Surgical Aspects of Osseointegration for Transfemoral Amputees

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1

Why?

2

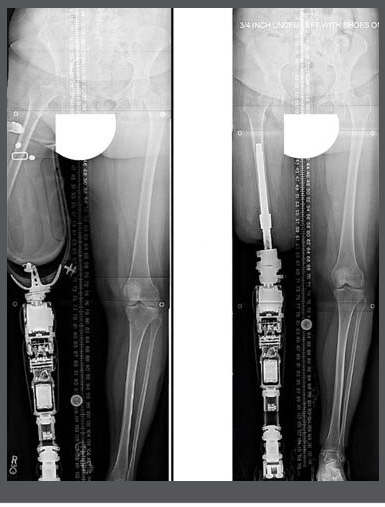
Benefits

- Eliminates intrinsic flaws of traditional sockets
  - Indirect weight bearing
  - Soft tissue shifting
  - Decreased efficiency of movement
  - Lengthy / difficult donning and doffing
- Eliminates pain associated with socket
  - Bursa formation
  - Skin irritation
  - Neuroma activation
  - Sores / wounds

3

Benefits

- Better skeletal alignment
- Reduced gait disturbance
  - Joint pain
  - Arthritis
- Improved proprioception and control
  - Increased range of motion



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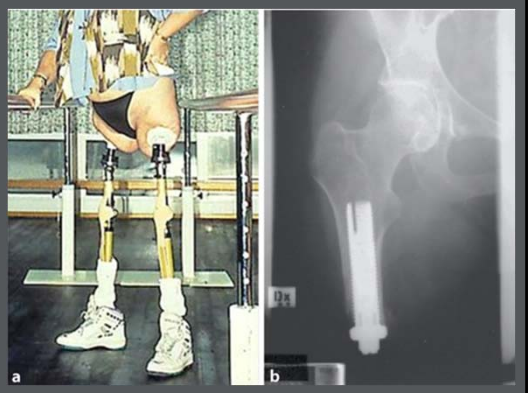
Benefits

- Allows ambulation with residual limbs that are too short for conventional sockets.
- Easy attachment / removal



Li, Y. & Brånemark, R. Osseointegrated prostheses for rehabilitation following amputation. *Der Unfallchirurg* **120**, 285–292 (2017).

5

Who is a candidate?*

- Transfemoral amputees
  - "Above knee amputation"
- Highly functional, motivated, compliant
- Difficulty using traditional prosthetic socket
- Age between 22 – 65 yrs

* In civilian population / "On-label in US"

6

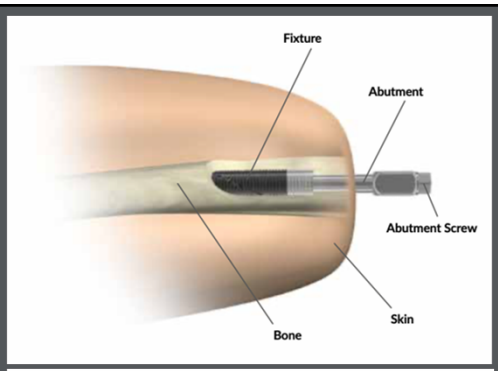
Who is NOT a candidate?*

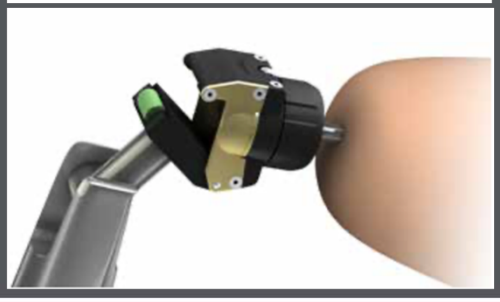
- Amputation levels other than AKA
- Bony abnormalities
- Osteoporosis
- Weight > 220 lbs
  - Including prosthesis
- Diabetes
- PVD
- Skin disorders
- Neuropathy
- Active or chronic infection
- Pregnancy
- Noncompliace

7

The device

- Fixture
- Abutment
- Connector





8

The Surgeries

Pre-op

- Pre-op visit & exam
- X-rays
- CT scan

9

The Surgeries – 1 year total process

Stage 1

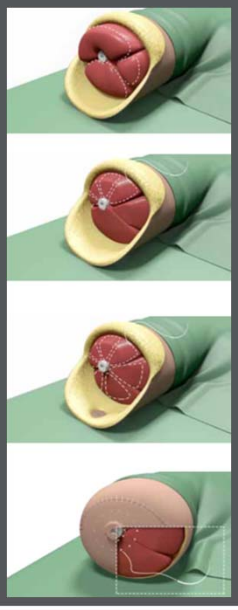
- Insertion of fixture
- Wait 6 months
- Potentially use traditional prosthetic socket during this time, depending on patient

Stage 2

- Attach abutment through the skin
- Wait 6 months
- Potentially use traditional prosthetic socket during this time, depending on patient

10

Stage 2



11

Surgical Follow-up Care

Table 1: Follow-up Times with Actions

Action	Day 21	Month 3	Month 6	Month 12	Ongoing
Amputation status	•	•	•	•	Every 6 months
Inspection of components	•	•	•	•	Every 6 months
X-ray			•	•	Years 2, 3, 5, 7, 10, 15 etc.

12

The Numbers

Improvements

- ***Cumulative Success:*** 92% at 5 years
- 89% reported daily prosthetic use
- Mean Prosthetic Use Score Increased
  - 47/100 pre-op
  - 79/100 post-op
- All quality of life scores increased significantly

Complications

- Superficial infection most common
  - Avg once every 2 years
  - Resolves with oral antibiotics
- 3/51 – Implant failed to integrate
- 1/51 – Deep infection

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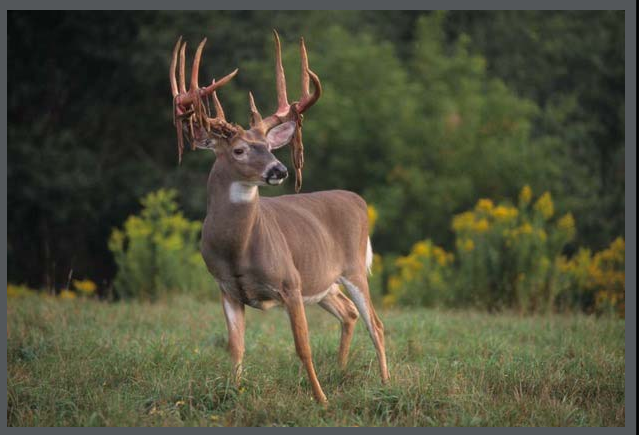
13

Challenges

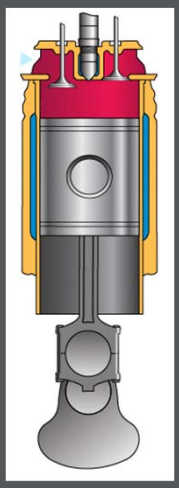
- Skin / implant interface



14

Challenges

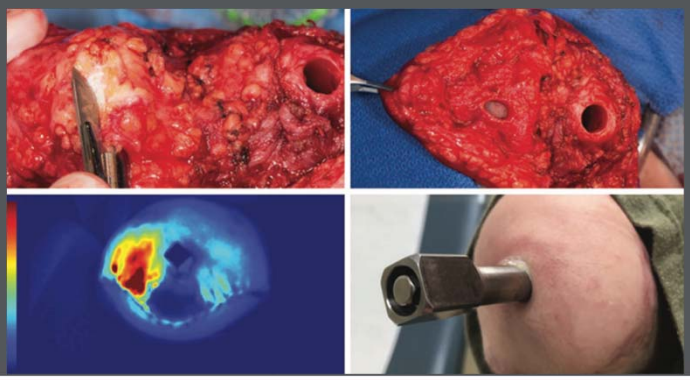
- Skin / implant interface
- "Pistoning"
- Introduces bacteria
- Causes skin irritation / drainage



15

Overcoming Challenges

- Skin / implant interface
- Skin must be aggressively thinned around implant
- Skin adheres directly to bone
- Reduces movement at interface



16

Challenges

- Skin redundancy / contour abnormalities

17

Overcoming Challenges

- ”Thighplasty” / Excision of excess tissue

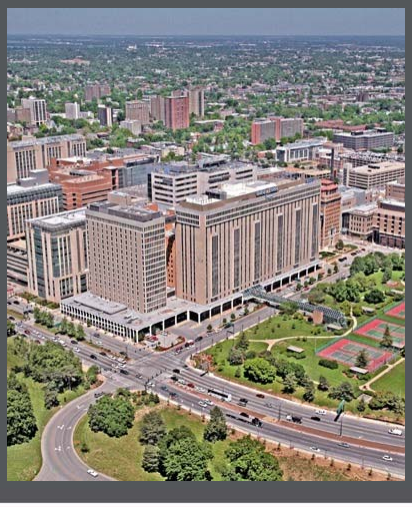
18

Summary

- Revolutionary technology to drastically improve the lives of a disabled and vulnerable population
- Outcomes depend on careful patient selection and meticulous surgical technique
- Patients with amputations due to common chronic diseases (diabetes, PVD) are not candidates
- Challenges of skin/implant interface can be managed with surgical technique
- Most complications are minor and treatable without further surgery

19

Thank you!



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20