

Gait rehabilitation: a new biofeedback device for monitoring and enhancing weight-bearing over the affected lower limb

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Aim. Gait rehabilitation programs often require either partial weight-bearing (PWB) or encourage full weight-bearing (FWB) on the affected limb. Until recently, there was no objective and practical way to measure correct weight-bearing during ambulation. The present study evaluates a new in-shoe device (SmartStep, Andante Medical Devices Ltd.) for measuring the amount of weight on the affected limb and for biofeedback gait training.

Methods. The first part of the study aimed to establish the validity of the SmartStep by comparing the results obtained from this device with the results obtained from a force plate. The second part aimed to evaluate the effectiveness of the SmartStep as a biofeedback method in patients who have been referred for FWB gait rehabilitation. Analysis was based on independent samples t-test and χ^2 test for evaluating statistically significant differences between the 2 gait rehabilitation modes.

Results. The SmartStep could repeat the same results with 0.53 kg error of mean. Statistically significant correlation was found between results obtained from the SmartStep and from the force plate ($R^2=0.9067$ and $P=0.004$). The use of the SmartStep auditory biofeedback, significantly ($P=0.00031$) improved patients' weight-bearing over the affected limb in the experimental group ($7.9 \text{ kg} \pm 5.28$) as compared to the control group ($0.7 \pm 2.41 \text{ kg}$).

Conclusion. The SmartStep proved to be very reliable since it generated significant repeatable results which correlated significantly with those obtained from a force plate. Patients recommended for FWB gait can significantly

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cantly improve body weight loading over the affected limb by the use of the SmartStep auditory biofeedback.

Key words: Gait - Rehabilitation - Body weight.

Training to achieve a functionally efficient and cosmetically smooth pattern of gait is a high priority in the rehabilitation of patients with a physical limitation involving the lower limbs. Gait rehabilitation programs often require either limited or partial weight-bearing (PWB) or encourage full weight-bearing (FWB) on an affected limb. Ambulation with PWB or FWB is a sensorimotor skill that physical therapists teach. In daily clinical practice it is possible to distinguish two different groups of patients in need for ambulation rehabilitation. The first group includes patients where controlled PWB has been recommended. These include patients following surgery for fixation of a fractured lower limb bone in the lower limb, complicated hip, knee or ankle joint replacement, reconstruction of knee ligaments and patients who have joint infections, sprains or stress fractures. In these patients, gait with PWB over an affected lower limb is the result of apprehension and anxiety. The second group includes patients where early mobilization and ambulation with FWB are encouraged. Among them are those on prosthetic rehabilitation

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following lower limb amputation, hemiparetics following stroke and patients with gait disorders due to muscle weakness for different reasons.

The current methods for PWB or FWB gait training are mainly subjective. The most popular methods used by physical therapists to teach weight-bearing are the following: 1) while patient is standing, the therapist places her/his hand under the foot of the involved lower limb to estimate the amount of weight bearing;¹ 2) standing on 2 bathroom scales, allowing the patient to observe and control weight distribution between the extremities and recall that weight during gait;² 3) using a full-length mirror to visually remind the patient to stand while placing equal weight on both the affected and sound lower limbs; 4) providing verbal instructions for standing and walking with the body weight equally distributed over both lower limbs. Studies performed on healthy subjects confirmed the inability of the average individual to reproduce the required weight-bearing. A bathroom scale has been used to train weight-bearing control. Immediately after the training, the subjects took 20 steps but they exceeded target load (31.75 ± 2.27 kg) by 50% or more.³ In another study, healthy subjects were trained to adjust their weight to each of 3 target levels; 25%, 50% and 75% of their total body weight, while standing on a scale supporting themselves on one leg. The mean errors of the obtained results were 6.5%, 3.2% and 17.6%, respectively.⁴ Similar results have been obtained in another study where diabetic subjects with neuropathic feet were evaluated. Mean errors ranged from 8.5% to 9.7% of their total body weight.^{5, 6}

In transtibial amputees, it was also found that the residual limb would be overloaded using the conventional bathroom scale method during early postoperative ambulatory training. It was shown that audio biofeedback was useful in preventing the residual limb from being overloaded beyond the prescribed load.⁷ Most researchers concluded that clinicians should not expect patients to accurately follow instructions to weightbear at a specific percentage of full weight, particularly when using an assistive device to adjust weight-bearing. Furthermore, perception of weight-bearing percent may be more difficult during a dynamic activity such as gait. A literature review shows that there have been attempts to monitor weight loading during ambulation with different devices.^{5, 8, 9} The main disadvantages of these devices are the inability to monitor and store data, the heavy weight of the devices and the discomfort and restricted indoor or outdoor gait.

The present study evaluates a new in-shoe device for measuring the amount of weight on the affected limb and for biofeedback gait training. The study incorporates 2 parts: the first part aimed to establish the validity of the new device by comparing the results obtained from this device with the results obtained from a force plate which served as a criterion measure; the second part aimed to evaluate the effectiveness of the new device as a biofeedback method in patients referred for FWB gait rehabilitation.

Materials and methods

Instrumentation

The new in-shoe body weight measuring and biofeedback device (SmartStep, Andante Medical Devices Ltd.) consists of 3 main subelements: 1) a flexible, ergonomically designed reusable polyuretan insole containing 2 separate air pockets and weighing 20 g; 3 mm wide flexible tubes are used to inflate/deflate each pocket and to connect the pocket to a control unit; 2) a wireless miniature control unit based on a micro-processor control. The unit, attached to the patient's ankle, contains 2 pressure sensors connected to each of the 2 insole air pockets. Loading weight on the lower limb during gait causes an increase in pressure in both the insole pockets and the activation of the relative pressure sensors located in the control unit. The control unit stores the electric signals taken from the pressure sensors at a rate of 40 s/min. A standard cable connected to a PC enables raw data to be downloaded from the control unit. The control unit also functions as a biofeedback system. A recommended amount of body weight loading over the affected limb can be precalibrated. An audio signal is generated each time the patient reaches this value while walking; 3) special software converts the electrical output signals into kilogram units. The desktop software is used to create a patient's file, set assessments and treatment sessions and to view and analyze the results.

Part 1

SUBJECTS

Six females and 5 males with no known orthopedic or neurological problem volunteered to participate in the first part of the research. Informed consent was obtained. The mean and standard deviation of their

TABLE I.—Distribution of patients according to their clinical condition.

	Experimental group		Control group	
	Female	Male	Female	Male
Below knee amputation	2	3	3	2
Above knee amputation	1	3	1	2
Total hip replacement	2	4	2	3
Total knee replacement	1	2	1	1
Femoral neck fracture	2	2	3	2

ages and body mass was 26.4±3.8 years and 65.5±9.2 kg, respectively.

PROCEDURES

The subjects were fitted with the proper size insole to their right shoe. They were instructed to walk at a self-selected speed along a 10 m walkway. The testing procedure required the subject to walk 9 to 11 separate times and to step with the right leg on the force plate (Advanced Mechanical Technology Inc., model OR/6-5-1000) positioned halfway along the walkway. At the end of each walk, the subject took off his right shoe, took out the insole, and then reinserted the insole and put on his shoe. Data obtained from the new in-shoe body weight measuring device were compared with those obtained simultaneously from the force plate.

STATISTICAL ANALYSIS

The statistical analysis in the first part of this research aimed to assess the ability of the SmartStep to repeat the same results in the different walking sequences and to measure the accuracy of the new in-shoe body weight measuring system in predicting the force-plate measurements. In order to evaluate any statistically significant difference regarding the accuracy test, general linear models including Pearson correlation values were calculated, as well as calculation of the absolute margin between SmartStep results and the force platform were applied.

Part 2

SUBJECTS

Forty-two subjects in an inpatient rehabilitation program participated in the second part of the study. They were randomly divided into an experimental

TABLE II.—Summary of results obtained from 11 subjects who performed 9 to 11 tests.

Subject	Tests	Mean±SD (kg)	Range (kg)	Standard error of mean (kg)
1	10	88.5±1.72	86-91	0.54
2	9	84.4±1.13	83-86	0.38
3	9	84.8±1.64	81-86	0.55
4	10	70.2±1.14	69-72	0.36
5	10	66.4±1.17	65-68	0.37
6	10	66.3±2.45	62-69	0.78
7	10	66.8±2.62	61-70	0.83
8	10	72.6±1.35	71-74	0.43
9	11	68.0±2.19	65-71	0.66
10	10	69.6±1.35	68-71	0.43
11	10	56.5±1.43	54-58	0.45

TABLE III.—The SmartStep repeated the same results within system error of mean of 0.53 kg, while maximal standard error of mean was set to be 0.83 kg.

	95% confidence interval for mean			SD	Min	Max
	Mean	Lower bound	Upper bound			
Standard error of mean (kg)	0.53	0.41	0.64	0.165	0.36	0.83

group (24 patients) and a control group (18 patients). The mean age and body mass were 62±12 years and 76±15 kg in the experimental group and 66±15 years and 70±13 kg in the control group with no statistical differences in age or gender between the 2 groups. FWB over the affected limb was recommended in both groups. Clinical conditions of the patients in both groups are detailed in Table I.

PROCEDURES

Patients from both experimental and control groups, were fitted with the proper size insole into the shoe of their affected leg. They were instructed to walk for few meters, with or without supporting aids. The amount of weight applied over the affected leg was observed on the PC screen. In the experimental group, the control unit was precalibrated to send an audio biofeedback signal whenever the patient was loading the affected limb to the amount equal to weight endured in the first trial plus 10% of the patient body weight. This precalibration procedure was completed at the beginning of each physiotherapy treatment. During the treatment, the physiotherapist instructed the

TABLE IV.—General linear model for evaluation of the ability of the SmartStep to predict the force plate results. The statistically significant correlation between the results obtained by the two systems, proved that the SmartStep can predict the force plate results ($R^2=0.9067$, $P=0.004$). * Predictors: (constant) SmartStep.

		Force plate					
SmartStep	Pearson correlation	0.952					
	Significance (1-tailed)	0.0002					
	n	90					
		Changes statistics					
Mode	R	R ²	R ² change	F Change	df1	df2	Sig. F Change
1	0.952*	0.9067	0.907	855.615	1	88	0.0004

patient to load his affected limb while walking until the biofeedback signal was heard. At the end of each treatment session, the patient was asked to walk for at least 10 m and the amount of weight applied over the affected leg was recorded again. In the control group, the physiotherapist used one or more of the current methods in use for teaching and training FWB gait. Duration of each physiotherapy session was 30 min. Data was collected from 4 sessions during a 14 day period.

STATISTICAL ANALYSIS

The statistical analysis in the second part of this research aimed to assess the differences in gait rehabilitation outcome between the experimental and control groups. Results obtained in the first physiotherapy session were compared with results obtained in the fourth physiotherapy session. Analysis was based on independent samples t-test and χ^2 test for evaluating statistically significant differences between the 2 gait rehabilitation methods. Results were judged to be significant at $P<0.05$.

Results

Part 1

Mean, standard deviation (SD), range and the standard error of mean obtained in 9 to 11 separate tests are summarized in Table II. It was found (Table III) that the SmartStep could repeat the same results with 0.53 kg error of mean, while maximal standard error of mean was set to be 0.83 kg only. The overall accu-

TABLE V.—Average improvements in weight bearing during ambulation obtained in the experimental group (7.9 kg) and in the control group (0.7 kg).

	Group	No.	Mean±SD	Standard error mean
Walking test (kg)	Experimental	24	7.9±5.28	0.64
	Control	18	0.7±2.41	0.34

TABLE VI.—The average estimated margins of the improvement value obtained in the experimental group (7.9 kg) was found to be statistically significant ($P=0.00031$).

t-test for equality of means							
	t	df	Significance (2-tailed)	Mean difference	Standard error difference	95% Confidence interval of the difference	
						Lower	Upper
Walking test (kg)	9.09	117	0.00031	7.2	0.79	5.7	8.8

racy of the SmartStep to predict the force plate results was evaluated with a general linear model. Correlation between the results obtained from the SmartStep and the force plate was found to be statistically significant; $R^2=0.9067$ and P value= $0.004<0.01$ (Table IV).

Part 2

Table V summarizes the average improvements in weight bearing over the affected lower limb obtained at the end of the treatment period using the SmartStep auditory biofeedback (increase in 7.9 ± 5.28 kg and 0.7 ± 2.41 kg in the experimental and control groups, respectively). The average estimated margin of improvement in body weight bearing (7.2 ± 0.79 kg) was found to be statistically significant ($P=0.00031$) as shown in Table VI.

Discussion

The ability to walk normally and freely is one of the major goals of physical rehabilitation. In patients where FWB during gait is prescribed, it is of enormous importance to evaluate and quantify amount of weight-bearing over the affected limb. This information is necessary since pain, restricted joint range of motion and impaired muscle function of the lower

limbs often affect independent and undisturbed ambulation. During the physical therapy session, the ability to monitor weight-bearing and to record the patients' progress over time, will help the therapist to assess and decide on the most suitable treatment method for gait rehabilitation. The ability of the therapist to motivate his patient further by demonstrating gait improvement is an additional benefit of weight-bearing monitoring. The present study aimed to evaluate the validity and the effectiveness of a new in-shoe body weight measuring and biofeedback device that has been recommended for the treatment of patients referred for FWB gait rehabilitation.

The first part of the present study aimed to evaluate a new device (SmartStep) for body weight measurement during gait. The results obtained show that this device is highly reliable since almost the same values of body weight could be repeated in consecutive trials with a mean error of 0.53 kg only. In addition, the SmartStep results significantly correlated with those obtained from a force plate ($R^2=0.9067$, $P=0.0004$) which proves that the SmartStep can record weight-bearing accurately. In the second part of the present study, the efficacy of the SmartStep to improve body weight-bearing was assessed in a group of patients admitted for rehabilitation. Subjects in the experimental group practiced gait and received feedback from the audio control signals delivered by the SmartStep system. During the treatment session, those patients who used the SmartStep were able to add 7.9 kg of their body weight over the affected limb as compared to the control group, where the mean increase was 0.7 kg. These differences were found to be statistically significant ($P=0.00031$).

The second part of the present study aimed to assess the use of the SmartStep as a biofeedback system for enhancing and improving weight bearing during gait rehabilitation. Unlike other methods used for gait training, the SmartStep aimed at enabling the patient to control his own step execution during ambulation. This is achieved by means of a sound signal delivered each time the patient is loading the affected leg to amount higher than the precalibrated signal level. The efficacy of the device to improve weight shifting capacity by delivering visual biofeedback, was also investigated in postacute stroke patients.¹⁰ It has been recommended to use audio biofeedback signals rather than conventional bathroom scale to improve weight-bearing of transtibial amputees.⁷ Researchers confirm that it is clinically difficult or

impossible to prescribe with reasonable accuracy a load bearing limit for patients using crutches, canes, or prosthetic devices. Furthermore, physical therapists are unable to load the lower extremity at a designed target of weight-bearing if the therapist uses traditional teaching methods such as the hand-under-the-foot, a mirror, verbal explanations, or a bathroom weight scale.

In this study, the efficacy of the SmartStep to improve body weight-bearing was assessed in a group of in-patients admitted for rehabilitation. This device delivers an audio signal each time a designed target of weight-bearing is being reached. This biofeedback method encourages the user to improve weight-bearing within a short period of time. In fact, at the end of 4 physical therapy treatments, patients who used the SmartStep were able to add 7.9 kg of their body weight over the affected limb, while the mean increase in the control group was only 0.7 kg. These differences were found to be statistically significant ($P=0.00031$). It can be, therefore, expected that by using this biofeedback method, the patient will be able to reach a better quality of weight-bearing during ambulation and in a shorter period of time as compared to other methods for gait training.

Conclusions

The present study assessed the validity of a new in-shoe device for body weight measurement during ambulation. This device proved to be very reliable, since it generated significant repeatable results with a low standard deviation, results which correlated significantly with those obtained from a force plate. Since this device incorporates a biofeedback system, it was also shown that patients recommended for FWB gait can significantly improve body weight loading over the affected limb during physical therapy gait rehabilitation.

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