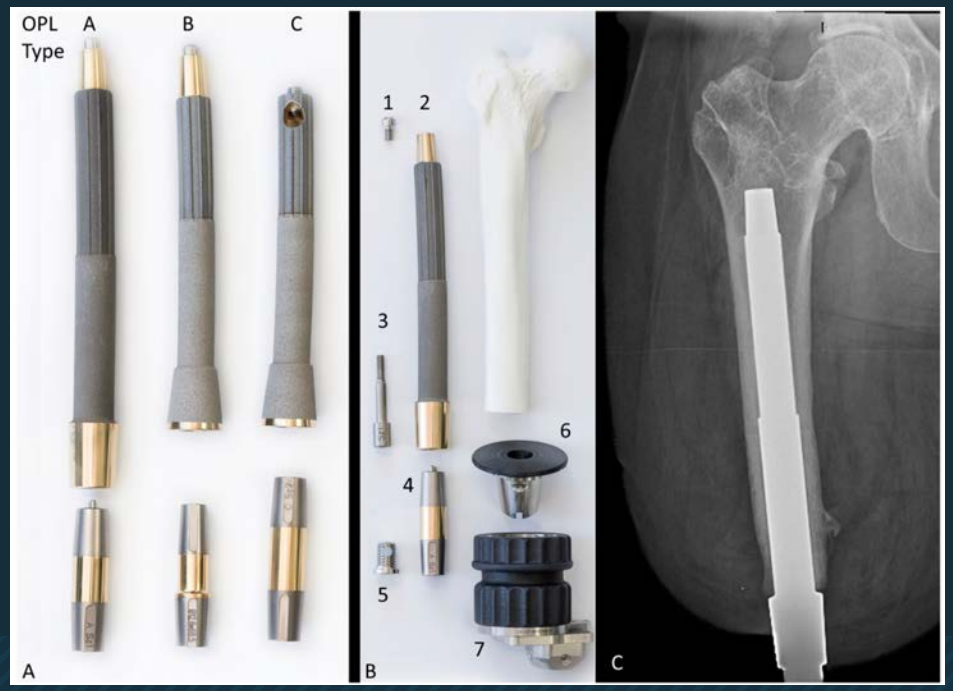
OPRA
(2-Stage)

Osseointegrated Prostheses for the Rehabilitation of Amputees

OPL/OTN
(1 or 2 Stage)

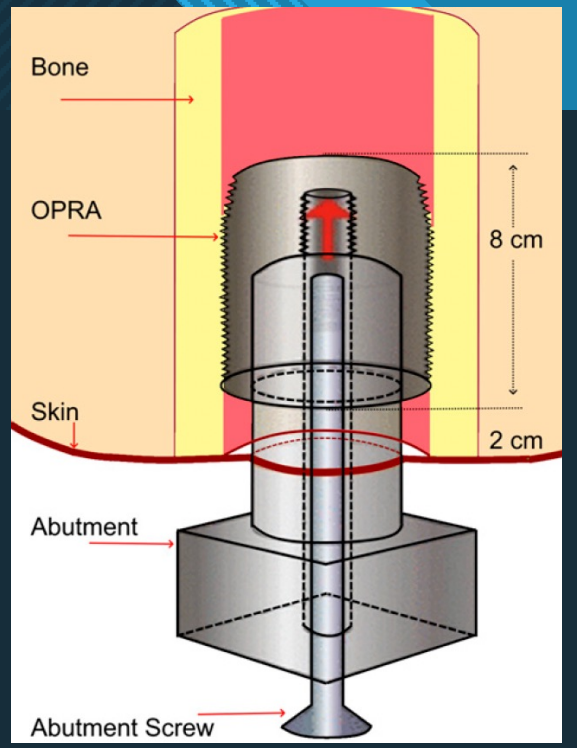
Osseointegrated Prosthetic Limb

Osseointegrated Tibia and Femur



Biology

- Metal-to-bone binding
  - Titanium alloy (Ti6Al4V)
  - Osteoconductive
  - No intermediate layer



- OPRA – screw in – laser-etched
- OPL/OTN – press fit – plasma-spray coating

Problems with Socket Protheses

- Soft tissue envelope swells / shrinks
- Poor fit / suction
- Pressure sores
- Sweating
- Blistering
- Neuroma pain
- Tedious donning / doffing
- Mechanical inefficiencies

SUMMIT ORTHOPAEDICS

Benefits of Osseointegration

- No soft tissue loading
  - Skin
  - Nerve
- Direct Skeletal Connection
  - Prosthesis handling
  - Limb control
  - Range of motion
- “Osseoperception”

Indications

- **Prior Amputation**
  - Multiple sockets / prostheses
  - Skin irritation / blistering
  - Symptomatic neuroma
  - Pain – direct and phantom

- Primary Amputation
  - Trauma
  - Nonunion/Malunion
  - Neuropathic pain

SUMMIT ORTHOPAEDICS

- Relative Contraindications
  - Comorbidities
    - Diabetes
    - Vascular disease
  - Morbid Obesity
  - Opioid dependence
  - Psychiatric conditions
  - Prior radiation
  - Severe osteoporosis
  - Extremely short segments

  - Extreme Activity?

SUMMIT ORTHOPAEDICS

OPL Timeline

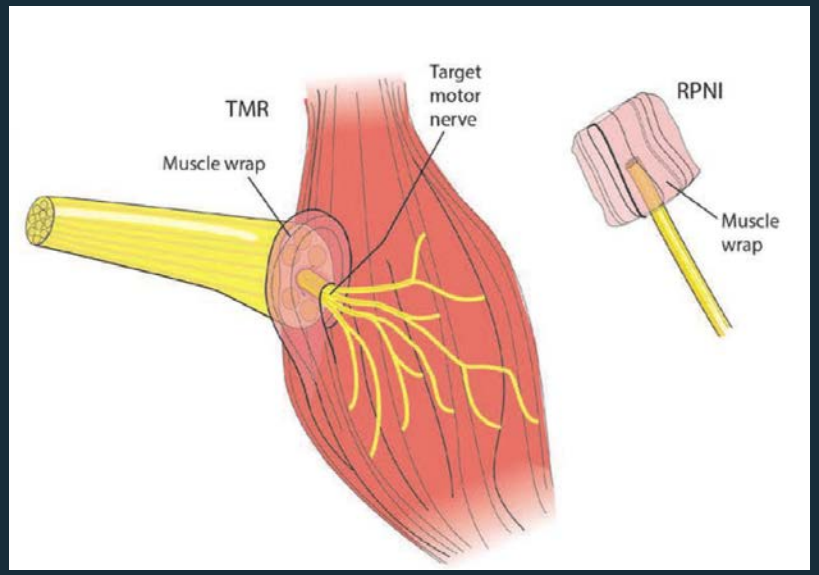
- Initial Consultation / CT Scan
  - 4-6 weeks for fabrication and delivery
- One stage implantation
  - Inpatient – progressive loading protocol
  - @6 weeks – full weight bearing
  - @10 weeks – attach prosthetic

SUMMIT ORTHOPAEDICS

SUMMIT ORTHOPAEDICS

Adjuncts

- Debridement / Infection Control
- Soft Tissue Reconstruction
- Nerve Pain
  - Targeted Muscle Reinnervation (TMR)
  - Regenerative Peripheral Nerve Interface (RPNI)



SUMMIT ORTHOPAEDICS

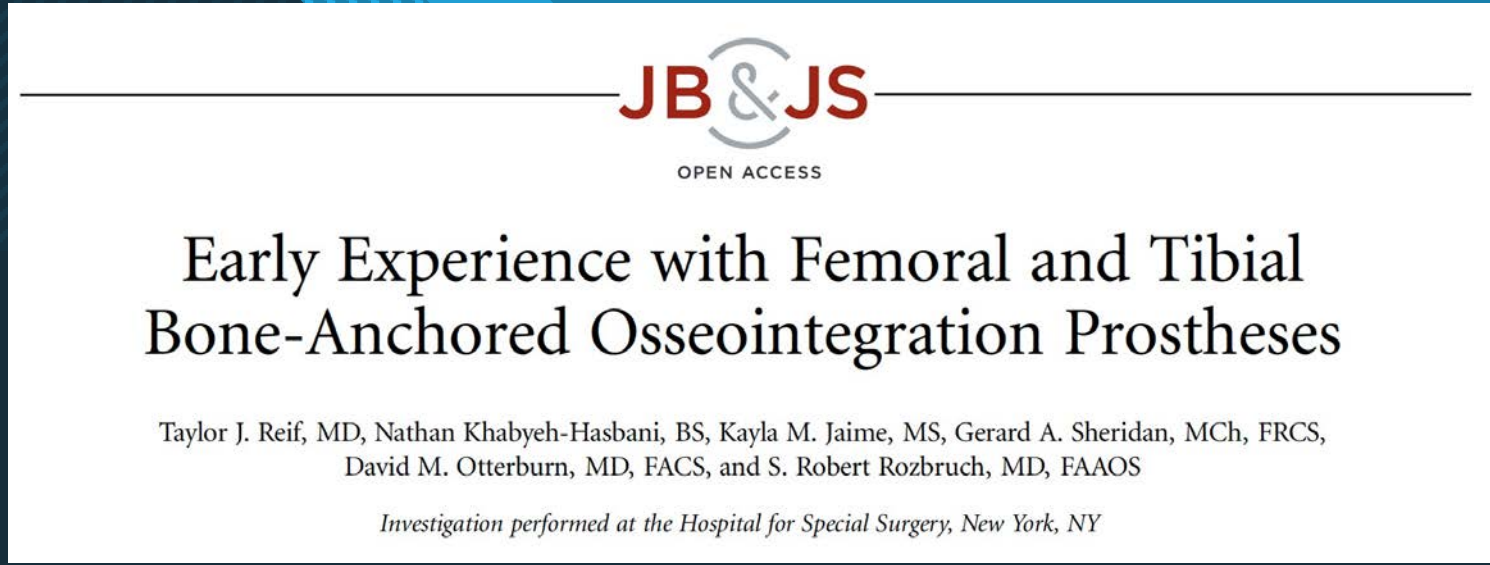
Team Based Approach

- Orthopaedic Surgeon
- Soft Tissue Surgeon
  - Soft Tissue Contouring
  - TMR / RPNI
- Prosthetists & Orthotists
- Physical and Occupational Therapists

SUMMIT ORTHOPAEDICS

Outcomes

- First 31 patients
  - 2017 onward
  - Femur and Tibia only
  - now 60+ implanted
- 6 month minimum follow up
- Outcome Scores (Q-TFA, LD-SRS, PROMIS)
- Complications



JB&JS

OPEN ACCESS

Early Experience with Femoral and Tibial Bone-Anchored Osseointegration Prostheses

Taylor J. Reif, MD, Nathan Khabyeh-Hasbani, BS, Kayla M. Jaime, MS, Gerard A. Sheridan, MCh, FRCS, David M. Otterburn, MD, FACS, and S. Robert Rozbruch, MD, FAAOS

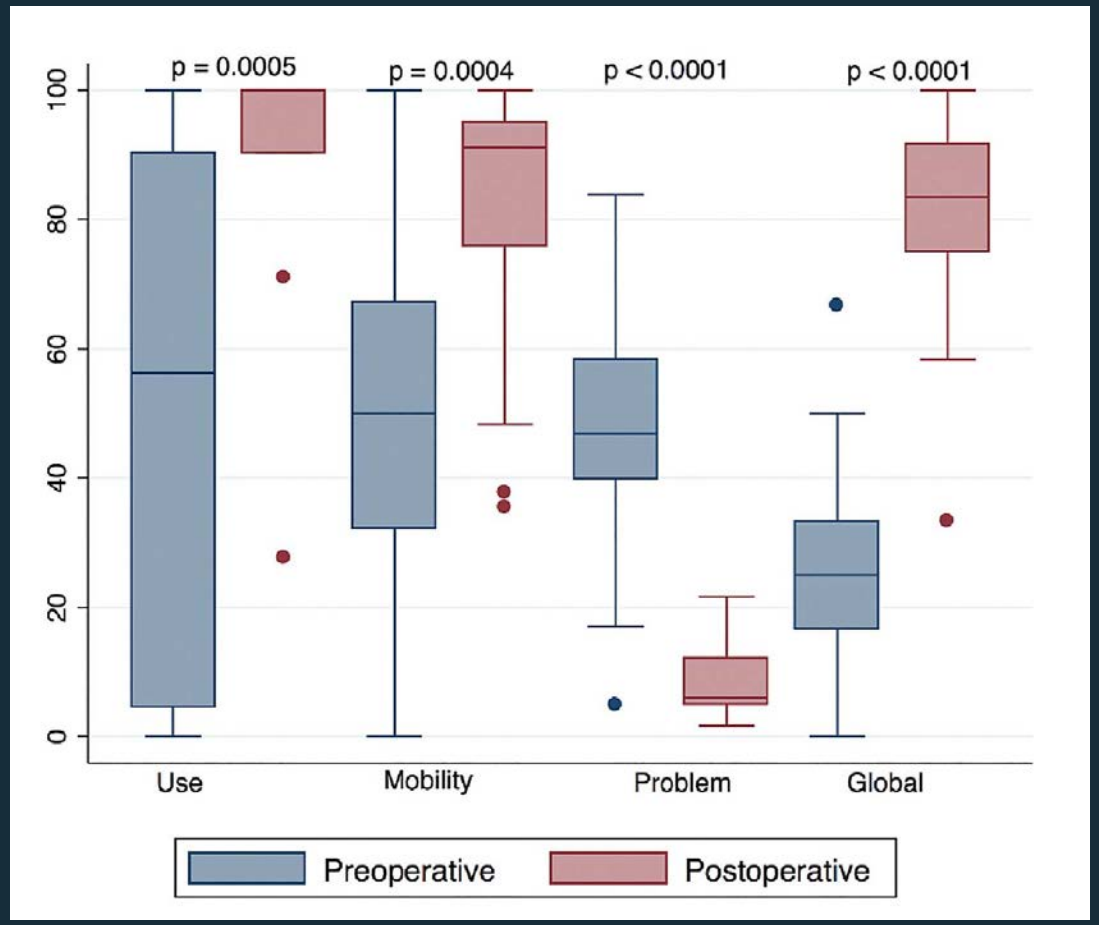
Investigation performed at the Hospital for Special Surgery, New York, NY

TABLE I Patient Demographic Characteristics

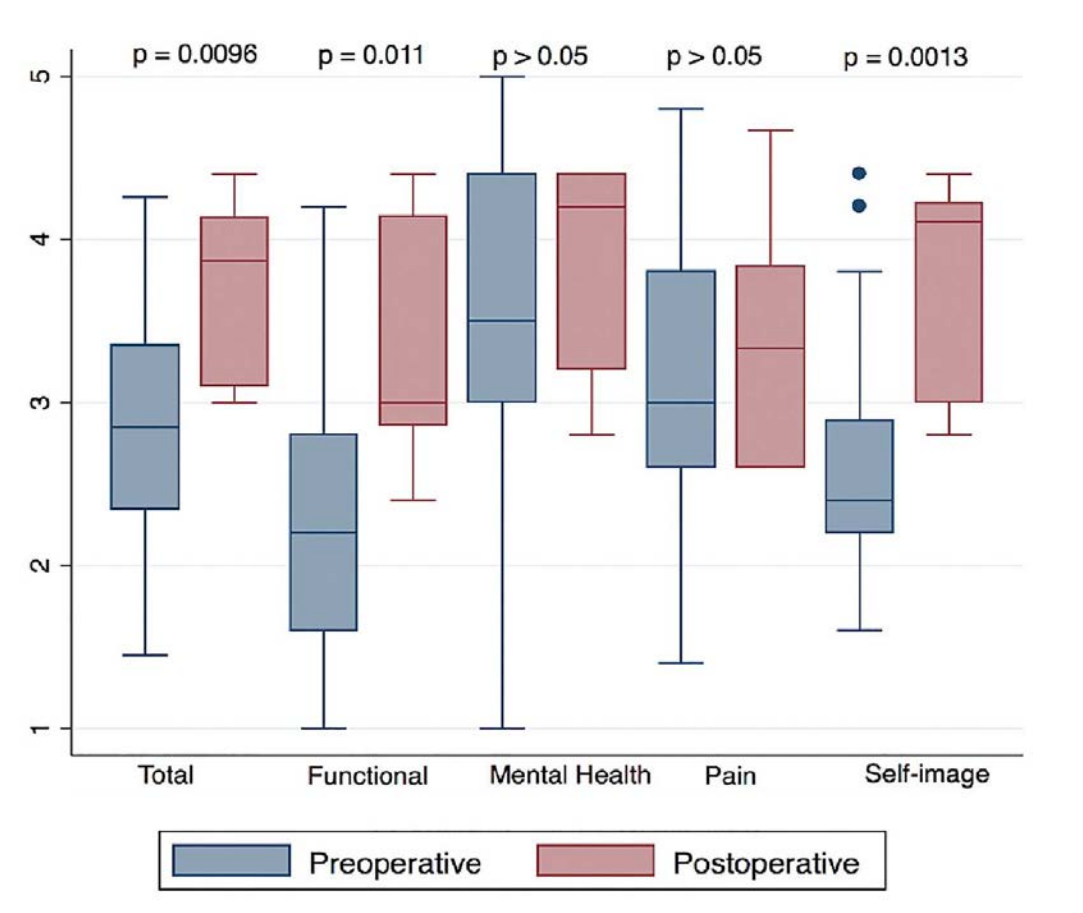
	Femoral Reconstruction Group (N = 18)	Tibial Reconstruction Group (N = 13)
Patient characteristics		
Sex*		
Male	11	8
Female	7	5
Age† *(yr)*	49.6 ± 12.0	51.3 ± 14.1
Time since amputation† *(yr)*	7.8 ± 8.8	9.4 ± 12.5
Amputation etiology*		
Trauma	13	9
Necrotizing fasciitis	1	—
Chronic periprosthetic infection	2	—
Vascular injury	2	—
Neurologic injury or complex regional pain syndrome	—	3
Deformity	—	1
Residual bone length† *(mm)*	222 ± 94	119 ± 34

SUMMIT ORTHOPAEDICS

Q-TFA

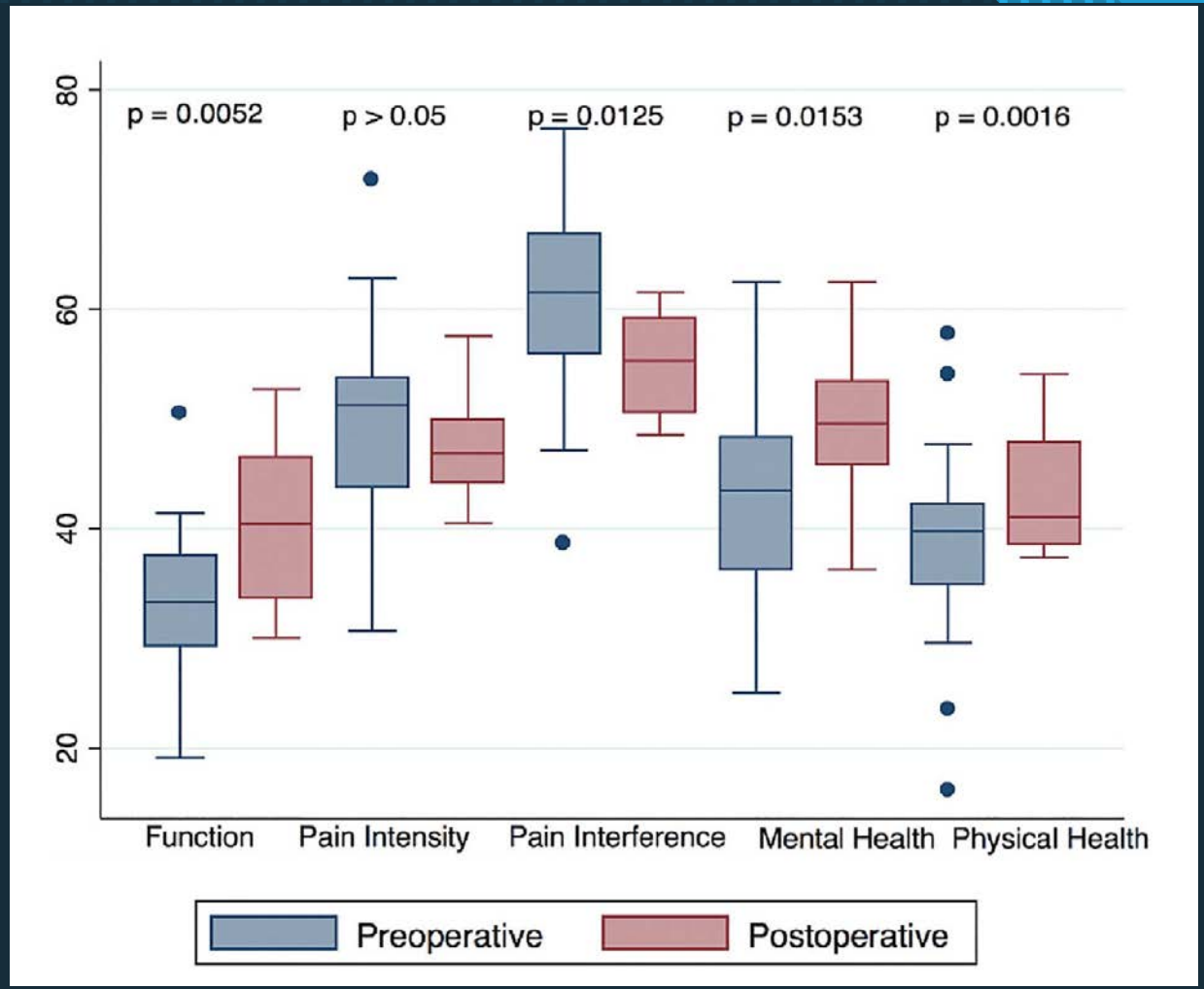

p = 0.0005
p = 0.0004
p < 0.0001
p < 0.0001
100
80
60
40
20
0
Use
Mobility
Problem
Global
Preoperative
Postoperative

LD-SRS



SUMMIT ORTHOPAEDICS

PROMIS



SUMMIT ORTHOPAEDICS

Complications

- Intraoperative
  - Routine specimens - 6 positive cultures
    - 2 treated with oral antibiotics
    - 4 treated with IV antibiotics – 1 required boney debridement
      - Implant retention
- Postoperative
  - 23 soft tissue infections in 15 patients
    - 20 treated with oral antibiotics; 3 required IV antibiotics
  - 2 patients with proximal femur fractures
    - Treated with ORIF, implant retention
  - 1 patient with septic implant loosening
    - Reimplantation 5 months later
  - 1 patient with aseptic implant loosening
    - Reimplantation 9 months later

Summary

- Improvement in Functional PROs
- Improved Pain
- Low-grade, soft tissue infections common, but most managed with oral antibiotics
- 2 patients with loosening
  - both requested reimplantation

Regulation

- Clinical trails (U.S. Department of Defense)
- OPRA
  - Full FDA approval in December 2020

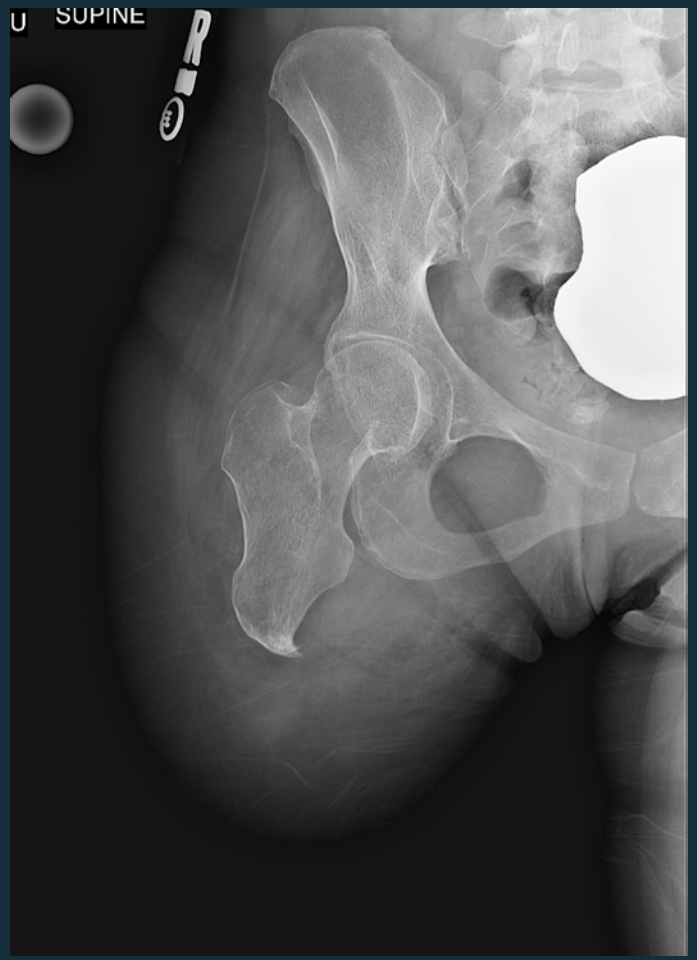
- OPL/OTN
  - FDA approval with compassionate use (case by case)

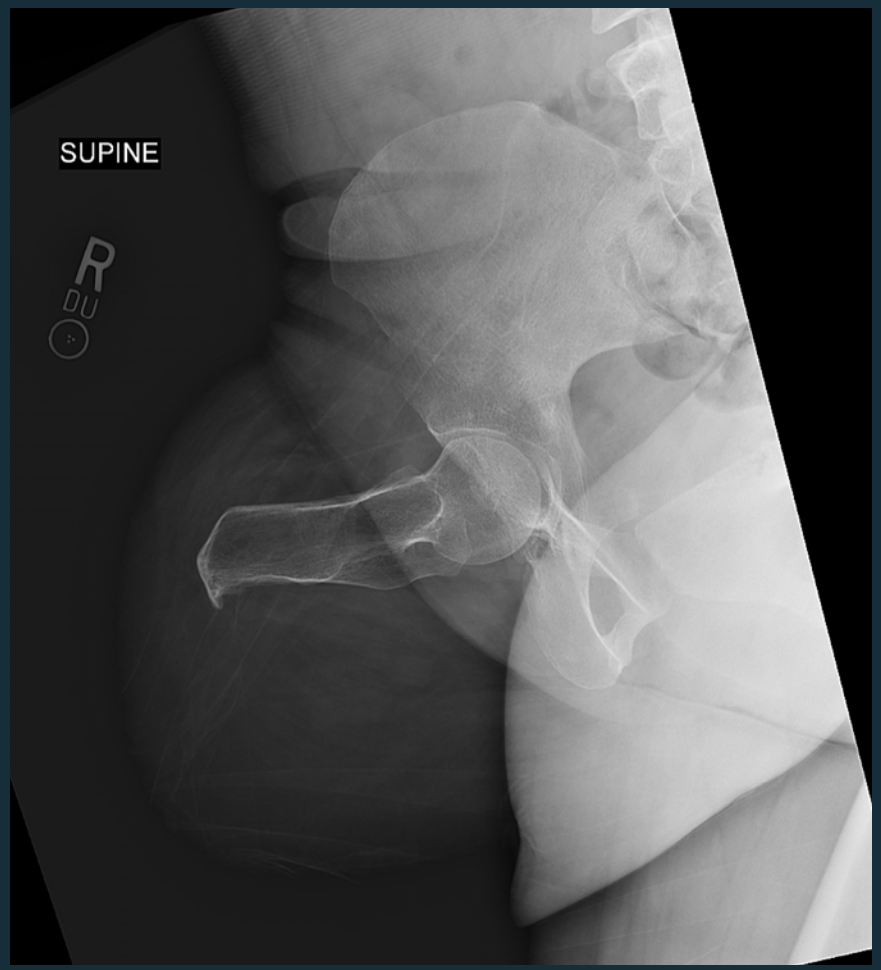
Osseointegration @ Summit

- ✓ FDA Approval
  - ✓5 patients (compassionate use)
  - ✓Formal Investigational Device Exemption (IDE) – on the way!
- ✓ IRB Approval
- ❑ Cases scheduled – November 2023

SUMMIT ORTHOPAEDICS

Distraction Osteogenesis + Osseointegration

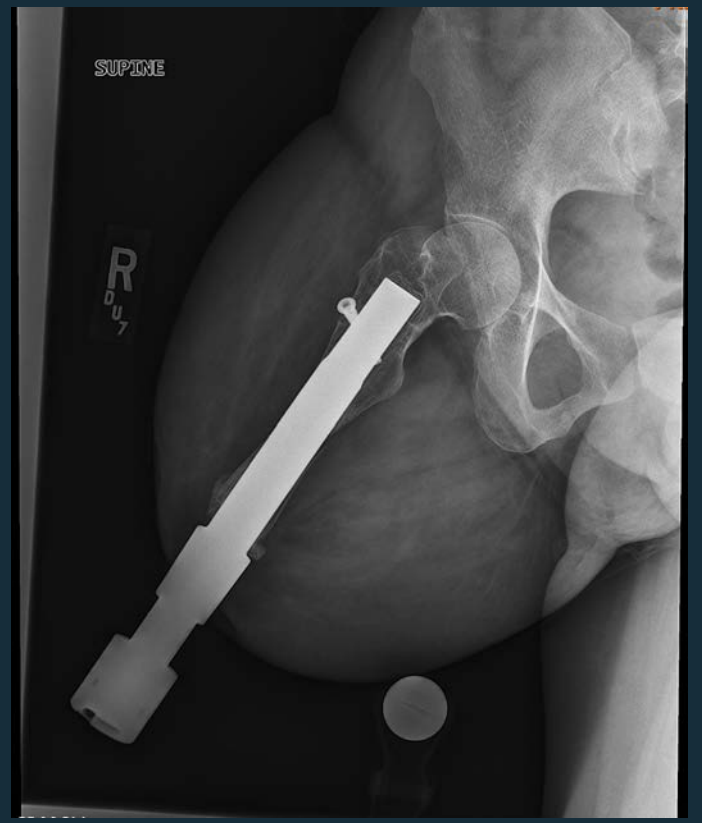


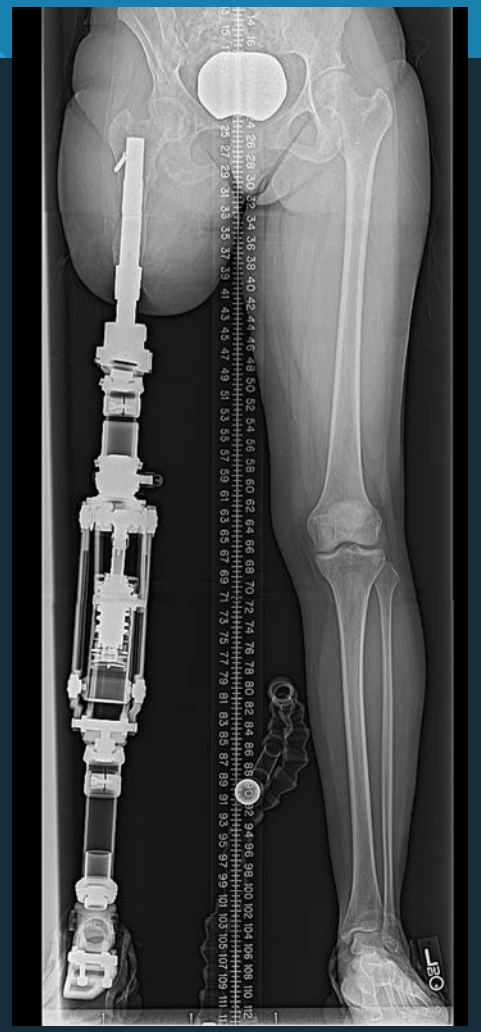


Distraction Osteogenesis + Osseointegration

SUMMIT ORTHOPAEDICS

Distraction Osteogenesis + Osseointegration



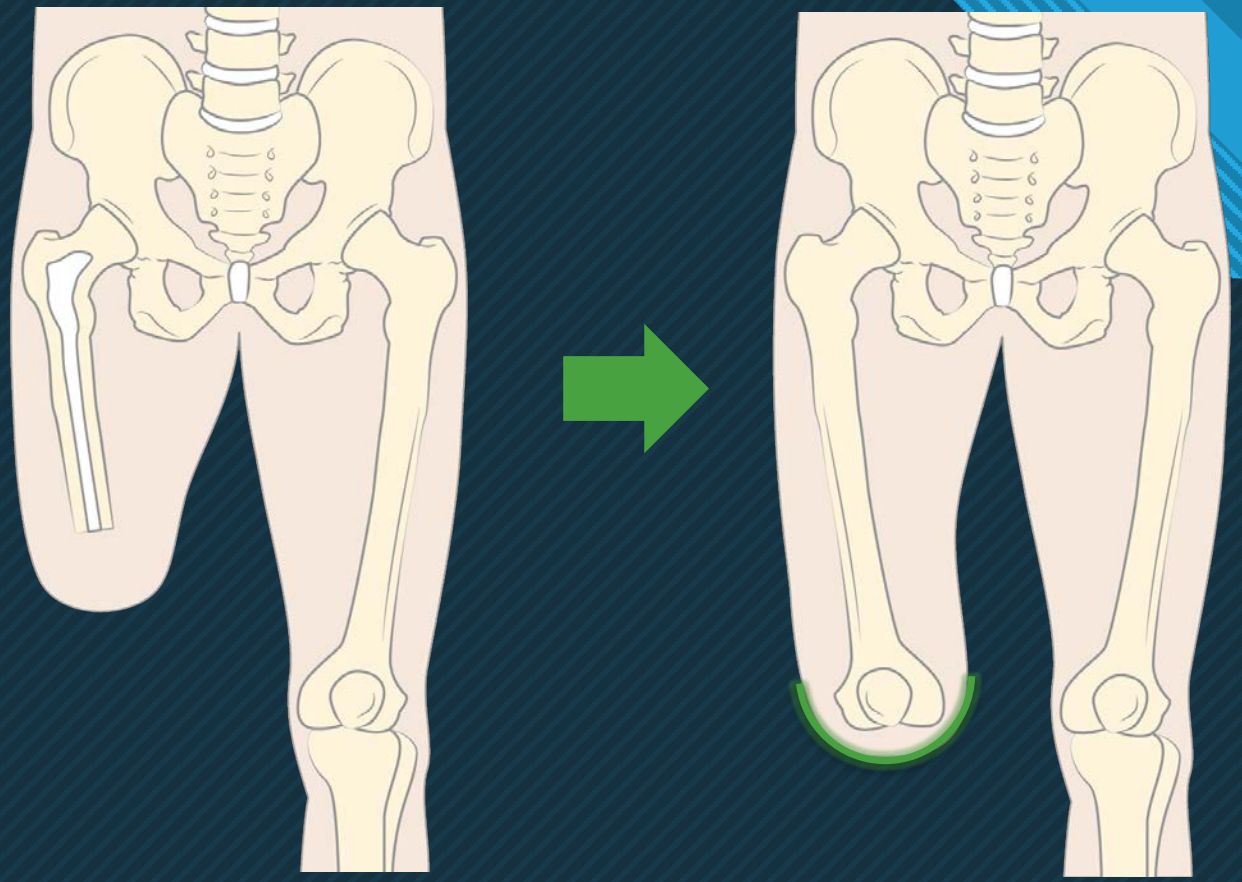


Keep Walking

The Keep Walking Implant

A **Distal Weight Bearing Implant**
for transfemoral amputated patients

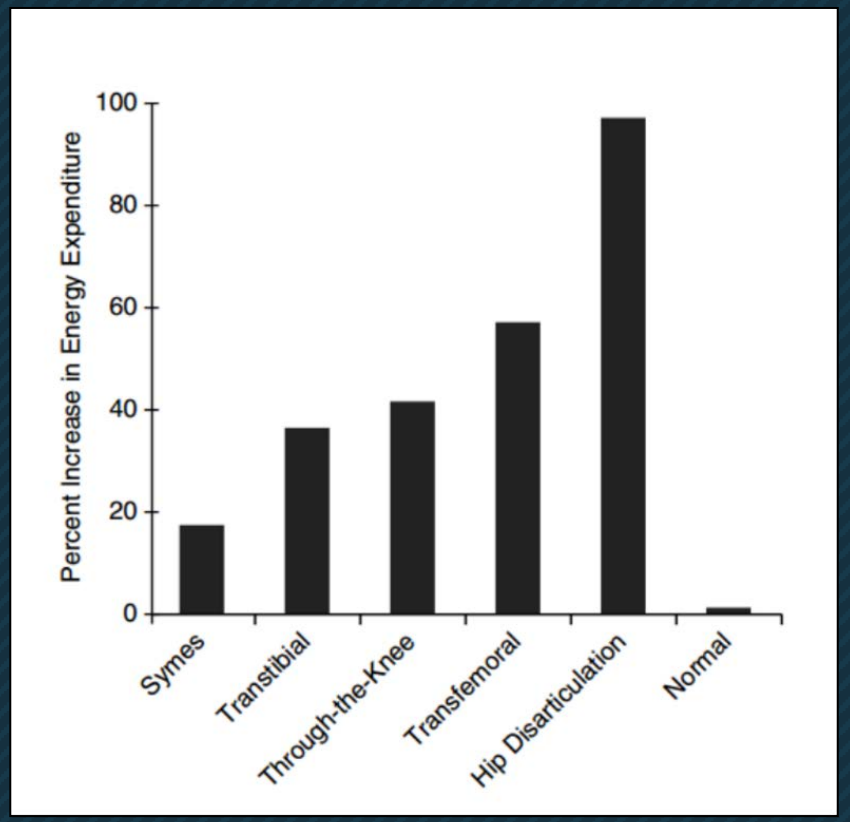
Objective

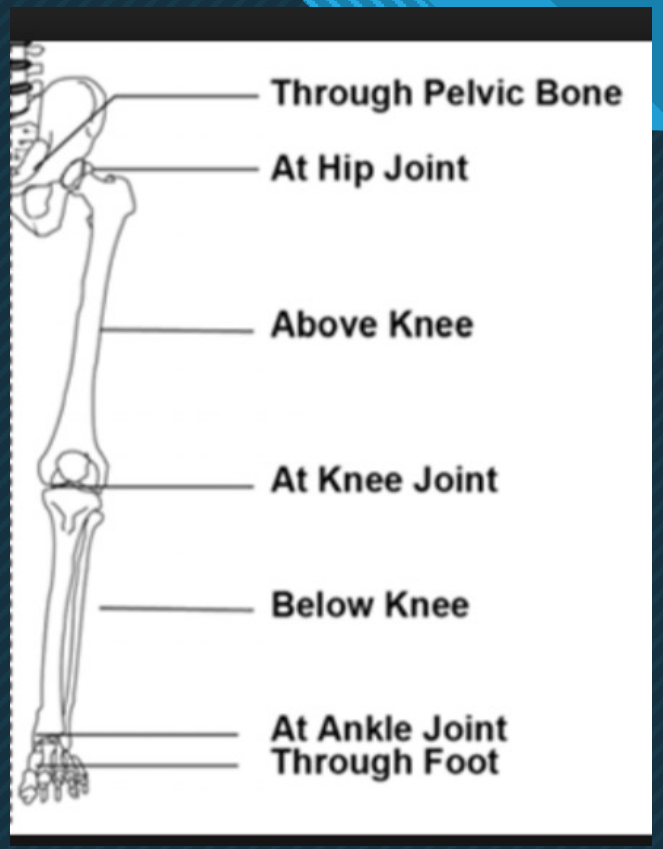


To offer a transfemoral amputee the aforementioned benefits of a knee disarticulation by restoring the capacity to put their weight on the distal part of the stump.

Objective: Energy Cost

ENERGY EXPENDITURE AND FUNCTIONALITY

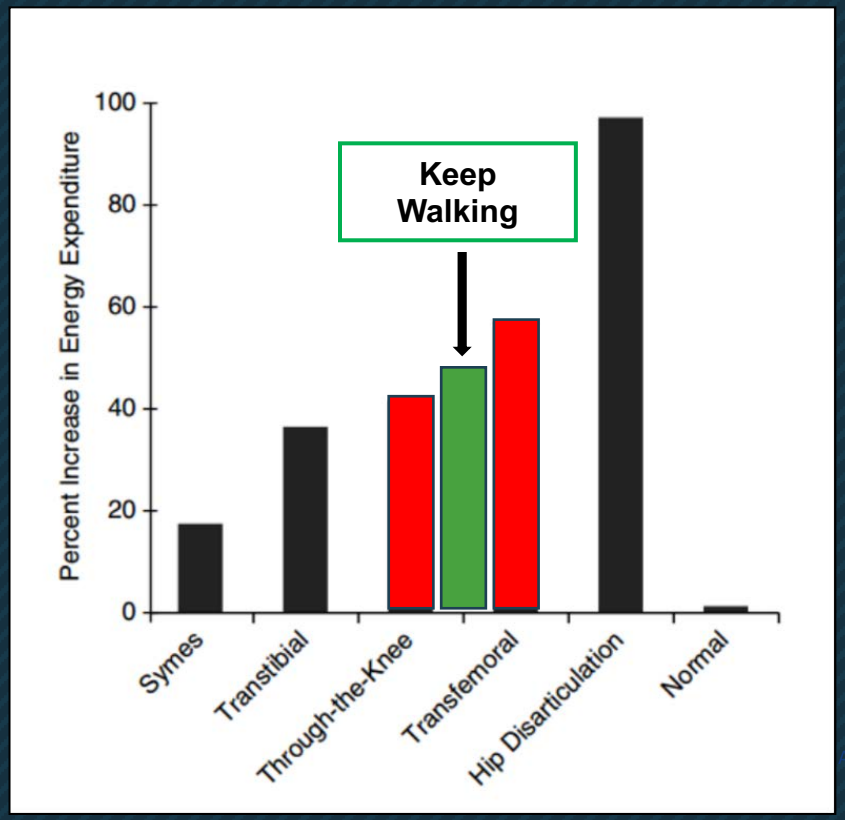


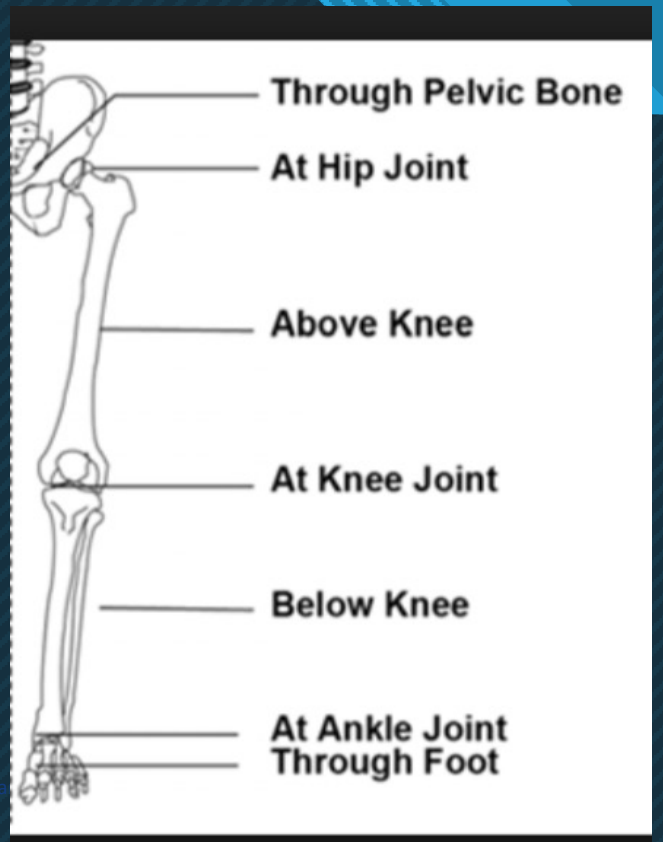


Alberto Esquenazi MD, Robert DiGiacomo PT. "Rehabilitation after amputation" J Am Podiatr Med Assoc 91(1): 13-22, 2001

Objective: Energy Cost

ENERGY EXPENDITURE AND FUNCTIONALITY





Transfemoral Amputee (Peripheral Vascular Disease)

The Keep Walking implant

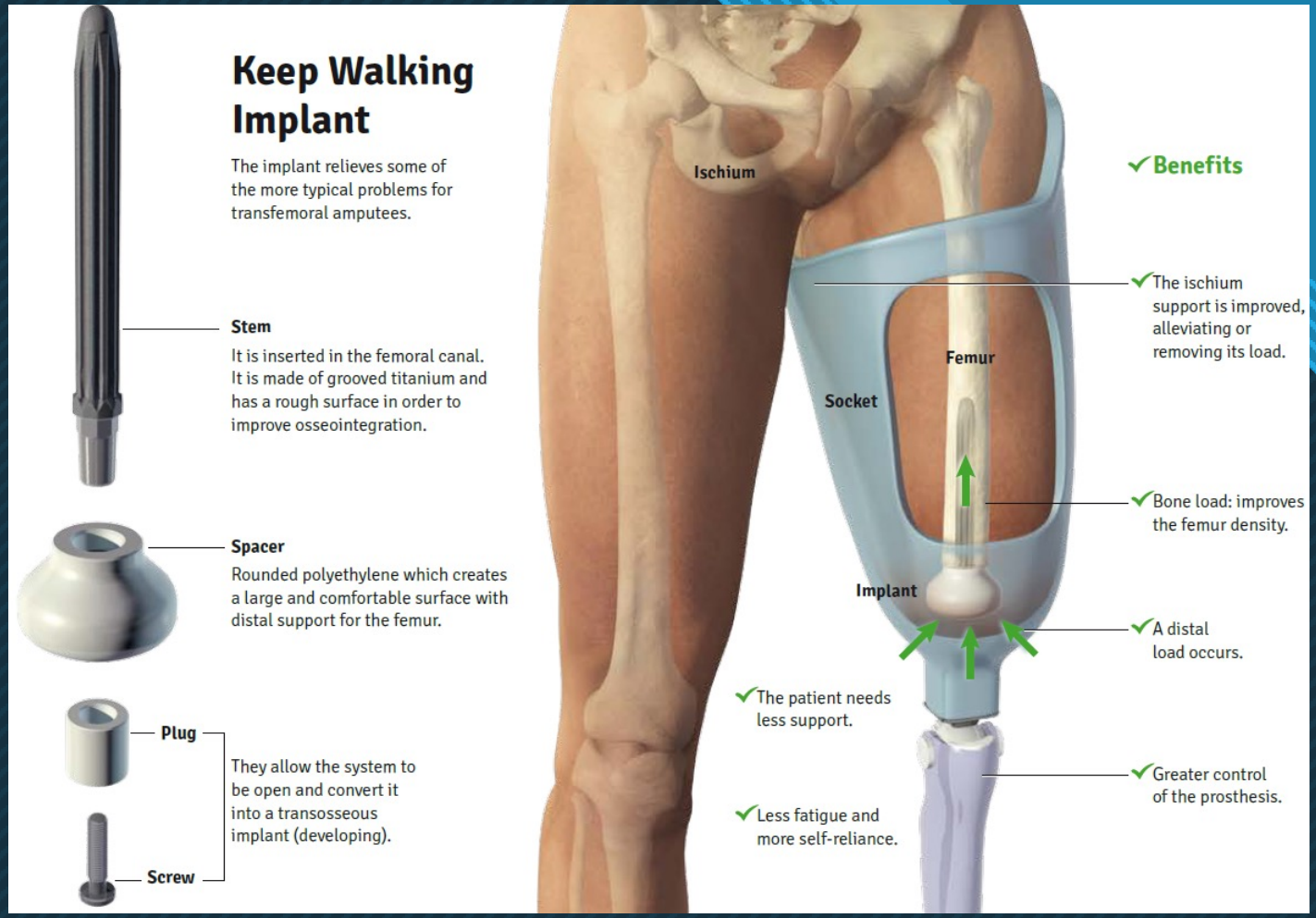
Stem: titanium Ti6Al4V
4 lengths and 6 diameters

Spacer: UHMW polyethylene
3 sizes

Plug: UHMW polyethylene

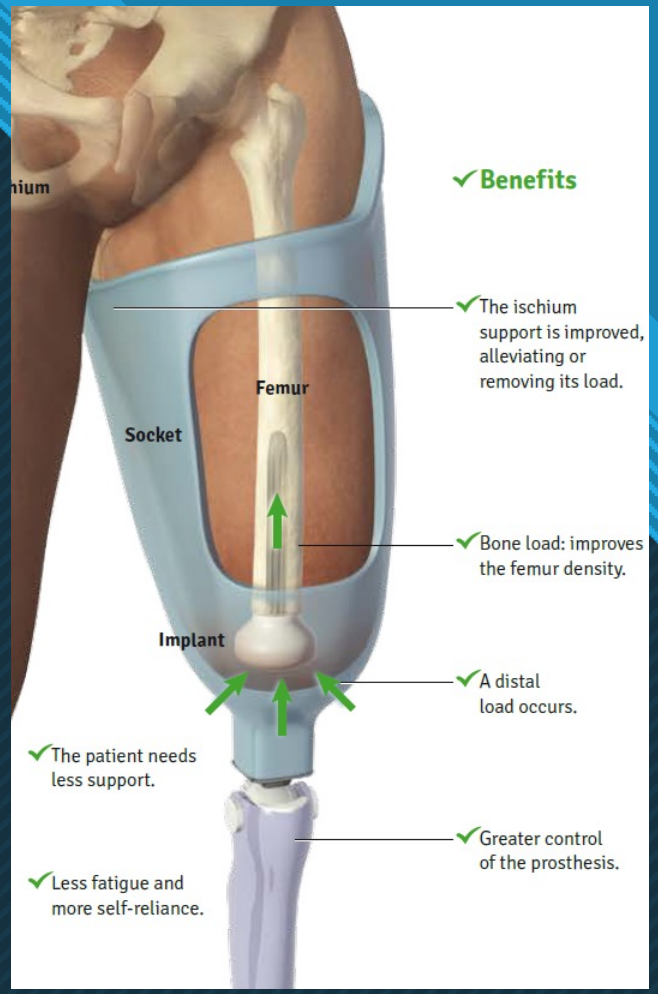
Screw: titanium Ti6Al4V

The Keep Walking implant

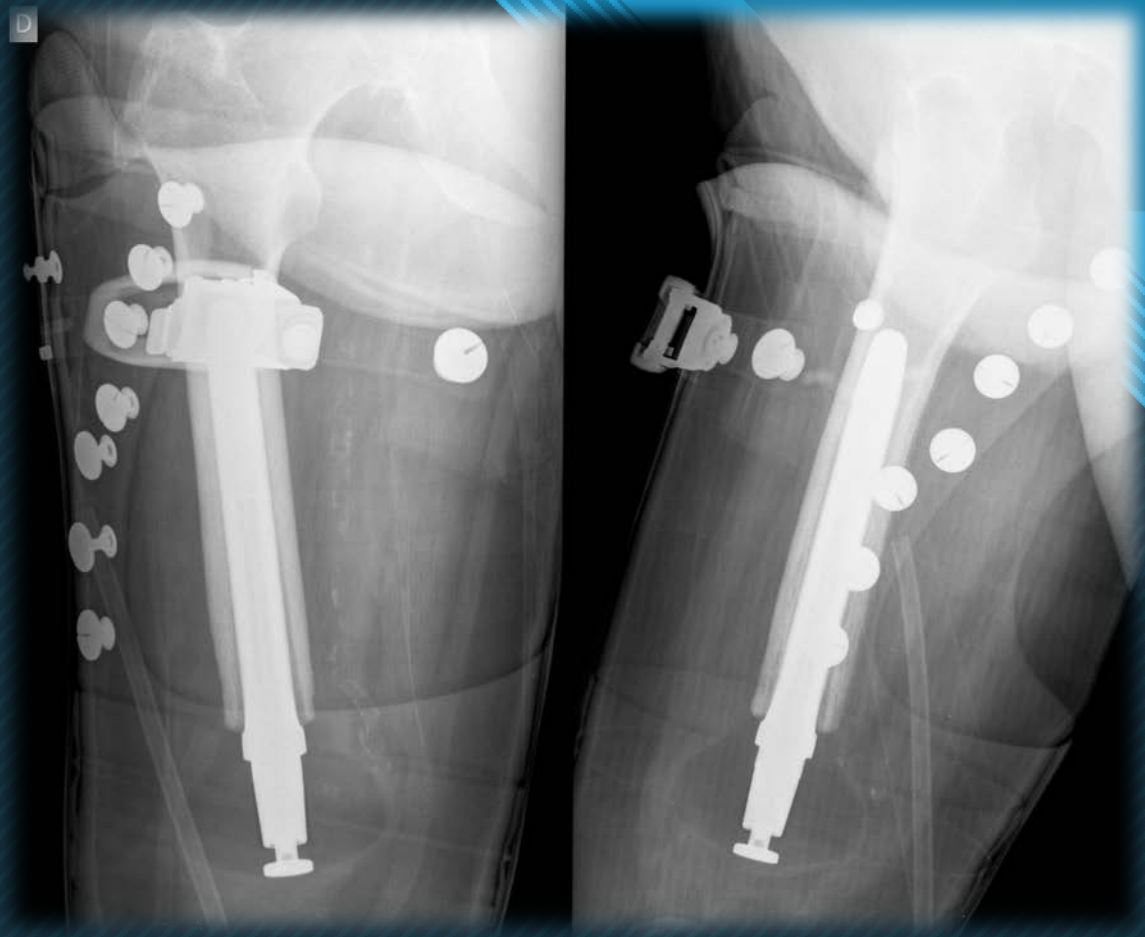


Characteristics/Benefits

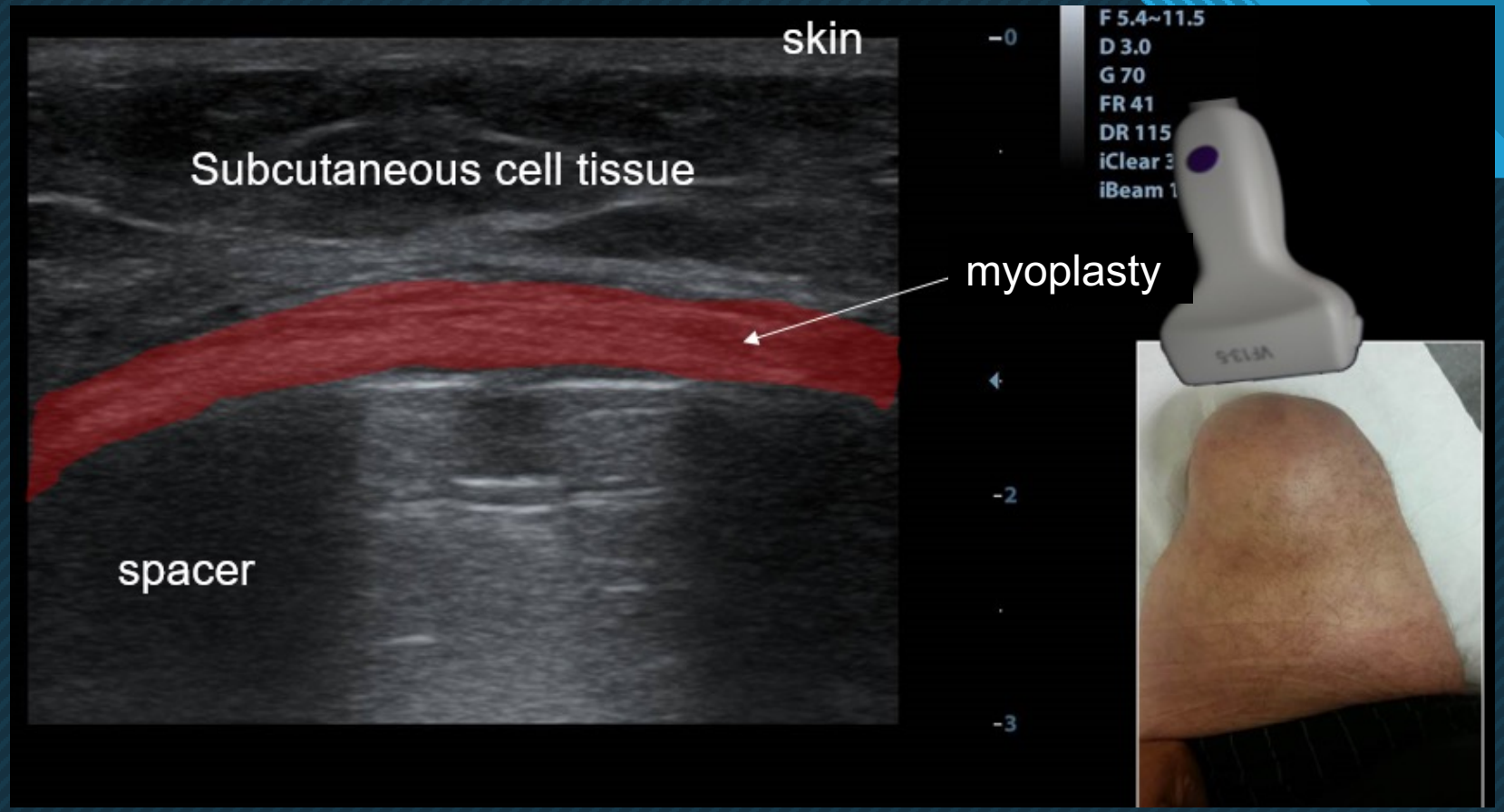
- Valid for amputees of **vascular**, traumatic, congenital or oncologic etiology
- Permits ***distal weight bearing***
- Transmits loads to the femur (better bone health)
- Permits the use of a more comfortable socket with more hip range
- Permits walking with lighter or no technical aids



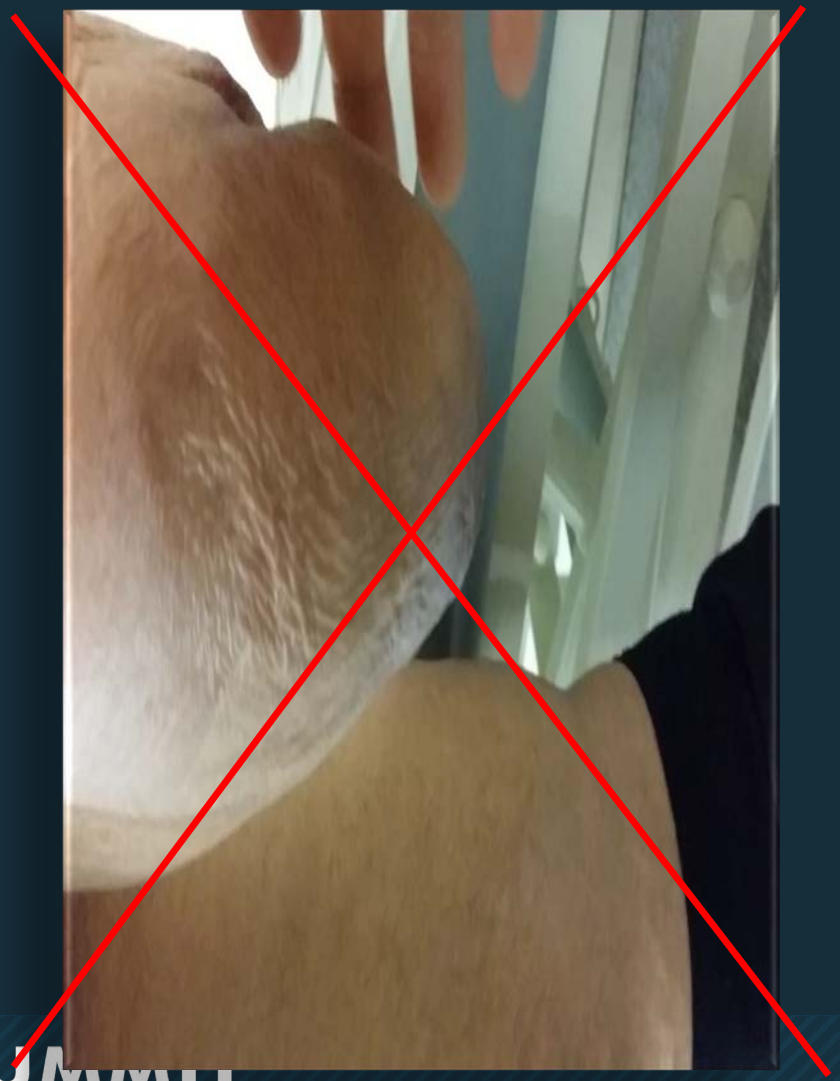
Example Case



Myoplasty


skin
Subcutaneous cell tissue
myoplasty
spacer
F 5.4~11.5
D 3.0
G 70
FR 41
DR 115
iClear 3
iBeam 1
-0
-2
-3

Keep Walking Residuum



SUMMIT ORTHOPAEDICS

Progression

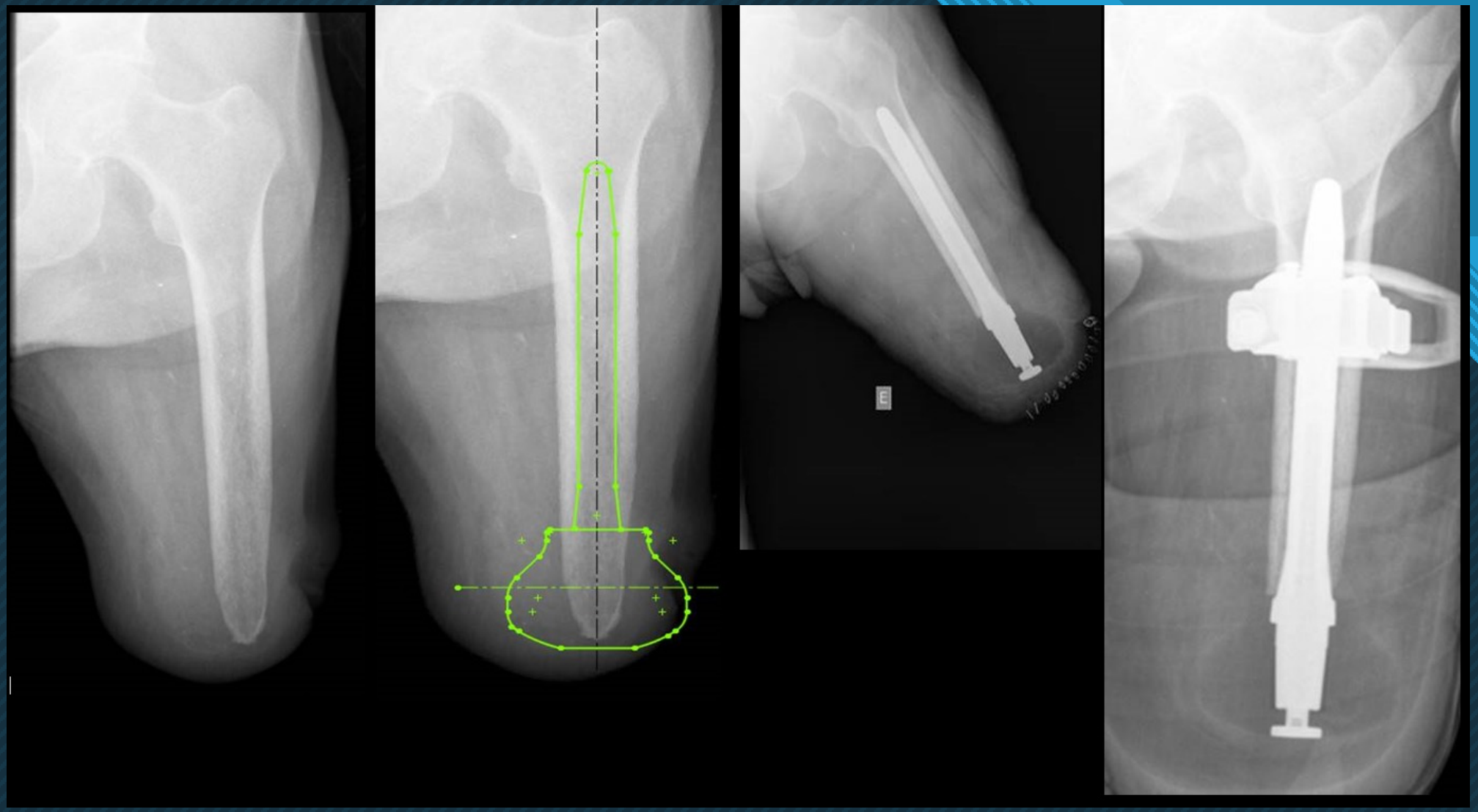
SUMMIT ORTHOPAEDICS

Rehabilitation: Socket (elastic bands)

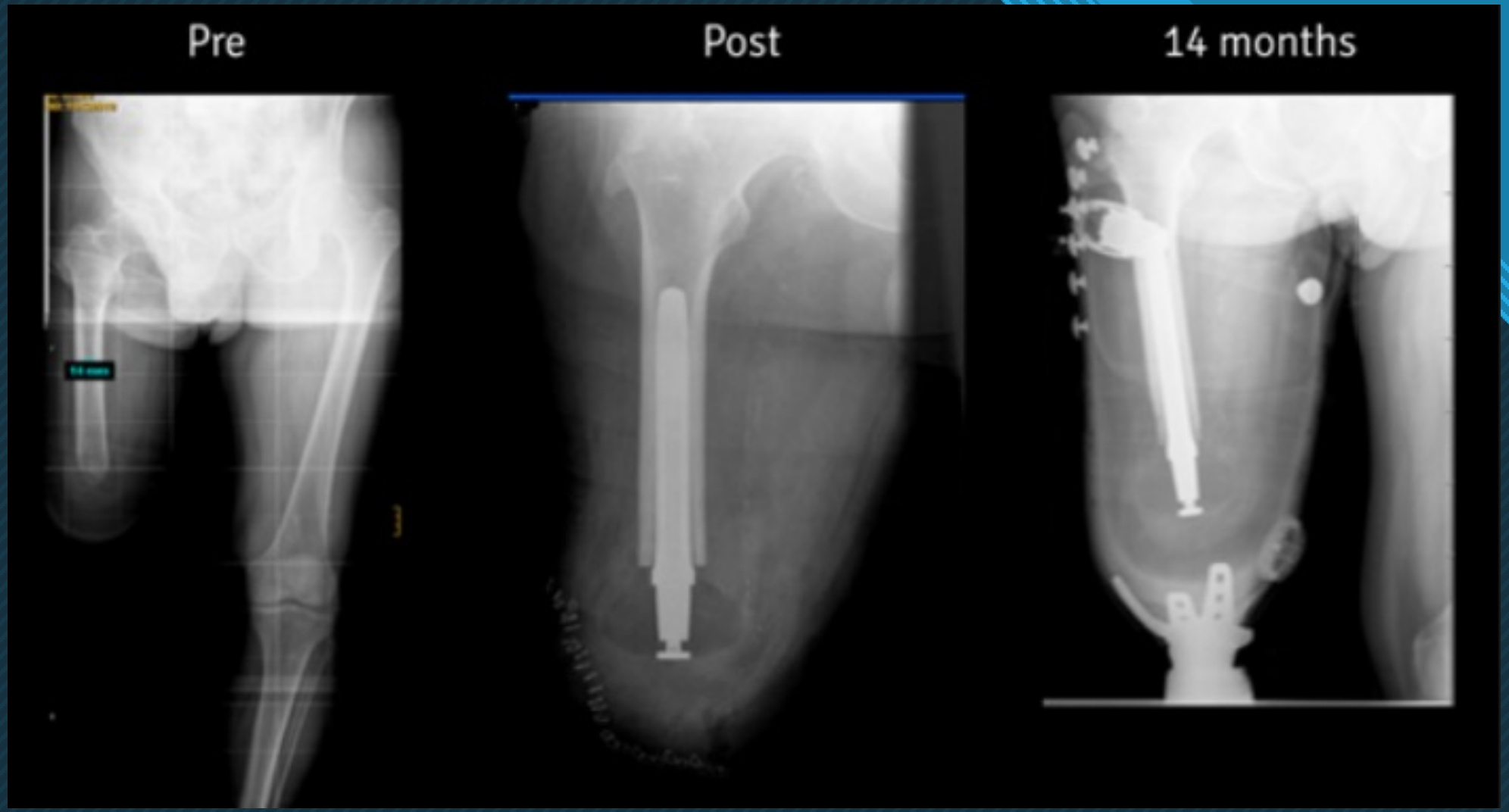
Rehabilitation: Socket
Posterior openings

Rehabilitation: Socket
Sub-ischial support

Cases

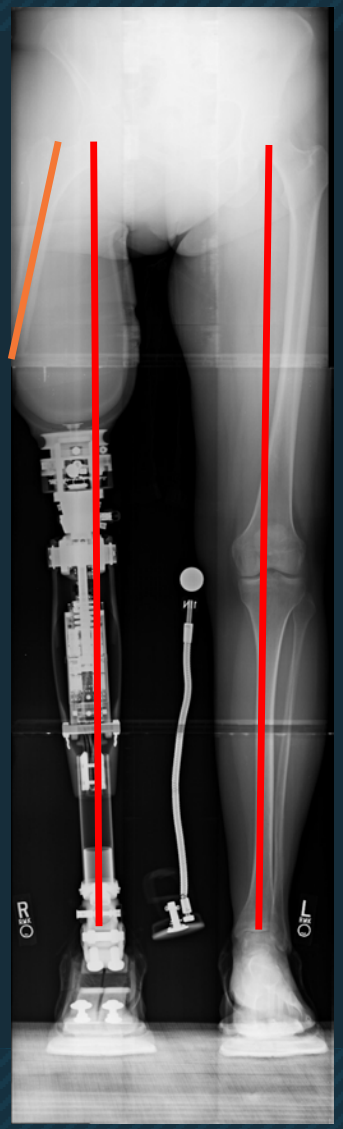


Cases

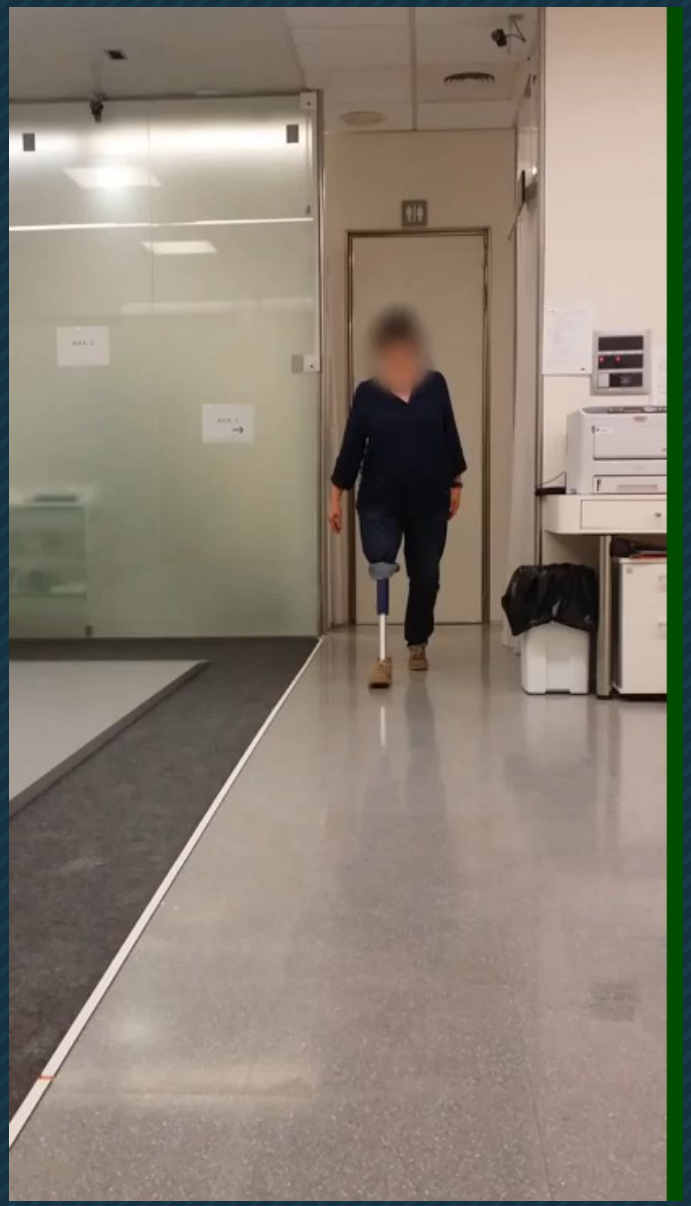


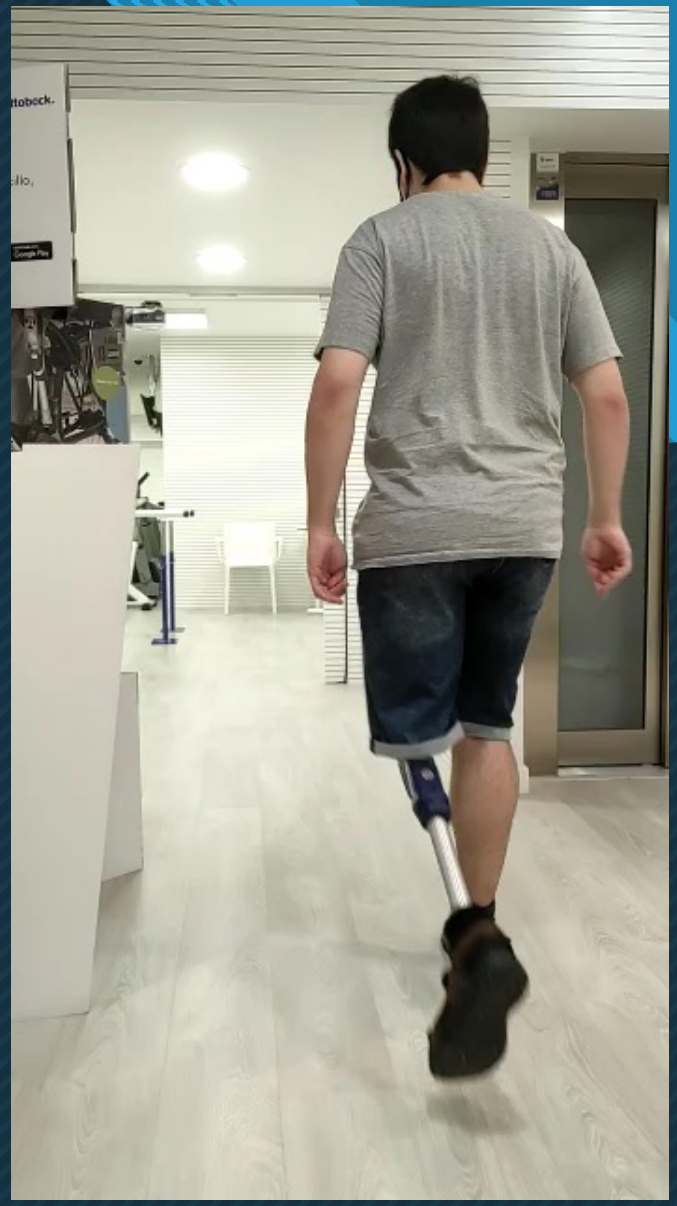
Cases

Improved Biomechanics



SUMMIT ORTHOPAEDICS





Recap

Osseointegration

- What is Osseointegration?
- Problems with Traditional Socket Prothesis
- Functional Outcomes
- Early Experience

wallace@summitdocs.com

@westcoastlengthening

SUMMIT ORTHOPAEDICS