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TITLE: Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries for the Military Treatment Facilities (PRIORITI-MTF)

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Abstract

The purpose of this study is to examine the benefits (and cost-benefits) of an integrated orthotic and rehabilitation program that incorporates the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and the Return to Run (RTR) physical therapy regimen, but designed for scalability in the broader military environment (i.e. beyond San Antonio Military Medical Center where the program was developed). We intend to assess immediate and long-term improvements in functional performance and self reported outcomes in 85 patients from 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 and have chronic muscle weakness and/or limited range of motion at the ankle that translates into functional deficits that interfere with daily activities and overall quality of life.

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1. INTRODUCTION:

The purpose of this study is to examine the overall benefits (and cost-benefits) of an integrated orthotic and rehabilitation program that incorporates the Intrepid Dynamic Exoskeletal Orthosis (IDEO) and the Return to Run (RTR) physical therapy regimen currently employed at San Antonio Military 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 90 patients from three military treatment facilities (MTF's). The intended study population includes patients from three military treatment facilities (MTF's) who have chronic muscle weakness and/or limited range of motion at the ankle that translates into functional deficits that interfere with daily activities and overall quality of life.

2. KEYWORDS:

Dynamic Ankle Foot Orthosis, Extremity War Injuries, IDEO, rehabilitation

3. BODY

Overall Progress

This annual report reflects progress and accomplishments from 7/1/14 to 6/30/15.

Challenges in getting the study approved by all relevant stakeholders and regulatory review boards has resulted in overall delays that has impacted our ability to complete the study in the original three-year time frame. We have just completed year 3. Overall, progress has been excellent. We have now enrolled 65 patients and are confident that we will reach our target enrollment goal of 90 patients by October 2015.

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.

NMCS D 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 NMCS D

This task was completed in 2013 and captured in the 2014 annual report.

Task 6: Conduct Study

All sites are currently enrolling patients. A total of 65 patients have been enrolled. Enrollment totals at each site are as follows: SAMMC 28, WRNMMC 22 and NMCS D 15.

Recruitment and Screening Strategies continue to be discussed with the sites. All sites have established weekly IDEO clinics to screen potential patients. All study team members are available to see patients during these clinics.

The following list summarizes our activities to advertise the study over the last year:

- Outreach to the Outreach to Army Times resulted in an article that was posted in early January 2015.
- The Baltimore Sun resulted in this article that appeared on the front page on Sunday, March 2, 2015. <http://www.baltimoresun.com/health/bs-hs-wounded-warrior-brace-20150301-story.html#page=1>
- IDEO/PRIORITI Study presentation by Johnny Owens at the American Physical Therapist Association Combined Sections Meeting, February 2015.
- O and P Edge posted the following story to their website on January 2, 2015:
 - http://www.oandp.com/articles/news_2015-01-02_02.asp#.VQG4tO-Se-0.email
- Stars and Stripes: Contact with national correspondent on to discuss possible story
- Twitter: Developed tweets and continue to tweet at regular intervals:
<https://twitter.com/JohnsHopkinsSPH/status/572424293319122944>
- Outreach to Iraq and Afghanistan Veterans of America (IAVA).
- Study brochures have been posted locally at each of the 3 participating centers.
- Outreach to the San Diego Union Tribune resulted in a story on April 25, 2015:
<http://www.utsandiego.com/news/2015/apr/25/ideo-brace-military-veterans/>
- Regular FaceBook text and a photo advertisements targeting individuals with military interests.

- The PI at NMCS D will be presenting information on the IDEO and Study at the Wounded Warrior Games in July 2015.

We continue to utilize our website (see <http://www.prioriti-mtf.org/>) to identify potential patients. The website also houses an initial questionnaire that pre-screens participants. Respondents who screen 'in' as potential participants are asked for contact information which is sent automatically to the Coordinating Center. The Coordinating Center then forwards the information to the appropriate military center to arrange an appointment for final screening and enrollment into the study. Those who screen 'out' are directed to relevant resources and encouraged to contact their health care provider and/or nearest military facility to see if other options might exist for them.

Data Collection Tools. All sites are utilizing Case Report Forms developed for the study. RedCap is being used for electronic data entry.

Summary of Results

There are no results to report at this time.

Discussion

Goals for the upcoming months include completing enrollment by October 2015 and completion of all RTR sessions by the end of the calendar year. All 12-month follow up visits will be completed by December 2016.

4. KEY RESEARCH ACCOMPLISHMENTS:

- All three sites are enrolling patients and are confident that the enrollment goal of 90 patients will be met by October 2015.
- We have initiated Redcap data analysis for the baseline visits.
- The METRC study director provided a training session in San Diego for the new coordinator that started working on the PRIORITI study on July 8, 2015.
- We have initiated regular coordinator conference calls involving the 3 coordinators and the study director to ensure consistency of study procedures across sites.

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 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, SAMMC and the Center for the Intrepid. It has become the standard of care for limb salvage patients at SAMMC/CFI. This success is due in large part to the

IDEO, which has been demonstrated superior performance in standardized physical performance measures compared to commercially available ankle-foot orthoses.

The PRIORITI affords the opportunity to study this intervention at other Military Treatment Facilities and in a relevant subset of civilian trauma patients with similar disabilities due to extremity injury as those from war. This PRIORITI- MTF proposal 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.

We are also hopeful that the intervention will have a similar positive effect on outcomes in the severely injured civilian population. Without rigorous evaluation of the technology and rehabilitation pathway of the PRIORITI and its translation to the civilian sector, there is substantial risk that this intervention will be lost for the future of our current Wounded Warriors as they leave the Center for the Intrepid. Furthermore, without refinement of the technology and maintenance in the commercial sector, this intervention may disappear altogether for Wounded Warriors in future conflicts. Broader evaluation and dissemination of the technology could also help many veterans today who are living with an impairment that interferes with their quality of life.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

Nothing to report.

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.

9. OTHER ACHIEVEMENTS:

Nothing to report.

10. REFERENCES:

Nothing to report.

11. APPENDICES: