Noninvasive biomechanical therapy improves objective and subjective measurements of pain and function in patients with knee osteoarthritis: a retrospective analysis

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ABSTRACT

Background:
Biomechanical interventions for the management of knee osteoarthritis (OA) are emerging. AposTherapy is one type of biomechanical therapy that has been shown to reduce knee adduction moment and improve gait patterns and clinical symptoms. The purpose of the current study was to further investigate the changes in gait patterns after this biomechanical therapy and to define its possible clinical benefits for patients with knee OA.

Methods:
Four hundred and twelve patients with knee OA were evaluated using a computerized gait test, as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) and the SF-36 Health Survey self-evaluation questionnaires. After these measurements, the Apos system was individually calibrated to each patient according to his or her gait patterns and clinical evaluation. All patients received exercise guidelines and underwent 3 months of therapy. A second evaluation of gait and clinical symptoms was conducted after 3 months of therapy.

Results:
After 3 months of therapy, a significant improvement was found in all gait parameters (all $P < 0.01$), as well as in the level of pain, function, and quality of life (all $P < 0.01$). High correlations were found between the improvement in gait parameters and the improvement in self-evaluation questionnaires.

Conclusions:
The examined biomechanical therapy led to a significant reduction in pain and improvement in function, quality of life, and gait patterns. These findings support previous findings and deepen the understanding of this new noninvasive biomechanical therapy in patients with knee OA.

Key Words
knee, osteoarthritis, gait, pain, biomechanical therapy

INTRODUCTION

Osteoarthritis (OA) is the most prevalent form of arthritis.[1,2] More than one third of elderly Americans over the age of 70 years have some degree of radiographic findings indicating knee OA,[1,2] and approximately 10-12% of adults have symptomatic OA.[3] Rates of knee OA are 1.7 times higher in women than in men[4] and positively correlate with obesity.[5] Common symptoms include pain, joint stiffness, tenderness, deformity, and muscle weakness. These symptoms may considerably alter a patients' function and quality of life.[4,6] It is estimated that by the year 2020, the number of people with OA will have doubled because of the exploding prevalence of obesity and the aging of the baby boomer generation.[7] One of the main goals of nonsurgical management of knee OA focuses on reducing knee pain and minimizing the accompanying functional limitation.

Patients with knee OA demonstrate pathologic gait patterns compared with healthy age-matched controls.[8,9] Patients with knee OA tend to have a slower walking speed, shorter step length, and shorter single-limb support (SLS).[8,10] In addition, patients with knee OA demonstrate elevated knee adduction moment (KAM) values compared with matched controls.[11,12] The KAM is a primary biomechanical factor in knee OA. It tends to adduct the tibiofemoral joint, providing a major contribution to the elevated medial compartment loads. Subsequently, KAM was found to correlate with the progression of knee OA.[13] One of the reasons for the altered gait patterns of these patients is impaired neuromuscular control.[14,15] This impaired neuromuscular control affects the coordinated activity of the muscles surrounding the knee and its dynamic joint

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stability.[16] Consequently, some of these patients are at risk for functional instability that can ultimately result in further microtrauma and reinjury.[17] Several studies have shown that neuromuscular control deterioration leads the patient to adopt a less coordinative strategy of joint stabilization, such as global simultaneous concentric contraction of agonist and antagonist muscles to create a bracing effect for the unstable damaged compartment (coactivation/co-contraction), which may lead to further cartilage destruction and exacerbation of joint pain.[18,19]

Several noninvasive interventions exist for knee OA and among them are biomechanical interventions. Previous studies have shown varying results of the effect of biomechanical interventions focused on foot center of pressure (COP) manipulation, agility, and perturbation training in patients with knee OA.[20–26] Haim *et al*.[27,28] recently investigated a novel foot-worn biomechanical device and therapy. The therapy includes daily exercise with the device, according to an individually set training program. The therapy is aimed at reducing the magnitude of external moments acting on the knee joint, such as the knee adduction moment,[8] through changing the patient's center of pressure during walking and enhances stimulation of the neuromuscular control of the knee joint.[29] A recent study looking at 46 patients treated with this device and exercise protocol reported an overall improvement in the gait patterns, level of pain, and level of function in patients with knee OA after 3 months of treatment.[20] The sample size of this study was relatively small, therefore there is a need to examine the effect of this therapy on a larger population.

The present study was conducted on a larger cohort of patients after this new therapy, comparing the objective measurements with the subjective scores commonly used, and defining the possible clinical benefits of its use for patients with knee OA.

MATERIALS AND METHODS

This was a retrospective study on the database of one AposTherapy center, which is thought to represent real-life behavior of patients. Patients are referred to this treatment by general practice and orthopaedic doctors from the general community medical care. As such, not all patients had data at the follow-up time of this analysis (4 months of therapy) for several reasons, including early visit to the therapy center (6 weeks), postponing follow-up date because of time problems, patients did not feel they needed to come since they were feeling well etc. In a small number of patients, a lack of follow-up examination was because of worsening symptoms. The study protocol was approved by the Institutional Helsinki Committee Registry (Helsinki registration number 141/08 and NIH clinical trial registration number NCT00767780). Inclusion criteria were patients suffering from symptomatic bilateral knee OA at the medial compartment for at least 6 months, fulfilling the American College of Rheumatology clinical criteria for OA of the knee.[30] Exclusion criteria were: (1) acute septic arthritis; (2) inflammatory arthritis; (3) corticosteroid injection within 3 months of the study; (4) avascular necrosis of the knee; (5) history of knee buckling or recent knee injury; (6) joint replacement; (7) neuropathic arthropathy; (8) history of pathological osteoporotic fracture; (9) symptomatic degenerative arthritis in lower limb joints other than the knees; and (12) patients with an overall Western Ontario and McMaster Universities (WOMAC) arthritis index score less than 20 at baseline. The head researcher used these criteria to determine the inclusion or exclusion of patients from the existing database.

A biomechanical device composed of four modular elements attached to foot-worn platforms was used in the study as a treatment device (Apos system, Apos – Medical and Sports Technologies Ltd. Herzliya, Israel). The modules are convex shaped biomechanical elements attached to each foot. One is located under the hindfoot region and the other is located under the forefoot region. The elements are attached to the subject's foot through a platform in the form of a shoe. The platform is equipped with a specially designed sole that consists of two mounting rails that enable flexible positioning of each element under each region. Each element can be individually calibrated to induce specific biomechanical challenges in multiple planes (Figure 1).

The GaitMat system (E.Q., Inc. Chalfont, PA) was used to measure spatiotemporal parameters.[31] During the gait test, all patients walked barefoot at a self-selected speed. Patients walked 3 meters before and after the walkway mat to allow sufficient acceleration and deceleration time outside the measurement area. Each gait test included four walks, and the mean value of the four walks 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 single-limb support (SLS) phase (% GC). An improvement in any of these parameters was considered an improvement in gait. A change was considered to be clinically significant if it was accompanied by an improvement in the WOMAC index that qualified under the Outcome Measures in Rheumatology Clinical Trials (OMERACT) OARSI guidelines for clinical improvement.[32] The WOMAC questionnaire and Short Form (SF)-36 Health Survey were used to evaluate changes in pain, function, and quality of life perception. The WOMAC questionnaire contains 24 visual analogue scale (VAS) questions. Results range from 0-100 mm, in which 0 mm indicates no pain or limitation in function, and 100 mm indicates the most severe pain or limitation in function. The SF-36 contains 36 Likert scale questions, scored between 0-100, with 0 indicating the worst quality of life and 100 indicating the best quality of life.

Before their baseline and 4-month examinations, patients were instructed not to consume pain medication for at least 72 h to eliminate the effect of these medications on the patient's pain levels and gait patterns. Anthropometric measurements were drawn from the medical records of each patient. All patients underwent a gait test on the computerized mat and completed the WOMAC questionnaire and the SF-36 health survey during their first visit to the therapy center. 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

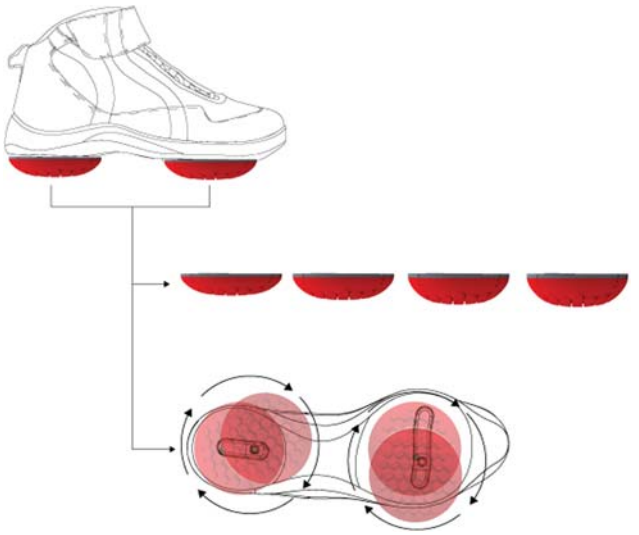


FIGURE 1. The Apos system and mobile elements.

patient's knee joint to a position that allows diminished pain while walking. A previous study indicated that shifting the hindfoot element of the Apos system laterally from the neutral position together with shifting the forefoot element medially from the neutral position will reduce knee adduction moment.[27] These forces often are seen in patients with knee OA and may be a major cause of pain and disability.[8] Calibration of the device was done as follows: each patient was asked to walk away from and then back towards the therapist. A visual gait evaluation was carried out by the therapist, and the device was calibrated. First, the biomechanical elements were calibrated to create minimal inversion/eversion torques on the foot (assessed visually by the therapist), defined as the neutral position. Second, the element under the hindfoot was shifted laterally from the neutral position, and the forefoot element was shifted medially. Third, appropriate calibration was defined as bringing the damaged joint to a biomechanical alignment that minimizes or eliminates pain as reported by the patient; hence the patient's feedback also is considered. This methodology was applied to all patients. All patients received exercise instructions and began the therapy the day after their first visit to the therapy center. Treatment was then initiated and continued on a daily basis. Patients were instructed to wear the Apos system and go about their activities of daily living for 10 min once a day during the first week and gradually increase it to 30 min once a day at the fourth week and for the rest of the treatment period. After four months of treatment, patients underwent a second gait test and completed the WOMAC questionnaire as well as the SF-36 Health Survey.

Statistical analysis

Data were analyzed with SPSS software version 19.0*. The significance levels were set at two-sided $P \leq 0.05$. Data were presented as mean and standard deviation for gait spatiotemporal parameters and self-evaluation questionnaires. The distributions of continuous parameters were examined using the Kolmogorov-Smirnov noparametric test. To evaluate the improvement after 4 months of treatment, for all parameters, the paired t-tests were performed followed by 95% confidence interval for the differences between the repeated measures. We further used the Pearson correlation to demonstrate linear relationship between gait parameters, self-evaluation questionnaires and body mass index (BMI). To measure the change in self-evaluation questionnaires by quintiles of SLS improvement we used the analysis of variance (ANOVA) test. Repeated measure analysis with one nested variable was calculated to demonstrate possible interaction between gender and level of improvement in the SF-36 physical and mental scale.

RESULTS

One thousand four hundred and ten patients came to AposTherapy center. Nine hundred and eighty-eight patients had a follow-up examination after an average of 4 months (range, 12-24 weeks) of therapy. One hundred and twenty-three patients did not have one or more of the following: gait test, questionnaires, follow-up examination. One hundred and seventy-three patients were excluded based on the exclusion criteria list below, and 126 patients had an overall WOMAC score less than 20 mm (Table 1).

A significant improvement in gait measurements was found in all clinical and investigational parameters of the 988 patients. The gait spatiotemporal measurements at baseline and after 4 months of therapy are summarized in Table 2. WOMAC-pain and WOMAC-function subscales were significantly lower after 4 months of therapy (Table 3). Pain decreased by 31% ($P = 0.001$) and function improved by 28% ($P < 0.001$). The improvement in WOMAC pain and WOMAC function met with the OMERACT OARSI clinical response to treatment.[32] All eight categories of the SF-36 health survey, significantly improved after 4 months of therapy. The largest improvement was observed in limitation because of physical health (50.5% increase) ($P < 0.001$) and pain (37.2% increase) ($P < 0.001$) (Table 3).

The association between improvement in SLS gait parameter and both subjective questionnaires (WOMAC and SF-36) was further examined using a correlation analysis. The overall range of improvements in SLS from baseline to 4 months was divided into five equal groups (quintiles). The changes in self-evaluation questionnaire parameters after 4 months were calculated for each of these five SLS groups. A significant trend was found between the improvement in SLS and the improvement in self-reported questionnaires (Figure 2).

A gender analysis was carried out on the SF-36 questionnaire results. In the physical scale, male patients improved

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

	All	Female	Male
Frequency	988	652	336
Age (years)	65.5 (8.8)	64.7 (8.4)	67.1 (9.3)
Height (cm)	162.7 (8.8)	159.2 (6.7)	170.0 (7.9)
Weight (kg)	81.8 (15.8)	78.6 (15.3)	88.3 (14.8)
BMI (kg/m^2)	30.8 (5.1)	30.9 (5.4)	30.5 (4.4)

TABLE 2. Changes in gait spatiotemporal parameters after 4 months of AposTherapy. Results are presented as mean (sd)

	Baseline	4 months	Mean difference	95% CI of the difference-lower bound	95% CI of the difference-upper bound	P*
Velocity (cm/sec)	88.1 (18.7)	96.8 (18.6)	8.7 (15.0)	9.8	9.6	$P<0.001$
Cadence (steps/min)	67.9 (7.1)	71.4 (6.4)	3.5 (6.2)	3.1	3.9	$P<0.001$
Step length more affected knee (cm)	51.5 (8.1)	53.9 (8.1)	2.4 (4.9)	2.1	2.7	$P<0.001$
Step length less affected knee (cm)	51.8 (8.1)	54.2 (7.9)	2.4 (4.9)	2.2	2.8	$P<0.001$
Base of support (cm)	6.8 (3.1)	6.5 (3.1)	−0.3 (2.2)	−0.4	−0.2	0.002
Stance phase more affected knee (% GC)	62.7 (2.6)	62.1 (2.3)	−0.6 (1.9)	−0.8	−0.5	$P<0.001$
Stance phase less affected knee (% GC)	62.9 (2.6)	62.3 (2.4)	−0.6 (2.0)	−0.8	−0.5	$P<0.001$
SLS phase more affected knee (% GC)	37.2 (2.5)	37.9 (2.3)	0.7 (1.7)	0.6	0.8	$P<0.001$
SLS phase less affected knee (% GC)	37.4 (2.5)	38.0 (2.3)	0.6 (1.7)	0.5	0.7	$P<0.001$

*Significance level was set to $P<0.05$.
CI indicates confidence interval; GC, gait cycle; SLS, single-limb support.

from 46.7 to 54.8 (17.3%) and female patients improved from 41.0 to 50.6 (23.4%). With regard to the mental scale, male patients improved from 60.8 to 66.6 (9.5%) and female patients improved from 55.2 to 62.6 (13.4%).

A correlation analysis was carried out between patients' BMI and the results of the gait analysis, SF-36, and WOMAC at baseline and after 4 months of therapy. Significant moderate correlations were found between BMI and most of the spatiotemporal parameters (range 0.41-0.50). Specifically, a moderate negative correlation between BMI and SLS was observed at both time measurements (−0.43 and −0.44, respectively). Low correlation was found between BMI and the level of pain, function, and quality of life (range 0.008-0.26). The measured correlations in all parameters did not change significantly after 4 months of treatment.

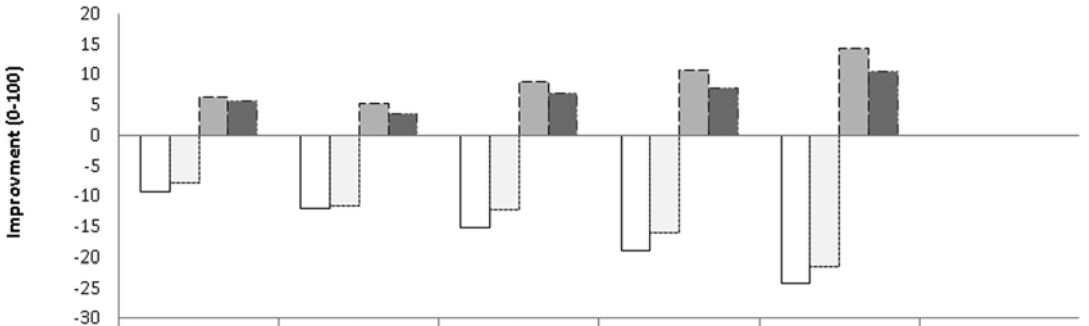
DISCUSSION

The present study evaluated the clinical effect of the examined therapy using objective gait measurements (spatiotemporal parameters) and subjective measurements (WOMAC and SF-36 questionnaires) on a large population of patients with knee OA. After 4 months of therapy, a statistically

TABLE 3. Changes in self-evaluation questionnaires after months of AposTherapy. Results are presented as mean (sd)

	Baseline	4 months	Mean difference	95% CI of the difference-lower bound	95% CI of the difference-upper bound	P*
WOMAC Index†						
Pain	51.4 (20.2)	35.4 (22.1)	−16.0 (22.2)	−17.3	−14.6	$P<0.001$
Function	49.9 (19.7)	36.0 (22.3)	−13.9 (20.2)	−15.1	−12.6	$P<0.001$
SF-36 Health Survey‡						
Physical function	42.4 (18.8)	48.7 (20.3)	6.3 (17.8)	5.2	7.4	$P<0.001$
Pain	37.1 (19.4)	50.9 (21.7)	13.8 (23.9)	12.3	15.3	$P<0.001$
Role limitation due to physical health	29.1 (33.5)	43.8 (38.9)	14.7 (40.2)	12.2	17.2	$P<0.001$
Energy/fatigue	50.9 (19.4)	55.8 (18.0)	4.9 (17.2)	3.7	5.9	$P<0.001$
Emotional well being	66.3 (18.8)	70.7 (17.0)	4.4 (16.5)	3.4	5.4	$P<0.001$
Role limitation due to emotional health	47.4 (42.5)	58.6 (42.3)	11.2 (47.0)	8.3	14.2	$P<0.001$
Social functioning	65.6 (26.9)	73.9 (23.5)	8.3 (25.8)	6.7	9.9	$P<0.001$
General health	55.4 (17.5)	61.1 (17.7)	5.7 (15.4)	4.8	6.7	$P<0.001$
SF-36 physical scale	43.0 (15.4)	52.1 (17.9)	9.1 (15.3)	8.1	10.0	$P<0.001$
SF-36 mental scale	57.1 (18.9)	64.0 (18.5)	6.9 (16.4)	5.9	7.9	$P<0.001$

*Significance level was set to $P<0.05$.
†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).
CI indicates Confidence interval.



	Q1 (<-1.14)	Q2 (-1.13-0.99)	Q3 (1.00-3.00)	Q4 (3.01-5.88)	Q5 (>5.89)	P ט
Womac-Pain	-9.3	-12.1	-15.1	-18.9	-24.3	p<0.01
Womac-Function	-7.8	-11.6	-12.3	-16	-21.5	p<0.01
SF-36 Physical scale	6.2	5.2	8.8	10.8	14.3	p<0.01
SF-36 Mental scale	5.7	3.5	7	7.7	10.5	p<0.01

FIGURE 2. Changes in WOMAC-Pain, WOMAC-Function, SF-36 Physical scale and SF-36 Mental scale within the quintiles of SLS improvement. *P*-values represent ''*P* for trend''. Q1-Q5 represents quintiles of SLS improvement. The difference between the first and second test was calculated and the range of results were divided into quintiles. A negative value represents a decrease in SLS, whereas a positive value represents an increase in SLS. For example, Q1 = fifth of the study population had a decrease of 0.63 or more in their more affected SLS after 3 months of therapy; Q5 = fifth of the study population had an increase of 1.74 or more in their more affected SLS after 3 months of therapy. A decrease in the mean score of the WOMAC domains is considered as improvement, and an increase in the mean score of the SF-36 domains is considered as improvement. WOMAC, Western Ontarior and McMaster University Score, SF-36, short form-36, SLS, shorter single-limb support.

significant improvement in all objective gait parameters was recorded. The results of the current study support the results of Elbaz *et al*.[20] who examined the effect of AposTherapy on the same parameters (i.e. spatiotemporal gait parameters, pain function, and quality of life) but on a small sample size. Specifically, patients increased their SLS phase, indicating that they improved their ability to maintain single-limb loads on the affected limb. In addition, patients demonstrated a significantly higher walking speed, cadence, and step length. These gait improvements suggest an overall improvement in the patients' function. Alongside the improvement in gait there was a significant improvement in both pain and function in patients after therapy. After 4 months of therapy, the WOMAC and SF-36 results showed that patients reported significant improvement in their levels of pain, function, and quality of life. These reported improvements in patients' symptoms met with the OMERACT OARSI guidelines for a clinical response to treatment.[32] In addition, the improvement in gait correlated with the improvement in self-evaluation assessment of pain, function, and quality of life. We could not find validated criteria that quantify the amount of improvement in spatiotemporal gait parameters that may be considered clinically relevant. It may be assumed that since the improvement in gait was accompanied by improvement in symptoms meeting the OMERACT OARSI criteria, a clinically relevant improvement in gait had occurred. This supports the findings of an overall improvement in patients treated with this biomechanical therapy.

Previous studies examined the correlation between objective gait parameters and self-evaluation questionnaires in patients with knee OA.[33,34] Specifically, one study showed that SLS can be a good and objective indicator of the symptomatic severity in patients with knee OA.[34] These studies, however, were cross-sectional and did not investigate these correlations over time. In the current study, we examined the correlation between the improvement in SLS and the improvement in self-evaluation questionnaires after treatment with the biomechanical device. To fully understand the type of correlation (linear, exponential, etc) and its strength and to clearly present this correlation, we divided the results to five equal groups. A high correlation was found between the improvement in the objective SLS and the subjective pain and function. These results further demonstrate that SLS can serve as an objective measure to evaluate changes in the functional condition of patients with knee OA.

Investigating and understanding differences between men and women in the knee OA population is of great interest for researchers. Several studies have reported differences between the sexes in patients with OA, both in gait patterns and in symptoms.[9,35–40] Although the differences between men and women in regards to pain sensation have been previously examined, results remain unclear. Some studies indicate that women report more severe pain than men, while other studies did not find differences in pain levels between the sexes.[36,37] Significant differences between men and women also were found in the patient's quality of life perception, in which women with knee OA reported poorer quality of life compared with men.[40] The results of this study support the findings of previous studies and show that women have a poorer quality of life compared with men at the beginning of the study. Although both sexes reported an improvement in the physical scale and the mental scale, women reported a greater improvement after 4 months of treatment compared with men (23.4% compared with 17.3% improvement in the physical scale score for women and men, respectively and 13.4% compared with 9.5% in the mental scale score for women and men, respectively). These results indicate that women have a different clinical response compared with men after therapy with this biomechanical device. A possible explanation for the greater

improvement seen in women compared with men could be attributed to a different compliance in therapy. However, previous studies did not find gender to affect compliance to therapy in patients with knee OA[41] or in patients with low back pain.[42] Moreover, all patients in the current study reported full compliance with the exercise guidelines.

BMI correlates strongly with symptomatic knee OA and is considered to be one of the greatest risk factors for knee OA.[5,43,44] The results of the current study do not completely support the findings of these previous studies. In the current study, BMI was shown to moderately correlate with most of the spatiotemporal parameters at baseline and after 4 months. However, there was only a weak correlation between BMI and WOMAC pain and function scores and the SF-36 physical and mental scores. The correlations between all measured variables and BMI were similar at baseline and after 4 months of therapy. This suggests that BMI had only a minor effect on the response of patients to the biomechanical therapy and should not be regarded as a significant contraindication to this mode of therapy. A possible explanation for the discrepancies between this study and former studies can be related to differences in demographics. In the United States the prevalence of overweight adults is 65.7% of the population and the prevalence of obese adults is 30.6% of the population.[45] The prevalence of overweight adults in this study population is 39.3% of the population and the prevalence of obese adults is 22.9% of the population.[46] A clear difference exists in the prevalence of overweight and obese adults between the US and the examined population of this study, whereas the prevelance of knee OA is similar.

This study has some limitations. First, the study is limited by the fact that there was no control group to compare to the research group. To the best of our knowledge, a validated sham (placebo) device for noninvasive knee OA mechanical treatment does not exist. As the need for level I studies to validate this treatment arises, such a device is essential. Nevertheless, the primary measurements of this study were objective gait parameters of these patients. These measurements were found to correlate with the patient's subjective assessments, thus validating, to a certain extent, the success of this suggested therapy. Last, this study was a retrospective analysis of knee OA patients whose data were drawn from the therapy center's database. Future studies should further examine the gait patterns and clinical effect of the biomechanical device and treatment methodology in a prospective, randomized, controlled study design that incorporates a control group. Ideally, such a control group should be given a sham device; however, a control group also can be patients who receive standard care or supervised exercise. Future studies also should include long-term follow-up of a large cohort that includes both objective and subjective measurements.

CONCLUSION

In conclusion, nonoperative treatments for knee OA have evolved in the past years. The current study examined the effect of a new noninvasive biomechanical therapy on the gait patterns and clinical symptoms of a large cohort of patients with knee OA. Overall, a significant improvement and clinical response was reported in both objective and subjective parameters. These findings are of great clinical significance as they validate the success of the treatment in a large cohort.

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