Advances in Rehabilitation following Extremity Trauma and Amputation

2013 University of Utah PM&R Update Conference

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Presentation Goal

Appreciate the impact of recent rehabilitation advances on the management of extremity trauma and amputation.
Presentation Overview

• Problem / Population

• Advances in Care
  – Systems of Care
  – Prosthetic Technology
  – Amputation Care
  – Limb Salvage Management

• Future Considerations
Extremity Trauma

- Pattern and severity of combat injuries have changed over time.
- Personal protective equipment has mitigated head, eye and torso injuries. Extensive burn injuries have diminished.
- **Extremity trauma is the most common combat-related injury.**
- Majority of these injuries result in significant impairments and associated functional limitations.

*DCBI Task Force Report; June 16, 2011.*
Dismounted Complex Blast Injury (DCBI)

- DCBIs - high-energy blast exposures to dismounted Soldiers
- Increase in volume of DCBI since Summer 2010 in ATO
- Typically involve both LEs and non-dominant UE
- Open pelvic fractures, abdominal and GU trauma also common


*DCBI Task Force Report; June 16, 2011.*
Extremity Trauma

- Initial / early management must prioritize life-saving intervention

- Longer-term functional outcomes are secondary considerations

- Advances in the surgical and rehabilitation care of limb salvage and amputation have complicated extremity trauma decision-making and management
Limb Salvage

- No consistent definition
- Injury typically involves at least 3 of 4 systems (soft tissue, bone, nerves and vessels)
- Requires advanced surgical interventions in order to avoid amputation

Limb Sparing and Salvage

- 4 severe extremity injuries for every major limb amputation
- 1/7 who undergo limb salvage efforts, one will ultimately undergo a late amputation

Limb Salvage

• Limb salvage considerations different for the upper limb

• More reasonable to advocate for limb salvage in the upper limb even if minimal residual motor/sensory function possible

• Upper limb with severe limitations may be more useful than prosthetic device

Combat-Related Amputations

- 1581 OEF/OIF/OND Servicemembers have sustained combat-related major limb amputations as of January 1, 2013
- 30% have multiple limb amputations
- 17% have upper limb amputations
Percentages of Veterans Who Transitioned to VA Health Care within the First 5 Years after Discharge, by Amputation Status.

Graph showing the percentage of veterans transitioning to VA health care over the first 5 years after discharge, categorized by amputation status.
Trauma Associated Injuries

- Combat-related amputations are associated with moderate to severe injury severity scores (Scores in the 9-15 range).

- Higher Injury Severity Scores associated with: upper extremity, more proximal, and bilateral amputations.

- Commonly associated injuries include: TBI, extremity injuries, burns, vision and hearing loss.

References:


Trauma Associated Injuries
Mental Health Considerations

- PTSD 66%
- Depression / Adjustment Disorders 46%
- Anxiety Disorders 38%
- Substance Abuse 16%

- Some association with co-morbid injuries, injury severity, but not necessarily with the number of limb amputations (50% with multiple limb loss report a better QOL)

JRRD. 2010;47(4):373-86.
DoD System of Care

• Implementation of a formal military trauma system with evidence-based practices including:

• aggressive tourniquet use
• early use of fresh whole blood and blood products
• hypothermia prevention and management
• damage control resuscitation and surgery
• rapid strategic evacuation (STRATEVAC)
• comprehensive and multidisciplinary approaches to pain management and rehabilitation

DoD System of Care

- **Military Advanced Training Center (MATC)**
  Walter Reed National Military Medical Center (WRNMMC)

- **Comprehensive Combat and Complex Casualty Care (C5)**
  National Naval Medical Center San Diego

- **Center for the Intrepid (CFI)**
  San Antonio Military Medical Center
VA Amputation System of Care

- Implementation began in 2008 with the purpose to enhance the environment of care and ensure consistency in the delivery of rehabilitation services for Veterans with amputations

- ASoC provides specialized expertise in amputation care incorporating the latest practices in medical rehabilitation, therapy services, and prosthetic technology

- Be a world leader in providing lifelong amputation care
ASoC Organizational Components

Regional Amputation Centers - RACs (7)
- Medical Director
- Amputation Rehabilitation Coordinator
- Program Support Assistant
- Prosthetist

Polytrauma Amputation Network Sites - PANS (15)
- Amputation Rehabilitation Coordinator
- Program Support Assistant

Amputation Clinic Teams - ACTs (111)

Amputation Points of Contact - APOCs (22)
Amputation Specialty Accreditation

- CARF Amputation Specialty Accreditation established in 2008
- 17 of 22 VA Regional Amputation Centers (RACs) and Polytrauma Amputation Network Sites (PANS) facilities have received the specialty accreditation
- VA has approx. 25% of all accredited sites across the world
DOD/ASoC Education Conferences

Improving the competency of providers, the quality of care, and the consistency of services across the System

• Orientation Meetings - 2008 and 2009

• Military Advanced Amputation Skills Training (MAAST) Course – San Diego (May 2009) with DoD

• Amputation Teams, Treatment and Technology Conference – Seattle (June 2009)

• VA Advanced Amputation Skills (VAAMPS) Course – Tampa (June 2010)

• 7 Regional Education Conferences – Each RAC (2010)

• National Education Conference – Indianapolis (July 2011)

• VAAMPS Course on Upper Limb Amputation – San Antonio (July 2012)
VA / DoD Amputation Collaborations

- Clinical Practice Guideline following Lower Limb Amputation
- The Next Step Patient Education Book
- Joint VHA/DOD Amputation Task Force / Site Visit
- Joint Incentive Funding (JIF) project
- Clinical Practice Guideline following Upper Extremity Amputation
- Extremity Trauma and Amputation Center of Excellence (EACE)
Extremity Trauma and Amputation Center of Excellence (EACE)

DEFINITION OF IOC = 50% manning at each Amputation Care Center, Directorate and Executive Office - Concept Plan submitted

DEFINITION OF FOC = 90% manning at each Amputation Care Center, Directorate and Executive Office - Concept Plan implemented

Oct 2011 Initial CONOPS submitted for review

May 2011 TSG decision to place EACE Executive Office in San Antonio

Dec 2009 EACE Interim Director Dr. Charles Scoville appointed

Oct 2009 SMMAC designates Army as DoD lead component

Congress legisitates creation of the EACE in the FY09 NDAA

DoD Amputee Care Centers established at WRAMC, BAMC and NMCSD

LTG Peake conducts initial staff estimate on the number of amputee patients expected from the war in Afghanistan

Oct 2011 EACE Director Mr. John Shero appointed

Jan 2012 CONOPS approved

Mar 2012 MEDCOM CoS Decision brief on EACE organizational elements

Oct 2012 -- Achieve IOC

Oct 2013 Achieve FOC
Benefits of MPKs: Overall Summary

- Benefit in improving safety, balance, and reducing falls
- Benefit in stair and hill descent
- Possible benefit in energy expenditure reduction
- Subjective benefit in reduced cognitive demand
- Some evidence supporting cost effectiveness

Evidence Note. Mar 2011 O&P Edge Supplement
X2/Genium by Otto Bock

- Microprocessor swing and stance control
- Hydraulic resistance in both swing and stance
- Stance control by default
- Analysis of gait at a rate of 100 times per sec
- Greater ROM to 135 degrees
- Increased battery life
- 330 pound weight limit
- 5 additional modes/X2 Running mode
<table>
<thead>
<tr>
<th>X2/Genium</th>
<th>Sensors</th>
<th>Cleg</th>
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<tbody>
<tr>
<td>X</td>
<td>Knee Angle +Velocity</td>
<td>X</td>
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<tr>
<td>X</td>
<td>Ankle Moment</td>
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<td>X</td>
<td>Axial Load</td>
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<td>X</td>
<td>Knee Moment</td>
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<td>X</td>
<td>Gyro</td>
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<tr>
<td>X</td>
<td>Two Axis Accelerometer</td>
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</table>
Stairs and Obstacle Function
Step over step stair accent and crossing raise obstacles

• Engaging Function
  • Rapid hip extension followed by rapid hip flexion
  • Knee must be fully extended with load
  • Knee blocks flexion if shank remains forward tilted

Disengaging Function
• Un-weighting the prosthesis
• Knee shank tilts backwards
MicroProcessor Foot

Motion Sensors measure stress and ankle position to determine specific moment of the gait cycle.

Microprocessor utilizes Terrain Logic™ artificial intelligence to initiate active ankle movement.

Internal Stepper Motor provides pro-active ankle movement.

Pivot Axis provides active single axis ankle movement.

Carbon Composite foot provides active energy storing function.

Rechargeable battery powers sensors, motor and microprocessor.
Biom Foot

• First prosthetic foot with propulsive plantarflexion

• 3 processors and 12 sensors allow the limb to make around 500 adjustments each second

• Integral Force/Torque/Angle sensing

• Enough force to really augment movement
BiOM Gait Cycle

• Initial Contact/Loading Response
  – FlexFoot Compresses
  – Ankle joint plantarflexes
    • Rate controlled by adjusting motor stiffness
BiOM Gait Cycle

• Terminal Stance / Pre-Swing
  – Review Goal: Progression of the body beyond the supporting foot
  – Stored Flex Foot and Series Elastic spring energy released simultaneously with power from motor.
  – For the first time...powered “push off”!
• The SYMBIONIC LEG by Ossur combines a powered ankle (Proprio) and an adaptive microprocessor knee (Rheo)

• The active toe lift in swing

• Advanced stumble recovery feature

• Heel height adjustment feature
Multi-articulating Hands

- Most advanced terminal devices
- Independently powered and controlled fingers
- Articulating fingers and rotating thumb
- Myoelectric control
- Microprocessors used to process information
• Individual finger actuators with advanced onboard electronics allows the hand to perform up to 14 selectable grip patterns

• The myoelectric hand reacts quickly for smooth, proportional control

• Onboard microprocessors continually monitor the motion of individual digits for the creation of grip patterns that may be reliably repeated

• The weight distribution of the hand has been optimized

• More closely resembles the natural form in movement and appearance.

• A custom silicone glove is available
Michelangelo® Hand by Otto Bock

- 4 movable fingers and a thumb that can be separately positioned
- Innovative gripping kinematics and new degrees of freedom
- Equipped with two drive units
- Actively driven components are the thumb, index finger and middle finger
- “neutral mode” for resting the hand in a natural position, and a repositionable wrist joint offers a more natural shape and movement
• Defense Advanced Research Project Agency (DARPA) announced the Revolutionizing Prosthetics Program in 2005

• RP 2007 – $18.1 million project awarded to DEKA

• RP 2009 - $30.4 million project awarded to APL at Johns Hopkins
DEKA Arm

- Multiple advanced features to provide enhanced function including a flexible socket design and innovative control features

- Partnership with the VA for clinical research evaluations
  - 2008-9 Optimization Study
  - 2012-3 Take home study

DEKA Arm

Design Features

• “Strap and Go” System
• Primarily for proximal amputation levels
• Multiple degrees of Powered Movement (10 degrees)
• Multiple control options (EMG signals, FSRs, gyroscopes)
• End-point control – coordinated, simultaneous control scheme of multiple joints

APL/MPL Arm

- Applied Physics Lab (APL) or Modular Prosthetic Limb (MPL)
- Advanced neural control systems (Myoelectric with or without TMR to BCI)
- Advanced control systems and sensory feedback
- Initial fittings and trials currently in progress
Targeted Muscle Reinnervation (TMR)

- Primarily used for above-elbow and higher level amputations
- Improved myoelectric control
- More physiologic control
- Potential utilization for sensory feedback
- Potential utilization for PLP
Osseointegration
Potential Advantages

- Reduced skin irritation and breakdown
- Improved comfort and reduced pain
- Bone, not residual limb, is load bearing
- Improved mechanical transfer of motion
- Improved mobility and reduced fall risk

Prosthet Orthot Int 2008;32:29-41.
Potential Advantages

- Secure and stable suspension
- Ease and speed of donning and doffing
- Increased ROM and improved sitting comfort
- Improved proprioception (osseoperception)

*Prosthet Orthot Int* 2008;32:29-41.


*Gait and Posture* 31 (2010);223-8.
Osseointegration

- Currently being performed in several European countries

- Progress has been made regarding infection prevention strategies and enhancing timeliness of rehabilitation

- Initial Human subject trials scheduled to begin in U.S. in 2013 under an FDA early feasibility protocol

- Transfemoral amputation level will be initial population

- Preliminary planning in progress for implementation in the upper extremity amputation population
Rehabilitation Advances

Vascularized Composite Allotransplantation (VCA)

Composite Tissue Allotransplantation (CTA)

Limb / Hand Transplant
Vascularized Composite Allotransplantation (VCA)

- **What is VCA?**
  - Module of skin, muscle, ligament, tendon, nerve, bone, joint, cartilage, lymph nodes, with *vascular supply*

- **What are the benefits of VCA?**
  - Use of **identical tissue** for reconstruction, minimize repeated reconstructions, reduce prolonged morbidity
Hand Transplantation Current Status

- 1998 – First “successful” hand transplant (France)

- Tremendous recent increase in programs offering VCA (13 programs in U.S. and 20+ World-wide)

- Limb Transplant being performed in U.S. both inside and outside of research protocols

- 73 hand transplantations performed worldwide (46 patients)

- 24 hands in 18 U.S. patients (9 prior to 2010)

Hand Transplantation

Keys to Success

• Proper Patient Selection

• Technically Successful Operation

• Postoperative Rehabilitation

• Immunotherapy Regimen

Hand Transplantation Considerations

- Not lifesaving
- Quality of life
- Psychological impact
- Cost
- Importance of comprehensive screening
- Consequences of long-term immunosuppression
- Variable success thus far

2009 ASSH annual meeting, HS paper 20.
Limb Salvage

Early Management

• Aggressive debridement and irrigation

• Fasciotomies

• Delayed definitive closure

• Preserve reconstructive options via salvage of all viable tissue

Limb Salvage

Staged Management

- Fracture fixation
- Bone lengthening
- Infection control
- VAC Therapy
- Soft tissue expansion
- Skin grafts
- Microvascular tissue transfer

Intrepid Dynamic Exoskeletal Orthosis (IDEO)

- New type of orthosis developed at the Center for the Intrepid (CFI)
- Ryan Blanck, CPO, lead developer
- “Game Changer” in regard to functional outcomes following limb salvage

Outcome Measures

- **Agility, Power, and Speed**
  - 4 square test
  - Sit to Stand x 5
  - Self-Selected Walking Speed
  - Stair Ascent
  - 40 yard Dash

- **Satisfaction Survey**

- **Amputation Questionnaire**
# Results

<table>
<thead>
<tr>
<th>Test</th>
<th>No Brace (N = 18)</th>
<th>Posterior Leaf Spring (N = 11)</th>
<th>BlueRocker (N = 16)</th>
<th>IDEO (N = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four-square step test (s)</td>
<td>7.0 ± 2.0&lt;sup&gt;a&lt;/sup&gt; (3.1-12.4)</td>
<td>6.5 ± 2.1&lt;sup&gt;a&lt;/sup&gt; (3.9-10.5)</td>
<td>6.9 ± 1.9&lt;sup&gt;a&lt;/sup&gt; (4.2-11.3)</td>
<td>5.8 ± 1.8&lt;sup&gt;b&lt;/sup&gt; (3.1-10.0)</td>
</tr>
<tr>
<td>Sit-to-stand 5 times (s)</td>
<td>8.5 ± 2.0&lt;sup&gt;a,b&lt;/sup&gt; (4.8-12.6)</td>
<td>8.6 ± 2.0&lt;sup&gt;a,b&lt;/sup&gt; (4.6-12.4)</td>
<td>9.1 ± 1.9&lt;sup&gt;a,c&lt;/sup&gt; (5.1-13.3)</td>
<td>8.2 ± 1.8&lt;sup&gt;b&lt;/sup&gt; (5.2-13.6)</td>
</tr>
<tr>
<td>Timed stair ascent (s)</td>
<td>6.8 ± 1.6&lt;sup&gt;a&lt;/sup&gt; (3.9-11.5)</td>
<td>7.1 ± 1.7&lt;sup&gt;a&lt;/sup&gt; (3.7-10.5)</td>
<td>7.4 ± 2.6&lt;sup&gt;a&lt;/sup&gt; (5.0-24.4)</td>
<td>5.7 ± 1.3&lt;sup&gt;b&lt;/sup&gt; (3.0-8.6)</td>
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<tr>
<td>Self-selected walking velocity (m/s)</td>
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<td></td>
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<tr>
<td>On level terrain</td>
<td>1.25 ± 0.23&lt;sup&gt;a&lt;/sup&gt; (0.96-2.09)</td>
<td>1.28 ± 0.24&lt;sup&gt;a&lt;/sup&gt; (1.02-2.18)</td>
<td>1.31 ± 0.14&lt;sup&gt;b&lt;/sup&gt; (1.00-1.63)</td>
<td>1.50 ± 0.32&lt;sup&gt;c&lt;/sup&gt; (1.22-3.04)</td>
</tr>
<tr>
<td>On rocky terrain</td>
<td>1.12 ± 0.23&lt;sup&gt;a&lt;/sup&gt; (0.85-2.00)</td>
<td>1.11 ± 0.38&lt;sup&gt;a&lt;/sup&gt; (0.78-2.34)</td>
<td>1.12 ± 0.14&lt;sup&gt;a&lt;/sup&gt; (0.88-1.46)</td>
<td>1.32 ± 0.34&lt;sup&gt;b&lt;/sup&gt; (0.78-2.67)</td>
</tr>
<tr>
<td>40-&lt;sup&gt;y&lt;/sup&gt;d dash (s)</td>
<td>13.4 ± 5.3&lt;sup&gt;a&lt;/sup&gt; (7.0-25.9)</td>
<td>12.8 ± 4.1&lt;sup&gt;a,b&lt;/sup&gt; (7.6-21.6)</td>
<td>11.9 ± 4.1&lt;sup&gt;b&lt;/sup&gt; (6.4-21.7)</td>
<td>8.5 ± 2.4&lt;sup&gt;c&lt;/sup&gt; (5.3-14.6)</td>
</tr>
</tbody>
</table>

*The values are given as means and standard deviation with the range in parentheses. An “a” indicates that the group is significantly different from the groups labeled with a “b” or “c.” A “b” indicates that the group is significantly different from the groups labeled with an “a” or “c.” A “c” indicates that the group is significantly different from the groups labeled with an “a” or “b.” Groups that share a letter are not significantly different from one another. Different letters signify a difference among groups (p < 0.05).
Conclusions

- The IDEO:
  - improved functional performance
  - well-tolerated
  - potential to serve as an alternative to late amputation for patients with severe weakness about the leg and ankle.

- 19% rate of return to military and deployment

Lower Extremity Assessment Project (LEAP)

- Project funded by NIH
- 8 Level 1 Trauma Centers
- 569 patients with severe lower extremity injuries
- Cohort followed prospectively for 24 months
- Functional Outcomes measured with the Sickness Impact Profile (SIP)

Lower Extremity Assessment Project (LEAP) Results

- 68% underwent limb reconstruction / 32% amputation
- 84.4% of patients followed for 24 months
- Amputation population noted to have more severe injuries
- 42% with residual “severe disability”
- Re-hospitalization rate higher in with limb reconstruction
- No differences in functional outcomes between limb reconstruction and amputation

Lower Extremity Assessment Project (LEAP) Complications

- **Limb Reconstruction**
  - Nonunion (31.5 %)
  - Wound infection (23.2 %)
  - Osteomyelitis (8.6 %)
  - Post-traumatic arthrosis (9.4 %)

- **Amputation**
  - Wound infection (34.2 %)
  - Stump revision (14.5 %)
  - Phantom limb pain and wound breakdown (13.4 % each)
  - Stump complications (10.7 %)

*J Orthop Trauma 23:1–6.*
Lower Extremity Assessment Project (LEAP) Long-term Follow-up

- 397/569 patients contacted by phone (Avg. 84 months post-injury)
- Most of the patients reported that physical and psychosocial functioning had deteriorated since their 24-month follow-up
- 50% of the patients indicated severe disability
- One third in both groups re-hospitalized between 2 and 7 years
- No difference in SIP scores across both treatment groups

Meta-Analysis

- The Evidence-Based Orthopedic Trauma Working Group

- Meta-analysis of observational studies on complex limb salvage or early amputation for severe lower-limb injury

- No significant differences in functional outcome at least up to 7 years

*J Orthop Trauma. 21:70–76.*
The Military Extremity Trauma Amputation/Limb Salvage (METALS) Study

- Retrospective cohort study of 324 OEF/OIF Servicemembers with lower-limb injuries requiring either amputation or limb salvage

- **Limb salvage** requiring revascularization, bone graft/bone transport, local/free flap coverage, repair of a major nerve injury, or a complete compartment injury/compartment syndrome

- The Short Musculoskeletal Function Assessment (SMFA) questionnaire was used to measure overall function

- Standard instruments were used to measure depression, posttraumatic stress disorder (PTSD), chronic pain, and engagement in sports and leisure activities

The Military Extremity Trauma Amputation/Limb Salvage (METALS) Study

- The outcomes controlled for age, time until the interview, military rank, upper-limb and bilateral injuries, social support, and intensity of combat

- Overall response rate 59.2% with higher rate in amputation group

- Amputation group had better scores in all SMFA domains

- Amputation group with lower likelihood of PTSD and a higher likelihood of being engaged in vigorous sports

- There were no significant differences between the groups with regard to the percentage of patients with depressive symptoms, pain interfering with daily activities, or work/school status

Rehabilitation Advances

Future Considerations
Future Considerations

- Advanced Surgical Reconstructive Techniques
- Osseointegration
- Targeted Muscle Reinnervation
- Sensory function replacement
- Limb (Vascularized Composite Allograft) Transplant
- Regenerative Medicine / Biologic therapies
Dilemma

Decision-making between **amputation** vs. **limb salvage** complicated by advances in surgical techniques, prosthetic technology and rehabilitation care
Limb Salvage

- [link]

Future Considerations

- Improved functional outcomes with advanced prostheses and neural control (Targeted Muscle Reinnervation)
- Improved functional outcomes with limb salvage
- Option of limb transplant (VCA)
- Future option of Osseointegration
- Regenerative Medicine / Biologic therapies
Questions