After lower-extremity orthopedic trauma and surgery, patients are often advised to restrict weight bearing on the affected limb. Conventional training methods are not effective at enabling patients to comply with recommendations for partial weight bearing. The current study assessed a novel method of using real-time haptic (vibratory/vibrotactile) biofeedback to improve compliance with instructions for partial weight bearing. Thirty healthy, asymptomatic participants were randomized into 1 of 3 groups: verbal instruction, bathroom scale training, and haptic biofeedback. Participants were instructed to restrict lower-extremity weight bearing in a walking boot with crutches to 25 lb, with an acceptable range of 15 to 35 lb. A custom weight bearing sensor and biofeedback system was attached to all participants, but only those in the haptic biofeedback group were given a vibrotactile signal if they exceeded the acceptable range. Weight bearing in all groups was measured with a separate validated commercial system. The verbal instruction group bore an average of 60.3±30.5 lb (mean±standard deviation). The bathroom scale group averaged 43.8±17.2 lb, whereas the haptic biofeedback group averaged 22.4±9.1 lb (P<.05). As a percentage of body weight, the verbal instruction group averaged 40.2±19.3%, the bathroom scale group averaged 32.5±16.9%, and the haptic biofeedback group averaged 14.5±6.3% (P<.05). In this initial evaluation of the use of haptic biofeedback to improve compliance with lower-extremity partial weight bearing, haptic biofeedback was superior to conventional physical therapy methods. Further studies in patients with clinical orthopedic trauma are warranted.

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After lower-extremity orthopedic trauma and surgery, patients are often recommended to restrict weight bearing on the affected limb. This restriction protects the injury site or surgical construct from excess stresses that may lead to failure while ensuring a minimal amount of weight bearing to stimulate osteoblastic activity and fracture healing.\textsuperscript{1,2} Therefore, common instructions for weight bearing include touchdown weight bearing, partial weight bearing, and weight bearing as tolerated. At the authors’ institution, touchdown weight bearing is the most commonly prescribed weight bearing restriction after lower-extremity trauma, and it is defined as a target of 25 lb.

The ability of patients to comply with these weight bearing instructions has been questioned.\textsuperscript{3-5} At the authors’ inpatient medical center, patients typically begin working with physical therapists on the first day after surgery or injury and continue until discharge. Patients are usually given only verbal instructions by the therapist as they learn how to restrict weight bearing. Occasionally, conventional spring-loaded bathroom scales are used as an adjunct to training. Bathroom scale training has been shown to be superior to verbal instruction; however, it is still suboptimal.\textsuperscript{6-9}

Given the ubiquity of prescribing partial weight bearing restrictions and the lack of effective methods of training and maintaining compliance, biofeedback devices have been developed to measure weight bearing status and deliver feedback in real time.\textsuperscript{5} Such biofeedback systems using auditory feedback for patients have been shown to be superior to verbal instruction and bathroom scale training for teaching partial weight bearing.\textsuperscript{10,11} The SmartStep system (Andante Medical Devices Inc, White Plains, New York) was used in this study. Despite its effectiveness, however, the complexity, auditory intrusiveness, and cost of the system prevent it from becoming a viable take-home rehabilitation aid. Because most recovery time that includes limited weight bearing is spent away from hospital and rehabilitation services, an easy-to-use, non-intrusive, and affordable biofeedback system may be valuable for teaching and maintaining compliance with partial weight bearing restrictions.

Although auditory feedback has been shown to function well in controlled research settings, there are concerns about intrusiveness and privacy with its use as a take-home device that patients would wear in public. Other feedback modalities, such as vibrotactile or haptic biofeedback, have shown promise in lower-extremity gait and prosthesis training\textsuperscript{12,13} and may be better suited to weight bearing applications. To the authors’ knowledge, this has not been previously studied. The goals of the study were to develop a simple weight bearing sensor and haptic biofeedback system and to determine its ability to improve compliance with restrictions on lower-extremity weight bearing.

**MATERIALS AND METHODS**

**Haptic Biofeedback System**

A biofeedback system was designed and developed with 3 main components: a force sensing plate, a haptic biofeedback belt, and a processing unit. After various sensor designs were considered, the final prototype sensing unit consisted of a steel plate with a custom 3-dimensional printed plastic enclosure with 4 force sensors. The force sensing unit was installed in a modified walking boot to ensure a standardized weight bearing surface across all study participants (Figure 1). The accuracy of the haptic biofeedback system for measuring weight bearing was validated against a calibrated spring-loaded scale, with an average error across 250 consecutive “loads” of 0.55 lb. The processing unit consisted of a microprocessor (Arduino Nano, Arduino, Italy) and software necessary to run the system. It was contained in a custom plastic enclosure that includes a 2.2-in liquid crystal display screen that displays calibration instructions. Depending on the patient’s weight bearing status, the preset weight thresholds, and the biofeedback program installed, the processor computes whether a haptic signal should be delivered. Further, detected weight bearing loads can be exported to a memory card for posttraining analysis. Details of the design and engineering of the processing unit were described elsewhere.\textsuperscript{14}

**Figure 1:** Haptic partial weight bearing biofeedback system, including the walking boot, force sensing plate, processing unit, and haptic feedback belt (A). Research subject using the haptic biofeedback system to ambulate with partial weight bearing (B).
Haptic biofeedback is delivered through 3 vibration motors attached to a custom belt. Multiple feedback modalities can be used, and several were pilot-tested. This study used a pure negative-feedback modality because of its simplicity and ease of understanding.

**Experimental Groups and Power Calculation**

At the authors’ institution, the most commonly used methods for teaching partial weight bearing to patients after orthopedic surgery are verbal instruction and bathroom scale training. To compare the efficacy of haptic biofeedback training with that of current teaching modalities, the study included 3 experimental groups: verbal instruction, bathroom scale training, and haptic biofeedback. Based on previous studies that examined partial weight bearing in healthy participants who were given verbal instruction and bathroom scale training, the authors anticipated a difference in weight bearing of approximately 20 lb, with standard deviation of 10 lb. With an alpha error level of 5% and a statistical power of 90%, a power calculation showed that 6 participants would be needed in each of the 3 experimental groups, for a total of 18 participants.

**Participants**

To account for potential technical difficulties and the possibility of smaller-than-anticipated differences in weight bearing, 30 healthy participants were recruited from the authors’ institution. Each study group included 10 participants, and all participants provided informed consent. Inclusion criteria were overall good health, ability to walk without assistive devices, and sufficient upper-body coordination and strength to perform partial weight bearing with crutches. Exclusion criteria were current restriction on lower-extremity weight bearing and inability to use crutches (eg, upper-extremity weakness, injury, or neuropathy). The study was approved by the human investigation committee at the authors’ institution.

**Measurement of Weight Bearing**

The weight bearing status of the study participants was measured with the commercially available SmartStep, which detects continuous real-time weight bearing status of the forefoot and hindfoot. For this study, weight bearing of the forefoot and weight bearing of the hindfoot were treated as a combined total weight bearing measure. This system consists of an inflatable insole placed inside the participant’s shoe, a measurement device connected to the insole and strapped around the participant’s ankle, and a software program executed from a laptop computer that communicates with the measurement device wirelessly via Bluetooth and collects the weight bearing data. This system has been found to be highly accurate in comparison with a force plate ($R^2 = .907$, $P < .05$) with a standard error of ±0.12 lb.

**Instructions for Partial Weight Bearing and Data Collection**

After participants provided informed consent, each was randomly assigned to the verbal instruction, bathroom scale, or haptic biofeedback training group. The SmartStep system was then attached to the participant, with the inflatable insole placed within the right shoe and calibrated according to the manufacturer’s specifications. Regardless of experimental group assignment, all participants then placed the right lower extremity, with the SmartStep insole inside the right shoe, into the modified walking boot of the biofeedback system for the duration of the study.

All participants were first trained on the proper use of crutches to reduce weight bearing on the right lower extremity to a target of 25 lb while wearing the walking boot and SmartStep system, using a standard 3-point crutch stance. Participants were informed that a weight bearing range of ±10 lb from the target, or 15 to 35 lb, was acceptable.
Participants in the verbal instruction group were instructed to limit weight bearing on the right lower extremity to 25 lb. Those in the bathroom scale group were instructed to place the right lower extremity, with the attached sensors and equipment, on a conventional spring-loaded bathroom scale and to load to 25 lb as many times as necessary until they were confident in their ability to reproduce this level of weight bearing independently. Finally, participants in the haptic biofeedback group were instructed to limit weight bearing on the right lower extremity to 25±10 lb, with an acceptable range of 15 to 35 lb, and told that they would receive a haptic signal on the belt if they exceeded the upper limit of the acceptable range.

Previous studies of partial weight bearing showed that it takes approximately 50 steps for participants to acclimate to the use of crutches to offset lower-extremity weight bearing before equilibrating to a relatively stable weight bearing status. Therefore, participants in all 3 experimental groups were asked to first take 50 practice steps. Their weight bearing over the next 50 steps was then recorded.

**Data Analysis**

For each participant, weight bearing was averaged over the 50 steps taken immediately after the initial 50 practice steps. These mean weight bearing values were then averaged across all participants within each experimental group to determine the overall mean absolute weight bearing for each training modality. Standard deviation and standard error of the mean were calculated. To account for each individual’s body weight, average weight bearing as a percentage of body weight was also calculated. Independent 2-tailed t tests without assuming equal variances were performed between the verbal instruction and haptic biofeedback groups and between the bathroom scale and haptic biofeedback groups.

**Results**

Participants included 30 healthy individuals (16 men, 14 women), 22 to 32 years old (average, 25.8). Participants had an average height of 68.1 in (range, 62-74), average weight of 151.1 lb (range, 106-200), and average body mass index of 22.8 kg/m² (range, 19.1-30.4).

The verbal instruction cohort included 4 men and 6 women, with a mean age of 26.2 years, height of 67.5 in, weight of 152.5 lb, and body mass index of 23.4 kg/m². The bathroom scale group included 5 men and 5 women, with a mean age of 25.4 years, height of 67.8 in, weight of 142.9 lb, and body mass index of 21.6 kg/m². The haptic biofeedback group included 7 men and 3 women, with a mean age of 25.9 years, height of 69.1 in, weight of 158.0 lb, and body mass index of 23.2 kg/m².

In terms of absolute weight bearing, the verbal instruction group bore an average of 60.3±30.5 lb (mean±standard deviation) (Figure 2). The bathroom scale group bore an average of 43.8±17.2 lb, and the haptic biofeedback group bore an average of 22.4±9.1 lb. All 3 groups were instructed with a weight bearing target of 25 lb, with an acceptable range of 15 to 35 lb. The differences between the verbal instruction and haptic biofeedback groups and between the bathroom scale and haptic biofeedback groups were statistically significant (P=.003 and P=.004, respectively).

As a percentage of participants’ body weight, the verbal instruction group averaged 40.2±19.3%, the bathroom scale group averaged 32.5±16.9%, and the haptic biofeedback group averaged 14.5±6.3% (Figure 3). Again, the differences between the verbal instruction and haptic biofeedback groups and between the bathroom scale and haptic biofeedback groups were statistically significant (P=.002 and P=.009, respectively).

**Discussion**

Partial weight bearing is commonly prescribed to patients after lower-extremity orthopedic trauma and surgery. There is some controversy regarding the practice of prescribing limited weight bearing.
bearing, and no prospective randomized clinical trial to date has compared outcomes with and without weight bearing restriction. Nonetheless, prescribing such restrictions is a common and accepted part of regular clinical practice. In support of initiating early weight bearing, studies have shown that controlled physiologic loading is associated with stimulating osteoblastic activity and bony healing.\textsuperscript{5,7,16,17} This is countered by the concern for potential loss of alignment and/or implant failure as a result of excessive weight bearing loads. Some argue that instruction and training in partial weight bearing is not necessary after lower-extremity trauma or surgery because patients self-limit their weight bearing because of pain and gradually increase weight bearing over time.\textsuperscript{18,19} On the other hand, excessive loading is an important concern because patients can exert more than double their body weight on an injured extremity, depending on the crutch walking technique and the acceleration of body mass in different phases of the gait.\textsuperscript{7} These extreme loads may place the surgical fixation and implants at risk for failure. In addition, premature and excessive loads after injury have been shown to impair bone healing.\textsuperscript{20,21}

Overall, based on the available evidence and the noted concerns, restriction of weight bearing remains ubiquitous in clinical practice after injury and surgical intervention. Thus, identifying methods to optimize compliance with such restrictions is of clinical importance. Several studies have shown that weight bearing biofeedback is vastly superior to conventional physical therapy methods, such as verbal instruction, weight bearing on the therapist’s hand, and bathroom scale training.\textsuperscript{9,11,15} Haptic, or tactile, biofeedback is an intuitive and potentially powerful feedback modality that has not been explored for partial weight bearing applications.

In this initial study of the efficacy of haptic biofeedback compared with verbal instruction and bathroom scale training in improving compliance with partial weight bearing orders, haptic biofeedback was markedly better at helping participants to comply with a defined weight bearing restriction. This improvement was significant in terms of both absolute weight bearing and weight bearing as a percentage of body weight. The improvement in compliance with recommendations for weight bearing seen in this study was accomplished with a simple weight bearing sensor and haptic biofeedback system that was substantially simpler and less expensive than commercially available devices used in many previous studies. For example, the SmartStep system, which was used as a measurement device in the current study and as an auditory feedback delivery system in others,\textsuperscript{9,10,15} costs approximately $7000.\textsuperscript{5} In comparison, the haptic biofeedback system used in this study was created at a cost of less than $200. Because weight bearing restrictions are typically prescribed for several weeks postoperatively, there seems to be a potential role for a simple, inexpensive biofeedback system that may be viable as a take-home rehabilitation aid.

Although most studies examining the use of biofeedback for partial weight bearing training have used auditory biofeedback, given the intended purpose of the authors’ system as a long-term take-home rehabilitation aid, it was decided that haptic biofeedback would be less intrusive and more intuitive. This initial study used a simple negative feedback scheme. Participants were alerted with a haptic signal when their weight bearing exceeded the upper limit of the acceptable range. Although this was suitable for an initial study and was easy for participants to understand, other novel feedback modalities are also possible. For example, because some degree of weight bearing is desired to stimulate osteoblastic activity and fracture healing, a mixed positive-negative feedback modality is programmable in the system. A low-intensity, gentle haptic signal could indicate that the participant is in the desired weight bearing range and should not increase weight bearing further, whereas a high-intensity haptic signal could be triggered once the participant exceeds the upper limit.

In addition to these permutations in feedback schemes, the location of feedback may warrant further investigation. In this study, the haptic signal was delivered through a belt for ease of use and access to the processor module. However, there is evidence that, in addition to physical coordination and experience with using crutches, proprioception may play a role in how participants learn to restrict weight bearing.\textsuperscript{8} Therefore, delivering tactile feedback through the injured extremity may be synergistic with the participants’ own proprioceptive inputs and enhance the efficacy of biofeedback for partial weight bearing. This study had several important limitations. First, the participants were healthy and asymptomatic, and their weight bearing abilities may not be representative of those of clinical patients with lower-extremity injuries. However, healthy volunteers were specifically chosen because the effectiveness of haptic biofeedback for teaching partial weight bearing has not been previously described and the authors wished to validate the use of this feedback modality before examining its efficacy in postoperative patients. A study by Dabke et al\textsuperscript{7} compared healthy participants and postoperative patients and showed that both groups had similar responses to biofeedback training.

An additional limitation of this study was that the retention of partial weight bearing biofeedback training over time was not measured. The results of research on retention are mixed, with some showing that compliance with weight bearing restrictions is not retained past 24 hours\textsuperscript{4,22} and others showing good retention at 1 hour and up to 24 hours after an initial training session.\textsuperscript{5,10} Nevertheless, in the context of recovering from a lower-extremity fracture and the healing period of at least several weeks, even good retention for up to 24 hours is insufficient.
Therefore, the authors’ goal was to develop a system that could be sent home with postoperative patients and that could deliver feedback and record weight bearing status over a period of weeks.

**CONCLUSION**

Although the clinical benefit of restricting weight bearing after lower-extremity orthopedic trauma and fixation has not been completely elucidated, postoperative compliance with weight bearing is broadly believed to have an effect on bony healing and recovery. As such, partial weight bearing is commonly prescribed for postoperative patients. Although compliance is relatively poor with conventional physical therapy teaching methods, haptic biofeedback as part of a long-term postoperative rehabilitation training system may be an effective method of maintaining partial weight bearing.

**REFERENCES**


