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ABSTRACT

Background. The Intrepid Dynamic Exoskeletal Orthosis (IDEO^{TM}) is a custom, energy-storing carbon fiber ankle-foot orthosis developed for lower extremity trauma patients. Studies conducted at one military treatment facility (MTF) where the IDEO^{TM} was developed demonstrated benefits of the IDEO^{TM} when used with the Return to Run physical therapy program (RTR PT). The PRIORITI-MTF study was designed to see if these results could be replicated at other MTFs and examine whether early performance gains translate into longer-term improvements in patient-reported functional outcomes. ***Methods.*** Study participants included service members at least 1 year after a traumatic unilateral lower extremity injury at or below the knee with functional deficits interfering with daily activities. Participants were evaluated before receiving the IDEO^{TM}, immediately following completion of PT, and at 6 and 12 months. Agility, strength/power and speed were assessed using well-established performance tests. Self-reported function was measured using the Short Form Musculoskeletal Assessment (SMFA). The Orthotics and Prosthetics Users' Survey was administered to assess satisfaction with the IDEO^{TM}. Of 87 participants with complete baseline data, 6 did not complete any PT and were excluded from analysis. Follow-up rates immediately following completion of the RTR PT and at 6 and 12 months were 88%, 75% and 79%. ***Results.*** Compared to baseline, improvement at completion of RTR PT was observed in all but 1 performance test. SMFA scores for all domains except Arm/Hand Function were lower (improved function) at 6 and 12 months. Satisfaction with the IDEO^{TM} was high following completion of RTR PT with some attenuation at follow-up. ***Conclusion.*** This study adds to the evidence supporting the efficacy of the IDEO^{TM} coupled with RTR PT. However, despite improvement in both performance and self-reported functioning, deficits persist compared to population norms.

Table of Contents

1. INTRODUCTION:

High-energy open fractures, blast, gunshot wound and crush injuries to the distal tibia, ankle, hind foot and midfoot are common challenges for military and civilian trauma surgeons. Management of these injuries is often complicated by soft tissue injury and contamination, ectopic bone, and neurovascular injuries. While surgical advances in limb preservation have enhanced the potential for limb salvage in these patients, reported outcomes have been suboptimal. [1-4] As prosthetic care for individuals with amputation have advanced, major improvements in orthotics and rehabilitation for limb salvage patients have not kept pace. [5] As a result, many limb salvage patients have been unable to achieve their desired functional goals.

The Intrepid Dynamic Exoskeletal Orthosis (IDEO^{TM}) is a custom, energy-storing carbon fiber orthosis developed at the Center for the Intrepid (CFI) and Brooke Army Medical Center (BAMC) specifically for trauma patients following limb salvage. The IDEO^{TM} differs from other orthoses in that it allows patients with ankle weakness to have more normal ankle biomechanics and increased ankle power. To maximize an individual's potential success in utilizing the IDEO^{TM}, a high intensity, sports medicine based approach to rehabilitation, the Return to Run (RTR) Physical Therapy (PT) program was developed and provided to individuals fitted with an IDEO^{TM}. The multidisciplinary RTR PT program focuses on strength, agility and speed with the goal of enabling patients to return to running, sports and military deployment [6-8].

Early studies evaluating the IDEO^{TM} produced promising results. One study of 18 patients demonstrated improvement in function compared to no orthosis and 2 commercially available orthoses).[9] Another prospective observational study of 84 patients demonstrated significant improvements in physical performance measures, patient reported outcome measures (using the SMFA and VR-12), and pain four weeks after receiving the IDEO^{TM} and completing the RTR PT program. [10] Among subjects who initially considered amputation, the majority favored limb salvage after this non-invasive intervention. It was equally effective in patients presenting within two years from injury versus those presenting after two years from injury.

Most recently, a systematic review found moderate evidence supporting the development of 4 empirical evidence statements regarding the IDEO^{TM} used with RTR PT.[11]

While collectively these studies point to the benefits of the IDEO^{TM} and the RTR PT program, they have limitations. First, all studies were performed at only one military treatment facility where the IDEO^{TM} and the RTR PT program were developed. In addition, there was an emphasis on showing short-term effects using measures of functional performance assessed in a controlled environment. Data are needed to replicate the positive results of these studies at other military treatment facilities and provide evidence that improvements in performance translate into longer term improvements in patient reported functional outcomes and quality of life.

The PRIORTI-MTF study was designed to address these limitations. It established an integrated orthotic and rehabilitation program that incorporates the IDEO^{TM} and the RTR PT program at two additional military treatment facilities and assessed immediate and long-term improvements in functional performance and self-reported outcomes in service members or military retirees

who were one or more years out from a traumatic lower extremity injury at or below the knee who are able to bear weight but have functional deficits.

If the positive results obtained thus far can be confirmed in this broader population, this approach could significantly influence the risk-benefit analysis patients consider in making the decision to proceed with amputation versus limb salvage.

2. KEYWORDS:

Dynamic Ankle Foot Orthosis, Extremity War Injuries, IDEO, Orthopedic Rehabilitation

3. BODY

Overall Progress

This final report reflects progress and accomplishments from 7/1/12 to 12/30/17.

We have completed all patient enrollment and follow-up. Study procedures have been described in a protocol paper published in the Journal of Orthopedic Trauma .[12] The main analysis has been completed, presented at national meetings and accepted for publication in Journal of Bone and Joint Surgery. [13]

The investigators are currently involved in the analysis of the data to address research questions ancillary to the main objectives of the study.

Summary Progress Relevant to Specific Tasks

Task 2: Regulatory Review of Study Protocol
The Johns Hopkins School of Public Health IRB granted final approval to the master protocol on January 17, 2014. Approval was granted by DoD HRPO for the master protocol on January 29, 2014.

SAMMC/CFI received final approval from their local IRB on April 29, 2014 and from the DoD OHRP on May 15, 2014.

WRNMMC received approval from local IRB on March 2, 2014 (IRB approval letter dated March 10, 2014). WRNMMC received final approval from DoD OHRP on July 31, 2014.

NMCSD received final approval from the local IRB (WRNMMC is IRB of record) on June 11, 2014 and final approval from DoD OHRP on September 16, 2014.

Task 3: Hire/ Train Certified Prosthetist Orthotist (CPO), Orthotist and Prosthetist (O&P) technician and Physical Therapy Assistant (PTA) to work at WRNMMC
This task was completed in 2013 and captured in the 2014 annual report.

Task 4: Develop Training Materials
This task was completed in 2013 and captured in the 2014 annual report.

Task 5: Hire/Train CPO, O&P technician and (PTA) to work at NMCSD
This task was completed in 2013 and captured in the 2014 annual report.

Task 6: Conduct Study
In this section we briefly describe; (1) Overall methods of the study; (2) Primary outcomes; and (3) Characteristics of the study participants. Details can be found in the published protocol paper (Appendix 1).

Overall Methods: In this pre-post intervention, study participants served as their own controls. Study procedures have been described elsewhere and are summarized here.[12] Participants were recruited by three military treatment facilities: WRNMMC and NMCSD. Eligible for the study were active duty, retired or separated service members who were at least 1 year out from a traumatic unilateral lower extremity injury at or below the knee, who were able to bear weight but had functional deficits interfering with daily activities. To ensure a clinically "stable" population, the study excluded individuals with unhealed fractures and soft tissue injuries or for whom additional surgery was planned within 6 months.

The PRIORITI intervention consisted of custom fitting of the IDEO™ and the RTR PT program, modified for delivery in 2–3 sessions per week. The IDEO™ device is FDA exempt under 21 CFR 890.3475 and 21 CFR 890.3410. All devices were fabricated and custom-fit by a Certified Prosthetist Orthotist (CPO) and an orthotic technician at the center where the participant was enrolled. RTR PT was delivered by physical therapists or physical therapy assistants with documented training in sports medicine and experience treating trauma patients.

After the participant provided consent for the study, the CPO team took a cast of the leg which was used to develop a diagnostic test device. The test device was fitted, adjusted, and evaluated for comfort and function prior to fabricating the definitive carbon fiber and customized orthosis. After being fitted with the definitive IDEO™, participants were encouraged to participate in 4 weeks of RTR PT (2–3 sessions per week). During these 4 weeks, adjustments to the orthosis were made to optimize function.

Participants were scheduled for evaluation at baseline (before receiving the IDEO™), immediately following completion of RTR PT and at 6 months and 12 months. At baseline, data were collected to characterize participants (socio-demographics, self-efficacy, social support, co-morbidities) and their current levels of physical impairment (range of motion, strength), pain, and psychological well-being (evidence of depression and post-traumatic stress).

Primary Outcomes: Primary study outcomes were: functional performance (at baseline and immediately following completion of RTR PT); self-reported functioning (at baseline, 6 and 12 months); and satisfaction with the device (immediately following completion of RTR PT and at 6 and 12 months), as described below:

- Functional performance was assessed using tests for agility (Four Square Step and Illinois Agility Tests), strength/power (Sit to Stand and Timed Stair Ascent Tests), and speed (Self Selected Walking Speed and 10 meter Shuttle Run).[14]

- Self-reported functioning was measured using the Short Form Musculoskeletal Assessment (SMFA).[15]

- Use and satisfaction with the IDEO™ was assessed by the Orthotics and Prosthetics Users' Survey (OPUS),[16] consisting of 11 items pertaining to device satisfaction: weight, comfort, pain associated with use, ease of use, cosmesis, durability, fit and effect of the device on clothing.

Study Participants: Ninety-one participants were initially enrolled in the study and received a customized IDEO™. Four patients did not complete the baseline assessments and were withdrawn from the study. An additional 6 patients received an IDEO™ but did not return for any RTR PT sessions. These 10 patients were excluded from the main analysis. The mean number of sessions attended by the remaining 81 participants was 9.1 (SD 3.1); 77% completed 8 or more sessions and 6% completed fewer than 4 sessions.

Seventy-one (88%) participants completed the evaluation immediately following completion of RTR PT. Follow-up rates at 6 and 12 months were 75% and 79% respectively.

Baseline characteristics of the study participants have been reported. [12] Overall, 40% indicated their health was very good or excellent. The mean (±SD) VR-12 physical component summary (PCS) at baseline was 32.8 ± 9.1, reflecting poor overall physical functioning at the time of enrollment. Scores on the VR-12 mental health component summary (MCS) were more similar to population norms, [17] although 24% had scores on the Patient Health Questionnaire (PHQ-9) consistent with moderate to severe depressive symptoms[18] , 21% screened positive for post-traumatic stress based on the PTSD Checklist. [19]

At time of enrollment, 33% were currently using a non-IDEO™ orthosis; an additional 31% reported having used an orthosis in the past.

Task 7: Conduct the Main Analysis and Report the Results

In this section we briefly describe the results of the main analysis. Details can be found in the published main results paper (Appendix 2).

With the exception of self-selected walking speed, there were improvements in functional performance between the completion of RTR PT and baseline. SMFA scores for all domains except Arm/Hand Function and Emotional Status showed improvement (lower scores) at 6 and at 12 months compared to baseline, with more impressive results at 12 months. Improvements at 12 months for mobility and daily activities exceeded one-half a standard deviation, often used as a threshold for clinically meaningful changes in health-related quality of life measures: 8.9 points in Mobility scores (95% CI of paired difference: -13.0, -4.9) and 10.6 points in Daily Activities (95% CI of paired difference: -14.7, -6.5). [20] There were no appreciable differences in treatment

effect by center (BAMC versus WRNMMC or NMCSD) or by number of RTR PT sessions attended (<8 versus 8 or more).

Satisfaction with the IDEO™ was very high following completion of RTR PT program (OPUS scores averaged 84.6 of a possible 100 points), with some attenuation at 6 and 12 months (mean scores of 73.1 and 71.5 respectively). Satisfaction with the IDEO™ at 12 months was higher than satisfaction with non-IDEO AFOs reported being used by 53 participants prior to study enrollment (mean OPUS of 55.0).

Of note, 4 participants underwent amputation after enrolling in the study, all due to pain; 3 occurred between 6 and 12-months and 1 after 12 months. Removing the 3 participants who underwent amputation within 12 months from the analysis did not change the results. These individuals reported greater dysfunction at baseline in terms of overall SMFA scores (42.4 for amputees *versus* 27.9 for the remainder of the study cohort), self-efficacy (23.6 *versus* 39.0) and baseline depression and PTSD (75% *versus* 18% and 20%, respectively).

4. KEY RESEARCH ACCOMPLISHMENTS

- Both components of the PRIORITI program were successfully replicated at 2 additional military treatment facilities.
- The targeted sample size for the study was 90 patients. We met our enrollment target (91 patients enrolled). However, four patients did not complete the baseline assessments and were withdrawn from the study. An additional 6 patients received an IDEO™ but did not return for any RTR PT sessions and were excluded from the main analysis, leaving a final sample size of 81 for the main analysis.
- Follow-up rates immediately following completion of RTR PT and at 6 and 12 months were 88%, 75% and 79% respectively. These follow-up rates were consistent with what we anticipated (80% at one year).
- The detailed protocol for the study was published in the Journal of Orthopaedic Trauma.
- The final analysis has been completed and published in a leading peer-reviewed journal, the Journal of Bone and Joint Surgery.

5. CONCLUSION:

Results of the PRIORITI-MTF add to a growing body of evidence regarding the effectiveness of the IDEO™ when coupled with RTR PT. Of particular note, improvements in function associated with the program implemented at NMCSD and WRNMMC were similar to those found at BAMC, where the device and the RTR PT program were developed and broadly employed at the time of study initiation.

These positive results could significantly influence the risk-benefit analysis that patients and providers consider when deciding to proceed with amputation versus limb salvage following major foot and ankle trauma. Growing evidence suggests particularly poor outcomes for these

patients, with some indication that outcomes would improve had the limb been amputated. Incorporating the provision of an IDEO™ and RTR PT in limb salvage protocols could significantly alter these conclusions.

To explore comparative cost-effectiveness, future studies should consider randomizing civilian trauma patients to receive the IDEO™ versus a less expensive, more widely available carbon fiber AFO. These comparisons will be critical in convincing providers and payers to establish widespread access to the IDEO™. Translation to the civilian sector not only has the potential to impact veterans' and limb salvage patients' lives, it will also ensure that program refinement continues after a de-escalation of combat activity. Without collaborating with the civilian sector, there is substantial risk that the program will be lost for future Wounded Warriors.[21]

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Publications:

Hsu JR, Owens JG, DeSanto J, Fergason JR, Kuhn KM, Potter BK, Stinner DJ, Sheu RG, Waggoner SL, Wilken JM, Huang Y, Scharfstein DO, MacKenzie EJ; METRC. Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries: The PRIORITI-MTF Study.J Orthop Trauma. 2017 Apr;31 Suppl 1:S56-S62.

Potter BK, Sheu RG, Stinner D, Fergason J, Hsu JR, Kuhn K, Owens JG, Rivera J, Shawen SB, Wilken JM, DeSanto J, Huang Y, Scharfstein DO, MacKenzie EJ. Multisite Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Patients with Residual Disability After Lower-Limb Trauma. J Bone Joint Surg Am. 2018 Oct 17;100(20):1781-1789. PMID: 30334889.

Podium Presentations/Abstracts:

Potter BK and the METRC PRIORITI Team. Multisite Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Patients with Residual Disability After Lower-Limb Trauma. The 2017 Annual Meeting of the Orthopedic Trauma Association.

Potter BK and the METRC PRIORITI Team. Multi-Site Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Lower Limb Trauma Patients with Residual Disability. The 2017 Annual Military Health Services Research Symposium.

Potter BK and the METRC PRIORITI Team. Multi-Site Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Lower Limb Trauma Patients with Residual Disability. The 2018 Extremity War Injuries Symposium.

7. INVENTIONS, PATENTS AND LICENSES:

A provisional patent was filed in April, 2011 by Ryan Blanck, CPO in conjunction with the United States Government, as represented by the Secretary of the Army (Application Serial No. 61/518,801). The final patent was filed by Ryan Blanck,CPO in conjunction with The Government of the United States of America on February 28, 2013 (Publication number

WO2013158221 A1).

8. REPORTABLE OUTCOMES:

- Overall physical function was poor at time of enrollment into the study. Scores on the VR-12 mental health component summary (MCS) were more similar to population norms, although 24% had scores PHQ-9 consistent with moderate to severe depressive symptoms; 21% screened positive for post-traumatic stress based on the PTSD Checklist.
- At time of enrollment, 33% were currently using a non-IDEO^{TM} orthosis; an additional 31% reported having used an orthosis in the past.
- The mean number of sessions attended by the 81 participants to be included in the main analysis was 9.1 (SD 3.1); 77% completed 8 or more sessions and 6% completed fewer than 4 sessions.
- Compared to baseline, improvement at completion of RTR PT was observed in all but one performance test (i.e. self-selected walking speed). SMFA scores for all domains except Arm/Hand Function were lower (improved function) at 6 and 12 months.
- Satisfaction with the IDEO^{TM} was high following completion of RTR PT with some attenuation at follow-up.
- There were no appreciable differences in treatment effect by center (BAMC versus NMCSD or WRNMMC) or by number of RTR PT sessions attended (<8 versus 8 or more).
- Four participants underwent amputation after enrolling in the study, all due to pain; 3 occurred between 6 and 12-months and 1 after 12 months. Removing the 3 participants who underwent amputation within 12 months from the analysis did not change the results. These individuals reported greater dysfunction at baseline.
- Despite improvement in both performance and self-reported functioning, deficits persist compared to population norms.

9. OTHER ACHIEVEMENTS:

As a result of this study, NMCSD and WRNMMC now have the capability to manufacture and fit IDEO^{TM} devices and offer RTR PT. To date, over 300 patients have received the IDEO^{TM} from these two facilities, further demonstrating the importance of expanding this capability beyond a single site.

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11. APPENDICES:

Appendix 1: Hsu JR, Owens JG, DeSanto J, Fergason JR, Kuhn KM, Potter BK, Stinner DJ, Sheu RG, Waggoner SL, Wilken JM, Huang Y, Scharfstein DO, MacKenzie EJ; METRC. Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries: The PRIORITI-MTF Study.J Orthop Trauma. 2017 Apr;31 Suppl 1:S56-S62.

Appendix 2: Potter BK, Sheu RG, Stinner D, Fergason J, Hsu JR, Kuhn K, Owens JG, Rivera J, Shawen SB, Wilken JM, DeSanto J, Huang Y, Scharfstein DO, MacKenzie EJ. Multisite Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Patients with Residual Disability After Lower-Limb Trauma. J Bone Joint Surg Am. 2018 Oct 17;100(20):1781-1789. PMID: 30334889.

A commentary by Alastair Younger, MB ChB, MSc ChM, FRCSC, is linked to the online version of this article at jbjs.org.

Multisite Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Patients with Residual Disability After Lower-Limb Trauma

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Investigation performed at the Naval Medical Center San Diego, San Diego, California; Brooke Army Medical Center, Fort Sam Houston, Texas; and Walter Reed National Military Medical Center, Bethesda, Maryland

Background: The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a custom energy-storing carbon fiber ankle-foot orthosis developed for lower-extremity trauma patients. Studies conducted at the military treatment facility where the IDEO was developed demonstrated benefits of the IDEO when used with the Return to Run Physical Therapy (RTR PT) program. The current study was designed to determine if results could be replicated at other military treatment facilities and to examine whether early performance gains in patient-reported functional outcomes remained at 12 months.

Methods: Study participants included service members who had functional deficits that interfered with daily activities at least 1 year after a traumatic unilateral lower-extremity injury at or below the knee. Participants were evaluated before receiving the IDEO, immediately following completion of RTR PT, and at 6 and 12 months. Agility, strength/power, and speed were assessed using well-established performance tests. Self-reported function was measured using the Short Musculoskeletal Function Assessment (SMFA). The Orthotics and Prosthetics Users' Survey was administered to assess satisfaction with the IDEO. Of 87 participants with complete baseline data, 6 did not complete any physical therapy and were excluded from the analysis. Follow-up rates immediately following completion of the RTR PT and at 6 and 12 months were 88%, 75%, and 79%, respectively.

Results: Compared with baseline, improvement at completion of RTR PT was observed in all but 1 performance test. SMFA scores for all domains except hand and arm function were lower (improved function) at 6 and 12 months. Satisfaction with the IDEO was high following completion of RTR PT, with some attenuation at the time of follow-up.

Conclusions: This study adds to the evidence supporting the efficacy of the IDEO coupled with RTR PT. However, despite improvement in both performance and self-reported functioning, deficits persist compared with population norms.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Limb salvage has become feasible for many high-energy, open fractures of the distal aspect of the tibia, ankle, and foot, but outcomes are often suboptimal[1-4]. Orthotic options for improving function are limited[5]. Conventional ankle-foot orthoses (AFOs) consist of a hard plastic shell extending from the metatarsal heads to the proximal aspect of

*Major Extremity Trauma and Rehabilitation Consortium (METRC) Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries at Military Treatment Facilities (PRIORITI-MTF) Team: Andrew DePratti, Richard S. Miltenberger, Sally Morgan, Carter Sigmon, Brian Zalewski, Vincent Reeves, Victor M. Donald, Xochitl Ceniceros, Jeffrey G. Fay, Michael J. Bosse, and Susan Collins

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the tibia. These are most useful for foot drop or plantar-flexion weakness and provide no assistance in plantar flexion in terminal stances, resulting in a "steppage gait."[6-8] Patellar-tendon-bearing AFOs have been beneficial in decreasing pain by limiting ankle and subtalar motion while off-loading the limb[9,10].

Newer, dynamic AFOs store and return energy to provide more plantar-flexion power, typically by incorporating a carbon fiber material into the posterior aspect of the orthosis. Biomechanical data suggest that deformation (i.e., flexing) of the carbon fiber spring, which occurs during ankle dorsiflexion in stance as the tibia progresses forward and then returns to its original position as the limb is unloaded, allows for more powerful plantar flexion during step-off, although some degree of steppage gait remains because of the plantar-flexed posture of the footplate. This improved ankle power leads to increased gait velocity and decreased work of ambulation, and provides adequate running power[7,8].

The Center for the Intrepid and Brooke Army Medical Center developed a custom energy-storing and off-loading carbon fiber ankle-foot orthosis specifically for trauma patients (Fig. 1). The Intrepid Dynamic Exoskeletal Orthosis (IDEO) incorporates dual, posteriorly mounted carbon fiber struts spanning from a proximal ground reaction cuff, providing circumferential support similar to a patellar-tendon-bearing prosthesis, to a plantar-flexed supramalleolar solid ankle AFO and footplate. A custom external solid ankle cushion heel (SACH) made of urethane foam is placed under the heel section of the IDEO, allowing for shock absorption during loading. Loading response is adjustable by altering the SACH height and/or density of the material. Terminal stance resistance is controlled by the stiffness of the posterior carbon fiber struts, available in 4 diameters. The design maximizes strut dynamics, energy storage, and power while off-loading and protecting the ankle and foot. The Return to Run Physical Therapy (RTR PT) program, a high-intensity, sports-medicine-based approach to rehabilitation, was developed by the Center for the Intrepid-Brooke Army Medical Center to maximize use of and satisfaction with the IDEO, with an aim toward returning users to athletics and military service[11-14].

Fig. 1
Clinical photograph of the Intrepid Dynamic Exoskeletal Orthosis (IDEO).

Early studies evaluating the IDEO and RTR PT yielded encouraging results. One study of 18 patients demonstrated improvement in function compared with no orthosis and 2 commercially available orthoses[12]. A larger study of 84 patients found improvement in both physical performance measures and patient-reported outcomes after completion of RTR PT[13]. In a retrospective study of 146 service members who received an IDEO, return-to-duty rates were higher (51%) among those who participated in RTR PT than among those who did not (13%), although selection bias may have influenced the magnitude of these differences[15]. Most recently, a systematic review found moderate evidence supporting the development of 4 empirical evidence statements regarding the IDEO used with RTR PT[16]. However, the IDEO had only been utilized and studied at the facility where it was developed. Furthermore, there was little evidence that short-term improvements in performance translate into longer-term improvements in patient-reported functional outcomes and quality of life.

To address this evidence gap, the Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries at Military Treatment Facilities (PRIORITI-MTF) study was designed to evaluate the efficacy of an integrated IDEO and RTR PT program at 2 additional military treatment facilities. Assessments included immediate improvements in physical performance, satisfaction with the IDEO, and 12-month improvements in self-reported outcomes among military patients who had experienced persistent functional deficits after a traumatic lower-extremity injury at or below the knee at least 1 year prior to enrollment[17]. We hypothesized that, compared with baseline (before fitting of the IDEO), physical performance would improve immediately following completion of RTR PT, and patient-reported outcomes would show improvement at 6 and 12 months following program completion. We also hypothesized that initial satisfaction with the IDEO would be high and remain high at the time of follow-up.

Materials and Methods

The study protocol, including the informed-consent form, was approved by the Johns Hopkins Bloomberg School of Public Health institutional review board (location of the Major Extremity Trauma and Rehabilitation Consortium [METRC] Coordinating Center), the U.S. Department of Defense Human Research Protection Office (DoD HRPO; study sponsor), and the local institutional review board at each military facility.

Additionally, each site obtained certification by the Coordinating Center to ensure proper training on study procedures and data collection prior to initiating the study. The trial was registered with clinicaltrials.gov (NCT02158884).

In this pre-post intervention investigation, study participants served as their own controls. Study procedures were previously described elsewhere[17] and are summarized here. Participants were recruited by 3 military treatment facilities: Naval Medical Center San Diego, Brooke Army Medical Center, and Walter Reed National Military Medical Center. Eligible for the study were active-duty, retired, or separated service members who were at least 1 year out from a traumatic, unilateral lower-extremity injury at or below the knee and who were able to bear weight but had functional deficits interfering with daily activities. To ensure a clinically "stable" population, the study excluded individuals with unhealed fractures and soft-tissue injuries or for whom additional surgery was planned within 6 months.

The PRIORITI-MTF intervention consisted of custom-fitting the IDEO and the RTR PT program[17], modified for delivery in 2 to 3 sessions per week. The IDEO device is U.S. Food and Drug Administration (FDA)-exempt under 21 CFR (Code of Federal Regulations) 890.3475 and 21 CFR 890.3410. All devices were fabricated and custom-fitted by a certified prosthetist orthotist (CPO) and an orthotic technician at the center at which the participant was enrolled. The CPO and technician were trained as a team at the Center for the Intrepid in the fabrication and fitting of the IDEO. RTR PT was delivered by physical therapists or physical therapy assistants with documented training in sports medicine and experience in treating trauma patients. They were provided with a manual detailing elements of the program and trained at the Center for the Intrepid over a 3-day period.

After the participant provided consent for the study, the CPO team created a plaster cast of the leg, which (along with other measures needed for fabrication) was used to develop a diagnostic test device. Strut stiffness was selected by the treating CPO, on the basis of the patient's body weight and anticipated functional demand level. The test device was fitted, adjusted, and evaluated for comfort and function prior to fabricating the definitive custom carbon fiber orthosis. After being fitted with the definitive IDEO, participants were encouraged to participate in 4 weeks of RTR PT (2 to 3 sessions per week). During these 4 weeks, adjustments to the orthosis were made to optimize function. Notably, the full program, including both onsite fabrication and RTR PT, was operational at Naval Medical Center San Diego and Walter Reed National Military Medical Center for 9 months before the first study participant was enrolled.

Participants were scheduled for evaluation at baseline (before fitting of the IDEO), immediately following completion of RTR PT, and at 6 months and 12 months following program completion. At baseline, data were collected pertaining to participant characteristics (sociodemographics, self-efficacy, social support, comorbidities) and current level of physical impairment (range of motion, strength), pain, and psychological well-being (evidence of depression and posttraumatic stress disorder [PTSD])[17].

Primary study outcomes were functional performance (at baseline and immediately following completion of RTR PT) and self-reported functioning (at baseline and 6 and 12 months). Functional performance was assessed using tests for agility (Four Square Step Test and Illinois Agility Test), strength/power (sit-to-stand and timed stair ascent tests), and speed (self-selected walking speed and 10-m shuttle run)[18]. Self-reported functioning was measured using the Short Musculoskeletal Function Assessment (SMFA)[19]. Use of and satisfaction with the IDEO were assessed using the Orthotics and Prosthetics Users' Survey (OPUS)[20], consisting of 11 items pertaining to device satisfaction, including weight, comfort, pain associated with use, ease of use, cosmesis, durability, fit, and effect of the device on clothing.

For functional performance tests, median scores were determined for patients as evaluated at both baseline and the end of RTR PT. For each test at each time point, patient scores were ranked from "worst" to "best." Patients "unable to participate due to pain or impairment" were ranked "worst," followed by those "unable to complete the test due to pain or impairment," followed by those who were able to complete the test, sorted by their test results. The 95% confidence intervals (CIs) for differences in median values between time points were computed with paired bootstrap resampling.

For self-reported functional outcomes, paired differences between follow-up visits (6 and 12 months) and baseline for all subdomains were used to fit a multivariate mixed-effects regression model with patient as a random effect and variance depending on the subdomain, and full interactions between visit and subdomain as fixed effects. For each subdomain, 95% CIs of the mean differences between 6 months and baseline, 12 months and baseline, and 12 months and 6 months are reported. This analysis used all available self-reported functional outcome data from the 81 enrolled patients who completed the program.

Differences in treatment effects were examined by center (Brooke Army Medical Center versus Walter Reed National Military Medical Center or Naval Medical Center San Diego) and by the number of RTR PT sessions attended (<8 versus ≥8).

Results

Ninety-one participants were initially enrolled in the study and received a customized IDEO. Four of these patients did not complete the baseline assessments and were withdrawn from the study. An additional 6 patients received an IDEO but did not return for any RTR PT sessions. These 10 patients were excluded from the analysis. The remaining 81 participants attended a mean (and standard deviation) of 9.1 ± 3.1 sessions; 77% completed ≥8 sessions and 6% completed <4 sessions. Seventy-one (88%) of the participants completed the evaluation immediately following the completion of RTR PT. Follow-up rates at 6 and 12 months were 75% and 79%, respectively.

Participant demographics and baseline self-efficacy data are reported in Table I. Overall, 40% indicated that their health

was very good or excellent, and most patients had >1 neuromuscular or orthopaedic condition that made them good candidates for the brace (Table II). The mean Veterans RAND 12-Item Health Survey (VR-12) physical component summary (PCS) score at baseline was 32.8 ± 9.1, reflecting poor overall physical functioning at the time of enrollment. Scores on the VR-12 mental health component summary (MCS) were more similar to population norms[21], although 23% had scores on the

TABLE I Demographic Characteristics of the Study Participants (N = 81)*

		Treatment Facility†		
	All (N = 81)	BAMC (N = 39)	NMCSD (N = 23)	WRNMMC (N = 19)
Age at enrollment *(yr)*	36.2 ± 8.5	37.6 ± 8.2	33.4 ± 8.8	36.8 ± 8.3
Distribution by age group				
<25 yr	5 (6%)	1 (3%)	2 (9%)	2 (11%)
25-34 yr	33 (41%)	17 (44%)	12 (52%)	4 (21%)
35-44 yr	25 (31%)	12 (31%)	4 (17%)	9 (47%)
≥45 yr	18 (22%)	9 (23%)	5 (22%)	4 (21%)
Sex				
Male	72 (89%)	37 (95%)	18 (78%)	17 (89%)
Female	9 (11%)	2 (5%)	5 (22%)	2 (11%)
Race/ethnicity				
Hispanic	10 (12%)	9 (23%)	1 (4%)	0 (0%)
Non-Hispanic non-white	15 (19%)	7 (18%)	3 (13%)	5 (26%)
Non-Hispanic white	54 (67%)	21 (54%)	19 (83%)	14 (74%)
Refused/unknown/missing	2 (2%)	2 (5%)	0 (0%)	0 (0%)
Education at enrollment				
High school or GED‡	13 (16%)	4 (10%)	4 (17%)	5 (26%)
Some college or higher	68 (84%)	35 (90%)	19 (83%)	14 (74%)
Usual major activity at enrollment				
Active duty	53 (65%)	24 (62%)	17 (74%)	12 (63%)
Working	12 (15%)	7 (18%)	2 (9%)	3 (16%)
Going to school	4 (5%)	0 (0%)	2 (9%)	2 (11%)
Other	12 (15%)	8 (21%)	2 (9%)	2 (11%)
Branch of military				
Army	29 (36%)	20 (51%)	0 (0%)	9 (47%)
Air Force	14 (17%)	7 (18%)	1 (4%)	6 (32%)
Navy	18 (22%)	4 (10%)	13 (57%)	1 (5%)
Marines	16 (20%)	6 (15%)	7 (30%)	3 (16%)
Other	4 (5%)	2 (5%)	2 (9%)	0 (0%)
Pay grade				
Enlisted	66 (81%)	35 (90%)	18 (78%)	13 (68%)
Officer	15 (19%)	4 (10%)	5 (22%)	6 (32%)
Marital status at enrollment				
Married (or cohabitating)	60 (74%)	32 (82%)	11 (48%)	17 (89%)
Never married	16 (20%)	4 (10%)	10 (43%)	2 (11%)
Widowed, divorced, or separated	5 (6%)	3 (8%)	2 (9%)	0 (0%)
Self-efficacy				
Score (0-60)	38.4 ± 12.1	39.5 ± 12.1	37.0 ± 12.3	37.7 ± 12.4
Refused/unknown/missing	3 (4%)	2 (5%)	0 (0%)	1 (5%)

*The values are given as the number with the percentage in parentheses, with the exception of age at enrollment and self-efficacy score, which are given as the mean and standard deviation. †BAMC = Brooke Army Medical Center, NMCSD = Naval Medical Center San Diego, and WRNMMC = Walter Reed National Military Medical Center. ‡GED = general equivalency diploma.

TABLE II Baseline Health and Overall Functional Status (N = 81)*

	All (N = 81)	Treatment Facility†		
		BAMC (N = 39)	NMCSD (N = 23)	WRNMMC (N = 19)
No. of functional deficits				
1	36 (44%)	14 (36%)	17 (74%)	5 (26%)
2	30 (37%)	15 (38%)	5 (22%)	10 (53%)
≥3	15 (19%)	10 (26%)	1 (4%)	4 (21%)
Functional deficits, by type				
Weakness of ankle dorsiflexors and/or plantar flexors resulting from leg injury	36 (44%)	25 (64%)	1 (4%)	10 (53%)
Limited ankle dorsiflexion and/or limited ankle plantar flexion resulting from leg injury	40 (49%)	21 (54%)	7 (30%)	12 (63%)
Mechanical pain with loading to hindfoot/midfoot	49 (60%)	17 (44%)	20 (87%)	12 (63%)
Ankle or hindfoot fusion or candidate for ankle or hindfoot fusion	15 (19%)	10 (26%)	1 (4%)	4 (21%)
Candidate for amputation secondary to ankle/foot impairment	3 (4%)	2 (5%)	1 (4%)	0 (0%)
Use of brace/orthosis				
Never	29 (36%)	11 (28%)	16 (70%)	2 (11%)
Yes, in the past	25 (31%)	14 (36%)	2 (9%)	9 (47%)
Yes, currently	27 (33%)	14 (36%)	5 (22%)	8 (42%)
Type of brace/orthosis (among current or past users)				
Custom passive	10/52 (19%)	6/28 (21%)	1/7 (14%)	3/17 (18%)
Custom energy-storing	3/52 (6%)	3/28 (11%)	0/7 (0%)	0/17 (0%)
Off-the-shelf passive	31/52 (60%)	13/28 (46%)	5/7 (71%)	13/17 (76%)
Off-the-shelf energy-storing	0/52 (0%)	0/28 (0%)	0/7 (0%)	0/17 (0%)
Unknown	8/52 (15%)	6/28 (21%)	1/7 (14%)	1/17 (6%)
VR-12: overall health status				
Excellent	8 (10%)	1 (3%)	6 (26%)	1 (5%)
Very good	24 (30%)	11 (28%)	7 (30%)	6 (32%)
Good	34 (42%)	18 (46%)	7 (30%)	9 (47%)
Fair or poor	15 (19%)	9 (23%)	3 (13%)	3 (16%)
VR-12: PCS	32.8 ± 9.1	33.7 ± 9.2	31.1 ± 9.2	33.2 ± 8.9
VR-12: MCS	53.4 ± 11.8	50.8 ± 13.5	54.7 ± 10.5	57.1 ± 8.3
BMI† *(kg/m²)*	29.7 ± 4.4	30.2 ± 4.8	28.7 ± 3.6	29.8 ± 4.4
Distribution by BMI category				
<25 kg/m²	8 (10%)	3 (8%)	4 (17%)	1 (5%)
25-30 kg/m²	36 (44%)	17 (44%)	10 (43%)	9 (47%)
>30 kg/m²	31 (38%)	15 (38%)	8 (35%)	8 (42%)
No. of major comorbidities				
0	28 (35%)	16 (41%)	7 (30%)	5 (26%)
1	16 (20%)	9 (23%)	5 (22%)	2 (11%)
≥2	37 (46%)	14 (36%)	11 (48%)	12 (63%)
Tobacco use				
Current use	11 (14%)	8 (21%)	2 (9%)	1 (5%)
Former use	21 (26%)	11 (28%)	3 (13%)	7 (37%)
No use	48 (59%)	20 (51%)	17 (74%)	11 (58%)
Refused/unknown	1 (1%)	0 (0%)	1 (4%)	0 (0%)

continued

TABLE II (*continued*)

	All (N = 81)	Treatment Facility†		
		BAMC (N = 39)	NMCSD (N = 23)	WRNMMC (N = 19)
Depressive symptoms (PHQ)				
Minimal (0-4)	44 (54%)	20 (51%)	12 (52%)	12 (63%)
Mild (5-9)	17 (21%)	8 (21%)	5 (22%)	4 (21%)
Moderate (10-14)	11 (14%)	4 (10%)	5 (22%)	2 (11%)
Moderately severe to severe (≥15)	8 (10%)	6 (15%)	1 (4%)	1 (5%)
Refused/unknown/missing	1 (1%)	1 (3%)	0 (0%)	0 (0%)
PTSD symptoms (PCL)				
DSM-IV symptom criteria; moderately severe or severe§	17 (21%)	10 (26%)	5 (22%)	2 (11%)

*The values are given as the number with the percentage in parentheses, with the exception of VR-12 physical and mental component summary scores and body mass index (BMI), which are given as the mean and standard deviation. †BAMC = Brooke Army Medical Center, NMCSD = Naval Medical Center San Diego, and WRNMMC = Walter Reed National Military Medical Center. ‡BMI data not available for all patients. §DSM-IV = Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition.

Patient Health Questionnaire (PHQ-9) consistent with moderate to severe depressive symptoms[22]; 21% screened positive for posttraumatic stress based on the PTSD Checklist (PCL)[23]. At the time of enrollment, 33% were using a non-IDEO orthosis; an additional 31% reported having used an orthosis in the past.

With the exception of self-selected walking speed, there were improvements in functional performance between the completion of RTR PT and baseline (Table III). SMFA scores for all domains except hand and arm function showed improvement (lower scores) at 6 and at 12 months compared with baseline (Table IV), with more impressive results at 12 months. Improvements at 12 months for mobility and daily activities exceeded one-half of a standard deviation, often used as a threshold for clinically meaningful changes in health-related quality-of-life measures[24]: mean improvement of 8.9 points for mobility (95% CI of paired difference, −13.0 to −4.9) and 10.6 points for daily activities (95% CI of paired difference, −14.7 to −6.5). There were no appreciable differences in treatment effect by center (Brooke Army Medical Center versus Walter Reed National Military Medical Center or Naval Medical Center San Diego) or by the number of RTR PT sessions attended (<8 versus ≥8) (data not shown).

Satisfaction with the IDEO was very high following completion of RTR PT (OPUS scores averaged 84.6 of a possible 100 points), with some attenuation at 6 and 12 months (mean scores of 73.1 and 71.5, respectively). Satisfaction with the IDEO at 12 months was higher than satisfaction with non-IDEO AFOs reported being used by 52 participants prior to the study enrollment (mean OPUS of 55.0).

Four participants underwent amputation after enrolling in the study, all due to pain: 3 between 6 and 12 months and 1, after 12 months. Removing the 3 participants who underwent amputation within 12 months from the analysis did not change the results and thus, they remained in the analyses. These individuals reported greater dysfunction at baseline in terms of mean overall SMFA scores (42.4 for amputees compared with 27.9 for the remainder of the study cohort), self-efficacy (23.6 compared with 39.0), and baseline depression and PTSD (75% and 75% compared with 18% and 20%, respectively).

TABLE III Performance Tests at Baseline and Immediately Following Completion of RTR PT (N = 71)

Measure	Median Score (No. Unable)*		Median Difference (95% CI) in Paired Scores: End of RTR PT Vs. Baseline
	Baseline	Completion of RTR PT	
Four Square Step Test *(sec)*	8.0 (1)	6.0 (1)	−2.0 (−2.5, −1.0)
Illinois Agility Test *(sec)*	29.0 (8)	22.5 (4)	−6.5 (−12.0, −3.3)
Sit-to-stand test ×5 *(sec)*	10.0 (0)	7.5 (0)	−2.5 (−3.5, −1.5)
Timed stair ascent test *(sec)*	5.0 (2)	4.0 (0)	−1.0 (−2.0, −0.5)
Self-selected walking speed *(m/sec)*	1.5 (0)	1.5 (0)	0.0 (0.0, 0.3)
Shuttle run *(m/sec)*	2.2 (6)	2.8 (4)	0.6 (0.3, 0.9)

*For patients who were unable to participate in or complete the tests because of pain or impairment, the worst rankings were assigned.

TABLE IV Self-Reported Outcomes at Baseline and 6 and 12 Months Following Completion of RTR PT*

Short Musculoskeletal Function Assessment (SMFA)	Mean Score at Baseline (Population Norm)	Estimated Mean Difference (95% CI)		
		6 Mo. Vs. Baseline	12 Mo. Vs. Baseline	12 Vs. 6 Mo.
Overall dysfunction	28.6 (12.5)	−4.2 (−6.1, −2.2)	−6.9 (−9.0, −4.9)	−2.8 (−4.8, −0.7)
Mobility	37.1 (13.6)	−6.7 (−10.8, −2.6)	−8.9 (−13.0, −4.9)	−2.3 (−6.1, 1.6)
Daily activities	31.0 (11.8)	−6.7 (−10.7, −2.8)	−10.6 (−14.7, −6.5)	−3.9 (−7.5, −0.3)
Hand and arm function	2.0 (6.0)	1.0 (−1.9, 3.8)	0.7 (−2.3, 3.7)	−0.3 (−4.5, 3.9)
Emotional status	44.4 (20.5)	−3.1 (−7.7, 1.4)	−7.9 (−12.6, −3.1)	−4.7 (−9.8, 0.3)

*N = 81 at baseline, n = 61 at 6 months, and n = 64 at 12 months.

Discussion

Both components of the PRIORITI-MTF program were successfully replicated at 2 additional military treatment facilities: Naval Medical Center San Diego and Walter Reed National Military Medical Center. Improvements in function associated with the program implemented at these facilities were similar to those found at Brooke Army Medical Center, where the IDEO and the RTR PT program were developed and broadly employed at the time of study initiation. Naval Medical Center San Diego and Walter Reed National Military Medical Center now have the capability to manufacture and fit the IDEO and offer RTR PT. To date, >300 patients have received the IDEO from these 2 facilities (data not shown), further demonstrating the importance of expanding this capability beyond a single site.

Improvements in functional performance were observed immediately following completion of RTR PT. These improvements were similar in size to those reported by Bedigrew and colleagues[13] in their study of 31 participants who were ≥2 years out from their fracture (mean difference of 2.5 seconds for the Four Square Step Test, 2.0 seconds for the timed stair ascent, and 0.2 and 0.8 m/sec for the self-selected walking speed and shuttle run, respectively). Satisfaction with the IDEO was very high immediately following completion of RTR PT, with some attenuation in scores at 6 months and 12 months.

A strength of this study was its assessment of patient-reported outcomes at 6 and 12 months following completion of RTR PT. Importantly, improvements over baseline were not just sustained but continued, increasing between 6 and 12 months. This may reflect one of the advantages of the program among select patients: early improvements in physical function with the IDEO may improve overall capabilities without it, decreasing the necessity of orthosis use, particularly for daily, low-impact activities, over time. Thus, the IDEO and RTR PT may function as a rehabilitation tool for some patients, eventually facilitating obsolescence of the orthosis itself. While some patients will always require the IDEO for unimpeded ambulation, others may require it only for high-impact activities, and yet others may eventually discontinue its use altogether. Notably, 12-month SMFA scores remained significantly ($p < 0.01$) higher (i.e., worse) than population norms in all domains except hand and arm function[25].

Limitations of the study were the inability to blind subjects and investigators and the lack of a control group. Blinding of patients was not possible because nearly all of our study candidates were aware of the IDEO prior to enrollment and were interested in receiving the brace; however, this does raise the possibility of improvement inflation due to the so-called halo effect. Another important assumption inherent in this design is that any observed improvement in function can be attributable to the intervention, not to the natural course of recovery. This assumption is addressed by including only participants who were ≥1 year out from their injury. Although most recovery occurs within the first year post-injury, additional patient improvement is possible. However, the effects of time and natural history were likely minimal in this study, as the mean time from injury to enrollment was 7.4 years.

Another limitation was the inability to unbundle the effects of the IDEO, its components, and RTR PT on outcomes. The relative contribution of RTR PT is of particular interest. The idea that physical therapy is necessary to maximize the IDEO's benefits is not controversial, but the optimal amount and intensity of physical therapy remain an open question. While there was no appreciable difference in the effect of the device when comparing participants who completed ≥8 sessions with those who completed fewer sessions, the modest number of participants precluded a deeper evaluation of the relationship between engagement in RTR PT and outcome. However, these findings suggest that a reduced or streamlined version of RTR PT may produce similar results. Lastly, mental health and resilience are increasingly recognized as important factors in determining physical and health-related quality-of-life outcomes. Although we did note baseline VR-12 MCS scores near population norms, nearly a quarter of our patients had symptoms of depression and/or PTSD at enrollment. These measures were not repeated during follow-up, and so we cannot comment on changes in mental well-being afforded by the brace and program. We did note a moderate improvement in the emotional component of the SMFA, however.

Despite these limitations, the PRIORITI-MTF results add to a growing body of evidence regarding the effectiveness of the IDEO when coupled with RTR PT. These positive results

could substantially influence the risk-benefit analysis that patients and providers consider when deciding to proceed with amputation versus limb salvage following major foot and ankle trauma. Growing evidence suggests particularly poor outcomes for these patients, with some indication that outcomes would improve had the limb been amputated[1-4]. Incorporating the provision of an IDEO and RTR PT in limb-salvage protocols could substantially alter these conclusions[13,15,26,27].

To explore the comparative cost-effectiveness, future studies should consider randomizing civilian trauma patients to receive the IDEO versus a less-expensive, more widely available carbon fiber AFO. These comparisons will be critical in determining differences in effectiveness and cost-effectiveness compared with the IDEO. Translation to the civilian sector not only has the potential to impact veterans' and limb salvage patients' lives, it will also ensure that program refinement continues after a de-escalation of combat activity. Without collaborating with the civilian sector, there is substantial risk that the program will be lost for future Wounded Warriors[28]. ■

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