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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Introduction

Knee osteoarthritis (OA) can result in decreased function and discernible pain in an estimated 3.8% of the population in the United States [1], and the annual cost for pain management can be over $5000 per person [2]. It is estimated that over 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 span of the population [4]. Many patients often require joint arthroplasty as the osteoarthritis progresses to end-stage degenerative joint disease. Additionally, it is estimated that the incidence of total knee arthroplasty 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 healthcare system.

Non-invasive treatment options such as non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy, and corticosteroid injections can provide symptom relief for knee osteoarthritis; however they have no affect on disease progression. It is essential to employ an adjunctive treatment that could potentially prevent or delay the need for total knee arthroplasty as well as reduce the monetary burden on the healthcare system associated with such procedure. The use of a novel brace has been shown in pilot studies to decrease pain and increase muscle strength in patients with knee osteoarthritis, due to its key features such as active swing-assist, neuromuscular retaining properties, and pneumatic unloader [6]. Additionally, a randomized trial demonstrated improvements in muscle strength, functional tests, and patients reported outcomes when compared to a matched cohort [7]. This device may have the potential to delay the need for surgery, improve function, and the quality of life.

Currently, there is not sufficient evidence describing the clinical impact of these braces and their efficacy in the treatment of knee OA in the United States. We evaluated the brace in order to explore its effects on late-stage knee osteoarthritis (Kellgren Lawrence grade 3 and 4) [8]. 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 were randomized to receive either a pneumatic unloader brace and conventional treatment or conventional treatment alone.

Methods

We performed a prospective, randomized, single center study of patients who had Kellgren-Lawrence grades 3–4 osteoarthritis 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. Patients were eligible for recruitment if they were: between the ages of 30 and 90 years of age, had Kellgren-Lawrence grades 3–4 osteoarthritis in medial or lateral compartment of the knee, persistent pain beyond current treatment, able to comply with study requirements, and no history of corticosteroid injection in the last 3 months. Patients were ineligible if they: were under the age of 30 years or greater than 90 years of age, had a history of peripheral vascular disease with femoral stenting or graft (e.g. graft surgery/aorto-femoral-popliteal bypass) on the affected side, history of diabetic neuropathy, traumatic onset of knee pain, had undergone surgery on either lower limb within 6 months, had received corticosteroid injections in the affected knee within 3 months of the study, had equal osteoarthritis in both medial and lateral compartments, or were unable to comply with study requirements. We observed 50 prospective, randomized patients (25 study, 25 control) with Kellgren-Lawrence grades 3–4 osteoarthritis [5] who were to either receive the pneumatic brace or standard of care treatment used at our institution. Of the 50 patients, 5 were excluded from the

final analysis resulting in a total of 45 patients who successfully completed the study. There were a total of 5 patients excluded in the brace study cohort, as the patients were unable to obtain the brace for various reasons.

The final brace cohort was comprised of 20 patients (11 men and 9 women) with a mean age of 58 years (range, 34–78 years). The final control cohort was comprised of 25 patients (6 men and 19 women) with a mean age of 63 years (range, 41–86 years). All demographics characteristic were not significant between the two cohorts except for gender (p=0.033) (Table 1).

All study patients in the randomized bracing cohort were fitted with an OA Rehabilitator™ brace (Guardian Brace, Pinellas Park, Florida). 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 medio-lateral stability is established by using rigid composite material for the uprights. The pneumatic unloading is achieved via strategically 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. It is recommended that during vigorous activity (such as exercise) the bladder be inflated more, when compared to walking. One squeeze of the pump inflates bladders with 30 cc of air. As a result, for normal activities each bladder was inflated about 60 cc and for more extraneous activities it was inflated up to 90 cc. The swing-assist is established via the use of an elastic cord implanted within the hinge of the brace. During flexion of 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 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. For adults typically, the elastic bands are tensioned at 5 pounds per inch displacement. In heavier patients (> 250 lb), the cords can reach up to 7 pounds per inch of displacement. Patients were instructed to wear the brace for at least three hours per day when ambulating. 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 of physical therapy, corticosteroid injections, and self-guided home exercise programs. In patients who opted to receive a corticosteroid injection: the affected knee was prepped and draped in the normal fashion, and was injected intra-articularly with a combination of 1 mL Kenalog 40 mg and 4 mL of 1% lidocaine. Pressure was held as the needle was withdrawn, and a bandage was applied to the site of injection. 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 3 exercise motions. In the first motion, the patients initially lay on their back, lift their leg up 6 inches off the floor with a slight bend in their knee and hold it for 5 seconds, then slowly relax the leg back to floor. This move is repeated 10 times on one leg, and then the same sequence is repeated on the opposite leg. The second motion, consist of the patient lying on their side and holding the leg up 6 inches laterally from their body for 5 seconds, then slowly relaxing it back down. This move is repeated in the same fashion as the first motion.

In the third motion, the patient lies on their abdomen and raises their thigh off the floor and holds it for 5 seconds, and goes through the same sequence described in the two previous motions. Each motion is conducted on both lower extremities, and patients repeat this cycle two more time for a total of 3 sets with 10 repetitions each. Patients were instructed to perform the exercise every other day and to incrementally increase resistance by using ankle weights until they were able to reach 7.5 and 10 pounds per leg in all motions for women and men, respectively. 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 these patients and they continued using the brace. Data record and statistical analysis was conducted using Excel and SPSS version 21 (IBM corporation, Armonk, New York). Student's t-test were used to evaluate continuous data, and chi-square was used for categorical data between the treatment and control groups. Additionally, we performed a Kaplan Meier analysis to determine if there was a difference in the time to TKA. A p-value of < 0.05 was used to determine significance.

Results

At a minimum follow-up of 1-year (mean 27 months, range 12-41 months) There was no significant difference in the number of patients who underwent an eventual TKA in the bracing cohort as compared to the non bracing cohort (11 vs 7), $p=0.07$. There was no significant difference in the Kaplan meiri analysis of time to TKA ($p=0.409$). The mean number of days from enrollment to TKA was significantly different between those who had and did not have the brace (524 vs 407, $p =0.054$). There was no significant difference in opioid use between the two groups. There was a significantly lower number of patients who received injections in the bracing cohort as compared to the non-bracing cohort (11 vs 19, $p=0.049$).

Discussion

With the increasing burden of knee osteoarthritis and projected increases in the number of total knee arthroplasties 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 to the non bracing cohort. Additionally, we found that the mean number of days to TKA was close to approaching statistical significance, with the bracing cohort having a lower number of days. However, the Kaplan Meier analysis revealed no significant difference in the time to TKA between the cohorts. Additionally we found no significant difference in the number of patients who took opioids between the groups.
There are several limitations in this study. 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 mean number of days to TKA almost approached statistical significance which may indicate the potential of the unloader brace delaying the time to TKA. 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. 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. 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 reevaluate 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 osteoarthritis. 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 osteoarthritis. 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 VAS-pain and 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 week later. There was also a significant improvement in lower-limb joint angles, power, and moments with the use of the brace.

Komistek and colleagues 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] 12 of the 15 patients 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 tibio-femoral 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 non-addictive, non-invasive 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 osteoarthritis of the knee for 12 months, with follow-up at 3 months, 6 months, 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 and colleagues recognize there is a need for further studies with larger patient populations due to fact that at least 25% of their patient population was non-compliant. 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 and colleagues 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. It is important to take into consideration that these studies may not have been able to demonstrate significant differences in the patient populations without compliance data because they did not take into account the compliance to treatment as well as the fit of the device.

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 osteoarthritis 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 [13]. 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 believe unloader brace may be a valuable adjunct to the current knee OA treatment pending further investigation. This option may allow patients to avoid the potential side effects of injections, as well as delay the potential risks of invasive procedures. Performing a larger prospective randomized study to adequately power subsequent studies are warranted to definitively demonstrate clinical improvements with the use of unloader bracing in the treatment of knee osteoarthritis.

Table 1. Demographic Characteristics

	Brace N (%)	**No Brace N (%)**	**p-value**
Total	20	25	
Age (mean) (range)	58 (34 to 78)	63 (41 to 86)	0.171
Gender			
Men (%)	11 (55)	6 (24)	0.033
Women (%)	9 (45)	19 (76)	
BMI (mean) (range)	31 (20 to 46)	33 (23 to 48)	0.474

Table 2. Study Endpoints

	Brace N (%)	**No Brace N (%)**	**p-value**
Total	20	25	
Follow-up in months (mean) (range)	27 (15 to 41)	27 (12 to 36)	0.989
Eventual TKA	11 (55)	7 (28)	0.07
Time to TKA in days (mean) (range)	524 (237 to 1005)	407 (186 to 906)	0.054
Opioid use	6 (30)	5 (21.7)	0.536
Injections (Steroid/ Anesthetic combination)	11 (55)	19 (83)	0.049

Figure 1. Kaplan-Meier analysis of time to TKA (log rank, p = 0.409)

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