Biofeedback Versus Physiotherapy in Patients With Partial Weight-Bearing

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Abstract

Medical instructions for partial weight-bearing after lower limb surgery and fractures are commonly given. The techniques for instruction are mainly verbal cues. Our aim was to evaluate the efficiency of a new biofeedback device compared with traditional intervention for gait rehabilitation.

After orthopedic surgery, 33 patients, randomly divided into a study group (n = 15) and a control group (n = 18), completed 10 days of a rehabilitation protocol. A significant difference (P<.05) was found between the groups. Study subjects were able to follow weight-bearing instructions better.

We suggest that gait rehabilitation is more efficient when biofeedback is used to instruct patients regarding partial weight-bearing.

edical instructions for partial weight-bearing (PWB) are well known among therapists in hospitals and rehabilitation centers. Studies supporting weight-bearing restriction are based on several histopathology principles related to bone-healing processes after fracture or surgery. One recommendation for the acute stages of bone-tissue growth is to restrict mechanical loads in the fracture zone.^{1,2} Common practice is to restrict weight-bearing after some hip surgeries,³⁻⁵ knee surgeries,^{3,6} intra-articular fractures, and ankle fractures.⁷ Restriction of weight-bearing is sometimes recommended for wound-healing stages in patients with neuropathy or after amputations.⁸

Teaching patients how to walk with PWB is usually done by physical therapists (PTs).⁹ The most common teaching techniques involve verbal instructions or use of

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bathroom scales.⁹⁻¹¹ Results from several studies showed that patients could not follow the instructions accurately without receiving immediate feedback.¹²⁻¹⁴ In laboratory studies, forced plate with feedback was found to be very efficient.^{11,15} However, some researchers have claimed that biofeedback systems should be mobile and should be used by the patients and therapists outside the laboratory, in daily activities such as walking and climbing stairs.^{15,16}

In the present study, we assessed 2 types of postoperative instructions, 1 with biofeedback and 1 without biofeedback. We hypothesized that, in cases in which patients bear weight beyond the permitted limit, a combination of biofeedback and the usual instruction would be more efficient than instruction alone. We also hypothesized that, after a few days, patients would not remember their limitations, and patients with a high pain level would be bearing less weight. To our knowledge, no study has been conducted using this system.

MATERIALS AND METHODS Subjects

Between April 2005 and October 2005, 50 patients with PWB instruction were admitted to the Department of Rehabilitation at Bet-Hadar Medical Center. After inclusion and exclusion criteria were applied, only 33 patients were eligible to participate in the research. Inclusion criteria were fracture or surgery in a lower limb with medical instruction for PWB, walking with or without assistive device before operative treatment, and no major cognitive impairment. Exclusion criteria included medical instruction for no weight-bearing or for full weight-bearing, fractures or operations in the opposite lower limb, and neurologic diseases such as stroke or Parkinson disease. Subjects were randomly divided into a study group (n = 15) and a control group (n = 18) according to paired-andunpaired alternating design (ie, subjects were numbered from 1 to 33 and were divided into 2 groups of paired and unpaired numbers). Mean age was 68 years (SD, 9.5 years), and there was no significant difference in background variables or in primary diagnosis between the study and control groups. The primary and most frequent medical diagnosis of patients in the study and control groups was total hip arthroplasty (50%), followed by hip intramedullary nailing (15%), tibial plateau surgery (10%), hip hemiarthroplasty (10%), hip Richard's nailing (10%), and acetabular surgery (5%).

All subjects signed a consent form, and the study was approved by the Helsinki Committee of the Kaplan Medical Center in Rehovot, Israel, and by the chief medical doctor at the Bet-Hadar Medical Center.

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Figure 1. Comparison of weight-bearing in study and control patients instructed for toe-touch. Values express assessment results with feedback turned off. The black line in each column represents the median.

Measurement Tools

Our search of the literature for a model for translating common medical instructions to percentage of body weight was unsuccessful. After we consulted 6 senior orthopedic surgeons (3 locals, 3 from abroad), medical instructions for PWB were validated as follows: Toe-Touch / Touch Down / Touch Weight-Bearing = up to 20% of body weight, and PWB = 21% to 50% of body weight.

Peak vertical ground reaction force (in kilograms) was measured with the SmartStep Gait System (Andante Medical Devices, Ltd, Omer, Israel), which was found to be valid and reliable in relation to the force plate. Isakov¹⁷ found this system to be highly accurate in comparison with the force plate (P<.05) and its results to correlate highly $(R^2, .907)$ with force plate. Standard error of mean was 0.53 kg. This wireless system has 3 principal components: a 5-mm-thick insole that contains 2 pneumatic pressure sensors (in forefoot and hindfoot); a data logger attached to the thigh using Velcro; and computer software that processes data from the sensors and displays the data graphically in weight units (kilograms) or as percentage of body weight. This system provides 2 types of audio feedback in a predetermined weight range and can be used to encourage or restrict weight-bearing. Before being used for measurement, the system was calibrated with the inner sole in the shoe and with the subject sitting without bearing weight on the foot. Before the start of treatments with feedback (study group only), the weight-bearing limit was set to warn the subject during walking. All subjects were asked to walk at least 40 sequential steps.

Analysis of results was based on a mean of 30 steps, with the first and last 5 steps omitted. All subjects used an assistive device (eg, walker, crutches) to enable PWB. The same device was used for all treatments and all measurements. Results showed that type of assistive device affected the subject's ability to limit PWB.⁹



Figure 2. Comparison of weight-bearing in study and control patients instructed for partial weight-bearing. Values express assessment results with feedback turned off. The black line in each column represents the median.

Balance ability in walking was measured with a functional test, the timed up-and-go test (TUGT), using a stopwatch. The TUGT was found to be valid and reliable for evaluating adults' balance in walking.^{18,19} Taking less than 10 seconds to perform the test corresponds to a low risk for falling; taking more than 30 seconds corresponds to a high risk for falling.

Pain level was measured with the visual analog scale (VAS) ruler (a 1-to-10 scale), which was found to be valid and reliable.²⁰ The pain factor was described as an important variable because of its effect on the ability of the patient to limit weight-bearing.

Measurements

On the first day and the last day of the study, 3 tests were conducted on each subject: (1) SmartStep (feedback turned off) was used to assess weight-bearing on the injured leg; (2) TUGT was used to measure performance time, with SmartStep (feedback turned off) assessing weight-bearing on the injured leg; and (3) VAS was used to assess pain levels.

Two additional tests were conducted on each study subject on day 5, with the aim being to check the ability to limit weight-bearing after 5 training days. The first assessment was performed with activated feedback; the second assessment was performed 20 minutes later, with feedback turned off. On the remaining 5 days, study subjects continued training with feedback turned off. This process was performed to check the ability to learn and memorize (short- and longterm retention ability) throughout the 10 days.

Treatment Protocol

Each subject received physical therapy for 45 minutes for 10 days. On the first day of the study, one meeting was held for assessment, another to begin the treatment. Study and control subjects were treated by 2 PTs in the rehabilitation department.



Figure 3. Short- and long-term retention ability in study subjects and difference between toe-touch and partial weight-bearing instructions. First assessment was made at beginning of study (no feedback), second and third assessments in middle of study (with feedback and without feedback after 15 minutes), and fourth assessment at end of study (no feedback). The black line in each column represents the median.

Study subjects were treated according to a study protocol. In the first 20 minutes, the measurements were explained, the system was calibrated, and the patients began training while standing in front of the computer display with audio and visual feedback. Over the next 15 minutes, subjects practiced walking with audio feedback (for concurrent feedback²¹) and an assistive device. Another 5 minutes were needed for downloading the data and creating a summing feedback ("Knowledge of result"). During the last 10 minutes, subjects practiced transfers in and out of bed and were instructed with strengthening exercises for the injured limb.

Control subjects were treated according to a control protocol. In the first 20 minutes, weight-bearing restriction was explained, and practice while standing was begun. Over the next 20 minutes, subjects practiced walking with an assistive device and restricted weight-bearing under PT supervision, and a summing feedback was provided by the PT. During the last 10 minutes, subjects practiced transfers in and out of bed and were instructed with strengthening exercises for the injured limb.

Data Analysis

Background variables were described by means, SDs, and box plots. For comparisons of the groups' background variables, t and χ^2 tests were used. For variability and differences between groups, an analysis of variance for repeated measurements was used. Data processing was performed with SPSS 11.5 software (SPSS, Chicago, III). P<.05 was considered statistically significant.

RESULTS

The weight-bearing limit in toe-touch (TT) instruction was up to 20% of body weight. At the beginning of the



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Figure 4. Comparison of performance on timed up-and-go test between study and control subjects for toe-touch and partial weight-bearing instructions together. The black line in each column represents the median.

study, most study and control subjects were weight-bearing beyond the permitted range; respective means were 49.06% (SD, 14.37%) and 50.78% (SD, 20.71%).

The weight-bearing limit in PWB instruction was 21% to 50% of body weight.

TUGT time performance was measured in seconds and in 10ths of seconds, at the beginning and the end of the study. Results are presented for TT and PWB instructions together, as no significant difference was found between those instructions.

Study Group Versus Control Group

Study subjects who practiced physical therapy with feedback improved significantly (mean, 20.52%; SD, 9.06%; P= .0001), whereas control subjects did not improve significantly (mean, 48.81%; SD, 25.7%) (Figure 1).

At the beginning of the study, most subjects were weightbearing beyond the permitted range: The study group mean was 63.36% (SD, 13.59%), and the control group mean was 59.45% (SD, 12%). Study subjects improved significantly (mean, 49.13%; SD, 9.73%; P = .011), but control subjects did not improve (mean, 64.35%; SD, 16.43%) (Figure 2).

At the beginning of the study, study subjects exceeded weight-bearing limits; means were 49.06% (SD, 14.47%) for TT and 63.36% (SD, 13.36%) for PWB. After 5 days of training, when tested with active feedback, they reached maximal accuracy; means were 17.21% (SD, 5.55%) for TT and 39.58% (SD, 4.84%) for PWB. Twenty minutes later, when tested with feedback turned off, they showed good short-term retention ability with a slight rise in weight-bearing means: 18.98% (SD, 8.15%) for TT and 44.18% (SD, 6.03%) for PWB. At the end of the study, after an additional 5 days of treatment with no feedback, study subjects showed good long-term retention ability: Means were 20.52% (SD, 9.06%) for TT and 49.13% (SD, 9.73%) for PWB (though there was an additional increase

in weight-bearing means). Overall, there was significant improvement in this group (P = .001). There was no significant difference (P = .105) between TT and PWB instructions regarding retention ability (Figure 3).

Time means decreased significantly (P = .0001) for study subjects from the beginning of the study (67.33; SD, 38.96) to the end of the study (38.72; SD, 20.08) and for control subjects from the beginning (64.10; SD, 38.17) to the end (49.73; SD, 39.39). There were no significant differences (P = .199) between groups (Figure 4).

Pain values changed slightly for study subjects from the beginning of the study (mean, 4.9; SD, 2.5) to the end of the study (mean, 4.43; SD, 2.8) and for control subjects from the beginning (mean, 3.16; SD, 2.4) to the end (mean, 3.72; SD, 3.1). There were no significant differences between groups (P = .913).

DISCUSSION

Gait with restricted weight-bearing (TT, PWB) is usually taught by a PT using verbal feedback and bathroom scales and is based mainly on the PT's experience. Previous study results showed that young and healthy subjects could restrict their weight-bearing with a high level of accuracy using these methods,^{9,10} but these methods were inefficient in elderly subjects.^{8,15} In the present study, combining PT instruction with a new biofeedback system was found to be highly efficient compared with PT instruction only.

A major limitation of our study was its lack of blinding. It was almost impossible to blind patients and PTs from knowing the treatment protocol when using the biofeedback system. However, patients and PTs were blinded to the results of the assessments made during the study in order to minimize an "out-of-treatment" feedback effect.

The relatively small sample size is less likely to well represent population characteristics, and, therefore, true differences between the groups are less likely to be recognized. However, to reflect a stronger power of the study, we reduced the variability within groups and used repeated measures.

This study showed that the SmartStep system is capable of measuring weight-bearing while patients walk outside the laboratory, of logging data, and of providing an immediate audio warning that the injured limb is being overloaded. This system is cheap, easily operated, and convenient to use and enables more accurate and controlled gait training. If weight-bearing restriction is important for healing after fractures or orthopedic surgeries, then such a system has value. Our results support those of other studies, which found high efficiency in teaching PWB through use of various insole systems capable of providing feedback when patients exceed certain thresholds.^{22,23}

No model or protocol defining weight-bearing ranges was found in the literature reviewed, perhaps because instruments that accurately measure weight-bearing are not used extensively in clinics. There is also a lack of directions for standard units, such as kilogram and percentage of body weight. In 2005, Malviya and colleagues¹⁰ suggested dividing the ranges to body weight percentage in 25% intervals. This suggestion was intended to create unity in physician instructions. In the present study, weight-bearing instructions were separated into 2 sets, as these are the most common instructions given to patients admitted to our medical center. Bet-Hadar Medical Center patients come mostly from 4 general hospitals. According to surgeons at one of these hospitals, TT instruction means 5 kg; at another hospital, the same instruction means 20% of body weight. In our study, it meant up to 20% of body weight, with PWB instruction meaning 21% to 50% of body weight. These ranges were accepted by several senior surgeons. It seems there is a need to establish weight-bearing ranges and measurement units that will be accepted as standard in different disciplines. We suggest using body weight percentage or kilograms in 2 ranges, as described in TT and PWB instructions. These instructions are easily measurable by the insole system used in this study.

Despite a slight increase in weight-bearing means on the study subjects' retention tests (third and fourth assessments with feedback turned off), most subjects were able to remember weight-bearing instruction even 5 days later. In other studies, a poor retention effect was described.^{8,21} This problem was attributed to, among other things, a short-term learning effect of concurrent feedback. However, it was also stated that this kind of feedback is necessary in order to warn the patient at every step. Knowledge-of-result feedback was described as a long-term learning effect and as more efficient than concurrent feedback in retention tests. In our study, both types of feedback were used. Concurrent feedback provides an immediate warning and knowledgeof-result feedback with completion of the test. This might explain why subjects could remember weight-bearing instruction 5 days later. However, subjects tend to bear more weight over time. As PWB instruction was usually valid for 6 weeks, it is necessary to continue practicing with feedback even in subjects' homes after discharge from the hospital. More studies should be carried out to determine the best training program and a more effective frequency for using biofeedback.

The accuracy level of weight-bearing improved in study subjects, and yet the values presented in this study are means only. Means scattering shows that some patients exceeded weight-bearing limits even while using feedback. In 1975, Warren and Lehmann¹¹ described the *overshoot phenomenon*, in which patients continue to load after an alarm is activated. This phenomenon was attributed to a physiologic response time of 150 to 250 milliseconds. In that time, patients continue to load on the injured limb and exceed weight-bearing limits. Therefore, we suggest setting the alarm a little lower than the upper weight-bearing limit to compensate for the response time and the extra loading.

Several studies showed that restriction of weight-bearing in elderly patients might reduce functional capability and delay rehabilitation.²⁴⁻²⁷ In our study and control subjects, TUGT results were significantly improved, and there was no difference between the groups. When tested for weightbearing while performing the TUGT (ie, high-speed walking), most subjects exceeded significant weight-bearing limits. This finding supports the common knowledge that restricted weight-bearing might delay functional rehabilitation.

Other study results showed that patients who underwent lower limb surgery restricted postoperative loading because of pain.^{28,29} At the beginning of the present study, study and control subjects exceeded up to 60% of body weight beyond the permitted range, but none of them walked with full weight-bearing. Similar findings have been described in various reports.^{11,16,29} These findings lead to the conclusion that, in cases in which minimal restriction is required—that is, loading up to 75%-80% of body weight is allowed patients may walk without using a feedback system. In all other cases, particularly with low weight-bearing limits, it seems necessary to use a feedback system.

AUTHORS' DISCLOSURE STATEMENT

The Israeli Physical Therapy Society supported this study.

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