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A Non-Invasive Foot-Worn Biomechanical Device for Patients with Hip Osteoarthritis

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Abstract

Objective: The purpose of this study was to evaluate the effect of a biomechanical therapy on the pain, function, quality of life and spatio-temporal gait patterns of patients with hip osteoarthritis (OA).

Design: 60 patients with hip OA were examined before and after twelve weeks of a personalized biomechanical therapy (AposTherapy). Patients were evaluated using the WOMAC questionnaire for pain and function and the SF-36 Health Survey for quality of life, and underwent a computerized gait test.

Results: After twelve weeks of treatment, a significant improvement was found in the patients' velocity, step length and cadence ($P \leq 0.001$). WOMAC-pain, stiffness and function subscales were significantly improved compared to baseline ($P \leq 0.001$). SF-36 physical score subscale improved significantly ($P=0.007$).

Conclusions: Patients with bilateral hip OA treated with AposTherapy for twelve weeks showed statistically and clinically significant improvements in pain, function and gait patterns.

Keywords: Osteoarthritis; Hip; Gait; Biomechanics; Pain; Quality of life

Introduction

Osteoarthritis (OA) is a major health concern in modern society, affecting 10% of men and 21% of women over age 65. The hip joint is the second most common lower limb site after the knee [1], with an estimated prevalence of 1% - 11% [2].

Several articles have described locomotor deviations typical of individuals suffering from hip OA. The spatio-temporal gait of this population is characterized by a lower walking speed, lower cadence, shorter step length and shorter single limb support phase of the involved leg [3-5]. It is likely that patients continuously adapt their gait in response to pain, deformity or laxity in the joints of the lower extremities as their disease progresses [6] These gait adaptations may influence the motion of the lower back and other joints of the lower extremities [7]. A recent study by Shakoor et al. explained that unilateral end-stage hip (OA) can lead to degenerative changes and eventually end-stage knee OA in the contralateral limb. Moreover, the loading and structural asymmetries appear early in the disease course, while the knees are still asymptomatic [8].

Treatments for OA are typically directed at the management of symptoms, with a goal of pain relief and improved function. Several studies emphasize the importance of physical therapy and biomechanical intervention for patients with hip OA, claiming that such therapies should aim to restore or maintain gait patterns close to normal, as well as improve walking efficiency and quality of life (QoL) [9,10]. However, a recent meta-analysis from 2009, which reviewed more than 4,000 articles, concluded that there was insufficient evidence to suggest that exercise therapy was an effective short-term management approach for reducing pain levels, improving joint function and QoL [11]. A novel biomechanical device (Apos System, APOS—Medical and Sports Technologies Ltd.) was recently introduces as a non-invasive therapy for different musculoskeletal problems [12-15]. Haim et al. showed that by using this biomechanical intervention for symptomatic bilateral knee OA, walking velocity and functional activity were increased while knee adduction moment and pain were reduced [16]. The effect of this therapy has not been assessed in patients with hip OA, although it may be assumed that the same biomechanical principles apply.

The purpose of this current study was to examine the efficiency of this biomechanical therapy on the gait patterns and clinical symptoms in patients with hip OA. We hypothesize that patients who undergo this therapy will show improvement in gait patterns and function, as well as a relief in pain.

Methods

Participants

This was a retrospective study. The protocol was approved by the Institutional Helsinki Committee Registry (Registration number NCT00767780). A search for eligible data was performed through the research database of AposTherapy Center. Eligibility for the study was defined as follows: 1. Patients suffering from symptomatic hip OA for at least six months and who fulfilled the American College of Rheumatology clinical criteria for OA of the hip [17]; 2. Patients who completed a gait test, the Western Ontario and McMaster Osteoarthritis Index WOMAC [18] questionnaire and the Short Form SF-36 Health Survey [19] at the start of therapy (study baseline) and after twelve weeks of therapy. Exclusion criteria were: 1. Neurological and rheumatic inflammatory diseases; 2. Corticosteroid injection within 3 months of the study; 3. Earlier hip surgery excluding arthroscopy; 4. Joint replacement of the hip or knee; 5. Instability of the hip due to traumatic ligament injury; 6. OA in other lower extremity joints other

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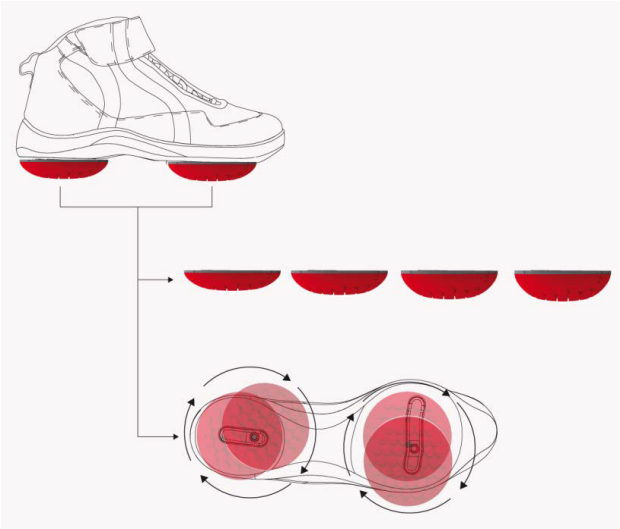

Figure 1: Biomechanical platform and mobile elements.
A unique biomechanical device comprising of two individually calibrated biomechanical elements that are attached to a specially designed sole with two mounting rails and positioning matrix to enable flexible positioning of each biomechanical element. One element is attached under the hindfoot and the second element is attached under the forefoot. The biomechanical elements are available in different degrees of convexity and resilience.

than hips 7. Other trauma to the hip joint 8. OA due to Developmental Dislocation of the Hip (DDH).

Three hundred and eighty patients with primary hip OA joined AposTherapy between May 2009 and July 2012. Two hundred and thirteen did not have a gait test and/or questionnaires at pre-treatment assessments and/or post 3 months of treatment. Ninety seven patients had one of more of the exclusion criteria. Overall, 60 patients met inclusion criteria. Patients' characteristics are summarized in Table 1.

Intervention

A novel biomechanical device (Apos System, Apos medical and sports technologies Ltdl) comprised of convex adjustable pods placed under the hind-foot and fore-foot regions of each foot were used (Figure 1). This device enables customized calibration of the biomechanical elements, which allows for control of body alignment and promotion of perturbation throughout all phases of the step cycle.

Protocol

Prior to their first and second examinations, patients were instructed not to consume pain medications for at least 72 hours in order to eliminate the effect of these medications on the results. Anthropometric measurements were drawn from the medical file of the patients. All patients underwent a computerized gait analysis using the GaitMat system (E.Q., Inc. Chalfont, and PA) [20]. During the gait test, all patients walked barefoot at a self-selected speed. Each gait test included 4 walks and the mean value of the 4 walks was calculated for each of the following parameters: velocity (cm/s), cadence (steps/min), step length (cm), stance phase (% gait cycle), Single Limb Support (SLS) (% gait cycle).

Patients were then asked to complete the WOMAC questionnaire and the SF-36 Health Survey. The WOMAC questionnaire is a Visual Analogue Scale (VAS), with 3 sub-categories: pain, stiffness and function, ranging from 0 to 100 mm, with 0 mm indicating no pain or limitation in function and 100 mm indicating the most severe pain or limitation in function. The SF-36 has 8 sub-categories from which two scores are calculated: A Physical score and mental score. Results range between 0 and 100, with 0 indicating the worst QoL and 100 indicating the best QoL.

After the completion of the baseline measurements, the biomechanical device was individually calibrated to each patient by a physiotherapist certified in AposTherapy methodology. The principle of calibration is to bring each of the patient's joint to a position that allows for diminished pain while walking. Biomechanically, shifting the elements on the shoe changes the foot's COP during gait, thus altering the orientation of the Ground Reaction Force (GRF) vector and reducing loads from the affected area of the joint while walking [21-23]. Once the desired alignment is achieved, the patient should report immediate pain relief while walking. Treatment was then initiated and continued on a daily basis for a period of 12 weeks. Patients were instructed to put on the biomechanical device and go about their ADL for 10 minutes each day during the first week (actual walking time of 3-4 minutes) and gradually increase to 60 minutes a day by the fourth week and for the remainder of the treatment period (actual walking time of 20-25 minutes). After 12 weeks of therapy, patients underwent a second gait analysis and completed a second WOMAC questionnaire and SF-36 Health Survey.

Statistical analysis

Data were analyzed with SPSS software version 19.0 and were presented as mean and standard deviation for all gait spatio-temporal parameters and self-evaluation questionnaires. The distributions of the variables in the study were examined using the Kolmogorov-Smirnov non-parametric test. To demonstrate the level of improvement of gait spatio-temporal parameters and self-evaluation questionnaires, over time, paired sample t-tests were performed and the percent of improvement, compared to baseline, were calculated. Correlations between baseline measurements including age, gender and BMI, and the differences of the measurements over time were demonstrated using Pearson correlations. Independent t-tests were calculated to found differences in the extent of improvement in gait parameters between sub-groups of gender and obesity (BMI>30). Significance levels were set at 0.05.

Results

Baseline and changes in gait spatio-temporal and questionnaires following twelve weeks of therapy are presented in Tables 1 and 2, respectively. There were no reports of any adverse events, including imbalance, tripping or other physical problems during the study period.

A significant improvement was found in the patient's velocity with more than an 11% increase (P=<0.001), patients had increased their step length and cadence in about 6% and 5%, respectively (P<0.001). Patients demonstrated a mean reduction of 0.9% in stance phase (P<0.001) and a 2.4% increase in SLS (P=0.003). All other gait parameters did not differ significantly over time. Results are summarized in Table 2.

	Study population
N (Female, %)	60 (41, 22.3%)
Age (years)	65.0 (8.4)
Height (cm)	1.64 (0.09)
Weight (kg)	78.9 (20.1)
BMI (kg/m^2)	29.0 (7.5)
Duration of symptoms	**43.1 (54.4)**

Table 1: Patients characteristics. Results are presented as mean (sd).

	Baseline	3 Months	Mean difference	P*
Velocity (cm/sec)	91.7 (22.3)	102.4 (19.9)	10.7 (15.3)	<0.001
Cadence (steps/min)	70.2 (7.4)	73.9 (6.0)	3.7 (5.7)	<0.001
SL more affected hip (cm)	53.1 (9.0)	56.5 (9.2)	3.4 (5.0)	<0.001
SL less affected hip (cm)	51.2 (10.5)	54.7 (9.7)	3.5 (5.9)	<0.001
BOS more affected hip (cm)	6.6 (3.3)	6.7 (4.0)	0.1 (2.6)	0.887
BOS less affected hip (cm)	6.7 (3.5)	6.7 (4.1)	0.0 (2.6)	0.943
Stance phase more affected hip (% GC)	61.3 (2.8)	60.8 (2.1)	-0.5 (1.2)	<0.001
Stance phase less affected hip (% GC)	62.5 (3.2)	61.7 (2.5)	-0.8 (2.3)	P=0.005
SLS phase more affected hip (% GC)	37.5 (3.2)	38.5 (2.6)	1.0 (2.3)	P=0.003
SLS phase less affected hip (% GC)	38.7 (2.3)	39.3 (2.1)	0.6 (1.3)	<0.001

Abbreviations: SL: Step Length; BOS: Base of Support; GC: Gait Cycle; SLS: Single Limb Support
* Significant level was set to P ≤ 0.05

Table 2: Gait spatio-temporal changes following 12 weeks of Therapy. Results are presented as mean (sd).

	Baseline	3 Months	Mean difference	P***
WOMAC Index*				
Pain	48.0 (19.7)	31.2 (20.9)	-16.8 (18.80)	P<0.001
Stiffness	49.9 (26.8)	37.3 (28.6)	-12.6 (25.2)	P<0.001
Function	44.5 (17.9)	34.1 (20.9)	-10.4 (11.3)	P<0.001
SF-36 Health Survey**				
SF-36 overall score	52.2 (14.2)	56.0 (15.8)	3.8 (13.5)	0.032
SF-36 physical scale	45.8 (15.1)	51.1 (16.8)	5.3 (13.8)	P=0.007
SF-36 mental scale	61.2 (15.6)	64.1 (15.6)	2.9 (15.3)	P=0.141

*WOMAC Index - Western Ontario and McMaster Universities Index. The WOMAC questionnaire includes 24 questions in a VAS format (0=no pain/stiffness/difficulty, 100=severe pain/stiffness/difficulty).
** SF-36 Health Survey includes 36 questions. Results range between 0-100 (0=poor quality of life, 100=high quality of life).
*** p-value was set to p<0.05.

Table 3: Self-evaluation questionnaires changes following 12 weeks of therapy. Results are presented as mean (sd).

After 12 weeks of treatment the WOMAC-pain, WOMAC-stiffness and WOMAC-function subscales were significantly lower. Pain decreased by 35.0% (P<0.001), stiffness decreased by 25.3% (P<0.001), and functional disability decreased by 23.4% (P<0.001). The extent of improvement in the level of pain and function meets with the OARSI-OMERACT criteria for clinical response to treatment. The SF-36 health survey improved after 12 weeks of treatment with an overall improvement of 7.3%. Physical score subscale improved by 11.6% (P=0.007) whereas the mental score increased by 4.7% but did not reach a level of statistical significance. Results are summarized in Table 3.

A correlation between the extent of improvement and patients' characteristics (age, gender and BMI) was calculated. There was no significant correlation between age/gender and the extent of improvement neither in gait parameters nor in self-evaluation questionnaires. A significant positive correlation was found between BMI and the extent of improvement in gait parameters (P<0.05). There was no significant correlation between BMI and the extent of improvement in pain, function and quality of life. In order to further understand the effect of BMI of treatment outcomes a more specific analysis was conducted. Patients were divided into two groups of BMI (Below and above a BMI value of 30 kg/m^2). Thirty-five patients were with a BMI below 30 kg/m^2 and 15 patients were with a BMI value above 30 kg/m^2. There were no significant differences in none of the measured variables between the groups at baseline. Nevertheless, a significant difference was found between the groups in the extent of improvement in the following gait parameters: more and less symptomatic step length (P=0.011 and P=0.004, respectively), more and less symptomatic swing phase (P=0.010 and P=0.013 respectively), more and less symptomatic stance phase (P=0.010 and P=0.013, respectively), more and less symptomatic SLS phase (P=0.013 and P=0.015, respectively) and more and less symptomatic DLS (P=0.002 and P=0.002, respectively). This phenomenon is presented in Figure 2.

Discussion

The American College of Sports Medicine and Physical Activity Guidelines Advisory Committee formulated recommendations for adults with arthritis [24]. These guidelines prescribe a minimum of 30 minutes of moderate intensity exercise at least five times a week to promote cardiovascular health, with at least a couple of sessions of muscle strengthening activity each week as well. These guidelines are clearly demanding for individuals with OA of the hip, given the associated pain, loss of function, depression and poor self-efficacy [25]. Epidemiology data concerning physical activity levels of individuals demonstrates that approximately 42% of men and 32% of women older than 65 years were participating at these recommended levels of physical activity [26].

Several studies have emphasized the importance of physical therapy for patients with hip OA [9,11]. Recommended modalities specific to hip OA include manual therapy, exercise program, hydrotherapy, electro-acupuncture, acupuncture with advice and home exercises. There is, however, 'insufficient evidence' to support exercise as a treatment to decrease pain or to improve function [11,27-31].

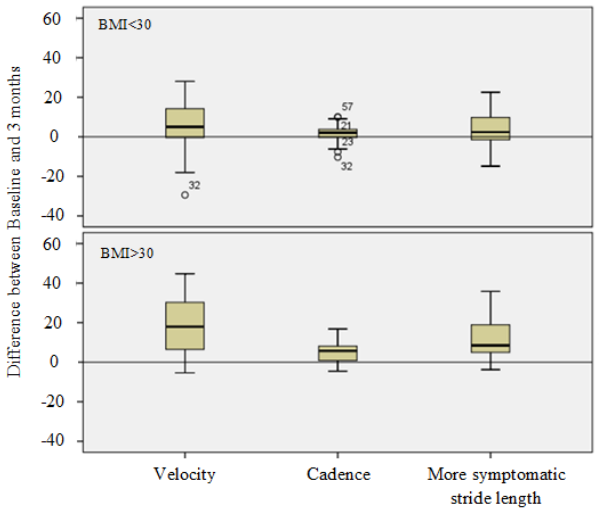

Figure 2. Differences in the extent of improvement between the two BMI groups.
Figure 2 represents the variation in improvements rates in selected gait parameters (velocity, cadence and more symptomatic stride length). The upper graph represents patients with a BMI<30 kg/m^2 and the lower graph represent patients with a BMI>30 kg/m^2. The Y axis represents the level of improvement (i.e. the difference between the end-point results minus the pre-treatment results). The units of the Y axis are the absolute values of the measured parameter (velocity=cm/s, cadence=steps/min, more symptomatic step length=cm). A positive value indicates an improvement in gait measures and a negative value represent worsening of gait measures. Although both groups improve significantly following therapy, patients with a BMI>30 kg/m^2 improved to a greater extent (velocity – p=0.002, cadence – p=0.018, More symptomatic stride length – p=0.005).

The use of AposTherapy in the present study showed significant improvement in the subjective reports of pain and function after twelve weeks, as demonstrated by the significant improvement in the self-evaluation symptoms and QoL assessment questionnaires, as well as in the significant improvement in gait patterns. The improvement in the WOMAC-pain and WOMAC-function subscales met the OMERAC-OARSI guidelines for the minimum improvement threshold that would qualify as a clinical improvement for the patient [32].

A statistically significant improvement was seen in all objective gait analysis parameters, excluding BOS. Patients demonstrated a significantly higher walking speed (91.7 cm/s to 102.4 cm/s), step length (53.1 cm to 56.5 cm) and cadence (70.2 steps/min to 73.9 steps/min). In addition, patients decreased their stance phase of the more affected hip from 61.3% GC to 60.8% GC and increased their SLS phase in the more affected hip from 37.5 to 38.5 indicating an improved ability to maintain single limb loads on the more affected limb. These improvements alongside an improvement in function and a reduction in pain suggest an overall improvement in patients' functional state.

The examined biomechanical therapy is theorized to work via two principles: changing the location of the COP (alignment) and repetitive perturbation movements (neuromuscular). The device is calibrated to each patient after baseline assessment. Calibration of the biomechanical elements changes the location of the COP and lead to a shift in the external moments acting on the hip joint [22]. The resultant shift can reduce the load on the affected side of the leg, improving both pain and functional disability. Repetitive unconscious perturbation movements that train neuromuscular performance (a requirement for motor learning), is achieved due to the fact that the patient is wearing the device during his working environment while performing activities of daily living. These continuous repetitive perturbation movements performed at hundreds of repetitions per day allow the body to learn, even without realizing it, correct movement patterns. This makes the treatment easy to comply with.

Bar-Ziv et al., in a prospective, sham control study that evaluated the effect of this therapy in patients suffering from knee OA, demonstrated an improvement in function and a reduction in pain following eight weeks of therapy in the experimental group, without similar changes in the level of pain and function in the control group [13]. Elbaz et al. in a study on patients with knee OA, showed that three months of therapy with the biomechanical device led to significant improvement in function, pain and gait parameters [14]. The current study supports these findings, demonstrating similar improvements in pain, function, QoL and gait patterns in patients with bilateral hip OA. An interesting finding of this study was the correlation between BMI and the extent of improvement in gait parameters. A significant positive correlation was found between BMI and the extent of improvement. Patients were divided into two groups of BMI (Below and above a BMI value of 30 kg/m^2). There were no significant differences in none of the measured variables between the groups at baseline. Nevertheless, a significant positive correlation was found. Although both groups demonstrated improved gait patterns, heavier patients might have improved to a greater extent in their gait patter. The fact that heavier patients improved to a greater extent in their gait patterns but not in their levels of pain, function and quality of life was surprising, especially since the overall cohort did demonstrate a significant improvement in both the gait patterns and in the pain, function and quality of life. It is difficult to determine the reasons for this finding, and we suggest that future studies will examine this to a greater depth including monitoring changes in BMI following therapy.

This study had some limitations. First, the study lacked a control group. The study, however, evaluated changes in objective gait parameters, which should minimize the placebo effect. A future randomized study should examine the effects of this therapy compared to a placebo control group to support and strengthen the preliminary findings of this study. Secondly, the impressive finding of this study could result from regression to the mean. Patients tend to seek help when the severity of their symptoms is high and may improve with or without any treatment. Furthermore, there is missing information regarding other treatment modalities during the study period including pain medication consumption, injections and other exercise modalities, which could have affected the results of this study. Thirdly, longer follow-up studies are needed.

Conclusions

Patients with bilateral hip OA treated with AposTherapy for twelve weeks showed statistically and clinically significant improvements in pain, function and objective gait parameters. In light of this evidence, this therapy may be an additional useful tool for conservatively treating patients with hip OA.

Acknowledgements

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Conflict of Interest

Avi Elbaz and Amit Mor hold shares in AposTherapy, Ganit Segal is a salaried employee of AposTherapy, Michael Drexler, Amir Haim, Udi Rath and Moshe Salai 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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