It is an honor and privilege today to have the opportunity to report on cutting edge research that has been underway at our own Bone & Joint Research Lab, Dept of Orthopedics UofU for the past 5 years.
Background

- “So what is the latest update with the development of osseointegration?”

I evaluated a veteran at the VA P&O clinic. Transfemoral amputee since Vietnam. Had worn various types of prosthetics over the decades. Osseointegration? What? I quickly googled the term when the patient left. I felt obligated to investigate and report to my fellow colleagues.
Osseointegration Overview

- Historical Perspective
- Definition & Applications
- Amputee Population Growth
- Conventional Socket Docking System Issues
- European Solution & Models
- US Solution & Sheep Model at U of U - VAMC
- Future Human Clinical Trials & Rehab Implications
Historical Perspective

- Per-Ingvar Branemark, of Sweden, utilized a titanium implant chamber to study blood flow in rabbit bone in 1950s.
- He could not remove the chamber because the bone had become permanently incorporated with the implant.
- He coined his discovery as “OSSEOINTEGRATION” and saw potential for human application.

At the end of his investigation, he was annoyed. But it wasn’t really put into human application until a decade later.
Osseointegration

- from Greek, osteon = bone
- from Latin, integrare = to make whole
- “the direct structural and functional connection between living bone and the surface of a load-bearing artificial implant”
- “No progressive relative movement between the implant and bone with which it has direct contact”

Branemark, R. J Rehabil Res Dev, 2001

photos: (Scanning electron micrograph showing a bone cell attaching to titanium)
Stems from....
The first definition used was....
The working and now current accepted definition is.....
Applications

- Dental Implants
- Craniofacial Reconstruction
- Bone Anchored Hearing Implants
- Knee and Joint Replacement
- Upper and Lower Limb Prosthetics

Since the 1960s, successfully used in the field of dentistry. Later applied to maxillofacial reconstruction and hearing implants and later in Hand Surgery, as well as joint replacement and most recently in upper and lower limb amputees.
Our own amputee population in the US has grown considerably since the onset of war conflict in the middle east, Operation Iraqi Freedom & Operation Enduring Freedom of Afghanistan.
Amputee Population Grows

Comparison of Death, Wounded, & Amputation Statistics in American Conflicts up to Jan 2009

<table>
<thead>
<tr>
<th></th>
<th>Deaths</th>
<th>Wounded</th>
<th>Amputated</th>
<th>Amputations / Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>OIF</td>
<td>4,301</td>
<td>31,430</td>
<td>1,112</td>
<td>1:3.9</td>
</tr>
<tr>
<td>OEF</td>
<td>714</td>
<td>3,162</td>
<td>112</td>
<td>1:6.4</td>
</tr>
<tr>
<td>Vietnam</td>
<td>58,220</td>
<td>153,303</td>
<td>5,283</td>
<td>1:11.0</td>
</tr>
<tr>
<td>Korea</td>
<td>36,574</td>
<td>103,284</td>
<td>1,477</td>
<td>1:24.8</td>
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<tr>
<td>WWII</td>
<td>405,399</td>
<td>670,846</td>
<td>7,489</td>
<td>1:54.1</td>
</tr>
<tr>
<td>WWI</td>
<td>116,516</td>
<td>204,022</td>
<td>2,610</td>
<td>1:44.6</td>
</tr>
</tbody>
</table>

Congressional Research Service Report, 2010

Historically, advances in amputation surgery have been closely linked to armed conflict, in turn, spurring improvements in prosthetic technology & care. Better surgery/sockets after WWII led to demands for sophisticated components, initially developed from govt research funding then later from private investment.
Amputee Population Grows

- ~96% of warfighters wounded in Iraq & Afghanistan conflicts survive
- From 2009 US Military Casualty Statistics Report states the amputee pop in US Military from OIF/OEF is >1,091 service members
- More than 50% were caused by improvised explosive devices (IEDs)
- Healthcare for Multiple Limb Loss and High Level Injuries

The use of advanced helmets/body armor and advanced in-field resuscitation techniques esp the use of the turniquette in the field has led to these high survival rates and ultimately high numbers of amputees. Military casualty info from DOD personnel & procurement files online = no amputee %
A recent article in USA Today discussed the growing numbers of service men and women loosing limbs to IEDs.
Prosthetic Cost Projections for Veterans of Vietnam & OIF/OEF

- National Survey - veterans from Vietnam conflict (1961-1973) & servicemembers from OIF/OEF conflict (2000-2008) were invited to participate
- Purpose - 1) to estimate cost of prostheses based on Medicare costs 2) project future costs of prosthetic devices used by two conflict-era cohorts (Vietnam, OIF/OEF)
- Participants - 298 from Vietnam (65% response rate), 283 from OIF/OEF (59%) via mail, telephone, online
- Results - estimated 5yr, 10yr, 20yr, & lifetime cost


1. purpose to provide VA clinicians and policy makers with information on recent changes in prosthetic-device utilization patterns, cost comparisons, and expert recommendations
2. results: estimated 5-year, 10-year, 20-year, and lifetime prosthetic and assistive device costs for veterans and servicemembers with major traumatic limb loss associated with combat-theater injury
3. 10-year, 20-year, and lifetime costs ranged from 2.8-fold to 6.2-fold higher for the OIF/OEF group than the Vietnam group.
1. higher costs associated with the OIF/OEF servicemembers, especially those with multiple limb loss, given the higher number of devices used and newer advanced technologies.
2. Future technologies such as the arm created by Defense Advanced Research Projects Agency (DARPA) may dramatically increase future costs.
The prosthetic arm The DEKA arm was developed at a cost of over $100 million by Pentagon as a joint project between the Defense Advanced Research Projects Agency and the U.S. Army Research Office with Johns Hopkins University over the past five years, is controlled by a microchip in the brain.

Overall, results have been disappointing in light of the millions of dollars thrown into this project because the utility and practicality of the arm for the amputee is poor.
“I use this prosthetic limb as a paper weight”
Relevant Problem:
Traditional Socket Prosthetic Docking System
Relevant Problems:
Traditional Socket Prosthetic Docking System

- Pressure Sores and Skin Breakdown
- Excessive Warmth and Sweating
- Stump Volume Fluctuations
- Muscle Atrophy
- Residual Phantom Limb Pain, Neuromas
- Heterotopic Ossification
- Non-physiologic loads lead to Osteopenia

Perceived Benefits found in most of the literature through subject surveys.
Unable to produce evidence with head to head comparison between OI amputee vs amputee with traditional socket system.
Early OA has been documented in WWII veterans. Perceived Benefits found in most of the literature through subject surveys. Unable to produce evidence with head to head comparison between OI amputee vs amputee with traditional socket system.
Loss of skin integrity can disrupt daily prosthetic use
Decrease in mobility and function
Weight gain, depression, musculoskeletal pain
15-41% prevalence rate of skin problems in amputees
Most common were wounds, abscesses, and blisters


15–41% prevalence rate appears lower than expected but lifetime risk may be much higher.
One study by Allende compared bacterial flora found on residual limb vs flora of the sound limb. All subjects wore conventional socket prostheses and reported the skin of residual limb harbored more abundant bacterial flora than the sound limb.
1. Distal Stump Edema and Hemorrhage in residual limb of a transtibial amputee
2. Contact dermatitis 2/2 use of new plastic pad at bottom of socket
1. Acute bacterial infection and abscess at distal residual limb of a 28yo patient with transtibial amputation
2. Edema, cellulitis, and pyogenic ulcer on residual limb of 50yo female diabetic patient with transtibial amputation
1. Blister on distal residual limb of transtibial amputee
2. Pretibial blister from rubbing prosthesis
Reversible verrucous hyperplasia of 2yrs duration on residual limb of 34yo transtibial amputee

1. Before appropriate intervention/compression, skin has warty appearance
2. After correction of fit and partial end-bearing compression, the skin clears
The Solution to the problematic conventional socket docking system is the: considered for amputees who have been unable to achieve a satisfactory experience with the conventional socket.
The Solution:
Percutaneous Osseointegrated Docking System

- Eliminates the need for sockets especially for short residual limbs
- Direct skeletal loading ➔ strong bone & muscle
- Reduces pain and contact with neuromas
- Decreases rate of skin breakdown
- Improves mobility of proximal joint, gait pattern

-improved suspension of the prosthesis with no functional lengthening during swing phase and a direct transmission of movements.
The Solution:
Percutaneous Osseointegrated Docking System

- Diminishes phantom limb pain
- Allows unrestricted wear time
- Enables rapid donning/doffing
- Improves comfort of sitting/crossing limbs
- Allows for osseoperception

-improved sitting esp at a low chair, ability to fully flex hip to tie shoes, improved cycling
Osseoperception will be discussed shortly but first, a video courtesy of Dr. Aschoff from Germany which shows just how remarkable the OI system is allowing for improved suspension of the prosthesis, eliminating problems with socket interface, and ease of donning/doffing.
Osseoperception

- Sensory conduction through bone
- Haroldson 1979 study of bite force and oral function established importance of sensory feedback control
- Tactile thresholds transmitted through anchoring prostheses via titanium implants
- Phenomenon NOT observed with traditional prostheses

Osseoperception

- Vibrometric analyses performed on patients with upper and lower limb amputations using a vibrometer
- 2 groups, gender, age, and amputation level matched:
  - Grp 1 - amputees with osseointegrated implants
  - Grp 2 - amputees wearing conventional sockets
- Vibratory threshold determination was carried out on the control limb & the prosthetic limb: AKA/BKAs vs contra great toe, fifth toe or metarsal; Upper limbs vs contra thumb, index, and fifth digit


the control “SOUND” limb
Osseoperception

- Osseointegrated prosthesis had similar perception of intact limb
- Conventional prosthesis ~30% less perception compared to osseointegrated prosthesis
- Fixture (abutment) perceived vibrations more strongly than intact limb
- Further Swedish studies reported similar findings


Metal obviously is a great conductor.
Existing European Osseointegrated Implant Techniques

- (1) Rickard Branemark (Sahlgrenska University Hospital in Gothenburg, Sweden)
- (2) Staubach and Grundeit, Horst-Heinrich Aschoff, MD (Eska Implants GmbH and Co, in Lubeck, Germany)
- (3) Norvert Kang and Gordon Blunn (Royal Free Hospital in University College, UK)
Existing European Osseointegrated Implant Techniques

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1. Branemark: Titanium implant is screwed into the bone shaft much like the dental implant. Rickard Branemark is the Swedish orthopedic surgeon & son of PI Branemark.

2. German design is stainless steel with cobalt chrome coating like jacks. No skin seal and serous drainage allows biofilms to form.

3. UK design is coated with Hydroxyapatite crystals which are not chemically bound and has been shown to lead to foreign body response.
European Surgical Model: Two Stage Procedure

- Stage 1: Amputation is revised & Fixture is inserted into medullary canal of bone of residual limb & skin is closed
- Stage 2 (~6 months): Abutment is inserted, muscle platform and skin flap modification are constructed

In 2009 the Swedish group reported on 100 patients with OI from 1990 to date. Contraindications: vascular disease, chemotx, immunosuppr, growing children, age>70 of the 4 not using: 2 with severe phantom limb pain, 1 with osteomyelitis, 1 with contralateral limb disability, not specified
The Swedish Report: The Problems of the Solution

- **Prolonged Rehab** (12-18 months before full weight bearing)
- **High Bacterial Infection Rates:**
  - 39 patients with UE/LE amputations
  - 5% (two) at inclusion
  - 18% (seven) at 3 year followup
  - Most common sup/deep infections were S. aureus & Coag Neg Staph

Prospectively followed a cohort of ONLY 39, why not all? not sure. They used five different definitions of implant infection including definite, probable, and possible. Very confusing. Many limitations. Short followup.

11 had local infections during 6 month period enroll; 4–6 treated with short term oral antibiotics, 14 had secretion from skin pocket; 10 patients had purulent secretion
## The Swedish Report: The Problems of the Solution

<table>
<thead>
<tr>
<th>Type of Infection</th>
<th>Initial assessment</th>
<th>Follow up (2-3 years)</th>
<th>% Infection (inclusion)</th>
<th>% Infection (follow-up)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible/probable implant infection</td>
<td>2</td>
<td>6</td>
<td>5.1</td>
<td>17.1</td>
</tr>
<tr>
<td>Local soft tissue infection in the skin penetration area</td>
<td>7</td>
<td>11</td>
<td>17.9</td>
<td>31.4</td>
</tr>
<tr>
<td>Superficial colonization without signs of infection</td>
<td>23 (24)</td>
<td>16 (17)</td>
<td></td>
<td>45.7</td>
</tr>
<tr>
<td>No growth of bacteria or signs of infection</td>
<td>7 (12)</td>
<td>2 (4)</td>
<td></td>
<td>5.7</td>
</tr>
<tr>
<td>Lost for follow up</td>
<td></td>
<td>4</td>
<td></td>
<td>10.8</td>
</tr>
</tbody>
</table>

Calculated from Table 1 of Tillander et al, *Clin Ortho Rel Research*, 2010

Local Researchers are more interested in local soft tissue infection report which was roughly 30%. In fact, similar infection reports from Germany.
Branemark Rehab Protocols
Normal Speed

- Initial 1-2 weeks, patients are immobilized for skin healing
- at 2 wks, ROM exercises to prevent joint contractures
- at 4-6 weeks, light axial weight-bearing and weight-shifting standing on short training prosthesis for total 5-6 wks
- Start at 20kg, performed 2x/day for 30mins; increase by 10kg/wk
- Pain recorded at VAS level 2-3 is safe; VAS >5 activity avoided
- Prosthetic gait training begins 12 weeks with double support
- at 6 months, Xrays/clinical status determines ambulation wo aide
- Total Protocol: ~12 months from S1 to unrestricted prosthetic use

Besides infection, another shortcoming is their long duration rehab protocol. During the first 5 years, rehab process was not standardized. In 1999 they developed a treatment protocol called OPRA (Osseointegrated Prostheses for the Rehabilitation of Amputees)
Branemark Rehab Protocols

Half Speed

- Reserved for patients with poorer bone quality
- Partial weight bearing is increased at slower rate
- Gait training with prosthesis and double support crutches starts at ~6 months
- Gradually advanced over next 4-6 months
- VAS pain is maintained < 3
- Total Protocol: ~18 months from S1 to unrestricted
The German method calls for a very aggressive and dangerous coating. The bone actually gets so deeply imbedded into these “jacks” that retrieval of the implant after complication is devastating. Ultimately, the German group has a poor design for removal.
For a patient with a short residual limb, an osseointegration implant complication leading to implant removal and ultimately higher bone resection can be devastating.
The German Report:
The Problems of the Solution

Infection, Device Removal, & Surgical Revision

Courtesy of: Drs Aschoff & Clausen, Lubeck, Germany
The German Report: Results To Date

- Total 54 patients/56 transplants from 2003-2011
- Subjects: Avg age=32.6
  Etiology: Trauma=40, Tumor=6, Other=8
- Outcomes: 9 early soft tissue infections, 9 late soft tissue infections, 17 stoma problems w/o infection, 1 failed implant, 5 fractures; 100/212 surgical interventions were unscheduled
- QOL questionnaire: 51/54 patients would decide again to have implant placed

They attributed the 1 failed implant to wrong patient selection and wrong indication who was a 47yo male who had h/o tumor at age 14. Theory was thinning of cortical bone due to arrest of appropriate bone growth during adolescence
We’ll speak in more depth on the importance of design. Removal of the smooth metal is key. They have taken steps to include quality improvement including development of a Patient Registry, QOL questionnaire, and gait analysis.
Smooth with HA crystals & pores. Evidence that if not chemically bound, the HA crystals shower off in 1–2 yrs, cause a foreign body reaction. No infection to date but 4/5 required reconstruction and Bone cement use which now does not meet the definition of osseointegration if there is not an intimate adherence of bone to implant.
The English Report: 
The Problems of the Solution

- 11 subjects with transfemoral amputations underwent osseointegration in UK
- 5 abutment failures required replacement
- 2 (18%) required removal 2/2 infection during 5 year period
- Negative aspects included the multiple medical visits and slowness of rehabilitation program

Sullivan J, Prosth Orth Int, 2003

5 abutments replaced due to mechanical deformation following falls; 2 of 5 cases the abutment fractured. No implant damaged.
9 of 11 are using OI prostheses all day every day.
Sullivan out of UK has since aborted this OI project 2/2 to multiple complications/infxn’s
Utah Research Team
Members

- Roy D. Bloebaum, PhD
- Kent Bachus, PhD
- John Hibbs, MD
- Larry Meyer, MD, PhD
- Joe Webster, MD
- James Peter Beck, MD
- Brad Isaacson, PhD
- Dustin Williams, BS
- Kristofer Sinclair, PhD
- Aaron Hofmann, MD
- Charles Saltzman, MD
- Douglas Hutchinson, MD
- Ray Olsen, MS
- Sujee Jeyapalina, PhD
- Brian Holt, PhD
- Sarina Sinclair, PhD
- Catherine Loc Carrillo, PhD

Bone and Joint Research Laboratory, part of the Dept of Orthopaedic Surgery, Univ of Utah
Utah Research Disciplines

- Anatomist
- Implant Designers
- Technicians
- Prosthetists
- Bioengineers
- Mechanical Engineers
- Physical Therapists
- Orthopedic Surgeons
- Infectious Disease
- PM&R
- Veterinary Medicine

Multi-Disciplinary Team Approach
RESEARCH GOALS:

- Follow Scientific Method
- Introduce Osseointegration SAFELY into the United States

Plus, Used years of bone and joint research to guide their design and study which the Europeans have ignored
RESEARCH GOALS:

- Answer the Unanswered Questions.....
- What is happening at the skin surface?
- How fast does OI occur?
- What happens to bone over time?
- Can we prevent periprosthetic infection?
- Can we reduce rehab time?
- Is single stage surgery possible?
- When is it safe to bear full weight?
- What is the construct pull out strength?
- Does implant design impact bone ingrowth & skin attachment?
The sheep model was chosen because bone remodeling is similar to humans. A 220lb animal that bears 60% of its load through the forelimb, 40% in hindlimb, approximately 600-1000lbs of load.

With the large animal model, they have achieved showing:

- Direct load bearing
- Bone integration
- Skin-seal
- Infection was prevented
Objectives

- Infection Prevention materials and methods validation on a larger animal model
- Tissue Compatibility evaluation of osseointegration on a sheep model
- Biomechanical Testing for implant attachment strength (load bearing and strain tolerance) & gait analysis
- Histopathological Examination to characterize the structural and mineral changes of the host bone

1. PROVE
2. DEMONSTRATE
3. PERFORM
4. PERFORM
Nature’s model: the deer antler

- Antlers are a natural analogue of transcutaneous implants
- Pedicle is subcutaneous living bone that undergoes continuous remodeling throughout the antler cycle
- Marsupilization phenomenon observed in transcutaneous implants
- Dermal tissues adhere to the pedicle with strength to prevent infection, marsupilization, and ultimate failure of soft-hard tissue interface


1. because they have successfully overcome the problems associated with penetrating the skin barrier.
2. Pendergrass et al reports how the adaptations of the deer antler can be mimicked to develop a successful amputation prosthesis design
3. Marsupilization results from epithelial cell migration causing downgrowth around the skin-penetrating object to re-establish continuity in the skin layers
Nature’s model:
the deer antler

- Surface of pedicle is highly porous, significantly higher # than antler proper \((P<0.05)\)
- Mean pore diameter of Pedicle 217 \(\mu m\) +/- 19 VS Mean pore diameter of antler 40 \(\mu m\) +/- 3 \((P<0.05)\)
- Successful use of deer antler as biomimetic model for development of intraosseous implant

Porous Coating: “The Velcro Effect”

Similar to the 2 distinct pore size populations of the deer antler (40 - 240 µm)

Implant Design: Infection Prevention

Figure 2. Epithelial downgrowth adjacent to smooth post with keratin-filled gap and fibrous capsule adjacent to smooth disk (10x). Fibrous capsule adjacent to porous disk (10x).

Figure 3. A. Fibroblasts and collagen fibers directed into pore (red arrow) (10x). B. Adipocytes and fibroblasts seen within pores (10x). C. Vasculature seen within pores (red arrows)(10x).
Implant Design:
“Fit & Fill” Model

Zone 1 is the distal tip, the guide zone. Narrows to avoid too much contact to prevent hypertrophy.
Zone 2 is the mechanical interlocking zone which is fluted and allows for immediate attachment.
Zone 3 is the mechanical capture for bony ingrowth, the interface for the cancellous bone.
Implant Design:
“Fit & Fill” Model

Radiograph during the implant design stage.
Study Design:

**Porous Implant**

- Time “0”  
  $n = 12$
- 5-month group  
  $n = 21$
- 6-month group  
  $n = 16$
- 9-month group  
  $n = 14$
- 12-month group  
  $n = 14$

**Smooth Implant**

- 9-month group  
  $n = 9$
Study Design & Methodology

- Ongoing clinical monitoring for infection/pain
- Serial radiography
- Serial histological evaluation of the tissue-implant interfaces
  - ABI (appositional bone index)
  - MAR (mineral apposition rate)
  - Porosity
  - Bone Ingrowth
- Serial gait analysis
- Biomechanical testing ➔ serial pull-out strength

Now let's take a closer look at Single Stage Surgery in the sheep model
Single Stage Amputation & Implantation Surgery
Results

Finished Product
Draw a line to make the axis and top dot does not move. Motion is limited.
On smooth, all 3 dots move away from the axis line. They achieved Immediate skin capture.
Collagen fibers showing immediate capture to porous implant
Rate of Migration
Time at 9 months

Porous 0.56mm/month VS Smooth 2.10mm/month

Rate of epithelial cell migration downgrowth/ “marsupialization”
Infection Rates:
Porous vs Smooth
Survival Rates
Smooth vs Porous

Smooth group was N=9, now N=8 after 1 perioperative fracture. So at 9 month follow up, 2 of the 8 sheep had an infection at implant site. So the team has been able to show a positive infection signal in the control group to prove infection prevention in their porous implant design.
# Infection Rates: Porous vs Smooth

<table>
<thead>
<tr>
<th>Sampling site</th>
<th>Group I (Time 0)</th>
<th>Group II (3-month)</th>
<th>Group III (6-month)</th>
<th>Group IV (9-month)</th>
<th>Group V (12-month)</th>
<th>Group VI (9-month control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin-implant interface</td>
<td>Porous coated implants</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Skin</td>
<td>Colonized Infected</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tissue</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2.3%</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood</td>
<td>-</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
Gait Analysis

- Record data at Time 0 (Pre-operative Eval)
- Data at 1, 2, 3, 6, 9, and 12 months post-surgery

The sheep are bearing weight as soon as the anesthesia wears off. Many are angry and banging their limb right away. One of the subjects jumped 3 1/2 feet out of the rink and didn’t harm the implant fixture or abutment piece.
Stride Length & Stance Phase

Conclusion: NO LIMP postoperatively

Essentially the same, no change.
Matches the human amputee loading of residual limb vs sound limb ~ 80% of full wt bearing
Peak vertical force distribution in Right Forelimb with OI implant (PVF postop as a percentage of preop) with statistical significance showing >>>>>>>>
Zone 1 is the distal tip, the guide zone. Narrows to avoid too much contact to prevent hypertrophy.
Zone 2 is the mechanical interlocking zone which is fluted and allows for immediate attachment.
Zone 3 is the mechanical capture for bony ingrowth. The interface for the cancellous bone.
Bone Ingrowth Analysis:
Porous Coated Region

White is titanium. Gray is the layering of osteoblasts remodeling and filling.
Black is the bone marrow.
Most Ortho research labs do histo and not BSE. BSE allows for precise thin slices; electrons penetrate up to only 1–5 microns.
Plateaus roughly 3–6 months and may imply full weight bearing much earlier than the European models; ~6wks partial loading with gait aid, 12 weeks full wt bearing
Also matches human models from Bone & Joint Literature
Biomechanical Testing:
Pull-out Strength

Force displacement curve shows the force in newtons to displace the implant in mm which 5000 newtons equates to 1000lbs of force.
This pull out force patterns the in-growth
Perhaps more aggressive rehab at 6 month mark
Conclusions from the Sheep Model

- No porous implant related infections despite living conditions
- Single Stage Surgery is successful
- Skin Seal at the skin-implant interface is critical
- Histology and Biomechanical Testing support use of the porous coated implant design
- Biomechanical Testing demonstrates successful weight-bearing and function

Though the porous implant did not prevent marsupialization, it did limit its progression compared to smooth implant model. The 2nd generation of sheep will be followed out until 24 months to follow the true progression of marsupialization.
Prospective Survey Study
Perceptions & Acceptance of OI in Lower Limb Amputees

- Ages 28-65 with Lower Limb Amputations (TT & above)
- Excluded if not used prosthesis in last 3 months
- 73 surveys completed (78% TT level, 74% used prosthesis >8hrs/day, 50% long-distance community ambulators, 61% no assist device)

Survey Results
Would you consider OI?

35% - Yes
41% - No
24% - uncertain


Subjects with following characteristics were more likely to consider OI:
Pain interfering with activity level (P=0.038); Difficulties with prosthesis falling off (P=0.007)
Living in rural location (P=0.004)
Our population reported a high incidence of skin breakdown with 24% of the population reporting skin breakdown at the time of the survey and 62% reporting skin irritation and skin breakdown during the past year. The lack of a correlation between skin breakdown on the residual limb and acceptance of osseointegration, however, was somewhat surprising to the investigators because it is anticipated that reduction of residual limb skin breakdown will be one of the primary benefits of the osseointegration suspension technique, because it will eliminate the need for the prosthetic socket interface with the residual limb.
Next Stage: Human Clinical Trial

- The Bone & Joint Research Lab has FDA approval for a feasibility trial
- The team will select 10 patients to implant the OI systems by May 2013
- The FIRST human study in the VA since the 1970s
- The FIRST to perform osseointegration in the VA System
- SLC VAMC will be the major clinical training center for Osseointegration

The Feasibility trial allow the team to move forward to initiate human clinical trials while the device implant is still being refined. The 2nd generation of sheep will be followed out until 24 months to follow the true progression of marsupialization.

Department of Defense has approved their intent for human clinical trial and is hoping for financial support which would help the VAMC acquire a gait lab; Goal to start with 10 patients and grow to 300 patients in 3–4 years after expanding to include other surgical centers across the nation.
Human Clinical Trial: Roles for Rehab

- Clearly define subject selection criteria
- Consider premorbid exercise program
- Serial Radiographic analysis
- Rehab Protocol for successful implantation

1. bone length, bone quality, bone maturation, amputation level, gait analysis, infection history b/c potential candidates wishing to improve their gait pattern may be disappointed
2. comorbidities – medical (diabetes, body mass, vascular disease) and psychological
Human Clinical Trial: Roles for Rehab

- Monitor load: stationary scale vs. patient perception
- Vibration & Electrical Stim Therapy for bone health
- Skin & Infection monitoring
- Gait training & Analysis
Potential for Ongoing Research Opportunities Are Endless

- Develop Endoprostheses with Neuro-Controlled Myoelectric Component
- Protect implants with an Overload Protection Device
- Monitor implants with Rotasafe Device to protect the abutment and internal fixture from excessive torsion

Potential for **Ongoing Research**

“Intelligent Implants”

- Biological monitors for:
  - Infection
  - Blood Flow
  - Biofilm
  - Skin Downtgrowth

- Mechanical monitors for:
  - Loads
  - Accelerations
  - Loosening
  - Gait analysis
The Future of Amputee Care Is In Our Own Backyard
SPECIAL THANK YOU TO...

-Dr. Roy Bloebaum & the Bone & Joint Research Lab

-Dr. Joseph Webster
References


References


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Questions?