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The Effect of Knee Braces on Quadriceps Strength and Inhibition in Subjects With Patellofemoral Osteoarthritis

STUDY DESIGN: Secondary analysis of a randomized controlled trial.

BACKGROUND: The use of external supports has been questioned because they may lead to weakness in the surrounding muscles. To our knowledge, there is no investigation into the effect of knee supports or braces on quadriceps muscle strength and quadriceps inhibition in individuals with patellofemoral joint (PFJ) osteoarthritis (OA).

OBJECTIVES: To investigate the effects of a flexible knee support on quadriceps maximum voluntary contraction (MVC) and arthrogenous muscle inhibition (AMI) in patients with PFJ OA.

METHODS: The study included 108 participants who had at least 3 months of patellofemoral pain and a Kellgren-Lawrence score of 2 or 3 for PFJ OA. The participants were randomized to a group that wore a flexible knee support (brace) or a group that did not wear a support (no brace) in a 6-week randomized controlled trial, followed by an open-label trial, in which all participants wore the brace for a total of 12 weeks. Quadriceps MVC, measured isometrically, and quadriceps AMI, measured by twitch interpolation, were assessed at the 6-week and 12-week time points.

RESULTS: After 6 weeks, MVC did not differ between the brace and no-brace groups (9.09 Nm; 95% confidence interval [CI]: −4.89, 23.07; P = .20). Arthrogenous muscle inhibition significantly decreased in the brace group (−8.62%; 95% CI: −13.90%, −3.33%; P = .002). After 12 weeks, in all of the participants who wore a flexible knee support, MVC increased by 7.98 Nm (95% CI: 2.52, 13.45; P = .004) and AMI decreased (−8.42%; 95% CI: −11.48%, −5.36%; P<.001). Although statistically significant, these results have doubtful clinical significance.

CONCLUSION: A patellofemoral flexible knee support in participants with PFJ OA does not have an adverse effect on quadriceps MVC or AMI. Using a knee support should not be discouraged because of concerns about deleterious effects on quadriceps strength and inhibition.

LEVEL OF EVIDENCE: Therapy, level 1b.
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KEY WORDS: *AMI, arthrogenous muscle inhibition, isometric strength, MVC*

Patellofemoral joint (PFJ) osteoarthritis (OA) is a common subtype of knee OA[8] and a neglected area of research.[4] It is a major cause of pain with activities such as stair climbing, rising from a chair, kneeling, or squatting. Braces are recommended in treatment guidelines for all types of knee OA.[2,5] For medial knee OA, their efficacy is likely due to unloading the medial compartment. For PFJ OA, braces in the form of flexible knee supports are recommended, as they are thought to enhance proprioceptive input and to create a feeling of stability, which may encourage activity.[7] While there is evidence from randomized trials on PFJ OA that flexible knee supports have a favorable effect on pain,[2,14] little else is known about the effects of these types of braces in those with PFJ OA.

Quadriceps weakness is common in knee OA.[13] While wearing flexible knee supports can be beneficial, a recent survey of physical therapists and athletic trainers confirmed that clinicians are reluctant to recommend these types of braces due to a perception that they cause weakness in the surrounding muscles.[6] The potentially negative effects on a muscle can be measured by a maximum voluntary contraction (MVC) and arthrogenous muscle inhibition (AMI). The latter is determined by the interpolated twitch technique, which uses supramaximal electrical stimulation to assess the inhibition associated with skeletal muscle activation during a voluntary contraction. However, no studies have investigated the effects of flexible knee supports on either quadriceps MVC (strength) or AMI (inhibition).

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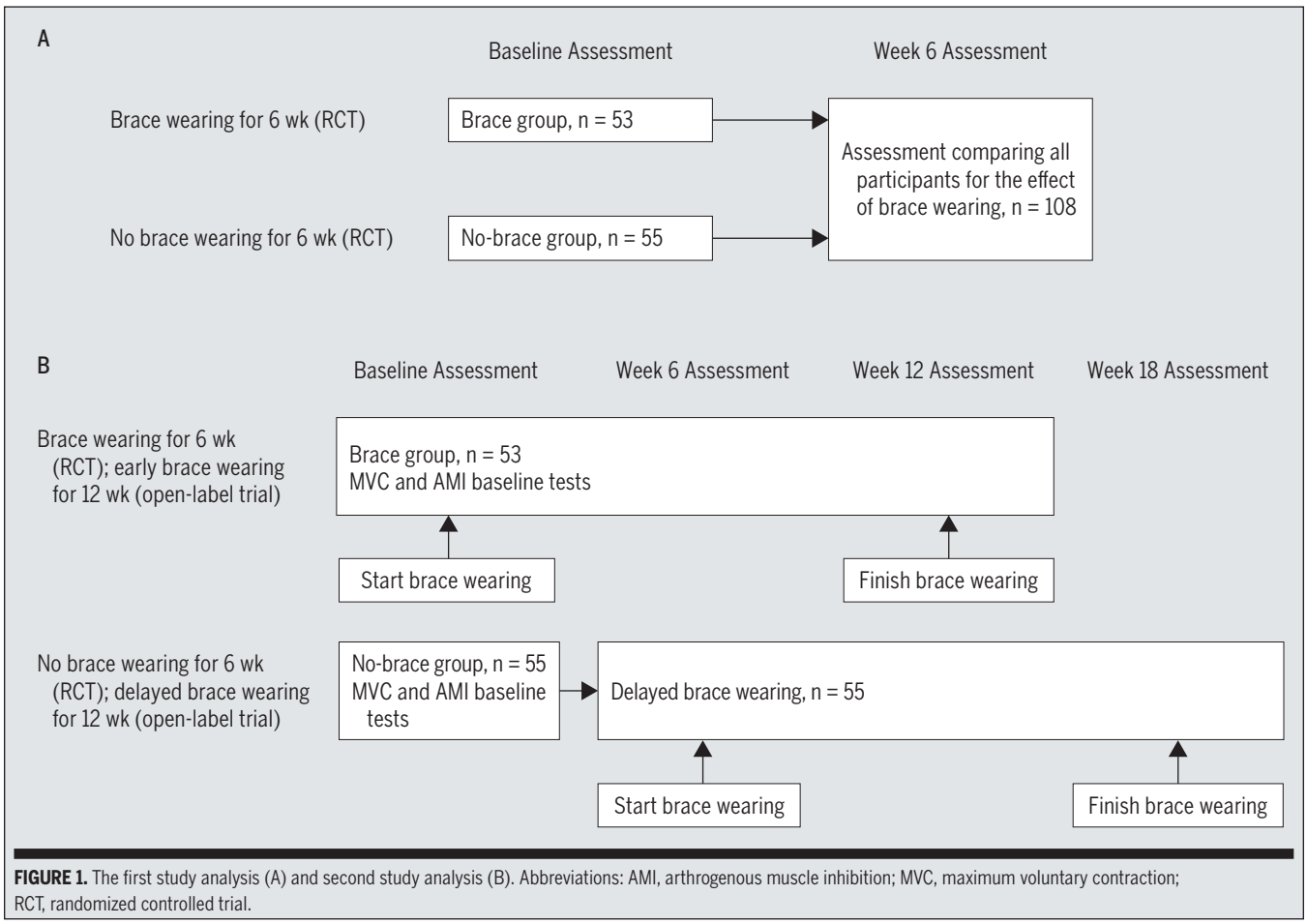

FIGURE 1. The first study analysis (A) and second study analysis (B). Abbreviations: AMI, arthrogenous muscle inhibition; MVC, maximum voluntary contraction; RCT, randomized controlled trial.

The present study had 2 objectives, both of which focused on the outcomes of quadriceps MVC and AMI: to investigate the between-group effects after 6 weeks of wearing a brace daily versus not wearing a brace, and to investigate the within-subject effects after 12 weeks of daily brace wearing. Our hypothesis was that wearing a patellofemoral flexible knee support would be associated at 6 weeks and 12 weeks with a worsening of quadriceps MVC and AMI in participants with PFJ OA.

METHODS

Participants and Setting

Participants aged 40 to 70 years were enrolled as part of a randomized trial of patellar brace treatment for those with PFJ OA.[2] This trial design was a cross-matched, delayed-start study (ISRCTN50380458), initially comparing a brace versus no brace for 6 weeks, then comparing the within-subject change following 12 weeks of brace use (**FIGURES 1A** and **1B**). Participants were included if they had a Kellgren-Lawrence score of 2 or 3 for the PFJ that was greater than the Kellgren-Lawrence score for the tibiofemoral compartments, which required at least probable joint space narrowing and definite osteophytes in the patellofemoral compartment on a plain radiograph.[16] Participants were also assessed for PFJ symptoms, such as pain reproduced with stair climbing or rising from a chair but no pain when walking on level ground,[14] and were required to have lateral or medial patellar facet tenderness on palpation.[5] Daily pain for the previous 3 months had to be 40 or greater on a visual analog scale (range, 0-100 mm, with 0 as no pain and 100 as the worst pain imaginable). Participants were excluded if they had a previous patellar fracture or patellar realignment surgery, predominant knee symptoms emanating from the tibiofemoral joint, a history of meniscal or ligament injury, rheumatoid arthritis or other forms of inflammatory arthritis, or an intra-articular steroid injection into the painful knee in the previous month. All participants gave their informed written consent. The study was approved by the Stockport Local Research Ethics Committee (reference 09/H1012/35) and the Wellcome Trust Clinical Research Facility, Scientific Advisory Board. The study was performed at the National Institute for Health Research/Wellcome Trust Manchester Clinical Research Facility, Manchester, UK.

FIGURE 2. The BioSkin® Q Brace™ Knee Support used in this study. Published with permission.

Intervention and Randomization

We report a secondary analysis of a clinical trial whose primary aims focused on the effect of PFJ bracing on PFJ OA pain.[2] Participants were given a BioSkin Q Brace (Ossur UK, Manchester, UK) knee support made of Lycra (Invista, Wichita, KS), which allows free range of knee motion (**FIGURE 2**). Participants were randomly allocated at baseline to receive either brace or no-brace treatment for 6 weeks. Then, after 6 weeks, an open-label study continued, with everyone receiving the knee support for 12 weeks: the no-brace group started 12 weeks of treatment after the 6-week randomized controlled trial (RCT) and the brace group continued for an additional 6 weeks. This design allowed us to compare the effect of wearing versus not wearing the knee support in the 2 groups after 6 weeks and to assess the effect of wearing the knee support for 12 weeks in all of the participants who completed the study (n = 108) (**FIGURES 1A** and **1B**). The participants did not receive any form of physical therapy, rehabilitation, or treatment other than the knee support and were allowed to take their regular analgesic. Participants were requested to wear the knee support for a minimum of 3 hours daily. They were questioned at each visit about the number of hours per day of brace wearing.

Participants were randomly allocated to group by prepared sealed envelopes under the supervision of the study statistician, who was not involved in the patient assessments. The order of tests at each study visit (MVC or AMI) could not be randomized, as MVC had to be tested prior to AMI. Neither the participants nor those providing the intervention or performing assessments were blinded to the treatment allocation.

Outcomes

Quadriceps Muscle Strength Quadriceps muscle strength was determined by an isometric MVC measured on a dynamometer (ISOCOM; Eurokinetics, Leeds, UK). Participants sat upright with their hip and knee in 90° of flexion. The tibial pad was placed 5 cm above the lateral malleolus. Restraining straps were placed over the torso, hips, and thigh. Each MVC attempt lasted 4 to 5 seconds, with a rest of 2 minutes between each attempt. The participants were given standardized verbal encouragement and visual feedback from the monitor (they were asked to grasp the chair handles). After a familiarization trial, the peak isometric quadriceps MVC (the best) from 3 attempts was collected. Reliability of this protocol for isometric quadriceps MVC has been established in our facility (intraclass correlation coefficient [ICC]$_{2,1}$ = 0.97; standard error of measurement [SEM], 11.54 Nm; SDD, 31 Nm).[22]

Quadriceps Inhibition Evaluation All AMI measurements were performed on the same dynamometer in the same positions using a Digitimer High Voltage Stimulator (DS7AH; Digitimer Ltd, Welwyn Garden City, UK). Two electrodes (100 × 130 mm; Axelgaard Manufacturing Company, Ltd, Fallbrook, CA) were placed on the quadriceps muscle at one third and two thirds of the distance from the anterior superior iliac spine to the upper border of the patella. A resting twitch was activated before the MVC attempt, and then a single 1-Hz pulse of 200-millisecond duration was triggered manually by the investigator when the MVC force reached a plateau on the monitor (interpolated twitch technique). Quadriceps inhibition was determined by the activation deficit at 100% MVC using the formula (interpolated twitch technique/resting twitch) × 100. The smaller the activation deficit, the less the inhibition. A deficit of less than 10% has been recorded from healthy individuals and indicates that the muscle has over 90% voluntary activation during the MVC.[22] In knee OA, deficits of approximately 30% have been recorded,[12] indicating that these individuals have only about 70% of voluntary activation. This technique has been assessed for reliability in our facility (ICC$_{2,1}$ = 0.73; SEM, 3.26%; SDD, 9.03%).[22] Both MVC and AMI were measured without wearing the knee support.

Statistical Analysis

The parent study was powered to test whether the effects of bracing on pain were mediated by magnetic resonance imaging–detected structural changes of bone marrow lesions and synovitis induced by the knee support, using the methods described by Fritz and MacKinnon.[10] We assumed a moderate effect of bracing on knee structure (improvement in structural score of 0.5 SD in the brace group compared to the no-brace group) and a moderate effect of structural score on pain (R^2 = 0.13 for regression), which provided 80% power to detect the mediated effect with a sample size of 120. Statistical analysis was performed using the software package Stata (Version 13.1; StataCorp LP, College Station, TX). The analysis took place in 2 parts.

The first of these tested for between-group differences after 6 weeks of bracing (the RCT analysis) (**FIGURE 1A**). To provide

an estimate of the mean difference in MVC between the brace and no-brace conditions, we used linear regression at the 6-week visit with MVC as the outcome; group allocation as the predictor variable; and baseline MVC, age, sex, and body mass index (BMI) as covariates.[23] To provide an estimate of the mean difference in AMI between brace and no-brace conditions, this model was repeated, with AMI replacing MVC as the baseline and 6-week outcome, and age, sex, and BMI as covariates.

The second analysis investigated the longer-term, 12-week effect of wearing a knee support, pooling data from both groups (the open-label analysis) (**FIGURE 1B**). Data from the baseline, week 6, and week 12 visits from the early-brace group were pooled with the week 6, week 12, and week 18 visits from the delayed-brace group, creating a total group of 108 patients who received the intervention for 12 weeks continuously. To estimate change in MVC and AMI, a fixed-effects linear regression model was used. This allowed us to assess change in MVC and AMI using data from all 3 visits while removing the effect of change over time, accounting for within-subject correlation while adjusting for within-subject correlated measures.[11] With MVC as the outcome, weeks of brace wearing as the predictor variable (a discrete variable relating to baseline, 6 weeks, or 12 weeks of brace wearing), and patient ID as a panel variable, this model produced estimates of the average change in MVC over 12 weeks by using data from 3 time points and assuming a constant (ie, linear) effect over time. This assumed that the change in MVC would be the same between 0 and 6 weeks of brace wearing as that between 6 and 12 weeks. To test if this linear-effect assumption was reasonable, a sensitivity analysis was also conducted as a separate model that allowed different effects between 0 and 6 weeks and between 6 and 12 weeks. The same model was used to test the change in AMI, with AMI as the predictor variable. In all models, outlying values were investigated for influence on regression coefficients, and residuals were assessed for normality and heteroskedasticity, through residual versus fitted plots. Patients were analyzed according to the groups to which they were randomized. We excluded patients

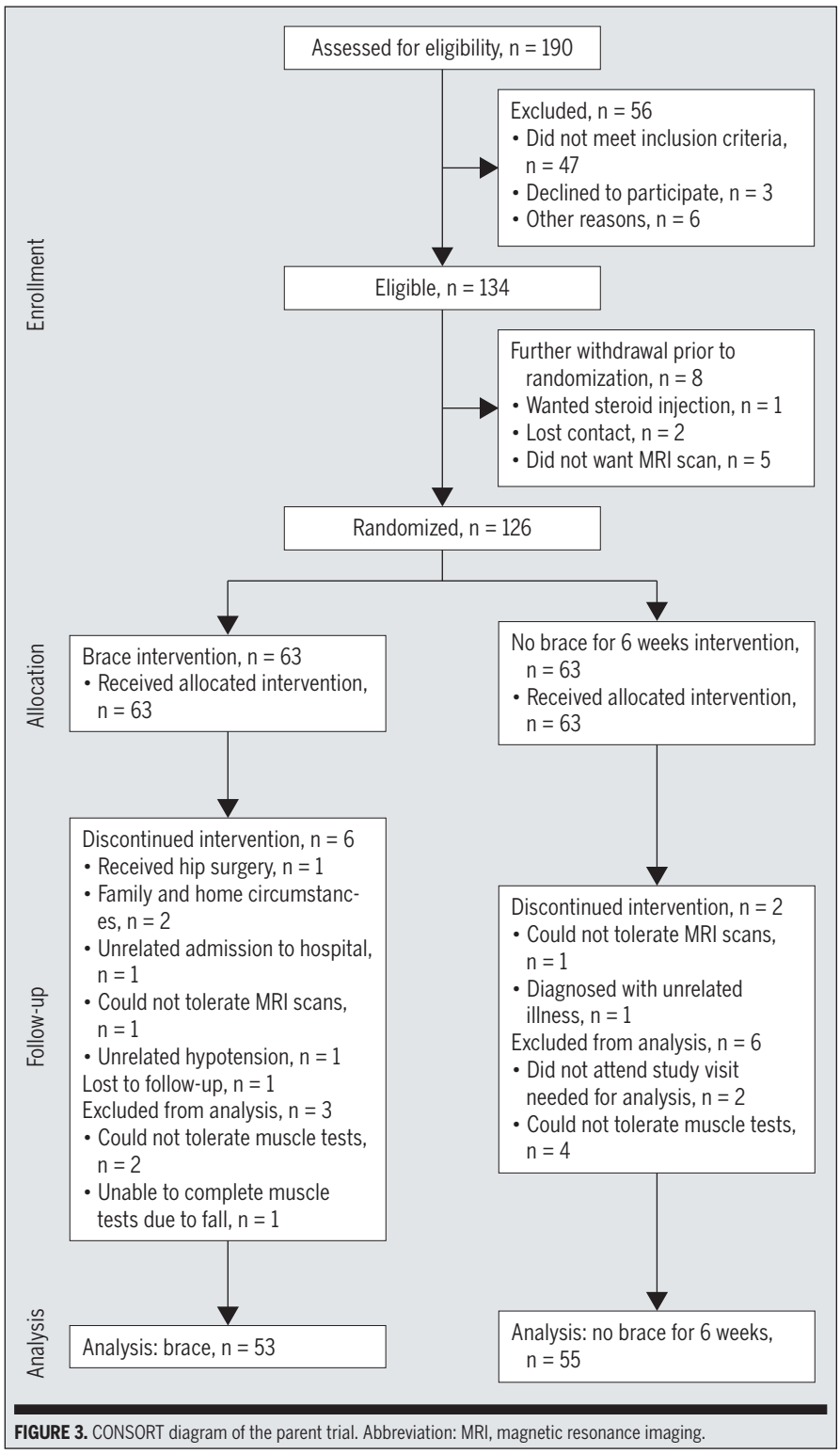

FIGURE 3. CONSORT diagram of the parent trial. Abbreviation: MRI, magnetic resonance imaging.

TABLE 1 Demographics and Descriptive Statistics of Study Participants*

	No-Brace Group (n = 55)	Brace Group (n = 53)	Groups Combined (n = 108)
Age, y	57 ± 7	55 ± 7	56 ± 7
Females, n (%)	28 (51)	31 (59)	59 (55)
BMI, kg/m^2	30.3 ± 5.1	31.0 ± 6.3	30.7 ± 5.7
Baseline MVC, Nm†	99.3 (71.7-138.5)	104.3 (71.4-165.0)	99.5 (71.5-150.1)
Baseline AMI, %†	29 (17.7-44.3)	25 (19.7-34.4)	27 (18.1-39.6)

Abbreviations: AMI, arthrogenous muscle inhibition; BMI, body mass index; MVC, maximum voluntary contraction.
**Values are mean ± SD unless otherwise indicated.*
†Due to positively skewed distributions, MVC and AMI are reported as median (interquartile range) rather than as mean ± SD.

who had missing MVC or AMI values on 1 or more of the study visits required for the 6-week RCT or the 12-week open-label analysis. The level of significance was set at $P<.05$ (2-tailed test).

RESULTS

One hundred twenty-six participants with predominant PFJ OA were recruited and randomized starting in August 2009 and followed up until September 2012. Nine patients withdrew from the study and 9 patients had missing MVC or AMI data on 1 or more of the study visits, leaving 108 patients to be included in the final analysis. At baseline, the 2 groups were similar in terms of demographics (**TABLE 1**). The CONSORT flow chart of participants in the trial, reasons for discontinuation, and numbers used in the analyses are shown in **FIGURE 3**. There were no adverse events or unintended effects. Participants in the brace group reported that they wore the brace for 7.7 ± 3.1 hours daily. After those in the no-brace group had commenced treatment following the 6-week RCT, they reported 7.01 ± 3.1 hours of brace wearing daily.

Between-Group Comparison of MVC and AMI After 6 Weeks of Brace Wearing (RCT Analysis)

After 6 weeks of brace wearing, no difference in MVC was found between the brace group and the no-brace group after adjusting for covariates of age, sex, BMI, and baseline MVC (between-group difference, 9.09 Nm; 95% confidence interval [CI]: −4.89, 23.07; P = .20). There was a significant decrease in AMI in the brace group compared with the no-brace group after adjusting for covariates (between-group difference, −8.62%; 95% CI: −13.90%, −3.33%; P = .002). The results can be seen in **TABLE 2**.

Within-Group Comparison of MVC and AMI After 12 Weeks of Brace Wearing (Open-Label Analysis)

After 12 weeks of brace wearing, within-group tests (all 108 subjects) revealed that MVC increased significantly (7.98 Nm; 95% CI: 2.52, 13.45; P = .004), while AMI decreased significantly (−8.42%; 95% CI: −11.48%, −5.36%; $P<.001$). Using a linear model to estimate change in MVC and AMI, the effect of bracing after 6 weeks was half that of the 0-to-12-week difference, giving a change in MVC after 6 weeks of bracing of 3.99 Nm (95% CI: 1.26, 6.72; P = .004), and a change in AMI of −4.21% (95% CI: −5.74%, −2.68%; $P<.001$). The results can be viewed in **TABLE 2**. The sensitivity analysis showed no difference between the slope of the 0-to-6-week change and that of the 6-to-12-week change in brace wearing.

DISCUSSION

To our knowledge, this is the first published study in those with predominant PFJ OA to produce data that contradict a perception recently revealed in a clinical survey that the wearing of braces or supports has an adverse effect on muscle strength[6]; it is also the first published study to evaluate effects of bracing on muscle inhibition. Our hypothesis was that wearing a flexible knee support would worsen quadriceps strength and inhibition in PFJ OA compared to no treatment. This study found no significant between-group difference in MVC after 6 weeks, but a significant improvement (decrease) in AMI (**TABLE 2**).

We are unaware of any studies of the relatively long-term (after 6 and 12 weeks) effects of a flexible knee support on muscle strength. We recorded an increased MVC of 9.09 Nm after wearing a support for 6 weeks compared to no treatment, and an average within-person increase of 7.98 Nm for all participants after 12 weeks of wearing the support. There are no data available in the literature with comparable time points. Several studies have evaluated the effect of the immediate on/off application of various knee braces on quadriceps muscle function,[1,17,19,21] and only 2 studies have assessed bracing specifically for the PFJ.[17,21] The increases we recorded in torque values are small and probably of little clinical significance, as the SEM for isometric MVC in our facility is 11.54 Nm.[22] However, the fact that there was no decrease in quadriceps torque after wearing a knee support daily provides first-time evidence that a flexible knee support is not detrimental to quadriceps torque output or activation. This is an important clinical message if such a brace is being considered as a treatment option for PFJ OA. Indeed, of the 2 clinical trials[2,14] that have used this knee support specifically, Callaghan et al[2] have shown clinical efficacy with visual analog scale outcomes of statistical and clinical significance, suggesting that a knee support for PFJ OA may be a viable treatment option.

The present study is the first, to our knowledge, to investigate the effect of a knee support on quadriceps inhibition. The interpolated twitch technique we used is commonly employed to assess the completeness of skeletal muscle activation during voluntary contractions. We chose to quantify this using activation deficit, as this has been found to be the primary determinant of strength in the OA-affected limb.[20] Our data show a significant improvement in quadriceps AMI after 6 weeks and 12 weeks of wearing a flexible knee support. Hassan et al[12] recorded improvements of quadriceps AMI of approximately −10% after knee injection of local anesthetic, which is similar to the average value of −8.42% we recorded for AMI after 12 weeks of brace wearing. Previous work[22] indicates that the minimal clinically important difference for quadriceps AMI is approximately 9%. This suggests that this statistically significant improvement is below the cutoff for clinical significance and, like MVC, may also be clinically insignificant. The results for quadriceps MVC and AMI were contrary to the study hypothesis, which was in line with a clinical perception that braces would worsen muscle performance.[6] As the parent trial found clinically significant beneficial outcomes in pain and structure,[2] it is important to confirm or refute other perceived effects of external supports before recommending their use.

The mechanism for the mild beneficial effects on the quadriceps from the knee support used in this study is still speculative. The trial participants told us that the flexible support provided a sensation of stability, security, and confidence in the knee and surrounding musculature. This may have resulted in using the braced knee more during activities such as stair ascent and descent and getting out of a chair, generally raising their activity levels. Furthermore, as prolonged ankle bracing has been found to increase lateral ankle muscle stretch reflex amplitude,[3] this might have happened in the quadriceps after wearing a flexible knee support.

TABLE 2 Baseline and Adjusted Values for MVC and AMI of Individuals in the 6-Week RCT and the 12-Week Open-Label Trial

	MVC, Nm	AMI, %
Baseline values		
No-brace group (n = 55)*	100.3 (67.10-135.50)	34.92 (23.83-50.00)
Brace group (n = 53)*	104.3 (71.40-165.00)	25.2 (19.74-34.43)
Both groups combined (n = 108)*	100.3 (69.90-149.75)	30.21 (20.55-43.20)
After 6 wk of brace wearing (RCT)		
No-brace group (n = 55)*	102.6 (78.40-144.10)	24.39 (15.31-42.35)
Brace group (n = 53)*	107.2 (79.00-167.00)	22.47 (15.27-34.13)
Both groups combined (n = 108)*	105.75 (78.70-150.10)	23.04 (15.29-38.12)
Adjusted between-group difference (n = 108)†‡	9.09 (−4.89, 23.07)	−8.62 (−13.90, −3.33)
P value	.20	.002
After 12 wk of brace wearing (open-label trial)		
No-brace group (n = 55)*	105.3 (73.40-144.80)	18.02 (10.32-31.96)
Brace group (n = 53)*	110.6 (89.30-173.70)	20.1 (11.25-31.54)
Both groups combined (n = 108)*	108.9 (81.50-153.05)	18.81 (11.00-31.65)
Adjusted within-group difference (n = 108)†‡	7.98 (2.52, 13.45)	−8.42 (−11.48, −5.36)
P value	.004	<.001

Abbreviations: AMI, arthrogenous muscle inhibition; MVC, maximum voluntary contraction; RCT, randomized controlled trial.
**Values are median (interquartile range).*
†Values are mean (95% confidence interval).
‡Between-group differences and within-group changes described do not equate to the difference between the groups above. This is due to the figures above being medians and the treatment estimates in the text being means of treatment effects after adjustment for covariates. "Adjusted" refers to the mean estimates from the analysis-of-covariance models, which represent the mean MVC/AMI at follow-up, adjusted for baseline MVC/AMI, age, sex, and body mass index.

Although the effects on proprioception and sensorimotor function from bracing,[9] exercise, and rehabilitation[24] have been shown to occur in the ankle, these nonsurgical strategies need to be further investigated in the knee. It may be that the knee support provided enough support and confidence to maintain strength and activation simply by creating more symptom-free walking time.

A limitation of the present study is that the outcomes may not be generalized to other knee supports or braces in general, or other types of patellar braces in particular. However, we are not aware of any reason why the results for these other types of supports should differ. Two previous studies have noted that braces designed to offload the medial compartment in predominantly medial knee OA did not have a deleterious effect on quadriceps strength at 6 months[15] and 12 months.[18] Another limitation of this study was the lack of a no-brace control group at the 12-week time point. It is possible, therefore, that the analyses could not separate the effect of brace alone from the effects of time or placebo. The possibility of a type II statistical error is unlikely because the RCT from which this analysis came was powered for structural changes on magnetic resonance imaging[2]; ultimately, an RCT powered with MVC and AMI as the primary outcomes is needed. A final limitation is that quadriceps MVC and AMI testing was performed using standardized, single-joint procedures, which do not reflect daily function and activity.

CONCLUSION

In individuals with PFJ OA, 6 weeks of wearing a flexible knee support compared to a no-treatment control condition did not impair quadriceps strength or increase quadriceps inhibition. After 12 weeks of brace wearing in all participants, neither decreased muscle strength nor increased inhibition were found. In fact, wearing the knee support modestly increased quadriceps strength and reduced quadriceps inhibition. While these increases were statistically significant, the magnitude of their clinical effect was small. This indicates that individuals with knee PFJ OA may consider using a flexible knee support without concern that this type of device will impair muscle strength or activation. ◉

KEY POINTS

FINDINGS: A flexible knee support worn for about 7 hours daily for at least 6 weeks neither decreased strength nor increased inhibition of the quadriceps muscles. In fact, the knee support modestly increased strength and reduced inhibition.

IMPLICATIONS: Clinicians can encourage individuals with PFJ OA pain to use a flexible knee support without concern of a deleterious effect on quadriceps strength or activation over a 12-week period.

CAUTION: Comparison between the brace and no-brace groups was limited to 6-week follow-up; longer-term effects are unknown.

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