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Abstract

The purpose of this study is to examine the benefits of an integrated orthotic and rehabilitation program that incorporates the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and the Return to Run (RTR) physical therapy (PT) regimen, but designed for scalability in the broader military environment (i.e. beyond Brooke Army Medical Center where the program was developed). We will assess immediate and long-term improvements in functional performance and self reported outcomes in active and retired service members treated at three military treatment facilities (MTF's) who are currently one or more years out from a traumatic unilateral lower extremity injury at or below the knee with functional deficits interfering with daily activities.

Participants are evaluated before receiving the IDEO™, immediately following completion of RTR PT, and at 6 and 12 months. Agility, strength/power and speed are assessed using well-established performance tests. Self-reported function is measured using the Short Form Musculoskeletal Assessment (SMFA). The Orthotics and Prosthetics Users' Survey is administered to assess satisfaction with the IDEO™.

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1. INTRODUCTION:

The purpose of this study is to examine the overall benefits of an integrated orthotic and rehabilitation program that incorporates the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and the Return to Run physical therapy regimen (RTR PT) currently employed at the Brooke Army Medical Center where it was developed. Using a before-after study design, immediate and long-term improvements in functional performance and self-reported outcomes will be assessed in patients treated at military treatment facilities (MTF's)- the Naval Medical Center San Diego (NMCSD), Brooke Army Medical Center (BAMC) and Walter Reed National Military Medical Center (WRNMMC). The study population includes active and retired service members who are one or more years out from a traumatic unilateral lower extremity injury at or below the knee with functional deficits interfering with daily activities.

Primary outcomes include functional performance, measured using well-validated assessments of speed, agility, power, and postural stability and self-reported functioning using the Short Form Musculoskeletal Assessment (SMFA) and the Veterans Health Survey (VR-12). Secondary outcomes include pain, depression, post-traumatic stress and satisfaction with the IDEO^{TM}**.**

Without rigorous evaluation of the technology and rehabilitation pathway of the PRIORITI, there is substantial risk that this intervention will be lost for the future of our current Wounded Warriors. If the positive results obtained in previous studies 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, orthopaedic rehabilitation

3. BODY

Overall Progress

This annual report reflects progress and accomplishments from 7/1/16 to 6/30/17.

We have completed all enrollment and follow-up. A total of 91 total participants were enrolled across the three participating military treatment facilities (40 at BAMC, 23 at WRNMMC, and 28 at NMCSD). However, of these 91 patients, 4 did not complete a baseline assessment and 6 were fitted for a brace but did not participate in the RTR PT, leaving 81 available for a valid before-after outcomes comparison.

Follow-up rates immediately following completion of RTR PT and at 6 and 12 months were 88%, 75% and 79% respectively. Providing an option to complete the 6 and/or 12

month follow-up by telephone or on-line helped capture self-reported data for study participants who were unable to return to the clinical center for a complete assessment. Providing such a option, however, led to missing performance assessments (12% of all patients enrolled).

We are currently working with the three study sites to clean the final data and develop analysis files.

We are also developing the final analysis plan for examining changes in functional outcomes before and after receiving the IDEO and RTR PT. These analyses will take into account missing data associated with loss to follow-up or lack of clinical (performance) assessment at follow-up.

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
As stated above, all enrollment and follow-up was completed by the end of the project year as planned.

The protocol for the study was published in the Journal of Orthopaedic Trauma (April, 2017).

Task 7: Conduct the Analysis and Report Results
We are currently in the process of characterizing the study participants and conducting the main analysis.

Participant demographics and baseline self-efficacy data are reported in Appendix Table 1. Overall, 40% indicated their health was very good or excellent (Appendix Table 2). 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,[23] although 24% had scores on the Patient Health Questionnaire (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 is 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.

4. KEY RESEARCH ACCOMPLISHMENTS

- 91 patients were enrolled into the study (81 are available 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.
- Data quality and data cleaning reports were sent to each of the sites.
- Baseline characteristics were summarized by site; overall physical function was poor at time of enrollment into the study.
- The mean number of sessions attended by the 81 participants to be included in the main analysis was 9.1 (SD 3.1)

5. CONCLUSION:

While we currently have no conclusions to report, we would like to re-state our intended military relevance, which includes the following:

The PRIORITI study has the ability to refine the Return to Run Clinical Pathway and the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and translate its use outside BAMC and the Center for the Intrepid. This program for rehabilitation of wounded warriors has

already created a paradigm shift in the level of expectation for function in the limb salvage patient at its place of origin; it has become the standard of care for limb salvage patients at BAMC/CFI.

The PRIORITI-MTF affords the opportunity to study this intervention at other Military Treatment Facilities. It will focus on building and testing the clinical pathway and the IDEO at military centers where the capability does not currently exist. We believe that the military benefit will be immediate for those active duty service members enrolled in the study. The larger military benefit will come from establishing the capability at the major MTFs, proving its effectiveness outside the primary center, and refining the pathway and technology for future generations of service members.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

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. PMID: 28323803

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:

Nothing to report at this time.

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 2 facilities, further demonstrating the importance of expanding this capability beyond a single site.

10. REFERENCES:

None

11. APPENDICES:

Appendix Table 1:

	All (n = 81)	BAMC (n = 39)	NMCSD (n = 23)	WRNMMC (n = 19)
Age at Enrollment				
Mean(SD)	36.2 (8.5)	37.6 (8.2)	33.4 (8.8)	36.8 (8.3)
< 25	5 (6%)	1 (3%)	2 (9%)	2 (11%)
25−34	33 (41%)	17 (44%)	12 (52%)	4 (21%)
35−44	25 (31%)	12 (31%)	4 (17%)	9 (47%)
>=45	18 (22%)	9 (23%)	5 (22%)	4 (21%)
Gender				
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%)	4 (17%)	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 (0−60)				
Mean (SD)	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%)

Appendix Table 2: Baseline Health and Overall Functional Status (n = 81)

	All (n = 81)	BAMC (n = 39)	NMCSD (n = 23)	WRNMMC (n = 19)
Number 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 plantarflexors resulting from leg injury	36 (44%)	25 (64%)	1 (4%)	10 (53%)
Limited ankle dorsiflexion and / or limited ankle plantarflexion 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%)
Types 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: Physical component score				

Mean(SD)	32.8 (9.1)	33.7 (9.2)	31.1 (9.2)	33.2 (8.9)
VR-12: Mental component score				
Mean(SD)	53.4 (11.8)	50.8 (13.5)	54.7 (10.5)	57.1 (8.3)
Body Mass Index				
Mean (SD)	29.7 (4.4)	30.2 (4.8)	28.7 (3.6)	29.8 (4.4)
< 25	8 (10%)	3 (8%)	4 (17%)	1 (5%)
25−30	36 (44%)	17 (44%)	10 (43%)	9 (47%)
≥ 30	31 (38%)	15 (38%)	8 (35%)	8 (42%)
Number of Major Co-morbidities				
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%)
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%)

Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries: The PRIORITI-MTF Study

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Summary: Although limb salvage is now possible for many high-energy open fractures and crush injuries to the distal tibia, ankle, hindfoot, and midfoot, orthotic options are limited. The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a custom, energy-storing carbon fiber orthosis developed for trauma patients undergoing limb salvage. The IDEO differs from other orthoses in that it allows patients with ankle weakness to have more normal ankle biomechanics and increased ankle power. This article describes the design of a study to evaluate the effectiveness of the IDEO when delivered together with a high-intensity, sports medicine–based approach to rehabilitation. It builds on earlier studies by testing the program at military treatment facilities beyond the Brooke Army Medical Center and the Center for the Intrepid where the device was developed. The PRIORITI-MTF study is a multicenter before-after program evaluation where participants at least 1 year out from a traumatic lower extremity injury serve as their own controls. Participants are evaluated before receiving the IDEO, immediately after 4 weeks of physical therapy with the IDEO and at 6 and 12 months after the completion of physical therapy. Primary outcomes include functional performance, measured using well-validated assessments of speed, agility, power, and postural stability and self-reported functioning using the Short Musculoskeletal Function Assessment (SMFA) and the Veterans Health Survey (VR-12). Secondary outcomes include pain, depression, posttraumatic stress, and satisfaction with the IDEO.

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The authors report no conflict of interest.

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Key Words: IDEO, lower limb orthoses, limb salvage, Return to Run, high-energy foot and ankle injuries

(*J Orthop Trauma* 2017;31:S56–S62)

BACKGROUND AND RATIONALE

High-energy open fractures, blast, gunshot wound, and crush injuries to the distal tibia, ankle, hindfoot, and midfoot are common challenges for military and civilian trauma surgeons.[1–12] Management of these injuries is often complicated by soft tissue injury and contamination, ectopic bone, and neurovascular injuries. Although surgical advances in limb preservation have enhanced the potential for limb salvage in these patients, reported outcomes have been suboptimal.[1,7,8] As prosthetic care for individuals with amputation has advanced, major improvements in orthotics and rehabilitation for limb salvage patients have not kept pace.[9] As a result, many limb salvage patients have been unable to achieve their desired functional goals.

Numerous types of ankle-foot orthoses (AFOs) exist for different clinical scenarios, each with specific clinical goals for their use. Conventional AFOs designed to support the limb after trauma resulting in weakness and impairment typically consist of a hard plastic shell extending from the metatarsal head to the proximal tibia. These AFOs hold the ankle in a neutral position and help to prevent excessive plantarflexion during the swing phase that may lead to a "steppage gait," and ensure that the heel contacts the ground at initial strike.[13] They do not, however, provide any assistance with plantarflexion power and cannot contribute to push-off at terminal stance.[14,15] Patellar tendon–bearing AFOs have demonstrated the ability to decrease pain by limiting ankle and subtalar motion while offloading the limb.[16,17]

In an effort to provide more plantarflexion power, passive dynamic orthoses which store and return energy were introduced. Their design typically incorporates a carbon fiber material into the posterior aspect of the AFO. Biomechanical data suggest that deformation 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 plantarflexion during step-off. The intent is to allow patients with

both plantarflexion and dorsiflexion weaknesses to have more normal ankle biomechanics and increased ankle power. This improved ankle power, in turn, can lead to increased gait velocity, decreased work of ambulation, and may provide the patient adequate power to run.[14,15] In small series of patients, energy-storing carbon fiber orthoses have been associated with abnormal gait patterns, temporal–spatial parameters, increased stride length, ankle power, and range of motion.[15,18–20] However, these studies largely address pediatric patients with cerebral palsy, myelomeningocele or other motor disorders, or adults with hemiplegia. Not until recently has any study investigated the use of energy-storing orthoses for trauma patients who have undergone limb salvage.

The IDEO 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 after limb salvage (Fig. 1). The most recent and commonly used version of the IDEO incorporates dual posteriorly mounted carbon fiber struts (MediUSA, Whitsett, NC) connecting a proximal ground reaction cuff to the distal supramalleolar AFO. The proximal ground reaction cuff is a circumferential support designed with characteristics of a patellar tendon–bearing prosthesis, where the proximal end of the carbon fiber struts is bonded to the posterior wall of the cuff. The distal supramalleolar AFO spans from the posterior strut attachment, which is proximal to the calcaneus, to the distal end of the carbon fiber strut, around the ankle joint, and under the foot to encompass the toes. A custom external SACH heel cushion (Kingsley Manufacturing Co, Costa Mesa, CA) is placed under the heel section of the IDEO and allows for shock absorption during the loading response. Loading response can be adjusted by altering the heel cushion in length, height, and durometer. The laminated carbon fiber footplate, which is inspired by prosthetic running feet, is rigid, resulting in ankle stabilization while deformation of the IDEO occurs through the posteriorly positioned carbon fiber struts. This design maximizes strut dynamics and power. The plantarflexed position of the footplate combined with a gradual roller shape allows for increased deflection and energy storage of the strut as the tibia progresses forward from mid-to-terminal stance. It also allows for forefoot loading during agility and running activities.

FIGURE 1. IDEO image.

To maximize an individual's potential success in using the IDEO, 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. The multidisciplinary RTR PT program focuses on strength, agility, and speed with the goal of enabling patients to RTR, sports, and military deployment.[21] Running was chosen as a surrogate for the return to a higher level of functional activity based on the success of amputation rehabilitation programs.[22,23] Several aspects of RTR were designed to build self-efficacy, one of the most important predictors of positive outcomes and return to usual activity. First, patients are treated in cohorts, so they can work alongside similar patients to provide a built-in support group and peer mentoring. Second, RTR is designed in repeating progressions with timed, and sometimes recorded, tests that allow for a tangible demonstration of improvement with each progression.[21,22] Third, occupation-specific adaptive training is conducted with an emphasis on skills needed to return to duty.[24,25]

Early studies evaluating the IDEO have produced promising results. In a small study of 18 subjects with unilateral dorsiflexion and/or plantarflexion weakness, the functional performance of the IDEO was compared against no orthosis and 2 commercially available orthoses—the Allard BlueRocker (BR) and a rigid plastic posterior leaf spring.[26,27] All participants in this study also completed the PT component of the RTR program. Subjects were evaluated on 6 functional tests, wearing the IDEO, BR, posterior leaf spring, and none. Brace order was randomized and 5 trials were completed for each measure. Performance was significantly better with the IDEO on all functional measures compared with all other bracing conditions ($P < 0.004$), with the exception of the sit-to-stand 5 times, in which there was only a significant improvement against the BR ($P = 0.014$). This study did not, however, evaluate the impact of the intervention on patient-reported outcomes.

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 4 weeks after receiving the IDEO and completing the RTR PT program.[28] Among subjects who initially considered amputation, the majority favored limb salvage after this noninvasive intervention. It was equally effective in patients presenting within 2 years from injury versus those presenting after 2 years from injury.

A more recent study underscores the importance of the RTR PT program. In a retrospective study of 146 service members who received the IDEO, Blair et al[25] showed that return-to-duty rates were 51% among the subgroup of 115 service members who participated in the RTR PT program including the AFO, whereas those rates were only 13% with the 59 service members who were fitted with the IDEO alone.

Although collectively these studies point to the benefits of the IDEO and the RTR PT program, they have limitations. First and foremost, all studies were conducted at only 1 military treatment facility where the IDEO 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 Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries at Military Treatment Facilities (PRIORITI-MTF) study was designed to establish an integrated orthotic and rehabilitation program that incorporates the IDEO and the RTR PT program at 2 additional military treatment facilities and to assess immediate and long-term improvements in functional performance and self-reported outcomes in service members or military retirees who are currently 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.

METHODS: TRIAL DESIGN AND PARTICIPANT SELECTION

Overview of Trial Design

The study is a before-after program evaluation where participants serve as their own controls. Participants were recruited from 3 military treatment facilities: Naval Medical Center San Diego (NMCSD), Brooke Army Medical Center (BAMC), and Walter Reed National Military Medical Center (WRNMMC). The study protocol, including the written informed consent form, was approved by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board (IRB) (location of the METRC Coordinating Center), the Department of Defense Human Research Protection Office (DoD HRPO) (study sponsor), and the local IRB at each military treatment facility. In addition, each site was required to obtain DoD HRPO approval of local IRB documents and certification by the METRC Coordinating Center (MCC) to ensure proper training on study procedures and data collection before the initiation of the study.

Study procedures are summarized in Figure 2. At Time 0, the Site Prosthetist/Orthotist (CPO) (trained and certified for the PRIORITI-MTF study) takes a cast of the leg and other pertinent measures that are needed for fabrication of the IDEO. During the 2–4 weeks while the device is being fabricated (by the local site CPO team), the participant is instructed to engage in a home PT program to improve conditioning and build self-efficacy. Within 4 weeks, the participants are fitted with the IDEO and participate in 4 weeks of the RTR PT program at the study center. During these 4 weeks, adjustments to the brace are made and participants learn how to optimize its use. Participants are evaluated before receiving the IDEO (T0), immediately after 4 weeks of the RTR PT with the IDEO (T2), and at 6 (T3) and 12 months (T4) after the completion of PT. Primary hypotheses for the study were as follows:

1. Compared with baseline (T0), functional performance will be significantly better immediately after the completion of the PRIORITI program (T2) and at 1 year (T4).
2. Compared with baseline (T0), patient-reported outcomes will be significantly better at 1 year after the completion of the PRIORITI program (T4).

Also measured was satisfaction with the comfort, cosmesis, ease of use, and durability of the IDEO, with the expectation that satisfaction would be high immediately after 4 weeks of the RTR PT and maintained at 1 year.

Participant Selection

Eligibility criteria 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 that interfere with daily activities. Specific inclusion and exclusion criteria are listed in Table 1. Potentially eligible

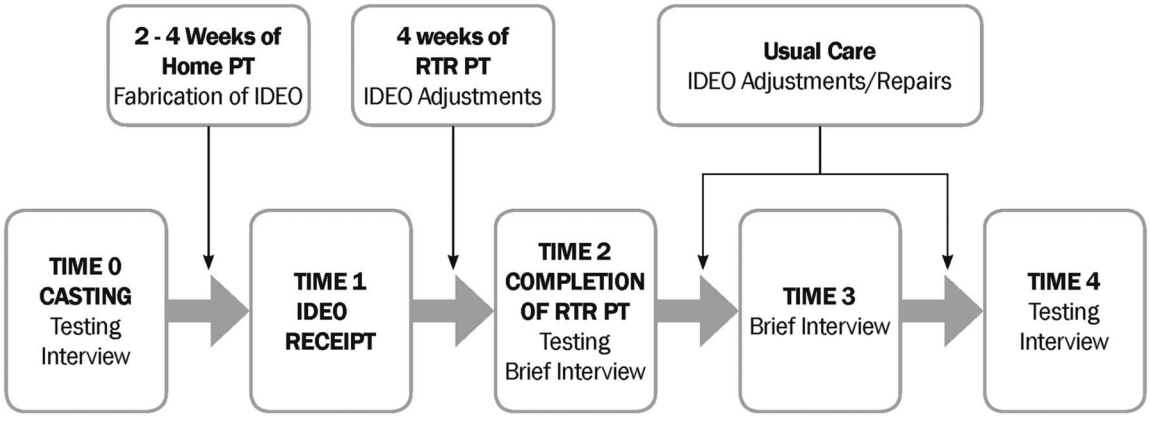

FIGURE 2. PRIORITI flowchart.

TABLE 1. PRIORITI-MTF Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
1. Ages 18–60 2. Currently one or more years out from a traumatic unilateral lower extremity injury at or below the knee 3. Healed fracture and able to fully weight bear 4. Evidence of either: Weakness of ankle dorsiflexors and/or plantarflexors resulting from leg injury (defined as less than 4 of 5 on manual muscle test) Limited ankle dorsiflexion (<10°) and/or limited ankle plantarflexion (<20°) resulting from leg injury Mechanical pain with loading to hindfoot/midfoot (≥50 mm on a 0–100-mm visual analog scale assessing average daily pain) Ankle or hindfoot fusion or candidate for ankle or hindfoot fusion 5. Candidate for amputation secondary to ankle/foot impairment	1. Ankle plantarflexion or dorsiflexion weakness as a result of spinal cord injury or central nervous system pathology 2. Nonambulatory 3. Surgery on study limb anticipated in next 6 mo 4. Medical or psychological conditions that would preclude functional testing (eg, severe traumatic brain injury, stroke, renal failure, heart disease, severe anemia) 5. Neurologic, musculoskeletal, or other conditions affecting contralateral extremity preventing the study of a healthy control limb 6. Unable or unwilling to participate in two 4-wk PT programs 7. Pregnancy 8. Non-English speaking

participants were recruited using a variety of mechanisms including (1) having sites identify patients treated one or more years ago for a severe lower extremity injury and sending them information about the study; (2) direct advertising campaign, targeting appropriate media outlets frequented by service members and veterans; and (3) a social media campaign using both Twitter and Facebook. Potential participants were directed to the PRIORITI-MTF web site (http://prioriti-mtf.org) where they were able to access additional information about the IDEO, the RTR program and the study, and complete a short screening questionnaire. The local site research coordinator confirmed potential eligibility with a telephone call and, if appropriate, scheduled a final (in-person) screen that consisted of a clinical assessment, medical history, and interview.

Informed consent took place at the study center before beginning the final in-person screen. Consent by Legally Authorized Representatives was not permitted. METRC uses a comprehensive informed consent process that involves the treating surgeon, the clinical site research coordinators, and material and resources for patients and family members to facilitate informed decision making about participation. Details of this process are described in the online supplement material (see **Figure 1**, **Supplemental Digital Content 1**, http://links.lww.com/BOT/A900).

Protocol Changes

The initial protocol stipulated that participants had to be 2 years out from their injury to ensure levels of function had stabilized. After 5 months of screening, it became evident that many potentially eligible participants were not enrolled because they were between 1 and 2 years out from their injury. After careful review by the protocol committee, a decision was made to include patients who were one or more years out from injury (as opposed to 2 or more years out from injury). This decision was made based on clinical experience and evidence that suggests most patients 1 year out from injury have typically explored all treatment options and show little improvement in function after 1 year. The Lower Extremity Assessment Project (LEAP), for instance, demonstrated that 85%–90% of 2-year disability outcomes were determined by 1 year.29 Additional changes made to the protocol were administrative in nature.

METHODS: INTERVENTION

The PRIORITI intervention consisted of 2 components: (1) custom fitting of the IDEO and (2) the RTR PT program designed specifically for recipients of the IDEO.

Fabrication and Fitting of the IDEO

The IDEO device is an FDA exempt device under 21 CFR 890.3475 and 21 CFR 890.3410. The traditional version of the IDEO design was used for this study with 2 struts directly laminated into the footplate and calf sections. The IDEO is constructed primarily of laminated, reinforced carbon fiber to withstand high impact forces and cyclical loading; its components are described above. The final fabricated device given to each subject is labeled with the following information: "*CAUTION—Investigational device. Limited by Federal law to investigational use*."

Teams from WRNMMC and NMCSD consisting of a Certified Prosthetist Orthotist (CPO) and an Orthotic Technician were trained in IDEO fabrication and fitting at the Center for the Intrepid (CFI) over a 2–4-week period. Once able to replicate the process, the CPO teams returned to implement the program at their institutions, with expert trainers from CFI available for ongoing consultation. Programs at both WRNMMC and NMCSD were up and running for at least 9 months before the first PRIORITI participant was enrolled.

RTR PT Protocol

The specifics of the RTR PT program have been described in the literature.[21,22,26] The program is based on a sports medicine approach and focuses on strength, agility, and speed. This study required delivery of the RTR program by a physical therapist or physical therapy assistant (PTA) with documented training in sports medicine and experience working with limb trauma patients. The intensity of the program was tailored to the individual's ability and overall goals. In the military, the goal is often return to active duty and vigorous sports activities. Among veterans who are several years out from their injury, goals and expectations are often more modest with a focus on return to work with no pain, increased work productivity, and participation in moderate-to-vigorous recreational and sports activities. A detailed, illustrated manual was developed to assist with a 3-day training of the PTs and PTAs; the manual is available on request from the authors.

METHODS: DATA COLLECTION

Participants were evaluated at baseline (before receiving the IDEO), immediately after 4 weeks of PT with the IDEO, and at 6 and 12 months after the

completion of PT (see **Table 1**, **Supplemental Digital Content 5**, http://links.lww.com/BOT/A904). At baseline, data were collected to characterize the participant (sociodemographics, self-efficacy, social support, comorbidities), his or her current levels of impairment (range of motion, strength, pain, evidence of posttraumatic osteoarthritis), and the study injury (mechanism and fracture classification). Outcomes are described below.

Primary Outcomes

The primary outcomes for the study are functional performance and self-reported functioning. Functional performance (at baseline, immediately after the completion of the RTR PT program, and at 12 months) was assessed using a test battery that included a dyad of a "less demanding" tests and "more demanding" tests for the following domains: agility (using the Four Square Step Test and the Illinois Agility Test), strength/power (using the Sit-to-Stand and Timed Stair Ascent Tests), and speed (using Self-Selected Walking Speed and the 10-m Shuttle Run). Postural stability was assessed through the Single Leg Stance test (see **Figure 2**, **Supplemental Digital Content 2**, http://links.lww.com/BOT/A901). All functional performance tests were conducted by local PTAs who were trained and certified to conduct these assessments. Self-reported functioning (at baseline and at 6 and 12 months) was measured using the SMFA[30] and the VR-12.[31]

Secondary Outcomes

Secondary outcomes included additional self-reported measures of participation {including return to usual major activity and if working, the Work Productivity and Activity Impairment (WPAI)[32] questionnaire, pain [measured using the Brief Pain Inventory (BPI)],[33] depression [using the Patient Health Questionnaire 9 (PHQ-9)],[34] and posttraumatic stress [assessed using the standard PTSD Checklist (PCL)]}.[35] Vigorous physical activity was also assessed using the Paffenbarger Activity Scale (PAS)[36] which asks participants to report the frequency and duration of their participation in recreation or sports activities in the past week.

Use and Satisfaction with the IDEO and Related Services was assessed using the Orthotics and Prosthetics Users' Survey (OPUS).[37] The OPUS consists of an 11-item measure for satisfaction with devices and a 10-item measure for satisfaction with services. Items pertaining to device satisfaction include weight, comfort, pain associated with use, ease of use, cosmesis, durability, fit, and effect of the device on clothing. Items used to measure satisfaction with services, include wait time, respect, communication, consumer's input, team approach, and training with the device. Also captured were all hospitalizations and use of physical and occupational therapy.

METHODS: DATA MANAGEMENT AND ANALYSIS

Data Management and Quality Assurance

Data were collected by research coordinators and clinical investigators using paper case report forms designed specifically for this study. All data were entered into REDCap, the web-based distributed data system used for all METRC studies (see **Figure 3**, **Supplemental Digital Content 3**, http://links.lww.com/BOT/A903).

The monitoring plan is designed to verify site compliance with the protocol, with study-specific standard operating procedures on data collection, procedures, and applicable FDA regulations. The MCC's monitoring plan incorporates a risk-based approach to monitoring that includes a combination of on-site and centralized monitoring of clinical activities (see **Figure 4**, **Supplemental Digital Content 4**, http://links.lww.com/BOT/A902).

Sample Size and Data Analysis

One-sided paired *t* tests will be used to test for improvements in outcomes immediately after the completion of the RTR PT program and at 6 and 12 months as compared to baseline. Differences in means between follow-up and baseline will be reported along with 95% confidence intervals. To the extent possible, we will explore, using stratification and regression, how differences are associated with site, characteristics of the participants, baseline measures of impairment, and the percent of RTR PT sessions attended. Variations in use and satisfaction with the IDEO will be documented and compared with other studies reported in the literature.

The targeted sample size for the study was 90 patients, assuming 1-year follow-up data on 80 of the participants enrolled. The proposed sample size yields 80% power to detect an effect size (mean of the difference in outcomes between follow-up and baseline divided by the SD of the difference) of 0.28 (a modest treatment effect). To put this effect size in perspective, Patzkowski et al[27] report effect sizes for the Four Square Step Test, Timed Stair Ascent, Self-Selected Walking Speed, and the Shuttle Run of approximately 0.6, 0.7, 1.0, and 1.0, respectively.

STUDY ENROLLMENT AND BASELINE DATA

A total of 91 participants from 3 military treatment facilities were enrolled into the study and received an IDEO, although only 87 had complete baseline assessments. Of these 87 participants, 6 (6.7%) did not participate in any RTR PT sessions, despite repeated attempts by the site team to schedule the RTR sessions. The mean number of sessions attended by the remaining 81 participants was 9.2 (SD 2.9) (83% attended 7 or more sessions).

Of the 87 participants with complete baseline assessments, 90% were men with an average overall age of 36.2 (SD 8.5). Most participants reported that they were on active duty at the time of enrollment (65%); 17% were officers at the time of the injury. At the time of enrollment, 35% were currently using a non-IDEO brace; an additional 31% reported having used a non-IDEO brace in the past.

The percentage who were obese at baseline (49% with BMI $\geq$ 30) was somewhat higher than the general population of adults greater than 20 years only (35.7% obese).[38] Two-thirds had one or more comorbidities. The mean ($\pm$SD) Physical Component Summary (PCS) score of the VR-12 at baseline was 32.9 $\pm$ 9.2, reflecting poor overall

physical functioning at the time of enrollment (compared with standardized scores for the US population of 50.0 ± 10.0). Scores on the mental health component summary (MCS) were more similar, on average, to population norms (53.2 ± 11.7).

DISCUSSION

PRIORITI-MTF is the first prospective, multicenter study to examine the benefits of the IDEO and RTR PT program outside the Brooke Army Medical Center and Center for the Intrepid where the programs were developed. Fabrication and fitting of the device were standardized across the 3 participating centers as was implementation of the RTR PT program. Strict inclusion and exclusion criteria help ensure comparable participants across sites. An important strength of the study is its assessment of both patient-reported outcomes and functional performance.

The study has been successful in replicating both components of the integrated orthotics and rehabilitation program at 2 additional military treatment facilities—Naval Medical Center San Diego and Walter Reed National Military Medical Center. These facilities now have the capability to manufacture and fit the devices as well as conduct the RTR PT program. To date, over 295 patients have received the IDEO from these 2 facilities (email communication December 2016).

Enrollment targets were met for the study, although baseline assessments were not completed for 4 participants. In addition, participation in the RTR program was variable; this factor will need to be accounted for in the analysis.

A weakness of the study is its before-after design, with no control group. An important assumption inherent in this design is that any observed improvement in function can be attributable to the intervention and not to the natural course of recovery. This assumption is addressed by including only participants who are one or more years out from their injury. Although most recovery occurs within the first year after injury, some additional patient improvement is possible. To help ensure a "stable" population, individuals whose fractures and soft tissue injuries are not healed at the time of screening or for whom additional surgery is planned within the next 6 months were excluded. Future studies should consider randomizing participants to receive the IDEO versus a less expensive and more widely available noncustom carbon fiber AFO, such as the BlueRocker (Allard Int.) to study comparative effectiveness and cost-effectiveness.

Another limitation of the study is its inability to unbundle the effects of the IDEO, its componentry, and RTR PT program on outcome. If the combined program is shown to be effective, future studies must explore whether specific aspects of the integrated program could be removed or refined. Although recent publications suggest that multiple design parameters do not need to be tightly controlled, investigations are currently ongoing to evaluate other potentially important factors such as alignment and heel cushioning. The disconnect between the pure biomechanics of the device and patient function supports the notion that there are other elements of the pathway (ie, guided rehabilitation) that have a demonstrated impact on outcome.

Despite these limitations, results of the PRIORITI-MTF will add to a growing body of evidence regarding the effectiveness of the IDEO when coupled with the RTR PT program. 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. Positive results will also argue for translation of the program to the civilian sector. Not only will translation to the civilian sector have the potential to affect the lives of veterans and limb salvage patients who are injured every day in the United States, it will help ensure that refinement of this unique program continues when there is a de-escalation of combat activity. Without collaborating with the civilian sector to translate the IDEO program from the military population, there is substantial risk that it will be lost for future Wounded Warriors.

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