Can an Ankle-Foot Orthosis Change Hearts and Minds?

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The current military conflicts of Operation Enduring Freedom and Operation Iraqi Freedom have been characterized by high-energy explosive wounding patterns, with the majority affecting the extremities. While many injuries have resulted in amputation, surgical advances have allowed the orthopaedic surgeon to pursue limb salvage in the face of injuries once considered unsalvageable. The military limb salvage patient is frequently highly active and motivated and expresses significant frustration with the slow nature of limb salvage rehabilitation and continued functional deficits. Inspired by these patients, efforts at this institution began to provide them with a more dynamic orthosis. Utilizing techniques and technology resulting from cerebral palsy, stroke, and amputation research, the Intrepid Dynamic Exoskeletal Orthosis was created. To date, this device has significantly improved the functional capabilities of the limb salvage wounded warrior population when combined with a high-intensity rehabilitation program. Clinical and biomechanical research is currently underway at this institution in order to fully characterize the device, its effect on patients, and what can be done to modify future generations of the device to best serve the combat-wounded limb salvage population. (Journal of Surgical Orthopaedic Advances 20(1):8–18, 2011)

Key words: carbon fiber ankle-foot orthosis, combat wounds, energy-storing ankle-foot orthosis, limb salvage

The majority of combat wounds sustained by United States (U.S.) Army soldiers in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) are extremity wounds (1). Review of the Joint Theatre Trauma Registry, a database of medical treatment information on U.S. military patients, demonstrates that 26% of patients with extremity wounds have fractures, 82% of which are open, divided evenly between the upper and lower extremities. The most common fracture of the lower extremity is to the tibia and fibula. As opposed to prior military conflicts and civilian trauma, the majority of combat wounds sustained in our current conflicts are the result of explosive mechanisms (52%), with gunshot wounds (16%), mortar attacks (9%), and fragmentation wounds (8%) also contributing to the injury burden (1, 2). These are high-energy injuries typically complicated by massive soft tissue injury, severe contamination, and vascular and neurologic injury (3). In the combat theater, reconstruction options are limited, and treatment is aimed primarily at temporary fixation, thorough debridement, rapid revascularization, and evacuation to higher levels of care, where more complex surgical procedures and long-term rehabilitation may be performed (4–6).

Recent surgical advances have increased the orthopaedic surgeon's ability to pursue limb salvage in cases of severely injured lower extremities. However, when to pursue limb salvage over amputation is controversial, and long-term follow-up in the military, combat-wounded population is lacking (5, 6). The largest study to date comparing limb salvage to amputation after severe limb-threatening lower extremity trauma [the Lower Extremity Assessment Project (LEAP) Study Group] demonstrated no significant difference in functional outcomes at 2 and 7 years postinjury, although both patient groups were found to be severely disabled as compared to a normative population. Although a large comprehensive study, the authors excluded active duty military personnel from their patient population. Additionally, the majority of injuries in their

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cohort were due to motor vehicle, motorcycle, and pedestrian versus motor vehicle mechanisms, as opposed to the primarily explosive mechanisms found in our patient population (2). Based on these differences, it is difficult to properly apply the conclusions of the LEAP study group to our combat-wounded soldiers.

Our wounded warriors are a unique population. They are accustomed to being incredibly physically fit and being able to participate in a large variety of high-demand athletic and recreational activities. Once injured, many of these soldiers will intensely focus on returning to their combat units, with the overall goal of returning to the same military occupational specialty that they had before injury. These specialties include combat infantry, artillery, and similar occupations that require high levels of physical activity and the ability to respond appropriately to dangerous situations almost instantaneously. The LEAP study demonstrated that self-efficacy, or the confidence in one's ability to perform specific tasks or activities, was one of the strongest predictors of improved disability scores and return to work rates (7). Although a military population is often presumed to have higher self-efficacy than their civilian trauma counterparts, no studies have examined the effects of severe trauma and lifestyle-altering injury on the self-efficacy of combat-wounded soldiers.

Applying lessons learned from World War II and the Vietnam War, several military centers of excellence for amputees have been created since the start of OEF and OIF. These include the Military Advanced Training Center at the Walter Reed National Military Medical Center in Washington, DC, the Comprehensive Combat and Complex Casualty Care rehabilitation facility at the Naval Medical Center in San Diego, CA, and the Center for the Intrepid (CFI) at the San Antonio Military Medical Center in San Antonio, TX. Initially designed to provide centralized care to combat-wounded amputees, these centers now provide multidisciplinary care to all extremity-wounded soldiers and allow our wounded warriors the opportunity to interact with other warriors at multiple stages of care (6, 8).

With regard to the limb salvage population, occasionally this interaction with amputees can have deleterious effects on their rehabilitation. For example, many amputees initially report improved pain and function in the early stages of their rehabilitation as compared to the limb salvage population. They are also frequently observed walking, running, and participating in recreational sporting activities relatively early in the course of their recovery due to the innovations and dedication of the prosthetics and physical therapy staff. The limb salvage population, composed of equally motivated and active young individuals, may find this difference in progress disheartening, leading to decreased motivation to continue with limb salvage attempts and increased interest in delayed amputation of their salvaged limb (9). While many innovative and adaptive prosthetics have been created for the amputee population (10), few options have been available to the limb salvage patients with deficits in ankle strength, motion, stability, nerve damage, or pain with attempts at higher intensity activities.

At our institution we have combined a high-intensity limb salvage rehabilitation program with the development of a novel energy-storing carbon fiber orthosis, the Intrepid Dynamic Exoskeletal Orthosis (IDEO). Utilizing a multidisciplinary approach, we have tailored both the orthosis and rehabilitation to each individual limb salvage patient in the hopes of allowing them to return to their desired levels of activity.

Who Is the Patient and What Can He Do? A Case Study

The featured patient is a 29-year-old male active duty Army soldier who was injured in a rollover motor vehicle collision in June 2009 while serving in OIF. He sustained a severe open ankle fracture and underwent irrigation and debridement with splint immobilization in theater on the day of injury. Thereafter he was evacuated to Landstuhl Regional Medical Center (Germany) where he underwent an additional irrigation and debridement before evacuation to the San Antonio Military Medical Center (SAMMC) in San Antonio, TX. Radiographs obtained at SAMMC demonstrated severe comminution and bone loss of the distal fibula as well as apparent ligamentous instability with widening of the medial clear space (Fig. 1). He was taken to the operating room the day after his arrival at SAMMC for irrigation and debridement. At this time he was noted to have large open wounds on the medial and lateral aspects of the ankle and dorsal aspect of the foot. The lateral and medial malleoli were visible in the wound beds.

After consultation with both the Orthopaedic Trauma and Foot and Ankle Services, it was felt that reconstruction was unlikely to succeed because of the complex nature of his fracture pattern with significant bone loss and ligamentous instability. The decision was made to proceed with acute ankle arthrodesis utilizing circular external fixation (Figs. 2 and 3) with the Taylor Spatial Frame (Smith and Nephew, Memphis, TN). At the time of surgery, the remaining distal fibula was found to be completely devitalized and was excised. All open wounds underwent delayed primary closure without the assistance of flaps or skin grafting once clean wounds beds with nonedematous soft tissues were confirmed. Several days following external fixator application, the patient was

FIGURE 1 Initial injury radiograph (ankle mortise view).

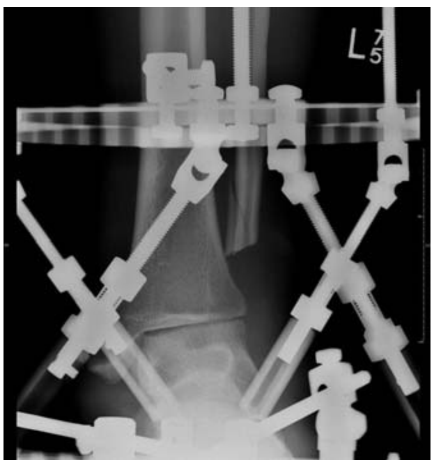

FIGURE 2 Acute ankle fusion utilizing a Taylor Spatial Frame (anteroposterior view).

fitted with a custom footplate by the hospital orthotists and he was allowed to advance to weightbearing as tolerated.

Upon discharge the patient was referred to our limb salvage physical therapist for high-intensity rehabilitation while still in external fixation. He expressed frustration with his continued need for high-dose narcotic pain medication and was referred to the Chronic Pain Clinic with significant reduction of his narcotic requirement. He made substantial gains in physical therapy and demonstrated apparent fusion on his plain radiographs in September 2009 (Fig. 4). A computed tomography scan obtained at this time confirmed complete fusion, and the frame was removed on September 30, 2009. He was restricted to nonweightbearing status in a cam walker for the next 4 weeks. By December 1 he had progressed to full weightbearing and discontinued the use of the cam walker.

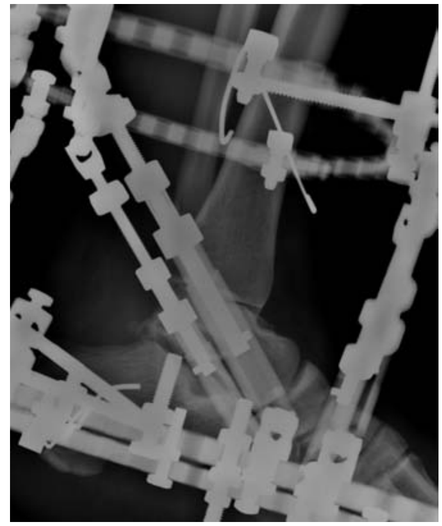

FIGURE 3 Acute ankle fusion utilizing a Taylor Spatial Frame (lateral view).

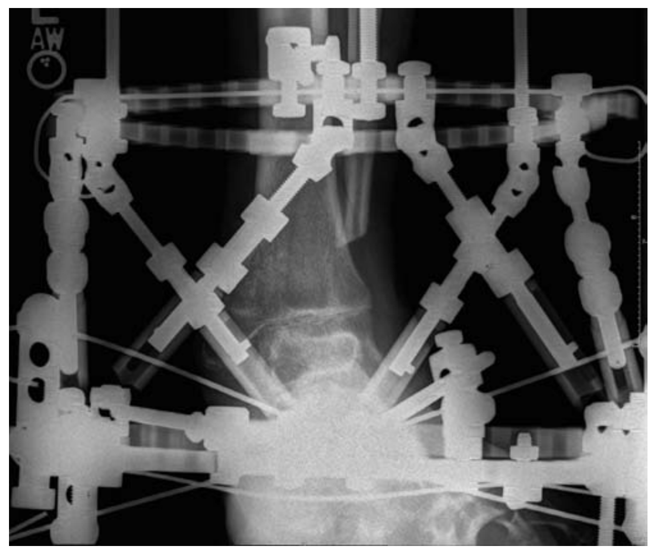

FIGURE 4 Completion of ankle fusion in a Taylor Spatial Frame (anteroposterior view).

In January 2010 the patient was provided with a custom, commercially made carbon fiber ankle-foot orthosis (AFO). He was able to run and perform high-intensity physical exercise in this orthosis (Dynamic Bracing Solutions Inc., San Diego, CA), but found it to be uncomfortable after several hours and had significant difficulty with donning and doffing the brace. In June 2010 he was fitted for the IDEO and noted significant improvement over the commercial brace in both comfort and function. He continued to progress in his therapy, returning to recreational softball with a local team of noninjured athletes and was found fit for return to combat duty in late July 2010 (Figs. 5–8).

FIGURE 5 Anteroposterior ankle at clearance to return to military duty.

FIGURE 6 Lateral ankle at clearance to return to military duty.

Reconstructive Considerations and Surgical Options

Preoperative counseling for our institution's limb salvage patients has changed considerably over the past years. Our patients are demanding higher and more complicated function than ever before. Not only do our patients wish to return to running, recreational sports, and even skydiving, others wish to return to an active duty combat environment (11, 12). Many limb salvage patients are aware of the apparent successes of our large amputee population and come to our clinic insisting on an amputation. The patient is informed of published limb salvage versus amputation data (2) as well as internal data currently in press. Once the patient has made the decision to proceed with limb salvage, a number of surgical considerations come into play, such as the necessity for joint fusion, position of potential joint fusion, and postoperative limb lengthening.

There has been a decreased incidence of elective ankle fusions in our limb salvage population. The largest change to our current practice has been in those individuals with nerve injury or significant muscle loss. Before the IDEO, many patients with nerve and muscle loss required an ankle fusion or tendon transfers to address a loss of active dorsiflexion. After extensive discussion with our prosthetists and orthotists, we feel it is better to have a mobile ankle that is capable of any active plantarflexion than a fused ankle. This allows for eventual increased energy storage capabilities with our advanced bracing techniques.

Patients may have injuries to the distal tibia or talus that preclude the salvage of the tibiotalar joint. Initially, these patients were concerned about their eventual ability to participate in athletics with an ankle fusion; however, they are counseled that a joint fusion is no longer a contraindication to running and jumping (11) as it once was (13). We continue to fuse the tibiotalar joint in neutral dorsiflexion because the IDEO design seems to be more efficient with ankle joint at neutral flexion.

Many patients with segmental bone loss injuries require postoperative limb lengthening. Initially, an attempt was made to achieve equal limb lengths in all patients. However, the limb-lengthening process is now halted when the patient's injured extremity is within 2 cm of the contralateral side. The amount of IDEO bracing material on the plantar surface of the patient's foot compensates for the limb length discrepancy. We will not make any surgical changes to the patient's injured limb if an equal limb length is achieved after fracture healing.

Brace Development and Design

The CFI's IDEO is a custom, energy-storing device that is designed to support and protect an extensive array of high-energy lower extremity trauma limb salvage injuries. The inspiration to develop the IDEO came from experience with treating limb salvage patients at the CFI when the first nonamputee patients began treatment in the fall of 2008. When first treated at the CFI, several of these patients had been provided with a noncustom, rigid, plastic AFO. While this orthosis allowed patients to progress

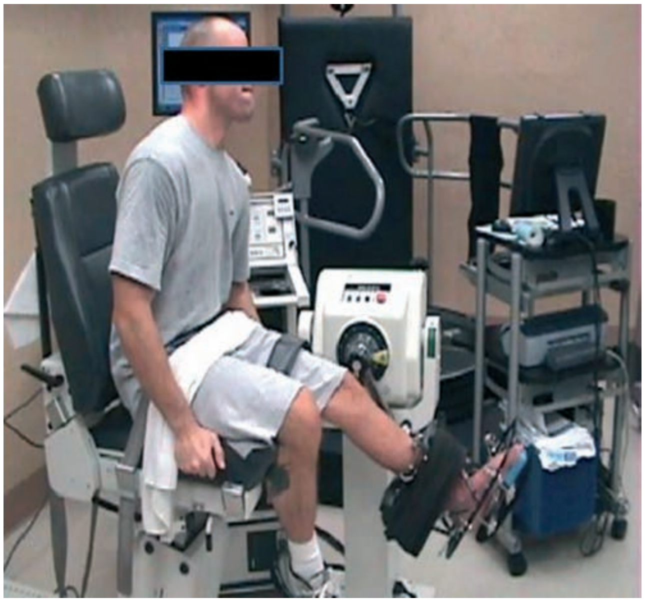

FIGURE 7 Isokinetic testing of knee extension and flexion strength while in a Taylor Spatial Frame.

FIGURE 8 An IDEO user with a fused ankle developing plyometric power.

through their initial therapy and achieve general community independence, they were limited in their ability to perform the agility, impact, and running exercises that the amputees at the CFI were able to achieve relatively early in the course of their rehabilitation. After discussion with the patients and their primary therapist, efforts to create an orthosis that would increase their ability to perform high-intensity activities began.

Several types of AFOs have been created with the hopes of providing dynamic energy storage and return to patients with neuromuscular dysfunction, particularly children with cerebral palsy or myelomeningocoele (14–16). In the case of plantarflexion weakness, the goal of the energy-storing AFO is to store energy as the tibia progresses forward and the ankle dorsiflexes during midstance and terminal stance and then return it to the patient in the form of ankle power during initial swing as the limb is unloaded. Early designs such as the posterior leaf spring (PLS) AFO (Fig. 9) were quickly found to provide almost no mechanical energy return during push-off. Subsequent efforts incorporated the use of carbon fiber, with improvements in gait velocity, ankle power, and push-off (14–17). Utilizing these advances, the initial concept for the IDEO was born.

The IDEO is crafted primarily from carbon fiber, incorporating a modified Ottobock Carbon 7 posterior-mounted strut, a proximal ground reaction cuff, and distal supramalleolar AFO (Fig. 10). The initial system incorporated traditional ground reaction force AFO stability with controlled distal ankle mobility through the posterior strut. This initial orthotic intervention provided the patients with immediate increased subjective functional abilities, including variable walking speeds, improved stability, agility, accommodation of uneven surfaces, and running. In some instances, Biodex testing demonstrated a nearly 300% increase in quadriceps strength following fitting of the initial IDEO and the associated rehabilitation at the CFI.

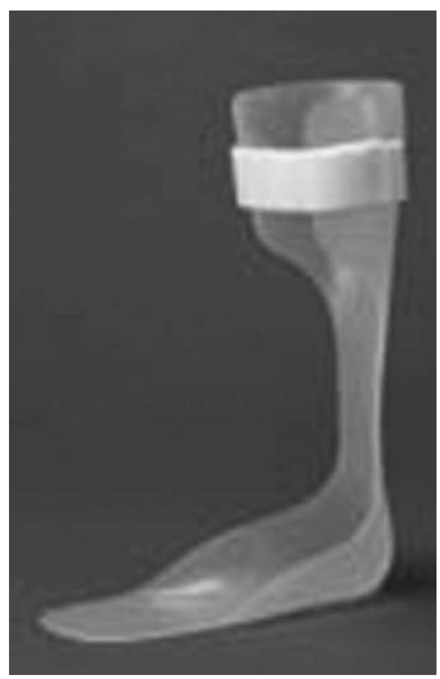

FIGURE 9 Posterior leaf spring ankle-foot orthosis (image courtesy of Capston Orthopedics).

FIGURE 10 Initial IDEO.

FIGURE 11 Current IDEO plantar surface design.

The plantar surface of the IDEO footplate is crucial in allowing optimal function of the dynamic strut and long-term durability of the device (Fig. 11). The footplate has a gradual roller shape that begins just distal to the 3/4-inch heel cushion. During heel strike, the cushioned heel decreases impact on the limb and allows the patient to easily bring the forefoot to the floor. The cushoined heel has an intentional and added advantage of allowing a gradually increasing load to the strut as the tibia moves forward, while the plantarflexed foot position increases the degree of deflection and amount of energy storage from midstance through terminal stance. Energy storage and return is also evident during agility drills, running, and sprinting activities, which are primarily performed while up on the forefoot. The distal third of the plantar surface has a dorsiflexion radius design that maintains solid metatarsal contact to the ground for increased proprioception and control. The inspiration for the shape of the footplate can be seen in the design of many high-level prosthetic sprint and run feet, furthering the connection between prosthetic and orthotic design and development at the CFI (10).

The early success seen with the IDEO spurred the creation of orthoses to help other limb salvage patients undergoing treatment at the CFI. Computerized gait analysis conducted within the Military Performance Laboratory (MPL) was used to better understand the benefits and limitations of orthoses provided to individual patients. In several cases the function of the initial brace was compared to function with no brace, various off-the-shelf designs, and other commercially available dynamic orthosis systems. Both clinical observation and data collected from MPL have provided valuable feedback that has been utilized to further brace development and design and to create modifications specific to the individual needs of a very heterogeneous patient population.

Data analysis obtained from the MPL utilizing the early versions of the IDEO demonstrated two particular areas for modification: the need for proximal off-loading and strut dynamics. Due to the often severely compromised anatomy of the salvaged limb, many of these patients could not participate in high-intensity activities because of pain, limited neuromuscular control, and decreased ankle range of motion. Using concepts arising from innovations that had been designed into the prosthetic limbs for the amputee population, increased attention was placed in the design of the proximal cuff component of the IDEO (10). Each limb salvage case is unique. As such, each patient is evaluated for the level of off-loading that is most appropriate for his or her specific injury pattern. For example, a patient with severe ankle pain and stiffness may have the IDEO adjusted to off-load the ankle joint and transfer the load-bearing center to the midfoot.

Study of the amputee population demonstrated improved function of prosthetic limbs with a shift of the run feet to a more posterior position (10). Application of this idea to the IDEO was accomplished by mounting a modular Littig strut along the posterior proximal and distal sections of the AFO and utilizing Ossur Run foot posterior-mounted lamination plates. This adaptation provided significantly increased strut dynamics and power as well as the ability to adjust the alignment of the IDEO. Alignment adjustment allowed the ability to progressively optimize the final position of the ankle joint following months of external fixation, varying degrees of malalignment, and associated tissue contractures. The alignment of the IDEO

FIGURE 12 Current modular IDEO.

FIGURE 13 Clever Strut IDEO.

can be adjusted on average up to 7° of dorsiflexion, plantarflexion, and external or internal rotation and 5° of inversion or eversion (Fig. 12).

As the patient progresses through high-intensity rehabilitation and increases his or her strength, the need to exchange a carbon fiber strut of lower resistance for one of higher (stiffer) resistance may arise. Strut stiffness may also be adjusted to prevent excessive sagittal plane motion that might otherwise result in tibiotalar impingement. The modular design of the IDEO is advantageous in that it allows these strut changes to coincide with changes in strength and motion, but also allows easier ability to don and doff the orthosis to accommodate changes in muscle volume or leg edema.

Once patients have demonstrated an adequate level of rehabilitation using the initial modular IDEO system, they are considered for the lighter, more dynamic and streamlined definitive Clever Strut IDEO system (Fig. 13). This system utilizes a tandem Medi Clever Bone pylon system that was originally designed to be used in transtibial prostheses to provide sagittal, tranverse, and coronal plane dynamics to the amputee. This strut system is permamently incorporated into the posterior aspect of the carbon proximal and distal sections of the IDEO system in place of the initial modular Littig strut design. This particular design has proven to exhibit increased energy return, improved torsional dynamics, and a general increase in responsiveness to the patient. This system is also the primary system considered for military combat deployment due to its sleek, lightweight, and durable design. At the time of this writing, approximately seven patients were actively deployed around the world in military combat duties utilizing the IDEO system.

Device durability is a critical component to a successful orthosis in our patient population. These motivated individuals are infrequently satisfied with simple ambulation following extensive lower extramity trauma. Instead, their goals often include running, jumping, skydiving, and return to active duty service, particulary the ability to re-deploy to the combat environment in their prior military profession. Considering that many soldiers will be expected to carry upwards of 120 pounds of gear, the IDEO must be fabricated with strength and longevity in mind. The high cyclic loads and forces applied to the strut make material failure inevitible. The modularity of the IDEO with the ability to change a damaged strut and ability to adjust the alignment of the orthosis allows the orthotist to avoid catastrophic damage to the IDEO. Another area of concern is the footplate, because this section currently incorporates multiple layers of carbon, kevlar, and high-strength aralon stockinette. Patients are taught to recognize signs of footplate damage and to address them quickly so modifications can be made before the risk of material fracture becomes too great. Current colloborative efforts with various academic centers are focused on strut dynamics, materials, durabilty, and other features that may improve and influence future iterations of the IDEO.

Integration of Bracing and High-Intensity Rehabilitation

The ability to return to running and sports participation after high-energy, lower extremity trauma (HELET) has been poorly documented. With the development of the IDEO, the gap has been bridged for the patient involved in HELET to return to active duty and an active recreational lifestyle. From this, the limb salvage run program was developed to maximize the patient's potential success when utilizing the IDEO. The program is based on a sports medicine approach and separated into two phases: the in-frame phase and the IDEO phase. The in-frame phase was named for the large amount of patients utilizing circular external fixation in our program. However, any patient who is a potential candidate for an IDEO, regardless of surgical fixation or injury pattern, may participate in this phase. The patients in the IDEO phase performing high-level rehabilitation work alongside their in-frame counterparts. This enables the more acutely injured patients the ability to see the potential activities that they may eventually achieve.

As with any rehabilitation program, restoring normal range of motion after injury is an early goal. Unfortunately, the limb salvage patients involved in HELET sustain severe soft tissue and bone injuries to the lower leg that often leaves limited foot and ankle mobility. Early and aggressive mobilization is the key to make the most gains in range of motion. A recent systematic review of ankle fractures concluded that early ankle mobility exercises allowed an earlier return to normal activities, reduced pain, and improved ankle motion (18). Still, many patients are left with limited motion in the ankle, foot, and toes that would normally preclude a return to high-demand activities. To combat this problem, the IDEO utilizes a custom footplate that allows very little ankle or foot motion while still providing energy return through the posterior strut. With this design, we have been able to return patients with fused ankles to running, basketball, softball, skydiving, and combat arms deployments. We have not been as successful with contractures at the knee, because knee flexion less than 90° can significantly hinder performance in the IDEO. Thus, aggressive restoration of knee range of motion is implemented in the early stages of rehabilitation.

A strength and power component to our program is essential to maximize the potential of the IDEO. Strengthening is started early while in-frame with an emphasis on functional patterns. Isokinetic testing has been utilized to measure baseline strength as well as track progress with the program (Fig. 7). Isokinetic testing has been shown to be a reliable instrument for assessing strength; however, its utility to measure strength while in external fixation has not been validated (19).

Strengthening is begun in bilateral stance and progressed to lunging or split squat patterns. Eccentric strength is the cornerstone to build sufficient strength for deceleration while running or playing sports. Increasing loads are applied using weighted vests or dumbbells while the patient performs functional movements. Of note, our isokinetic testing has revealed significant gains in quadriceps strength once the IDEO is utilized. This may be a training effect from the quadriceps controlling the extensor moment that the brace imparts or from increased use of the leg while using the IDEO. Although it has not been tested in our population, there is evidence to support an increase in running economy in normal subjects with a strength training program (20).

The energy return in the IDEO can be fostered through loading the brace during ground reaction. Often patients suffering lower extremity trauma have difficulty applying an impact force through their injured leg. Therefore, agility and plyometric training is initiated during the in-frame phase of the program (Fig. 14). This allows the limb salvage patient to become comfortable loading the leg and to advance to developing the rapid footwork and ground reaction needed when using the IDEO. Linear agility patterns in the sagittal plane are advanced to lateral and transverse plane movements to develop the multidirectional movement pattern that the IDEO allows. Often while wearing the IDEO, patients note that they have found the "sweet spot" in the brace. This seems to correlate with the area of the footplate that allows the greatest amount of energy return with the least amount of impact stress. It is usually located in the midfoot section of the brace and the patient's awareness of this area during agility and ladder training will become beneficial during the run training phase.

As the program advances, plyometrics are introduced to the in-frame patient. These are done on the horizontal plane, usually in a sled or leg press. Once the patient moves into the IDEO phase, plyometric training is advanced to upright or vertical loading utilizing jumps, bounds, and hops. This phase allows the IDEO user to feel and harness the energy return from the IDEO and to become accustomed to loading his or her injured limb (Fig. 8). Recent evidence suggests that plyometric training may have a correlation to an improved running economy in normal subjects (21).

The run phase is begun as the patient becomes accustomed to loading the injured leg in the IDEO. Due to the plantarflexed design of the IDEO, a heel strike running pattern can impart a sudden extensor moment at the knee. To avoid this, we teach a forefoot strike to our IDEO patients. This allows proper loading of the distal footplate of the brace to maximize energy return. This running pattern may also have the beneficial effect of decreasing the impact stress to the leg. Recent evidence suggests that

FIGURE 14 An in-frame patient practicing footwork skills in the agility ladder in preparation for a future IDEO.

runners who use a forefoot strike have a lower impact transient compared to heel strikers. The midfoot or forefoot striking pattern can also impart the lower leg's translational kinetic energy into rotational kinetic energy and reduces the effective mass of the impact compared to heel striking (22). This reduced impact is ideal for our patients with injured lower legs and the energy return is perfectly suited for the IDEO.

Run retraining is implemented using visual (i.e., videotaping) as well as verbal feedback. Patients often are given a metronome to produce consistent and rapid forefoot strikes, ideally around 180 beats per minute. It has come to our attention that our limb salvage patients often have a very asymmetrical arm swing during running, with one arm either not moving or outstretched. This may be an attempt at balancing or a difference in energy production between the lower legs. Although the role of the arms in running is not clearly established, it is thought that the arms act as passive mass dampers, which reduce torso and head rotation, and that upper body movement is primarily powered by lower body movement (23). Thus the arms can be used as a guide for the patient to note differences in loading the lower legs or asymmetries between the IDEO and the uninjured limb (Fig. 15). We have found that as patients' arm movement becomes more symmetrical, their lower leg movement does as well.

Last, the majority of our patients are active duty soldiers and a deployment scenario may be in their future. It is with these patients that the strength, power, plyometrics, agility, and run retraining all come together. Soldiers are started on walking programs with progressive loads, usually with a "ruck sack" (Fig. 16). As they become accustomed to the loads, a run program is introduced to ensure that they have the ability to move quickly if need be while under a load. If they develop pain in their leg, the load is reduced until they build up sufficient strength and endurance to handle heavier loads. As mentioned earlier, we currently have several soldiers deployed utilizing the IDEO for their injured limb.

FIGURE 15 Run retraining utilizing a midfoot strike and proper arm mechanics in an IDEO user.

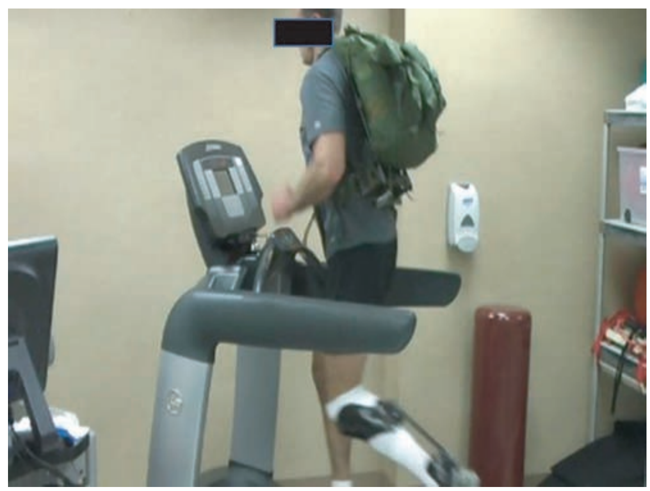

FIGURE 16 Predeployment training of a limb salvage patient with an 80-pound ruck sack.

Current and Future Research Efforts

While the underlying concepts behind the IDEO design are biomechanically sound, and the device has yielded clinically observed benefits for numerous service members with severe lower extremity trauma, there is limited objective data quantifying the extent to which the device improves physical activity performance. Published data are available for AFOs that are conceptually similar to the IDEO in patient populations ranging from individuals with postpolio syndrome to stroke (15, 16, 24, 25). These studies demonstrate the benefit of carbon fiber energy-storing AFOs for overground (level) walking in controlled environments. Improved walking efficiency and mechanics, while necessary, are not sufficient for injured service members who often seek to perform far more physically challenging activities. There is a paucity of established measures for assessment of AFO function during performance of high-level activities, which limits the ability to assess the IDEO. To further enhance patient performance and expedite the development process, it is necessary to use reliable and valid measures that capture the functional domains influenced by an AFO prescription. For injured service members, the IDEO must yield improvement in speed, agility, and power during performance of highly demanding tasks while also improving performance of basic daily activities such as overground walking.

Currently the IDEO devices are highly customized, requiring significant fabrication time, cost, and trial and error due to the requirement of clinical expertise in the design, fabrication, alignment, and fitting of the device. Both clinical and biomechanical research is currently underway to determine if the IDEO improves physical performance relative to commercially available devices and to fully characterize the IDEO in an effort to further refine the design with the goal of optimizing individual patient performance.

The first line of research includes the development and application of reliable and valid physical performance measures drawn from sports medicine and other literature to quantify the performance of challenging gross motor activities. It is this type of assessment that is laying the foundation for comparative effectiveness studies to determine which patients are most likely to benefit from IDEO prescription as opposed to an off-the-shelf or commercially available noncustom device. The objective data can be used as part of subsequent cost–benefit analyses to guide reimbursement for the relatively costly devices.

The second line of research includes the biomechanical assessment of common activities, such as walking, stair climbing, and running, to better understand how variations in the mechanical properties of the IDEO influence patient performance. Additionally, a key challenge to refining the fitting process relates to the high level of complexity associated with controlling the limb while also accommodating load-intolerant areas and irregular limb shapes. We are working to fully characterize the current IDEO design and understand the benefits and limitations associated with current fitting and fabrication techniques. The end goal of these efforts is to develop standardized methods of fitting and manufacture that are able to meet the unique functional needs of each injured individual.

Selective laser sintering (SLS) holds great promise as a tool for both improving the current design of the IDEO and lowering its cost, making it available to more individuals. During the SLS manufacturing process, a powdered material is heated with a laser to transform the powder into a solid object. A key advantage of this approach is the ability to rapidly produce complex shapes while tightly controlling the mechanical properties of the finished product. SLS provides several key advantages over current fabrication techniques, mainly the ability to readily produce complex shapes, provide complete control of the mechanical properties of the device, ensure consistency of manufacturing, and limit the manpower requirements for fabrication.

It is likely that with focused study, the most desirable general mechanical properties of the IDEO can be determined for service members across a wide range of injury types and severity. Given the complexity of injuries observed in injured service members and the custom nature of the devices, the greatest challenge to making the IDEO more widely available is the quantification of the clinical decision-making process. Although the development of fully parameterized models to create customized AFOs has been proposed (26), to date, SLS has only been used to replicate orthoses created by clinical experts (27). Subtle variations in alignment, location of loading, or material stiffness can lead to the rejection of otherwise satisfactory devices. To guide device development, measures are needed that have sufficient sensitivity to detect sometimes subtle but meaningful changes in performance that result from design modification. These measures may include biomechanical assessment of gait to assess the temporal-spatial parameters, asymmetry, and energy storage and return within the device. These results can then be used to tailor the IDEO mechanical properties to effectively address the needs of individual patients and allow them to better attain their individual goals. Research efforts are underway currently in order to fully develop and validate such measures.

Conclusion

Our wounded warrior population is representative of a young population with high-intensity physical demands in the face of severe lower extremity trauma. They are highly motivated and dedicated to returning to prior levels of functioning and their prior military occupational specialty and to rejoin their military units in a combat setting. With improved surgical techniques, limbs that previously were considered too damaged to avoid amputation may now be salvaged. However, the prolonged rehabilitation, repeat hospitalizations, and complications associated with limb salvage have prompted many patients in the past to request elective amputation of their salvaged limb. This may be more frequent when limb salvage patients witness amputees making what appears to be more rapid progress through their rehabilitation. We suspect that decreased self-efficacy in the wake of these severe combat injuries with resultant functional limitations can be devastating to the rehabilitation efforts of limb salvage patients. The unique, energy-storing Intrepid Dynamic Exoskeletal Orthosis allows our combat-wounded limb salvage patients to engage in high-intensity rehabilitation, thereby improving their ability to return to desired levels of activity and even to prior military duties. The use of such braces in a clinical setting may dramatically alter the rehabilitation potential of limb salvage patients across numerous patient populations. By allowing patients to return to sports, running, and high-intensity employment settings, use of the brace with specific rehabilitation efforts may decrease requests for amputation of salvaged limbs. Future research efforts are ongoing to further characterize the effect of the IDEO on limb salvage patients and to assist with ongoing brace design and modification.

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