A novel self-care biomechanical treatment for obese patients with knee osteoarthritis

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Abstract

Aim: To examine the effect of a novel biomechanical, home-based, gait training device on gait patterns of obese individuals with knee OA.

Methods: This was a retrospective analysis of 105 (32 males, 73 females) obese (body mass index > 30 kg/m²) subjects with knee OA who completed a 12-month program using a biomechanical gait training device and performing specified exercises. They underwent a computerized gait test to characterize spatiotemporal parameters, and completed the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and Short Form-36 (SF-36) Health Survey. They were then fitted with biomechanical gait training devices and began a home-based exercise program. Gait patterns and clinical symptoms were assessed after 3 and 12 months of therapy.

Results: Each gait parameter improved significantly at 3 months and more so at 12 months (P = 0.03 overall). Gait velocity increased by 11.8% and by 16.1%, respectively. Single limb support of the more symptomatic knee increased by 2.5% and by 3.6%, respectively. There was a significant reduction in pain, stiffness and functional limitation at 3 months (P < 0.001 for each) that further improved at 12 months. Pain decreased by 34.7% and by 45.7%, respectively. Functional limitation decreased by 35.0% and by 44.7%, respectively. Both the Physical and Mental Scales of the SF-36 increased significantly (P < 0.001) at 3 months and more so following 12 months.

Conclusions: Obese subjects with knee OA who complied with a home-based exercise program using a biomechanical gait training device demonstrated a significant improvement in gait patterns and clinical symptoms after 3 months, followed by an additional improvement after 12 months.

Key words: biomechanical device, function, gait, knee osteoarthritis, pain.

INTRODUCTION

Knee osteoarthritis (OA) is a common disease caused by multiple factors. It is well established that obesity is strongly linked to knee OA and is considered a risk factor for both incidence and progression.1,2 Obese people (body mass index [BMI] > 30 kg/m²) are at a 4.2–6.8 times higher risk of developing knee OA than matched normal weight controls.3,4 Ettinger et al. examined the effects of comorbid diseases on disability and found that knee OA and obesity were each significantly associated with poorer physical function, with odds ratios of 4.3 and 1.7, respectively. When obesity was combined with knee OA, the odds ratio increased to 9.8.4

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The gait patterns of obese people have been well characterized. Those with knee OA tend to walk slower, have shorter step length, lower cadence and single-limb support (SLS). Lower SLS values indicate that patients have difficulty in bearing body weight on the arthritic knee while the contralateral limb swings forward. They also demonstrate higher knee adduction moment, a feature that has been linked to the severity of knee OA. Excessive mechanical loading has been implicated in the progression of knee OA. Potentially increased cumulative load in obese subjects and the fact that they spend a greater proportion of the gait cycle in stance phase during which the greatest loading occurs, contribute to the development of OA.

A recent review and meta-analysis by Christensen et al. examined the effect of weight reduction in obese patients diagnosed as having knee OA. They found that disability could be significantly improved when weight was reduced by 5.1% of body weight within a 20-week period, or at the rate of > 0.24% of body weight reduction per week. However, individuals with knee OA are less active due to pain and physical limitation. It is, therefore, often difficult for them to comply with an exercise program.

Several biomechanical treatments for knee OA have emerged with the goal of reducing pain, improving function and halting disease progression. These treatments aim to unload the diseased articular surface by using wedged insoles, foot orthoses, special shoes or valgus braces. Other treatments have been designed to modify neuromuscular patterns, with a specific goal of improving gait patterns. One biomechanical device and therapy (AposTherapy) that has received attention in recent years is thought to both unload the diseased articular surface, as well as train neuromuscular control (Fig. 1). The aim of this study was to examine the effect of this unique biomechanical gait-training device on gait patterns of obese individuals with knee OA.

METHODS

Study design and population

This was a retrospective study based on the information retrieved from the database of one AposTherapy center. Individuals are referred to this treatment by general practitioners and orthopedic surgeons from general community medical care services. The study protocol was approved by the Helsinki Committee Registry of Assaf Harofeh Medical Center (Helsinki registration number 141/08 and NIH clinical trial registration number NCT00767780). Inclusion criteria were: diagnosis of symptomatic bilateral knee OA of the medial compartment for at least 6 months, fulfilling the American College of Rheumatology clinical criteria for OA of the knee, a body mass index (BMI) > 30 kg/m², having undergone a gait test and having completed questionnaires at baseline and after 3 and 12 months of therapy. Exclusion criteria were acute septic or inflammatory arthritis, corticosteroid injection within 3 months of study entry, avascular necrosis of the knee, history of knee buckling or recent knee injury, joint replacement, neuropathic arthropathy, history of pathological osteoporotic fracture, and/or symptomatic degenerative arthritis in lower limb joints other than the knees. Also excluded were individuals known to have diabetes, major cardiac conditions, pulmonary diseases and any other pathology that precludes their carrying out the required exercises.

Intervention

The biomechanical device and treatment methodology have been previously described in depth. The biomechanical device is attached to the hindfoot and forefoot regions of the platform. The elements are available in different degrees of convexity and resilience. The specially designed sole of the platform includes two mounting rails and a positioning matrix to enable flexible positioning of each biomechanical element.
Physiotherapist. The protocol was similar to the one reported by Drexler et al. In summary, treatment was initiated after first calibration of the biomechanical device and continued on a daily basis for a period of 12 months. Patients were instructed to put on the biomechanical device and continue with the daily activity for 10 min once a day during the first week, and gradually increase to 90 min once a day at 12 weeks and for the rest of the treatment period. Patients returned for a follow-up examination after 3–4 weeks, 3, 6, 9 and 12 months from the initial consultation. If necessary, the Apos system was recalibrated. The patient then continued with the therapy in his or her personal environment according to the physiotherapist’s instructions.

Measurements

The Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and Short Form-36 (SF-36) Health Survey were used to evaluate changes in pain, function and quality of life (QoL) perception. The WOMAC questionnaire contains 24 visual analogue scale (VAS) questions. Results range from 0 to 100 mm, in which 0 mm indicates no pain or no limitation in function, and 100 mm indicates the most severe pain or highly limited function. The SF-36 contains 36 Likert scale questions, scored between 0 and 100, with 0 indicating the worst QoL and 100 indicating the best QoL.

The GaitMat system (E.Q., Inc. Chalfont, PA, USA) was used to measure spatiotemporal parameters. During the gait test, all subjects walked barefoot at a self-selected speed. They walked 3 m before and after stepping onto the walkway mat to allow sufficient acceleration and deceleration time outside the measurement area. Each gait test included four walking episodes mean value of which was calculated for each parameter. The following gait parameters were recorded and calculated: velocity (cm/s), step length (cm), cadence (steps/min), base of support (cm), stance phase (% gait cycle, GC) and SLS phase (% GC).

Patients were evaluated pre-treatment and after 3 and 12 months of therapy. They were contacted by telephone after 2 weeks of treatment onset to verify compliance with the program.

Statistical analysis

Data were analyzed with IBM SPSS Statistics for Windows, Version 21.0. (IBM Corp, Armonk, NY, USA) and were presented as frequencies and percentages for baseline characteristics (categorical variables) and as means and standard deviations for all gait spatiotemporal parameters and self-evaluation questionnaires. The distributions of the variables in the study were examined using the Kolmogorov–Smirnov non-parametric test. The correlation between BMI levels and the rates of improvement (the difference between the results at baseline and following 12 months of therapy) were calculated using Spearman nonparametric correlations.

The GLM Repeated Measures procedures were used to provide an analysis of variance for gait parameters and self-evaluation questionnaires when each subject underwent the same measurement three times. Furthermore, differences within gender and BMI subgroups were also evaluated with the GLM Repeated Measures procedure to demonstrate the differences in time and the interaction of the differences and the groups over time. The significance level was set at 0.05.

RESULTS

Between April 2009 and December 2012, 105 subjects (32 males and 73 females) met the inclusion criteria and were recruited into the study. Their mean (SD) age was 65.6 years (7.9 years) and their mean (SD) BMI was 35.0 kg/m² (4.1 kg/m²). The study participants’ characteristics are summarized in Table 1.

There were significant improvements in gait pattern in all parameters when measured at 3 months (P = 0.03 overall). These improvements further improved following 12 months of therapy. However, the improvements in the 3-month scores and the 12-month scores did not reach a level of significance. Gait velocity increased by 11.8% following 3 months of therapy and by an additional 4.3% at 12 months. The more symptomatic SLS, defined by the patients as the limb with worse symptoms, increased by 2.5% following 3 months of therapy and further improved by an additional 1.1% after 12 months. All gait parameter changes are summarized in Table 2.

There was a significant reduction in pain, stiffness and functional limitation after 3 months of therapy (P = 0.001) with an additional improvement following
12 months of therapy (Fig. 2). Pain decreased by 17.2 mm corresponding to a 34.7% reduction following 3 months of therapy and further decreased by 3.2 mm corresponding to an additional 11.0% reduction after 12 months. The overall pain level (i.e., from baseline to the end of 12 months of therapy) decreased by 45.7%. Functional limitation decreased by 17.8 mm corresponding to a 35.0% reduction following 3 months of therapy and further decreased by an additional 3.2 mm corresponding to a 9.7% reduction after 12 months. The overall functional limitation decreased by 44.7%. Stiffness decreased by 14.1 mm corresponding to a 29.7% reduction following 3 months of therapy and further decreased by an additional 2.9 mm corresponding to an 8.7% reduction at 12 months. The improvements met the Outcome Measures in Rheumatology – Osteoarthritis Research Society International (OMERACT – OARSI) guidelines for the minimum improvement threshold that would have an actual clinical impact on the patient.29

Table 3 summarizes the changes in SF-36 subcategories following 12 months of therapy. Both the Physical Scale and Mental Scale increased significantly following 3 months of therapy (P = 0.001) and further increased following 12 months of therapy.

The mean (SD) baseline BMI for men was 34.6 kg/m² (4.0 kg/m²) compared to 35.2 kg/m² (4.2 kg/m²) for women. Unfortunately, these values at the end of the 12-month course of therapy were not available. There were significant differences between genders in the levels of pain and functional limitation, with the women reporting higher levels of pain and functional limitations compared to the men. Both genders had a significant reduction in pain and improvement in function following 12 months of therapy.

The correlations between baseline BMI levels and the rates of improvement in all gait parameters (as expressed by the difference between the results at baseline and following 12 months of therapy) were calculated and revealed no significant correlations between them or between them and the WOMAC subscales and SF-36 subscales. Dividing the study population into two BMI groups according to the median (BMI = 35.0 kg/m²) yielded no significant differences in the improvement rates of both groups in all gait parameters. However, in the WOMAC subscales and SF-
36 subscales there were differences in WOMAC-pain, WOMAC-function, SF-36 role limitation due to emotional health and SF-36 social functioning scores, where subjects with a baseline BMI < 35 kg/m² improved to a greater extent than subjects with a baseline BMI > 35 kg/m² following 12 months of therapy.

**DISCUSSION**

Obesity is an important risk factor for knee OA. Obese individuals with knee OA tend to walk slower, have a shorter step length, lower cadence and SLS. Lower SLS values indicate that patients have difficulty in bearing body weight on the arthritic knee while the contralateral limb swings forward. They also demonstrate a higher knee adduction moment that has been linked to the severity of knee OA. Excessive mechanical loading has been implicated as being a contributing factor in the progression of knee OA. Potentially increased cumulative load in obese subjects and the fact that they spend a greater than normal proportion of the stance phase, all indicating an improved gait pattern. These improvements were accompanied by self-reported improved symptoms of pain, function and QoL. The improvements in pain and function corresponded to the OMERACT – OARSI world guidelines for clinical significance.

Weight loss may be the best way to improve knee OA symptoms for obese people with knee OA. The European League Against Rheumatism (EULAR) strongly encourages them to lose weight in order to reduce loads, relieve pain and improve function and mobility. However, they tend to have difficulties in embarking on weight loss programs and those who try usually fail to comply. It may very well be that the alleviation of their symptoms while wearing the device allowed the study participants to increase their level of activity gradually for reaching the goals set by EULAR.

**Strengths and limitations of the study**

The main strength of the current study is the improvement in pain, function, QoL and gait pattern following treatment with this non-invasive biomechanical treatment. Patients were able to exercise with the device on a daily basis while training the neuromuscular control and gaining new motor pattern. One limitation of this study is the absence of a control group. Ideally, a control group should include obese individuals with knee OA who participate in a similar exercise program but without the biomechanical device. Another limitation is the difficulty in determining the actual source of improvement. A recent review and meta-analysis by Christensen et al. examined the effect of weight reduction in obese individuals diagnosed as having knee OA. Those authors found that the level of disability could

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**Table 3** Change in SF-36 subscales and Physical summary score and Mental summary score following 3 and 12 months of therapy

<table>
<thead>
<tr>
<th>SF-36 (0–100)</th>
<th>Baseline (SD) [95% CI]</th>
<th>3 months (SD) [95% CI]</th>
<th>12 months (SD) [95% CI]</th>
<th>P-value† Baseline vs. 3 months</th>
<th>P-value† Baseline vs. 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical functioning</td>
<td>43.6 (19.0) [40.1–47.1]</td>
<td>48.0 (18.9) [44.5–51.5]</td>
<td>50.9 (21.1) [47.0–54.8]</td>
<td>0.003</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>35.2 (22.4) [31.1–39.3]</td>
<td>53.0 (21.0) [49.1–56.8]</td>
<td>54.9 (22.3) [50.8–58.9]</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Limitation due to physical health</td>
<td>31.6 (35.0) [25.2–38.0]</td>
<td>42.7 (38.1) [35.8–49.7]</td>
<td>45.7 (37.3) [38.9–52.6]</td>
<td>0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Energy/fatigue</td>
<td>49.6 (18.0) [46.3–52.9]</td>
<td>55.3 (16.2) [52.3–58.2]</td>
<td>56.5 (18.3) [53.1–59.8]</td>
<td>0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>65.8 (17.3) [62.6–68.9]</td>
<td>71.6 (14.5) [68.9–74.3]</td>
<td>73.6 (16.2) [70.6–76.6]</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Limitation due to emotional health</td>
<td>50.1 (42.4) [42.4–57.9]</td>
<td>57.3 (40.3) [49.9–64.6]</td>
<td>55.3 (41.8) [47.6–62.9]</td>
<td>0.087</td>
<td>0.257</td>
</tr>
<tr>
<td>Social functioning</td>
<td>64.4 (25.7) [59.7–69.1]</td>
<td>71.8 (23.7) [67.4–76.1]</td>
<td>76.4 (21.6) [72.4–80.4]</td>
<td>0.006</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>General health</td>
<td>54.3 (15.3) [51.5–57.1]</td>
<td>61.0 (17.1) [57.9–64.2]</td>
<td>63.6 (15.8) [60.7–66.5]</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Physical scale</td>
<td>42.9 (16.3) [39.9–45.8]</td>
<td>52.0 (16.9) [48.9–55.1]</td>
<td>54.3 (18.3) [50.9–57.7]</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mental scale</td>
<td>56.8 (18.1) [53.5–60.1]</td>
<td>63.4 (17.5) [60.2–66.6]</td>
<td>65.1 (18.2) [61.7–68.4]</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

†Significance was set at P < 0.05.
be significantly improved when the subject’s weight was reduced by over 5.1%. Since we did not monitor our study participants’ weight following treatment, we cannot determine whether (or to what extent) the improvements we documented in gait pattern, pain and function are due to weight reduction or something else, such as their acquisition of new motor patterns. Future studies should monitor changes in weight following this treatment and include a BMI- and gender-matched control group. Furthermore, researchers should be careful in generalizing the results of the current study to the general population, as this study did not have a control group. Future studies should compare this treatment with a control group and also include BMI monitoring throughout the study.

CONCLUSIONS
Adverse loading during locomotion may have been an initiator in the harmful cycle of obesity and knee OA, but current biomechanical strategies may be able to prevent further damage or disease progression. The study participants reported relief in pain and showed significant improvement in gait pattern after following the combined device and exercise program for 12 months.

CONFLICT OF INTEREST
Ronen Debi, Amit Mor, Gabriel Agar and Avi Elbaz hold shares in AposTherapy. Omri Lubovsky, EHUD Atoun, Yiftah Beer, Doron Norman and Eli Peled 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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REFERENCES


