Gait and Clinical Improvements with a Novel Knee Brace for Knee OA

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J Knee Surg

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Abstract

Introduction Knee osteoarthritis causes debilitating pain, and results in characteristic gait changes. Some authors believe that a system of neuromuscular retraining may improve these parameters. We therefore evaluated a novel brace that combines pneumatic joint unloading and active swing-assist to assess: (1) differences in pain levels or medication usage; (2) reductions in additional interventions; (3) changes in quadriceps muscle strength; and (4) improvements in specific gait measurements after 3 months.

Patients and methods A prospective pilot series of 10 knee osteoarthritis patients who had exhausted other nonoperative treatment measures were enrolled. These patients were compared with the previous 15 knee osteoarthritis patients who met similar criteria, but were not braced. Quadriceps muscle strength was measured, as were pain levels, and additional interventions such as injections or total knee arthroplasty procedures. Gait parameters measured included: walking speed, total range-of-motion, knee flexion at foot-strike, and knee adduction moment.

Results All but one of the compliant patients reported a decrease of at least two pain points after 3 months of use. There was one additional intervention in the brace cohort versus a statistical increase of 10 in the nonbrace cohort. All patients who were compliant with the brace showed an increase in thigh girth measurements, compared with none in the nonbrace cohort. Braced patients experienced retained improvements in at least one gait parameter including improved walking speed, total range of motion, and improved knee-angle at heel strike. The mean improvement in knee adduction moment was a decrease of 0.2255 Nm/kg (range, 0.56 to 0.564 Nm/kg), showing a mean improvement of 48% (range, 16 to 76% of original peak moment).

Conclusions The use of a brace that has features including a combination of unloader characteristics along with active swing-assist, provided neuromuscular retraining benefits for patients who have knee osteoarthritis. In summary, although quite encouraging, future larger scale and prospective randomized studies need to assess the potential benefits of this brace for treating knee osteoarthritis.

Level of evidence Level II

Keywords
- knee
- osteoarthritis
- TKA
- bracing
- neuromuscular retraining

received
July 10, 2012
accepted
July 22, 2012

DOI http://dx.doi.org/10.1055/s-0032-1327452.
ISSN 1538-8506.

Knee osteoarthritis affects nearly 60 million adults in the United States.[1] It causes debilitating pain and structural deformity ultimately leading to decreased functionality and ability to perform activities of daily living.[2] As an increasingly obese population continues to age and live longer,[3–7] this number is expected to rise. Numerous nonoperative therapies are utilized to treat knee osteoarthritis and include: nonsteroidal anti-inflammatory drugs, strengthening exercises, bracing, weight-loss programs, corticosteroid injections, hyaluronic acid injections, as well as narcotics. Despite these treatments, we currently have no method that alters or stops the disease process, and consequently nearly 700,000 patients undergo total knee arthroplasty every year in the United States.[8]

As knee osteoarthritis worsens, there are characteristic patterns of gait changes typically observed including decreased peak flexion angles,[9–11] increased knee flexion angles at heel strike,[9,12] decreased cadences and walking speeds, as well as increased adduction moments.[9] However, the pathologic response to arthritic pain creates a cyclical cause-and-effect relationship, whereby as pain increases, the body further alters knee joint position to a more protected position during gait, which further exacerbates the cycle. Improved quadriceps strength has been shown to decrease osteoarthritis pain.[13–15] Furthermore, some authors believe that a highly specialized system of neuromuscular retraining may have the ability to (1) strengthen the quadriceps muscle, and thereby reduce pain, and (2) decrease the knee adduction moment,[16–20] which could potentially slow disease progression. Despite potentially encouraging results with these systems, they often involve numerous complex exercises that must be supervised by trained therapists or athletic trainers, making them difficult to be applicable to the population as a whole.

The primary purpose of this study was to evaluate a novel brace that combines three elements: pneumatic joint unloading to improve alignment and decrease pain, active swing-assist for quadriceps muscle strengthening and neuromuscular gait retraining, and use of a flexible and elastically deformable material that passively responds to changes in thigh circumference during the gait cycle to improve patient fit and comfort. The primary goal of this study was to evaluate a group of patients who were undergoing nonoperative management of knee osteoarthritis; a cohort was given the brace for a minimum of 3 months, and compared with a series of patients who did not use the brace. The following questions were addressed: (1) was there a difference in pain levels or medication usage after brace use; (2) was there a reduction in additional interventions such as injections or total knee arthroplasty due to brace use; (3) was there a change in quadriceps muscle strength due to brace use; and (4) were there improvements in specific gait measurements after a minimum of 3 months of brace use?

Materials and Methods

A prospective series of 10 patients who had exhausted other nonoperative treatment measures for knee osteoarthritis and who were considering undergoing total knee arthroplasty were enrolled in this study. All patients had Kellgren–Lawrence Grade 2 to 3 osteoarthritis of the knee,[21] and had not undergone any prior arthroplasty procedures, or any previous surgery for the treatment of knee osteoarthritis (e.g., high tibial osteotomy, cartilage repair surgeries, etc.). There were six men and four women who had a mean age of 60 years (range, 44 to 85 years). All patients had less than 10 degrees of varus or valgus deformity. These patients were compared with the previously treated 15 knee osteoarthritis patients who met the same radiographic osteoarthritis criteria, but who were not prescribed the brace. These 25 patients consisted of 11 women and 14 men who had a mean age of 59 years (range, 37 to 83 years).

Pain level was assessed using an 11-point visual analog scale and was recorded as a numeric value ranging between 0 (no pain) and 10 (maximum pain score).[22,23] A reduction in pain level by a minimum of 2 points was considered a positive change. The type and amount of pain medication used on a daily basis was also recorded during the initial and 3-month follow-up visits. Short-Form-36 questionnaires were completed by patients at initial and final visits.[24]

Additional interventions were monitored for all patients during the subsequent 3-month period. These included minor interventions (e.g., corticosteroid injections or hyaluronic acid injections, increased narcotic use, etc.) or major interventions (e.g., surgical intervention).

Thigh girth measurements were taken as an indicator of quadriceps muscle strength. These were taken by one of the authors (AJJ) at initial brace fitting, as well as after 3 months of brace use. All measurements were taken at 4.5 cm above the knee joint line for both the affected and unaffected side. For the patients who were not prescribed the brace, thigh girth measurements were taken at 3-month intervals for comparison.

After enrollment, all patients had thigh girth measurements taken on both the affected and unaffected side, Short-Form-36 evaluations, and were measured for a brace. After being fitted for the brace, they had an initial gait study, which was repeated at a minimum of 3 months afterward. The gait laboratory uses eight Falcon cameras (Motion Analysis Corporation, Santa Rosa, CA) recording at 60 Hz, and two centrally located force plates (Advanced Material Technology Industry Company, Watertown, MA). A group of 26 reflective markers was placed on the patient, which provided information that was later used to recreate a skeletal model. Each study was completed in ~90 minutes, during which time patients were instructed to complete multiple walking trials at a self-selected speed over a 10 m distance until 10 consistent force-plate measurements were recorded for each side. A previously described method was used to correct for patients who had increased soft tissue mass obscuring bony prominences[25] using Real Time software (Motion Analysis Corporation, Santa Rosa, CA). Postprocessing data analysis was performed using OrthoTrak software (Motion Analysis Corporation, Santa Rosa, CA), and parameters analyzed included walking velocity, total knee arc of flexion, knee flexion angle at heel strike, and the knee adduction moment.

Fig. 1 OrthoPro OA Brace (Pinellas Park, FL). Note the strategically placed pneumatic air bladders that allow for patient-directed off-loading of the knee. Additionally, the "active swing-assist" consists of an elastic band within the hinge on both the medial and lateral aspect of the brace.

Prior to their first gait study, all patients were fitted with an OrthoPro OA brace (Ongoing Care Solutions, Inc., Pinellas Park, FL; see ►**Fig. 1**). The brace combines the three elements previously mentioned: pneumatic joint unloading, active swing-assist, and construction made of a proprietary flexible and elastically deformable material. The pneumatic unloading is accomplished through strategically placed air bladders that are inflated until the desired pressure has been achieved. This is patient-controlled, and can be increased or decreased accordingly to the level of activity the patient anticipates performing. It is recommended that the bladder is inflated more when the patient plans to perform more vigorous activity (such as exercise) when compared with walking. The swing-assist is accomplished through the use of an elastic band embedded within the hinge of the brace, thereby providing a dampening effect during knee flexion, and an active swing-assist during the swing phase of the gait cycle.

All patients were instructed to wear the device for a minimum of three 30-minute sessions per day. They were encouraged to use the brace while performing physical activity rather than during sedentary activities. The patients did not participate in any other physical therapy rehabilitation or strengthening programs during the 3-month study period.

Of the 10 patients who were prospectively enrolled, there were 3 who were lost to follow-up. The first was a patient who was diagnosed with gastric cancer, and underwent multiple procedures for treatment, and who died 3 months after enrollment in the study. Another patient who did not show any history of cardiac or vascular disease was noted at the time of brace fitting to have peripheral vascular disease. On further evaluation she was noted to have previously undergone an aorto-bifemoral grafting procedure. To prevent compressing the graft on the affected side, the decision was made that bracing would be inappropriate, as it could potentially occlude the graft. The third patient was contacted multiple times unsuccessfully after the initial fitting and gait study, but was not located. Of the remaining 7 patients, one was not compliant and did not wear the brace. Of the 15 patients who were not prescribed the brace, 14 patients returned to clinic at the 3-month follow-up period for comparison.

All data was collected and analyzed in a database (JMP 8, SAS Institute, Inc., Cary, NC). Continuous variables (age, weight, thigh girth) were compared using a Student's *t*-test. Gait parameters were evaluated as either "improved" or "no change." Changes in gait parameters were considered "improvements" if their walking speed increased, total range-of-motion increased, or the degree of knee flexion at heel strike decreased. All discrete outcomes were compared using a Fisher's exact test. For knee adduction moments, values were normalized to present the moment as a proportion of a patient's height and weight. The change in the normalized adduction moment was considered an "improvement" if the moment decreased after 3 months of brace use. All follow-up gait parameters were measured with the patient *not* wearing the brace. A *p*-value of less than 0.05 was considered statistically significant. The incidences of secondary outcomes (e.g., additional major and minor interventions) were compared using a Fisher's exact test. Institutional review board approval was obtained for this study, and all patients provided written informed consent prior to enrollment in the study.

Results

Of the compliant patients, all but one reported a decrease of at least two pain points after 3 months of use. The mean VAS pain levels improved from 7 points (range, 5 to 8) to 4 points (range, 2 to 6 points). Only 1 out of 14 patients in the nonbrace cohort showed improvements in pain scores of greater than 2 points ($p = 0.002$).

SF-36 scores improved from a mean of 38 points (range, 20 to 50) to 40 points (range, 20 to 52 points) for the Physical Component Summary ($p = 0.04$), and improved from 52 points (range, 40 to 59 points) to 54 points (range, 36 to 62 points) for the Mental Component Summary ($p = 0.01$) in patients who wore the brace. There was no change in SF-36 scores in the nonbrace cohort.

There was one additional intervention in the brace cohort, and a total of 10 additional interventions in the nonbrace cohort ($p = 0.05$). There was one patient who wore the brace for 3 months and still requested an additional corticosteroid injection in the affected knee at follow-up visit. Of the 10 interventions in the nonbrace cohort, there were 6 patients who received injections (4 patients had corticosteroid injections, and 2 patients received hyaluronic acid injections), and 4 patients who made the decision to proceed to total knee arthroplasty.

All patients who were compliant with the brace showed an increase in thigh girth measurements, compared with none in the nonbrace cohort ($p = 0.0004$). The mean thigh girth improvement was 0.75 inches (range, 0.25 to 1.5 inches).

All compliant patients experienced retained improvements in at least one gait parameter. These included improvements in walking speed, total range of motion, and

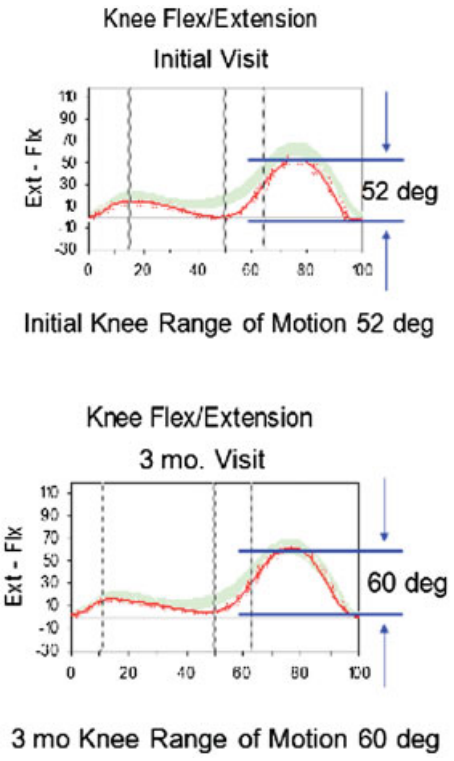

Fig. 2 A representative example of the improvement in total peak-to-peak knee range-of-motion. The top graph details the patient's initial visit and the bottom is from the 3-month follow-up visit. Deg, degree; Ext, extension; Flx, flexion.

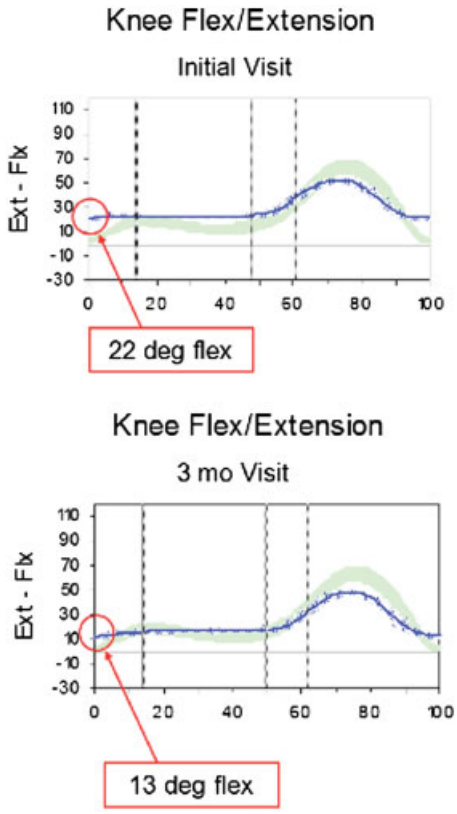

Fig. 3 A representative example of the improvement in knee flexion angle at heel strike. The top graph details the patient's initial visit and the bottom is from the 3-month follow-up visit. Deg, degree; Ext, extension; Flx, flexion.

knee-angle at heel strike. The mean walking speed improved from a mean of 100 cm/s (range, 63 to 123 cm/s) to 112 cm/s (range, 90 to 146 cm/s). The total knee peak-to-peak range-of-motion improved from a mean of 44 degrees (range, 31 to 51) to 48 degrees (range, 37 to 60 degrees) (►**Fig. 2**). The knee-angle at heel strike improved from a mean of 9 degrees (range, 1 to 22 degrees) to 6 degrees (range, 0 to 15 degrees) (►**Fig. 3**). All compliant patients showed improvement in their knee adduction moment. The mean knee adduction moment in the compliant patients improved from 0.4115 Nm/kg (range, 0.273 to 0.74 Nm/kg) to 0.186 Nm/kg (range, 0.1 to 0.279 Nm/kg) (►**Fig. 4**). The mean improvement was a decrease in the moment of 0.2255 Nm/kg (range, 0.56 to 0.564 Nm/kg), a mean improvement of the knee adductor moment of 48% (range, 16 to 76% of original peak moment).

Discussion

Knee osteoarthritis is a devastating disease that makes life difficult for the patients who suffer from it, and creates a treatment burden for the healthcare system. As the population continues to age, and the "Baby Boomer" generation advances in years in an era of diminishing insurance reimbursements, it will become even more critical that conservative and nonoperative treatment measures are exhausted before patients make the decision to proceed to total knee arthroplasty. With this in mind, we assessed the ability of a novel bracing technology to neuromuscularly retrain patients who have knee osteoarthritis and help decrease pain, increase function, and potentially delay the time until the patient undergoes total knee arthroplasty. Consequently, we assessed whether there (1) were retained improvements in specific gait measurements while not wearing the brace, (2) were improvements in quadriceps muscle strength, and (3) was a change in pain levels or medication usage during this time period?

There were several limitations of this study. Although this was a prospective case series, the cohort size was small due to the design of the study as a pilot. Future larger and prospective studies will use these preliminary results to determine an effective size for power analysis calculations. Another limitation was that three patients were lost to follow-up and one patient was noncompliant. Although we do not typically observe that compliance is an issue when prescribing this brace in our practice, it is of interest that the patient who was noncompliant did not see the same improvements as the compliant patients. The results of larger studies will need to document what the actual compliance rate is for this brace. Additionally, the results of this study are limited to short-term changes in gait patterns and pain scores. It is uncertain, albeit promising, whether these changes will translate into a clinically important alteration in the course of their disease.

Previous studies have noted the benefits of neuromuscular retraining on the arthritic knee.[17–20] A 2007 study by Thorstensson et al evaluated gait parameters and knee adduction

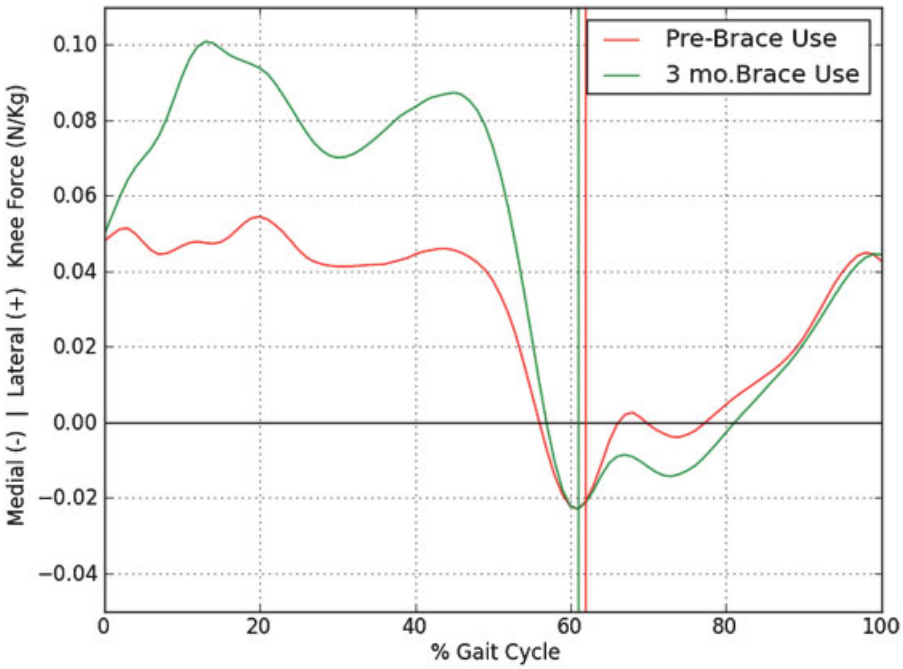

Fig. 4 A representative example of the improvement in the force component of the knee adduction moment. The graph in red represents the patient's initial visit and the graph in green represents the 3-month follow-up visit.

moments in 13 patients who had early (Kellgren–Lawrence Grade 1 to 3) knee osteoarthritis and who underwent a neuromuscular strengthening program.[17] They concluded that through the use of a specific, supervised training program, knee adduction moments could be reduced to an average of 14% in these patients during single-leg chair raise ($p = 0.03$), although the improvements seen during gait were not significant ($p = 0.42$). The difference between the present study and that by Thorstensson et al is that (1) the changes imparted by the brace were retained during the gait cycles, and (2) the mean reduction in adduction moment in our study was 48%, compared with their average improvement reduction of 14%. This indicates that there may be a neuromuscular retraining effect of the brace on the patients, as the combination of re-alignment and active swing-assist significantly altered the patients' gait with ultimate reductions in knee adduction moment across the affected joint.

Our results differ from previous studies that have been unable to show improvements in knee adductor moments through nonoperative measures.[26–28] In a randomized study, Foroughi et al evaluated 50 women who had knee osteoarthritis[27] who were randomized into a 6-month quadriceps muscle resistance-training exercise program or a sham program. They evaluated clinical symptomatology and gait parameters. Although the patients' who had the strength training demonstrated improvements in their osteoarthritis symptoms (mean 38% decrease in WOMAC scores), there was no change in their knee adductor moments, which were 2.63 (% bodyweight × height) at baseline, and 2.65 (% bodyweight × height) at follow-up after the patients underwent the strengthening program. It is encouraging that in addition to reducing pain, the brace evaluated in the present study demonstrated retained improvements in multiple gait parameters, most notably the knee adductor moment. Although there are no studies to our knowledge that assess the ability of a traditional unloader brace to decrease the knee adductor moment, a recent study by Hurley et al concluded that although the use of a medial unloader brace may facilitate increased activity levels, there was no dose–response capacity for increasing lower-body strength with increased usage. The brace evaluated in the present study, conversely, showed significant improvement in thigh girth measurements, with a mean improvement of 0.75 in circumference increase. This indicates that the brace evaluated in the present study, unlike the unloader brace studied by Hurley et al, increased lower-body strength with use. Future studies should further quantify the specific quadriceps and hamstring muscle strength gains.

In conclusion, the use of a brace that had a combination of unloader characteristics along with active swing-assist provided neuromuscular retraining benefits for patients who have knee osteoarthritis. Additionally, the arthritic knee patients demonstrated retained improvement when the gait analysis was performed without the brace on, indicating that its use for a minimum of 30 minutes for three times a day had beneficial and potentially permanent improvements in their gait. The encouraging results of this study can be used to design larger, prospective, randomized studies to determine the clinical efficacy of the brace in treating early-stage knee osteoarthritis, as well as in treating end-stage osteoarthritis in patients who are preparing to receive a total knee arthroplasty. In summary, the authors advocate the use of this novel brace as a potential conservative, nonoperative treatment option for knee osteoarthritis.

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