Eur Spine J
DOI 10.1007/s00586-015-4004-0

ORIGINAL ARTICLE

Patients with chronic non-specific low back pain who reported reduction in pain and improvement in function also demonstrated an improvement in gait pattern

Yair Barzilay[1] · Ganit Segal[2] · Raphael Lotan[3] · Gilad Regev[4] · Yiftah Beer[5] · Baron S. Lonner[6] · Amit Mor[2] · Avi Elbaz[2]

Received: 29 January 2015 / Revised: 4 May 2015 / Accepted: 5 May 2015

Abstract
Purpose To assess the changes in gait pattern and clinical symptoms of patients with chronic non-specific low back pain (CNSLBP) following a home-based biomechanical treatment (HBBT).
Methods This was a retrospective analysis of 60 CNSLBP patients. All patients underwent a gait evaluation and completed self-assessment questionnaires at pre-treatment and after 3 and 6 months of a HBBT (AposTherapy). Twenty-four healthy, aged-matched individuals served as a reference group.
Results Significant differences were found in all gait parameters and clinical symptoms between patients with CNSLBP and healthy people before treatment. Significant improvements were found in all gait parameters and clinical measures following 6 months of therapy including an increase in gait velocity (10.6 %), step length (5.6 %), cadence (5 %), and quality of life and a decrease in pain (13.3 %). There were no significant differences between groups in the gait parameters following 6 months of treatment.
Conclusions Significant differences exist between patients with CNSLBP and healthy controls in terms of gait pattern and self-assessed health status. The examined HBBT led to significant improvements in gait pattern, reduction in pain, improved function and increased quality of life. However, future studies should validate these results while comparing this treatment to other treatment modalities.

Keywords Gait · Non-specific low back pain · Biomechanical treatment · Physical function · Pain

✉ Amit Mor
researchdept10@gmail.com

[1] Spine Division, Department of Orthopedic Surgery, Hadassah-Hebrew University Medical Center, Jerusalem, Israel

[2] AposTherapy Research Group, 1st Abba Even Blvd, Herzliya, Israel

[3] Department of Orthopaedic Surgery, Edith Wolfson Medical Center, Holon, Israel

[4] Department of Orthopaedic Surgery, Sourasky Medical Center, Tel Aviv, Israel

[5] Department of Orthopaedic Surgery, Assaf Harofeh Medical Center, Zerifin, Israel

[6] Spine Division, Department of Orthopaedic Surgery, Mount Sinai Medical Center Beth Israel Hospital, New York, USA

Introduction

Low back pain (LBP) is a leading cause of office visits to physicians and accounts for a significant percentage of disability claims [1]. It has an estimated lifetime incidence of 60–80 %. Of LBP patients, 80 % were categorized as suffering from non-specific LBP (NSLBP), defined as pain not attributable to any recognizable pathology. Within this category, 7–10 % of patients proceeded to develop chronic NSLBP with profound effects on their quality of life and work productivity [2, 3].

Patients with NSLBP have a different gait pattern compared to matched controls. They demonstrate slower walking speed, shorter step length and asymmetrical step length [4]. These changes are considered a protective strategy, as patients try to avoid extensive hip and spine ranges of motion and minimize forces acting on the body [5–7] which may cause pain. In addition, earlier studies examining gait found that NSLBP patients with diminished

Published online: 16 May 2015

gait characteristics suffer from impaired physical function [8, 9] and increased pain [4].

An important feature in NSLBP is the deterioration in neuromuscular control. NSLBP patients have been shown to suffer from changes in their biceps brachii activation [9], in balancing abilities [4, 5], anticipated perturbation [6], response to perturbations [7], reaching tasks [9] and gait [8, 10, 11]. These findings suggest that the rehabilitation of chronic NSLBP should not concentrate on a particular muscle or function. It must address wider perspectives of generalized neuromuscular control. In recent years, several publications regarding the effect of a novel non-invasive biomechanical device for different musculoskeletal disorders have been published [12–15]. A unique foot-worn device enables the relocation of the center of pressure [16] while training neuromuscular control [17]. More precisely, in a cohort of NSLBP patients treated with this device, an improved gait pattern was noted, as defined by increased walking speed through greater step length and the elimination of asymmetrical gait differences [18]. This study was limited by a small cohort, a short follow-up period and the absence of clinical measures of pain and function as well as a normal age-matched control.

The aims of the current study were:

1. To examine changes in spatiotemporal gait pattern following 3 and 6 months of treatment with the biomechanical device.
2. To study the effect of this treatment on physical function, pain and quality of life following 3 and 6 months of treatment.
3. To compare the baseline characteristics of patients with CNSLBP with the results of healthy age-matched group.
4. To compare the results of patients with CNSLBP after 6 months of treatment with the results of healthy age-matched group.

Materials and methods

Patients

A retrospective analysis was conducted by querying the AposTherapy database, which routinely collects spatiotemporal gait data and evaluates clinical symptoms during treatment. 544 patients with NSLBP joined AposTherapy between May 2009 and April 2013. Of the 544 patients, 108 had a gait test and self-administrated questionnaires at pre-treatment examination and following 3 and 6 months of therapy. Of the 108 patients, 48 were excluded due to one or more of the exclusion criteria (detailed below). Sixty eligible patients (25 men and 35 women) diagnosed with CNSLBP were analyzed. Their mean age (±SD) was 53.3 ± 14.0 years, mean (±SD) height was 168.2 ± 9.2 cm and mean (±SD) body mass index was 27.0 ± 5.1 kg/m^2. Chronic NSLBP was defined as low back pain not directly attributable to a specific pathology in accordance with the Quebec Task Force guidelines affecting patients for more than 3 months [19]. Exclusion criteria were specific back pain, non-specific back pain with referred pain to the lower/upper extremities, radiculopathy, severe systematic diseases, lower extremity orthopedic surgery, lower extremity joint pain or neurological deficits. During the activity of the therapy center, we asked healthy people to volunteer and undergo a gait test and complete self-administrated questionnaires. This group included healthy caregivers and family members of treated patients. The control group consisted of 24 healthy, aged-matched volunteers with a mean (±SD) age of 48.4 ± 13.1 years, a mean (±SD) height of 169.4 ± 8.6 cm and a mean (±SD) body mass index of 24.9 ± 3.6 kg/m^2. There were no significant differences between groups in age and height, whereas a significant difference was found in BMI. The demographic details of the two groups are summarized in Table 1. The study was approved by the medical center internal review board (IRB). The study was registered in the NIH clinical trial registration system (No. NCT00767780).

Gait analysis

The GaitMat^{TM} system (E.Q., Inc. Chalfont, PA) was used to measure gait spatiotemporal parameters. The computerized mat is an electronic walkway carpet that is 3.84 m long. The spatiotemporal characteristics are measured, processed and stored on a PC computer running the GaitMat software (version 2).

Physical function and pain assessment

The Oswestry Disability Index (ODI) was used as a disease-specific outcome measure. It consists of a series of self-reported questions measuring pain and physical

Table 1 Patients' characteristics

	CNSLBP	Healthy	*P**
No. patients	60	24	
Age (years)	53.3 (14.0)	48.4 (13.1)	0.146
Height (cm)	168.2 (9.2)	169.4 (8.6)	0.601
BMI (kg/m^2)	27.0 (5.1)	24.9 (3.6)	0.037

Results are presented as mean (SD)

* P value was set to $P < 0.05$

function and is scored from 0 to 100, where 0 is the best and 100 is the worst condition.

The Short Form Health Survey (SF-36) was used as a generic outcome measure. It consists of eight domains (pain, physical function, general health perceptions, physical role function, emotional role function, social function, emotional well-being and vitality) which can be tallied to create a physical score and a mental score. Each measure is scored from 0 to 100, where 0 indicates the worst and 100 the best patient health.

Intervention

The biomechanical device is a home-based functional rehabilitation treatment program that integrates the use of a novel biomechanical device into the patient's daily routine. The biomechanical device is made up of four convex biomechanical units attached to two foot-worn platforms in the form of shoes (AposTherapy System, APOS—Medical and Sports Technologies Ltd., Herzliya, Israel) (Fig. 1). Each shoe is equipped with a specially designed sole, which consists of two mounting rails that enable flexible positioning of each element under each region. One element is located under the hindfoot and the other is located in the forefoot region. Each element can be individually calibrated to induce specific biomechanical challenges in multiple planes.

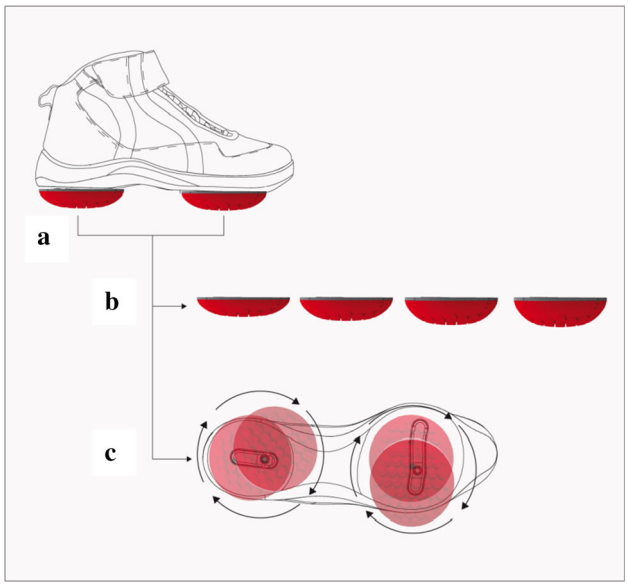

Fig. 1 The biomechanical device. **a** Biomechanical device comprising two individually calibrated elements and a foot-worn platform. The elements are attached under the hindfoot and forefoot regions of the platform. **b** The biomechanical elements are available in different degrees of convexity and resilience. **c** The specially designed sole of the platform includes two mounting rails and a positioning matrix to enable flexible positioning of each biomechanical element

Protocol

All patients conducted a computerized gait test. During the test, all patients walked barefoot at a self-selected speed. Patients walked 3 m before and after the mat to allow for sufficient acceleration and deceleration time outside the measurement area. Each gait test included four walks, and a mean value was calculated for each parameter. The following gait parameters were evaluated: velocity (cm/s), cadence (steps/m), step length for each leg (cm), stance phase (% gait cycle, GC) for each leg and single limb support (SLS) phase (% GC) for each leg. In addition, patients were asked to complete the ODI and the SF-36 questionnaires. After the first gait test, the biomechanical device was individually calibrated to each patient by a physiotherapist specialized in AposTherapy methodologies.

Patients commenced therapy the day after they met the physiotherapist. It continued on a daily basis for a period of 6 months. Patients were instructed to wear the device indoors while doing their routine for 10 min and gradually reaching to 2 h (accumulating 45–60 min walk). After 1 month of therapy, patients were encouraged to walk outdoors with the device for a few minutes every day. All patients received a telephone call after the first and second week to verify compliance. Patients underwent a second and a third evaluation of their gait pattern, ODI and SF-36 questionnaires after 3 and 6 months of therapy.

A group of 24 healthy aged-matched people conducted a gait test and were asked to complete the ODI and SF-36 questionnaires and served as a control group representing normative values.

Statistical analysis

All spatiotemporal gait parameters and questionnaires scores were presented as means and standard deviations, followed by 95 % confidence interval for all time periods. Non-parametric one-sample Kolmogorov–Smirnov tests were calculated to compare the observed cumulative distribution function for the continuous variables with the normal theoretical distribution. Differences between CNSLBP patients and the control group were measured by the independent t test. The general linear model (GLM) repeated measures procedures were used to provide analysis of variance for gait parameters and self-administered questionnaires when the same measurement was made three times on each subject. The correlation between the level of improvement of the gait parameters (post-treatment results minus pre-treatment results) and the level of symptoms pre-treatment was calculated using linear Pearson correlation.

Data were analyzed with IBM SPSS software version 21.0 and the significant level was set at 0.05.

Results

Patients received a telephone call after 1 week to verify compliance. Patients were also interrogated on compliance at every follow-up session. All patients complied with the study protocol and none reported any adverse events that disqualified them from the study.

Significant differences were found in all gait parameters following 3 months of treatment and maintained at 6 months ($P < 0.01$). Table 2 summarizes the improvement in gait velocity (a 10.6 % increase), cadence (a 5.0 % increase), step length (a 5.6 % increase), stance phase (a 1.2 % decrease) and single limb support phase (a 2.1 % increase) following 6 months of therapy. Table 2 also summarizes the parameters of the control group. Significant differences were found in pre-treatment gait pattern of patients with CNSLBP compared to healthy people ($P < 0.05$). There were no significant differences in gait parameters between groups following 6 months of therapy.

The clinical patient-reported outcome measures of the two groups are summarized in Table 3. A statistically significant improvement was found in the ODI score and the SF-36 scores after 6 months in the treatment group ($P < 0.01$). The ODI score decreased by 3.7 points with an overall improvement of 13.3 % ($P = 0.047$) following 6 months of treatment. SF-36 physical score increase by 8.1 s points with an overall improvement of 15.9 % following 6 months of treatment ($P = 0.018$) and SF-36 mental score increased by 6.6 points with an overall improvement of 10.5 % following 6 months of treatment ($P = 0.052$). Table 3 also presents the results of healthy people. Statistically significant differences were found in the ODI scores and the SF-36 physical and mental scores of patients with CNSLBP and healthy people pre-treatment and following 6 months of treatment ($P < 0.01$).

The correlation values between the level of improvement of gait parameters (post-treatment results minus pre-treatment results) and the level of symptoms pre-treatment were minuscule, ranging between 0.028 and 0.096.

Discussion

According to the European guidelines for the management of CNSLBP, the numerous aspects of diagnostic assessments and therapy modalities have limited positive evidence. Multidisciplinary rehabilitation programs are aimed at reducing the disability of CNSLBP patients, rather than concentrating on improvement of pain [20]. There is no single intervention that was found to be effective in treating the overall problem of CNSLBP, mainly due to its multidimensional nature. However, the most promising approaches seem to be combined cognitive–behavioral–endurance based interventions encouraging activity/exercise [21]. The current study evaluated the effect of a home-based non-invasive biomechanical treatment that is based on self-exercise during the patient's daily routine. Following 6 months of treatment, patients normalized their

Table 2 Changes in gait characteristics following 6 months of therapy

	Baseline	3 months	6 months	Healthy controls	*P* Base 3 m	*P* Base 6 m
Velocity (cm/s)	102.6 ± 17.3 [98.1–107.0]	111.5 ± 15.3 [107.5–115.5]	113.5 ± 17.3 [109.1–118.0]	117.1 ± 16.9 [110.0–124.2]	<0.001	<0.001
Cadence (steps/m)	107.2 ± 8.4 [105.0–109.4]	112.0 ± 8.2 [109.8–114.1]	112.6 ± 8.6 [110.4–114.8]	111.0 ± 7.1 [108.0–114.0]	<0.001	<0.001
Left step length (cm)	57.2 ± 8.0 [55.2–59.3]	59.6 ± 7.2 [57.7–61.4]	60.3 ± 8.1 [58.2–62.4]	63.0 ± 7.0 [60.1–66.0]	<0.001	<0.001
Right step length (cm)	57.3 ± 7.7 [55.3–59.3]	59.9 ± 6.7 [58.2–61.6]	60.6 ± 7.8 [58.6–62.6]	63.2 ± 7.5 [60.1–66.4]	<0.001	<0.001
Left stance (% GC)	61.1 ± 1.9 [60.6–61.6]	60.6 ± 2.1 [60.3–61.3]	60.3 ± 1.8 [59.8–60.7]	60.1 ± 1.3 [59.6–60.7]	0.010	<0.001
Right stance (% GC)	61.3 ± 2.1 [60.8–61.9]	60.8 ± 1.9 [60.3–61.3]	60.6 ± 2.0 [60.1–61.1]	60.4 ± 1.4 [59.8–61.0]	<0.001	<0.001
Left SLS (% GC)	38.7 ± 2.0 [38.2–39.2]	39.3 ± 1.9 [38.8–39.8]	39.5 ± 2.0 [39.0–40.0]	39.7 ± 1.5 [39.1–40.3]	<0.001	<0.001
Right SLS (% GC)	39.0 ± 1.8 [38.5–39.5]	39.4 ± 1.8 [39.0–39.9]	39.8 ± 1.7 [39.4–40.3]	40.0 ± 1.2 [39.5–40.5]	0.009	<0.001

Results are presented as mean ± SD [95 % CI]

SLS single limb support, *GC* gait cycle

Table 3 Questionnaire results following 6 months of therapy

	Baseline	3 months	6 months	Healthy controls	*P* Base 3 m	*P* Base 6 m
Oswestry Disability Index (0–100 %)	27.8 ± 12.6 [24.6–31.1]	24.8 ± 11.9 [21.7–27.9]	24.1 ± 13.3 [20.7–27.6]	5.7 ± 5.7 [3.2–8.1]	0.028	0.047
SF-36 Health Survey						
SF-36 Physical score	50.9 ± 16.4 [46.9–55.4]	60.1 ± 16.6 [56.2–64.8]	59.0 ± 19.1 [54.0–64.0]	82.8 ± 8.3 [79.3–86.3]	<0.001	0.018
SF-36 Mental score	62.6 ± 17.4 [57.9–67.1]	70.9 ± 16.1 [66.6–75.1]	69.2 ± 16.9 [64.8–73.6]	79.2 ± 13.9 [73.4–85.1]	<0.001	0.052

Results are presented as mean ± SD [95 % CI]

gait pattern including increased velocity, cadence, step length and single limb support. These results correspond to an earlier report on the same biomechanical device [18]. In addition, there was a smaller, but statistically significant reduction in disability and a significant improvement in function and quality of life.

Patients with NSLBP have different gait pattern compared to matched controls which is considered a protective strategy as patients try to avoid extensive hip and spine ranges of motion and minimize forces acting on the body [5–7], which may cause pain. Furthermore, the lower back and lower extremity musculoskeletal pathologies are often characterized by abnormal gait, which may deteriorate over time and lead to worsening of symptoms and even result in the presence of pain in other lower extremity joints [22]. In the current study, at pre-treatment evaluation, patients demonstrated altered gait pattern compared to healthy matched controls. Previous studies have shown that when patients with LBP are asked to increase their gait velocity, they tend to increase cadence rather than step length, as opposed to pain-free individuals. This strategy is considered a protective mechanism as patients try to avoid extensive hip and spine ranges of motion and minimize forces and moments acting on the body [5]. Interestingly, when comparing the pre-treatment results of the CNSLBP patients and the control group, a prominent difference in step length rather than cadence was noted, supporting previous knowledge. Following 6 months of treatment, there were no significant differences between CNSLBP patients and healthy age-matched people, which may indicate that CNSLBP patients felt more confident while walking.

The improvements in gait pattern were accompanied by a reduction in pain and improvement in function and quality of life. With regard to the changes in ODI scores, there was a statistically significant reduction of 3.7 points equal to 13.3 %. Several studies have calculated the minimum clinically significant change in ODI score with results ranging from 4 to 15 points [23, 24]. In the current study, the patients started with a mean ODI score of 27.8, a relatively low score, indicating mild disability. The improvement found in the present study does not fall within the minimal clinically important change mentioned in most of the studies above. A possible explanation is the low initial score pre-treatment that makes it difficult to see a clinically significant improvement. According to Davidson and Keating, when the initial ODI score is low, very small changes should be perceived as important [23]. It is possible that had this study included patients with more significant functional limitations, a clinically significant improvement would have been recorded. Future studies should include a group of CNSLBP patients with higher ODI and pain scores at baseline. With regard to the SF-36 Health Survey, patients demonstrated a significant increase of 15.9 and 10.5 % in the physical score and mental score, respectively. Although both the ODI and the SF-36 scores improved following treatment, they did not reach those of healthy age-matched people.

In summary, although patients with CNSLBP improved their gait pattern to match healthy people following treatment, they demonstrated inferior self-assessed levels of pain and function. It is difficult to determine the reasons for these results. However, we assume that having suffered for a long time makes it difficult to internalize the positive improvement seen in the objective gait parameters. It may also be that patients are more active than before and pain still exists. Future study should examine the changes in pain, function and quality of life after a longer follow-up period, or in combination with behavioral interventions.

Some drawbacks to this study should be acknowledged. First, this is a retrospective study with no placebo control group. Although this study included a group of healthy age-matched patients that served as a reference group representing normal values, there is a need for a prospective study including a control group to determine the actual effect of this treatment and denounce a placebo effect. Second, this study included only spatiotemporal gait data rather than a three-dimensional gait analysis that provide more information on the kinematics and kinetics. A three-dimensional gait test, however, is relatively cumbersome and costly. We sought to define objective gait parameters

that can be easily obtained at a relatively low cost, thus making them ideal for clinical practice.

Conflict of interest Avi Elbaz and Amit Mor hold shares in AposTherapy. Ganit Segal is a salaried employee of AposTherapy. Yair Barzilay, Raphael Lotan, Gilad Regev, Yiftah Beer and Baron S Lonner are co-researchers in a number of studies. They do not receive and are not entitled to any financial compensation from AposTherapy.

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