Case Report

Prosthetics and Orthotics International

OPEN

Changes in functional outcomes in people with high-energy ankle trauma after the use of the ReAktiv Posterior Dynamic Element™ orthosis and a rehabilitation program: A case series

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Abstract

The aim of this study was to examine lower-limb function in 2 patients that received a ReAktiv Posterior Dynamic Element™ (PDE) orthosis and 6-week rehabilitation program after a high-energy trauma injury to the lower limb. Lower-limb function was assessed using the lower extremity functional score, walking performance through the 2-minute walk test, and dynamic mobility and balance through the single-leg balance, timed stair ascent, and the 4-square step test. A 6-week physiotherapy-led rehabilitation program was also implemented. Data showed improvements in lower extremity function, walking performance, mobility, and balance measures after 8 weeks of wearing the ReAktiv PDE™ orthosis and completion of the rehabilitation program. The ReAktiv PDE™ orthosis combined with a lower-limb rehabilitation program shows potential as a treatment option to improve lower-limb function and walking performance and return sufferers of high-energy trauma injury to functional levels seen in healthy cohorts.

Keywords

ankle injuries, ankle joint, ankle foot orthoses

Date received: 2 December 2022; accepted 20 July 2023.

Background

High-energy trauma (HET) injuries can occur after a significant traumatic event such as a motor vehicle accident, impact injury, falls from height, or combat injury.[1] High-energy trauma injuries are prevalent and account for approximately 250,000 hospitalizations in the United States every year.[2] Poly traumatic ankle fractures that occur due to HET often result in severe damage within the foot–ankle complex and subsequent misalignment of the foot and ankle. High-energy trauma injuries also often involve complex wounds that are further complicated by severe soft-tissue loss, pain, nerve injury, and volumetric muscle loss. As a result, surgical intervention (amputation or extensive limb salvage) is typically indicated over conservative treatment.[2] Over time, the long-term complications associated with these injuries can include chronic pain, post-traumatic arthritis, ongoing impairment, and functional deficits which can contribute to delayed amputation of the affected limb.

Ankle foot orthoses (AFO) are a common conservative management strategy after a HET injury.[3] One example of an AFO is the ReAktiv Posterior Dynamic Element (PDE™) orthosis. Similar in design to the Intrepid Dynamic Exoskeletal Orthosis (IDEO™), these passive dynamic AFOs are intended to allow wearers that have suffered extensive damage to the foot–ankle complex to return to high-level physical activity while unloading the damaged joint structures. The ReAktiv PDE™ orthosis consists of 3 carbon fiber components: a custom-made proximal cuff for circumferential support providing off-loading, a PDE™ modular composite spring system (Fabtec™ Systems), and a full-length rigid supramalleolar orthoses foot piece[4] (Figure 1). The ReAktiv braces differ from conventional AFO through the provision of the PDE™ posterior strut system. The PDE™ system can be tuned based on the height, weight, activity level, and degree of unloading that is needed from the orthosis to meet the patients specific rehabilitative, recreational, or occupational needs.

Cross-sectional research investigating the effectiveness of the ReAktiv PDE™ orthosis is limited to one study.[4] Jonkergouw et al[4] evaluated the impact of the ReAktiv PDE orthosis and rehabilitation program on pain, walking performance, and mobility in 17 military veterans. Data showed significant reductions in pain and notable improvements in walking performance and mobility tests after the participants wore the ReAktiv orthoses and underwent rehabilitation for 6 weeks.

Case descriptions and methods

Patients were recruited from a private Podiatry Clinic (Auckland, New Zealand). Patients were eligible for inclusion into the study if

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Associate Editor: Ambreen Chohan

DOI: 10.1097/PXR.0000000000000291

Figure 1. The ReAktiv Posterior Dynamic Element™ orthosis.

they had received the ReAktiv PDE™ orthosis as part of their treatment after HET within the past 12 months and excluded if they had a neuromuscular condition or received the ReAktiv PDE™ orthosis for management of a congenital ankle pathology such as talipes equinovarus. Two men who suffered a HET injury to the lower limb consented to participate in the study. Ethical approval was obtained from the university ethics committee (21/137).

Participant 1 was a 43-year-old man of European ethnicity. Initial injury was classified as a severe Weber A fracture plus dislocation of ankle after a motor vehicle accident 20 years prior. Initial surgical management involved open reduction and internal fixation, bone grafts, and subsequent arthroscopic surgeries to remove osteophytes. Postsurgical complications led to a spontaneous subtalar joint fusion. He had no history of bracing or orthotics before receiving the ReAktiv brace, and pain had typically been managed through the use of pain medication and/or restriction of activity. At his last surgical follow-up, the surgeon suggested a complete (triplanar) fusion of the ankle; however, as a patient had a young family at the time and being aware of how long he would be off his feet, unable to drive, and recovery time needed, he wanted to avoid this option for as long as possible.

Participant 2 was a 54-year-old man of European ethnicity. After a fall from height 2 years prior, the patient sustained an osteochondral injury to the medial talar dome and moderate partial tear to the deltoid ligament. Medullary infarction of the posterior tibia and chronic partial tear to the anterior syndesmotic ligament was also sustained. Initial surgery consisted of open reduction and internal fixation of the ankle; subsequent surgical management involved an arthroscope and retrograde drilling of the medial talus with bone graft after onset of necrosis of the talus. Before being fitted with the ReAktiv brace, he had tried various over the counter ankle braces, commercially available rocker shoes, and prefabricated foot orthoses, all of which only had minimal effect on his pain and mobility. His pain was managed through the use of medication, activity restriction/modification, and occasional physiotherapy where needed. The participant was self-employed and had already had a considerable amount of time off work after his injury; he was eager to be able to get back to work and be able to keep his business afloat and was looking for a nonsurgical option that would allow him to do this.

ReAktiv PDE orthoses

The ReAktiv PDE orthoses was prescribed and fitted by a podiatrist with 15 years' experience in musculoskeletal, orthopedic, and postsurgical rehabilitation.

Rehabilitation program

The main objective of the rehabilitation program was to introduce the participants to ReAktiv PDE orthoses to ensure patient safety and to help develop new movement patterns for the specific individual when using the ReAktiv brace. The rehabilitation program was led and managed by an experienced physiotherapist who specializes in musculoskeletal physiotherapy, complex pain, and postsurgical rehabilitation. The program was specifically designed to the requirements of the individuals in recognition of their differing goals and abilities and varied at each session. The rehabilitation program consisted of 6-weekly sessions that progressed from establishing new walking gait patterns and improving balance and stability while in the brace and improving strength and muscle deficits due to years of compensation related to their injury. The initial session involved assessment of current mobility and recording of baseline measures, session 2 worked on movement in the sagittal plane, session 3 movement in coronal plane, session 4 started to add multidirectional and combined movements, session 5 introduced dynamic and plyometric movements, and session 6 involved rerecording of outcome measures.

Sagittal plane lower-body movements were classified into 3 functional patterns—squat, hinge, and lunge. Exercises were provided at the appropriate level for each individual, for example, a sit to stand for those with lower function, progressing to body weight squat and through to a weighted squat for those with higher levels of function. Similarly with hinge movements, some began with a glute bridge, progressing to a standing good morning and then onto a deadlift. The lunge pattern began with arm-assisted split squats, progressing to unassisted split squat, then forward or backward lunge with or without weight depending on ability.

Coronal plane movements focused on using a combination of floor-based and standing exercises. Again, exercises were provided at the appropriate level of difficulty for the individual. Floor-based exercises included side lying abductor and adductor strengthening while standing exercises involved resisted side stepping, lateral box step ups, and lateral lunges.

For all participants, there was continued progression in difficulty of their sagittal and coronal plane exercises throughout the program. The multidirectional and combined movement session built on the base of the previous sessions. In these sessions, more balance exercises with multidirection perturbations were added. Exercises such as clock face single leg balance or lunging around the clock were included for those with higher function. Functional exercises focused on movements in diagonal patterns.

Finally, dynamic and plyometric exercises were added. This included progression from walking to jogging and running.

Plyometric exercises such as skipping, jumping on and off low steps, and progression to higher box jumps were undertaken by those with higher functional ability. Exercises such as agility ladders and drills were used to encourage speed and accuracy of foot position.

Outcome measures

Outcomes were assessed at baseline (before receiving the brace), at 2 weeks (the commencement of the rehabilitation program), and at 8 weeks (the conclusion of the 6-week rehabilitation program) by 2 clinicians (physiotherapist and podiatrist).

Assessment of lower-limb function

Lower-limb function was assessed using the lower extremity functional score (LEFS).[5] Walking performance was measured using the 2-minute walk test because of its use as a reliable and valid measure for those with lower-extremity injuries and/or amputations.[6] The 4-square step test (FSST) was used to assess dynamic balance and mobility because of its high inter-rater and test–retest reliability.[7] Lower-limb mobility and power were assessed using the timed stair ascent (TSA).[8] Balance was measured using the single-leg balance (SLB) test, a commonly used test to assess standing balance, more often in older adults to assess falls risk, and is considered to have good test–retest reliability.[9]

Findings and discussion

Outcome measures before and after intervention used to assess lower-limb function are presented in Table 1. The LEFS improved in both participants with varying magnitude. Participant 1 (increase of 25 points) exceeded the minimal clinical important difference (MCID) reported for the LEFS of 9 to 12 points.[10] Participant 2 (increase of 7 points) fell short of the reported MCID. The improvements in participant 1 aligns with the results obtained by Ikeda et al[11] who reported a 26-point difference in their study on 99 participants when walking with an IDEO™ brace, compared with participants without a brace.

Walking speed and distance improved in both participants after completion of the rehabilitation program, participant 1 increasing their distance by 80 m and speed by 1.67 $m{\cdot}s^{-1}$ and participant 2 increasing their distance by 14 m and speed by 0.15 $m{\cdot}s^{-1}$. The 2-minute walk test results at completion of the program exceeded the normative data for age-matched individuals (mean 200.9 m [197.2–204.6]).[12] Carse et al[13] proposed an increase of 0.21 $m{\cdot}s^{-1}$ be used as the MCID value for walking velocity in a population with lower-limb amputation. Participant 1 (increase of 1.67 $m{\cdot}s^{-1}$) exceed the proposed MCID with participant 2 (increase of 0.15 $m{\cdot}s^{-1}$) not exceeding the MCID. These findings support the notion that the combined effect of ReAktiv PDE orthoses and customized rehabilitation walking performance can be improved and returned to results similar to that seen in normal populations. The improvements in walking performance align with previous research of Jonkergouw et al[4] who reported a significant increase in 6-minute walk test scores in a military cohort that had sustained HET injuries, after 6 weeks of using the ReAktiv PDE™ orthosis.

The observed improvements in the FSST (participant 1 −2 s and participant 2 −0.5 s) were consistent with Bedigrew et al[14] who reported a reduction in FSST time at 8 weeks after the provision of an IDEO™ brace. In participant 1, the FSST improved to a value better than reported normative data of 6.3 to 6.9 s,[15] with a minimal decease in participant 2 recorded. There are no reported MCID values for people who have suffered HET injuries; however, a decrease of greater than 5.5 s has been reported to be clinically meaningful in a population of people with hip or knee joint replacements.[16] These improvements in the FSST may be attributed to the design of the orthosis and its ability to allow loading of the device through more pressure tolerant areas of the leg.[11]

Improvements in the TSA in our study participants (1.2–1.4 s) were smaller than the findings of Bedigrew et al[14] who showed in 31 IDEO™ users reductions in TSA times after brace wearing and the implementation of a 6-week rehabilitative program, with mean TSA reducing from 6.2 s to 4.2 s. There are no reported MCID values in populations using AFOs to enable determination if our reported TSA results were clinical meaningful.

Our data indicated varying improvement in SLB timing between participants (participant 1 +32 s and participant 2 +1 s). These improvements SLB time are a novel finding of this case study. Mazzone et al[17] reported that an IDEO™ brace did not improve

Table 1. Measures of lower-limb function.

Outcome measures	Participant	Baseline	Week 2	Week 8	Change (baseline to week 8)
LEFS (unit)	1	50/80	61/80	75/80	+25
	2	32/80	46/80	39/80	+7
2MWT m ($m{\cdot}s^{-1}$)	1	220 (1.83)	255 (2.13)	300 (2.5)	+80 (+1.67)
	2	235 (1.95)	160 (1.33)	249 (2.1)	+14 (+0.15)
FSST (s)	1	6.0	NR	4.0	−2.0
	2	9.0	NR	8.5	−0.5
TSA (s)	1	6.0	NR	4.8	−1.2
	2	8.0	NR	6.6	−1.4
SLB (s)	1	14.0	NR	46.0	+32
	2	3.0	NR	4.0	+1

Abbreviations: 2MWT, 2-minute walk test; FSST, 4-square step test; LEFS, Lower Extremity Functional Scale; NR, not recorded; SLB, single leg balance; TSA, timed stair assent.

SLB time at 6 weeks in a military cohort. This could be attributed to the injury sustained, the shape of the brace foot piece, footwear worn during testing, and brace stiffness, and this not being considered a priority during rehabilitation in this cohort. During the 6-week rehabilitation program with the ReAktiv PDE orthosis, emphasis was made on practicing SLB in the orthosis to help contribute to an improvement in overall functional outcomes. In relation to MCID values, there are no established values for the population who use AFOs with reference to HET. However, in older adult populations, increases in SLB of 24.1 s have been proposed as clinically meaningful.[18] Using these benchmarks, only participant 1 made what could be considered a clinically meaningful improvement.

Clinical relevance

The improvements seen while using the ReAktiv PDE™ orthosis combined with a rehabilitative program allowed participants in this case study with significant reductions in function to return to a higher level of mobility and functionality. However, the data did show variation in the magnitude of functional improvement between the 2 participants. This may be reflective of the complexity of HET injuries and their long-standing and wide-ranging impact on function. The improvements in function may have significant benefits for those that have previously been unable to work or partake in physical activities due to their HET injury. Although data indicated improvements in all functional outcomes, interpretation of the true clinical difference is limited by the lack of data investigating the clinical meaningfulness of functional outcome measures in populations that have suffered HET or significant ankle trauma from other mechanisms. There is potential for the ReAktiv PDE™ orthosis to benefit other populations who suffer from chronic ankle pain that has led to diminished function. This may include people with chronic ankle arthritis, postsurgical rehabilitation after ankle arthrodesis, and congenital conditions such as talipes equinovarus. The study also highlights the importance of a combined rehabilitative approach for populations who have suffered HET; rehabilitation must consider not only the effect of the AFO but the functional needs of the individual.

Conclusion

The use of ReAktiv PDE™ orthosis combined with a lower-limb rehabilitation program shows potential as a treatment option to improve walking performance and lower-limb function to levels seen in healthy cohorts.

Declaration of conflicting interest

The authors disclosed no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Supplemental material

No supplemental digital content is available in this article.

References

1. Peterson SL, Kingsbury TD, Djafar T, et al. Military service members with major lower extremity fractures return to running with a Passive-Dynamic Ankle-foot Orthosis: comparison with a normative population. *Clin Orthop Relat Res* 2021; 479: 2375–2384.
2. Highsmith MJ, Nelson LM, Carbone NT, et al. Outcomes associated with the Intrepid Dynamic Exoskeletal Orthosis (IDEO): a systematic review of the literature. *Mil Med* 2016; 181: 69–76.
3. Mangan KI, Kingsbury TD, Mazzone BN, et al. Limb salvage with Intrepid Dynamic Exoskeletal Orthosis versus transtibial amputation: a comparison of functional gait outcomes. *J Orthop Trauma* 2016; 30: e390–e395.
4. Jonkergouw N, de Kruijff LGM, Bongers REG, et al. A modified passive-dynamic ankle-foot orthosis: can it prevent amputation and arthrodesis in patients with ankle-foot trauma? *Arch Orthop Trauma Surg* 2021; 142: 2719–2726.
5. Binkley JM, Stratford PW, Lott SA, et al. The Lower Extremity Functional Scale (LEFS): scale sevelopment, measurement properties, and clinical application. *Phys Ther* 1999; 79: 371–383.
6. Newton KL, Evans C and Osmotherly PG. The timed up and go and two-minute walk test: exploration of a method for establishing normative values for established lower limb prosthetic users. *Eur J Physiother* 2016; 18: 161–166.
7. Sawers A, Kim J, Balkman G, et al. Interrater and test-retest reliability of performance-based clinical tests administered to established users of lower limb prostheses. *Phys Ther* 2020; 100: 1206–1216.
8. Wilken JM, Roy CW, Shaffer SW, et al. Physical performance limitations after severe lower extremity trauma in military service members. *J Orthop Trauma* 2018; 32: 183–189.
9. Bohannon RW and Tudini F. Unipedal balance test for older adults: a systematic review and meta-analysis of studies providing normative data. *Physiotherapy* 2018; 104: 376–382.
10. Binkley JM, Stratford PW, Lott SA, et al. The Lower Extremity Functional Scale (LEFS): scale development, measurement properties and clinical application. *Phys Ther* 1999; 79: 372–383.
11. Ikeda AJ, Fergason JR and Wilken JM. Clinical outcomes with the Intrepid Dynamic Exoskeletal Orthosis: a retrospective analysis. *Mil Med* 2019; 184: 601–605.
12. Bohannon RW, Wang YC and Gershon RC. Two-minute walk test performance by adults 18 to 85 years: normative values, reliability, and responsiveness. *Arch Phys Med Rehabil* 2015; 96: 472–477.
13. Carse B, Scott H, Davie-Smith F, et al. Minimal clinically important difference in walking velocity, gait profile score and two minute walk test for individuals with lower limb amputation. *Gait Posture* 2021; 88: 221–224.
14. Bedigrew KM, Patzkowski JC, Wilken JM, et al. Can an integrated orthotic and rehabilitation program decrease pain and improve function after lower extremity trauma? *Clin Orthop Relat Res* 2014; 472: 3017–3025.
15. Torlak F and Moffat M. Four square step test normative data for healthy young adults. *Br J Sports Med* 2014; 48: A11.
16. Batting M and Barker K. Minimal clinically important difference of the four square step test in people with hip or knee joint replacements. *Physiotherapy* 2022; 114: e189.
17. Mazzone B, Farrokhi S, Depratti A, et al. High-level performance after the return to run clinical pathway in patients using the Intrepid Dynamic Exoskeletal Orthosis. *J Orthop Sports Phys Ther* 2019; 49: 529–535.
18. Goldberg A, Casby A and Wasielewski M. Minimum detectable change for single-leg-stance-time in older adults. *Gait Posture* 2011; 33: 737–739.