Lower-extremity Weight-bearing Compliance Is Maintained Over Time After Biofeedback Training

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Abstract

Previous studies have shown immediate compliance with weight-bearing instructions to be better after biofeedback training than after verbal or scale training. This study assessed retention of biofeedback training to determine potential clinical applicability.

Twelve participants were enrolled in a prospective clinical study at an academic orthopedic center. Participants were trained with a biofeedback device to comply with touch-down weight-bearing instructions (25 lb). Immediately following the training session, weight bearing was assessed for each participant. The retention of this training was then reassessed at 2 to 4, 6 to 8, and 22 to 24 hours. Two control participants were given no biofeedback training (verbal instructions only) and were followed similarly. Following initial biofeedback training at 25 lb, participants bore an average of 20.4 ± 2.12 lb. Retention tests during the 24-hour period showed no significant difference from the original testing, with 2- to 4-hour retention of 19.98 ± 4.75 lb, 6- to 8-hour retention of 25.07 ± 6.60 lb, and 22- to 24-hour retention of 21.75 ± 4.58 lb. Participants who only received verbal instructions consistently bore several-fold greater weight than instructed.

Biofeedback training has previously been shown to have a strong immediate effect on partial weight-bearing compliance. This study demonstrated that this effect lasts up to 24 hours. This maintained weight-bearing compliance after biofeedback training suggests that this method may be an effective way to train patients to comply with given instructions for limited weight bearing.

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Orthopedic patients are often instructed on how much weight to bear through an injured or post-operative extremity. Common instructions are for touchdown weight bearing, partial weight bearing (often prescribed in number of pounds), or weight bearing as tolerated. While specific weight-bearing instructions are given to the majority of lower-extremity orthopedic patients, the ability of patients to comply with these instructions is poor.1,2

The rationale for restricting weight bearing is to limit the load seen by an injured or operative site.3 Potentially, a single load or repetitive loading above a tolerance point could lead to deformation or loss of the alignment or fixation of a surgical construct.4 Conversely, the rationale for advancing weight bearing is that loads can stimulate osteoblastic activity in certain fracture patterns and fixation constructs.5 Thus, a common recommendation for an affected extremity is for restricted weight bearing that is gradually liberalized as healing occurs.

Patients have traditionally been trained to apply defined loads to an affected extremity via verbal or bathroom scale instruction. Recently, biofeedback devices, or devices capable of making real-time physiologic measurements and providing immediate user feedback, have been developed to facilitate such training with better immediate compliance for given weight-bearing scenarios.6-11 However, to the current authors’ knowledge, no studies have evaluated the retention of such biofeedback training.

The current study was designed to examine the retention effect of biofeedback training by following participants over a 24-hour period. The hypothesis was that participants would initially comply with limited weight-bearing instructions but over time would forget the training and place increasing amounts of weight on the weight-restricted extremity.

**Materials and Methods**

**Participants**

Twelve healthy participants (7 men and 5 women) aged 22 to 29 years (average, 24.9 years) gave informed consent to participate in this study. All participants were recruited from within the authors’ institution. The participants had an average weight of 154.8 lb (range, 115-205 lb), an average height of 67.8 in (range, 62-76 in), and an average body mass index of 22.6 kg/m² (range, 19.4-28.9 kg/m²).

Inclusion criteria were 20 to 30 years of age, overall good health, the ability to walk while bearing total body weight on either lower extremity, and sufficient upper-body strength and coordination to use crutches. Exclusion criteria were any restriction to full weight bearing on the lower extremities and any reason to be unable to use crutches to offset lower-extremity weight (eg, upper-extremity injury, weakness, or neuropathy).

The Human Investigative Committee of the authors’ institution approved the study.

**Selection of Experimental and Control Groups**

Participants were assigned to the experimental group or the control group. Ten participants (5 men and 5 women) were assigned to the experimental group and underwent the experimental intervention described below.

Two participants (2 men) were assigned to the control group. Control group participants were selected to assess the possible confounding factor that, even without biofeedback training, participants would decrease weight bearing over time as they became increasing comfortable walking with the use of crutches.

Both groups received a formal tutorial and practice session on the proper use of crutches prior to beginning the study.

**Weight-bearing Monitoring**

Weight bearing was monitored with a mobile SmartStep device (Andante Medical Devices, Inc, White Plains, New York) that offers continuous weight-bearing monitoring of the forefoot and hindfoot (these were treated as a combined total weight-bearing measure for the purpose of this study).

The device consists of 3 components: (1) a 5-mm-thick air-inflated insole worn in the participant’s shoe, (2) a measurement device strapped to the participant’s ankle and connected to the air-inflated insole (Figure 1), and (3) a software program that allows for continuous Bluetooth (Belkin, Playa Vista, California) communication between the measurement device and a laptop computer. Previous studies have found this system to be highly accurate compared with a force plate (P<.05; R²=0.907), with a standard error of ±0.116 lb.10

Participants were asked to walk with crutches for 50 consecutive steps for each measurement. A 50-step increment has been shown to offer a representative sample of a participant’s average weight bearing.6 All participants used a 3-point crutch stance to limit weight borne over the right extremity.

**Biofeedback Weight-bearing Instruction**

Biofeedback training used an internal function from the gait monitoring system. In addition to measuring ground reaction forces, the device can be configured to offer auditory feedback to the participant. The system provides 2 types of audio feedback—a lower-limit alarm (single beep) and an upper-limit alarm (triple beep)—to help train patients to comply.

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**Figure 1:** Photograph of the SmartStep weight-monitoring device (Andante Medical Devices, Inc, White Plains, New York).
with a specified range of weight bearing. This feature can be turned on and off, and in this study, auditory feedback was only used during the biofeedback training sessions. During all other times, the device was configured only to measure ground reaction forces.

**Experimental Group Data Collection**

At the beginning of the 24-hour study period, participants were instructed with the use of the biofeedback mechanism of the SmartStep device. Participants were instructed to follow touchdown weight bearing, defined as 25 lb. To train participants to comply with the 25-lb weight range, a lower limit of 15 lb and an upper limit of 35 lb were used on the biofeedback device. These weight ranges were selected because previous studies have shown a lag time in responding to biofeedback. Therefore, optimal training is achieved when a weight limitation signal is set just below the desired weight-bearing goal.

Participants were asked to walk with the use of biofeedback until they felt comfortable with the weight-bearing instructions; on average, this was 2 to 5 minutes. Immediately following, the biofeedback was turned off and the participants were assessed for 50 consecutive steps to obtain the baseline learning effect of biofeedback training. This initial assessment was called biofeedback at 0 hours.

Throughout the study, participants were asked to limit their weight bearing to 25 lb with the use of crutches. During this time, study personnel intermittently met the participants to assess the retention or deterioration of the initial biofeedback. At each time point, participants were monitored for 50 consecutive steps with the use of crutches. The SmartStep device was used to measure ground reaction forces only (no additional biofeedback training was given). Retention assessments occurred at 2 to 4 hours, 6 to 8 hours, and 22 to 24 hours after initial biofeedback training.

**Data Analysis**

For each time point, the first 5 steps and the last 5 steps for each participant were omitted, leaving 40 steps to be used to determine each participant’s average weight bearing. Friedman’s analysis of variance for nonparametric data was used to determine statistical difference between time points for all participants. A P value of .05 indicated significance.

Because the purpose of the study was to estimate the population mean based on the use of the sample means collected, standard error calculations were used throughout the study. Data analysis was conducted using SPSS version 18.0 statistical software (SPSS, Inc, Chicago, Illinois).

**RESULTS**

**24-hour Retention of Biofeedback Training**

Ten participants (5 men and 5 women) completed training and all assessment sessions. Following initial biofeedback training, participants bore an average of 20.4±2.1 lb. Participants showed retention of 20.0±4.8 lb at 2 to 4 hours, 25.1±6.6 lb at 6 to 8 hours, and 21.8±4.6 lb at 22 to 24 hours. Weight bearing did not significantly change over the 24-hour period (chi-square test=2.81; P=.590).

Figure 2 presents the study findings. The graph includes reference values from the authors’ previous work comparing verbal instructions with scale training (2 of the most commonly used clinical training methods) in age-matched participants with those currently being studied.

**Control Participants**

In addition to the study population, 2 male participants completed assessments for the control group. The results are included in Figure 2. Control participants received identical formal training and practice on the use of crutches as the experimental group. However, control participants received no biofeedback training. Control participants were asked to limit their weight bearing to 25 lb with verbal instructions and were followed in an identical manner to the experimental group. Both control participants bore severalfold greater weight than the target weight and showed high variability in their weight bearing, suggesting difficulty following weight-bearing instructions without training. Control participant 1 started with an average weight bearing of 89.9 lb and finished with an average of 43.3 lb; control participant 2 started with an average weight bearing of 65.6 lb and finished with an average of 80.0 lb.

**DISCUSSION**

Specific weight-bearing instructions are commonly prescribed for many injured or postoperative orthopedic patients. However, most researchers believe that
a majority of patients do not adequately comply with instructions for limited weight bearing on the lower extremities.1,2,9 In previous studies, the current authors reported that without training, participants greatly exceeded given weight-bearing instructions but that following biofeedback training compliance improved.6,7 Although these results were promising, they were limited by no long-term follow-up of the retention of the training.6,7 However, the current study highlights that biofeedback training is maintained at least up to 24 hours.

Partial weight-bearing instructions are essential for many lower-extremity fracture patterns, yet the majority of patients greatly exceed these instructions if not given proper training. Hershkó et al8 reported that without training, patients with lower-limb fractures exceeded given weight-bearing restrictions up to 2.5-fold above those given biofeedback training. Hustedt et al6,7 reported that asymptomatic individuals exceeded weight-bearing restrictions up to 3-fold when given standard verbal physical therapy instructions. Therefore, it is imperative to find effective long-term training methods for patients.

Some researchers and clinicians have reported that partial weight-bearing limitations are not necessary because patients will self-limit their weight bearing due to postoperative pain. Koval et al12 reported that patients self-limited weight bearing following femoral neck and intertrochanteric fractures and gradually liberalized weight bearing over 6 weeks. Although this is true in hip fractures, the same evidence has not been found in lower-extremity fracture patterns of the tibia, fibula, and foot. The standard of care is to limit weight bearing in lower-extremity fracture patterns.13

Even with the widespread understanding of the necessity of partial weight-bearing limitations, little congruency exists between institutions. The current authors chose to examine a 25-lb weight limitation because this is the definition of touchdown weight bearing used by the traumatologists and physical therapists at their institution. The definition of touchdown weight bearing differs widely, but the overall goal of this study was to show an ability to train to a specific weight that can be defined by the necessity of the clinician.

The success of biofeedback training has been shown to be superior to verbal and bathroom scale training.5,7 However, its long-term efficacy is still in question. Hershkó et al8 reported that patients with lower-extremity fractures who were trained with biofeedback were superior to those trained with physiotherapy and that the training effect lasted up to 10 days. However, Pataky et al1 reported that although initial training with biofeedback was successful in patients following total hip arthroplasty, the effect was lost after 1 day.

The difficulty in interpreting the varying results stems from the rapid implementation of biofeedback into many different study populations with differing fracture patterns. This rapid implantation without proper preliminary evaluation has left the field with little understanding and shallow ground for future research. The current authors found it necessary to perform this study with asymptomatic individuals to first identify the effectiveness of biofeedback prior to subjecting the potential beneficial findings to confounding factors of varying fracture patterns. The findings of this study lay the groundwork for future studies in defined fracture pattern populations.

The study had some limitations. An important confounding factor that the authors attempted to control for was a changing perception of weight bearing over time. It was conceivable that because none of the participants had previously used crutches or received weight-bearing training, they would decrease their weight bearing over time simply due to comfort with the use of crutches. To control for this, 2 matched control participants were enrolled in the study. These control participants varied significantly in each weight-bearing session and bore several-fold greater weight than had been requested, suggesting that without training it is difficult to gain an understanding of lower-extremity weight-bearing. These findings further highlight the need for proper training of patients given lower-extremity partial weight-bearing instructions.

Other limitations to the study include that only asymptomatic healthy participants were assessed and that it was only feasible to measure weight bearing for a 24-hour period. To participate in the study, participants were asked to limit their weight bearing for the full 24-hour period. This greatly reduced their overall capacity, and although they were remunerated for their efforts, it was only feasible to carry out the trial for 24 hours. However, even with the study’s time limit, the results are important because this is one of the first studies to suggest a long-term retention effect in an asymptomatic population. Without such preliminary studies, a clinical trial of longer duration would not be prudent.

CONCLUSION

This study suggests that biofeedback is an effective way to train patients to comply with partial weight-bearing instructions and that this is retained over an initial monitoring period. Because prescribing specific instructions is a routine part of orthopedic practice and defining and controlling this compliance variable is clinically important, biofeedback may be an appropriate avenue to pursue for such training.

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