

THIGHPLASTY PROCEDURE FOR IMPROVED PROSTHESIS FIT AND FUNCTION

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THE CHALLENGE: FAT RESIDUAL LIMBS

Facts

- 2/3 of Americans are overweight
- 1/3 are obese
- Subcutaneous fat is soft.
 - It has low compliance
 - This reduces efficiency and control of this important interface
- · Residual limbs with excess fat are more difficult to fit
 - Hard to pull soft tissues into sockets
 - Hard to grab skeletal structures
 - Distal femur
 - Ischium
- · Residual limbs with excess fat have more complications
 - Pain from tissues hanging over walls
 - Sores from walls not getting into the socket
 - Worse prosthesis control due to compliant interface
- Very few people lose significant amounts of weight



WHY NOT PERFORM SURGERY TO REMOVE EXCESS FAT?

Options:

- -Thighplasty
- -Liposuction

Change the human to better fit the technology.



COMPREHENSIVE CASE STUDY

Pre- and post-thighplasty

Obese transfemoral amputee

1. Tissue distribution

- MRI
- 2. Socket-limb stiffness
- 2 kinds of sockets tested
- 3. Comprehensive Outcomes
- Clinical, questionnaire, metabolics



TISSUE DISTRIBUTION AND SURGERY

- Patient was an overweight 50-year-old Hispanic female (adjusted BMI of 29)
- Had a right transfemoral amputation over 35 years ago secondary to osteosarcoma
- Tissue removal liposuction (2 liters; 2042 g, 4.5 lbs)
- Tissue removal medial excision (772.5 g, 1.7 lbs)
- Total: **6.2 lbs**





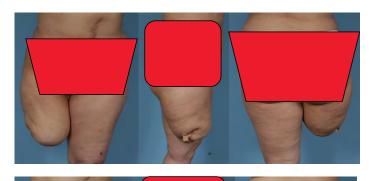




APPEARANCE

Pre

| Limb circumference | | | | |
|--------------------|-----|--------|----------------|--|
| proximal | mid | distal | | |
| 65 | 58 | 54 | cm pre | |
| | | | | |
| 64 | 55 | 47 | cm post | |





Post



APPEARANCE

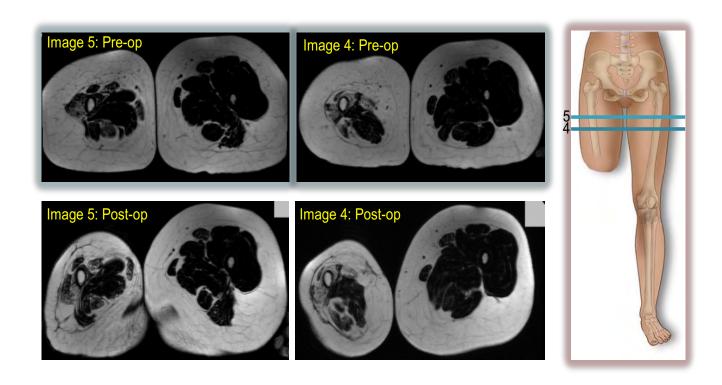


Amputated leg is now smaller than her intact limb, even with her prosthesis on.



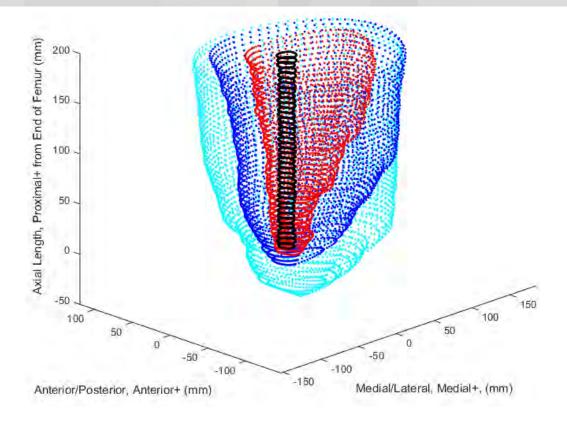


PRE- AND POST-OPERATIVE MRI





INFLUENCE ON TISSUE DISTRIBUTION



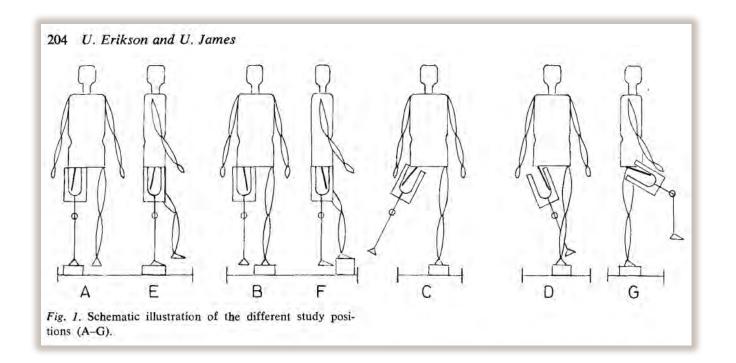


CLINICAL OUTCOMES OF PATIENT PRE- AND POST-SURGERY

| A. Clinical Outcome | Pre- Surgery | Post- surgery | % Improvement |
|--|-----------------|------------------|------------------|
| 10-Meter Walk Test (comfortable, m/s) | 0.76 | 0.80 | +5.3 |
| 10-Meter Walk Test (fast, m/s) | 1.01 | 1.01 | 0 |
| 6-Minute Walk Test (ft.) | 1202 | 1339 | +11.4 |
| 5-times Sit-to-Stand Test (sec.) | 17.11 | 12.88 | +24.7 |
| 4-Square Step Test (sec.) | 9.80 | 7.73 | +21.1 |
| 4-Square, half prosthesis inside (sec.) | 4.62 | 3.21 | +30.6 |
| 4-Square, half prosthesis outside (sec.) | 4.78 | 3.54 | +26.1 |



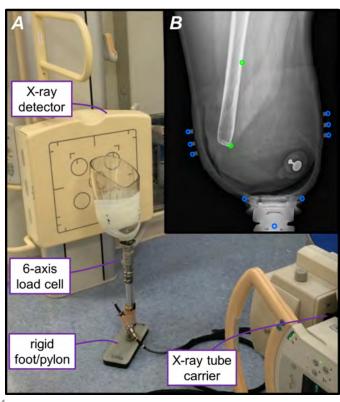
X-RAY FOR DISPLACEMENT¹



1. Erikson and James 1973



INTERFACE STIFFNESS AND INFLUENCE OF SOCKET GEOMETRY



- Isometric patient loading while weight-bearing
- 6-axis load cell
- Visual feedback of load target
- Compute multi-axis stiffness

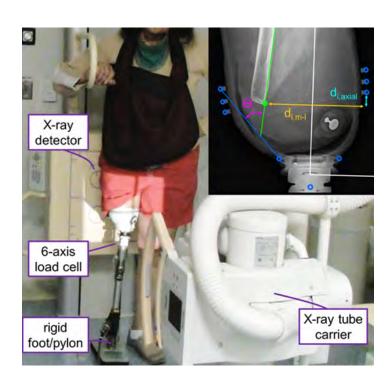


1. Fey et al. *ASB* 2015

2. Fey et al. EMBC 2015

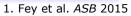


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2. Fey et al. EMBC 2015



FEMUR ORIENTATION

Ischial Containment Containment

Sub-Ischial

Pre-Op

| | Isch. | Sub |
|------|-------|-------|
| | Cont. | lsch. |
| Pre | 8.13° | 6.81° |
| Post | 4.14° | 2.09° |













PRE- AND POST- STIFFNESS DATA IN SUB-ISCHIAL SOCKET

| | Pre- surgical | Post- Surgical | Units | % Change |
|----------------------|-------------------------|--------------------------|--------|-------------|
| Axial | 19 (0.81) | 28 (2.9) | N/mm | +47.3 |
| Frontal (medial) | 160 (6.5) | 261 (13) | Nm/rad | +63.1 |
| Frontal (lateral) | 610 (38) | 545 (38) | Nm/rad | -10.7 |
| Sagittal (anterior) | 170 (5.0) | 310 (20) | Nm/rad | +82.2 |
| Sagittal (posterior) | 470 (20) | 502 (13) | Nm/rad | +6.8 |
| | | | • | |

$$K = E \frac{w_b S^3}{6(w_t - w_b)}$$

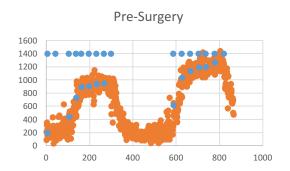
Potential influence of limb length (S^3) or E?

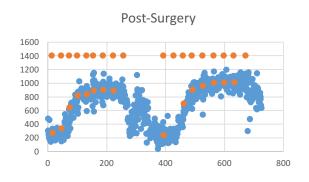


CLINICAL OUTCOMES AND QUESTIONNAIRE

| | Pre- | Post- | % Improvement | |
|---|-------|-------|---------------|--------------|
| Clinical Outcomes | | | | |
| 10-meter walk test (comfortable, m/s) | 0.76 | 0.80 | 5.3 | |
| 10-meter walk test (fast, m/s) | 1.01 | 1.01 | 0.0 | |
| 6-minute walk test (ft.) | 1202 | 1339 | 11.4 | |
| 5 times sit-to-stand test (sec.) | 17.11 | 12.88 | 24.7 | |
| 4-square step test (sec.) | 9.80 | 7.73 | 21.1 | |
| 4-square, half prosthesis inside (sec.) | 4.62 | 3.21 | 30.6 | |
| 4-square, half prosthesis outside (sec.) | 4.78 | 3.54 | 26.1 | |
| Patient Questionnaire (1-7, 1=strongly agree, 4=neither agree nor disagree, 7 | | | | |
| strongly disagree) | Pre- | Post- | Change | |
| Is your socket painful to wear? | 3 | 7 | 4 | |
| Is your socket easy to put on? | 1 | 1 | 0 | |
| Are you able to wear your socket for long periods of time? | 3 | 1 | 2 | |
| Is your socket comfortable while seated? | 2 | 1 | 1 | |
| Is it easy to go from sitting to standing in your socket? | 2 | 1 | 1 | |
| Does your socket affect your ability to walk in your home? | 3 | 7 | 4 | |
| Does your socket affect your ability to walk in the community? | 3 | 7 | 4 | |
| Does your socket affect the distance you can walk in the community? | 1 | 7 | 6 | |
| Do you feel you have good control of your prosthesis with this socket? | 7 | 1 | 6 | |
| Do you feel stable on your prosthesis with this socket? | 3 | 1 | 2 | Shirley Ryan |
| Do you like the look/shape of your socket? | 7 | 5 | 2 | Abilitylah |

METABOLIC AND SPEED OUTCOMES WITH ISCHIAL CONTAINMENT SOCKET





| | Pre | Post | Units | % change |
|-----------------|---------------------|----------------------|-----------|----------|
| E Comfortable | 8.20 (2.66) | 6.65 (1.33) | mL/min/kg | -18.9 |
| E Fast | 11.73 (3.18) | 8.03 (1.64) | mL/min/kg | -33.5 |
| COT Comfortable | 0.158 (0.05) | 0.113 (0.023) | mL/kg/m | -28.5 |
| COT Fast | 0.175 (0.05) | 0.115 (0.026) | Nm/kg/m | -34.5 |

| | Speed (m/min) |
|------------------|--------------------|
| Pre Comfortable | 51.9 (2.04) |
| Pre Fast | 67.1 (1.72) |
| Post Comfortable | 58.8 (0.63) |
| Post Fast | 70.1 (2.32) |





IMPLICATIONS

DO DATA SUPPORT THE USE OF THIGHPLASTY?

Volume and cosmesis

Fat reduction

Anatomical femur containment

Questionnaire

Walking distance, long distance

Walking speed, short distance

Maneuverability

Sit-to-stand

Stiffness

Metabolics

Yes

Yes

Yes

Yes

Yes

Same

Yes

Yes

For subischial

Yes



FURTHER IMPLICATIONS

- May allow amputees to use sockets they previously could not wear
- Shifts the focus of research from external devices to improving the human residual limb to work with a prosthesis—an area with little research to date
- Procedure may help inform future clinical care for amputees

