

Clinical Outcomes of a Pneumatic Unloader Brace for Kellgren–Lawrence Grades 3 to 4 Osteoarthritis: A Minimum 1-Year Follow-Up Study

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Abstract

The use of a pneumatic unloader brace has been shown in pilot studies to decrease pain and increase muscle strength in patients with knee osteoarthritis (OA). Therefore, we analyzed patients who had knee OA, and either received a pneumatic unloader brace and conventional treatment or conventional treatment alone. Specifically, we assessed: (1) use of pain relieving injections; (2) opioid consumption; and (3) the eventual need for total knee arthroplasty (TKA) in the above-mentioned cohort. We performed an analysis of a longitudinally maintained database of patients from a prospective, randomized, single center study. This study randomized patients who had Kellgren–Lawrence grades 3 to 4 to receive either a pneumatic unloader brace and conventional treatment or conventional treatment alone. The brace cohort comprised 11 patients with a mean age of 55 years (range, 37–70 years). The final matched cohort comprised 25 patients with a mean age of 63 years (range, 41–86 years). The minimum follow-up was 1 year. There was a lower proportion of patients who underwent an eventual TKA in the bracing cohort as compared with the nonbracing cohort (18 vs. 36%). The mean time to TKA was longer in the bracing cohort as compared with the nonbracing cohort (482 vs. 389 days). The proportion of patients who used opioids was similar in both groups (27 vs. 22%). There was a significantly lower number of patients who received injections in the bracing cohort as compared with the nonbracing cohort (46 vs. 83%, $p = 0.026$). The bracing cohort had received a significantly lower number of injections and a lower rate of subsequent TKA as compared with the nonbracing cohort. The mean time to TKA was also longer among the bracing cohort. These results may demonstrate the potential of this brace to reduce the need for and prolonging the time to TKA. Performing larger prospective randomized studies, with built-in compliance monitors is warranted. This brace may be a valuable adjunct to the current knee OA treatment armamentarium pending further investigation.

Keywords

- ▶ unloader brace
- ▶ osteoarthritis
- ▶ nonoperative treatment
- ▶ total knee arthroplasty

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Knee osteoarthritis (OA) can result in decreased function and discernible pain in an estimated 13.9% of adults who are 25 years and older and 33.6% of people who are 65 years or older of the population in the United States,¹ and the annual cost for pain management can exceed \$5,000 per person.² It is estimated that more than 10 million people suffer from this disease in the United States,³ and this number is expected to nearly double in the next decade due to the growing obesity epidemic and longer life spans.⁴ Many patients often require joint arthroplasty as the OA progresses to end-stage degenerative joint disease. In addition, it is estimated that the number of total knee arthroplasty (TKA) will increase from 488,000 to 3.75 million by the year 2030.⁵ As the cost of managing these patients rises, it will put a tremendous economic burden on the health care system.

Nonoperative treatment options such as nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and injections can provide symptom relief for knee OA; however, they have minimal effects on disease progression. Braces are currently not standard treatment for knee OA; however, they are known to potentially improve pain and functionality, as well as potentially slow progression of disease. Currently, there are many types of knee braces on the market available to patients. Some include alignment braces, such as the valgus knee brace, which are designed to unload knee compartments. In addition, there are neoprene knee sleeves and neutral braces which are thought to provide stability to the knee. One such brace, the knee unloader brace, has key features such as active swing assist, neuromuscular retaining properties, and a pneumatic unloader.⁶ This brace has been shown in pilot studies to decrease pain and increase muscle strength in patients with knee OA. In addition, a randomized trial of 52 at their 3-month follow-up point demonstrated improvements in muscle strength, functional tests, and patients reported outcomes when compared with a matched cohort.⁷ This device may have the potential to delay the need for surgery, increase function, and improve quality of life; however, there are few studies that evaluated this brace beyond the 3 to 6 months.

Currently, there is no consensus of the clinical impact of these braces and their efficacy in the treatment of knee OA. We evaluated the brace to explore its effects on late-stage knee OA (Kellgren–Lawrence grades 3–4)⁸ in patients who had a minimum follow-up. Specifically, we assessed the pneumatic unloader brace by analyzing: (1) the eventual need for TKA; (2) opioid consumption; and (3) use of pain relieving injections in patients who had late-stage knee OA and either received a pneumatic unloader brace and conventional treatment or conventional treatment alone.

Methods

We conducted a study on a longitudinally maintain database of patients who were in a prospective, randomized, single center study of patients who had Kellgren–Lawrence grades 3 to 4 OA who were followed up for a minimum of 1 year to compare clinical outcomes of patient who received either a pneumatic unloader brace and conventional treatment or conventional

treatment alone. This study was approved by the Institutional Review Board. The inclusion criteria for patients were: (1) age between 30 and 90 years; (2) OA in medial or lateral compartment of the knee (Kellgren–Lawrence grades 3–4); (3) experiencing persistent pain beyond current treatment; (4) patient able to comply with study requirements; and (5) no history of corticosteroid injection in the last 3 months. Patients were ineligible if they: (1) were younger than the age of 30 years or older than 90 years of age; (2) had a history of peripheral vascular disease with femoral stenting or graft (e.g., graft surgery/aortofemoral-popliteal bypass) on the affected side; (3) history of diabetic neuropathy; (4) traumatic onset of knee pain; (5) had undergone surgery on either lower limb within 6 months; (6) had received corticosteroid injections in the affected knee within 3 months of the study; (7) had OA in both medial and lateral knee compartments; or (8) were unable to comply with study requirements.

Forty patients were potentially eligible for inclusion in this study (20 studies and 20 controls) who were to either receive the pneumatic brace or standard of care treatment used at our institution. For the bracing cohort, 4 of 20 patients did not comply with the brace use and therefore were excluded, resulting in 16 patients. Of the 16 patients who were enrolled into the bracing cohort, 5 were unable to receive the brace, and were therefore, enrolled into the control cohort. This resulted in 11 patients in the bracing cohort and 25 patients in the nonbracing cohort.

The final brace cohort comprised 11 patients (6 men and 5 women) who had a mean age of 55 years (range, 37–70 years). The final match cohort comprised 25 patients (6 men and 19 women) who had a mean age of 63 years (range, 41–86 years). All demographics characteristics such as age, gender, and body mass index were not significant between the two cohorts (►Table 1).

All study patients in the randomized bracing cohort were fit with an OA Rehabilitator brace (Guardian Brace, Pinellas Park, FL) (►Fig. 1). The brace combines three elements, previously mentioned: active swing assist, pneumatic joint unloading, and construction made of a flexible and elastically deformable material. Dynamic conformability of the brace is achieved with flexible cuffs and elastic strapping material. The mediolateral stability is established by using rigid composite material for the uprights. The pneumatic unloading is achieved via strategically

Table 1 Demographic characteristics

	Brace N (%)	No Brace N (%)	p-Value
Total	11	25	
Age (mean) (range)	55 (37–70)	63 (41–86)	0.048
Gender			
Men (%)	6 (55)	6 (24)	0.073
Women (%)	5 (46)	19 (76)	
BMI (mean) (range)	30 (20–46)	33 (23–48)	0.412

Abbreviation: BMI, body mass index.

Table 2 Study end points

	Brace N (%)	No brace N (%)	p-Value
Total	11	25	
Follow-up in mo (mean) (range)	28 (15–41)	27 (12–36)	0.832
Eventual TKA	2 (18)	9 (36)	0.285
Time to TKA in d (mean) (range)	482 (374–589)	389 (186–906)	0.610
Opioid use	3 (27)	5 (22)	0.722
Injections (steroid/anesthetic combination)	5 (46)	19 (83)	0.026

Abbreviation: TKA, total knee arthroplasty.

placing air bladders that are inflated to attain a desired pressure. This is patient controlled and can be adjusted according to the level of activity the patient engages in. Patients apply the brace first and then adjust the straps to fit it snugly before inflating pneumatic bladders for unloading the joint. The swing assist is established via the use of an elastic cord implanted within the hinge of the brace. During flexion of the knee, it provides a dampening effect and an active swing assist during the terminal swing phase of the gait cycle. In late swing phase of the gait cycle, the hamstrings have to work to

**Fig. 1** Pneumatic unloader brace used in this study.

direct knee extension, as the bands maintain rapid knee extension. In the loading response phase of the stance phase, the quadriceps muscles have to operate eccentrically against the extension assist bands to attain sufficient knee flexion. During the fitting process, the patients were educated and trained meticulously on the use of the brace and how to facilitate heel toe gait and employing swing phase knee flexion during use. They were permitted to use the brace while conducting physical activity such as using an elliptical, climbing stairs, or when riding a bike.

The current standard of care (used in both cohorts in this study) at our institutions comprises physical therapy, corticosteroid injections, and self-guided home exercise programs. For physical therapy, patients were provided with prescriptions for exercises for range of motion, gait training to the knee, and strengthening modalities, for three times a week for 6 weeks at our institution. At their primary appointment, all patients also underwent detailed counseling on self-guided exercise program used at our institution. Self-guided exercise therapy consisted of three exercise motions. Both treatment and control cohorts were permitted to use prescribed NSAIDs or opioids.

Any device-related adverse events were monitored and recorded in all patients during the study period. Complications due to device monitored included: local skin reactions, local skin irritation or breakdown due to the device, increased pain, or any abnormal electrical events due to improper use or malfunction of the device. No severe adverse reactions were observed with the use of the device (i.e., ulcerations); however, a single patient complained of minor irritation at pad placement sites. Pads were replaced for this patient and they continued using the brace.

Statistical analysis was conducted using Microsoft Excel spreadsheet (Redmond, WA) and SPSS version 21 (IBM corporation, Armonk, NY). Student *t*-test was used to evaluate continuous data, and chi-square was used for categorical data between the treatment and control groups. The eventual need for TKA, opioids use, and intra-articular injection use were recorded as categorical variables. The mean time to TKA was recorded in days as a continuous variable. A *p*-value of < 0.05 was used to determine significance.

Results

Eventual Total Knee Arthroplasty

At a minimum follow-up of 1 year (mean, 27 months; range, 12–41 months), the proportion of patients who underwent an eventual TKA in the bracing cohort was half that of the nonbracing cohort (18 vs. 36%) (→ **Table 2**). However, there was no significant difference in the number of patients who underwent an eventual TKA in the bracing cohort as compared with the nonbracing cohort (*p* = 0.285). The mean time from enrollment to TKA was not significantly different between those who had and did not have the brace (482 vs. 389, *p* = 0.610).

Opioids Use

The proportion of patients who used opioids in the bracing cohort was similar to that of in the nonbracing cohort (27 vs. 22%). There was no significant difference in the number of

patients who used opioids in the bracing cohort as compared with the nonbracing cohort (3 vs. 5, $p = 0.722$).

Intra-articular Injection

The proportion of patients who had an intra-articular injection in the bracing cohort was nearly half that of the nonbracing cohort (46 vs. 83%). There was a significantly lower number of patients who had an intra-articular injection in the bracing cohort as compared with the nonbracing cohort (5 vs. 19, $p = 0.026$).

Discussion

With the increasing burden of knee OA and projected increases in the number of TKAs being performed, it becomes important to evaluate modalities that may have the potential to decrease this burden. In the present study, we found a significantly lower number of patients who received injections in the bracing cohort as compared with the nonbracing cohort, which may be indicative of the therapeutic potential of this brace. In addition, there was a lower proportion of patients who had an eventual TKA in the bracing cohort as compared with the nonbracing cohort. The mean time to TKA was also shorter among the bracing cohort. Although these results may have not reached statistical significance due to the small sample size, these results point to the potential of potentially reducing the need for and prolonging the time to TKA.

There are several limitations in this study. There was only 80% compliance rate with this brace, which may realistically be lower. This may be due to the significant lifestyle adjustment required to adequately gain benefits from this device. In addition, given the size of this brace, it would need to be worn over most clothing, which may entice the patient to not use the brace in certain situations. To avoid this, extensive patient education regarding the potential benefits of this device may be required. In addition, we feel that a brace built-in compliance monitor would be useful to monitor frequency and duration of use, since compliance was assessed objectively and we had to rely on the patients for the information. The sample size of this study may not have been adequate to determine true statistical differences between the cohorts. Despite this, we found a significantly lower number of patients who received injections which may indicate that the unloader brace may have the potential to allow patients to avoid more invasive interventions, such as injections. In addition, the number of patients who underwent an eventual TKA was half that of the nonbracing cohort which may have been potentially unmasked by a larger sample size. The use of opioids was calculated as the number of patients who used opioids instead of the total milliequivalents, which would have been a more accurate method. However, patients may have varying tolerances to opioids, and thus, this may inaccurately represent differences in opioid milliequivalents. Yet, another limitation was the short-term follow-up period of a minimum of 1 year, a longer follow-up period may provide a more precise assessment of the unloader brace use as well as further confirm our results. Our goal is to re-evaluate these patients at 5-year follow-up to determine longer term benefit.

Conflicting evidence has been presented in recent literature regarding the beneficial effects of unloader bracing for the treatment of knee OA. It has been concluded by some studies that the use of unloader bracing provides significant pain relief and aids in functional recovery. Laroche et al tested the use of unloader bracing on 20 patients who had symptomatic medial knee OA. The study observed three-dimensional gait analysis, pain scores, and functional outcomes.⁹ The study revealed that after 5 weeks of regular brace use, patients had a substantial decrease in visual analog scale (VAS) pain and The Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores. Results of the gait parameters indicated patients' walking speed improved significantly at 5 weeks, while both foot progression angles and knee adduction moments significantly decreased in the push off and terminal stance, respectively, with bracing at the initial testing and 5 weeks later. There was also a significant improvement in lower limb joint angles, power, and moments with the use of the brace. Komistek et al conducted a gait analysis study using the unloading braces on 15 patients to assess whether patients had separation of the joint space resulting in pain relief.¹⁰ Of the 15 patients, 12 reported a decrease in pain symptoms and it was shown in those 12 patients via fluoroscopy that the brace achieved condylar separation of the medial tibiofemoral joint space. It was further noted that obesity and a poor fitting brace resulted in failure to achieve relief of symptoms. Unloader bracing led to results comparable to standard of care, hence making it an excellent nonaddictive, noninvasive alternative with easy compliance and minimal potential for adverse effects.

Although numerous studies on unloader bracing have indicated significant improvement in knee pain and associated symptoms, there are other studies that contradict those findings. Brouwer et al observed 117 patients with unicompartmental OA of the knee for 12 months, with follow-up at 3, 6, and 12 months.¹¹ Of those 117 patients, 60 were treated using the unloader brace and 57 received no intervention. The study did not indicate a significant difference in VAS pain or Hospital for Special Surgery knee function between the two groups at any point during the 12 months. However, Brouwer et al recognize there is a need for further studies with larger patient populations due to the fact that at least 25% of their patient population was noncompliant. Likewise, Kirkley et al followed 110 patients with varus gonarthrosis who underwent treatment with unloader brace (41), neoprene sleeve (36), or no intervention (33).¹² WOMAC and functional assessment were conducted on the patients at the beginning of the study and 6 months after the start of treatment. Kirkley et al determined that there was no statistically significant difference between the unloader brace and the neoprene sleeve cohorts in the number of stairs climbed or the WOMAC scores. Nevertheless, the study indicated that there was a trend toward significant differences, with improved results in the unloaded bracing group. Dessery et al stratified 24 patients with knee OA to wear three different knee braces: a valgus brace with a three-point bending system ($n = 7$), an unloader brace with valgus and external rotation functions ($n = 10$), and a ligament injury brace ($n = 7$) for 2 weeks.¹³

All three braces provided immediate pain relief and improvement in function during gait. However, the authors indicated that the unloader brace offered a comfort advantage and could result in better compliance. It is important to take into consideration that these studies may not have been able to demonstrate significant differences in the patient populations because of small cohorts and lack of compliance data.

Due to the conflicting study results involving the unloader brace, there have been inconsistent recommendations from various society guidelines regarding their use. The 2013 American Academy of Orthopedic Surgeons evidence-based guidelines for the treatment of OA of the knee concluded that they are unable to recommend for or against the use of a valgus-directed force brace for patients with symptomatic knee OA.¹⁴ However, they failed to address both types of braces that are able to produce valgus and varus force. Furthermore, the authors stated that practitioners should take patient preference into consideration rather than focusing solely on the recommendation.

According to the positive results obtained in this trial, we found that the brace cohort to receive a significantly lower number of injections as compared with the nonbracing cohort, which may be indicative of the therapeutic potential of this brace. In addition, there was a lower proportion of patients who had an eventual TKA in the bracing cohort as compared with the nonbracing cohort. The mean time to TKA was also longer in the bracing cohort, which may potentially be an indicator of a surgery-delaying effect. Patients compliance monitoring might be necessary to determine proper adherence to regular unloader brace use. Although these results may have not reached statistical significance due to the small sample size, these results point to the potential of potentially reducing the need for and prolonging the time to TKA. Performing a larger prospective randomized study to adequately power subsequent studies is warranted to definitively demonstrate clinical improvements with the use of unloader bracing in the treatment of knee OA. The unloader brace may be a valuable adjunct to the current knee OA treatment pending further investigation.

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