Lower Limb Orthoses: Prescription and Rehabilitation to Restore Lower Limb Function

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Friday, 23 Oct 2015
USUHS, Bethesda, MD
Military Performance Lab

- Over 20 full time research staff
  - Physical Therapist (3 – 2 PhD)
  - Biomedical Engineer PhD (3)
  - Occupational Therapist (1)
  - Prosthetist (1)
  - Prosthetic Technician (2)
  - Physical Therapy Assistant (1–3)
  - Virtual Reality Specialist (1)
  - Research Assistants (5)
  - Protocol Coordinators (2)

- 49 Publications in the last 5 years
The Problem

• High prevalence of function limiting limb injuries

• Persistent loss of limb function following limb salvage with broad impact
  – Depression
  – Decreased quality of life
  – Inability to return to duty
  – Long term disability cost

• Treatment options are limited for individuals who have undergone limb salvage and desire a full return to high level activity

The Clinical Challenge

- The ankle joint experiences large joint moments and power production (Achilles tendon force approx. 3X body weight)

- Widely available options are typically designed for lower level activity or limited diagnosis sets

https://www.allardusa.com
The IDEO and RTR Program
Are We On The Right Track?

- Early clinical assessments to determine optimal care for individual patients
- Literature reviews to identify outside efforts
- Prospective studies to determine effectiveness
- Biomechanics studies to guide clinical practice
Our Approach

• Applied research mission to understand and inform clinical practice

• Not academics for academics sake

• Often start with the clinical “solution” and work backward

www.facebook.com/BrookeArmyMedicalCenter/
Many Options for Assessment

- Assessment tools to help guide clinical practice and/or scientific study
- A foundation of reliable and valid measures
  - Digital video fluoroscopy
  - Biomechanical assessment
  - Metabolic assessment
  - Walking stability
  - Clinic friendly physical performance measures
Comparative Effect of Orthosis Design on Functional Performance

Jeanne C. Patzkowski, MD, Ryan V. Blanck, LCPO, Johnny G. Owens, MPT, Jason M. Wilken, PhD, MPT, Kevin L. Kirk, DO, Joseph C. Wenke, PhD, Joseph R. Hsu, MD, and the Skeletal Trauma Research Consortium (STReC)


**Question:**
Does the IDEO lead to improved performance on functional measures of speed, power and agility as compared to commercial off the shelf orthoses and no brace

www.allardint.com/products/bluerocker.html
www.flaorthopedics.com/srchproducts/contracturesplints/footdropsplint.htm
Performance Measures

Physical Performance Assessment in Military Service Members

Journal of the American Academy of Orthopaedic Surgeons
2012, Vol 20, Supplement 1

Jason M. Wilken, PT, PhD
Benjamin J. Darter, PT, PhD
Stephen L. Goffar, PT, PhD
Jesse C. Ellwein, PT
Rachel M. Snell, DPT, CSCS
Eric A. Tomalis, DPT, CSCS
Scott W. Shaffer, PT, PhD

• n = 180 (130 males; 50 females)
  – n= 25 inter-rater reliability
  – n= 20 test-retest (7 ± 3 days)

• Inclusion Criteria
  – Active duty
  – 18 – 45 years of age
  – No current (within the last 6 months) lower extremity or spine pathology
  – Full duty with no functional limitations
Outcomes Assessment

- Reliably assess physical performance
- Assess functional domains expected to change/improve with intervention
- Normative reference data
- Easy implementation allowing use in the clinic
Prospective Cohort Study

Can an Integrated Orthotic and Rehabilitation Program Decrease Pain and Improve Function After Lower Extremity Trauma?

Katherine M. Bedigrew MD, Jeanne C. Patzkowski MD, Jason M. Wilken PhD, MPT, Johnny G. Owens MPT, Ryan V. Blanck LCPO, Daniel J. Stinner MD, Kevin L. Kirk DO, Joseph R. Hsu MD, Skeletal Trauma Research Consortium (STReC)

Questions:
(1) Does an 8-week integrated orthotic and rehabilitation initiative improve physical performance, pain, and outcomes in patients with lower extremity functional deficits or pain?
(2) Is the magnitude of recovery different if enrolled more than 2 years after their injury versus earlier?
(3) Does participation decrease the number considering late amputation?
Running – Without
Running – With IDEO
Comparative Study

**40 Yard Dash**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Time (Seconds)</th>
<th>p-value</th>
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<tbody>
<tr>
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<td>18</td>
<td>p &lt; 0.01</td>
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<tr>
<td>PLS</td>
<td>15</td>
<td>p = 0.02</td>
</tr>
<tr>
<td>Blue Rocker</td>
<td>14</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>IDEO</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
Cohort Study

20-m Shuttle Run (Speed/Agility)

Healthy Controls

- Week 0: p = 0.22
- Week 4: p = 0.002
- Week 8

Velocity (m/s)

- Week 0
- Week 4
- Week 8
Four Square Step Test

Four Square Step Test (FSST)

- A dynamic test of balance and mobility (Whitney 2007, Dite 2007)
- Test measures ability to move forward, backwards, and laterally over an approximately one inch obstacle
- One practice trial followed by 4 timed trials
Comparative Study

Four Square Step Test

**Time (Seconds)**

<table>
<thead>
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<th>Condition</th>
<th>Time</th>
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</thead>
<tbody>
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<td>7.2 ± 0.5</td>
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<tr>
<td>PLS</td>
<td>6.8 ± 0.4</td>
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<tr>
<td>Blue Rocker</td>
<td>6.5 ± 0.3</td>
</tr>
<tr>
<td>IDEO</td>
<td>6.0 ± 0.2</td>
</tr>
</tbody>
</table>

Norm: 5.6 (1.1)s  MDC: 1.4s

*p < 0.001  p = 0.004  p < 0.001*
Cohort Study

Four Square Step Test (Balance/Agility)

- Week 0: $\text{Time} = 12.0$ s
- Week 4: $\text{Time} = 10.0$ s
- Week 8: $\text{Time} = 6.0$ s

Significance levels:
- $p = 0.018$
- $p < 0.0001$

Healthy Controls
• Timed Stair Ascent
  – An objective measure of mobility and power (Guralnik, 1995)
  – Greater strength and range of motion than level ground walking
  – 12 stairs
Timed Stair Ascent
Comparative Study

Timed Stair Ascent

- **NONE**: p < 0.001
- **PLS**: p < 0.001
- **Blue Rocker**: p = 0.001
- **IDEO**

**Condition**

Norm: 2.8 (0.4)s  MDC: 0.4s
Cohort Study

Timed Stair Ascent (Power/Balance)

- Week 0: 8.0 seconds
- Week 4: 6.0 seconds
- Week 8: 3.0 seconds

Healthy Controls

p < 0.0001
Clinical Outcomes

- 13 patients were considering amputation
  - 8 selected to continue limb salvage
  - 2 undecided
  - 3 selected amputation

- Forty-one of 50 (82%) patients initially considering amputation favored limb salvage at the end of 8 weeks

- Significant improvements in physical performance
Well…That Looks Promising

- Continued room for improvement

- Next step is to refine and guide the clinical prescription of passive dynamic ankle foot orthoses

- Determine what aspects of the fitting process require additional attention
What Design Parameters are Important?

- **Title:** Optimization of Dynamic Ankle-Foot Orthosis Design for High Level Activity Performance Following Limb Salvage for Severe Lower Extremity Trauma

- **Purpose:** To determine how ankle foot orthosis design influences walking and running performance in patients who have experienced severe lower limb trauma

- **Approach:** Mechanical and design properties were systematically varied to determine optimal AFO characteristics

- **Funding:** Center for Rehabilitation Sciences Research
Energy Storage and Return
Strut Deflection
Rapid Manufactured Struts
Strut Stiffness
Effect of Strut Stiffness on Walking

- Minimal effect of strut stiffness
- Ankle motion is significantly reduced in the IDEO compared to controls (56%; (p < 0.001)

Clin Orthop Relat Res
DOI 10.1007/s11999-014-3661-3
Effect of Stiffness on Running

Ankle Joint Stiffness

Stiffness = \( \frac{\Delta \text{ Moment}}{\Delta \text{ Angle}} \)

Ankle Moment (Nm/kg)

Ankle Angle (deg)
Effect of Stiffness on Running

• Ankle joint stiffness was significantly greater on the IDEO limb

• The compliant strut resulted in the lowest ankle joint stiffness

• Knee joint stiffness was significantly reduced on the IDEO limb
Bending Point
Effect of Bending Point on Walking

- No consistent changes in gait performance
- Low bending point → increased gastrocnemius activity
- Consideration when using IDEO as a rehabilitative device

Significant bending axis main effects (*), bending axis*limb interaction effects (†), and low to nominal bending axis comparisons (▲) are indicated. Large effect sizes between preference and iEMG are also indicated (○: $\eta^2 > 0.26$; ●: $\eta^2 > 0.50$).
Alignment
Effect of Alignment

- Preference for PF alignment
- Decreased knee extensor moment with PF alignment
- Decreased quadriceps activity with PF alignment
Effect of Alignment

Vastus Medialis Integrated EMG

% of PF Condition

0 50 100 150 200

DF Neutral PF

Rectus Femoris Integrated EMG

% of PF Condition

0 50 100 150 200

DF Neutral PF
Effect of Alignment on Roll-over Shape
Effect of Alignment on Roll-over Shape

Affected Limb Roll-Over Shape
Horizontal Displacement (m/height)

Unaffected Limb Roll-Over Shape
Horizontal Displacement (m/height)

Roll-Over Shape Radius

Wilken State of Science Meeting 2015 Slide 42 of 40 23 Oct 2015
Sharing Our Findings

New Submissions:

- Ranz EC, Russell Esposito E, Wilken JM, Neptune RR. The influence of passive-dynamic ankle-foot orthosis bending axis on gait performance in individuals with lower-limb impairments. *Clinical Biomechanics*

- Aldridge Whitehead J, Russell Esposito E, Wilken JM. Stair ascent and descent biomechanical adaptations while using a custom ankle-foot orthosis. *Journal of Biomechanics*

- Russell Esposito E, Wilken JM. Gait biomechanics following lower extremity trauma: Amputation vs. Reconstruction. *Gait & Posture*
Under “Real World” Conditions

• Title: Physical and Cognitive Assessment Battery for Severely Injured Service Members

• Purpose: To identify performance limitations that negatively impact an injured service member’s ability to successfully return to their desired role.

• Funding: Center for Rehabilitation Sciences Research
Under “Real World” Conditions
Simulated Patrol Activities

CFI MPL RTD M3
Assessments

• Prolonged bout of activity

• Use of repeated conditions to identify degradation in performance
  – Cognitive task
  – Slopes

• Apply a range of measures to assess performance
  – Heart rate
  – Reaction time
  – Accuracy
  – Walking stability
Angular Momentum

Frontal Plane

Transverse Plane

Sagittal Plane
Angular Momentum

- Range of angular momentum in the IDEO was significantly greater than able bodied individuals for all conditions (P<0.034)

- The greatest differences were observed during downhill walking (39%, P=0.002)
Cross-slope w/ IDEO downslope

Step width with the IDEO downslope was 16% narrower compared to the level condition (P<0.005)
Sharing Our Findings

Posters

Platforms/Briefs

Manuscripts
The Bottom Line

- Custom carbon fiber orthoses, when combined with intensive rehabilitation, have the potential to significantly improve multiple aspects of functional mobility

- Further refinement is clearly necessary

PubMed search for "Ankle Foot Orthosis"
Thank You