Manual physical therapy combined with high-intensity functional rehabilitation for severe lower extremity musculoskeletal injuries: a case series*

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Objectives: Severe lower extremity trauma accounts for large healthcare costs and often results in elective amputation and poor long-term outcomes. The purpose of this case series is to describe an orthopedic manual physical therapy (OMPT) approach combined with a return to run (RTR) clinical pathway consisting of high-intensity functional rehabilitation with a custom energy-storing orthosis.

Methods: Three consecutive male patients, aged 21–23 years, with severe lower extremity musculoskeletal injuries were treated with a combined intervention that included a mean (SD) of 12 (2.1) OMPT sessions and 24 (8.7) functional rehabilitation sessions over a mean of 6 weeks (1.0). Additional training with a custom energy-storing orthosis consisted of a mean of 15 (1.2) additional sessions over 4 weeks. Patient self-report outcome measures and a variety of physical performance tests captured change in function.

Results: Baseline lower extremity functional scale (LEFS) and foot and ankle ability measure activities of daily living subscale (FAAM-ADL) scores indicated severe disability. All patients exceeded the minimal clinically important difference (MCID) in at least one self-report outcome or physical performance test without a brace. Two of three patients exceeded the MCID for at least two physical performance tests after training with and utilizing a custom energy-storing orthosis.

Discussion: Clinically meaningful changes in self-reported function or physical performance were observed in all patients. A multi-modal approach, including manual therapy and functional exercise, may address the entire spectrum of impairments in patients with severe lower extremity trauma, resulting in improvements in both braced and un-braced function.

Keywords: Lower extremity trauma, Manual physical therapy, Functional rehabilitation

Introduction

Severe musculoskeletal injuries place a large burden on civilian and military healthcare and disability systems. In civilian healthcare, they are the second highest healthcare cost, accounting for over \$300 billion per year in lost wages and productivity.¹ In the military, musculoskeletal injuries, most commonly of the extremities, account for the most lost duty days and are the primary reason soldiers are discharged from military service.^{1–4}

Despite advances in limb-salvage surgery, impaired function and the high incidence of post-traumatic osteoarthritis frequently lead to patient dissatisfaction. Two recent studies illustrate the severe functional limitations and poor outcomes in patients undergoing limb salvage surgery or amputation. In the lower extremity assessment project (LEAP) study, there was no between group difference in functional outcomes at a 2 or 7-year follow-up in 397 patients who had undergone limb-salvage surgery or amputation. Over one-half of patients reported significant disability while only 35% reported physical function typical of the general population of similar age and gender.⁵ In the most recent military extremity trauma amputation/limb salvage (METALS) study, patients

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

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with an amputation reported significantly better function than those whose limbs had been salvaged, yet all patients continued to report moderate-to-high levels of disability at long-term follow-up.⁶

Individuals with high functional expectations and goals may be unsatisfied with lower levels of function after severe injuries. They may also display lower levels of self-efficacy, which predicted poor outcome in the LEAP study.⁵ Many soldiers request delayed amputation in an effort to improve function, despite the ability to ambulate with minimal pain, which is traditionally a successful outcome after limb-salvage surgery. Fifteen per cent of amputations from recent wars in Iraq and Afghanistan were delayed, which is defined as greater than 12 weeks from the date of injury.⁷ However, patients should carefully consider the decision to elect amputation. Amputees demonstrate increased risk for cardiovascular disease, metabolic disorders, joint pain (especially knee osteoarthritis), and low back pain.⁸ Phantom limb pain may persist after amputation⁸ and the lifetime cost of amputation is three times higher than limb-salvage due to the cost of prosthetics.⁵

Patients with complex and severe lower extremity musculoskeletal injuries present with an extensive variety of impairments and functional limitations. Owing to the challenges of defining and studying this population, there is no gold-standard rehabilitation program. In an attempt to give soldiers with severe lower extremity trauma an option in lieu of amputation or medical retirement, our facility developed an integrated orthotic and rehabilitation initiative, termed the return to run (RTR) clinical pathway. This pathway combines a custom energy-storing ankle-foot orthosis, the Intrepid Dynamic Exoskeletal Orthosis (Ideo™), with high-intensity functional rehabilitation. The Ideo™ has been shown to improve performance on tests of agility, power, and speed when compared to other orthoses that may be utilized after severe trauma,⁹ possibly due to the energy-storing/return capability that other orthoses lack. After completing the RTR clinical pathway, 80% of patients undergoing limb-salvage surgery returned to some form of running utilizing the Ideo™.¹⁰ Additionally, 20% of limb-salvage patients who completed the RTR clinical pathway deployed to combat utilizing the Ideo™.¹¹ Approximately 80% of patients who have completed the RTR clinical pathway and utilize the Ideo™ no longer desire amputation.⁹⁻¹²

As the foot and ankle do not contribute to movement while the patient wears the Ideo™, the RTR clinical pathway does not address joint-sparing exercise strategies and common lower-intensity functional activities where patients will not utilize the Ideo™. Improvements in proximal strength and braced functional movement may or may not carry over to improvements in un-braced function.

Additionally, we do not know the long-term ability of patients to continue with running, sports, and combat activities with the Ideo™. Joint injury¹³⁻¹⁵ and long-term participation in certain sports¹⁴⁻¹⁶ increase the risk for knee and hip osteoarthritis; continued participation in these types of high-intensity activities may also accelerate degenerative changes at the ankle joint.¹⁰

Orthopedic manual physical therapy (OMPT) is not utilized in the RTR clinical pathway and has the ability to address a broad spectrum of impairments, including impairments that may limit activities performed without a brace. The OMPT treatment approach is effective in reducing pain and improving function in a variety of musculoskeletal conditions, including arthritic disorders of the knee and hip.¹⁷⁻²¹ At the foot and ankle complex, manual physical therapy produces clinically meaningful improvements in function after sub-acute ankle sprain²² and may also improve ankle range of motion (ROM) following immobilization for ankle fracture or following ankle sprain.²³⁻²⁵ To our knowledge, there is no published research that describes the integration of OMPT to address impairments primarily limiting un-braced function with a high-intensity functional rehabilitation program such as the RTR clinical pathway that is designed primarily for braced function.

The purpose of this case series is to describe an OMPT treatment approach combined with the RTR clinical pathway in patients with severe lower extremity musculoskeletal injuries. Our hypothesis was that all patients would demonstrate clinically meaningful changes in at least one outcome measure of un-braced function.

Methods

Patients

Over a 6-month period (April–September 2012), consecutive patients with severe lower extremity musculoskeletal injuries who had undergone limb-salvage surgery and were referred for treatment in the RTR clinical pathway were screened for the eligibility criteria for this case series. Figure 1 shows the patient flow, subsequent treatment, and the inclusion/exclusion criteria. At the time of enrollment in the RTR clinical pathway, an orthopedic surgeon had evaluated each patient's injuries for sufficient healing and the ability to tolerate full weight bearing and functional rehabilitation. Each patient agreed to participate and provided informed consent. This case series was approved by the Institutional Review Board at the San Antonio Military Medical Center, Fort Sam Houston, Texas.

Examination

Patients completed baseline self-report questionnaires and physical performance tests, followed by a comprehensive patient interview and physical examination. Table 1 summarizes the relevant historical data

Figure 1 Flow diagram of patient enrollment/treatment and inclusion/exclusion criteria. OMPT: orthopedic manual physical therapy; RTR: return to run; Ideo™: Intrepid Dynamic Exoskeletal Orthosis.

and physical examination findings for each individual patient. Figure 2 depicts the severe bone and soft tissue injuries and demonstrates the complexity and potential for multi-tissue and joint involvement that are typical within this patient population.

A comprehensive examination of the foot, ankle, knee, hip, and lumbar spine was performed over the course of multiple patient visits. Examination began with the most involved, symptomatic, or dysfunctional region and progressed to other contributing regions.

Table 1 History and physical examination findings at baseline.

	Patient #1	Patient #2	Patient #3
Age (years)	21	22	23
Musculoskeletal injuries	* Bilateral pilon fracture * Multiple bilateral midfoot fractures	* L pilon fracture * L calcaneal fracture	* L proximal tibia and fibula fracture
MOI	IED	IED	RPG
Time from injury to Rx (months)	12	11	7
Acute injury treatment	* L external fixation × 5 months * R external fixation × 7 months	* ORIF tibial plafond and fibula * ORIF calcaneus w/subtalar fusion	* External fixation × 3 months * Fracture brace
Active range of motion	R: DF 2°//PF 10° L: DF 0°//PF 15°	R: DF 22°//PF 44° L: DF 11°//PF 32°	DF 12°//PF 32° Knee ext lacked 5°
Resisted tests	DF/inversion/eversion: 4/5	DF/inversion/eversion: 4+/5 PF: 3+/5	DF/inversion/eversion: 4+/5 PF: 3+/5
Neurologic testing	* Decreased to light touch deep peroneal nerve distribution * Plantar foot allodynia	* Plantar foot allodynia	* Intact to light touch throughout the lower extremity
Neurodynamic testing	R SLR: plantar foot pain at 75° L SLR: plantar foot pain at 90°	Not performed	(-) SLR
Soft tissue and flexibility	* Reduced soft tissue mobility below knee	* Normal soft tissue mobility * Good gastroc/soleus flexibility	* Large gastroc and distal hamstring soft tissue defect w/dec soft tissue mobility * Soleus/hamstring tightness
TCJ accessory motion	AP/PA: R stiff (+)//L stiff, painful	AP/PA: stiff (-), painful	AP/PA: stiff (-)
DTFJ accessory motion	AP/PA: bilateral stiff (+)	AP/PA: stiff (-), painful	AP/PA: stiff
STJ accessory motion	Med/lat glide: R stiff (+)//L stiff	Fused	Normal
Midfoot accessory motion	General: bilateral stiff	General: stiff (-) with crepitus and pain	Normal
Forefoot accessory motion	General: bilateral stiff	General: stiff (-) with crepitus and pain	Normal
Other findings	General R foot atrophy Partial R great toe amputation	Stiff (+) toe motion (s/p pinning)	Knee ext stiff PTFJ hypermobile w/crepitus PFJ sup/inf glide stiff

R: right; L: left; ORIF: open reduction external fixation; IED: improvised explosive device; RPG: rocket propelled grenade; DF: dorsiflexion; PF: plantarflexion; SLR: straight leg raise; AP: anterior-posterior; PA: posterior-anterior; med: medial; lat: lateral; ext: extension; TCJ: talocrural joint; DTFJ: distal tib-fib joint; STJ: subtalar joint; PTFJ: proximal tib-fib joint; PFJ: patellofemoral joint. Description of stiffness scale: stiff (-): mild stiffness; stiff: moderate stiffness; stiff (+): severe stiffness.

Figure 2 (A) Radiographs and (B) visualization of soft tissue injuries at the initial evaluation for Patient #3.

Elements of the physical examination included assessments of physiologic active and passive ROM, passive accessory motion, soft tissue mobility, muscle strength, and neurodynamic tests.²⁶ Active and passive ROM were assessed using a standard dual-arm goniometer for the ankle and knee, which demonstrates moderate to excellent intra-rater reliability, and was visually assessed for all other joints.^{27–30} Passive accessory motion and neurodynamic tests were performed as described by Maitland.²⁶ Strength was tested by manual muscle testing as described by Magee.³¹ Balance was assessed with single leg stance time on a firm surface.³² Gait was also assessed with visual observation of the trunk, pelvis, and lower extremities during ambulation on a level surface. Visual gait assessments are moderately reliable ($ICC=0.73$).³³ Deviations of interest were step length, step width, trunk deviations, knee motion, and ankle motion.

Interventions

Treatment combined an OMPT approach with the RTR clinical pathway, consisting of high-intensity functional rehabilitation and the Ideo™. The primary author, who is a board certified specialist in both orthopedic and sports physical therapy with 8 years of clinical practice experience, provided all OMPT examination and treatment. He was a fellow-in-training in an OMPT fellowship at the time of the study. A second physical therapist with over 10 years of clinical practice in sports physical therapy directed the high-intensity functional rehabilitation within the RTR clinical pathway.

Orthopedic manual physical therapy (OMPT)

All patients were treated with OMPT two times per week over a 5–7-week period and each session lasted approximately 45 minutes. This impairment-based approach was not based on a set protocol, but was a complex patient-centered process that utilized clinical reasoning and careful decision-making to tailor the examination and treatment to the individual patient. Clinical hypotheses, developed during the interview and subsequently tested in the physical examination, guided treatment. An example of the clinical reasoning process utilized to improve ankle motion is shown in Fig. 3. During each session, the physical therapist evaluated the likely tolerance of the patient to manual forces, then planned the overall amount of treatment, including which joints to mobilize, how vigorously to mobilize, and the intensity and dosage of manual techniques to ensure the treatment sessions would be both beneficial and well-tolerated.³⁴ The physical therapist continued this tailored treatment approach by assessing the patient's within and between-session response to each intervention and increasing the grade or duration of techniques that produced the desired effects. If two techniques both proved beneficial, the therapist prioritized the technique that demonstrated the largest change during a within-session reassessment. Other decisions included when to add techniques and when to initiate and sequence treatment at other contributing regions. Manual therapy techniques consisted of joint, soft-tissue, and neural mobilizations.^{26,35} Treatment was primarily directed toward the leg, ankle, and foot, with additional

Abbreviations: ROM, range of motion; DF, dorsiflexion; AP, anterior to posterior; PA, posterior to anterior; TCJ, talocrural joint; Tib-Fib, tibiofibular

Figure 3 General clinical reasoning for the progression of manual therapy techniques and typical progression of the talocrural anterior to posterior glide technique utilized in this case series.

techniques directed at more proximal joints such as the knee, hip, and spine if examination of the patient determined that those regions contributed to the patient's pain, stiffness, or functional limitation. The progression of techniques and detailed description of the most commonly utilized techniques are shown in Supplementary Material 1 <http://dx.doi.org/10.1179/2042618614Y.0000000076.S1>. Examination and treatment techniques performed in this study were originally defined by Maitland and Mulligan^{26,36} and more recently described in peer-reviewed research.^{22,23,25} Home exercises consisted of active or active-assisted ROM exercises, walking as tolerated, elliptical training, and stationary cycling,^{22,37} as available and as tolerated.

The foot and ankle complex was the primary focus of manual therapy treatment for all patients. Figure 4 describes the percentage of treatment directed at each region of the lower extremity. One manual therapy treatment 'dose' was defined as three sets of a 30-second mobilization, one thrust manipulation, or 3 minutes of soft-tissue mobilization.³⁸ All treatments performed in this study were grade III or IV

mobilizations, as described by Maitland, into the resistance of passive accessory or physiologic joint motion or grade V thrust manipulations.²⁶ Grade V thrust manipulations were frequently performed at the talocrural, distal tib-fib, midfoot, and forefoot

Figure 4 Patient treatment 'dose' by region expressed as a percentage of the total manual treatments. One treatment 'dose' was defined as either three sets of 30 seconds of non-thrust mobilizations, one thrust manipulation, or 3 minutes of soft tissue mobilization.

during subsequent treatment sessions if progression of forces and clinical reasoning led the physical therapist to believe they would be beneficial.

Return to run clinical pathway

The RTR clinical pathway is the current standard of care in our facility for patients with severe musculoskeletal injuries. The high-intensity functional rehabilitation program focuses on improving strength, power, and agility. There are two phases to this program: the pre-Ideo™ phase and the training with the Ideo™ phase. The pre-Ideo™ phase began when patients were fitted for their Ideo™, typically lasted 4–6 weeks, and ended when fabrication of the Ideo™ was complete. Treatment occurred four times per week for 60 minutes per session. Strength training focused on eccentric functional movements that approximated the patient's functional demands. Low-load plyometric exercises and agility training were also included.

The Ideo™ was fabricated by a single certified orthotist/prosthetist and is a custom orthosis created primarily from carbon fiber, incorporating a posteriorly mounted carbon fiber strut with a ground-reaction cuff and a distal supramalleolar ankle-foot orthosis (Fig. 5). Design details of the Ideo™ have been previously described.^{9,39} Ideo™ training began when the patient received their device and typically lasted 4 weeks. Treatment in this phase occurred four to five times per week for 60 minutes per session. Run re-training while wearing the Ideo™ was the cornerstone of this phase and began when the patient could perform agility drills without pain. As the Ideo™ typically positions the ankle in slight plantar-flexion, a midfoot strike during running is essential to maximize energy return.^{10,39} This midfoot strike technique was trained specifically during this phase. Patients were progressed from short intervals to continuous distance running for up to 2 miles. Details of the RTR program are summarized in Supplementary Material 2 <http://dx.doi.org/10.1179/2042618614Y.0000000076.S2>.

Outcome measures

Self-report outcome measures, which were primarily used to describe function without a brace, included the lower extremity functional scale (LEFS), the foot and ankle ability measure activities of daily living subscale (FAAM-ADL), and the patient-specific functional scale (PSFS). The LEFS and FAAM have been shown to be valid and reliable in a variety of lower extremity musculoskeletal disorders.^{40–44} The minimal clinically important difference (MCID) for the LEFS is 8 points.^{40,41,44} The MCID for the FAAM is 8 points for the activities of daily living (ADL) subscale.⁴² The PSFS has the potential to be more sensitive to change than other disease-specific or general health outcome measures.⁴⁵ The minimum

Figure 5 Intrepid Dynamic Exoskeletal Orthosis (Ideo™).

detectable change (MDC) for the PSFS has been shown to be 2 points for the average score of all activities and 3 points for any individual activity.^{45,46}

Physical performance assessments, as described by Wilken *et al.*,⁴⁷ captured both braced and un-braced function and included self-selected walking velocity (SSWV) over level ground, the 4-square step test (4SST), and a timed stair ascent. The MCID for gait speed after hip fracture has been reported as 0.10 m/second.⁴⁸ Normative and MDC values for each physical performance test have been established for young, healthy, active duty service members.⁴⁷ Each test has demonstrated excellent inter-rater and test-retest reliability.⁴⁷ Ankle dorsiflexion and plantar-flexion total arc ROM was also measured with a standard goniometer at the initial evaluation and at completion of manual physical therapy treatment.²⁸ The MDC for goniometric measurement of ankle dorsiflexion ROM has been estimated to be a minimum of 5°.²⁷

Video gait analysis was an outcome measure distinct from the visual gait assessment that the treating physical therapist utilized to guide treatment. It is a quick, cost-efficient, and clinically relevant method to analyze gait when compared to computer-assisted gait

Table 2 Results for the lower extremity functional scale (LEFS) and foot and ankle ability measure (FAAM)

Patient	LEFS		FAAM-ADL	
	Baseline	6-week f/u	Baseline	6-week f/u
1	43	42	47	48
2	45	56*	52	60*
3	19	34*	27	51*

LEFS: lower extremity functional scale; FAAM-ADL: foot and ankle ability activities of daily living subscale.

* Indicates change that exceeded the MCID; LEFS 8 points, FAAM-ADL 8 points.

analysis.^{49,50} Using a structured form, video gait analysis is moderately reliable in patients with orthopedic gait disorders and expert raters are capable of increased reliability.⁴⁹ Each patient was recorded in the frontal and sagittal planes over a 3 m distance. Variables of interest were step length, step width, medial/lateral deviation of the trunk, knee extension ROM, and foot/ankle ROM. Gait video was analyzed by an independent board-certified orthopedic physical therapist who was not a member of the research team and who was blind to whether the video was taken prior to or at the completion of treatment.

All outcomes were measured prior to the pre-Ideo™ phase and at completion of the pre-Ideo™ phase with the patient not utilizing the Ideo™. At the completion of Ideo™ training, SSWV, the 4SST, and the timed stair ascent were measured with the patient using the Ideo™.

Results

During a 6-month enrollment period, five consecutive patients referred to the RTR clinical pathway were screened for eligibility criteria for this case series. One patient was excluded because he was unable to participate in the treatment program over a 4–8-week period. Another patient was excluded due to a recent soft-tissue graft preventing manual forces required for treatment.

The patient's ages ranged from 21 to 23 years and the median time from injury to enrollment in the RTR clinical pathway was 10 months (range, 7–12). At baseline, the median LEFS score was 43 (range, 19–45) and FAAM-ADL score was 47 (range, 27–52), which indicated severe disability. During the treatment period, which included both OMPT and functional rehabilitation, the mean (SD) number of OMPT

treatment sessions was 12 (2.1) and functional rehabilitation treatment sessions was 24 (8.7) over a mean of 6 weeks (1.0). Training with the Ideo™ consisted of a mean of 15 (1.2) additional sessions over a period of 4 weeks.

Individual results for the LEFS and FAAM-ADL are shown in Table 2. Individual task scores and the average score for the PSFS are shown in Table 3. Patients #2 and #3 reported improvement in function that exceeded the MCID for the LEFS and moved them from a severe to a moderate amount of disability. Similarly, the change scores of patients #2 and #3 exceeded the MCID for the FAAM-ADL subscale. For the PSFS, the change score of patient #3 exceeded the MDC of 2 points for the average total score while the change scores of patients #2 and #3 exceeded the MDC of 3 points for an individual task score.

Table 4 shows results for the physical performance measures. Patient #2 demonstrated an improvement in SSWV without the Ideo™, which exceeded the MCID of 0.10 m/second. We considered a 25% improvement to be a meaningful change in the 4SST or timed stair ascent. Patient #1 showed a clinically meaningful improvement in the 4SST without using the Ideo™ at completion of the pre-Ideo™ phase. The total arc of ankle ROM improved by a median of 11° (range, 7–16), with all patients exceeding the MDC of 5°.

All patients demonstrated a clinically meaningful improvement from baseline in gait speed while wearing the Ideo™ at the completion of Ideo™ training. Patients #1 and #3 demonstrated a clinically meaningful improvement from baseline in the 4SST and timed stair ascent while wearing the Ideo™ at the completion of Ideo™ training.

Table 5 shows individual results for the video gait analysis. Patients #1 and #3 demonstrated improvement in at least three of seven gait parameters when assessed without the Ideo™.

Discussion

This case series describes the combination of impairment-based OMPT with high-intensity functional rehabilitation and a custom energy-storing orthosis in patients with severe lower extremity musculoskeletal injuries. All patients experienced clinically meaningful improvements in at least one outcome measure

Table 3 Results for the patient-specific functional scale (PSFS)

Patient	Activity #1	Activity #1		Activity #2	Activity #2		Activity #3	Activity #3		Baseline average	6-week f/u average
		Baseline	6-week f/u		Baseline	6-week f/u		Baseline	6-week f/u		
1	Walking	6	5	Squat	4	3	Heel raise	1	2	3.67	3.33
2	Walking	7	7	Dance '2-step'	4	7*	Stairs	7	8	6.00	7.50
3	Walking	3	7*	Squat	4	5	Stairs	4	5	3.67	5.67†

* Denotes change greater than minimum detectable change of 3 points for an individual activity score.

† Denotes change greater than minimum detectable change of 2 points for the average total score.

Table 4 Results for physical performance tests

Patient	Initial SSWV (m/second)	6-week SSWV (m/second)	10-week SSWV (m/second)	Initial 4SST (seconds)	6-week 4SST (seconds)	10-week 4SST (seconds)	Initial TSA (seconds)	6-week TSA (seconds)	10-week TSA (seconds)	Initial DF-PF total ROM (°)	6-week DF-PF total ROM (°)
1	1.19	1.06	1.49*	8.93	6.83*	6.22*	9.7	8.34	6.54*	15	26*
2	1.13	1.39*	1.29*	6.86	7.48	7.14	4.32	8.64	4.67	43	50*
3	0.91	0.81	1.18*	13.17	11.12	6.45*	8.4	6.92	4.54*	44	60*

SSWV: self-selected walking velocity; 4SST: 4-square step test; DF: dorsiflexion; PF: plantarflexion; ROM: range of motion; TSA: timed stair ascent

*Indicates change from baseline that exceeded the MCID/MDC; 0.10 m/s improvement in gait speed; 25% improvement in the 4-square step test or timed stair ascent, and 5 degrees for ankle range of motion. All baseline and 6-week follow-up measures were assessed without the Ideo™. All 10-week follow-up measures were assessed with the Ideo™.

when assessed without the Ideo™ after 5–7 weeks of a combined intervention. All patients demonstrated a clinically meaningful improvement in physical performance with the Ideo™ after an additional 4 weeks of training. To our knowledge, this is the first paper that has studied integration of OMPT with high-intensity functional rehabilitation in patients following severe lower extremity trauma.

A patient's functional ability, both with and without the Ideo™, has high clinical relevance. The RTR clinical pathway has been shown to allow patients with severe lower extremity musculoskeletal injuries to return to running, sports participation, and military deployments.^{10,11} However, the RTR pathway does not directly target the large amount of un-braced daily activity that may occur because the foot and ankle complex does not contribute to movement while the Ideo™ is worn. We would expect minimal functional improvement without direct intervention for un-braced tasks with a high motion demand on the foot and ankle complex.

We theorize that it would be unwise for patients to wear the Ideo™ during all daily activities because of the detrimental effects of long-term immobilization on the foot and ankle complex.^{51,52} Some patients may not tolerate the Ideo™, while others will fail to show additional improvements in physical performance when using the device. For example, the physical performance of patient #2 did not show a clinically meaningful change after training with Ideo™, yet he reported clinically meaningful improvements in all three primary self-report outcomes and one physical performance test measured without the Ideo™. Although patient #3 showed clinically meaningful changes in physical performance with use of the Ideo™, he eventually stopped using it due to pain. He also reported clinically meaningful improvements in all three primary patient self-report outcomes and two physical performance tests measured without the Ideo™.

The primary rationale for integrating manual physical therapy in this population's rehabilitation was to improve performance of un-braced activities without an orthosis such as the Ideo™. The observations of patients #2 and #3 highlight the need to continue to rehabilitate basic functional activities in addition to high-level physical performance. Patients with severe trauma typically receive more treatment sessions in military facilities than in civilian hospitals. In a study of health care cost in the LEAP study population, only 10% of patients were hospitalized for rehabilitation after limb-salvage surgery and they attended a mean of 36 outpatient physical therapy visits over a 2-year period.⁵³ In this case series, all patients were hospitalized for rehabilitation and 36 outpatient physical therapy visits

Table 5 Video gait analysis**Gait at baseline**

Patient	Step width increase	Step length asymmetry	Trunk LF	Hip ext	Knee ext	Ankle DF	Ankle PF
1	Normal	Mild	Mild	Mild	Moderate	Severe	Severe
2	Normal	Normal	Mild	Mild	Normal	Mild	Mild
3	Mild	Moderate	Severe	Moderate	Severe	Severe	Severe
Gait at the 6-week follow-up							
Patient	Step width increase	Step length asymmetry	Trunk LF	Hip ext	Knee ext	Ankle DF	Ankle PF
1	Normal	Mild	Mild	Mild	Mild*	Moderate*	Moderate*
2	Normal	Normal	Mild	Mild	Mild	Moderate	Moderate
3	Normal*	Mild*	Moderate*	Moderate	Severe	Moderate*	Mild*

LF: lateral flexion; ext: extension; DF: dorsiflexion; PF: plantarflexion.

* Indicates improvement from baseline.

occurred over a 6-week period. To maintain a reasonable number of patient visits in both civilian and military settings, an OMPT approach may be used initially for 4–6 weeks, followed by high-intensity functional rehabilitation with an Ideo™, or a similar energy-storing orthosis, if return to running and sports is a patient goal. Alternatively, a series of several episodes of four to six sessions of OMPT at various stages of the healing process and/or after each subsequent surgical procedure may be utilized.

While the clinical reasoning associated with this impairment-based manual therapy treatment approach is not unique,^{17,18,38,54,55} these patients with severe lower extremity trauma demonstrated atypical impairments. Complex fracture patterns often healed in less than ideal alignment with significant soft tissue damage and volumetric muscle loss. Proximal and distal regions were affected in unpredictable ways by joint and soft tissue mobility restrictions, joint instability, and neuropathic pain. These factors led to special considerations that altered decision-making and caused modification of the application of selected techniques. At baseline, all patients were recently cleared for full weight bearing but continued to require more time for complete fracture union. To minimize shear forces through healing fractures, long-axis distraction was the first technique chosen. The nature of these injuries and the extensive soft tissue damage often caused substantial joint stiffness with muscle scarring and contracture. As a result, the therapist applied manual techniques with high forces, long durations, and multiple bouts. Modifying hand contact and using pressure-distributing foam padding reduced hand pressure and improved patient comfort. Single plane physiologic and accessory manual treatment movements were quickly progressed to movements that combined accessory and physiological movement or combined two or more physiologic movements. By selecting combined movement techniques into restricted movement but producing less symptoms, sessions were generally well tolerated with less risk of

increasing the patient's symptoms after the session. Variations included providing slight joint compression or distraction to accessory movements and slightly varying the angles of forces away from the sagittal plane for both physiologic and accessory movements.

Patients #2 and #3 demonstrated clinically meaningful changes in multiple self-reported outcomes and at least one physical performance test. Patient #1, who had extensive bony and soft-tissue injuries, neuropathic pain, and was the only patient who had bilateral ankle fractures, only demonstrated a clinically meaningful improvement in one physical performance test without a brace. However, he did demonstrate clinically meaningful improvements in all physical performance tests with a brace. This contrasts with the results of the METALS study, where patients with bilateral or unilateral limb salvage self-reported similar functional outcomes.⁶ This patient's neuropathic pain may also have been a limiting factor in his functional outcome.

The combined intervention was highly valued by the patients in the case series. All patients expressed a desire to continue to receive manual physical therapy treatment after completion of Ideo™ training. There were no adverse events reported during the combined intervention period. One patient discontinued use of the Ideo™, during training with the device, due to increased pain associated with its use.

This case series describes a multi-modal intervention without a comparison group. We cannot infer any cause and effect relationship from this type of design and we are unable to evaluate the effects of any individual treatment component. However, we attempted to maximize the validity of this design by utilizing numerous dependent variables, including both self-report outcomes and physical performance tests, choosing outcome instruments with established reliability and validity indices, and reducing bias where possible. The sample size was small within a population whose injuries are by nature very diverse.

While lower extremity musculoskeletal injuries are common, the most severe injuries that require a

decision to perform limb-salvage surgery or amputate are a relatively small subgroup. If a researcher had access to a similar patient population of sufficient size, future research may utilize a prospective cohort design comparing a 4–6-week standardized rehabilitation program with and without OMPT. Outcomes should assess function both with and without the Ideo™. The challenge would be acquiring a large enough sample to overcome inherent variability in injury patterns with severe lower extremity trauma. Continued research of this population with long-term follow-up is essential to determine the ability of patients to continue high-intensity activities, the rate of development of post-traumatic osteoarthritis, and the number of patients who eventually elect amputation.

Conclusion

This case series describes the integration of impairment-based OMPT into an established rehabilitation pathway that combines high-intensity functional rehabilitation with a custom energy-storing orthosis. While the subgroup of patients with severe lower extremity musculoskeletal injuries that we described is relatively small, it has the potential to account for a large amount of cost in both civilian and military healthcare systems. These results suggest that a multimodal rehabilitation approach, including both manual therapy and functional exercise, may address the full spectrum of impairments in patients with severe lower extremity trauma. All patients experienced clinically meaningful changes in at least one outcome measure assessed without the Ideo™ following a 5–7-week combined intervention. All patients demonstrated a clinically meaningful improvement in physical performance after an additional 4 weeks of training with the Ideo™. Further research is needed to determine the effect of each individual treatment component and determine long-term treatment outcomes.

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