Comparative Effect of Orthosis Design on Functional Performance

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And the Skeletal Trauma Research Consortium (STReC)
Comparative Effect of Orthosis Design on Functional Performance

Jeanne Patzkowski, Ryan Blanck, Johnny Owens, Jason Wilken, Kevin Kirk, Joseph Wenke, Joseph Hsu

My disclosure is in the Final AOFAS Program Book
I have no potential conflicts with this presentation.

This study was conducted under a protocol reviewed and approved by the Brooke Army Medical Center Institutional Review Board, and in accordance with the approved protocol.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.
**Introduction**

High energy lower extremity trauma (HELET) is common in combat wounded soldiers\(^1,2\), and leads to severe neurovascular and soft tissue injury, gross contamination and fragmentation. Surgical management and rehabilitation are further complicated by chronic pain, nerve injury and volumetric muscle loss\(^3-5\). Advances in orthotic technology have not kept pace with advances in prosthetics\(^6\). Some military limb salvage patients may request late amputation in the hopes of improving functional performance\(^7-9\).

The Return to Run (RTR) clinical pathway combines the Intrepid Dynamic Exoskeletal Orthosis (IDEO), a custom carbon-fiber energy storage and return ankle foot orthosis, with high-intensity rehabilitation\(^10,11\).
Hypothesis

The IDEO:

- Improves functional performance more than commercial off the shelf orthoses and no brace
- Is well tolerated
- Serves as an alternative to late amputation
Methods

- **Inclusion Criteria**
  - $\geq 18$ years of age
  - Unilateral plantar/dorsiflexion weakness ($\leq 4/5$) with healthy contralateral limb

- **Exclusion criteria**
  - Weakness due to spinal cord or central nervous system pathology
  - Contralateral lower extremity injury

- **Four Bracing Conditions**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDEO</td>
<td>Custom carbon fiber</td>
<td><a href="http://www.allardint.com/products/bluerocker.html">www.allardint.com/products/bluerocker.html</a></td>
</tr>
<tr>
<td>Blue Rocker™ (BR)</td>
<td>Non-custom carbon fiber</td>
<td></td>
</tr>
<tr>
<td>Posterior Leaf Spring (PLS)</td>
<td>Non-custom rigid plastic</td>
<td><a href="http://www.flaorthopedics.com/srchproducts/contracturesplints/footdropsplint.htm">www.flaorthopedics.com/srchproducts/contracturesplints/footdropsplint.htm</a></td>
</tr>
<tr>
<td>No brace (NONE)</td>
<td>Subject wears own athletic shoes</td>
<td></td>
</tr>
</tbody>
</table>
Methods

- Brace order randomized for testing
- 5 Trials of each validated functional measure\textsuperscript{12} for each bracing condition
  - **Agility**
    - Four Square Step Test
  - **Power**
    - Five Time Sit to Stand
    - Timed Stair Ascent
  - **Speed**
    - Self-Selected Walking Velocity on Level Terrain
    - Self-Selected Walking Velocity on Rocky Terrain
    - 40 yard dash*

*One trial with two independent timers*
**Methods**

Satisfaction Questionnaire

1. Describe IDEO
2. Compare orthoses to one another
3. Have they considered amputation?
4. Do they favor limb salvage after completion of the clinical pathway?

<table>
<thead>
<tr>
<th>1. How comfortable do you find the IDEO to be?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>Not Comfortable</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. How frequently do you develop skin problems (blisters, rash, abrasions, etc) in the IDEO?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>Very Often</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. How difficult is it to put on or take off the IDEO?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>Very Difficult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. How difficult do you find it to keep the IDEO clean?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>Very Difficult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. How durable do you find the IDEO?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
</tr>
<tr>
<td>Not Durable</td>
</tr>
</tbody>
</table>
**Methods**

### Satisfaction Questionnaire

1. Describe IDEO
2. Compare orthoses to one another
3. Have they considered amputation?
4. Do they favor limb salvage after completion of the clinical pathway?

<table>
<thead>
<tr>
<th>6. How long can you wear each orthosis before it becomes uncomfortable (please be specific)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard plastic AFO (PLS): ________</td>
</tr>
<tr>
<td>Blue Rocker (BR): ________</td>
</tr>
</tbody>
</table>

7. Which AFO do you prefer for the following situations:
   - Walking: ________
   - Social settings: ________
   - Playing Sports: ________
   - Running: ________
   - While in uniform: ________
   - Military Activities: ________

8. Which AFO do you think has a better appearance?
   ________

9. Overall, which AFO do you prefer?
   ________

10. Have you ever considered amputation of your injured leg?
    - YES: ________
    - NO: ________

11. If so, why? (check all that apply)
    - Leg/ankle pain: ________
    - Nerve pain: ________
    - Weakness: ________
    - Inability to run/jump: ________
    - Other (please specify): ________

12. Are you now favoring keeping your injured leg?
    - YES: ________
    - NO: ________

13. If No, why? (check all that apply)
    - Leg/ankle pain: ________
    - Nerve pain: ________
    - Weakness: ________
    - Inability to run/jump: ________
    - Other (please specify): ________
Results

- Eighteen Subjects
- 18-49 years old
  - Average 31
- Mechanism of Injury
  - 6 Explosion
  - 4 Gunshot
  - 4 Motor Vehicle Collision
  - 1 Parachute Accident
  - 1 Fall From Height (>2m)
  - 1 Iatrogenic
  - 1 Achilles Tendon Deficiency

16 with HELET
Forty Yard Dash

<table>
<thead>
<tr>
<th>Group</th>
<th>Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NONE</td>
<td>13.4</td>
</tr>
<tr>
<td>PLS</td>
<td>12.8</td>
</tr>
<tr>
<td>BR</td>
<td>11.9</td>
</tr>
<tr>
<td>IDEO</td>
<td>8.5</td>
</tr>
</tbody>
</table>

** Significant difference between bracketed groups, p<0.05
The IDEO can be worn for longer periods without discomfort.
Request for Delayed Amputation

13 initially considered amputation

After completion of RTR

Due to:
- Pain (13/13)
- Weakness (11/13)
- Activity Limitations (11/13)

8

62% favor limb salvage after completion of the clinical pathway

2

Limb Salvage

Undecided

Amputation

Due to:
- Pain (3/3)
- Activity Limitations (2/3)

3
Discussion

Review of the Literature:

- Energy storing orthoses have been shown to improve functional performance in pediatric patients with Cerebral Palsy, Myelomeningocele and other motor disorders, and in adults with hemiplegia.\(^\text{13-16}\)

- Their use in a traumatic limb salvage population, and the comparative effectiveness between commercially available orthoses has not been studied.

Strengths:

- Validated functional measures that are easy to perform, require minimal equipment, and can be readily administered in an outpatient clinical setting.

- Consideration of the comparative effectiveness between the IDEO and two commercially available options made of both carbon fiber and rigid plastic.

Limitations:

- Small cohort of a heterogeneous patient population.

- Non-validated satisfaction questionnaire.

- Active duty population lacks external validity to a civilian trauma population.

Discussion

- IDEO significantly improved performance over all other conditions in all functional measures, with the sole exception of the Five Time Sit to Stand in which it only outperformed the BR.

- IDEO allowed a return to mean “normal” values\(^{12}\) on:
  - Self Selected Walking Velocity on Level Terrain
  - Self Selected Walking Velocity on Rocky Terrain
  - Four Square Step Test

- Aside from small but significant improvements using the BR in the 40 yard dash and in level walking, there was otherwise no significant difference between the BR, PLS and NONE in any other functional measure.

- 62% of those initially desiring amputation of their injured limb countermanded their request and favor limb salvage after completion of this non-invasive intervention.
Conclusion

Use of the IDEO leads to significant improvements in functional performance, is well tolerated, and serves as an alternative to late amputation in limb salvage Soldiers.

Image Courtesy of Jamie Bellamy, DO, CPT, MC, USA
References