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Original Article

New approach for the rehabilitation of patients following total knee arthroplasty

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ABSTRACT

Purpose: To investigate the effect of a biomechanical therapy on gait, function and clinical condition in patients following total knee arthroplasty (TKA).

Methods: Seventeen TKA patients participated in the study. Patients received a biomechanical therapy AposTherapy. Patients underwent a gait test, clinical examination and an assessment of pain, function and quality of life (QOL). Patients were examined again at one, three and six month follow-ups.

Results: A significant improvement over time was found in most gait measurements. Significant improvements were also found in pain, function and QOL.

Conclusions: The examined biomechanical therapy may help in the rehabilitation process following TKA.

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1. Introduction

Total knee arthroplasty (TKA) is the most common treatment for end-stage knee osteoarthritis (KOA). TKA has revolutionized the care of patients with KOA and the number of performed

surgeries has dramatically increased over the past decade. With the rise in life expectancy, projected increases in the incidence of KOA and TKA surgery will place an enormous burden on the healthcare system. A study based on the National Hospital Discharge Survey (1996–1999), predicts that in 2030 there will be over 474,000 TKA procedures performed in the U.S. alone.¹

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TKA surgery succeeds at significantly improving the pain, function and quality of life of KOA patients.² Nevertheless, some lower extremity kinematic and kinetic gait abnormalities have been shown to persist and continue to limit subjects' performance and quality of life.^{3,4} Even years after TKA, many patients do not achieve a normal gait pattern. They tend to walk with a slower velocity, shorter stride length and longer stance phase than control subjects.⁵

Recent data suggests that the abnormalities in gait parameters seen in patients after TKA are not solely due to the surgical procedure or implant misalignment, but rather can be remnants of patients' pathological gait patterns prior to surgery. Several studies have examined KOA gait patterns pre and post TKA and have shown that gait patterns after surgery mirror the gait patterns prior to surgery.^{5,6} These retained pathological gait patterns have dramatic long-term effects on TKA patients aside from immediate functional limitations post-surgery.

Recent research has suggested that the retained pathological gait patterns may significantly influence the function of the contralateral knee and hip. Since these gait patterns remain pathological even after the first TKA, the contralateral limb continues to deteriorate and may even deteriorate more rapidly.⁷ This process can be observed in the differences between limbs after TKA. After TKA there is limb asymmetry, in which the operated limb remains more functionally limited than the non-operated limb. Over time this limb asymmetry is reduced; however, instead of the newly operated knee achieving normality, the non-operated knee becomes more pathological.⁷

In light of these findings, there is a need to improve gait patterns after TKA. It has been shown that a biomechanical therapy was able to improve spatiotemporal, kinetic and kinematics gait parameters in patients with KOA,⁸ as well as self-evaluation questionnaires of pain, function and quality of life.⁹ The present study attempts to apply this therapy to patients after TKA due to end-stage KOA. The study was designed to test the hypothesis that the biomechanical therapy would be able to improve the spatiotemporal parameters, functional scores and self-evaluations scores of these individuals after surgery.

2. Methods

2.1. Participants

This was a prospective study of seventeen patients after unilateral TKA (seven males and ten females). The patients were enrolled to the study three months postoperatively. Patients had a mean age of 70.0 ± 6.1 years, height of 166.2 ± 8.7 cm and weight of 80.8 ± 14.0 kg. Exclusion criteria were severe degenerative changes in other lower extremity joints, except for the contralateral knee, other joint arthroplasties, and any neurological disorders. The study was approved by the institutional review board (NIH registry NCT01266382).

2.2. Intervention

Postoperatively, all patients underwent physical therapy as specified by their physician. At three months postoperatively,

all patients enrolled into the study and began the study therapy. The study therapy was carried out in addition to their typical physical therapy regiment. The biomechanical therapy (AposTherapy) used for the present study is designed to combine center of pressure (COP) manipulation in the foot with perturbation during walking. The therapy combines a biomechanical system (Fig. 1) with a specific walking protocol. The system consists of two convex shaped biomechanical elements attached to each of the patient's feet (i.e. 4 elements total). One is located under the hindfoot region and one is located under the forefoot region of each foot. The elements are attached to the patient's foot on mounting rails embedded within the sole of a shoe. The mounting rails enable flexible positioning of each element under each region. The device is calibrated by a physical therapist certified in the AposTherapy methodology.

Once the device was calibrated, the patient was sent home with the device and was requested to train with the device by walking with it indoors during activities of daily living for a specified amount of time each day. During the first two weeks the patient was guided to wear the device for 10 min a day while doing his daily routine and to accumulate a 5 min walk with the device. This was increased gradually to 30 min a day after 4 weeks. After 6 weeks of therapy patients were guided to wear the device for 60 min a day while doing their daily routine and to accumulate 30 min' walk with the device. The patient was also requested to return to the AposTherapy center for follow-up visits after 1 month, 3 months and 6 months. During each visit the patients were evaluated and the device was recalibrated if necessary. Compliance to the therapy was measured with a weekly log and follow-up phone calls.

2.3. Outcome measures

All patients were evaluated at three months postoperatively (baseline), as well as after one month, three months and six months of therapy. Walking speed (cm/s), step length (cm) and single-limb-support (SLS) (% gait cycle (GC)) were

Fig. 1 – Biomechanical device used in therapy.

Table 1 – Gait patterns changes following therapy with the biomechanical device. Results are presented as mean (SD) [95% CI].

	Baseline	1 Month	3 Months	6 Months	P-value
Velocity (cm/s)	69.7 (26.5) [54.4–85.0]	96.7 (23.2) [83.3–110.1]	103.0 (21.2) [90.8–115.2]	105.9 (21.5) [93.4–118.3]	$P < 0.001$
Operated step length (cm)	48.7 (9.8) [43.0–54.4]	56.6 (8.7) [51.5–61.6]	58.2 (8.7) [53.2–63.2]	59.3 (8.0) [53.2–63.2]	$P < 0.001$
Non-operated step length (cm)	45.1 (12.3) [38.0–52.3]	54.6 (9.5) [49.1–60.0]	56.3 (8.9) [51.1–61.4]	57.3 (8.4) [52.5–62.1]	$P < 0.001$
Operated SLS (%GC)	31.9 (5.3) [28.8–35.0]	36.4 (2.7) [34.9–38.0]	37.9 (2.4) [36.5–39.2]	37.8 (2.3) [36.4–39.1]	$P < 0.001$
Non-operated SLS (%GC)	38.6 (5.5) [35.4–41.8]	38.7 (2.6) [37.2–40.2]	38.9 (2.7) [37.4–40.5]	38.5 (2.6) [37.0–40.0]	$P = 0.392$

Abbreviations: SD = standard deviation; SLS = single-limb-support; GC = gait cycle.

measured by a computerized gait analysis using the GaitMat system (E.Q., Inc. Chalfont, PA). During the gait test, all patients walked barefoot at a self-selected speed. Patients walked 3 m before and after the walkway mat to allow sufficient acceleration and deceleration time outside the measurement area. Each gait test included 4 walks and the mean value of the 4 walks was calculated for each parameter.

Changes in pain, function and quality of life perception were evaluated using the visual-analog scale (VAS) for pain, the Western Ontario and McMaster Osteoarthritis Index (WOMAC) questionnaire and SF-36 Health Survey. The VAS for pain ranges from 0 cm to 10 cm, with 10 cm indicating the most severe pain. The WOMAC questionnaire is a VAS ranging from 0 to 100 mm, with 100 mm indicating the most severe pain or limitation in function. The WOMAC is divided into pain, function and stiffness subcategories. The SF-36 is scored between 0 and 100, with 0 indicating the worst quality of life, and is split into a physical score and mental score. The knee society score (KSS) was used to evaluate knee function (KSS-K) and overall function (KSS-F). A time up and go (TUG) functional test was carried out as well. A standard height chair was used and a line was placed 3 m from the chair. Each patient was asked to repeat the test 3 times and the average of the 3 trials was calculated for further analysis.

2.4. Statistics

All spatio-temporal gait parameters and self-evaluation questionnaires scores were presented as mean (standard deviation), followed by 95% confidence interval for all time periods. Non-parametric one-sample Kolmogorov–Smirnov tests were calculated to compare the observed cumulative distribution function for the continuous variables with the Normal theoretical distribution. The GLM Repeated Measures procedure were used to provides analysis of variance for gait parameters, VAS and KSS scores and self-evaluation questionnaires when the same measurement was made 4 times on each subject. WOMAC and SF36 changes are presented by Bar Graphs.

Data were analyzed with IBM SPSS software version 19.0 and the significant level was set at 0.05.

3. Results

All study participants completed the study and reported full compliance with the treatment protocol. All spatiotemporal gait parameters improved over time, with the exception of SLS in the non-operated limb (Table 1). Velocity improved by 46.9%,

Fig. 2 – WOMAC changes following 6 months of therapy with the biomechanical device compared to matched control. TKA population results were drawn from (26). 26 represents significant differences were found in WOMAC pain, stiffness and function following 6 months of therapy ($P < 0.05$).

Fig. 3 – SF-36 changes following 6 months of therapy with the biomechanical device compared to matched control. TKA population results were drawn from (26). 26 represents significant differences were found in SF-36 Physical and Mental scores following 6 months of therapy ($P < 0.05$).

SLS improved by 13.1% in the operated limb and limb asymmetry decreased from 9.3% to 1.3%. WOMAC pain, stiffness and function improved significantly by 65.3%, 57.6% and 64.0% over time, respectively (all $p < 0.05$) (Fig. 2). SF-36 physical score and SF-36 mental score improved significantly over time (Fig. 3). SF-36 overall score improved by 47.7% by six months. VAS scores improved significantly in the operated knee but not in the non-operated knee (Table 2). KSS-K and KSS-F improved significantly by 60.6% and 83.7%, respectively (Table 2). TUG improved significantly as well (Fig. 4).

4. Discussion

Many studies have shown that patients after TKA have a difficulty achieving normal function.^{4,10} A meta-analysis of physical therapy programs for TKA patients showed only small to moderate effect size with only short term benefits.¹¹ The purpose of the present study was to determine the effects of a biomechanical therapy on patients after TKA for end-stage KOA. Participants in the present study showed significant improvements in spatiotemporal gait parameters, functional scores and self-evaluation questionnaires. These improvements continue to improve at the study endpoint, suggesting that further improvements may occur with time that was not accounted for by the present study.

The present study evaluated patients at four months, six months and nine months after surgery. While several previous studies have examined the gait patterns of patients after TKA, most examine these patients after twelve months. A study by Bendetti et al evaluated patients after TKA at a similar time point to the present study (six months).³ At this time point, patients in their study reported a mean velocity of 85.1 cm/s. This is lower than the velocity observed in the present study (103.0 cm/s) at six months postoperatively (three months of therapy). A study by Smith et al shows that the gait patterns of patients after TKA at twelve months post-operation are similar to those reported by the present study at nine months post-operation (six months of therapy).⁶ These findings suggest that the patients in the present study may surpass the results of Smith et al by twelve months. In addition, a meta-analysis by McClelland et al showed that the average velocity of patients after TKA ranged between 80 and 110 cm/s.⁴ This was for an average follow-up time of several years after surgery. Since the velocity observe after six months of therapy was at the upper end of this range, the participants in the present study are expected to surpass this level as well. In comparison to other TKA therapies, it seems that the therapy examined in the present study has better results. A meta-analysis on TKA therapies by Minns Lowe et al showed effect size in gait velocity ranging from -0.25 to 0.5 and in function ranging from -0.2 to 0.3.¹¹ In the present study the effect size was 1.37 for gait velocity and 0.95 for function.

The results of the present study also show that the limb asymmetry improved with therapy. This occurred via an improvement in the operated limb, rather than a

Table 2 – VAS and KSS scores changes following therapy with the biomechanical device. Results are presented as mean (SD) [95% CI].

	Baseline	1 Month	3 Months	6 Months	P-value
VAS scores (0–10)					
Operated knee	6.3 (2.1) [4.8–7.8]	2.9 (2.3) [1.3–4.5]	3.2 (2.3) [1.5–4.9]	1.8 (2.4) [1.5–4.9]	$P < 0.001$
Non-operated knee	1.1 (1.2) [0.2–2.0]	1.1 (1.9) [0–2.4]	1.9 (1.8) [0.6–3.2]	2.4 (2.5) [0.6–4.2]	$P = 0.163$
Knee society score					
KSS	44.5 (13.1) [35.7–53.2]	66.6 (14.7) [56.7–76.4]	68.6 (18.9) [55.9–81.2]	77.6 (20.8) [63.6–91.5]	$P = 0.002$
KSS-F	40.5 (25.7) [23.2–57.7]	69.1 (16.9) [57.8–80.4]	74.6 (22.0) [59.8–89.3]	79.1 (19.7) [65.8–92.3]	$P < 0.001$

Abbreviations: VAS = visual analog scale; KSS = Knee society score.

Fig. 4 – Time Up & GO changes following 6 months of therapy with the biomechanical device compared to matched control and healthy adults. TKA population and Healthy adults results were drawn from (24). 24 represents significant differences were found in TUG following 6 months of therapy ($P < 0.05$).

deterioration of the non-operated limb. This finding is noteworthy, considering that a past study found that, while limb asymmetry is reduced over time in TKA patients, the non-operated knee becomes more pathological instead of the newly operated knee improving.⁷ In the present study, the changes in SLS in the non-operated limb were not significant. Instead, the operated limb was shown to improve significantly.

Participants in the present study showed significant improvements in WOMAC pain, stiffness and function, as well as in SF-36 physical and mental scores. These can also be compared to previous studies on these measures in patients after TKA. A study by Jones et al showed that patients after TKA demonstrate WOMAC and SF-36 scores that are worse than those observed in the present study for all parameters except WOMAC stiffness¹² (Figs. 2 & 3). Combined with the gait pattern results, these findings suggest that symptoms and function in the present study seemed to have improved due to therapy. This is complemented by the significant decrease in pain levels observed by the VAS score for pain over time in the operated limb (Table 2). However, in order to further validate these results, future studies should examine the effect of this therapy in comparison to a control group in a randomized trial.

Other measures of function in the present study were the TUG test and KSS. In comparison to other studies, the results of the TUG test were better in the patients in the present study¹² (Fig. 4). A study by Longstaff et al showed that at twelve months, patients after TKA showed a KSS function score that ranges between 56.7 and 73.6.¹³ The KSS function score reported in the present study after six months of therapy was greater than this range (79.1).

The results of this study may be explained by the neuromuscular status of patients after TKA. Most of these patients have suffered from years of mechanical instability and decreased proprioception in their affected knee.¹⁴ They have developed disease-specific gait patterns for accommodating.⁴ These gait patterns are hard to modify after surgery.¹¹

Rehabilitation is complicated by the fact that ligaments in the knee that contain the remaining proprioceptors and provide the remaining structural support of the knee are sacrificed during operation. Therefore gait patterns often deteriorate after surgery and can lead to OA in other joints.⁷ The therapy implemented in the present study seems to have improved the gait, function and symptoms of patients after surgery. As such, the therapy may have been able to improve the neuromuscular status of these patients. Researchers have suggested that this occurs because the therapy corrects the ground reaction force direction on each foot and gives constant perturbative stimuli under functional repetition.⁸ These make up the core of any motor learning therapy. Continued research is necessary to elucidate the details of this theory, specifically with controlled prospective studies on patients after TKA.

There were several limitations to the present study. The primary limitation is the lack of a control group with which to compare the results of the individuals participating in the biomechanical therapy. This limits the implication of the findings. Instead, the results were compared to previous studies on patients after TKA. Studies on TKA patients usually differ from each other due to methodology, prosthetic type and patient characteristics. While our comparisons support the hypothesis that the biomechanical therapy improved function after TKA, a valid control group is needed in future studies to strengthen our findings. This would also help in quantifying the magnitude of the effect that the biomechanical therapy may have on these individuals. Another limitation to the present study is the effect of the contralateral limb. Patients after TKA usually suffer from knee OA in their contralateral knee. This will also affect gait patterns to various degrees. In addition, the length of time the patient has suffered from OA prior to surgery also affects gait patterns after surgery. It is difficult to control for these factors. A randomized control group would also help account for these confounding variables.

Furthermore, the present study also examined only spatiotemporal parameters of gait rather than kinetic and kinematic parameters. Kinetic parameters such as knee adduction moment, knee flexion moment and knee extension moment have been shown to be important in postoperative functional analysis of these individuals. For example, a study by Levinger et al has shown that patients after TKA who have abnormal knee flexion moments remaining at four months post-operation will retain poor function in the future.¹⁵ For this reason, future studies implementing this or other biomechanical therapies for TKA should measure kinetic and kinematic measures of gait as well.

5. Conclusions

Patients after TKA due to end-stage KOA treated with a biomechanical therapy (AposTherapy) demonstrate improvements in gait patterns, functional scores and self-evaluations questionnaires. These findings suggest that the therapy presented in the present study may be beneficial for these types of patients.

Conflict of interest and source of funding

One or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article. Ronen Debi, Avi Elbaz and Amit Mor hold shares in AposTherapy. Ganit Segal and Ronit Shoham-Blonder are salaried employees of AposTherapy. Yaron Bar-Ziv, Steven Velkes, Vadim Benkovich, Nadav Shasha and Eytan Debbi are co-researchers in a number of studies. They do not receive and are not entitled to any financial compensation from AposTherapy. Funding – This study was not funded.

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