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Strength and Functional Improvement Using Pneumatic Brace with Extension Assist for End-Stage Knee Osteoarthritis: A Prospective, Randomized trial

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ABSTRACT

Pneumatic unloader bracing with extension assists have been proposed as a non-operative modality that may delay the need for knee surgery by reducing pain and improving function. This prospective, randomized trial evaluated 52 patients who had knee osteoarthritis for changes in: (1) muscle strength; (2) objective functional improvements; (3); subjective functional improvements; (4) pain; (5) quality of life; and (6) conversion to total knee arthroplasty (TKA) compared to standard of care. Patient outcomes were evaluated at a minimum 3 months. Braced patient's demonstrated significant improvements in muscle strength, several functional tests, and patient reported outcomes when compared to the matched cohort. These results are encouraging and suggest that this device may represent a promising alternative to standard treatment methods for knee osteoarthritis.

Osteoarthritis of the knee is a debilitating disease that results in decreased function and marked pain in an estimated 3.8% of the population in the United States [1], and costs over $5000 per person annually for pain management [2]. Currently, it is estimated that there are over 10 million people affected by this disease in the United States [3] and as the population continues to live longer, coupled with the growing obesity epidemic, this number is expected to nearly double in the next decade [4]. Furthermore, as the natural history of osteoarthritis progresses to end-stage degenerative joint disease, many patients often require joint arthroplasty. In light of the cost of managing these patients, and estimations that the incidence of total knee arthroplasty will increase from 488,000 to 3.75 million by the year 2030, this represents a tremendous potential economic burden on the healthcare system [5].

One of the challenges of treating patients with painful end-stage osteoarthritis is dealing with their common quadriceps and hamstring muscle weakness and their inability to tolerate exercises. In a painful arthritic joint, arthrogenic muscle inhibition (AMI) is a common occurrence [6]. This inhibition is caused by several factors such as pain, joint instability, joint effusion, and neural inhibition. Patients who have symptomatic osteoarthritis often present with the affected limb being weaker by up to 50% as compared to the unaffected limb as well as marked weakness when compared to published age and gender matched database (See Table 1). A brace that allows pain free rehabilitation and muscle strengthening by just simply walking in the device for up to 3 hours per day might be quite beneficial for these patients.

There are many non-operative treatment modalities for knee osteoarthritis, including physical therapy, non-steroidal anti-inflammatory drugs (NSAIDs), and corticosteroid injections; however, these only appear to offer transient symptomatic relief rather than affecting disease progression. Therefore, in an attempt to reduce the burden to the healthcare system, the needs for adjunctive treatment modalities, which delay or prevent the need for total knee arthroplasty are of paramount importance. The use of a novel brace with a combination of features such as a pneumatic unloader, active swing-assist, and neuromuscular retaining properties, has been previously shown in a pilot study to decrease pain and increase muscle strength in patients afflicted with knee osteoarthritis [7]. This has the potential to not only improve the quality of life, but also may delay the need for surgery as function improves.

Several studies have described the efficacy of knee brace for pain relief in knee osteoarthritis, however, the 2013 American Academy of Orthopaedic Surgeon evidence base guidelines for the treatment of knee osteoarthritis reported that there is currently limited level 1 evidence to support or refute the use of unloader bracing in unicompartmental knee OA [8]. Due to this limited number of level 1 trials evaluating the clinical efficacy and impact of these braces for the treatment of knee osteoarthritis in the United States. Therefore, we evaluated this novel brace in an attempt to elucidate its effects on patients who have late stage knee osteoarthritis (Kellgren Lawrence grade 3 and 4 [9]). Specifically, we assessed: (1) changes in isokinetic muscle strength; (2) objective

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Table 1
Comparison of Patients in Study to Uninvolved Side and Non-symptomatic Age and Gender Matched Normative Data[41].

Study Group Muscle Strength	Involved Side	Uninvolved Side	% Weaker Compared to Uninvolved Side	Fearon [41] data	% Weaker Compared to Normative Data	Significance
Quadriceps	24.7 (5–65)	34.5 (7.8–65)	46.5 (12–90)	56.7 (40–77)	55% (93– to 44)	0.001
Hamstrings	19.6 (4.4–48.1)	24.7 (6–47.7)	23.8 (−11 to 55)	34.6 (23–46)	42% (86–33)	0.001

functional improvements; (3); subjective functional improvements; (4) quality of life measures; (5) patients pain perceptions; and (6) conversion to total knee arthroplasty.

Materials and Methods

This was a prospective, randomized, single center, single blinded study of patients who had Kellgren-Lawrence grades 3–4 osteoarthritis [9] comparing pneumatic brace to standard of care treatments. Prior to enrollment initiation of the study appropriate institutional review board was obtained. Patient inclusion criteria were as follows: between the ages of 41 and 80 years of age, osteoarthritis in medial or lateral compartment with Kellgren-Lawrence grades 3–4 osteoarthritis, persistent pain beyond current treatment, able to comply with study requirements, and no history of corticosteroid injection in the last 3 months. Patients were excluded if they: had a history of diabetic neuropathy or peripheral vascular disease with femoral stenting or graft (e.g. aorto-femoral-popliteal bypass/graft surgery) on the affected side, history of traumatic onset of knee pain, had undergone surgery on either lower limb within 6 months, were unable to comply with study requirements, were under the age of 40 years or greater that 80 years of age, had previously received corticosteroid injections in the affected knee within 3 months of the study, had equal osteoarthritis in both medial and lateral compartments, and Kellgren-Lawrence grades 1–2 osteoarthritis. We studied prospective, randomized 59 patients (29 study, 30 control) who had Kellgren-Lawrence grades 3–4 osteoarthritis [9] to receive either the pneumatic brace or standard of care treatment used at our intuition. Of the 59 patients who underwent randomization, 7 patients were excluded from final analysis resulting in a total of 52 patients who completed the study. There were a total of 3 patients excluded in the brace cohort, 1 patient had irritation with the use of the brace and chose to no longer participate in the trial, 1 patient was considered to be lost to follow-up after failing to return for her scheduled appointments and numerous attempts to contact the patient were unsuccessful, and 1 individual chose to no longer participate in the study for medical/appointment concerns after being diagnosed small cell lung cancer. Of the 4 patients that were excluded in the matched cohort, 2 patients were considered to be lost to follow-up after several attempts to contact these patients to return were unsuccessful, 1 patient had severe pneumonia, which required hospitalization for 3 weeks during the study period and the patient was sent to rehabilitation for deconditioning after hospital stay, and 1 patient was withdrawn due to other medical concerns unrelated to knee arthritis.

The final brace cohort consisted of 26 patients (13 men and 13 women) who had a mean age of 59 years (range, 45–79 years). The final matching cohort consisted of 26 patients (14 men and 12 women) who had a mean age of 54 years (range, 41–69 years). Radiographic assessment was performed on patients using weight bearing standing films to assess mechanical axis. In the brace group, of the 26 patients who finished the study, 15 patients had genu varus alignment who had a mean angle of 5.5 degrees (range; 3–10 degrees), 3 patients were with in 2 degrees of neutral alignment, and 8 patients had a mild valgus deformity with a mean angle of 6.2 degrees (range; 3–11 degrees). In the matched group of the 26 patients who completed the study, 13 had varus alignment with a mean angle of 4.9 degrees (range; 4–11 degrees), 4 patients were within 2 degrees of neutral alignment, and 9 patients had mild had genu valgus deformity with a mean angle of 5.7 degrees (range; 3–10 degrees). There were no statistical differences between the two groups in terms of age, gender, or Kellgren-Lawrence osteoarthritis stage.

All study patients who randomized to the bracing cohort were fitted with an OA Rehabilitator™ brace (See Fig. 1), (Guardian Brace, Pinellas Park, Florida). The brace combines three elements previously mentioned: pneumatic joint unloading, active swing-assist, and construction made of a flexible and elastically deformable material. The cuffs on the brace are flexible and strapping material is elastic, which allows for dynamic conformability. The uprights are made of a rigid composite material and offer the medio-lateral stability to the brace. 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 according to the level of activity the patient anticipates performing. Patients wear the brace first and adjust straps to fit the brace snugly before inflating pneumatic bladders for unloading the joint. It is recommended that the bladder be inflated more when the patient plans to perform more vigorous activity (such as exercise) when compared to walking. Each squeeze

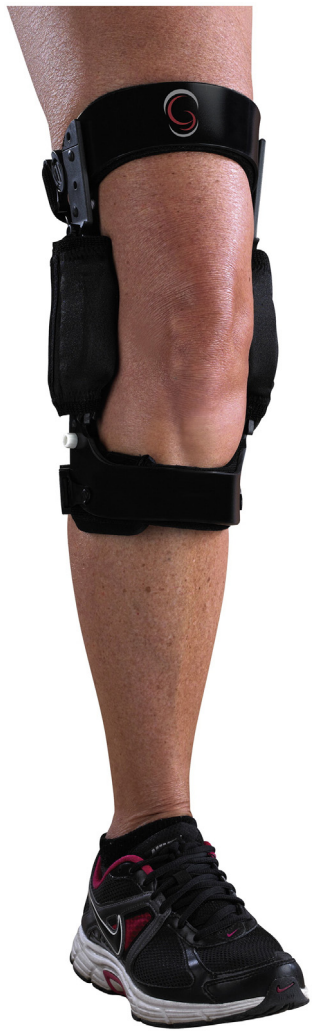

Fig. 1. Image of pneumatic brace with extension assist.

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on the pump to inflate bladders equals 30 cc of air, thus for normal activities each bladder was inflated about 60 cc and for heavier activities by up to 90 cc. The swing-assist is accomplished through the use of an elastic cord embedded within the hinge of the brace, thereby, providing a dampening effect during knee flexion, and an active swing assist during the terminal swing phase of the gait cycle. In late swing phase of the gait cycle, hamstrings have to work eccentrically to control knee extension as the bands promote rapid knee extension and in the loading response phase of the stance phase quadriceps muscle have to act eccentrically against the extension assist bands to achieve adequate knee flexion. During the fitting process, care was taken to educate patients about using the brace and training was given to use it to facilitate heel toe gait and employing swing phase knee flexion during use. Typically for adult patients, these elastic bands are tensioned at 5 pounds per inch displacement. In heavier patients (>250 lb), the cords can go up 7 pounds per inch of displacement. All patients were instructed to wear the device for a minimum of three hours per day when ambulating. They were allowed to use the brace while performing physical activity such as stairs, using an elliptical, or when riding a bike.

The current standard of care at our institutions consists of physical therapy, corticosteroid injections, and self-directed home exercise programs. Of the patients that were randomized to the control cohort, 12 individuals underwent treatment with corticosteroid injections, while the other 9 patients were treated with physical therapy. Patients who opted to have a corticosteroid injection: the knee was prepped and draped in the usual fashion, and was injected intra-articularly with a mixture of 1 mL Kenalog 40 mg and 4 mL of 1% lidocaine. Pressure was held as the needle was withdrawn, and bandage was applied. Patients who opted to undergo physical therapy were given prescriptions for physical therapy for range of motion, strengthening modalities, and gait training to the knee for three times a week for 6 weeks at our institution. At their initial appointment all patients who randomized to this cohort, also underwent thorough counseling on self-directed exercise program used at our institution. Self-directed exercise therapy consists of 3 exercise motions were patients initially lie on there back lift their leg 6 inches off the floor with a slight bend in there knee and hold it for 5 seconds and then relaxing the leg back to floor. This step is repeated 10 times, and then the opposite leg undergoes the same sequence. The second motion, consist of the patient lying on there sides hold the leg 6 inches laterally from their body for 5 seconds, then relaxing. This sequence is repeated as describe before for the first motion. In the third motion the patient lies on their abdomen and raises their thigh of the floor, and goes through the same sequence described in the two previous motions. Each motion is performed for both lower extremities, and patients repeat this cycle two more time. In all patients in the matching group performed each exercise 3 sets 10 repetitions. Patients are instructed it skip a day between performing exercises, and instructed to incrementally increase weight with ankle weights until they are able to reach 7.5 and 10 pounds per leg in all motion directions for women and men, respectively.

Both treatment and the matched cohorts were not prohibited from receiving previously prescribed NSAIDs. However, we instructed patients to remain taking the same dosage of NSAIDs medication throughout the study, and that if increase or change of dosage was needed, this would only occur after their three month follow-up appointment. In addition, no patients in the study were started on new pain medications at the time of enrollment and throughout the trial period by our institution. The rationale behind our choices for a corticosteroid injection/physical therapy and to allow the use of NSAID as the matching cohort was to compare the use of the brace to the current initial standard of care at our institution.

The following patient reported subjective metrics were evaluated at the initial appointment and at the 3 month follow-up visits: visual analog scale (VAS) for pain, the new Knee Society objective and functional scores, lower extremity functional scale (LEFS) and SF -36. In addition, the following functional and clinical objective tests were also performed: timed up and go test; a timed stair climb test; repeated chair rise (5 times) test; two minute walk test; single limb step (20 times) test; and an isokinetic quadriceps and hamstrings muscle strength test.

Pain evaluations were performed using the scores from the reported visual analog scores. The raw score was measured, and the difference in pain scores was calculated between the groups at baseline as well as at the 3-month follow-up visit. A change in 2 points on the visual analog pain scale was considered to be a clinically important change from baseline [10].

Subjective functional improvements were measured by patient-answered quantifiable objective scoring systems. These included the lower extremity functional scale (LEFS) [11], and the new Knee Society Knee Functional and Objective scores [12]. The LEFS is a patient-rated evaluation of their ability to perform activities of daily living, and provides a subjective measure of how patients feel that they were able to perform these activities [11]. The new Knee Society questionnaire is a validated measure of function and objective measures, which characterizes the satisfaction, expectations, and physical activities of patients [12,13]. The SF-36 is a general, multipurpose health survey, consisting of 36 questions, which provides a measure of physical and mental health.

Objective functional improvements were measured using a timed "up and go" (TUG) test, timed stair-climb test, two minute walk test, repeated chair rise (5 times) test, single limb step (20 times) test, and an isokinetic quadriceps and hamstrings muscle strength test [14]. The timed "up and go" test measures the amount of time required for a patient to stand from a seated position, walk to a pre-determined position 3 meters away, turn around, return to the chair, and return to a seated position. This should be performed within 10 to 18 seconds in the normal individual. This is a global measure of gait speed, balance, functional ability, and strength to rise from seated position, and expected results are normalized based on patient age [15–19]. The timed stair climb test was a measure of the amount of time it took patients to climb 15 steps and return back down. Patients were instructed that they must alternate using a single leg on each step, and were allowed to use stair rail. For consistency, we used same the staircase in our institution for all patients. The rise on the step for this staircase was 8 inches and is standard for all public buildings in the United States. The 2-minute walk test was a measurement of endurance by assessing the distance patients were able to ambulate over 2 minutes. This test was performed at the fastest speed possible and assistive devices were sometimes used, but should be documented and kept consistent from test to test [20,21]. The repeated chair rise test was a measure of functional lower extremity muscle strength. A straight back chair without arm rests was used and was placed against the wall. The subjects were instructed to sit in the seat with their feet, shoulder width apart and flat on the floor. From the sitting position, the patient was then instructed to stand completely up, then completely back down without the use of their hands. This was repeated 5 times and the duration was documented [22]. The single leg step test measured the duration of time it took patients to step up a 6-inch platform 20 times. This test was conducted on the limb under evaluation only.

The isokinetic quadriceps and hamstrings muscle strength testing was performed on both the involved as well as the uninvolved side. The strength test was conducted using a Dynamometer (Biodex Medical Systems, Shirley, New York). Dynamometer orientation utilized tilt kept at 10 degrees, ensuring that the hip joint was in 100 degrees of flexion. The dynamometer was adjusted to each patient so that the axis of the dynamometer was aligned with the center of the knee joint. Isokinetic knee flexion and extension muscle testing was performed with five repetitions at 60 degrees/second. Before each test, patients were allowed to do a practice run of 2 or 3 contractions at submaximal effort to get acclimatized. Peak torque (foot-pounds) was measured during each repetition. The highest and lowest measurements were discarded, and the remaining three values were averaged to calculate a mean torque for

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both hamstring and quadriceps muscle strength. These measurements were performed at the initial and 3-month visits. Special care was taken to accurately measure the length of the dynamometer arm from the knee axis and this was reproduced for all the measurements to keep torque measurements consistent. Peak torque measurements in foot-pounds were normalized to body weight (BW) and were expressed in ft- lb/ BW*100. Normalization of the data allowed us to compare strength data within and across study groups.

All patients were monitored for adverse events during the study period that were related to the use of the device. Specific complications monitored included increased pain, local skin reactions, local skin irritation or breakdown due to wear of the device, or any abnormal electrical events due to improper use or malfunction of the device. No severe adverse reactions were found with the use of wearing the device (i.e. ulcerations), however, 2 patients complained of minor irritation at pad placement sites, and pads were replaced with these patients continuing to use the brace.

Data was recorded in an Excel spreadsheet (Microsoft Corporation, Redmond, Washington) and statistical analysis was conducted using a SigmaStat version 3.0 (SystatInc, San Jose, CA). Pre- and post-treatment variables were evaluated using the Student's t-test to compare pre- and post-operative continuous data scores between the treatment and matching groups, as well as between visits. Significance was determined by a p-value of <0.05. In addition we performed sample size and power analysis using Statistical Solutions LLC, software program in order to validate adequacy of our sample size for statistical significance at less than 0.05.

Results

Treatment with the brace resulted in significant improvements in mean quadriceps muscle strength from 19.6 ft.lb*BW/100 (range, 5–44.7) to 28.1 ft.lb*BW/100 (range, 7.8–53.9; $p = 0.022$) and hamstrings muscle strength from 17.3 ft.lb*BW/100 (range, 6.5–48.1) to 21.5 ft.lb*BW/100 (range, 5.5–61.9; $p = 0.0016$). Patients in the brace group showed a 54% (range, 10.3–165%) improvement in their quadriceps muscle strength (See Fig. 2) and a 27.7% (range, −15 to 106%) gain in their hamstring muscle strength (See Fig. 3). In comparison, the matching cohort had a significant loss of quadriceps muscle strength from a mean of 28.7 ft.lb*BW/100 (range, 12.0–54.2) to 25.6 ft.lb*BW/100 (range, 8.8–34.4) ($p = 0.026$) and a non-significant loss of hamstring strength from 21.6 ft.lb*BW/100 (range, 4.4–34.3) to 20.1 ft.lb*BW/100 (range, 6.6–30.3; $p = 0.37$). Patients in the matching group lost a mean of 8% (range, 38–48.8%) quadriceps muscle strength and a mean of 1.8% (range, 43–47%) hamstring muscle strength. (Table 2). The quadriceps and hamstrings muscle strength

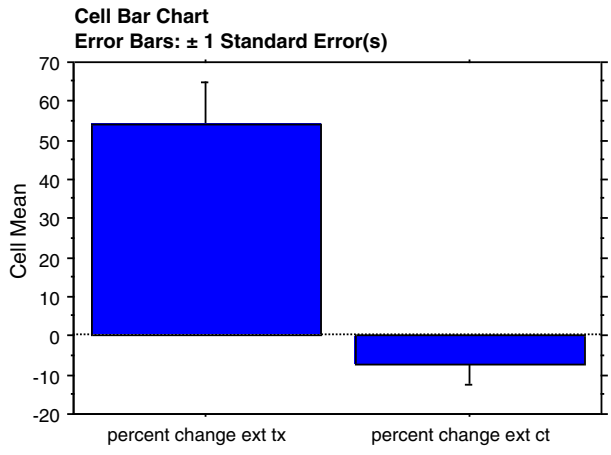

Fig. 2. Image demonstrating improvements in quadriceps muscle strength in the brace group compared to control. Vertical error bars represent the standard deviation.

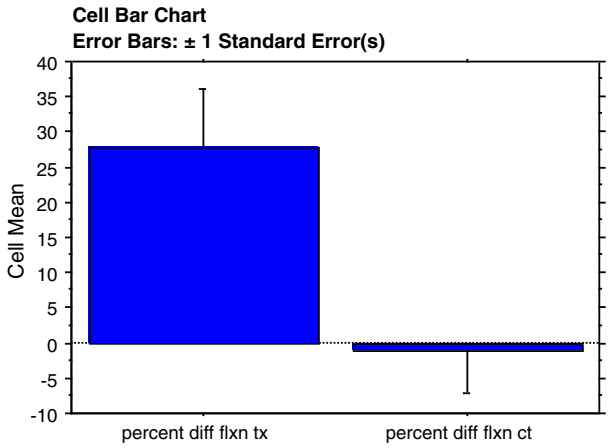

Fig. 3. Image demonstrating improvements in hamstring muscle strength in the brace group compared to control. Vertical error bars represent the standard deviation.

improvement in brace group as compared to loss/marginal improvement in the control group was statistically significant $p = 0.0001$.

Patients in the brace group demonstrated improvements in several functional tests. Timed to up and go test (TUG) improved significantly by 2.4 seconds (range, −2 to 11; $p = 0.007$) in the brace group as compared to a mean increase of 0.1 second (range, −3 to 6; $p = 0.096$) in the matched cohort (See Table 3). In addition, significant improvements in the study group were seen on evaluation of timed stair climb test 7.8 seconds improvement (mean, 3–30; $p = 0.007$), as compared to brace group the control group improved by mean of 1.7 (−7 to 14, $p = 0.065$). Furthermore, the patients in the bracing group demonstrated an improvement of 1.3 seconds in the 20 steps on 6-inch step (mean, 47.2–45.9; $p = 0.075$), compared to that patients in control group had mean loss of 7.5 seconds ($p = 0.28$), (See Table 3). Three patients in the brace group and 5 in matched group were unable to perform this test at their initial test. At the time of retesting, 4 patients in the matched group and 4 in the brace group could not perform 20 step up on a 6 inch step. In the 5 times repeated chair rise, patients were found to have a significant improvement of 1.4 seconds (mean, 19.4–18); $p = 0.059$, and in the 2-minute walk test, a 43 feet (mean, 397–440; $p = 0.019$) from their initial to 3 month follow-up. As compared to that patients in control group showed mean improvement of 1.1 seconds ($p = 0.23$) for repeated chair rise and mean loss of 27 feet ($p = 0.24$) for 2 minute walk distance. (See Table 3). The improvement in brace group as compared to change in the control group was statistically significant ($p = 0.001$–0.05) for TUG, stair climbing test and 2 minute walking distance.

When evaluating subjective functional metrics, the mean improvement in LEFS was 8.3 points ($p = 0.001$) in the brace group (Pre LEFS 43.6 points, range 29–75 to post LEFS 51.9 points, range 30–75) as compared to that the matched group, which showed a mean decrease of 3.5 points ($p = 0.25$) (Pre LEFS 36.2 points, range 20–52 to Post LEFS 32.6 points, range 10–60) (See Table 4). The Knee Society objective mean scores after brace use were significantly higher by 10.7 points in the study group ($p = 0.0067$) when compared to patients in the matched group showed insignificant improvement of 5 points in the mean score ($p = 0.28$). The Knee Society functional scores mean was higher by 3.4 points in the brace group, which was not significant ($p = 0.112$). as compared to that control group showed mean improvement of 3.7 point which was not significant ($p = 0.11$). When evaluating SF-36 scores, the study group showed mean improvement of 0.2 in mental score and mean improvement of 2.5 for physical score. These improvements were not statistically significant ($p = 0.73$, $p = 0.31$). In the control group there was mean improvement of 6.3 and 6.5 points in the mental and physical scores. These improvements also were not statistically significant ($p = 0.26$, $p = 0.25$). The improvement in LEFS

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Table 2
Strength Change After Brace Use for 90 Days as Compared to Control Group.

	Pre	Post	Difference	Significance	% Improvement
Braced condition (Quadriceps)	19.64 (5–44.7)	28.09 (7.8–53.9)	8.45 (2.3–23.5)	0.022	54.1 (10.3–165)
Control (Quadriceps)	28.7 (12–54.2)	25.6 (8.8–34.4)	−3.2 (21.1 to 5.8)	0.026	−7.6 (−38.9 to 48.8)
Braceed condition (Hamstrings)	17.3 (6.5–48.1)	21.5 (5.5–61.9)	4.2 (−2.8 to 13.8)	0.0016	27.7 (−15 to 106.2)
Control (Hamstrings)	21.6 (4.4–34.3)	20.1 (6.5–30.3)	−1.7 (−13.7 to 6.9)	0.37	−1.8 (−43.4 to 47.2)

score, and KSS objective score as compared to change in the control group was statistically significant ($p = 0.0089$), while as the improvement in the brace group as compared to change in the control group in KSS functional score, and SF 36 scores was not significant ($p = 0.45$).

Patients in the brace group had significant improvements in pain scores from a mean of 4.7 points (range, 2–8) to 2.8 points (range, 0–6) in VAS score ($p = 0.00075$) as compared to a insignificant increase in VAS score by 0.1 points, (range, −4 to 4) in the matching group (Pre VAS of 5.2 to Post VAS of 5.1 points; $p = 0.45$) (See Table 4). The mean improvement in VAS score for brace group as compared to improvement in the control group was statistically significant ($p = 0.0057$).

When analyzing the number of patient who ultimately went on to a total knee arthroplasty during the study period, we found that in the bracing group 2 patients elected to undergo TKA versus 5 patients in the matching cohort elected to have TKA surgery.

Discussion

Knee pain due to osteoarthritis can be difficult to treat. Many patients have limited functional mobility and become increasingly sedentary due to pain. Treatment options for osteoarthritis include muscle strengthening, non-steroidal anti-inflammatory drugs, weight loss, and corticosteroid injections. Often, these treatments only function to provide pain relief to temporarily forestall the need for a total knee arthroplasty for end-stage degenerative joint disease. The purpose of this study was to evaluate the effectiveness of a pneumatic unloader brace for decreasing pain scores (VAS values), improving subjective measurements of clinical outcomes (Knee Society objective and functional scores, Lower Extremity Functional Scores), improving objective measures of patient function (timed up-and-go test, repeated chair rise, and isokinetic muscle testing. This study demonstrated that the use of this pneumatic unloader brace for the treatment of knee arthritis resulted in significant improvements in quadriceps and hamstring muscle strength, several functional tests, and patient reported outcomes when compared to a matched cohort. This study is the first randomized control study in the literature (Table 5) on effectiveness of the brace in Kellegren Lawrence 3, 4 grades. All previous studies are on grade 1 through 3. In addition most studies in the literature rely on subjective scoring and patient reported function while as in the current study we performed testing using various functional tests as well as validated isokinetic muscle strength testing in addition to subjective scores.

There were several limitations of this study. It was conducted on a small number of patients ($n = 52$), which potentially can be explained by the extensive testing that is required to evaluate each patient carefully. Typically, these tests are not performed on patients who are undergoing treatment for osteoarthritis and therefore this increases the length of their visits extensively (3–4 hours). However, the authors believe that the number of patients analyzed was sufficiently large to provide statistically significant results in majority of the observed metrics since it was validated by sample and power analysis. This analysis showed that for all the tests that showed statistical significance (less than 0.05), we needed a sample size range of 12–21 subjects only. Similarly, there is a potential for confounding variable of treatment options in the matched cohort; however, we believe that these results are encouraging, that despite multiple modalities in the matched cohort that bracing was still able to demonstrate significant improvements over injections and Physical Therapy in several metrics. Additionally, although these results are encouraging at 3 months, it will be useful to repeat these outcomes at future time points to evaluate longer-term improvements in pain scores and patient functionality, which is planned. A more definitive outcome of whether or not a treatment has successfully improved the clinical nature of osteoarthritis would be if it could either (1) delay, or (2) prevent the need for total knee arthroplasty. Although this study was not sufficiently powered to detect a difference in the short-term incidence of total knee arthroplasty in these patient cohorts, the patients will be followed longitudinally in an effort to compare the effectiveness of the two treatment arms' ability to influence the need for this procedure. The incidence of TKA in the matching group was more than two fold compared to the study group, but longer-term data in a larger sample would be needed to evaluate these findings.

There are varying results concerning the efficacy of these braces for the treatment of osteoarthritis. Although previous studies have suggested that unloader knee brace may be effective at controlling pain and improving function in knee osteoarthritis [23–31], some studies have found questionable usefulness of for these devices [32,33]. In a

Table 3
Functional Tests.

	Pre Brace	Post Brace	Mean Change	Significance
	TUG	Tug		
Braced	14.2 (6–25)	11.8 (6–20)	2.4	$p = 0.007$
Control	15 (7–27)	14.9 (8–25)	0.1	$p = 0.096$
	Timed Stair Climb	Timed Stair Climb		
Braced	30 (10–80)	22.2(5–61)	7.8	$p = 0.0408$
Control	24.2 (10–42)	22.5 (11–38)	1.7	$p = 0.065$
	20 steps on 6 inch step	20 steps on 6 inch step		
Braced	47.2 (17–71)	45.9 (19–89)	1.3	$p = 0.075$
Control	57.8 (41–115)	65.3 (28–110)	-7.5	$p = 0.28$
	5* Repeated chair Rise	5* Repeated chair Rise		
Braced	19.4(7–35)	18 (7–37)	1.4	$p = 0.059$
Control	17.7 (10–36)	16.6 (6–27)	1.1	$p = 0.23$
	2 minute walk	2 minute walk		
Braced	396.9 (198–900)	440.2 (288–925)	43.3	$p = 0.019$
Control	323 (115–480)	296 (110–528)	27	$p = 0.24$

Table 4
Subjective Outcome Scores.

	Pre	Post	Mean Change	Significance
	VAS pain score	VAS pain score		
Braced	4.7 (2–8)	2.8 (0–6)	1.9	$p = 0.0075$
Control	5.3 (2–9)	5.1 (2–9)	0.1	$p = 0.77$
	LEFS	LEFS		
Braced	43.6 (29–75)	51.9 (30–75)	8.3	$p = 0.001$
Control	36.2(20–52)	32.6(10–60)	3.5	$p = 0.25$
	KSS Functional	KSS Functional		
Braced	51.9 (24–79)	55.3 (16–98)	3.4	0.112
Control	49.3 (32–68)	53 (33–68)	3.7	$p = 0.11$
	KSS Objective	KSS Objective		
Braced	59.2 (19–90)	69.9 (42–95)	10.7	$p = 0.0067$
Control	42.5 (25–72)	47.5(25–80)	5	$p = 0.28$
	SF-36 Mental	SF-36 Mental		
Braced	54.8 (21.2–71.8	55 (41.1–67)	0.2	$p = 0.73$
Control	46.2 (28–68)	52.7 (34–66)	6.5	$p = 0.26$
	SF-36 Physical	SF-36 Physical		
Braced	33.7 (14.6–49.9)	36.2 (24–53.2)	2.5	0.31
Control	35.8 (14–63)	42.1(19–62)	6.3	$p = 0.25$

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Table 5
Characteristics of Randomized Controlled Trials as Compared to Present Study.

Study	Study Group (n)	Control Group (n)	Kellegren Lawrence Score 1 to 4	Outcome Measures
Horlick et al 1993	19 10 degree valgus brace	21 Neutral brace	NA	VAS pain Sports Time
Kirkley et al 1999	41 Custom fit orthosis	36, Neoprene sleeve 33 Standard of care	NA	WOMAC VAS Pain, 6 minute walk test stair climbing test
Richards et al 2005 Crossover study	12 Custom fit orthosis	12 Off the shelf	2–4	VAS Pain score, HSS score Functional score
Draganich et al 2006 Crossover study	10	10	NA	WOMAC VAS pain score Stair climbing test
Brouwer et al 2006	60 Custom fit orthosis	57 Standard of care	1–2	VAS Pain score, HSS score walking distance Quality of Life EuroQoL – 5D Gait
Van Raaj et al 2010	46 Custom fit orthosis	45 shoe insert with lateral wedge	1–3	VAS pain score, WOMAC Full length X-ray
Hunter et al 2012	40 Off the shelf with motion control shoe	40 Neutral orthosis flexible shoe	2–4	WOMAC VAS Pain score,
Jones et al 2012 Crossover study	28 Off the shelf orthosis	28 Lateral wedge insole	2–3	WOMAC, Pain Gait
Current study 2014	26 Off the shelf custom fitted Pneumatic brace	26 Standard of care	3–4	Pain, KSS, LEFS, Gait Functional tests (TUG, Stair ascent, 20 steps, Repeated chair rise, 2 minute walk test) Isokinetic strength test

study that supports the use of braces in decreasing osteoarthritis pain, Laroche et al. [31], examined the use of unloader bracing on three-dimensional gait analysis, pain scores, functional outcomes and patient reported outcomes in twenty patients who had symptomatic medial knee osteoarthritis. The authors demonstrated that after 5 weeks of brace use, patients had significant decreases in VAS-pain and WOMAC scores ($p < 0.0001$ and 0.0001; respectively). When specifically examining gait parameters, they found that patients walking speed increased significantly at 5 weeks, while both knee adduction moments and foot progression angles significantly decreased in the terminal stance and push off, respectively, with bracing at the initial testing and 5 week later ($p < 0.05$). Similarly, lower-limb joint angles, moments, and power were significantly improved by wearing the brace at both time points. Komistek and colleagues,[34] performed a gait analysis study involving 15 patients using unloading braces to evaluate whether patients had separation of the joint space allowing for pain relief. The authors found that with the use of fluoroscopy, the brace achieved condylar separation of the medial tibio-femoral joint space in 12 of the 15 patients, all of which reported a decrease in pain symptoms.

The negative results seen with knee OA ultimately leads to increased inactivity, which lead decreased knee extensor strength, improper balance, decreased gait speed, stair-climbing speed, and difficulty with chair rising compared to healthy individuals [35–37]. This perpetuates the muscle weakness and atrophy, leading to a deleterious cycle of pain-weakness-pain [36]. Previous studies using unloader braces have found only marginal strength gains in the hamstring muscle and no change in quadriceps muscle strength [38]. Wang et al. [39], evaluated the relationship between changes in vastus medialis muscle cross-sectional area (CSA) and knee pain. The author's demonstrated that vastus medialis muscle CSA was inversely related to amount of knee pain ($p = 0.04$), and found that an increase in vastus medialis muscle CSA from baseline to 2 years was associated with a significant reduction in knee pain ($p = 0.007$). One of the most important findings in the present study is that by using the pneumatic unloader bracing system in combination with extension assist, was that there were improvements in quadriceps and hamstring muscle strength as measured objectively by an isokinetic dynamometer. It is also noteworthy that patients in the matching group, despite being prescribed a self-directed exercise program lost significant quadriceps muscle strength and had marginal loss of hamstring muscle strength. We believe that given these results, that even when patients were not wearing the brace, that patients substantially benefited from their effects due to neuromuscular retraining. In addition, these findings are further support the results of Johnson et al. [7] who demonstrated in a pilot study of this brace on pain, thigh girth, and gait parameters demonstrating that individuals had significant improvements in pain scores, SF-36, thigh girth, and gait parameters (walking speed, ROM, and knee abductor moments) compared to controls.

Patients who used the unloader pneumatic brace demonstrated statistical improvements in functional parameter tested: they had improvements in muscle strength, timed up and go tests, timed stair climbs, repeated chair rise tests, and 2-minute walk tests, as well as greater improvements in new Knee Society objective scores, higher LEFS scores, and decreased pain on the visual analog scale when compared to the matching group. These findings are supported by Draganich et al. [40] who evaluated the use of custom-made patient-adjustable, valgus producing knee unloader braces compared to off-the-shelf-bracing on pain relief, functionality, and stiffness. The authors demonstrated that both braces significantly reduced pain and stiffness ($p < 0.05$), with the custom brace reducing stiffness significantly more than the off-the-shelf brace ($p = 0.030$). Even though both braces resulted in improvements, the authors demonstrated that custom unloader bracing significantly improved function compared to that of the off-the-shelf brace ($p = 0.027$). The findings in the current study leads us to conclude, that bracing can reduced pain and provided a functional benefit to patients who have knee osteoarthritis.

The authors believe that this novel device was easy to use, had good patient compliance, resulted in adjuvant pain relief, and led to

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functional improvements in patients who had end-stage knee osteoarthritis. Additionally, unloader bracing may allow patients to avoid the potential dangerous side effects of NSAIDS and opioids, the substantial economic burden that accompanies multiple physical therapy sessions, as well as the potential risks of invasive procedures such as corticosteroid and hyaluronic acid injections. This treatment can be incorporated into all non-operative treatment algorithms for knee osteoarthritis (Kellgren Lawrence Grade 1 though 4). Additionally, the patients in this study will be followed in a long-term longitudinal manner in order to determine if any functional improvements from this therapy may lead to a decrease in knee arthroplasty procedures performed.

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