

A Novel Non-Invasive Adjuvant Biomechanical Treatment for Patients with Altered Rehabilitation after Total Knee Arthroplasty: Results of a Pilot Investigation

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Background: Many factors contribute to suboptimal results after total knee arthroplasty (TKA) but little is known regarding the value of postsurgical rehabilitation after TKA. We examined the effects of an enhanced closed kinematic chain exercises program (AposTherapy) on gait patterns and clinical outcomes among patients with a lack of progress in their postsurgical rehabilitation.

Methods: Twenty-two patients were prospectively followed during the study. Gait spatiotemporal parameters were measured at the initial evaluation, after 15 minutes of therapy, and after 3 months of therapy. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the short form (SF) 36 health survey were completed by patients before treatment and after 3 months of treatment.

Results: The WOMAC and SF-36 scores improved significantly after 3 months of treatment. Gait velocity, single limb support, and step length of the operated leg improved significantly even after a single 15 minutes treatment. Normal gait velocity was observed in 36% of patients after 3 months of treatment.

Conclusions: A physiotherapy program that included enhanced closed kinematic chain biomechanical therapy was beneficial for patients who experienced a suboptimal rehabilitation course after TKA.

Keywords: *Knee, Arthroplasty, Rehabilitation, Gait*

Total knee arthroplasty (TKA) reduces arthritic knee pain and provides most patients with adequate knee range of motion (ROM).^{1,2} TKA also typically diminishes limitations in patient activities.³ Improvements in these parameters is gradual and may take up to 1 year.⁴ Patients exhibit

marked impairments in voluntary activation of quadriceps strength and in functional performance (e.g., walking and stair climbing) during the early postoperative period after TKA, most probably due to the surgical insult.^{5,6} Most patients are expected to recover to their preoperative functional activity level within 1 year. However, impairments in strength and function may remain below a healthy age-matched population for years after TKA.⁶

Bourne et al.⁷ found that 19% of patients were dissatisfied after TKA. Many factors can contribute to a potentially suboptimal outcome after TKA, including patient characteristics, surgical technique, and postoperative factors. Patient-related factors include restricted pre-

Received September 17, 2014; Accepted December 29, 2014

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operative ROM and underlying etiology, e.g., rheumatoid arthritis, morbid obesity, multitude of comorbidities, sex, and patient personality.⁸⁻¹⁰ Surgical factors include errors in soft-tissue balancing, component malpositioning, and incorrect component sizing.¹¹ Incorrect joint-line height is another surgical cause of a ROM limitation and suboptimal performance.¹² Postoperative complications, such as infection, arthrofibrosis, and heterotopic ossification, hinder TKA outcomes.¹³ Yet, a significant number of patients have difficulties during postoperative rehabilitation with no apparent cause. However, this subset of patients is often diagnosed late, when the potential for full functional recovery has been compromised. There is a paucity of literature regarding appropriate surgical interventions or rehabilitation protocols for such patients.¹⁴

Previous reports indicate that physiotherapy in patients with knee osteoarthritis (OA) can be facilitated by all phases of step cycle (APOS) therapy. This therapy is based on a novel modular foot-worn biomechanical device that stimulates the patient to perform closed chain kinematic exercises by inducing controlled perturbations (further explained in the Methods section). Patients with knee OA have superior Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and short form (SF) 36 health survey questionnaire scores and gait parameters, such as higher walking speed and cadence, as well as step length.¹⁵ We assumed that the enhanced rehabilitation with this device might improve pain and functional outcomes in patients who have difficulties with routine postoperative rehabilitation after TKA.

The purpose of the study was to conduct a pilot investigation to examine the immediate and longer term effects of this device in patients 3 months after TKA. We evaluated gait patterns and self-assessment levels of pain, function, and quality of life. We hypothesized that this therapy would improve gait patterns, quality of life, and function, as well as reduce pain in these patients.

METHODS

The study included 22 patients who underwent cemented unilateral posterior stabilized TKA (Zimmer, Warsaw, IN, USA) for medial compartment OA using a medial parapatellar surgical approach. All patients were referred to therapy by three high volume (> 150 cases/yr) orthopedic surgeons who were concerned with their patient's insufficient improvement after routine physical therapy. Routine physical therapy is initiated immediately after TKA in Korea and consists of 30 minutes sessions three times per week for 3 months. The therapy focuses on ROM, muscle

strengthening, and proprioception exercises. Most patients have full extension and 90° to 100° of flexion in the operated knee 6 weeks after surgery.

Each patient underwent a thorough physical examination by the surgeon as well as anteroposterior (AP), lateral, sky, Rosenberg view, and long-standing radiographs of the involved limb postoperatively and an AP pelvic view to rule out hip OA prior to inclusion in the study. No clinical or radiographic reason for delayed progression was found in any of the patients, such as malalignment > 3° on a long standing radiograph, patellar tilt on a sky view, or soft tissue imbalance in flexion or extension on standing AP and Rosenberg views, respectively. In addition, medial-lateral balance was clinically examined in full extension, 20° of flexion, and 90° of flexion by the respective surgeon. Exclusion criteria were: other joint arthroplasties of the lower limbs; severe degenerative changes in other lower extremity joints, except the contralateral knee; neurological and rheumatic inflammatory diseases; malpositioning, incorrect sizing, and unbalanced soft tissue; postoperative dislocation; increased C-reactive protein level or erythrocyte sedimentation rate; and previous knee surgery.

The patient characteristics including age and body mass index (BMI) were collected. Pretreatment pain, patient function, and perception of quality of life were evaluated using the WOMAC questionnaire and the SF-36 health survey before treatment and after 3 months of treatment. Data were recorded prospectively in our database. All patients consented to participate in the study. This study was approved by the Institutional Review Board (NIH registry no. NCT01266382).

Patients were treated with biomechanical therapy (APOS therapy) that combines two well established treatment strategies for lower extremity and lower back musculoskeletal deformities, such as reducing load on the affected joint¹⁶⁻¹⁹ and training the neuromuscular system by perturbation.²⁰ This treatment is based on using a biomechanical device comprised of modular elements attached to foot-worn platforms. The modules are two 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 *via* 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 perturbations that challenge the patient in multiple planes while walking and standing (Fig. 1). The positioning of the biomechanical elements changes the location

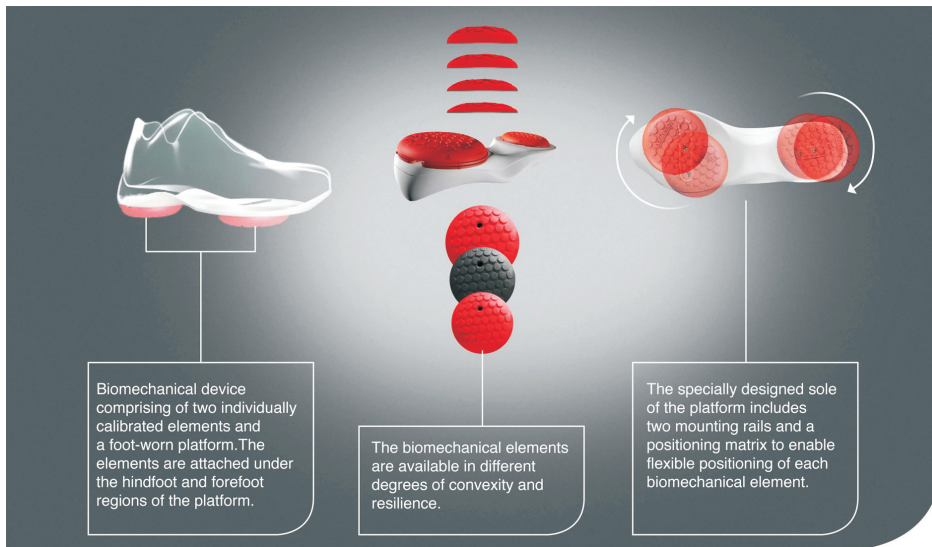


Fig. 1. The unique biomechanical device was comprised of two individually calibrated biomechanical elements attached to a specially designed sole with two mounting rails and a positioning matrix to enable flexible positioning of each biomechanical element. One element is attached under the hindfoot and the second element is attached under the forefoot. The biomechanical elements are available in different degrees of convexity and resilience.

of the center of pressure (COP),²¹⁾ which, in turn, causes changes in the moments acting within the kinetic chain. For example, shifting the biomechanical elements to the lateral aspect of the foot causes a lateral shift in the COP and a decrease in the knee adduction moment.^{16,18)} Shifting the biomechanical elements to the medial aspect of the foot causes a medial shift in the COP and a decrease in the hip adduction moment.¹⁹⁾ Once calibrated to achieve the correct functional alignment, neuromuscular learning is mediated by the convex nature of the elements that promotes a controlled perturbation during walking.²⁰⁾ Appropriate calibration was defined as bringing the joint into biomechanical alignment to alleviate pain by shifting the applied forces and decreasing the adductor moment arm. Consequently, pressure distribution within the joint improves.^{22,23)} These biomechanical perturbations are applied through all phases of the step-cycle (i.e., initial contact, mid-stance, and toe-off) when wearing the device. Thus, home-based, dynamic, functional, and repetitive training is enabled to improve neuromuscular control.^{22,23)} The patient performs a closed kinematic chain exercise while wearing the device during daily activities.

Gait spatiotemporal parameters were measured using a computerized mat (GaitMat System, E.Q. Inc., Chalfont, PA, USA) before and after a single therapy session. During the gait tests, all patients walked barefoot at a self-selected speed. Each cycle consisted of 3 m before and after the walkway mat to allow sufficient acceleration and deceleration time outside the measurement area. Each gait test included four cycles, and the mean value of the four cycles was calculated for each parameter. The following spatiotemporal parameters were evaluated for each gait test: (1) Gait velocity (cm/sec). Velocity is a basic gait parameter

that is often correlated with pathological gait changes. Gait velocity was graded from 30 cm/sec to > 110 cm/sec in 10 cm/sec increments. A gait velocity > 110 cm/sec was considered normal, whereas that < 80 cm/sec was considered pathological.²⁴⁾ (2) Step length (cm) of both the operated and non-operated knees. Step length was chosen, as it is directly related to velocity (velocity = step length × cadence).^{15,24)} (3) Single limb support (SLS) phase (% gait cycle) of both knees was chosen, as it represents the amount of time a person stands on one foot while the contralateral limb swings forward. This signifies the extent of a patient's limp, which is a common gait change in a patient with a painful knee.^{15,24)} (4) Foot base of support of both legs (cm).

After completing the pretreatment gait measurements, the biomechanical device was calibrated for each patient by a physiotherapist certified in this treatment mode. All patients completed the initial intervention, which was a single 15 minutes exercise session with the biomechanical device. Then, the gait test was repeated by all patients, and the results were documented. The patients continued training for 3 months, according to the guidelines they had received from the physiotherapist. Patients were instructed to wear the device daily at home. They were instructed to wear the device for 15 min/day (5 minutes cumulative walking time) during the first week. The patients were instructed to gradually increase the time they wore the device, reaching 60 min/day after 3 months, with a cumulative walking time of 15 to 20 minutes. Gait parameters were remeasured 3 months after initiating treatment.

The physiotherapist verified compliance with the treatment protocol in a weekly phone call. All patients complied completely with the treatment protocol, and

there were no reports of imbalance, tripping, or other physical problems during the study period.

Statistical Analysis

This pilot study was a one arm prospective study. We examined the effects of a single treatment session and 3 months of treatment with the biomechanical device on gait parameters of the operated and non-operated knees compared to their pretreatment values. In addition, we compared function and quality of life using the WOMAC and SF-36 questionnaires between pretreatment testing and testing after 3 months of treatment. We examined the

results according to the OMERACT-OARSI guidelines for clinical significance of a novel OA therapy, including limb functionality and patient pain.²⁵⁾

We could not determine the study sample size in advance because this was a pre-experimental study. The criterion for significance (alpha) was set at 0.05. The tests were two-tailed, indicating that an effect in either direction would be interpreted. This study had a power of 90% to yield statistically significant results with a total proposed sample size of 22. This computation assumed a mean difference of -4.0 (corresponding to means of 34.0 vs. 38.0), and the common within-group standard deviation (SD) was 4.0 (based on SD estimates of 5.0 and 2.5). This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance.

Data were analyzed with SPSS ver. 17.0 (SPSS Inc. Chicago, IL, USA). Gait characteristics were examined using the Kolmogorov-Smirnov nonparametric test. Data are presented as mean and SD for continuous variables with 95% confidence intervals for the mean. Changes over time for all measurements were calculated using repeated-measures analysis of variance.

Table 1. Patient Characteristics (n = 22)

Characteristic	Value
Sex (female:male)	13 (59) : 9 (41)
Age (yr)	67.3 ± 8.4 (45–82)
Height (cm)	1.67 ± 0.10 (151–180)
Weight (kg)	79.6 ± 12.7 (61–94)
Body mass index (kg/m ²)	28.3 ± 3.1 (23.3–32.8)

Values are presented number (%) or mean ± standard deviation (range).

Table 2. Changes in the WOMAC Index and the Short Form-36 Health Survey Scores between Pretreatment and after 3 Months of Treatment

Variable	Pretreatment	3 Months	Mean difference	95% Confidence interval		p-value*	Power (%)
				Lower	Upper		
WOMAC Index							
Pain	39.2 (24.3)	23.0 (23.2)	-16.2	-27.1	-5.3	0.005	60
Stiffness	40.2 (29.1)	31.7 (27.1)	-8.5	-19.6	2.7	0.131	15
Function	34.5 (24.8)	21.7 (20.0)	-12.7	-22.0	-3.5	0.009	40
Short form-36 health survey							
Physical function	46.5 (24.3)	63.7 (22.3)	17.2	8.6	25.8	<0.001	72
Limitation due to physical health	28.3 (37.2)	55.4 (39.9)	27.2	10.6	43.8	0.003	62
Limitation due to emotional problems	47.8 (47.0)	78.3 (32.8)	30.5	11.1	49.9	0.004	67
Energy/fatigue	50.7 (17.9)	66.7 (17.6)	16.1	9.4	22.8	<0.001	82
Emotional well-being	69.9 (19.8)	81.4 (11.9)	11.5	4.1	18.8	0.004	58
Social functioning	60.3 (26.8)	82.1 (23.2)	21.7	9.2	34.3	0.002	81
Pain	45.9 (24.8)	60.5 (21.9)	14.7	4.9	24.4	0.005	49
General health	63.8 (18.6)	70.3 (19.2)	6.5	0.4	12.6	0.038	18

*p-value < 0.05.

WOMAC: Western Ontario and McMaster Universities Osteoarthritis.

Table 3. Spatio-Temporal Changes between Pretreatment, after a Single Treatment Session, and after 3 Months of Treatment

Variable	Pretreatment	One session	3 Months	<i>p</i> -value*	Power (%)
Velocity (cm/sec)	70.7 ± 23.7 (60.2–81.2)	88.3 ± 21.2 (79.0–97.7)	100.2 ± 21.3 (90.8–109.7)	< 0.001	99
Operated knee step length (cm)	47.2 ± 9.4 (43.0–51.3)	51.8 ± 9.0 (47.8–55.8)	55.7 ± 7.9 (52.2–59.2)	< 0.001	93
Non-operated knee step length (cm)	45.0 ± 11.1 (40.1–49.9)	50.6 ± 9.0 (46.6–54.6)	54.4 ± 8.2 (50.7–58.0)	< 0.001	86
Operated knee single limb support (% gait cycle)	34.2 ± 5.4 (31.8–36.6)	36.2 ± 3.6 (34.7–37.8)	38.0 ± 2.5 (36.9–39.1)	< 0.001	91
Non-operated knee single limb support (% gait cycle)	38.6 ± 5.3 (36.2–40.9)	39.2 ± 2.7 (38.0–40.4)	39.2 ± 2.5 (38.1–40.3)	0.642	8
Operated knee base of support (cm)	8.0 ± 3.7 (6.4–9.7)	8.1 ± 2.7 (6.9–9.3)	7.1 ± 2.7 (5.9–8.3)	0.325	15
Non-operated knee base of support (cm)	8.1 ± 3.7 (6.4–9.7)	8.0 ± 2.7 (6.8–9.2)	7.3 ± 2.3 (6.3–8.3)	0.514	13

Values are presented mean ± standard deviation (95% confidence interval).
All gait tests were performed while walking barefooted at a self-selected speed.
**p*-value < 0.05.

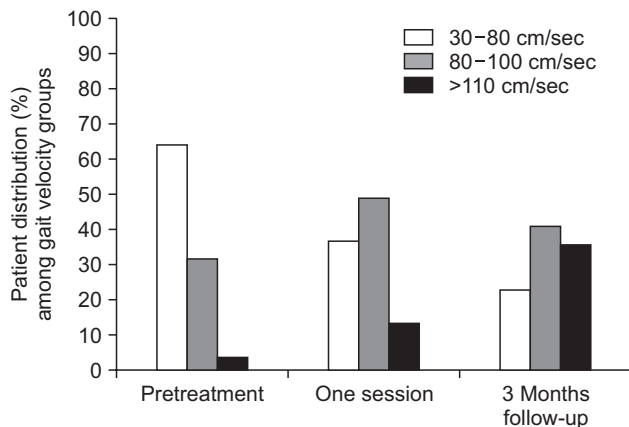


Fig. 2. Distribution (%) of gait velocity groups pretreatment, after a single treatment session, and after 3 months of treatment.

RESULTS

Twenty patients (thirteen women [59%] and nine men [41%]; mean age, 67.3 years; mean BMI, 28.3 kg/m²) were enrolled (Table 1). The mean pretreatment WOMAC pain score improved significantly (*p* = 0.005) from 39.2 to 23.0 points (range, –61.6 to 55.9 points). Similarly, the WOMAC dysfunction score improved significantly (*p* = 0.009) from 34.5 to 21.7 points (range, –62.0 to 33.7 points) after 3 months of treatment with the device. The mean WOMAC stiffness score tended to improve from 40.2 to 31.7 points (range, –69.0 to 33.3 points) (*p* = 0.13). Correspondingly, the mean final SF-36 score improved from 52.9 to 69.8 points (range, –14.2 to 50.1 points) (Table 2). All other specific SF-36 score parameters improved significantly between pretreatment and after 3 months of treatment (Table 2).

A significant increase was found in step length and SLS of the operated knee after a single treatment session and after 3 months of treatment with the biomechanical device (Table 3). Operated knee step length increased from 47.2 cm at baseline to 51.8 cm after a single treatment session and to 55.7 cm after 3 months of treatment (*p* < 0.001). Similarly, SLS increased from 34.2% of the gait cycle to 36.2% and 38.0%, respectively (*p* < 0.001). Consequently, gait velocity increased from 70.7 cm/sec to 88.3 cm/sec and to 100.0 cm/sec, respectively (*p* < 0.001). Although operated limb base of support tended to increase after treatment, the difference was not significant (*p* = 0.325) (Table 3).

In addition, step length of the non-operated knee increase significantly (45 cm vs. 54.4 cm, *p* < 0.001) after 3 months of treatment. Other parameters of the non-operated knee tended to increase after treatment, but the differences were not significant (Table 3).

Fig. 2 shows the gait velocity distribution (%) in patients at baseline, after a single treatment session, and after 3 months of treatment in 10 cm/sec increments. Prior to therapy, approximately two-thirds (64%) of the patients had a pathological gait velocity (< 80 cm/sec) and only 4.5% had a normal gait velocity (> 110 cm/sec). A single treatment session decreased the rate of pathological gait velocity to 37% and increased the rate of patients with normal velocity to 14%. Three months of treatment further lowered the rate of pathological gait velocity to 23% and increased the rate of normal gait velocity to 36%.

DISCUSSION

Despite the technological advances in TKA design and an

improved understanding of TKA surgical techniques and biomechanics, nearly 20% of patients are dissatisfied with their surgical outcome.⁷⁾ The surgeon's awareness of the incidence of such outcomes is important, as these patients may benefit from a more individualized postoperative rehabilitation plan. There is a lack of data regarding the appropriate physiotherapy protocol for these patients.²⁶⁾ A recent literature review and meta-analysis on the effectiveness of physiotherapy exercise after TKA concluded that interventions had minimal and only short-term effects.²⁷⁾

We present outcomes of patients who used enhanced biomechanical stimulation 3 months following TKA and who were referred by orthopedic surgeons due to their lack of progression during postsurgical rehabilitation as shown by low SF-36 and WOMAC scores. We examined the efficacy of a foot-worn device in this challenging group of patients. We used clinical questionnaires and gait parameters at baseline, after a single treatment session, and after 3 months of treatment to evaluate patient progress.

Significant improvement was achieved in many patients after a single treatment session; mean operated leg SLS increased significantly after a single treatment session. This improvement was enhanced after 3 months of treatment, bringing the SLS to 38% of the gait cycle, which is very close to a normal SLS value (38.5%). The improvement in SLS of the operated leg was attributed to the minor perturbations inflicted on the non-operated leg, which dynamically stimulated the patient to use the operated leg. Previous studies indicate that agility and perturbation training may play an important role in knee function by protecting it from potentially harmful loads. The initial improvement was further consolidated by a multitude of repetitions in a closed kinematic chain, which potentially enhance neuromuscular control of the operated leg and improve muscular coordination.^{28,29)}

Along with the improvement in operated knee SLS, operated knee step length increased significantly after a single treatment session and after 3 months of treatment. This improvement may reflect the patient's enhanced confidence with the operated leg, allowing them to take larger steps. More efficient gait patterns, with nearly normal mean operated knee SLS and larger step length, lead to greater gait velocity, which increased significantly after a single treatment session and after 3 months of treatment.

Step length of the non-operated knee increased significantly after 3 months of treatment. The improvements seen in the gait parameters of the contralateral leg support the findings of previous studies regarding the ability of this device to improve neuromuscular control and func-

tion.²²⁻²⁴⁾

The patients reported significant symptomatic relief in pain and dysfunction scores. These results meet the OMERACT-OARSI guidelines for clinical significance of a novel OA therapy, which integrates patient pain and functionality.²⁵⁾

A relatively modest improvement was seen in the WOMAC stiffness score. This finding together with the improvements in the gait parameters suggest that re-acquiring neuromuscular control of the operated leg is more important than improving ROM.

The present study had certain limitations. The study population was diverse, comprised of only 22 patients, and was referred from three different surgeons due to unexplained discomfort and lack of progression during rehabilitation. In addition, selection bias was observed by the surgeons who referred the patients to therapy. However, this limitation was not expected to improve treatment outcomes, as these patients were more prone to unfavorable outcomes and more challenging to treat. As this study considered a more complex rehabilitation population after TKA, the data are of value, despite the limited number of patients. An additional limitation was the lack of a control group, which has inherent methodological limitations. This study was technically difficult, as we assessed a very unique group of patients who had undergone routine rehabilitation for 3 months after surgery with unsatisfactory results for no apparent reason. After insufficient progression with physical therapy, other rehabilitation methods are sought by the patient and surgeon. As this was not a randomized study, bias and confounders were difficult to control. We emphasize that our results should be interpreted carefully because the interventional results were not compared to those from a control group. No significant conclusions should be drawn, as this study presents preliminary results of the effects of this therapy on patients after TKA. Future studies should examine the effects of this therapy compared to a control group. Nevertheless, all patients received the standard of care rehabilitation after TKA and were seeking other rehabilitation methods due to unsatisfactory results for no apparent reason; hence, this therapy may have additional rehabilitation value to these patients. Finally, this study had a relative short follow-up period. Ideally, patients would have benefitted from a long-term evaluation of the treatment to draw significant, long-term, clinical conclusions. However, this was a pilot evaluation of this therapy for patients after TKA. A previous study evaluated the long-term (2 years) effects of this therapy on pain and function in patients with knee OA³⁰⁾ and reported positive results. According to the results

of that study, the main improvement occurred after 2 months of treatment followed by maintenance of improvement.^{22,30} Thus, the first 2 months of therapy are a critical period and may apply to patients after TKA. Future studies should evaluate the long-term effects of this therapy to assess if the observed improvements are maintained in the long-term.

Based on our findings, we suggest that physiotherapy using enhanced closed kinematic chain biomechanical therapy may be beneficial 3 months following after TKA in patients with suboptimal outcomes after rehabilitation. These patients showed improved knee function and quality of life according to the WOMAC and SF-36 scores, respectively, as well as by the gait analysis. An initial substantial improvement was apparent even after a single

treatment session in some patients. Yet, more reproducible progress is expected after 3 months of treatment. Future randomized controlled clinical trials should examine the differences in spatiotemporal and clinical parameters of patients following TKA using this biomechanical device after failure of routine rehabilitation.

CONFLICT OF INTEREST

Debi Ronen, Mor Amit, and Elbaz Avi hold shares in AposTherapy. Segal Ganit is a salaried employee of AposTherapy. Yaari Lee, Kosashvili Yona, Shemesh Shai, Velkes Steven, and Bernfeld Benjamin 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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