



# Osseointegration

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**Osseointegration Work Group Summary**  
**VA/DOD Prosthetic Meeting**  
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# Statement of Problem

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- Residual limb comfort and the prevention of skin injury are the two most important issues that amputees experience.
- Current socket designs and interface materials although an improvement over those of the past continue to be limited.
- From an administrative perspective the resolution of these needs must be balanced by the multiple domains of need the amputee experiences, including psychological, novel prosthetic components, pain management, limb salvage and prevention of secondary disability.

# Aspects of Osseointegration Considered

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- Immediate Clinical use of osseointegration in VA/DOD
- Pilot Clinical Research Procedure
- Basic Science Research

# Clinical Osseointegration

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- Not Recommended
  - Primary amputation procedure (revisions only)
  - Need for further research
    - Better Outcome Data
    - Safety
    - Efficacy
    - Cost Effectiveness

# Pilot Clinical Research Study

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The primary population would be Transfemoral Amputees  
- greatest experience

Secondary populations would likely be Transhumeral,  
Thumb

# Pilot Clinical Research Study

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## First Step

Implement a Survey of VA/DoD Transfemoral Amputees

–Survey of potentially eligible VA/DOD population.

- Define the scope of the problem
- Define the potential population who might benefit
- Necessary background data to obtain an FDA Investigational Device Exemption (IDE)

# Survey Population

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- It has been used as a secondary procedure for those who have been a “failure” of conventional treatment.
- Veterans with traumatic injury Vietnam, ?Korea.
- Retired military with traumatic injury.
- Few who MVA, motorcycle other trauma while in the service.

# Survey Content

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- Prosthesis Use
  - Time, frequency, duration
  - Prosthesis Satisfaction (PEQ?)
  - Ease of donning doffing
- Mobility (Stanmore Mobility Scale)
- Quality of Life Measure

# Pilot Clinical Study

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- Structure
- Population
- Research Design
- Outcome Measures

# Structure

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- Establish a limited number of Clinical Osseointegration Centers
  - ? East Coast, West Coast
- Training
  - Team (PT, Prosthetist, Rehab, Surgeon) go to Goteburg to develop the skills and necessary program.
  - Dr. Branemark comes to US once subjects are identified to provide direct training of surgeon.

# Population

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- **Transfemoral Amputees**
- Not done as a primary procedure but for those who are “failures” of conventional treatment.
  - Questionnaire
  - Prosthetic Evaluation
  - Team clinical Evaluation
- This would indicate possible candidate.

# Population

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- Exclusionary Criteria
  - Poor bone density
  - Abnormal skeletal anatomy
  - Psychiatric diagnosis
  - Surgical Medical -----Excess surgical morbidity mortality
  - History of non-compliance with treatment program
  - Diabetes, PVD, Immuno-incompetence

# Study Design

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- Measure the effect in subject population before treatment/during treatment/after treatment.
- Control group with intensive prosthetic fitting and provision of optimum components, with physical therapy for gait training strengthening, conditioning, ROM.

# Outcome Measures

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- Pain (Numerical pain rating scale)
- Pain (functional social impact of)
- SF-36
- Quality of Life
- Stanmore mobility scale
- Gait Analysis/ $\text{VO}_2$
- Step Activity
- Balance (Kenton Kaufman)
- Cost/Benefit Analysis
- Body Image/Social Role Functioning

# Basic Science Research

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## Establish an Osseointegration Basic Science Center of Excellence

- Bone/Implant Interface

- Goal- Accelerate the time frame of osseointegration to reduce the time interval of the intervention.
- Accelerate the rate of bone adaptation.
- Strut mechanism to accelerate loading.
- Needs for accurate evaluation of integration and bone adaptation.

- Skin/Implant Interface

- Lack of consensus whether this is a problem.
- Goal - develop a new tissue engineering approach to eliminate the potential for ingress of bacteria.

# Bone/Implant Interface

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- Accelerate the rate of osseointegration and bone adaptation.
  - Pharmacologic
    - BMP Bone morphogenic protein
    - MMP matrix metallo-protein
    - Cytokines
  - Physical
    - US, Pulsed EM Fields, DC current, physical loading

# Skin/Implant Interface

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- Difference of opinion
  - ?If sound integration no risk of osteomyelitis.
  - ? Tissue engineering to develop an interface where there is integration of the skin and the implant.

# Summary

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- Persistent residual limb pain is a problem for lower extremity amputees.
- Preliminary published results are limited.
- These data suggest the potential for substantial benefit but not without risk.
- The potential benefits suggest that further work should be done to evaluate its efficacy with established outcome measures.
- Additional Basic Science research could expand its safety and make it a much more broadly used therapeutic tool.