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Effect of Biofeedback Devices in Partial Weight-Bearing Orthopaedic Patients

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degrees of Doctor of Medicine
and Masters of Health Sciences

by

Joshua W Hustedt

2013

This thesis is based on the compilation of the following publications:

1. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Current advances in training orthopaedic patients to comply with partial weight-bearing instructions. *Yale J Biol Med.* 2012;85(1): 119–125.
2. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Is it possible to train patients to limit weight-bearing on a lower extremity? *Orthopedics.* 2012;35(1):31-37.
3. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Effect of age on Partial Weight-bearing Training. *Orthopedics.* 2012;35(7):1061-1067.
4. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Lower Extremity Weight-Bearing Compliance is Maintained Over Time After Biofeedback Training. *Orthopedics.* 2012;35(11):e1644-1648.

Abstract

EFFECT OF BIOFEEDBACK DEVICES IN PARTIAL WEIGHT-BEARING

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Partial weight-bearing (PWB) instructions are commonly given to orthopaedic patients. However, the ability of patients to comply with these instructions is poorly defined. Recent advances in technology have created biofeedback devices capable of offering real-time feedback to patients given PWB instructions. These devices could potentially increase patient compliance with PWB instructions following orthopaedic surgery. This thesis was designed to evaluate the effectiveness of modulating partial weight-bearing using the SmartStep™ biofeedback device.

Fifty asymptomatic subjects aged 21-72 years were given three educational interventions designed to train them to limit weight-bearing on a lower extremity: verbal instructions, training with a bathroom scale, and training with a biofeedback device. Weight-bearing was measured after each activity to determine the effectiveness of biofeedback as compared to other clinical teaching methods. Additionally, another 14 subjects were given biofeedback training and retention was measured over a 24-hour period to assess retention of biofeedback training.

Subjects given only verbal touch down weight-bearing instructions (25lbs) initially bore an average of 61.25 ± 4.80 lbs (average \pm standard error). This was reduced

to 51.50 ± 4.47 lbs after training with a bathroom scale and was further reduced to 30.01 ± 2.33 lbs after biofeedback training.

Likewise, subjects given verbal partial weight-bearing instructions (75lbs) initially bore an average of 89.06 ± 5.58 lbs. There was no improvement with the use of a bathroom scale, with an average of 88.47 ± 4.75 lbs. After training with a biofeedback device, weight-bearing improved to an average of 68.11 ± 2.46 lbs. Mixed model analysis found age was not a significant predictor of subject compliance. However, higher BMI and male gender were predictive of heavier weight-bearing.

Additionally, subjects in the retention study initially bore 20.4 ± 2.12 lbs (average \pm standard error) after biofeedback training. Retention tests during the 24 hour period showed no significant difference from the original testing, with 2-4 hour retention of 19.98 ± 4.75 lbs; 6-8 hour retention of 25.07 ± 6.60 lbs; and 24 hour retention of 21.75 ± 4.58 lbs.

Biofeedback training leads to superior compliance with touch down and partial weight-bearing instructions as compared to verbal instructions or training with a bathroom scale. Compliance was negatively affected by BMI and male gender, but not age. Additionally, biofeedback training shows retention up to 24-hours. As partial weight-bearing instructions are commonly given to orthopaedic patients, training with such a device may be appropriately considered.

Acknowledgments

Dr. Jonathan Grauer must be first and foremost thanked for his mentorship and guidance throughout the project and during my years at Yale medical school. His mentorship was a help in the preparation of these manuscripts, but more importantly his support in applying in orthopedic surgery is one of the main reasons I will become an orthopedist.

I would also like to thank Dr. Michael Baumgaertner, Dr. Michael Leslie and the rest of the Yale Orthopaedic department for their commitment to student research and their guidance in the application process to residency.

Acknowledgment must also be given to the hard work of Mae Geter, Donna Carranzo, and Dr. John Forrest in the Office of Student Research and to the William U. Gardner family for their endowed grant that provided funding for my research year.

Finally, I am so thankful to my family who provided the support and upbringing that allowed me to find my way to Yale med. Graduating from Yale medical school with my wife Madison will no doubt be one of the finest days of my life and I can't wait to share that with my family, my mentors and our friends.

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Introduction

Orthopaedic patients are often instructed on how much weight to bear through an injured or postoperative extremity. Common instructions are for touch-down weight bearing, partial weight bearing (often prescribed in number of pounds), or weight-bearing as tolerated. While specific weight-bearing instructions are given to a majority of lower extremity orthopedic patients, it is often difficult for patients to comply with given instructions.^{1,2} Reasons for patient non-compliance with partial weight-bearing instructions include the difficulty in judging pressure over the lower extremities,³ and the difficulty in adequate training methodologies to ensure patient compliance.^{1,2,4,5}

While there have been studies written about the engineering of weight-bearing devices,⁶ there have been relatively few reviews that address the clinical applications of such devices. This thesis will therefore focus on the clinical application of partial weight-bearing training methodologies by examining the efficacy of currently used training methodologies, identifying clinical factors associated with partial weight-bearing compliance, and highlighting the clinical applications of a newly developed biofeedback device.

Rationale for restricting weight-bearing

Orthopaedic patients are given weight-bearing restrictions in a clinical balancing act between protecting the surgical construct and increasing bone growth at the fracture site. Weight-bearing is restricted based on the fear that excessive weight seen by an injured or operative site will lead to implant failure, therefore affecting the fracture

stability and alignment.⁷ Implant failure can occur when high loads are placed on the extremity causing deformation (plastic failure) or breakage (brittle failure) of the implant. However, by far the greatest risk of implant failure arises from repetitive loading above a tolerance point (fatigue failure).⁸ Therefore, as patients ambulate following surgery partial weight-bearing instructions are given to limit the risk of fatigue failure of the surgical construct.

Conversely, the rationale for advancing weight-bearing is that repetitive loads can stimulate osteoblastic activity in certain fracture patterns and fixation constructs.⁹ Therefore, the difficulty in ambulating an orthopaedic patient with an affected lower extremity is the dual desire to both protect the surgical construct by limiting weight while simultaneously stimulating bone growth by increasing weight-bearing. Thus, a common recommendation for an affected extremity is for restricted weight-bearing that is gradually liberalized as healing occurs.

Common instructions in partial weight-bearing are for touch-down weight-bearing, partial weight-bearing or weight-bearing as tolerated. No common practice is employed to define these three instructions. However, at our institution we employ specific poundage definitions of touch-down weight-bearing defined as 25 lbs and partial weight-bearing defined as 75 lbs.¹⁰ Other researchers have used similar definitions or percentage of patient body weight, with a common distinction of touch-down weight-bearing defined as 0-20% of body weight, and partial weight-bearing defined as 20-50% of body weight.¹¹

Difficulty in defining the clinical use of partial weight-bearing

Two questions remain unanswered in weight-bearing research: 1) what type of weight-bearing limitations yield the best clinical outcomes and 2) how best can patients be trained to comply with weight-bearing instructions.

Researchers and clinicians alike have struggled to define the best weight-bearing strategies to maximize clinical outcomes. To date there are no large, standardized clinical trials of weight-bearing regimes for specific clinical conditions. This is most likely due to the fact that surgical techniques and implants in orthopaedics are always evolving, which secondarily changes the rehabilitation period following surgery. Further, clinical recommendations are generally geared toward the conservative side of ensuring avoidance of catastrophic failures.

Some researchers have argued that weight-bearing limitations are not even necessary in certain clinical scenarios as patients will self-limit their weight-bearing because of pain in the post-operative period.^{12, 13} Koval et al. showed such a case of self-limited weight-bearing in intertrochanteric and femoral neck fracture patients, as did Aranzulla et al. in tibial fracture patients.^{12, 13} This, and similar research, has led to more liberal weight-bearing strategies at certain institutions, however, it is still common practice for clinicians to recommend restricted weight-bearing in many clinical scenarios.

Adding to the difficulty of defining the role of partial weight-bearing in the clinical setting is the overwhelming data that patients have difficulty in complying with given weight-bearing limitations.^{1, 2, 4, 5, 14} Researchers have argued that while patients may have a sense of weight in lifting objects, they do not share that same weight sense of

weight borne over an extremity.³ Therefore, adequate training needs to take place prior to expectation that patients will comply with weight-bearing instructions.

Thus, in order to better determine the proper ambulation of patients following lower extremity injury clinicians need to better educate patients with defined weight-bearing instructions. This will be the focus of the remainder of the manuscript.

Partial Weight-Bearing Training

Training of patients to comply with weight-bearing instructions is commonly done by physical therapists. Physical therapists utilize verbal instruction as well as devices such as scales, biofeedback systems and force plates to train patients to comply with partial weight-bearing instructions. A summary of common procedures and their effectiveness in clinical weight-bearing follows.

Clinical Examination. Physical therapists often use a clinical examination technique in which the amount of weight on the patient's extremity is estimated by placing the physical therapist's hand or foot underneath the foot of the patient. Gray et al. evaluated this technique and found it to be "subjective guesswork at best."¹⁵ Hurkmans et al. showed that on average even well trained physical therapists were up to 20-30% off from the target weight when attempting to train patients with the clinical examination technique.¹⁶ All studies suggest that this technique does not work to adequately train patients,¹ yet it continues to be one of the most widely used techniques due to its easy application.⁶

Scales. The scale technique utilizes scales to offer quantitative feedback to the patient. The patient can load and unload on the scale to a given weight restriction thereby ‘learning’ what it feels like to place a specific poundage on a lower extremity. The difficulty in using this method is that the static activity of standing on the scale does not adequately represent the dynamic activity of walking. Thus, researchers have shown that this technique works when patients are asked to stand only,^{17, 18} yet the technique fails when patients are asked to walk after using bathroom scales.^{4, 5} Chow et al. suggested that one possible method with the use of scales for weight training is to place a row of eight bathroom scales on the floor between parallel bars.¹⁹ Overall, the difficulty in transferring the static measurement of scales to the dynamic activity in walking has limited the use of scales in partial weight-bearing training.

Biofeedback Devices. To surmount the difficulty of providing dynamic feedback biofeedback devices have been developed that can give constant feedback to patients as they are walking. Biofeedback devices have been created for many years,²⁰⁻²⁵ yet these early devices had trouble with accuracy and portability. Bergmann et al. and Engel et al. showed that they were successful in instrumenting walking aids that showed promise in estimating patient weight-bearing,^{26, 27} however these techniques have not become commercially available.

New technological advances have provided commercially available biofeedback systems that are fully portable. The most notable systems are the Pedar (Novelgmbh, Munich, Germany), F-Scan (Tekscan Inc., Boston, MA, USA), and SmartStep (Andante Medical Devices, Beer Sheva, Israel) weight-monitoring systems. Many studies have

been undertaken to compare and validate the commercially available biofeedback systems.²⁸⁻³⁰ A comparative study between the Pedar and F-Scan system showed the superiority of the Pedar system in both validity and reliability.³¹ The SmartStep system has been shown to be accurate in comparison to a force plate.³⁰

Biofeedback systems have been shown to work better than conventional bathroom scales in training patients to comply with weight-bearing limitations.¹⁸ Hershko et al. showed that in comparison to normal physiotherapy, patients instructed with a biofeedback device complied significantly more with their weight-bearing limitations.¹¹ The excitement of the clinical use of these devices has been dampened by the question of the long-term retention of biofeedback training. Pataky et al. and Vasarhelyi et al. found that while patients initially complied with limitations, patients could not retain the training over longer periods of time greater than 24 hours.^{2, 14}

The lack of evidence showing long-term retention of biofeedback in clinical patients has raised questions about the proper implementation of the technology. Most studies have used biofeedback in a limited training session, training a patient for a period of time and then allowing the patient to ambulate on their own. This approach offers advantages as biofeedback devices are expensive and therefore could be used in a clinical setting and shared by patients, reducing overall cost. However, as retention of training seems to be a problem, future research could focus on the continuous use of biofeedback by devices taken home by patients and worn continually throughout the ambulatory period. This would most likely require individualized device purchasing, increasing cost, but possibly improving overall outcomes.

In summary, biofeedback devices offer significant improvements over bathroom scales, and clinical examinations, yet their full potential has yet to be elucidated. Future studies should examine the long-term effect of biofeedback devices in varying clinical scenarios.

Force Plates. Force plates are expensive, highly accurate measuring devices that are most important measuring devices in biomechanics. Force plates can accurately measure external forces during walking,³² and have been shown to be more accurate in training patients to comply with partial weight-bearing instructions than bathroom scales or a therapist's hand.¹⁵ However, due to their expense and their immobility, force plates do not have wide application in ambulating patients in the clinical setting.

Yet, force plates are often used to validate other weight-monitoring systems. Two systems that are highly regarded are the AMTI (Advanced Mechanical Technology, Inc., Watertown, MA, USA) and the Kistler (Kistler Instrumente AG Winterthur, Switzerland).⁶ These systems have been shown to have high accuracy and are considered by some to be the gold standard in the field.^{28, 29}

Research to define the effective use of biofeedback devices

The recent development of inexpensive, portable biofeedback devices has made their use appealing in lower extremity orthopaedic patients. However, the effectiveness of their use has yet to be fully established. This thesis covers three preliminary studies designed to better elucidate the use of biofeedback devices in the orthopaedic setting. All of the studies were conducted by the primary author, under the direction of the senior

author. Section one is a study designed to compare the relative effectiveness of training sessions with biofeedback to bathroom scales and verbal instructions in a healthy 20-30 year old population. Section two expands upon section one to examine the use of biofeedback devices in a more diverse patient population. And section three examines the long-term retention effect of biofeedback. These studies were undertaken to better understand the full clinical potential of biofeedback devices in training patients to comply with weight-bearing limitations.

Study One: Defining the Effectiveness of Biofeedback in Weight-Bearing

Objective

The purpose of this prospective investigation was to compare the effectiveness of a training session with biofeedback to verbal instructions and bathroom scale training for asymptomatic subjects given touch-down and partial weight-bearing instructions. The goal was to determine the relative effectiveness of different modes of weight-bearing training that might be implemented in clinical practice.

Patients and Methods

Participants

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

Inclusion criteria included >18 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 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 (upper extremity injury, weakness,

neuropathy etc.). All patients were considered to be healthy and without restriction for weight-bearing.

Our institution's Human Investigative Committee approved this study.

Monitoring of 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 three components: 1) A 5-mm thick air inflated insole worn in the subject's shoe, 2) A measurement device strapped to the subject's ankle that is connected to the air inflated insole (Figure 1), and 3) A software program that allows for continuous Bluetooth communication between the measurement device and a laptop computer. Previous studies have found this system to be highly accurate in comparison to a force plate ($p < 0.05$, $R^2 = 0.907$), with a standard error of ± 0.116 lbs.³⁰



Figure 1. Labeled diagram of the SmartStep weight-monitoring device (Andante Medical Devices, Ltd, Omer, Israel).

Weight-bearing goals

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

For the purpose of this study, touch-down weight-bearing was defined as 25lbs and partial weight-bearing was defined as 75 lbs. 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.

Methods of weight-bearing instruction

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 orthopaedist.

Bathroom scale training utilized a spring-loaded bathroom scale. Subjects 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 lbs or 75 lbs. This is the most common type of training provided by staff and physical therapists at most centers.

Biofeedback training utilized 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 subject. The system provides two 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 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 in order to determine the average weight-bearing for a subject, we asked three subjects to walk with crutches for 10 minutes at a weight-bearing goal of 50 lbs. Analysis of the data showed that after an initial acclimation period to the crutches, all patients settled into “their” weight-bearing average after 40-50 steps. Figure 2 shows the weight-bearing of two representative subjects asked to walk for 10 minutes at 50 lbs. The study was repeated in eight additional subjects 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 subject. Thereafter, 50 consecutive steps were measured for each activity as a representative sample of a subject’s weight-bearing.

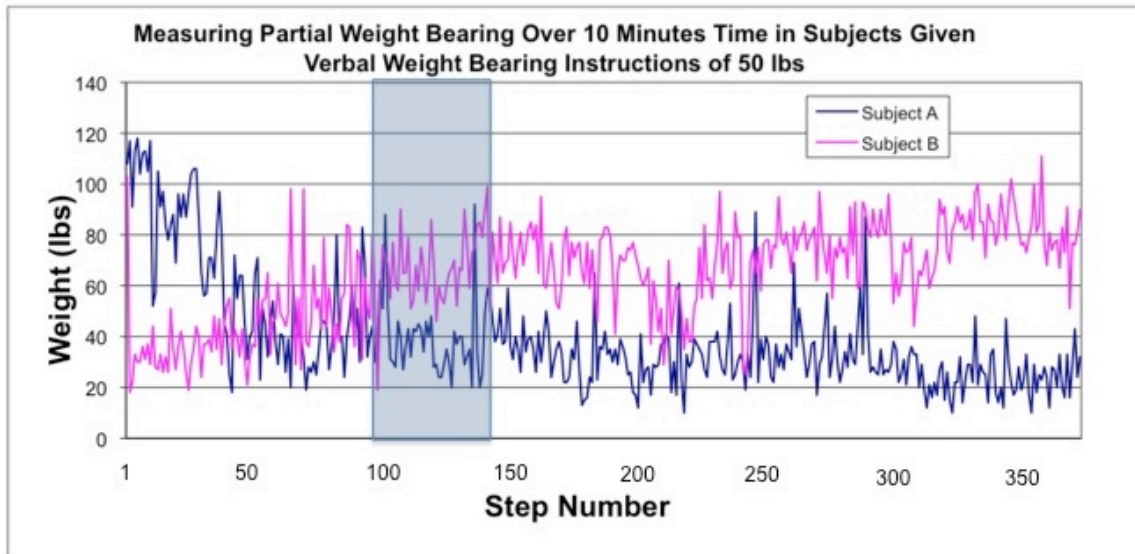


Figure 2. Figure 2: Graph depicting a representative sample from patients given partial weight-bearing instructions of 50 lb and asked to walk with crutches for 10 minutes. After an initial period of variability, patients settled into a weight-bearing average. Statistical analysis showed that after the first 50 steps, no 50-step subgroup was statistically different from another. A representative set of 50 steps is shown in the shaded box. This experiment was repeated in 9 additional patients who are not included in the graph, for sake of simplicity, but showed similar findings.

Data collection

Subjects were first instructed on the use of crutches by a member of the research staff. Subjects were taught a 3-point crutch stance to offset weight from their right lower extremity (a single extremity was chosen for consistency). Subjects 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). Subjects were asked to walk with crutches at weight-bearing instructions of 25 lbs and 75 lbs. The order in which the weight limitations were given was randomized for each subject. Throughout the study subjects would take a short break in between each activity to ensure they were not fatigued.

Next, subjects were instructed on the use of a bathroom scale as described above. Subjects would practice with the use of the scale, and then immediately walk without the scale for 50 consecutive steps. The order in which the subjects performed the 25 lbs and 75 lbs weight-bearing instructions was randomized.

Finally, subjects were instructed with the use of the biofeedback mechanism of the SmartStep™ device. For the 25 lbs weight range a lower limit of 15 lbs and an upper limit of 35lbs was used. For the 75 lbs weight range a lower limit of 65lbs and an upper limit of 85lbs was used. These weight ranges were used since previous studies have shown that there is a lag time in responding to biofeedback.⁵ Therefore, optimal training is achieved when a weight limitation signal is set just below the desired weight-bearing goal. Subjects were asked to walk with the use of biofeedback until they felt comfortable with the weight-bearing instructions, on average this was one to two minutes. Immediately following, 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 lbs and 75 lbs weight limits were performed was randomized for each patient.

Data Analysis

For each activity, the first 5 steps and the last 5 steps for each subject were omitted, leaving 40 steps to be used to determine each subject's average on each activity. A repeated-measures analysis of variance (ANOVA) with post hoc paired t-testing with Bonferroni adjustment (P=0.01) was used to compare the means of the verbal instructions, the bathroom scale training, and the biofeedback training for the 25 lbs and

75 lbs weight instructions for all 20 patients. The level used for significance was 0.05. A mixed model statistical design was used to determine statistically significant predictors of a subject's weight-bearing. The model included the subject's BMI, weight, and gender, as well as the type of instruction given (25 lbs vs 75lbs) and the activity type (verbal instructions, scale training or biofeedback training). The level used for significance was 0.05. As the purpose of the study was to make estimates of 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.

Results

Comparing types of training

All 20 subjects completed each activity (verbal instructions, scale training and biofeedback training) at 25 lbs and 75 lbs. Averages for each activity are presented for the 25 lbs goal and 75 lbs goal in Figures 3 and 4, respectively.

Figure 3 shows the average weight-bearing for subjects asked to bear 25 lbs. When given verbal instructions, subjects on average placed 63.57 ± 6.24 lbs (average \pm standard error) on their extremity, far exceeding the given instructions of 25 lbs. After training with a bathroom scale the average weight-bearing dropped to 44.75 ± 5.69 lbs, and after biofeedback training the average was 26.2 ± 1.57 lbs.

At 25 lbs, training with a bathroom scale and a biofeedback device showed improvements over verbal instructions alone ($p \leq 0.001$ for both comparisons). Additionally, biofeedback offered an additional improvement over training with a bathroom scale ($p = 0.011$).

Figure 4 shows the average weight-bearing for subjects asked to bear 75 lbs. When given verbal instructions subjects on average placed 92.28 ± 7.85 lbs on their extremity, exceeding the given instructions of 75 lbs. After training with a bathroom scale the average weight-bearing was 90.82 ± 7.19 lbs, and after biofeedback training the average was 69.67 ± 3.18 lbs.

At 75 lbs, only training with a biofeedback device offered improvements over verbal instructions alone. There was no statistically significant difference 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 ($p=0.027$) and scale training ($p=0.014$).

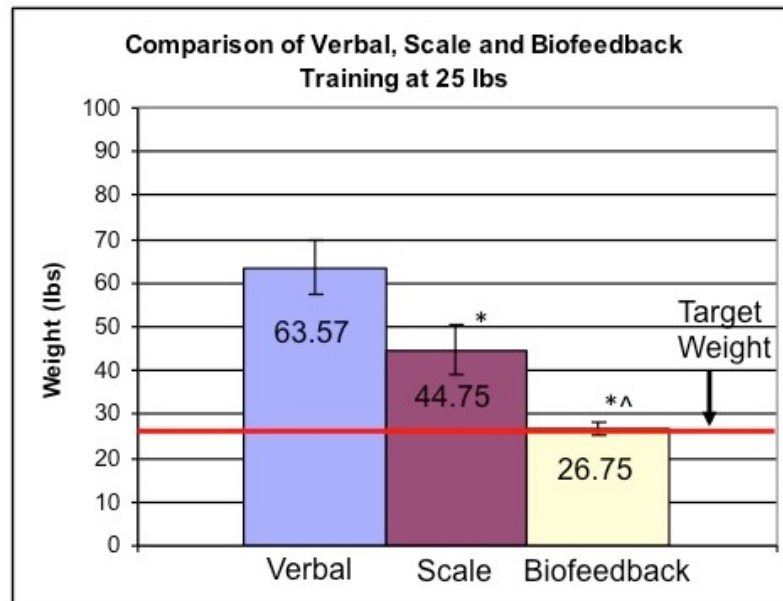


Figure 3: Comparison of verbal instructions with training with a scale and a biofeedback device at given weight-bearing of 25 lb. Mean values for all 20 patients are presented. Bars represent standard error, * represents a statistical difference from verbal, and ^ represents a statistical difference from scale. The reference line shows the 25-lb weight-bearing goal. Without training, patients were significantly over the desired weight of 25 lb. With biofeedback training, patients were significantly better at adhering to given weight instructions of 25 lb.

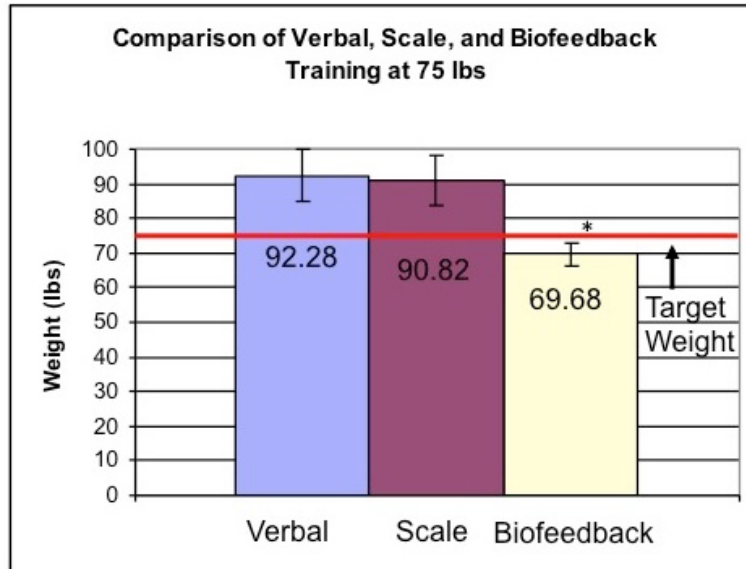


Figure 4: Comparison of verbal instructions with training with a scale and a biofeedback device at given weight-bearing of 75 lb. Mean values for all 20 patients are presented. Bars represent standard error and * represents statistical significance of $P < .05$. The reference line shows the 75-lb weight-bearing goal. Without training, patients were significantly over the desired weight of 75 lb. Only biofeedback training offered a significant improvement over verbal instructions.

Difference by weight instruction

Next, we compared subject compliance with the given weight-bearing instructions at 25 lbs versus 75 lbs. This was accomplished by calculating the difference between the subject's weight-bearing and the given weight-bearing instructions. We plotted the average difference from the given instructions for both 25 lbs and 75 lbs in Figure 5. Standard error bars are shown to represent the variation within the population. Statistical analysis of the differences between 25 lbs instructions and 75 lbs instructions finds that there is a significant difference only for the verbal instructions ($p=0.0002$), but not for scale ($p=0.418$) or biofeedback training ($p=0.0549$). Therefore, when verbal instructions are given subjects are much more likely to exceed weight-bearing instructions of 25 lbs than instructions of 75 lbs.

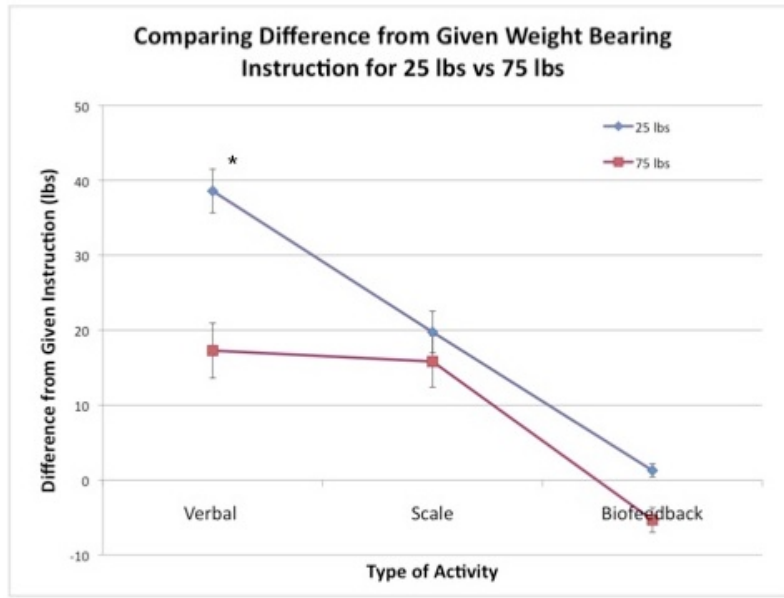


Figure 5: To compare patient compliance at 25 vs 75 lb, the mean difference from the given weight-bearing instruction was plotted by activity type (verbal instructions, scale training, or biofeedback training). Bars indicate standard error and * indicates statistical significance of $P < .05$. Statistical analysis showed no significant difference between patient compliance at 25 or 75 lb for scale or biofeedback training. However, a significant difference existed for verbal instructions, with 25-lb instructions being exceeded far greater than 75-lb instructions.

Inter-subject variability

The data in this study have to this point been presented in aggregate for all 20 subjects. Although the cumulative data has utility in establishing clinical effectiveness, presenting data in this way masks inter-subject variability. Variability among subjects is important to keep in mind, as training works differently for each subject and each type of training. Figure 6 shows a scatterplot with all 20 subjects' performance on each activity and with each instruction. It can be seen that there is a high variability of subject's weight-bearing under verbal commands and after scale training, but becomes much less after biofeedback training. No training methodology will be perfect for all subjects, but

biofeedback seemed to be much better at training all subjects than either verbal commands or scale training.

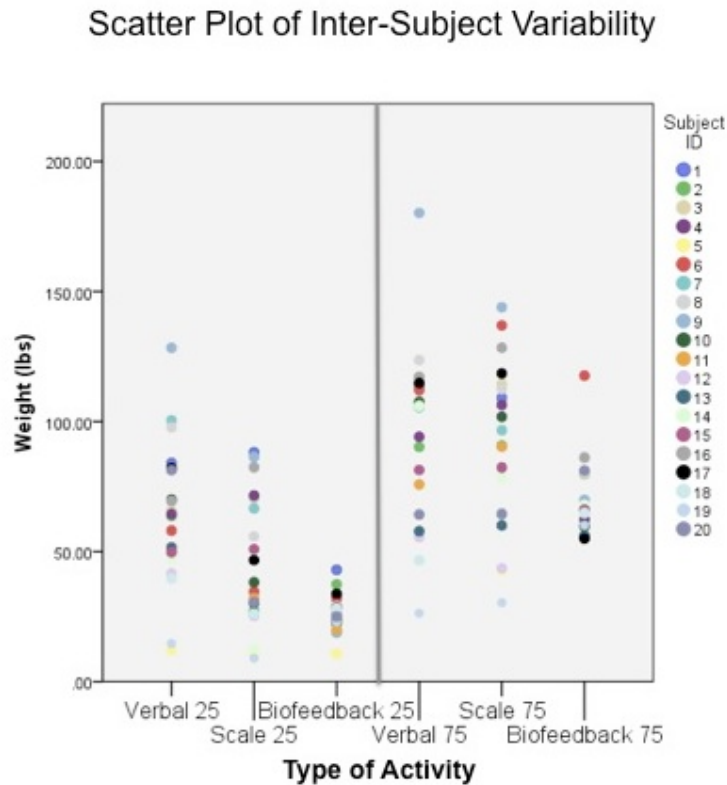


Figure 6: Scatter plot showing inter-patient variability in compliance with weight-bearing instructions. The plot shows a dot for each patient at each weight-bearing activity (verbal instructions, scale training, and biofeedback training) and for each weight-bearing instruction (25 or 75 lb). The graph shows a high variability in patient compliance with given instructions for verbal instructions and scale training. However, with biofeedback training, much less variability occurred.

Statistical modeling of factors affecting weight-bearing

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

The subject's weight was found to be the only statistically significant subject characteristic ($p=0.031$) affecting weight-bearing (with heavier individuals placing more weight on the extremity), while BMI ($p=0.131$) and subject gender were not found to be significant ($p=0.236$). Additionally, both the type of instruction (25 vs 75lbs) ($p=0.005$) and the activity type (verbal instructions, scale training or biofeedback training) ($p=0.001$) were statistically significant predictors of subject 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 (i.e. 25 lbs, 75lbs) verses using body weight percentages (i.e. 25%, 50%). We ultimately chose to give weight-bearing instructions in specific poundage (25 lbs, 75 lbs) as this was the common practice of the orthopaedic trauma unit at our institution. However, we understand that many other groups use body weight percentage.

In order to give our findings greater comparative ability to other studies we converted our findings into body weight percentages. The average body weight of the subjects in our study was 157.4 ± 5.01 lbs. We defined touch down weight-bearing as 25 lbs, and partial weight-bearing as 75 lbs. If the average subject weight is used, these instructions can be converted to touch down weight-bearing defined as 16% and partial weight-bearing defined as 48%. A recent study defined touch down weight-bearing as 0% to 20% of body weight and partial weight-bearing as 21%-50% of body weight.¹¹ Our findings fall within these given limitations.

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

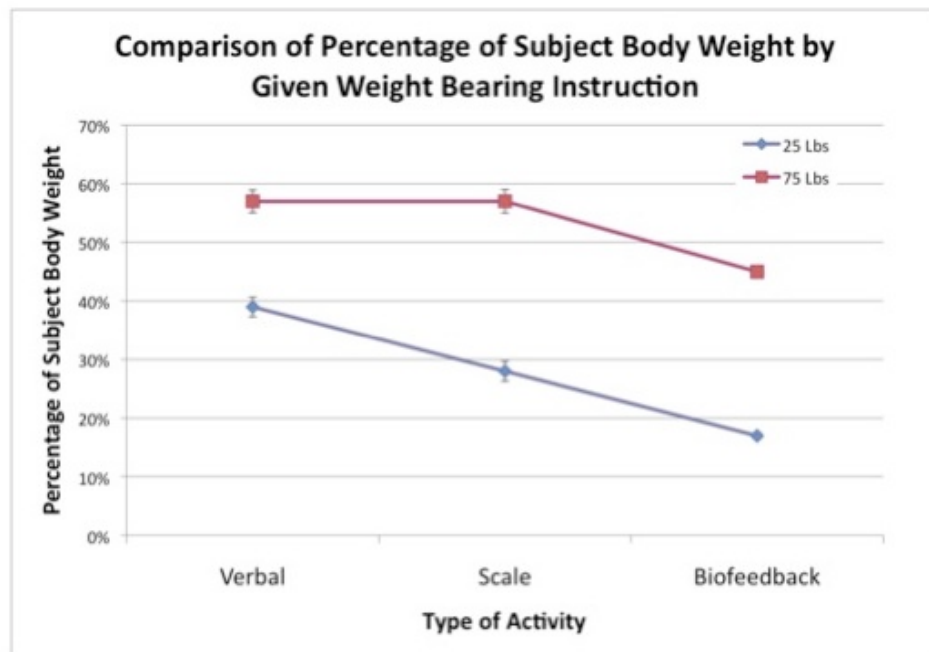


Figure 7: Graph showing the study findings converted from absolute poundage to percent of patient body weight. Bars indicate standard error. Many studies use percentage of body weight vs absolute poundage in weight-bearing instructions; to offer better comparative ability between studies, we presented our data in body weight percentage. Our results comply with previously published weight-bearing definitions of touchdown weight-bearing defined as 0% to 20% of body weight and partial weight-bearing defined as 21% to 50% of body weight. After biofeedback training at 25 lb, patients bore an average of 16% of body weight. After biofeedback training at 75 lb, patients bore an average of 48% of body weight.

Discussion

Specific weight-bearing instructions are commonly prescribed for many injured and/or post-operative orthopaedic patients. However, the effectiveness of such recommendations is heavily contested 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, 14} 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.^{4, 15, 17}

Our data show that it is in fact possible to train young, healthy subjects to comply with instructions for limited weight-bearing to the lower extremities. In evaluating different types of instruction / training, biofeedback training was clearly superior to verbal instructions alone or the use of a bathroom scale. With verbal instruction alone, subjects were much less likely to comply with touch down weight-bearing instructions (25 lbs) than partial weight-bearing instructions (75lbs), 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. In this study the biofeedback system was only utilized as a training device and was then turned off for assessments. As a relatively expensive device, the concept was that patients could be trained under the supervision of a care provider and that this would increase outpatient compliance.

A clear limitation of this study is that the compliance of weight-bearing over time was not assessed. However, if compliance cannot be achieved even in the presence of a

care provider as shown here, longer term compliance cannot even be considered. Other limitations in this study are that only asymptomatic young, healthy volunteers were assessed. Other studies to address these limitations follow in additional sections.

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

Study Two: Evaluating the effect of patient variables on ability to comply with weight-bearing instructions

Objective

The previous study found biofeedback to be an effective training method in young asymptomatic subjects. In order to determine its use in a clinical setting this study was designed with the purpose of defining the use of biofeedback in a more varied patient population. Therefore, the purpose of this prospective study was to determine the effect of patient demographic variables on weight-bearing and necessitated a greater spread in patient demographics.

Patients and Methods

Participants

Previously, twenty healthy subjects aged 20-30 (10 men, 10 women) were recruited for an initial evaluation of the biofeedback device, which was discussed in section one of this thesis.¹⁰ For this study we recruited an additional thirty subjects (11 men, 19 women) ages 30-78 in order to determine the effect of age on partial weight-bearing. All subjects offered verbal informed consent to participate in the study.

For the statistical evaluation of the effect of age we combined both sets of recruited subjects, yielding fifty healthy subjects (21 men, 29 women) aged 21-78 years old. Subjects had an average age of 41.48 years (range 21 to 78 years), an average

weight of 159.7 lbs (range 98 to 300 lbs), an average height of 67.74 inches (range 59 to 75 inches), and an average BMI of 24.33 kg/m² (range 15.8 to 40.7 kg/m²).

Inclusion criteria included age >18 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 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 (upper extremity injury, weakness, neuropathy, etc.). All patients were considered to be healthy and without restriction for weight-bearing.

Our institution's Human Investigative Committee approved this study.

Monitoring of weight-bearing

Weight-bearing was monitored with a mobile SmartStepTM 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) as described above.

³⁰Subjects were asked to walk for 50 consecutive steps for each activity. A 50 step sample increment has been shown in the previous study to offer a representative sample of a subject's average weight-bearing.¹⁰

Weight-bearing goals

One goal of this study was to measure the clinical effectiveness of different forms of training for partial weight-bearing. In order to do so specific weight-bearing goals needed to be established.

For the purpose of this study, touch-down weight-bearing was defined as 25 lbs and partial weight-bearing was defined as 75 lbs. 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.

Methods of weight-bearing instruction

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 descriptions of different weight-bearing goals. This is the most common level of intervention provided directly by an orthopaedist.

Bathroom scale training utilized a spring-loaded bathroom scale. Subjects 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 lbs or 75 lbs. This is the most common type of training provided by staff and physical therapists at most centers.

Biofeedback training utilized 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 subject. The system provides two 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 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.

Data collection

Subjects were first instructed on the use of crutches by a member of the research staff. Subjects were taught a 3-point crutch stance to offset weight from their right lower extremity (a single extremity was chosen for consistency). Subjects 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). Subjects were asked to walk with crutches at weight-bearing instructions of 25 lbs and 75 lbs. The order in which the weight limitations were given was randomized for each subject. Throughout the study subjects would take a short break in between each activity to ensure they were not fatigued.

Next, subjects were instructed on the use of a bathroom scale as described above. Subjects would practice with the use of the scale, and then immediately walk without the scale for 50 consecutive steps. The order in which the subjects performed the 25 lbs and 75 lbs weight-bearing instructions was randomized.

Finally, subjects were instructed with the use of the biofeedback mechanism of the SmartStep™ device. For the 25 lbs weight range a lower limit of 15 lbs and an upper

limit of 35lbs was used. For the 75 lbs weight range a lower limit of 65lbs and an upper limit of 85lbs was used. These weight ranges were used since previous studies have shown that there is a lag time in responding to biofeedback as described in study one.⁵ Subjects were asked to walk with the use of biofeedback until they felt comfortable with the weight-bearing instructions, on average this was one to two minutes. Immediately following, 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 lbs and 75 lbs weight limits were performed was randomized for each patient.

Data Analysis

For each activity, the first 5 steps and the last 5 steps for each subject were omitted, leaving 40 steps to be used for determination of each subject's average on each activity. A repeated-measures analysis of variance (ANOVA) with post hoc paired t-testing with Bonferroni adjustment was used to compare the means of the verbal instructions, the bathroom scale training, and the biofeedback training for the 25 lbs and 75 lbs weight instructions for all 50 patients. The level for significance was 0.05.

In order to determine statistically significant predictors associated with partial weight-bearing compliance a mixed linear-effects model was created. Covariates recorded in the study included: 1) subject characteristics of age, gender, BMI, weight (lbs), and height (inches) and 2) testing parameters including weight designation (25 lbs or 75 lbs) and instruction type (verbal, scale or biofeedback training). The level used for significance in the multivariate model was 0.05.

As the purpose of the study was to make estimates of 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.

Results

Determining the Most Effective Training Methodology

Comparing verbal, scale and biofeedback training

All 50 subjects completed each activity (verbal instructions, scale training and biofeedback training) at 25 lbs and 75 lbs. Averages for each activity are presented for the 25 and 75 lb goals in Figures 8 and 9, respectively.

Figure 8 shows the average weight-bearing for subjects asked to bear 25 lbs. When given verbal instructions, subjects on average bore 61.25 ± 4.80 lbs (average \pm standard error) on their extremity, far exceeding the given instructions of 25 lbs. After training with a bathroom scale the average weight borne dropped to 51.50 ± 4.47 lbs, and after biofeedback training the average dropped further to 30.01 ± 2.33 lbs.

At 25 lbs, training with a bathroom scale ($p=0.010$) and a biofeedback device ($p<0.001$) showed improvements over verbal instructions alone. Additionally, biofeedback offered an additional improvement over training with a bathroom scale ($p<0.001$).

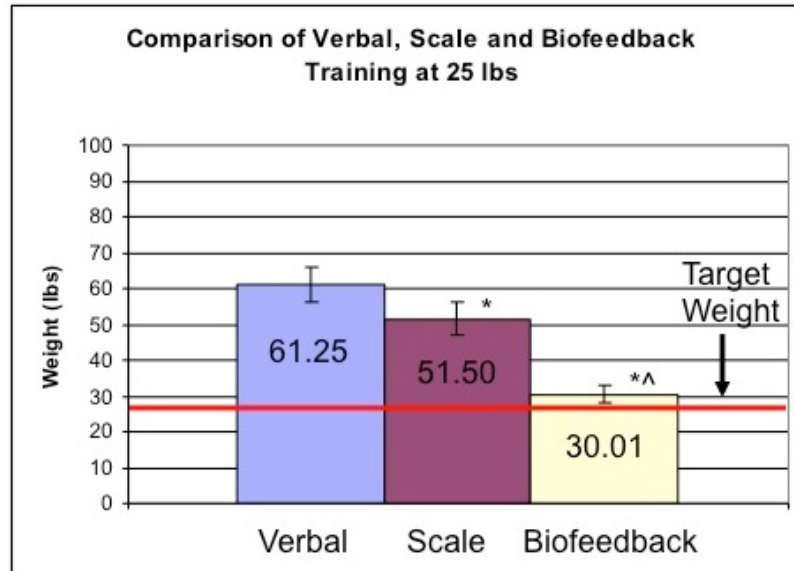


Figure 8: Graph showing comparison of verbal instructions to train with a scale and a biofeedback device at touchdown weight-bearing (25 lb). Mean values for all 50 participants are presented. Bars represent the standard error, asterisks represent a statistical difference from verbal instructions, and the arrowhead represents a statistical difference. The reference line shows the 25-lb weight-bearing goal.

Figure 9 shows the average weight-bearing for subjects asked to bear 75 lbs. When given verbal instructions subjects on average placed 89.06 ± 5.58 lbs on their extremity, exceeding the given instructions of 75 lbs. After training with a bathroom scale the average weight-bearing was 88.47 ± 4.75 lbs, and after biofeedback training the average was 68.11 ± 2.46 lbs.

At 75 lbs, only training with a biofeedback device offered improvements over verbal instructions alone. There was no statistically significant difference 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 ($p=0.001$) and scale training ($p<0.001$).

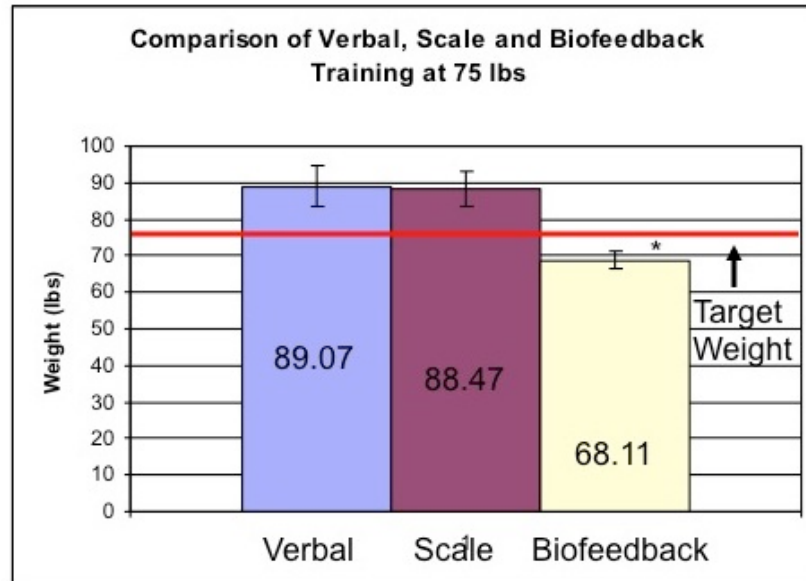


Figure 9. Graph showing comparison of verbal instructions to train with a scale and a biofeedback device at partial weight-bearing (75 lb). Mean values for all 50 participants are presented. Bars represent the standard error, and the asterisk represents statistical significance. The reference line shows the 75-lb weight-bearing goal.

Identifying Significant Predictors associated with Partial Weight-Bearing Compliance

In order to determine statistically significant predictors affecting partial weight-bearing a mixed linear-effects model was used to control for covariates. As mentioned above, the model included the age, gender, BMI and height of the subject as well as the type of activity (verbal, scale or biofeedback) and given instruction (25 lbs or 75 lbs). As BMI and weight were highly correlated ($r=0.863$, $p<.001$), as were weight and height ($r=0.647$, $p<.001$), only BMI or weight could be included in the multivariate model. Subject BMI was chosen to be included in the model as it accounted for both weight and height. The multivariate model therefore included BMI, age, gender, instruction type, and weight designation (25 or 75 lbs). Thus, in the model it was possible to predict a subject's outcome weight while controlling for confounding variables, thereby identifying possible clinical risk factors associated with partial weight-bearing patients.

BMI is a significant predictor in weight-bearing

The mixed model found BMI to be a significant predictor of compliance with partial weight-bearing instructions (beta=1.432, p=0.003). Therefore, the higher the BMI the more likely the subject will exceed given weight-bearing instructions. Figure 10 illustrates the effect of BMI compared across each activity type. Subjects with higher BMIs, therefore, will be at high risk of exceeding given weight-bearing limitations.

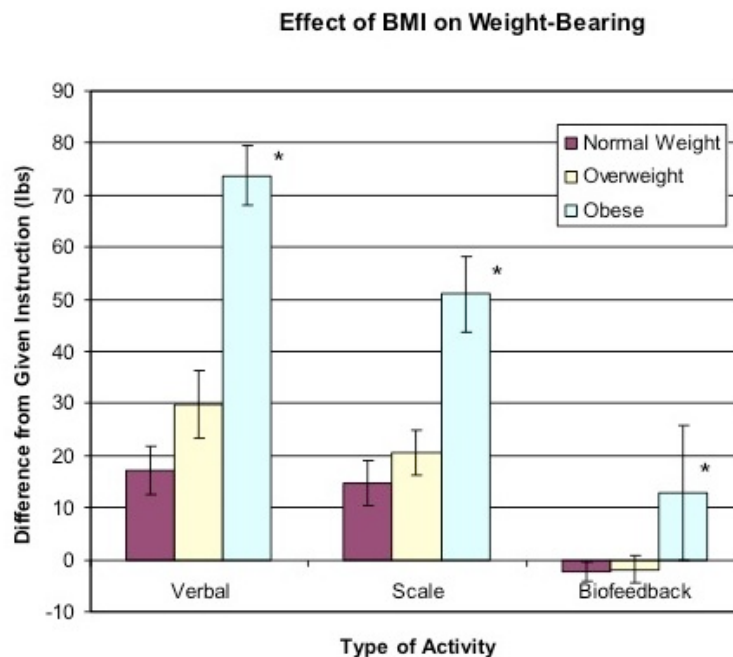


Figure 10. Graph showing the effect of body mass index on partial weight-bearing compliance. Mean differences from given instruction in lb are shown. Bars represent standard error, and asterisks represent statistically significant findings estimated from the mixed model analysis.

Touch-down weight-bearing (25 lbs) vs. partial weight-bearing (75 lbs)

The type of weight-bearing limitation given also affects subject compliance. When subjects are given touch-down weight-bearing instructions (25 lbs) they are significantly more likely to exceed the instructions than when given partial weight-

bearing instructions (75 lbs). This is true for verbal instructions ($p < 0.001$), scale training ($p < 0.001$), and biofeedback training ($p < 0.001$). The model predicted mean difference from the given weight-bearing instruction is shown in figure 11.

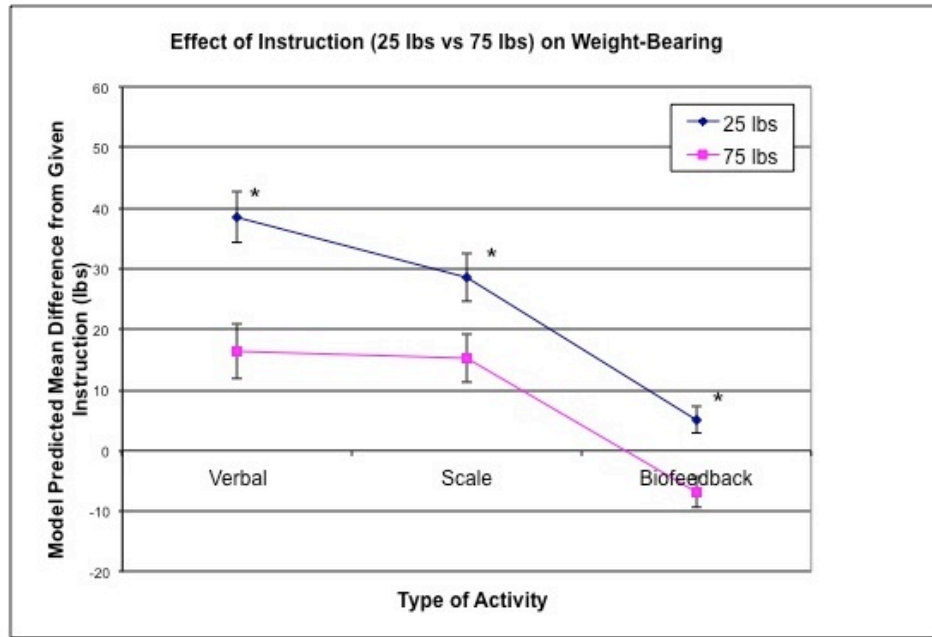


Figure 11. Graph showing the effect of instruction (25 vs 75 lb) on weight-bearing, as predicted by the mixed model. The mean estimated difference from the given weight-bearing instruction is plotted by activity type. Bars indicate standard error, and asterisks indicate a statistical significance of $P < 0.05$.

Effect of gender on partial weight-bearing

Gender had a significant effect on weight-bearing for verbal instructions ($p = 0.009$) and scale training ($p = 0.041$) but not for biofeedback training ($p = 1.000$). Males were more likely to exceed given instructions when given verbal instructions or after training with a bathroom scale even after the model controlled for other confounders such as higher weights and BMIs. Therefore, under verbal and scale training men will be more likely to exceed weight-bearing limitations. This is shown graphically in figure 12.

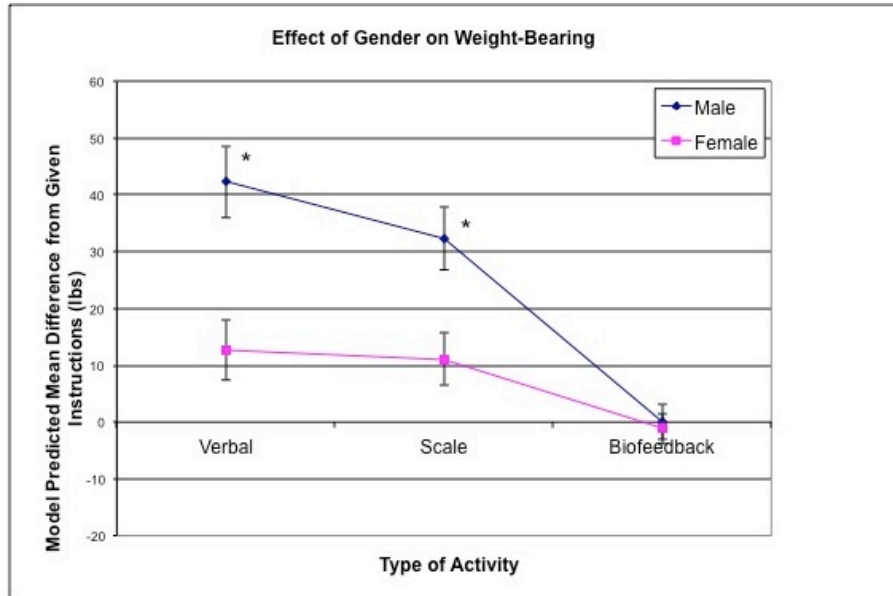


Figure 12. Graph showing the effect of sex on weight-bearing, as predicted by the mixed model. The mean estimated difference from the given weight-bearing instruction is plotted by activity type. Bars indicate standard error, and asterisks indicate a statistical significance of $P < 0.05$.

Age is not a significant predictor of partial weight-bearing compliance

Age was not found to be a significant predictor in partial weight-bearing in the model (beta=0.159, $p=0.126$). Figure 13 represents predicted weight-bearing outcomes for different ages as predicted by the mixed model. While there is a slight increase in weight-bearing as age increases at 25 lbs, this was not found to be statistically significant. Therefore, age is not a significant predictor of weight-bearing after training with a biofeedback device.

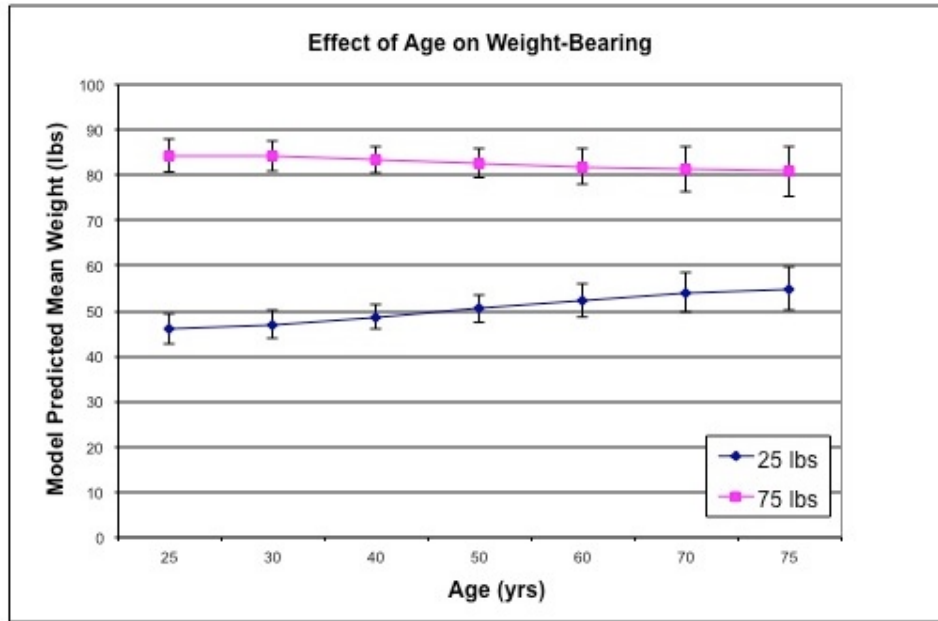


Figure 13. Graph showing mixed model prediction of weight-bearing as a factor of age. Age had no statistical effect on weight-bearing. Bars represent standard error.

Discussion

Specific weight-bearing instructions are commonly prescribed for many injured and/or post-operative orthopaedic patients. Yet many patients struggle to comply with weight-bearing instructions under current training methods.^{1, 2, 10, 14} Previously, we showed that a new biofeedback device, SmartStepTM, was successful in training young healthy subjects to comply with given weight-bearing instructions.¹⁰ Here, we have shown that this same biofeedback device is effective across age ranges, suggesting it could have high clinical applicability among partial-weight-bearing orthopaedic patients.

In addition to answering the important question of the effect of age on weight-bearing, the study had two additional important findings: 1) to verify that biofeedback training is superior to verbal or scale training in older age groups, and 2) to identify significant predictors associated with partial weight-bearing compliance. The larger number of subjects in this study allowed us to identify clinical factors that place subjects at greater risk of exceeding weight-bearing instructions which included: high BMI and touch down weight-bearing instructions.

Many researchers believe obtaining patient compliance in partial weight-bearing is unachievable.^{4, 15, 17} However, our studies suggest that with proper training it is in fact possible to train healthy subjects to comply with instructions for limited weight-bearing to the lower extremities.

There are two main limitations to the study: 1) training was done in an asymptomatic healthy population and 2) weight-bearing over time was not assessed. The study was performed in an asymptomatic population to avoid the confounding factor of

pain. Post-operative pain will obviously affect the patient's weight-bearing gait, however we chose to first test this device in an asymptomatic population to avoid the confounding effect of pain. Now that the device has been shown to be effective, further studies are being pursued in clinical populations. Additionally, we did not follow subjects over time to see if compliance lasted over longer time periods. An ongoing study has been designed to examine this and will be shown in study three.

Overall, the use of a biofeedback device was effective in training subjects to comply with partial weight-bearing instructions. Importantly, this effectiveness was seen across age ranges. Participants with increasing BMIs and those of male gender had a more difficult time following weight-bearing restrictions. As prescribing specific weight-bearing instructions is a routine part of orthopaedic practice, finding ways to define and control patient compliance is of clear clinical importance. Therefore, biofeedback devices may be an appropriate avenue to pursue for such training.

Study 3: Long-Term Retention of Biofeedback Training

Objective

The purpose of this prospective study was to determine the twenty-four hour retention of biofeedback training in asymptomatic subjects given touch-down weight-bearing instructions.

Patients and Methods

Participants

Twelve healthy subjects (7 men, 5 women) aged 22-29 years old (average 24.9 years old) gave informed consent to participate in this study. All subjects were recruited from within our institution. The subjects had an average weight of 154.8 lbs (range 115 to 205 lbs), an average height of 67.8 inches (range 62 to 76 inches), and an average BMI of 22.6 kg/m² (range 19.4 to 28.9 kg/m²).

Inclusion criteria included >18 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 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 (upper extremity injury, weakness, neuropathy, etc.).

Our institution's Human Investigative Committee approved this study.

Selection of Experimental Group and Control Group

Subjects were assigned to one of two groups: the experimental group or the control group. Ten subjects (5 men, 5 women) were assigned to the experimental group and underwent the entire experimental intervention described below.

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

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

Monitoring of weight-bearing

Weight-bearing was monitored with a mobile SmartStep™ (Andante Medical Devices, Inc, White Plains, NY, USA) 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).³⁰

Subjects 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 subject's average weight-bearing as discussed in study one.¹⁰ All subjects used a three-point crutch stance to limit weight born over the right extremity.

Biofeedback weight-bearing instruction

Biofeedback training utilized 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 subject. The system provides two 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 study the auditory feedback was only used during the biofeedback training sessions. During all other times the device was configured only to measure ground reaction forces.

Data collection for Experimental Group

At the beginning of the 24-hour study period subjects were instructed with the use of the biofeedback mechanism of the SmartStep™ device. Subjects were instructed to follow touch down weight-bearing, defined as 25 lbs. To train subjects to comply with the 25 lbs weight range, a lower limit of 15 lbs and an upper limit of 35 lbs were used on the biofeedback device. These weight ranges were selected since previous studies have shown that there is a lag time in responding to biofeedback as discussed in study one.⁵

Subjects were asked to walk with the use of biofeedback until they felt comfortable with the weight-bearing instructions, on average this was two to five minutes. Immediately following, the biofeedback was turned off and the patients 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, subjects were asked to limit their weight-bearing to 25 lbs with the use of crutches. During this time, study personnel intermittently met the study subjects to assess the retention or deterioration of the initial biofeedback. At each time point subjects 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 between 2-4 hours, 6-8 hours, and 22-24 hours after initial biofeedback training.

Data Analysis

For each time point, the first 5 steps and the last 5 steps for each subject were omitted, leaving 40 steps to be used to determine each subject's average for each session. A Friedman's analysis of variance for non-parametric data was used to determine statistical difference between time points for all subjects. The level used for significance was 0.05.

As the purpose of the study was to make estimates of 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 SPSS 18.0 statistical software package.

Results

24-hour retention of biofeedback training

Ten subjects (5 men, 5 women) completed training and all assessment sessions. Following initial biofeedback training, subjects bore an average of 20.4 ± 2.1 lbs (average \pm standard error). At 2-4 hours subjects showed retention of 20.0 ± 4.8 . At 6-8 hours retention was measured as an average of 25.1 ± 6.6 lbs, and at 22-24 hours subjects showed strong retention with an average of 21.8 ± 4.6 lbs. Weight-bearing did not significantly change over the 24 hour period, $\chi^2(4) = 2.81, p=0.590$.

Figure 14 presents the findings from the current study graphically. This graph includes reference values from our previous work in section one comparing verbal instructions and scale training (two of the most commonly used clinical training methods) in age matched subjects to those currently being studied.¹⁰

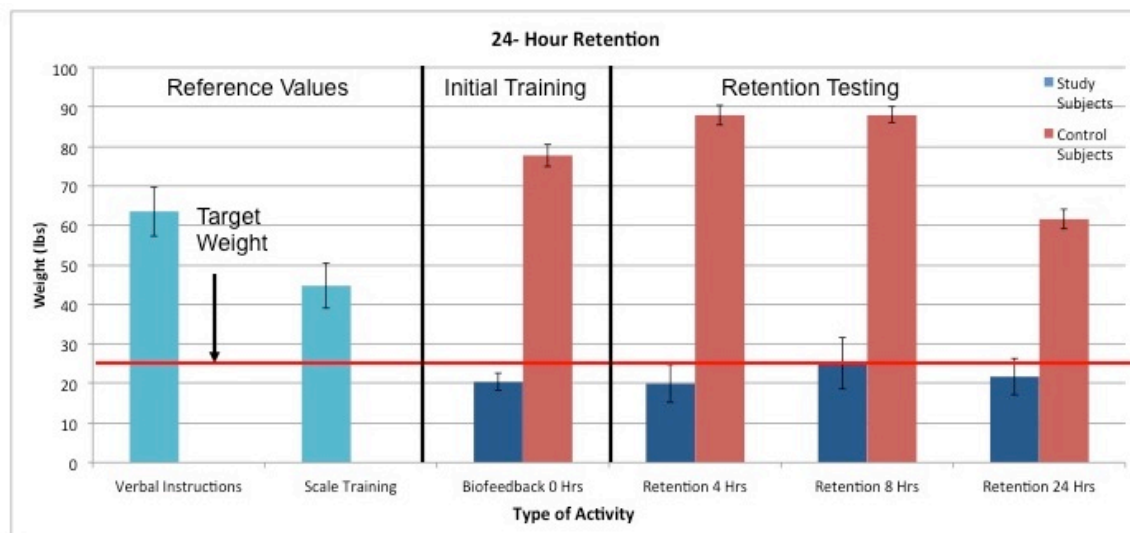


Figure 14. Graph showing 24-hour retention for all participants. Reference values from the current authors' previous study¹⁰ show that participants initially exceed instructions, but with biofeedback, participants comply with the given weight limitation over the 24-hour period. Bars represent standard error.

Control Subjects

In addition to the above study population, two male subjects completed assessments for the control group. The results are included in Figure 14. Control subjects received identical formal training and practice on the use of crutches as the experimental group. However, controls did not receive any biofeedback training. Controls were asked to limit their weight-bearing to 25 lbs with verbal instructions and were followed in an identical manner to the experimental group. Both control subjects bore an average several-fold greater than the target weight and showed high variability in their weight-bearing, suggesting difficulty following weight-bearing instructions without training. Control Subject 1 started with an average weight-bearing of 89.9 lbs and finished with an average of 43.3 lbs; while, Subject 2 started with an average weight-bearing of 65.6 lbs and finished with an average of 80.0 lbs.

Discussion

Specific weight-bearing instructions are commonly prescribed for many injured and/or post-operative orthopaedic patients. Yet, most researchers believe that a majority of patients do not adequately comply with instructions for limited weight-bearing on the lower extremities.^{1, 2, 14} In our previous studies we showed that without training subjects greatly exceeded given weight-bearing instructions, but that following biofeedback training compliance improved. While these results were promising they were limited in that there was no follow-up of the retention of the training^{10, 33} This study, however, highlights that biofeedback training is maintained at least up to 24 hours.

^{1110, 331334} The success of biofeedback training has been shown to be superior to both verbal and bathroom scale training.^{10, 33} However, its long-term efficacy is still in question. Hershko et al. found 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 ten days.¹¹ However, Pataky et al. found that while initial training with biofeedback was successful in patients following total hip arthroplasty that the effect was lost after only one day.¹⁴

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 grounds for future research. We found it necessary to undertake this project with asymptomatic individuals to first identify the effectiveness of biofeedback prior to subjecting the potential beneficial findings to

confounding factors of varying fracture patterns. We believe that the findings in this study lay the groundwork for future studies in defined fracture pattern populations.

The study does have limitations. An important confounding factor that we attempted to control for was a changing perception of weight-bearing over time. It was conceivable that since none of the subjects had previously used crutches or received weight-bearing training that they would decrease their weight-bearing over time simply due to comfort with the use of crutches. In order to control for this, we enrolled two matched control subjects. Interestingly, these control subjects varied significantly in each weight-bearing session and bore several fold greater weight than had been requested, suggesting that without training it is very difficult to gain any understanding of lower extremity weight-bearing. These findings further highlighted the need for proper training of patients given lower extremity partial weight-bearing instructions.

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

Overall, the 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. As prescribing specific instructions is a routine part of orthopaedic practice, and defining and controlling this compliance variable is of clear clinical importance, biofeedback may be an appropriate avenue to pursue for such training.

Summary Conclusions and Future Directions

Partial weight-bearing instructions are commonly given to orthopaedic patients, yet patient compliance with these instructions remains unclear. One of the main issues with partial weight-bearing is finding an effective way to train patients to comply with given weight-bearing instructions. New technological advances in orthopaedics have created biofeedback devices designed to offer dynamic gait feedback to patients while walking. These new devices show promise in aiding patients to comply with weight-bearing limitations. However, relatively few studies have been designed to examine the use of biofeedback in orthopaedic patients.

The three studies in this thesis helped to define biofeedback as a potentially effective training mechanism for partial weight-bearing patients. The first study showed that biofeedback is superior to both verbal instructions and training with a bathroom scale. The second study showed that biofeedback training was effective in all age groups (although negatively affected by increased BMI and male gender). Finally, the third study highlighted that a brief biofeedback training can have lasting effects. Therefore, these studies have laid the groundwork to suggest that biofeedback is an effective training method for orthopaedic patients given partial weight-bearing instructions. Furthermore, the studies have highlighted groups of patients at higher risk of exceeding given limitations, including males and patients with high BMIs.

The findings herein suggest biofeedback may be an effective tool with orthopaedic patients. Future work in this area will be in applying this technology to clinical patients. Plans are underway to compare biofeedback with the clinical examination technique currently used by physiotherapists at Yale-New Haven Hospital.

Further plans include a take home weight-bearing device system with the SmartStep device operating on an ipod touch and/or to develop a low cost alternative that could be used as part of regular clinical practice for the patient with limited weight-bearing instructions. Hopes are that patients may be prescribed a take home device that may be used for the period of post-surgical ambulation, therefore greatly enhancing patient compliance and surgical outcomes. With additional research biofeedback devices may very well become a part of the mainstay of clinical practice in orthopaedic partial weight-bearing patients.

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