Orthopedic patients are often instructed on how much weight to bear on an injured or postoperative extremity. Although specific weight-bearing instructions are given to a majority of lower-extremity orthopedic patients, the ability of patients to comply with these instructions is questioned in the medical literature. This study compared the effectiveness of new forms of clinical interventions designed to train patients on weight bearing, focusing on the use of biofeedback devices designed to offer real-time feedback to partial weight-bearing patients. Twenty healthy patients aged 20 to 30 years completed 3 interventions: (1) verbal instructions on weight bearing, (2) training with a bathroom scale, and (3) training with a biofeedback device.

Patients given touchdown weight-bearing instructions (25 lb) initially bore an average of 63.57 ± 6.24 lb when given verbal instructions. This was reduced to 44.75 ± 5.69 lb after training with a bathroom scale (P < .001), and was further reduced to 26.2 ± 1.57 lb with biofeedback training (P = .011). Likewise, patients given partial weight-bearing instructions (75 lb) initially bore an average of 92.28 ± 7.85 lb. No improvement occurred with the use of a bathroom scale (at 75 lb), which showed an average of 90.82 ± 7.19 lb (P = 1.000). Training with a biofeedback device improved the average weight bearing to 69.67 ± 3.18 lb (P = .014).

Biofeedback training led to superior compliance with touchdown and partial weight-bearing instructions. Because partial weight-bearing instructions are commonly given to orthopedic patients, training with such a device may be appropriately considered.
Orthopedic patients are often instructed on how much weight to bear on an injured or postoperative extremity. Common instructions are for touchdown weight bearing, partial weight bearing (often prescribed in number of pounds), or weight bearing as tolerated. Although specific weight-bearing instructions are given to a majority of lower-extremity orthopedic patients, the ability of patients to comply with these instructions is questioned in the medical literature.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/fixation of a surgical construct. Conversely, the rationale for advancing weight bearing is that loads can stimulate osteoblastic activity in certain fracture patterns and fixation constructs.4 Thus, a common recommendation for an affected extremity is for restricted weight bearing that is gradually liberalized as healing occurs.

Patients are most often given verbal weight-bearing instructions from their orthopedist. However, physical therapists are usually responsible for monitoring and training patients to comply with their weight-bearing prescription. Physical therapists most often use bathroom scales to train patients on weight bearing; however, the effectiveness of bathroom scales has been contested in the medical literature.5-8 Biofeedback devices have been developed that are capable of offering patients immediate feedback during weight-bearing activities. Initial studies have suggested these devices may be an effective way to train patients to comply with weight-bearing instructions.9,10

This study evaluates the effectiveness of biofeedback training by using an insole device (SmartStep; Andante Medical Devices, Ltd, Omer, Israel) in direct comparison with verbal instruction and training with a bathroom scale. The primary research question is whether the subjectivity of weight-bearing training allowed by verbal instruction and bathroom scale training may be eliminated by the use of biofeedback training, allowing for greater patient compliance with weight-bearing instructions. The purpose of this study was to determine the relative effectiveness of different modes of weight-bearing training that might be implemented in clinical practice.

Materials and Methods

Patients
Twenty healthy patients (10 men, 10 women) aged 20 to 30 years gave informed consent to participate in this study. All patients were recruited from within our institution. The patients had an average age of 26.15 years (range, 21-30 years), average weight of 157.4 lb (range, 124-205 lb), average height of 69.2 in (range, 63-75 in), and average body mass index (BMI) of 23.2 kg/m² (range, 19.8-27.5 kg/m²).

Inclusion criteria included age between 20 and 30 years, overall good health, ability to walk while bearing total body weight on either lower extremity, and sufficient upper-body strength and coordination to use crutches. Exclusion criteria included 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). All patients were considered to be healthy and without restriction for weight bearing.

Our institution’s Human Investigative Committee approved this study.

Monitoring Weight Bearing

Weight bearing was monitored with a mobile SmartStep device 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 patient’s shoe, (2) a measurement device strapped to the patient’s ankle that is connected to the air-inflated insole (Figure 1), and (3) a software program that allows for continuous communication between the measurement device and a laptop computer. Previous studies have found this system to be highly accurate as compared with a force plate (P<.05; R²=0.907), with a standard error of ±0.116 lb.11

Weight-bearing Goals

The purpose of this study was to measure compliance with specific weight-bearing instructions. However, no universally accepted increments of weight bearing exist for patients requiring partial weight-bearing status. As previously noted, the most common instructions are for touchdown weight bearing, partial weight bearing, and weight bearing as tolerated.

For the purpose of this study, touchdown weight bearing was defined as 25 lb, and partial weight bearing was defined as 75 lb. Although alternative numbers could have been chosen for these groups, these definitions afforded specific goals that could be studied and sufficient spread between the goal weights to create distinct study groups.

Weight-bearing Instruction Methods

Three different methods of weight-bearing instruction were used in this
study: verbal instruction, bathroom scale training, and biofeedback training. Each method was administered in a standardized fashion.

Verbal instruction consisted of simple description of different weight-bearing goals. This is the most common level of intervention provided directly by an orthopedist.

Bathroom scale training used a spring-loaded bathroom scale. Patients were instructed to place a crutch on either side of the scale and practice transferring weight on and off the scale to a given weight restriction of 25 or 75 lb. This is the most common type of training provided by staff and physical therapists at most institutions.

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 patient. 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 with a specified range of weight bearing. This feature can be turned on and off, and in the current study, the auditory feedback was only used during the biofeedback training session. During all other times, the device was configured only to measure ground reaction forces.

**Training Patients to Use Crutches**

To determine the adequate number of steps to monitor to determine the average weight bearing for a patient, 3 patients were asked to walk with crutches for 10 minutes at a weight-bearing goal of 50 lb. Data analysis showed that after an initial acclimation period to the crutches, all patients settled into their weight-bearing average after 40 to 50 steps. Figure 2 shows the weight bearing of 2 representative patients asked to walk for 10 minutes at 50 lb. The study was repeated in 8 additional patients for 3 minutes, and the same initial period of variability followed by a steady statistical average was again noted. Based on these early studies, an initial warm-up period of a minimum of 50 steps was instituted for each patient. Thereafter, 50 consecutive steps were measured for each activity as a representative sample of a patient’s weight bearing.

**Data Collection**

Patients were first instructed on the use of crutches by a member of the research staff. Patients were taught a 3-point crutch stance to offset weight from their right lower extremity (a single extremity was chosen for consistency). Patients were asked to practice walking with the crutches for a minimum of 50 steps and were continually instructed until they felt comfortable.

Testing began with verbal instructions (no training). Patients were asked to walk with crutches at weight-bearing instructions of 25 and 75 lb. The order in which the weight limitations were given was randomized for each patient. Throughout the study, patients took short breaks between each activity to ensure they were not fatigued.

Next, patients were instructed on the use of a bathroom scale as described above. Patients practiced with the use of the scale, and then immediately walked without the scale for 50 consecutive steps. The order in which the patients performed the 25- and 75-lb weight-bearing instructions was randomized.

Finally, patients were instructed with the use of the biofeedback mechanism of the SmartStep device. For the 25-lb weight range, a lower limit of 15 lb and an upper limit of 35 lb were used. For the 75-lb weight range, a lower limit of 65 lb and an upper limit of 85 lb were used. These weight ranges were used 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. Patients were asked to walk with the use of biofeedback until they felt comfortable with the weight-bearing instructions; on average this was 1 to 2 minutes. Immediately thereafter, the biofeedback was turned off and the patients were assessed for 50 consecutive steps. The process was repeated for the other weight-bearing limit. The order in which the 25- and 75-lb weight limits were performed was randomized for each patient.

**Data Analysis**

For each activity, the first and last 5 steps for each patient were omitted, leaving 40 steps to determine each patient’s average on
each activity. A repeated-measures analysis of variance (ANOVA) with post hoc paired $t$ testing with Bonferroni adjustment ($P < .01$) was used to compare the means of the verbal instructions, the bathroom scale training, and the biofeedback training for the 25- and 75-lb weight-bearing instructions for all 20 patients. The level used for significance was .05. A mixed model statistical design was used to determine statistically significant predictors of a patient’s weight bearing. The model included the patient’s BMI, weight, and sex, as well as the type of instruction given (25 vs 75 lb) and the activity type (verbal instructions, scale training, or biofeedback training). The level used for significance was .05. 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 the SAS 9.2 software package (SAS Institute Inc, Cary, North Carolina).

RESULTS
Comparing Training Types

All 20 patients completed each activity (verbal instructions, scale training, and biofeedback training) at 25 and 75 lb. Averages for each activity are presented for the 25 lb goal and 75 lb goal in Figures 3 and 4, respectively. Figures 3 and 4 show the average weight bearing for patients asked to bear 25 lb. When given verbal instructions, patients on average placed $63.57 \pm 6.24$ lb on their extremity, far exceeding the given instructions of 25 lb. After training with a bathroom scale, the average weight bearing dropped to $44.75 \pm 5.69$ lb, and after biofeedback training, the average was $26.75 \pm 1.57$ lb.

At 25 lb, training with a bathroom scale and biofeedback device showed improvements over verbal instructions alone ($P < .001$ for both comparisons). In addition, biofeedback offered an additional improvement over training with a bathroom scale ($P = .011$).

Figure 4 shows the average weight bearing for patients asked to bear 75 lb. When given verbal instructions, patients on average placed $92.28 \pm 7.85$ lb on their extremity, exceeding the given instructions of 75 lb. After training with a bathroom scale, the average weight bearing was $90.82 \pm 7.19$ lb, and after biofeedback training, the average was $69.68 \pm 3.18$ lb.

At 75 lb, only training with a biofeedback device offered improvements over verbal instructions alone. No statistically significant difference existed between verbal instructions and training with a bathroom scale ($P = 1.000$). However, training with a biofeedback device offered a statistically significant improvement over both verbal instructions ($P = .027$) and scale training ($P = .014$).

Difference by Weight Instruction

We compared patient compliance with the given weight-bearing instructions at 25 vs 75 lb. This was accomplished by calculating the difference between the patient’s weight bearing and the given weight-bearing instructions. The average difference from the given instructions for 25 and 75 lb is plotted in Figure 5. Standard error bars represent the variation within the population. Statistical analysis of the differences between 25-lb instructions and 75-lb instructions revealed that a significant difference existed only for the verbal instructions ($P = .0002$), but not for scale ($P = .418$) or biofeedback training.
Therefore, when verbal instructions are given, patients are much more likely to exceed weight-bearing instructions of 25 lb than instructions of 75 lb.

**Inter-patient Variability**

The study data have to this point been presented in aggregate for all 20 patients. Although the cumulative data are useful in establishing clinical effectiveness, presenting data in this way masks inter-patient variability. Variability among patients is important to keep in mind because training works differently for each patient and each type of training. Figure 6 shows a scatter plot with all 20 patients’ performance on each activity and with each instruction. A high variability of patient weight bearing exists under verbal commands and after scale training, but becomes much less after biofeedback training. No training methodology will be perfect for all patients, but biofeedback seemed to be much better at training all patients than either verbal commands or scale training.

**Statistical Modeling of Factors Affecting Weight Bearing**

To better understand factors that affect a patient’s weight bearing, we created a mixed-model statistical analysis to identify statistically significant predictors of weight bearing. Our model included patient BMI, weight, and sex, as well as the type of instruction given (25 vs 75 lb) and the activity type (verbal instructions, scale training, or biofeedback training).

The patient’s weight was found to be the only statistically significant patient characteristic ($P = .031$) affecting weight bearing (with heavier individuals placing more weight on the extremity), whereas BMI ($P = .131$) and patient sex ($P = .236$) were not found to be significant. In addition, the type of instruction (25 vs 75 lb) ($P = .005$) and the activity type (verbal instructions, scale training, or biofeedback training) ($P = .001$) were statistically significant predictors of patient weight bearing, as previously discussed.

**Comparing Specific Poundage Instructions to Body Weight Percentage**

While designing our study, we encountered the ambiguity of giving weight-bearing instructions in specific poundage (eg, 25 lb, 75 lb) vs using body weight percentages (eg, 25%, 50%). We ultimately chose to give weight-bearing instructions in specific poundage because this was the common practice of the orthopedic trauma unit at our institution. However, we understand that many other groups use body weight percentage.

To give our findings greater comparative ability to other studies, we converted our findings into body weight percentages. The average body weight of the patients in our study was 157.4 ± 5.01 lb. We defined touchdown weight bearing as 25 lb and partial weight bearing as 75 lb. If the average patient weight is used, these instructions can be converted to touchdown weight bearing defined as 16% and partial weight bearing defined as 48%. A recent study defined touchdown weight
bearing as 0% to 20% of body weight and partial weight bearing as 21% to 50% of body weight.9 Our findings fall within these given limitations.

Figure 7 shows a conversion to average body weight percentile for each instruction and each activity. At 25-lb instruction, patients bore 39% of body weight under verbal instructions, 28% after scale training, and 17% after biofeedback training. Likewise, at 75-lb instructions, patients bore 57% of body weight under verbal instructions, 57% after scale training, and 45% after biofeedback training.

DISCUSSION

Specific weight-bearing instructions are commonly prescribed for many injured or postoperative orthopedic patients. However, the effectiveness of such recommendations is highly questioned in the medical literature. Most researchers believe that a majority of patients do not adequately comply with instructions for limited weight bearing on the lower extremities.1,2,10 Furthermore, researchers question the effectiveness of the use of bathroom scales (currently the most widely used training method) to train patients to comply with such weight-bearing instructions.5-7

Our data show that it is possible to train young, healthy patients to comply with instructions for limited weight bearing to the lower extremities. In evaluating different types of instruction/training, biofeedback training was superior to verbal instruction or the use of a bathroom scale. With verbal instruction alone, patients were much less likely to comply with touchdown weight-bearing instructions (25 lb) than partial weight-bearing instructions (75 lb); however, this improved with other modes of training.

The strength of this study is its rigorous approach to define the relative effects of different types of training for limited weight bearing to the lower extremities. Even the biofeedback system was only used as a training device and was then turned off for assessments. The concept was that patients could be trained under the supervision of a care provider and that this would increase outpatient compliance.

A limitation of this study is that the compliance of weight bearing over time was not assessed. We chose to examine immediate responses to weight-bearing training to better characterize the use of this novel technology. Research surrounding the effectiveness of biofeedback training has been mixed, with some authors reporting that biofeedback is successful and others reporting that compliance with weight bearing is not attainable.1,2,10 Therefore, we found it pertinent to address the effectiveness of biofeedback in direct comparison with verbal instructions and training with a bathroom scale to settle the research question of the effectiveness of biofeedback prior to assessing its effectiveness over time. We felt that if biofeedback was initially effective, then further studies could then elucidate its effect over time, leading to proper training regimes for optimal outcomes. Furthermore, we chose a repeated-measures design as opposed to a randomized design under the assumption that verbal instructions and bathroom scales have already been shown to be ineffective in weight-bearing training.5,11,14 It can be postulated that as patients are continually trained over time, they increase their knowledge of weight bearing, which biases the results toward biofeedback. However, we attempted to control for this confounding factor by developing an adequate training period prior to weight-bearing assessment, and we pilot tested that training period in our study.

Other limitations of this study are that only asymptomatic young, healthy volunteers were assessed. We chose to assess healthy volunteers as opposed to postoperative patients because the effectiveness of biofeedback has yet to be fully elucidated in the medical literature. Some researchers have shown biofeedback to be effective in certain lower-extremity frac-
ture populations, whereas others have shown biofeedback to be ineffective in other populations. According to our literature search, we found no study showing the effectiveness of biofeedback in a healthy population alone, and therefore felt the need to validate the use of biofeedback prior to introducing the confounding factors associated with postoperative patients. Furthermore, we felt healthy patients would have a similar response to biofeedback as postoperative patients because this was shown in a side-by-side study by Dabke et al.

Our results are important because they define the use of biofeedback devices in a controlled setting with healthy patients. Researchers have shown that biofeedback can be effective in the use of postoperative patients following lower-limb surgery and transtibial amputation patients. However, some researchers report that the effect of biofeedback wanes over time, thereby limiting its effectiveness. Our study shows the effectiveness of biofeedback and suggests that although it may wane over time, there will be a role for biofeedback in orthopedic patients, with options including the constant use of biofeedback over the rehabilitation period or repeated training with biofeedback to acquire the skills of partial weight bearing. Either way, biofeedback offers superior training to both verbal instructions and bathroom scales, and therefore makes it an essential component of partial weight-bearing training.

The importance of compliance with limiting weight bearing to the lower extremity of orthopedic patients can be argued. Nonetheless, prescribing specific instructions is a routine part of orthopedic practice, and defining and controlling this compliance variable is of clinical importance. Biofeedback may be an appropriate avenue to pursue for such training.

REFERENCES