Measuring Relative Motion to Develop an Interface that Off-loads the Lower Limb

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DISCLAIMER

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ABSTRACT

This investigation seeks to understand how the interfaces between fracture orthoses and the body affect the relative motion between the user and device. Excessive relative motion can inadvertently load the fracture and prevent healing. Identifying interfaces that minimize relative motion will inform the designs of future fracture orthoses. Three *types of interfaces are used to offload the injured limb: a thigh corset, a sling that loaded the ischium, and a sling that loaded the patellar tendon. However, little is known how these interfaces interact or with one another. Eighteen able-bodied participants were fitted with an adjustable Interface Testing System (ITS) that redirected loads away from the foot and lower leg to more proximal parts of the body using different combinations of the three interfaces. A video motion capture system measured the relative motion between the ITS and the participants while varying the type of interface, load through the ITS, and tightness of the thigh corset. Average relative motion varied from 1.6-6.5 cm across all conditions. The thigh corset combined with either the ischial sling or patellar tendon-bearing sling allowed the least relative motion of the interface conditions tested. However, the combinations differ in the sagittal profile they create for the user as well as the breadth of injuries they can treat. All these factors need to be considered in the design of future fracture orthoses.*

Key Words: Orthoses, Soft Tissue Interfaces, Video Motion Capture, Biomechanics, Fractures

INTRODUCTION

Lower extremity fractures are a debilitating injury that can take months to years for rehabilitation [1-4]. Fractures of the tibia and femur are some of the most common sites for a fracture and this has been consistent across time [5-7]. Returning to work after a lower limb injury can range from 120 to 300 days. Injuries of greater impairment can require even more time before returning to work, or in some cases, make returning to work impossible. Early rehabilitation and joint mobilization decrease pain and time to return to work after lower limb fractures [8]. Whole person mobility is associated with improved health status after lower limb fracture [9] and reducing time to full weight bearing has been identified as an important clinical goal [10, 11]. Functional fracture orthoses can off-load the injured limb segment, subsequently promoting mobility and providing a tool for someone to return to their daily activities [12].

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Functional fracture orthoses have been used since the late 1960s as an effective, non-surgical means of stabilizing a closed tibia fracture or, in some cases, femur fracture [2, 13-17]. These devices typically consist of a plastic clamshell that stabilizes the fracture site through radial soft tissue compression and have features designed to unweight the limb. When the fracture orthosis crosses the ankle joint but not the knee joint, it can partially unweight the leg [18] and there are several commercially available systems that do this [19, 20]. Full unweighting of the limb has been anecdotally achieved with locking the knee joint in extension and having a rigid structure bypass the knee and ankle joints (known as a Knee Ankle Foot Orthosis or KAFO) to transfer the patient's weight to either a corset around the thigh or to a structure that supports the ischial tuberosity [21]. These types of interfaces between the user and the device have traditionally followed prosthetic design principles and their fabrication have been described in multiple technical manuals [13, 14, 22].

Interfaces that could provide off-loading to a fracture include a thigh corset, a method to support the ischial tuberosity, and bearing loads through the patellar tendon with a flexed knee like the iWalk brace (iWalkFree Inc., Long Beach, CA, USA). While each of these techniques have anecdotally demonstrated the ability to unweight the lower limb, this has not been definitively established in the literature and the interplay between these interfaces has not been established.

The purpose of this research was to verify that these interfaces could effectively off-load the lower limb. A critical performance metric is the relative motion between the user and the device when the user loads the device, specifically translational motion along the long axis of the leg. The low stiffness inherent of the soft tissues the interfaces act through will result in unwanted motion between the user and the device, where the user will settle downward into the device.

This downward motion may transmit load to the fracture if the distal end of the injured limb contacts the ground. The device will need to be lengthened to prevent this contact. However, lengthening the device could induce a leg length discrepancy which leads to injuries, such as muscle fatigue and back pain [23, 24], or gait compensations, such as hip hiking or circumduction [24]. By minimizing relative motion, the user would experience fewer collateral injuries and, thus, could be mobile for longer periods of time. An interface or a combination of interfaces that minimizes motion between the user and the device would indicate better performance.

Knowledge gained from this research will inform orthotic designs for fracture management and enable the clinical team to make the most informed decision when considering different orthotic management options.

METHODS

This study was approved by the San Antonio Institutional Review Board (Reference Number C.2021.111d). Individuals without musculoskeletal injuries were recruited from a convenience sample at a local military base. Participants wore compressive athletic-wear and sneakers and were fitted with a novel interface testing system (ITS), which helped evaluate the ability of different interfaces to offload the lower leg. The ITS was a modified commercially available KAFO (Fillauer, Chattanooga, TN, USA) that featured adjustable lateral and medial uprights, an adjustable thigh corset, a locking knee joint, a rigid footplate, and two detachable fabric slings that could support the wearer through their ischium or their patellar tendon (Fig. 1).

Interface Testing System Design

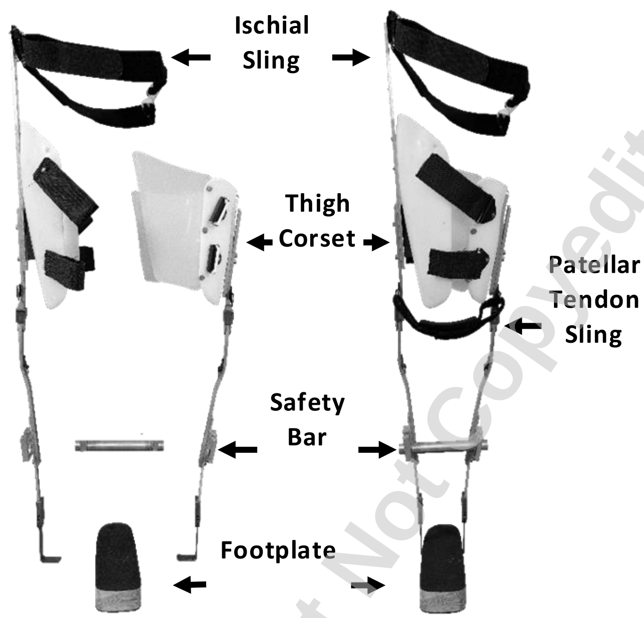

Figure 1: Each component of the interface testing system (ITS) is shown in an exploded view (left) and assembled view (right).

The adjustable thigh corset consisted of rigid lateral and medial thermoplastic panels. Four dacron straps extended from the lateral panel and looped around four corresponding D-rings on the medial panel. Pulling on the straps allowed the tightness of the thigh corset to be adjusted, and the straps were secured to themselves using Velcro. A pair of thin, flexible thermoplastic flaps also extended from the medial panel. These flaps went around the anterior and posterior surface of the wearer's thigh and slid under the lateral panel, so the thigh was completely encapsulated.

The ischial and patellar tendon slings were both made of Velcro-lined Dacron straps. The ischial sling had a soft, trough-shaped pad sewn in the middle of the strap to cradle the ischial tuberosity. When participants donned the ischial sling, they positioned the pad underneath their ischium and ran the straps around the anterior and posterior sides of their pelvis, looped around a pair of D-rings attached to the proximal end of the lateral upright. Much like the thigh corset, the ischial sling was tightened by pulling the straps and securing them using Velcro. The ischial sling was tightened such that thigh corset did not touch the ischium when the participant fully loaded the sling.

The patellar tendon sling wrapped around two D-rings near the knee joint of the medial and lateral uprights and was secured to itself using Velcro. The patellar tendon sling was tightened so that it wrapped closely around the wearer's knee when they flexed their knee 90 degrees. A soft pad was positioned between the wearer and the sling for comfort.

A custom aluminum 5" safety bar was created to prevent the double uprights from bowing under the users' weight during ITS loading. Slotted metal brackets were attached to each upright below the hinge joint and the safety bar had grooves cut near each end such that it fit within the slots to connect the two brackets. This safety bar was in place for the entire data collection.

The footplate was a 1 5/8" wooden block with stirrups cut in the bottom to hold the ends of the double uprights in place. The footplate was designed to withstand the loads applied to the ITS without breaking or plastically deforming. The outsole of the footplate was lined with rubber to prevent slipping during ITS loading.

ITS Data Collection

The ITS was fitted to participants' right leg. During fitment, each participant stood on the footplate without their right sneaker as the uprights were adjusted so that the thigh corset was in the middle of their thigh. After fitment, participants wore the device with their right knee bent to prevent the right foot from bearing any weight (Fig. 2).

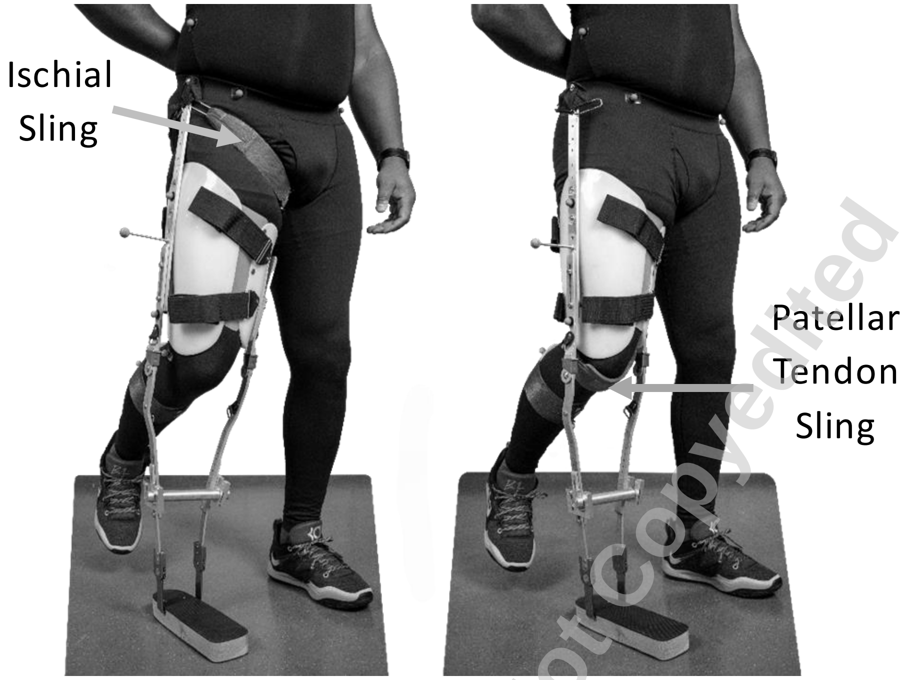

Figure 2: Photo of a person donning the ITS with different interface conditions. Interface A is shown on the left and interface C is shown on the right. The ischial and patellar tendon slings are colored in green to increase visibility.

Interface type, thigh corset tightness, and ITS loading were varied during data collection to evaluate their effect on relative motion. Three interfaces were tested: A) ischial sling combined with thigh corset, B) thigh corset only, and C) patellar tendon sling combined with thigh corset.

Thigh corset tightness was measured using a pressure sensor (Tekscan, Inc., MA, USA) that was positioned between participants' thigh and the thigh corset. At the beginning of the data collection, a maximum tolerable pressure was determined for each participant by tightening the thigh corset to a pressure that the participant reported they could tolerate for two hours. A percentage of this maximum tolerable pressure was used to determine the thigh corset tightness conditions for each interface. Interfaces A and C were tested at 0%, 33%, and 66% of the maximum tolerable thigh corset tightness. The 0% thigh corset tightness condition evaluated how well the slings performed alone under load. In this condition, the thigh corset straps were secured loosely so that they were not in tension around the thigh. The 33% and 66% thigh corset

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tightness conditions evaluated how well the combination of either sling with the thigh corset withstood loading. Interface B (thigh corset only) was tested at 33%, 66%, and 100% thigh corset tightness. Testing this interface at 0% thigh corset tightness would have been ineffective and unsafe for participants since the thigh corset was the sole weight-bearing component tested in this interface.

ITS loading was measured with a force plate (AMTI, Watertown, MA, USA) embedded in the floor. Participants loaded the ITS with either 50% or 100% of their body weight. A custom real-time biofeedback MATLAB program (MathWorks, Natick, MA, USA) allowed participants to visualize the magnitude of the vertical load they applied through the ITS. Participants started in a rest position with the footplate off the ground. Using the real-time biofeedback program, participants loaded the ITS to the target load and held that position for five seconds before returning to the rest position. To ensure loads were only born through the interfaces, participants maintained a flexed knee so that their foot did not touch the ground or the ITS footplate. Participants used a handrail to assist them in balancing in the ITS and study personnel spotted participants to prevent injury or fall. Participants repeated this task three times for each testing condition.

To measure motion between the user and the ITS, a 19-camera motion capture system (Motion Analysis, Corp., Santa Rosa, CA, USA) tracked the position of 15 reflective markers placed on the ITS and the participant's pelvis and lower leg. Visual3D (HAS-Motion, Kingston, Ontario, CA) was used to create a virtual landmark at the participant's hip joint center (HJC) and to create a local coordinate system (LCS) attached to the lateral upright of the ITS. The HJC was transformed into the LCS, and the average location of the HJC was calculated both when the ITS was unloaded and when the target load was applied. Displacement along the long axis of the thigh in the LCS (y) was calculated as the difference between the average HJC position while the ITS was loaded and unloaded (*Eq. 1*) and displacement was averaged across three trials.

$$Disp_y = \overline{HJC}_{target\ load(y)} - \overline{HJC}_{start(y)} \qquad \textit{Eq. 1}$$

Statistical Analysis

A two-factor repeated measures ANOVA (interface and ITS loading) was used in SPSS (IBM, Armonk, NY, USA) to determine whether interface or load had a significant effect on relative motion. Data were evaluated for sphericity and when those assumptions were violated, a Greenhouse-Geisser correction was used. T-tests were used to compare differences between different conditions and a Bonferroni correction was used to compensate for multiple comparisons. Effect sizes were calculated as partial η^2. Significance was set to $p < 0.05$. Continuous values are represented as mean±SD.

RESULTS

Eighteen active-duty Service members provided informed consent prior to participating in this study; however, data from one participant's were excluded due to errors with the pressure sensors. Therefore, data were analyzed for 17 participants (six female, age: 29.5 ± 5.5 years, 1.71 ± 0.07m, 75.6 ± 10.5kg).

There was a significant main effect for the different interfaces (F = 21.281, $p < 0.001$, η^2 = 0.571) and ITS loading (F = 214.7, $p < 0.001$, η^2 = 0.931), as well as a significant interaction effect (F = 4.84, p = 0.001, η^2 = 0.232). The interaction effect was driven by a lesser change in relative motion when interface C was loaded with 50% body weight (Fig. 3) than when loaded with 100% body weight (Fig. 4).

50% Body Weight Conditions

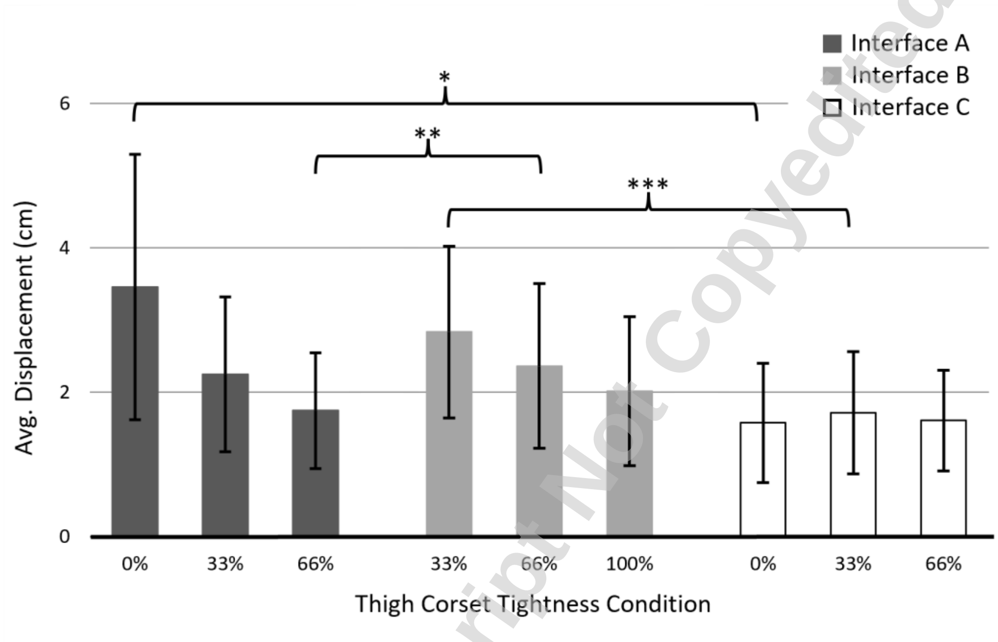

Figure 3: Average displacement in centimeters along the long axis of the thigh across 17 subjects for interface A (thigh corset and ischial sling), interface B (thigh corset only), and interface C (thigh corset and patellar tendon sling) when the ITS was loaded with 50% body weight. * indicates $p < 0.005$. ** indicates $p < 0.05$. *** indicates $p < 0.01$.

When the ITS was loaded to 50% body weight, average displacement ranged from 1.6±0.8 to 3.5±1.8cm across all testing conditions (Fig. 3). In general, as thigh corset tightness increased, average displacement decreased. Displacement changed the most for Interface A as thigh corset tightness increased from 0% to 66% of the maximum tolerable tightness, with average displacement dropping 50% from 3.5±1.8cm to 1.7±0.8cm ($p < 0.007$). Displacement decreased by 0.8 cm ($p < 0.005$) for Interface B as thigh corset tightness increased from 33% to 100% of the maximum tolerable tightness, and interface C maintained similar displacements, approximately 1.6cm, across all tightness percentages.

Interfaces A and C were significantly different at 0% thigh corset tightness ($p < 0.002$). Interfaces A and B were significantly different at 66% thigh corset tightness ($p < 0.02$) and interfaces B and C were significantly different at 33% thigh corset tightness ($p < 0.004$).

100% Body Weight Conditions

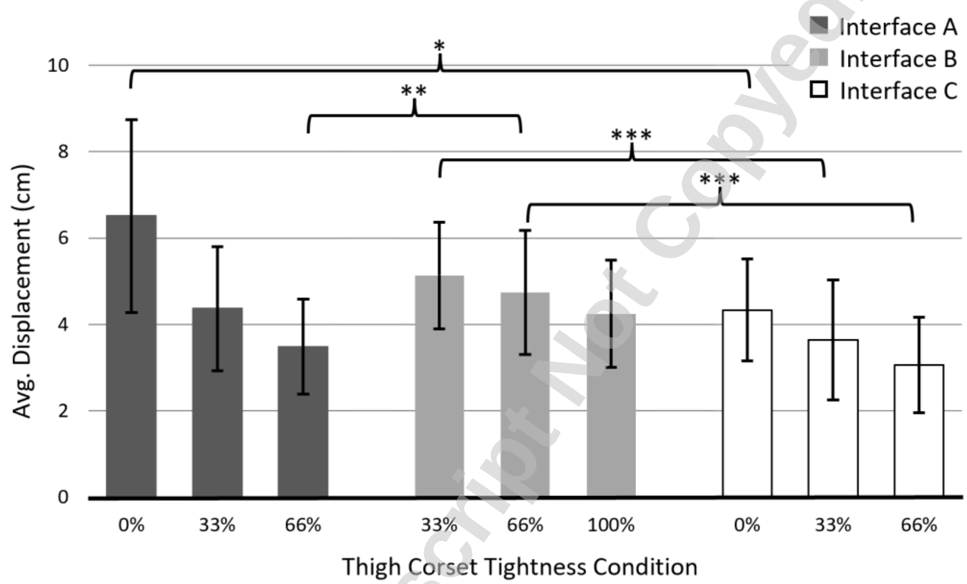

Figure 4: Average displacement in centimeters along the long axis of the thigh across 17 subjects for interface A (thigh corset and ischial sling), interface B (thigh corset only), and interface C (thigh corset and patellar tendon sling) when the ITS was loaded with 100% body weight. * indicates $p < 0.005$. ** indicates $p < 0.05$. *** indicates $p < 0.01$.

A greater average displacement was measured when the ITS was loaded to 100% body weight, which ranged from 3.1±1.1cm to 6.5±2.2cm (Fig. 4). Like 50% ITS loading, average displacement decreased for all testing conditions as thigh corset tightness increased. Displacement decreased the most for interface A as thigh corset tightness increased from 0% to 66% of the maximum tolerable tightness ($p < 0.000$), with average displacement dropping 53% from 6.5±2.2cm to 3.5±1.1cm. Increasing thigh corset tightness from 33% to 100% of the maximum tolerable tightness decreased displacement with Interfaces B 0.9cm ($p < 0.082$), and displacement reduced by 1.3cm ($p < 0.000$) for Interface C, as thigh corset tightness increased for 0% to 66% of the maximum tolerable tightness.

During 100% loading of the ITS, interfaces A and C were significantly different at 0% thigh corset tightness ($p < 0.004$) and interfaces A and B were significantly different at 66% thigh corset tightness ($p < 0.003$). Additionally, interfaces B and C were significantly different at 33% and 66% thigh corset tightness ($p < 0.01$ and $p < 0.003$, respectively).

Also of note, no significant differences were detected between interfaces A and C at the 33% and 66% thigh corset tightness conditions under either loading condition. The *p*-value for each of these comparisons was 1.000 except for the 50% ITS loading condition at 33% corset tightness, which had a *p*-value of 0.084.

DISCUSSION

The least relative motion between user and device was achieved when the thigh corset was tightened and used in combination with another weight-bearing component. When interfaces A and C were tightened to 33% and 66% thigh corset tightness, average displacement values were lower than interface B at the same tightness conditions, regardless of ITS loading. Furthermore, interfaces A and C had lower average displacement values when the thigh corset was at 66% tightness even when compared to interface B at 100% thigh corset tightness. These findings suggest that the ischial and patellar tendon slings in combination with a tightened thigh corset reduced relative motion more effectively than the thigh corset alone. Even though the corset was rigid, it interfaced with the compliant soft tissues around the thigh, which can allow relative motion. The slings interfaced with less compliant tissues, such as the bony ischium, which may explain how combining different interfaces can reduce the overall relative motion.

The most relative motion between user and device was measured when the thigh corset was not tightened (at 0% thigh corset tightness) as seen in interface A, with average displacement values of 3.5±1.8cm and 6.5±2.2cm for 50% and 100% ITS loading, respectively. These findings suggest that using an ischial sling sling by itself would allow excessive relative motion.

The mean plus one standard deviation of the relative motion during ITS loading was less than 9 cm for all interfaces, indicating that an ambulatory fracture orthosis featuring some of the interfaces would need to raise the injured leg at least 9 cm to prevent it from touching the ground and experiencing load during walking. A shoe lift would be required on the contralateral side to minimize the resulting leg length discrepancy. However, the mean relative motion was reduced when interfaces were combined, which may negate the need for correcting any leg length discrepancy caused by donning a fracture orthosis. The combination of an ischial sling and a moderately tightened thigh corset dropped the mean plus one standard deviation to 4.6cm. The heel height of a standard issue combat boot is ~4.5cm. With relative motion being at or below that heel height, excessive leg length discrepancies would not be created if the user had a boot on one side and a thinner fracture orthosis on the injured side.

Overall, these results demonstrate the feasibility of each interface to off-load the lower leg to more proximal parts of the body and the possibility to enhance performance through combining interface designs. All three interfaces enabled participants to load the ITS with 100% of their body weight.

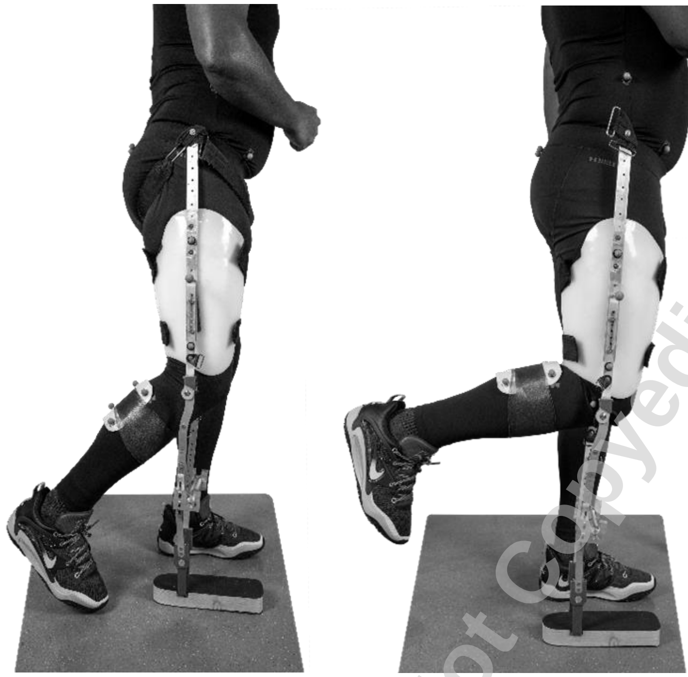

Figure 5: The sagittal plane profile of a user donning the ITS with interface A (left) and interface C (right).

There were no statistically significant differences between the ischial sling and patellar sling when the thigh corset was tightened. Thus, other factors that would benefit the user need to be considered when deciding which interface would best off-load the lower leg. When wearing a patellar tendon sling, users are required to flex their knee 90°, which increases their sagittal profile, places the injured leg outside of their field of vision, and increases the clearance of their foot to the ground (Fig. 5). In contrast, users could potentially fully extend their knee while using an ischial sling, which enables the user to have a narrower sagittal plane profile but reduces their foot clearance to the ground (Fig. 5). A narrower sagittal profile reduces the risk of accidentally hitting the injured limb with objects outside of the user's field of vision, which may be an issue in narrow spaces, but a greater foot clearance to the ground reduces the risk of the injured leg touching the ground on uneven terrain. Both interfaces provide benefits to the user and choosing which interface would best off-load the lower leg is scenario dependent.

The reliability of the interface to maintain contact with the user's body during ITS loading is another factor to consider. When the user wears a patellar tendon sling, their leg could slip out of the sling if they load the ITS with their knee extended beyond 90° (Fig. 5). Slipping out of the patellar tendon sling could cause further damage to the fracture site and possibly cause injury to other parts of the body; although, devices that have a rigid support for the shank like the iWalk would not have this problem. When the user wears an ischial sling, the sling goes underneath their ischium and wraps around their pelvis (Fig. 5), providing more contact with the body and security. Furthermore, the angle of the user's knee while they wear the ischial sling does not affect the sling position or its contact with their body.

Finally, the variety of injuries that could be accommodated is another important factor. Because the patellar tendon sling goes underneath the patellar tendon, which inserts on the tibial tuberosity, any proximal tibia fracture or fractures to the tibial plateau could not be off-loaded. Additionally, the patellar tendon sling would not be able to accommodate any distal femur fracture because the user would not be able to bear weight into it. Considering all these factors, an ischial sling or custom-made ischial shelf has greater benefits to the user than loading through a patellar tendon sling.

Limitations

The materials used in all interfaces may have contributed to relative motion. Velcro was used in the ischial and patellar tendon slings and in the straps that tightened the thigh corset. The Velcro may have slipped as thigh corset tightness and ITS loading increased. Additionally, the thigh corset was made of a thermoplastic, which did not adhere well to the compression garments the participants wore. This may have caused participants to slide within the thigh corset when they loaded the ITS, even when the thigh corset was at 100% tightness. Using ratchet straps and a material that adheres more to user clothing in future testing may reduce relative motion.

Participant thigh position and muscle activation affected pressure readings within the thigh corset. To control for these factors, participants were asked to adopt a comfortable standing position when the thigh corset was being adjusted with their right knee flexed at 90°, and their right foot resting on a stool placed behind them. This position ensured their right thigh was relaxed when pressure was being measured. Despite this systematic approach, returning to the relaxed position was self-reported and no measurements were made to determine the test-retest reliability of the corset tightness, so consistency for each participant was unknown. Again, more rigid ratchet straps could ameliorate this uncertainty by using ratchet position as a proxy for corset tightness. The ratchet position that achieved the target pressure within the corset could be identified once at the beginning of the experiment, and then the corset could be set to that same position for each corresponding tightness condition.

These study results were based on quasi-static loading. Participants were asked to load the ITS to a target load (50% or 100% of their body weight) and hold for five seconds. This was a very simple and steady load-off-load movement. However, greater and more complicated loads are expected in real-world environments. Future testing should evaluate how much relative motion occurs during more complex and dynamic movements, like walking and kneeling.

Other uncontrolled factors could also contribute to the results. While variations in subject height and thigh circumference were accommodated by the adjustability of the ITS, they may still have some effect on relative motion. Additionally, variations in sex, body weight, and tissue compliance could also play an important role in relative motion. Lastly, the sample population was produced from a larger pool of active duty military Service members and may not be representative of the general population.

Future Applications

These findings also have potential implications for devices outside the typical clinical setting. Fracture care in austere environments, such as the wilderness and war zones, requires quick assessment of the fracture site and medical evacuation. However, reaching an evacuation vehicle in these environments can be challenging. In the wilderness, lower extremity injuries often require helicopter evacuation [25] and those evacuations are typically long distances from the injury site. Wilderness adventurers will travel alone or in small groups thereby limiting their ability to carry the injured to an evacuation site. In war zones, Service members (SMs) with fractures are transported on a litter to an evacuation vehicle. However, during future conflicts with near-peer adversaries, medical evacuation will likely be delayed due to contested air space and disrupted communications [26]. Teams of SMs will need to remain mobile for survival but carrying casualties on a litter (especially over long distances) is exhausting for the unit and negatively affects their ability to remain effective in the battlespace. Thus, determining how to off-load lower leg fractures so that the injured can self-evacuate will be useful in the austere environments typical of wilderness and war zones.

CONCLUSION

These findings suggest that thigh corset tightness can be varied and still effectively off-load the lower leg, and the ischial and patellar tendon slings were equally effective at off-loading the lower leg and minimized relative motion between user and device when used with a tightened thigh corset. Because of these similarities, other benefits from these interfaces should be considered. The use of the patellar tendon sling provides the user with greater foot clearance to the ground but increases their sagittal profile, potentially compromising their fracture if they hit their leg on objects in the environment. The use of the ischial sling provides the user with less foot clearance from the ground but decreases their sagittal profile, potentially increasing their maneuverability through narrow spaces in the environment. The ischial sling could also accommodate more lower leg injuries than the patellar tendon sling could. These findings can guide the development of future fracture orthoses both for the clinic and in emergency situations.

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