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SOLEFORCE®: A Novel Biofeedback Device that Improves Patient Compliance with Lower Extremity Partial Weight-Bearing

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Abstract

Background: Previous studies have demonstrated that orthopedic patients' ability to accurately reproduce partial weight bearing is poor. When told to perform partial weight bearing, patients tend to significantly underestimate how much weight they are putting on their leg. We developed a customized thin film sensory insole Soleforce® (stylized "SOLEFORCE®", RGD Technologies LLC), which is placed inside the footwear of a patient to register forces transmitted through a lower limb to provide continuous biofeedback for actual weight bearing with each step. We hypothesize that patient compliance with weight-bearing restrictions improves with the use of mobile continuous force plate measurement.

Material and Methods: We prospectively evaluated 21 patients who had partial weight bearing restrictions after orthopedic surgery (absolute restrictions, in lb). Patients served as their own control: with and without Soleforce® feedback. We calculated a precision value for patients before and after Soleforce® feedback. We used a paired Student's t-test to compare the patients' precision values. We also used descriptive statistics to summarize patient improvement with biofeedback.

Results: The average precision value for the patients improved from 1.31 (range 0.23-2.00) before Soleforce® feedback to 1.09 (0.84-1.70) after feedback. This was statistically significant (P=0.037). With biofeedback, the proportion of patients who were within 25% of their allowed weight range improved from 9.5% to 90.5%. The proportion of steps which were within 25% of the allowed weight range improved from 18.7% to 71.9%.

Conclusion: Biofeedback using the Soleforce® leads to improved precision for adhering to weight-bearing restrictions. This should improve safety by empowering the patient to be more compliant with the physician's weight-bearing prescription.

Keywords: Partial weight bearing; Biofeedback; Physical therapy

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Introduction

Partial Weight Bearing (PWB) is a common post-operative rehabilitative recommendation after orthopedic reconstruction of the lower extremity [1]. The general guideline after surgery is early mobilization with a stepwise increase in weight-bearing amount until Full Weight-Bearing (FWB) status is achieved [1]. Recommendation on amount of weight bearing depends on factors such as operation performed, patient weight, patient tolerance, bone quality, anatomic location of surgery, biomechanical strength of the internal or external fixation, and neuropathy status [1].

Previous studies have demonstrated that orthopedic patients' ability to accurately reproduce PWB is poor [2-6]. This can overload the bone during fracture and osteotomy healing and may lead to failure and nonunion. When told to perform PWB, patients tend to significantly underestimate how much weight they are putting on their leg [2,5,6].

While biofeedback does facilitate accurate training for partial weight bearing, the effects last only as long as feedback is available [2-6]. We developed a customized thin film sensory insole Soleforce® (stylized "SOLEFORCE®", U.S. Patent #9,568,381, RGD Technologies LLC, Bayville, NJ), which is placed inside the footwear of a patient to register transmitted forces to provide continuous biofeedback for actual weight bearing with each step (Figure 1). We hypothesize that patient compliance with weight-bearing restrictions improves with the use of continuous force plate

Figure 1: SOLEFORCE® device with sensory insole and feedback monitor for patient.

measurement.

Material and Methods

Study design

We obtained institutional review board approval and prospectively evaluated 21 patients who had PWB restrictions after orthopedic surgery *via* a prospectively paired cohort design. Patients were limb reconstruction patients who underwent osteotomies and required a period of PWB. Patients were consecutive ones of the senior author (SRR), and other inclusion criteria included those who were English-speaking, at least 18 years of age, agreeable to participate, and able to use the biofeedback. Patients served as their own control: with and without Soleforce® feedback. The patients' weight bore for each step was recorded. The first phase of the study did not allow the patients to see the monitor's feedback while the second phase did.

Data collection

The Soleforce® insole was placed inside the footwear of the patient. This sensory insole was connected with wires *via* one connection to a small Foot Mounted Control Module (FMCM) and was mounted with a strap on the top surface of the footwear on the foot. The patient's maximum allowed weight per step (in lb) was inputted into the FMCM *via* a simple push button before use. As a patient took a step, the FMCM interpreted the input weight the patient applied, and outputted this weight to the user in real time.

There was a monitor on the FMCM that displayed the weight applied, as well as a linear array of lights that progressively illuminated based on the amount of force applied (Figure 2). As the user approached his or her target weight range, the lights illuminated incrementally to guide the user to his or her goal. If the patient exceeded the maximum, warning lights illuminated as well as an audible alarm notifying the patient that he or she had exceeded the maximum weight.

Each step was stored in the FMCM for review at a later time. The information was uploaded via cable to a computer. Patients walked at least 50 steps with 2 crutches using Soleforce® without feedback followed by at least 50 more steps with feedback, and the results were compared.

Statistical analysis

Each patient had a maximum weight he or she was allowed to bear (lb); the acceptable range was anywhere from that weight to 15 pounds less than that. For each step every patient took, a precision value was calculated. Any weight in the acceptable range was given a precision value of 1, and values below 1 represent an underweight condition with values over 1 an overweight condition. The amount of weight that the patient is above or below the perfect precision value of 1 is a percentage of either the lower or upper bound value (depending on if the patient is under or over the desired range). The primary outcome was the mean precision value.

As an example, a patient has a maximum allowed weight of 70 pounds. This means that the acceptable range is 55-70 pounds. This patient's precision value is 1 if any step is between 55 and 70 pounds. If this patient takes a step and only bears 35 pounds, this would equate to a precision value of 35/55=0.64. The overweight condition is just as simple to calculate, but the higher of the two values in the denominator is used. If the patient takes a 100-pound step, the precision value in this case would be 100/70=1.43.

We also calculated descriptive statistics such as means and proportions. All statistical analysis was performed in Microsoft Excel (Microsoft® Excel for Mac 2019). We used a paired Student's t-test to compare the patients' precision values before and after Soleforce® feedback. The significance level was chosen to be 0.05, and any p-value less than that was deemed significant.

Results

The average PWB allowed for the 21 patients was 55.2 pounds (range 30-90). The average precision value for the patients improved from 1.31 (0.23-2.00) before Soleforce® feedback to 1.09 (0.84-1.70) after feedback (Figure 3). This was statistically significant (P=0.037).

With biofeedback, the proportion of patients who were within 25% of their allowed weight range improved from 9.5% to 90.5%. The proportion of steps which were within 25% of the allowed weight range improved from 18.7% to 71.9%.

Discussion

Our study demonstrated an improvement in patient compliance with PWB prescription. We will first examine how this work fits with prior research and then conclude with the implications of this study.

Gait and PWB are usually taught by physical therapists with a variety of methods such as physical therapists' experience as well as more traditional methods such as bathroom scales. The ability

Figure 2: SOLEFORCE® monitor that displays feedback based on amount of weight patient bears.

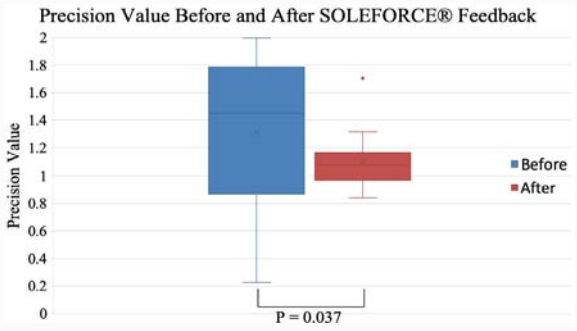

Figure 3: Precision value improved with SOLEFORCE® feedback in 21 partial weight-bearing patients. Xs depict means, and lines depict medians.

to reproduce a certain amount of weight in PWB patients has been studied using bathroom scales [2-4]. Overall, these studies have found that patients cannot reliably reproduce PWB consistently.

As early as 1998, researchers have attempted to innovate devices that provide feedback to PWB patients on amount of weight bore. Aranzulla et al. [7] found, with their limited sample size, that strapping a transducer to patients' ankles could influence the amount of weight bore by the patients. Another study in PWB patients after total hip arthroplasty found that their patients were able to significantly adjust the amount of force with each step, but that the patients were not able to retain any memory how to replicate these steps after 30 min, 1 day, or 2 days [8].

Moving forward chronologically, two studies analyzed the SmartStep™ Gait System (Andante Medical Devices, White Plains, NY) as a means of providing biofeedback to PWB patients. Isakov validated the SmartStep device by comparing it to a force plate, finding a statistically significant correlation between the two measurement methods [9]. Furthermore, the researcher demonstrated a significant difference in weight bore when using the SmartStep device. These results were corroborated by Hershko et al. [10] in finding that study subjects with SmartStep followed weight-bearing instructions significantly better.

One group in particular has conducted extensive research on these haptic biofeedback devices [11-14]. They first began their research with the same SmartStep device and compared it to verbal instructions as well as training with a bathroom scale [11]. They found that patients with touchdown weight-bearing instruction of 25 pounds bore 63.6 pounds with verbal instructions, 44.8 pounds with the bathroom scale, and 26.2 pounds with biofeedback ($P<0.05$). Similarly, for PWB of 75 pounds, verbal instruction patients bore 92.3 pounds, 90.8 pounds with the bathroom scale, and 69.7 pounds with the SmartStep device ($P<0.05$). These researchers also studied the reliability of PWB compliance temporally [12]. They found that patients were able to retain the amount of weight bore up to 24 h after training, which was replicated in patients who were given verbal instructions, contradicting the results published by Pataky et al. [8].

This same group carried out their research even further by creating a device that provides haptic feedback. Their device consists of a force-sensing plate attached to a commercial walking boot that provides feedback *via* a belt. DeLuke et al. [13] found that within a 5- to 50-pound weight-bearing range, their invention had an accuracy of 5.34 pounds. Finally, they tested their device against the conventional methods of verbal instruction and bathroom scale [14]. Patients were instructed to PWB 25 pounds with an acceptable range of 15-25 pounds. Patients with verbal instruction bore 60.3 pounds, bathroom scale 43.8 pounds, and haptic biofeedback 22.4 pounds ($P<0.05$). Fu et al. [14] were able to conclude that their initial evaluation haptic biofeedback demonstrated superiority as compared to more conventional methods.

Building on the research that has already been conducted [15]; we tested, in this study, whether biofeedback via an innovative device could improve lower-extremity PWB patient compliance. We gave each patient an acceptable range for his or her PWB amount, calculated a precision value, and compared precision values before and after feedback. We found that Soleforce® was excellent at increasing patient compliance in PWB. These results support our hypothesis that compliance with weight-bearing restrictions improves with the use of continuous force plate measurement.

There are several limitations to this study. First, the number of patients enrolled in this study was not large; however this is in line with the literature. Further research to test a larger number of subjects for longer periods of walking is underway. Second, all patients were from a single institution, specifically a high-volume, academic center. It is possible that these results are not generalizable given the nature of a single institution. We recommend enrollment of more patients at other institutions to validate this work in a generalizable way. Finally, our feedback for the patients was a visual method *via* the monitor with lights. There is literature to support that haptic feedback is a viable feedback method and perhaps even superior to visual feedback [16,17]. A future direction of our Soleforce® project could be to incorporate haptic biofeedback as well as, or in place of, visual feedback.

Biofeedback using the Soleforce® leads to improved precision for adhering to weight-bearing restrictions. This should improve safety by empowering the patient to be more compliant with the physician's weight-bearing prescription. Future directions for this project include: a 48-hour study with the first 24 h blinded and the second 24 h with feedback; an evaluation if the device feedback leads to improved clinical outcomes.

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In loving memory of our dear colleague Henry J Daniecki, one of the inventors of Soleforce®.

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