Improvements in Function and Strength with Decompressive Bracing of the Osteoarthritic Knee

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ABSTRACT

Introduction: The aim of this study was to investigate if a decompressive knee brace used in the presence of unicompartment knee osteoarthritis (OA) alters knee strength, walking endurance, balance abilities, perception of pain, symptoms, activities of daily living (ADLs), and quality of life (QoL).

Materials and Methods: Nineteen individuals with unilateral unicompartment knee OA participated. Participants wore a knee brace for 6 months that decompresses the OA compartment. Muscle strength, 6-minute walk test (6MWT) distance, and balance abilities were assessed at baseline and at 2 weeks (post) and 8 weeks (final) after receiving the brace. The Knee Osteoarthritis Outcome Survey (KOOS: domains of pain, symptoms, ADLs, and QoL) and the Activities-specific Balance Confidence (ABC) scale were used at baseline, brace fitting, post, final, 3 months, and 6 months.

Results: Muscle strength into knee extension and flexion increased at final compared with that at baseline ($P < 0.05$). The 6MWT distance improved by 68 m at final compared with that at baseline. Improvements on the KOOS and ABC were found at 6 months compared with that at baseline ($P < 0.05$). No changes in balance abilities were identified ($P > 0.05$).

Conclusions: Using a decompressive knee brace is beneficial for individuals with unicompartment knee OA. Brace use results in reduced pain, symptoms, improved ADLs, and QoL as well as increases in knee muscle strength and walking capacity. (*J Prosthet Orthot*. 2016;28:173–179).

KEY INDEXING TERMS: braces, unloader brace, muscle strength, pain

Knee osteoarthritis (OA) is a common progressive joint disease[1] characterized by pain, loss of motion, diminished strength, and gait and balance alterations.[2–4] These impairments commonly reduce an individual's activity,[1] participation in society, and quality of life (QoL).[5,6] Standard practice when treating knee OA typically involves exercise in combination with use of analgesic and anti-inflammatory agents, progressing to joint injections and eventually surgery.[7]

An additional method of treatment for knee OA is the use of a knee brace designed to alter the forces acting at the knee thereby decompressing the degenerating joint compartment during weight bearing. However, despite data on these braces confirming the biomechanical benefits[8–22] and role in mediating pain and improving function and QoL,[4,11,14,23,24] practitioners are slow to turn to this resource in the management of knee OA.[25] Most likely, this is due to a lack of appropriate studies and conflicting evidence on their effects.[4] The 2013 American Academy of Orthopaedic Surgeons osteoarthritis guidelines rate the quality of evidence supporting the routine use of valgus directing force braces as "inconclusive." According to the guidelines, "An inconclusive recommendation means that there is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm."[26] However, in 2014, guidelines were published from the Osteoarthritis Research Society International supporting biomechanical interventions with a recommendation of "appropriate," although the quality of evidence was only rated as "Fair."[27] Further, recent meta-analyses and systematic reviews have determined that there are at least moderate positive effects sizes reported when using valgus bracing in the areas of pain, function, and biomechanical outcomes.[28,29] Clearly, there is a debate regarding their use, and thus additional, well-designed studies are needed to inform practitioners regarding efficacy of decompressive bracing in knee OA.

Further, there is a common belief that prolonged use of a knee brace produces disuse muscle atrophy. In the arthritic knee, the presence of pain, in and of itself, reduces knee strength partly due to neural inhibition linked to the presence of joint swelling, inflammation, and damage to the structural integrity of the joint.[30] Few investigations have systematically looked at whether the use of decompressive bracing for knee OA helps

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or hinders neuromuscular function. If the use of a brace decreases pain and symptoms, then individuals will be able to participate in functional activities, thereby improving neuromuscular function. There is limited support on the statement that the use of a knee brace can positively alter the muscle activation pattern during gait.[31] Further, the findings from three studies that investigated decompressive knee bracing[15,32,33] suggest that after use there is either no change or an improvement in knee strength—not a decrement.

Potentially, reducing pain and symptoms and improving knee strength can lead to improved gait and balance and reduced disability for those with knee OA.[34,35] The primary purpose of this study was to systematically investigate if the Rebel Reliever decompressive knee brace (Townsend Design, Bakersfield, CA, USA) alters knee strength, walking endurance, balance abilities, perception of pain, symptoms, activities of daily living (ADLs), and QoL during 6 months of use.

METHODS

Individuals with diagnosed knee OA between the ages of 35 and 70 were recruited. Inclusion criteria were presence of unilateral, medial, or lateral compartment OA of the knee diagnosed by an orthopedic physician and classified on the Kellgren-Lawrence scale.[36] Specific exclusion criteria included cardiac or pulmonary disease that limits the ability to walk; presence of hip, ankle, foot, or contralateral knee OA; surgical procedure in either leg within the past 6 months; or the presence of other lower-limb pathology that limits the ability to walk. All participants received a prescription for the brace and provided informed written consent. This study was approved by the institutional review board of Stony Brook University. The trial was registered as "Effects of Bracing on Knee Osteoarthritis" with ClincalTrials.gov identifier number NCT01886144.

STUDY DESIGN

Participants were assessed at baseline and subsequently fit with the Rebel Reliever (Townsend Design, Bakersfield, CA, USA) decompressive knee brace to be worn throughout the study period of 6 months. Participants attended 4 sessions—baseline, brace fitting, 2 weeks after brace fitting (post), and 8 weeks after brace fitting (final). In addition, participants completed mail-in surveys 3 months and 6 months after brace fitting. At baseline, participants were measured for the knee brace and completed a 6-minute walk test (6MWT), a balance assessment, knee strength testing, and two different patient report outcome measures. One week after baseline, participants returned and were fitted with the knee brace by a certified orthotist. The Rebel Reliever (Figure 1) is a rigid type of brace that consists of a thigh shell and a calf shell attached by adjustable medial and lateral uprights that allow for the alteration of the frontal plane alignment to impart a decompressive force on the affected compartment. Velcro strapping exists on both the anterior and posterior portions of the thigh and calf components to position and hold the brace on the limb. Valgus alignment was used for participants with medial compartment disease and varus alignment for those with lateral compartment disease.

Figure 1. Photo of the Rebel Reliever.

The orthotist taught the participant how to don and doff the brace and provided instructions to wear the brace for a minimum of 3 hours per day, emphasizing use when engaged in weight-bearing activities.

PHYSICAL OUTCOME MEASURES

Muscle function test, 6MWT, and balance assessment were performed at baseline, post, and final. Muscle performance of

the knee flexor and extensors on the osteoarthritic side was assessed using a Biodex System 3 isokinetic dynamometer (Biodex Medical Systems, Ronkonkoma, NY, USA) at 60° per second for a set of six repetitions. Participants sat with 90° of hip and knee flexion, and the axis of the dynamometer was aligned with the center of the anatomical knee joint. Before testing, participants became acclimated to the task by performing 2 submaximal and 2 maximal repetitions. The average power generated for extension (power-ext) and flexion (power-flex) and the average peak torque normalized to body weight (ft lb/lb $\times$ 100) produced for extension (torque-ext) and flexion (torque-flex) were calculated for the 6 repetitions.

The 6MWT requires participants to walk as far as they could in 6 minutes and was completed to assess overground functional mobility and walking capacity.[37] The 6MWT is a performance-based measure used in those with knee OA.[38,39] In a recent study, the 6MWT demonstrated the smallest measurement error of outcome measures for assessing people with knee OA.[40] In the current study, the 6MWT was performed without the knee brace at baseline. At post and final, the knee brace was worn. The distance walked was recorded in feet and converted to meters.

Static and dynamic balance abilities were assessed using the BioSway (Biodex Medical Systems, Shirley, NY, USA). Static balance abilities were assessed by using the modified clinical test of sensory integration in balance (CTSIB). During the CTSIB, participants stood on the BioSway platform with feet-shoulder width apart and the amount of postural sway was quantified as participants remained as still as possible for 20 seconds under 4 conditions: eyes open (EO), eyes closed (EC), eyes open while standing on foam (EO-F), and eyes closed while standing on foam (EC-F). Dynamic balance abilities were assessed using the limits of stability test (LOS). During the LOS, participants stood on the BioSway platform with feet-shoulder width apart and weight being directed through a centrally displayed target on a computer screen. Without moving their feet, participants shifted their weight from the center position as quickly and with as little deviation as possible to various targets. The BioSway generates a proprietary LOS score based on the participant's accuracy and speed in moving from target to target. At baseline, balance was assessed without the use of the brace. At post and final, balance was assessed both with (post brace; final brace) and without the brace. The order of testing with or without the brace at post and final was counterbalanced.

PATIENT-REPORTED OUTCOMES

The Knee Osteoarthritis Outcomes Survey (KOOS) and the Activities-specific Balance Confidence (ABC) scale were given to the participants at baseline, post, final, 3 months, and 6 months. The KOOS is a reliable and valid tool for measuring outcomes in people living with knee OA.[41,42] The KOOS assesses five dimensions: pain (frequency and severity), symptoms (stiffness, swelling, clicking, and motion restriction), difficulty during ADLs, difficulty during sport activity, and QoL. Items are scored on a 5-point (0–4) Likert scale and transformed onto a 0-to-100 scale where 0 = extreme problems and 100 = no problems.[42] Because the study participants were not engaged in sport, we did not analyze this section. In addition, we calculated an average score (KOOS4) for each participant across the four dimensions. The ABC measures perceived ability to maintain balance during various functional activities.[43,44] Scores range from 0 to 100, where higher scores indicate greater confidence in balance capabilities.

STATISTICAL ANALYSIS

Separate one-way repeated measures analyses of variance (ANOVAs) were used to detect differences in 6MWT, muscle power, and torque from baseline to post and final. To detect differences on the ABC and KOOS, baseline was compared with fitting, post, final, and 3- and 6-month follow-up. To detect differences in balance, a separate one-way ANOVA was used for each condition (EO, EC, EO-F, EC-F, and LOS) comparing baseline to post, final, post brace, and final brace. For all statistical tests, when significant, Bonferonni post hoc tests were performed. Significance was considered at $P < 0.05$.

RESULTS

Fifty-five individuals were screened for eligibility. Twenty-six individuals were enrolled, participated in baseline assessment, and received the knee brace. Seven participants were removed from the study; 3 participants reported difficulty putting the brace on and, although remediation was offered, chose not to wear it; and 4 participants reported a fall and injury unrelated to brace wear but as a result became limited in their ability to walk. Characteristics for the 19 participants that completed the testing protocol through final are included in Table 1. Sixteen participants (84%) returned the 3-month survey, and 14 (74%) returned the 6-month survey. Data from all 19 participants were used to analyze the 6MWT and balance assessments. Muscle function data were analyzed using 17 participants; one participant reported verbally that they were not pushing or pulling their best, and data on a second participant were excluded due to computer malfunction. Survey data were analyzed using the 14 participants that returned the surveys through the 6-month period.

PHYSICAL OUTCOME MEASURES

The amount of knee extension and flexion muscle power and peak torque normalized to body weight differed significantly

Table 1. Participant characteristics (n = 19)

	Measure
Age, mean (range), y	55 (39–70)
Sex, n	14 m, 5 f
KL grade, n	KL2 = 5, KL3 = 10, KL4 = 4
Height, mean (range), cm	177 (161–188)
Weight, mean (range), kg	108 (68–151)
BMI, mean (range), kg/m^2	35 (24–49)
OA knee compartment, n	15 medial, 4 lateral

f, female; m, male; KL, Kellgren-Lawrence grade; BMI, body mass index; OA, osteoarthritis.

Table 2. Data from 6MWT and strength testing

	Baseline, Mean (SD)	Post, Mean (SD)	Final, Mean (SD)	% Improvement Baseline to Post	% Improvement Baseline to Final
6MWT (m) n = 19	496.3 (100.6)	536.5 (85.6)*	564.3 (6.0)*#	8.1%	13.7%
PK TQ/BW-Ext (%) n = 17	29.0 (14.1)	33.3 (12.3)	35.4 (13.2)*	14.9%	21.9%
PK TQ/BW-Flex (%) n = 17	10.7 (8.9)	13.8 (7.7)	15.9 (7.8)*	28.8%	48.8%
Power-Ext (Watts) n = 17	64.8 (28.7)	77.7 (26.0)*	82.2 (22.0)*	20.0%	27.0%
Power-Flex (Watts) n = 17	21.8 (18.2)	30.2 (15.7)*	33.6 (14.5)*	38.9%	54.2%

* Significantly different on the Bonferonni post hoc test when compared with baseline.
# Significantly different on the Bonferonni post hoc test when compared with post.
6MWT, 6-minute walk test; PK TQ/BW-Ext and PK TQ/BW-Flex, the peak torque normalized to body weight for knee extension and knee flexion.

($P < 0.001$ for all) throughout the study (Table 2). Post hoc analysis revealed a significant increase in both power and torque into knee extension and flexion at final when compared with that at baseline ($P < 0.05$ for all comparisons). In addition, there was a significant increase in power into knee extension and flexion when comparing post to baseline ($P < 0.05$).

Distance covered during the 6MWT differed significantly ($P < 0.001$) throughout the study (Table 2). Post hoc analysis revealed a significant improvement in the mean 6MWT distance at post and final when compared with that at baseline (40.2 m and 68.0 m improvement, respectively, $P < 0.001$ for both) and when comparing distance at final to post (27.8 m, $P = 0.007$).

Overall, the use of the knee brace did not alter balance abilities ($P > 0.05$ for all) as measured through CTSIB (EO, EC, and EO-F) and LOS assessments (Table 3). Under all conditions of the CTSIB and during the LOS testing, balance assessment was similar to baseline testing with the exception of testing performed with EC-F. During EC-F, sway differed significantly ($P < 0.05$). Post hoc analysis revealed a significant reduction in sway during the EC-F condition at final when compared with baseline both when wearing the brace (final brace; $P = 0.033$) and in the no brace condition (final; $P = 0.048$).

SURVEY MEASURES

Scores on the various dimensions of the KOOS, the KOOS4, and the ABC significantly differed ($P < 0.001$ for all) throughout the study (Table 4). Post hoc analysis revealed that scores did not significantly change ($P > 0.05$) from baseline to fitting, indicating that the baseline data were stable during the week before participants started using the brace. However, scores on the KOOS and ABC significantly improved at post, final, 3 months, and 6 months when compared with that at baseline ($P < 0.01$ for all).

DISCUSSION

Decompressive braces are intended to modulate and dampen forces that otherwise are directed through the diseased compartment of the knee, thereby reducing pain and symptoms.

The results of this study support the concept that using a decompressive knee brace is beneficial for people with knee OA. Specifically, we found that through 2 months of brace use there is an increase in knee muscle strength and walking capacity. Further, we found that using a knee brace does not negatively affect one's balance abilities. Moreover, we found that after 6 months of brace use there were improvements with regard to pain reduction, symptom mitigation, ability to perform ADLs, reported balance confidence, and QoL.

In the presence of OA, people commonly present with knee muscle weakness when compared with the unaffected side and to healthy peers.[32,45] Reduced knee muscle strength is associated with decreased function and QoL, and contributes to the progression of OA.[30] We found in this study that using a knee brace for 2 months improved knee muscle strength. This is

Table 3. Data from balance testing (n = 19)

	Baseline, Mean (SD)	Post, Mean (SD)	Final, Mean (SD)	Post Brace, Mean (SD)	Final Brace, Mean (SD)
CTSIB: EO	0.7 (0.3)	0.7 (0.2)	0.7 (0.3)	0.8 (0.2)	0.8 (0.3)
CTSIB: EC	1.0 (0.4)	1.0 (0.4)	0.9 (0.3)	1.0 (0.3)	1.0 (0.3)
CTSIB: EO-F	1.1 (0.4)	1.1 (0.4)	1.1 (0.4)	1.0 (0.3)	1.0 (0.3)
CTSIB: EC-F	2.3 (0.5)	2.1 (0.6)	2.0 (0.5)*	2.0 (0.4)	2.0 (0.4)*
LOS	54.7 (14.8)	60.5 (12.5)	57.9 (12.8)	58.3 (11.3)	58.6 (12.5)

* Significantly different on the Bonferonni post hoc test when compared with baseline.
CTSIB, clinical test of sensory integration in balance; EO, eyes open; EC, eyes closed; EO-F, eyes open standing on foam; EC-F, eyes closed standing on foam; LOS, limits of stability.

Table 4. Data from patient report outcome measures (n = 14)

	Baseline, Mean (SD)	Fitting, Mean (SD)	Post, Mean (SD)	Final, Mean (SD)	3-month, Mean (SD)	6-month, Mean (SD)	Improvement at 6 months, Score (% change)
KOOS Pain	51.4 (17.7)	56.5 (19.2)#	73.6 (12.2)*	73.6 (9.5)*	73.6 (12.4)*	73.0 (15.6)*	21.6 (42.0%)
KOOS Symptoms	52.0 (14.3)	51.8 (14.7)#	69.6 (14.6)*	73.7 (14.2)*	69.6 (15.9)*	68.9 (13.4)*	16.9 (32.5%)
KOOS ADLs	58.6 (16.8)	63.7 (16.5)#	80.8 (11.4)*	81.0 (9.6)*	80.8 (11.0)*	79.2 (14.3)*	20.6 (35.2%)
KOOS QoL	29.5 (15.2)	33.0 (13.1)#	49.6 (19.0)*	50.9 (16.1)*	53.6 (16.9)*	49.1 (22.3)*	19.6 (77.0%)
KOOS4	47.9 (13.7)	51.3 (13.8)#	68.4 (12.2)*	69.8 (11.3)*	69.4 (12.7)*	67.5 (15.4)*	19.6 (40.9%)
ABC	82.3 (14.0)	81.3 (14.5)#	91.8 (5.1)*	93.3 (4.0)*	92.8 (5.6)*	92.3 (6.2)	9.9 (12.0%)

Improvement at 6 months is the score and % change from baseline.

* Significantly different from baseline using the Bonferonni post hoc test.

Fitting is not significantly different from baseline using the Bonferonni post hoc test.

KOOS, knee osteoarthritis outcomes survey; ADLs, activities of daily living; QoL, quality of life; KOOS4, average of the 4 KOOS subdomains; ABC, Activities-specific Balance Confidence scale.

contrary to the notion that bracing results in disuse atrophy. However, in this case, the use of the decompressive knee brace resulted in a reduction in pain and symptoms, as supported through KOOS responses. This reduction in pain and symptoms allowed the participants to perform increased activity as supported through 6MWT distance and KOOS responses. Thus, we hypothesize that participants in this study were using their leg more and as a result increased knee muscle strength. Our results are similar to those found in a study by Cherian et al.[32] that investigated quadriceps and hamstring muscle strength throughout the range of motion after 3 months of using an unloader type of brace. Subjects in that study demonstrated a 54% improvement in quadriceps strength and 28% improvement in hamstring strength. Further, in a study completed by Matsuno et al.,[33] the mean isokinetic quadriceps strength improved 16% following 12 months of using an unloader type of brace. Here, we found a 22% improvement in quadriceps strength and a 48% improvement in hamstring strength. Contrary to these studies showing improvement in muscle strength, there is one recent study completed by Hurley et al.[15] in which participants used an unloader brace for approximately 6 months. In this study, knee strength did not change; however, strength testing was completed only at static positions not through the range of motion.

In the present study, we demonstrated that through the use of the knee brace improvements in pain, symptoms, ADLs, and QoL were realized on the KOOS patient-reported outcome measure. The KOOS is a validated measure that has published minimal detectable change (MDC) scores. In this study, the change in KOOS score at 6 months when compared with baseline for pain (change in this study 21.6, MDC = 13.4), symptoms (16.9, MDC = 15.5), ADLs (20.6, MDC = 15.4), and QoL (19.6, MDC = 21.1) exceeded the published MDCs.[41] Because the KOOS change score exceeded the MDC, we are more confident in suggesting that these changes were not due to measurement error and thus the participants improved in these domains as a result of using the brace.

As indicated by the results, we also demonstrated that as a result of using the brace, participants had a mean improvement in distance walked on the 6MWT at final when compared with that at baseline (68.0 m). As with the KOOS values, this change in distance capabilities exceeded published MDC values (66.3 m) for individuals with knee OA who were on a wait list for total knee arthroplasty.[40] Because we did not provide any type of rehabilitation training, it is likely that the improvements in distance walked on the 6MWT are attributable to decreased pain and symptoms. Further, we were interested in assessing balance. As the results indicate, balance abilities did not change from baseline. However, participants did report that they were more confident in their balance capabilities when performing various activities. This, in addition to the reduction in pain and symptoms, may be attributable to why we found significant improvements in function.

CONCLUSIONS

Participants reported reduced pain, reduced symptoms, improved ADLs, and improved QoL. In addition, participants demonstrated improvements in knee muscle strength and walking capacity. Providing a decompressive knee brace to individuals with unicompartment knee OA may be beneficial and improve QoL.

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