

A Mechanical Theory for the Effectiveness of Bracing for Medial Compartment Osteoarthritis of the Knee

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Background: Evidence that knee braces used for the treatment of osteoarthritis mediate pain relief and improve function by unloading the joint (increasing the joint separation) remains inconclusive. Alternatively, valgus-producing braces may mediate pain relief by mechanically stabilizing the joint and reducing muscle cocontractions and joint compression. In this study, therefore, we sought to examine the degree to which so-called unloader braces control knee instability and influence muscle cocontractions during gait.

Methods: Sixteen subjects with radiographic evidence of knee malalignment and medial compartment osteoarthritis were recruited and fitted with a custom Generation II Unloader brace. Gait analysis was performed without use of the brace and with the brace in neutral alignment and in 4° of valgus alignment. A two-week washout period separated the brace conditions. Muscle cocontraction indices were derived for agonist and antagonist muscle pairings. Pain, instability, and functional status were obtained with use of self-reported questionnaires, and the results were compared.

Results: The scores for pain, function, and stability were worst when the knee was unsupported (the baseline and washout conditions). At baseline, nine of the sixteen patients reported knee instability and five of the nine complained that it affected their activities of daily living. Poor knee stability was found to be correlated with low ratings for the activities of daily living, quality of life, and global knee function and with increased pain and symptoms. Knee function and stability scored best with the brace in the neutral setting compared with the brace in the valgus setting. The cocontraction of the vastus lateralis-lateral hamstrings was significantly reduced from baseline in both the neutral ($p = 0.014$) and valgus conditions ($p = 0.023$), and the cocontraction of the vastus medialis-medial hamstrings was significantly reduced with the valgus setting ($p = 0.068$), as a result of bracing. Patients with greater varus alignment had greater decreases in vastus lateralis-lateral hamstring muscle cocontraction.

Conclusions: When knees with medial compartment osteoarthritis are braced, neutral alignment performs as well as or better than valgus alignment in reducing pain, disability, muscle cocontraction, and knee adduction excursions. Pain relief may result from diminished muscle cocontractions rather than from so-called medial compartment unloading.

Level of Evidence: Therapeutic Level II. See Instructions to Authors for a complete description of levels of evidence.

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Osteoarthritis of the knee is the most common cause of functional disability among Americans, and the medial compartment is most often affected^{1,2}. To correct varus alignment, so-called unloader braces that provide an opposing valgus force are a common nonoperative intervention. In theory, braces apply an external three-point bending force to the knee and attenuate load on the medial compartment³⁻⁵. Evidence for joint unloading^{3,6-9} and effectiveness in decreasing pain and improving function^{3,7,10-15} have been reported.

Frontal plane laxity and mediolateral instability of the knee exacerbate functional decline and disease progression¹⁶⁻¹⁸. Varus-valgus knee laxity is exacerbated by meniscal and articular cartilage degeneration that decreases the distance between the tibiofemoral surfaces¹⁸⁻²¹. Frontal plane laxity appears to be localized to the medial compartment¹⁷. Greater laxity raises the likelihood of episodes of knee instability²². Many patients have reported functional instability^{17,22,23}, defined as the patient's perception of the knee shifting, buckling and giving-way during activities of daily living²⁴.

Joint laxity and mediolateral instability necessitate increased muscle activity and coactivation of antagonistic muscles to stabilize the knee^{17,18,23,25}. Individuals with a functionally unstable knee often stiffen the knee, which involves a reduction in knee flexion excursion and increased muscular cocontraction²⁶⁻³⁰. Knee flexion and adduction excursions are operationally defined as the difference in knee angle from initial contact to peak knee flexion during midstance. Increased cocontraction, while stabilizing the knee, increases joint contact pressures that could exacerbate joint destruction^{17,23,25,31}.

The aim of this study was to examine the degree to which valgus-producing unloader knee braces control instability and influence muscle cocontraction during gait. Our first hypothesis was that frontal plane laxity and functional instability of the knee would be controlled mechanically by means of the brace, whether set in normal varus alignment or at 4° of valgus alignment (relative to normal). Secondly, pain relief may be mediated by decreased muscle cocontraction, rather than by mechanically unloading (increasing joint separation) from an opposing valgus force. Thirdly, improved self-reported knee function and levels of pain would be similar for both brace conditions.

Materials and Methods

Patients

Sixteen subjects who had genu varum and medial compartment osteoarthritis of the knee were referred from a local orthopaedic practice. They had a mean age (and standard deviation) of 54.9 ± 8.8 years and a mean body mass index of 31.1 ± 4.2 kg/m². The diagnosis was based on the clinical history, physical examination, and joint space narrowing as observed from standing posteroanterior radiographs with the knee at 30° of flexion³²⁻³⁴. Demographic and radiographic data on the patients are presented in a table in the Appendix. Joint space width, the weight-bearing line (center of the femoral head to the center of the ankle mortise), and joint laxity from stress radiographs were measured by a single examiner (D.K.R.)^{17,35-38}.

Physical activity had been curtailed because of knee pain in all patients. None received physical therapy prior to the study. Patients with a history of ligament deficiency or reconstruction; cardiovascular disease; diabetes; neurological impairment; impaired balance; rheumatoid arthritis; total knee replacement in either knee; orthopaedic problems in the hips, ankles, or spine; or a body mass index of ≥ 40.0 were excluded. Intra-articular corticosteroid and hyaluronic acid injections were not administered within three months of the study. We did not control for the use of oral anti-inflammatory medications. The study was approved by the human subjects review board, and all patients provided informed consent to participate in the study.

Motion Analysis

The patients underwent three-dimensional lower-extremity gait analysis with simultaneous surface electromyographic measurement on three separate occasions (without braces, with the braces in neutral alignment, and with the braces in 4° of valgus correction). Kinematic data were collected at 120 Hz with use of a passive six-camera system (Vicon 512; Oxford Metrics, Oxford, United Kingdom), and ground reaction force data were recorded at 1800 Hz from a Bertec force platform (Bertec, Worthington, Ohio). Motion and kinetic recordings were synchronized for simultaneous collection.

Joint centers were defined, and rigid thermoplastic shells affixed with four orthogonal markers were attached to the thigh and shank with an elastic wrap to minimize movement artifacts. A marker triad placed on the sacrum and two additional markers on the heel counter along with the marker on the fifth metatarsal head were used to track pelvis and foot movement.

Electromyographic activity was recorded concurrently at 1800 Hz with use of a sixteen-channel system (Motion Lab Systems, Baton Rouge, Louisiana) and was bandpass filtered between 20 and 1000 Hz prior to sampling. Preamplified surface electrodes (20-mm interelectrode distance and 12-mm disk diameter) were placed over the medial and lateral hamstrings, vastus medialis and lateralis, and medial and lateral heads of the gastrocnemius muscles³⁹. Maximal voluntary isometric contractions were performed to ensure correct electrode placement. A maximal voluntary isometric contraction measurement and a resting baseline measurement were recorded for each muscle for normalization.

Brace

Patients performed three gait analyses, beginning with the baseline assessment (Test 1). Custom knee braces (Unloader Select; Generation II USA, Bothell, Washington) were then manufactured on the basis of measurements taken at the initial assessment. Braces were factory-set in 4° of valgus alignment, relative to the varus alignment measured at the time of fitting. To set the braces in neutral, the proximal and distal hinges were loosened one-half turn each to remove the valgus load. The same physical therapist confirmed proper brace fit and instructed the patients on brace application. The individuals wore the brace in neutral alignment throughout the day

for two weeks before returning for the second gait analysis (Test 2). Following Test 2, no brace was worn for two weeks (the washout period). After the washout period, braces were reset to the original setting at 4° of valgus, relative to the varus alignment measured at the time of fitting. Patients then wore the brace for an additional two weeks before the final gait analysis (Test 3). Tension in the dynamic force strap was standardized with use of a compact digital triple scale, which was accurate to within ± 0.05 kg, to ensure consistent strap tension between the neutral and valgus brace test sessions.

Pain and Functional Status Measurement

Pain and functional status were assessed during each of the brace conditions and the washout period with use of the Knee Injury and Osteoarthritis Outcome Score (KOOS)⁴⁰⁻⁴³. Instability was assessed with use of the question: "To what degree does giving-way, buckling, or shifting of the knee affect your level of daily activity?" taken from the Knee Outcome Survey-Activities of Daily Living Scale. The reliability and responsiveness of the questionnaire and of this particular question for assessing instability in individuals with osteoarthritis have been assessed and reported by others^{22,24}.

Data Management and Processing

Marker trajectories were low-pass filtered (Butterworth fourth order, phase lag) at 6 Hz with use of custom-written software (LabVIEW 7; National Instruments, Austin, Texas). Three-dimensional joint kinematics were calculated with use of the Euler angle sequence and were referenced to the coordinate system from a standing calibration taken prior to motion recordings (Visual3D; C-Motion, Rockville, Maryland). Stance was normalized to 100 data points and was averaged across ten trials for each patient and brace condition.

Raw electromyographic data were low-pass filtered at 350 Hz, full-wave rectified, and filtered a second time with a phase-corrected eighth order 20-Hz low-pass Butterworth filter to generate the linear envelope (LabVIEW 7; National Instruments). Linear envelopes were normalized to peak electromyographic measurements recorded during maximal vol-

untary isometric contractions. Cocontraction indices (simultaneous antagonist muscle activation) were derived for the following muscle pairs: vastus medialis-medial hamstring, vastus medialis-medial gastrocnemius, vastus lateralis-lateral hamstring, and vastus lateralis-lateral gastrocnemius muscles. Muscle responses were analyzed from 100 msec prior to initial contact (to account for an electromechanical delay⁴⁴) to the first peak knee adduction moment. This interval was normalized to 100 data points. Cocontraction indices for each pair were derived with use of the equations from Rudolph et al.⁴⁵.

Statistical Methods

Repeated-measures analysis of variance was performed with post hoc pairwise comparisons (least significant difference) for pain, function, instability, kinematic variables, and muscle cocontraction indices. Pearson product-moment correlations were used to assess salient relationships among parametric variables. Spearman rank correlations were performed to assess the relationship between instability and each of the five subscales, on the KOOS questionnaires for each period. Linear regression analysis was used to test the effect of knee alignment on muscle cocontraction for each brace condition. Significance was set at $p < 0.05$ except for muscle cocontraction indices. Significance was set at $p < 0.1$ in an effort to avoid a type-I error given the highly variable nature of electromyographic data⁴⁶. Using a general linear model for repeated measures for within-subjects effects, we obtained an observed power of >0.8 , indicating a good statistical level.

Results

Instability

Data from all sixteen patients are presented. During the baseline assessment (Test 1), nine patients reported the presence of knee instability and five of them indicated that it affected their ability to perform the activities of daily living (Table I). After two weeks of wearing the brace in neutral alignment (Test 2), one of sixteen patients reported that instability affected the activities of daily living. Eight patients complained that instability affected daily activity during the

TABLE I Response to the Knee Outcome Survey-Activities of Daily Living Question on Giving-Way, Buckling, or Shifting of the Knee

	Patient Response During Testing Conditions (N = 16)			
	Baseline	Neutral	Washout*	Valgus
I do not have giving-way, buckling, or shifting of the knee	7	7	6	8
I have the symptom, but it does not affect my activity	4	8	1	2
The symptom affects my activity slightly	2	1	7	5
The symptom affects my activity moderately	2		1	1
The symptom affects my activity severely	1			
The symptom prevents me from all daily activity				

*One subject did not fully complete the questionnaire.

KNEE OSTEOARTHRITIS OUTCOME SCORE

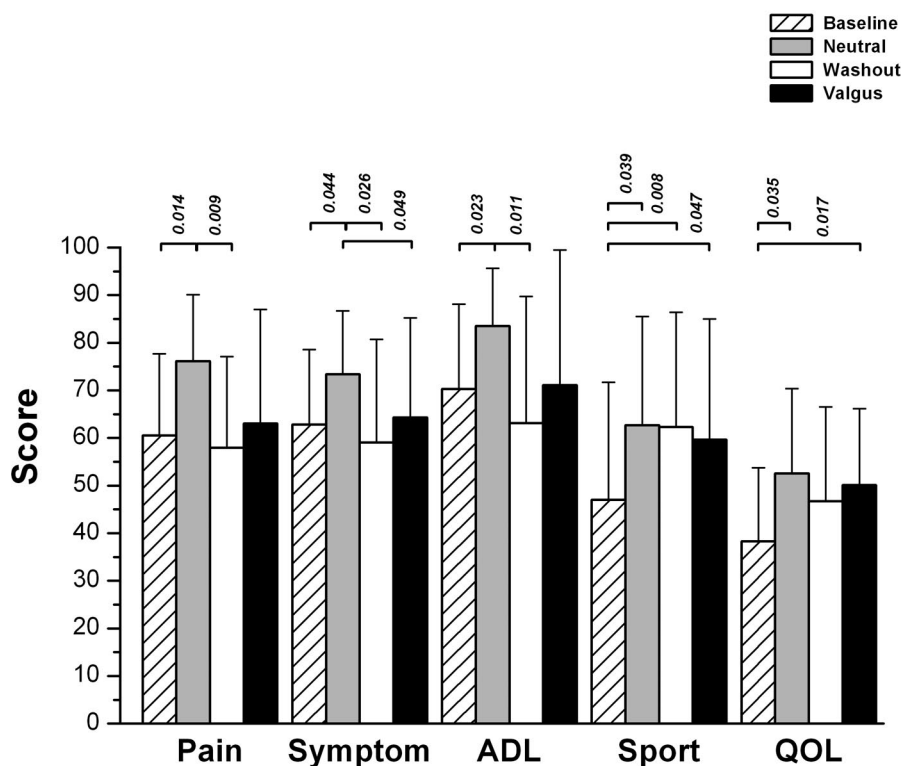


Fig. 1

The change in Knee Injury and Osteoarthritis Outcome Scores (KOOS) induced by brace setting.

ADL = activities of daily living, and QOL = quality of life.

washout period, and six reported that it did so with the brace in the valgus setting.

Self-Reported Questionnaire

Differences were found among the conditions for all five subscales on the KOOS questionnaire. Compared with the period when the braces were in the neutral setting, the scores for pain, symptoms, and activities of daily living were significantly lower (worse) during the baseline ($p = 0.014$, $p = 0.044$, and $p = 0.023$, respectively) and washout periods ($p = 0.009$, $p = 0.026$, and $p = 0.011$, respectively) (Fig. 1). On the basis of the numbers, no significant differences were evident between the washout and valgus condition or between the two bracing conditions with respect to the scores for pain and activities of daily living, but the scores for symptoms were worse in the valgus condition than in the neutral condition ($p = 0.049$). On the basis of the numbers, there were no differences between the baseline and washout conditions with respect to the scores for pain, symptoms, and activities of daily living. A significant improvement from baseline as a result of both bracing conditions was demonstrated for the scores for sports and recreation ($p = 0.039$ for the neutral setting and $p = 0.047$ for valgus setting) and for quality of life ($p = 0.035$ for the neutral

setting and $p = 0.017$ for the valgus setting). With the numbers available, no significant difference in the scores was detected between the bracing conditions or between the baseline assessment and the washout period except for the sports and recreation score, which remained significantly higher in the washout period ($p = 0.008$). Knee instability was found to be significantly correlated to self-reported rating of pain, symptoms, activities of daily living, and quality of life (Table II). Patients who reported instability had increased pain and symptoms with lower function scores for the activities of daily living and quality of life.

Muscle Cocontraction

The level of cocontraction of the vastus medialis-medial hamstring muscles was significantly reduced with the 4° of valgus setting ($p = 0.068$) (Figs. 2-A and 2-B). Cocontraction of the vastus lateralis-lateral hamstrings was significantly reduced from baseline in both the neutral and valgus conditions ($p = 0.014$ and $p = 0.023$, respectively). At the baseline measurement, the alignment of the knee in the frontal plane strongly predicted cocontraction of the vastus lateralis-lateral hamstrings ($p = 0.005$, $R^2 = 0.438$) and vastus medialis-medial hamstrings ($p = 0.066$, $R^2 = 0.221$), as greater cocontraction

TABLE II Correlation Between Knee Instability and Pain, Symptoms, Activities of Daily Living, and Quality of Life for Each Bracing Condition

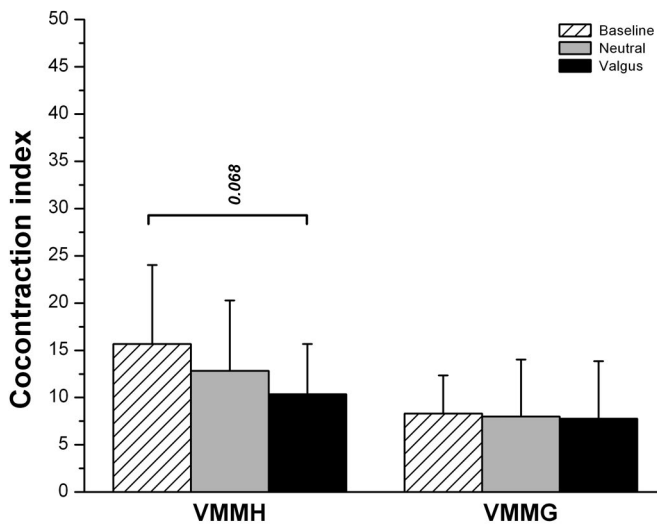
Instability During Testing Conditions	Pain	Symptom	Activities of Daily Living	Quality of Life
Baseline				
Correlation coefficient	0.506*	0.593†	0.470*	0.716†
Significance (one-tailed)	0.023	0.008	0.033	0.001
Neutral				
Correlation coefficient	0.557*	0.264	0.517*	0.444*
Significance (one-tailed)	0.012	0.162	0.020	0.043
Washout				
Correlation coefficient	0.395	0.463*	0.472*	0.452*
Significance (one-tailed)	0.073	0.041	0.038	0.045
Valgus				
Correlation coefficient	0.461*	0.304	0.474*	0.690†
Significance (one-tailed)	0.036	0.126	0.032	0.002

*The correlation was significant at the 0.05 level (one-tailed). †The correlation was significant at the 0.01 level (one-tailed).

was seen in patients with more varus angulation. The magnitude of the change in vastus lateralis-lateral hamstrings cocontraction seen in both of the braced conditions was observed to be related to the degree of varus angulation at baseline. Patients who had more varus alignment at baseline showed a greater decrease in vastus lateralis-lateral hamstrings cocontraction, both in the neutral setting ($p < 0.001$, $r = 0.801$, $R^2 =$

0.642) and the valgus setting ($p < 0.001$, $r = 0.772$, $R^2 = 0.596$) (Figs. 3-A and 3-B). A similar relationship was seen between the degree of varus alignment and the decrease in vastus medialis-medial hamstrings cocontraction measures from baseline to both the neutral brace condition ($p = 0.07$, $r = 0.464$, $R^2 = 0.215$) and the valgus-producing brace condition ($p = 0.06$, $r = 0.464$, $R^2 = 0.23$).

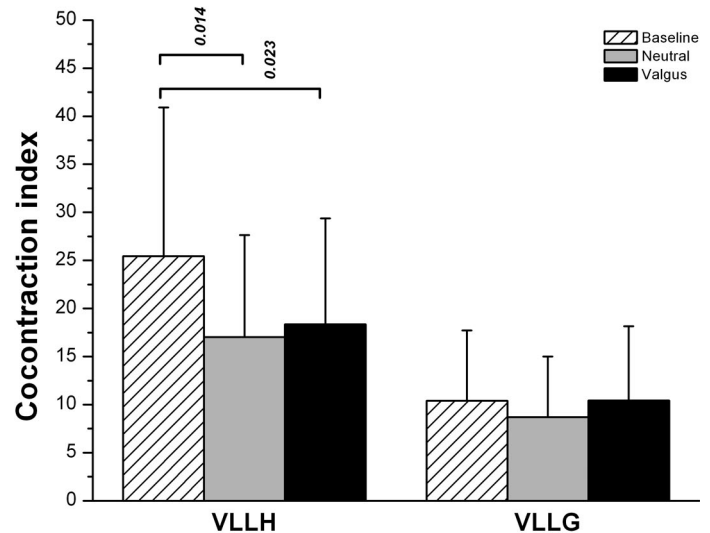
MEDIAL MUSCLE COCONTRACTIONS



p significant at 0.1, adjusted for multiple comparisons: Least Significant Difference

Fig. 2-A

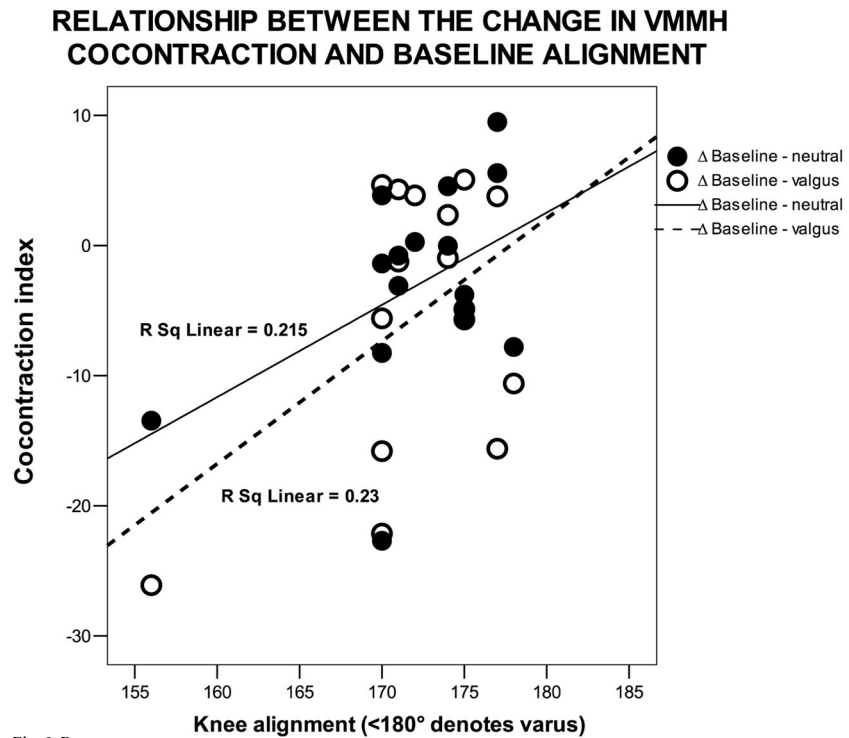
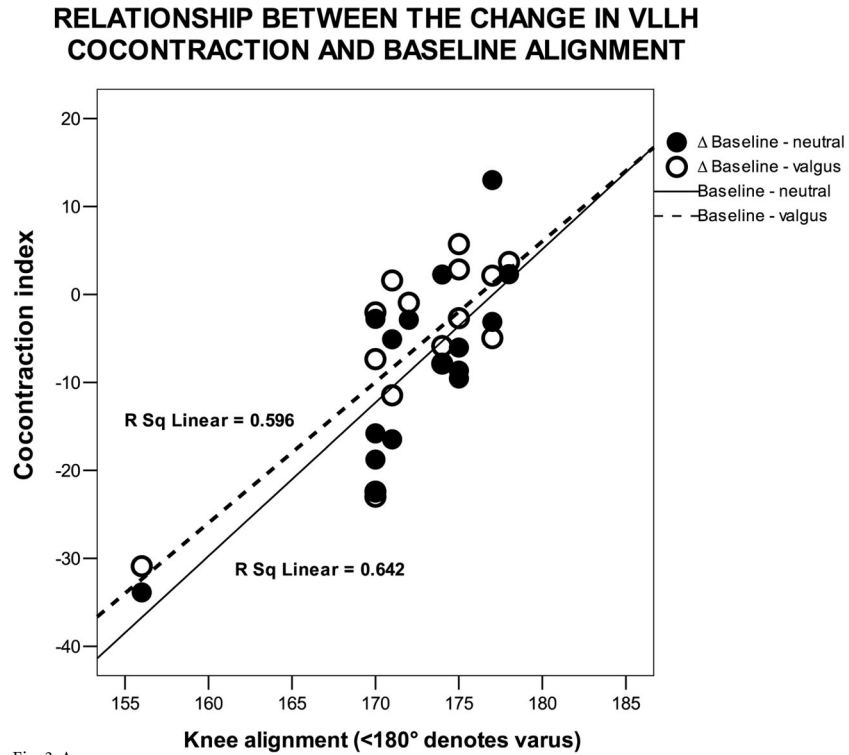
LATERAL MUSCLE COCONTRACTIONS



p significant at 0.1, adjusted for multiple comparisons: Least Significant Difference

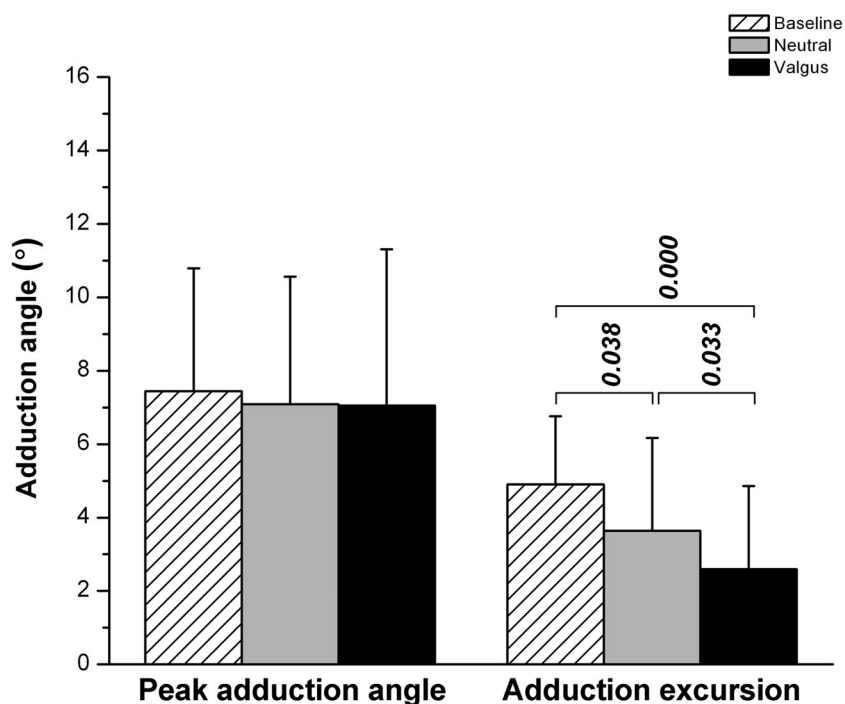
Fig. 2-B

Fig. 2-A and 2-B Muscle cocontraction values during gait, calculated from 100 msec prior to initial contact through peak knee adduction moment. The values represent the mean and standard deviation. **Fig. 2-A** Cocontraction values for vastus medialis-medial hamstrings (VMMH) and vastus medialis-medial gastrocnemius (VMMG). **Fig. 2-B** Cocontraction values for vastus lateralis-lateral hamstrings (VLLH) and vastus lateralis-lateral gastrocnemius (VLLG).



Figs. 3-A and 3-B Scatterplots depicting the association between the change in muscle cocontractions for the neutral setting and valgus-producing setting of the braces relative to the degree of varus alignment at baseline. Best-fit linear regression lines are superimposed on the data. **Fig. 3-A** Vastus lateralis-lateral hamstrings (VLLH). **Fig. 3-B** Vastus medialis-medial hamstrings (VMMH).

KNEE ADDUCTION



p significant at 0.05, adjusted for multiple comparisons: Least Significant Difference

Fig. 4

Knee adduction excursions during weight acceptance. Knee adduction excursion is defined as the difference in knee angle from initial contact to peak knee flexion during mid-stance. Knee adduction excursions were significantly reduced as a result of bracing.

Knee adduction excursions were significantly reduced as a result of bracing ($p = 0.038$ for the neutral setting and $p = 0.000$ for the valgus setting) (Fig. 4), with excursions being lowest at 4° of valgus correction. The magnitude of knee flexion excursion and medial joint-space narrowing were found to be strongly correlated, as those with substantial narrowing exhibited greater stiffening of the knee, as demonstrated by lower knee flexion excursions during weight acceptance ($p < 0.001$, $r = -0.776$). Peak knee flexion angle and flexion excursions remained unchanged from the conditions when the brace was not worn.

Discussion

Self-reported knee pain and functional disability in patients with medial compartment osteoarthritis were significantly reduced when the knee was braced in both the neutral condition and with a 4° of valgus correction. Muscle cocontraction and knee adduction excursions were also lower when the knees were braced. Our hypothesis that bracing in neutral alignment would afford the same benefits to patients with medial compartment osteoarthritis and varus malalignment as would bracing with 4° of valgus correction was supported by the results of this study.

All patients had medial joint laxity, the majority com-

plained of knee instability, and five of the sixteen said it affected their activities of daily living. Poor knee stability was significantly correlated with decreased ratings for the activities of daily living, quality of life, and global knee function and with worse pain and symptoms. Ultimately, functional stability was accomplished by compensatory neuromuscular adaptations, demonstrated by the higher levels of cocontraction of the vastus medialis-medial hamstrings and vastus lateralis-lateral hamstrings. As expected, functional knee stability improved with the neutral brace setting, with only one patient reporting that instability affected daily activity. Functional knee instability worsened during the washout period, with eight patients who reported that instability affected their activities of daily living. The fact that more individuals complained of functional instability during the washout period after having worn the brace in the neutral setting suggests that they may have had instability at the outset without realizing it. The neutral brace setting also resulted in the highest overall improvements in the pain and knee function scores. The equivalent baseline and washout scores clearly illustrate that the two-week washout period, a duration often reported in the literature⁴⁷⁻⁵⁰, was sufficient.

At the time of the baseline assessment when the knee was unsupported, the patients demonstrated significantly greater

cocontraction of the vastus medialis-medial hamstrings ($p = 0.068$) and vastus lateralis-lateral hamstrings ($p = 0.014$) during weight acceptance, which may be an attempt to stiffen the knee through use of increased joint compression. Work in our laboratory has shown that greater cocontraction of the vastus medialis-medial hamstrings in varus-aligned knees, coupled with the larger medial load (adduction moment), appears to be a response to stabilize the medial compartment through increased compression¹⁷. This strategy is counterintuitive because increased cocontraction, while stabilizing the knee, increases joint contact pressures that could exacerbate joint destruction and pain^{17,23,25,31}. The findings that the cocontractions of the vastus lateralis-lateral hamstrings were greater in magnitude than the cocontractions of the vastus medialis-medial hamstrings confirm the observations made in earlier studies, and they may represent an attempt to redistribute the load laterally as others have speculated^{51,52}. Both bracing conditions led to a significant overall lowering of antagonist muscle cocontractions on both the medial and lateral sides of the joint. This may result in decreased joint compression.

Valgus-producing unloader braces apply an external valgus (abduction) moment to the knee³⁻⁵. Radiographic evaluations have shown a 1.4° lateral shift of the femorotibial angle with bracing⁷, as well as a 2.2° change in condylar separation angle and a 1.2-mm increase in condylar separation at heel strike⁸. One study with small numbers, however, found no significant changes in the femorotibial angle or joint space⁹. Intuitively, unloader braces should reduce the varus angle of the knee and attenuate loads transmitted to the medial compartment. For knees in genu varum, the external varus (adduction) moment depends on the mechanical alignment of the knee and the frontal plane location of the ground reaction force vector relative to the knee when the foot contacts the ground during stance. Thus, the ground reaction force vector would be expected to shift laterally and the overall external varus moments to be reduced. With use of instrumented unloader braces to measure the valgus moment exerted by the brace, net varus moments have been shown to be significantly reduced at 20% ($p = 0.048$) and 25% ($p = 0.042$) during the stance phase of gait⁵³ and by an average of 13%³.

The data suggest that when a brace is worn for the treatment of medial compartment osteoarthritis of the knee, pain relief may be the result of reduced muscle contractions, mediated by the brace mechanically stabilizing the knee. While this study included only sixteen patients, we believe that the relatively consistent findings in the sample across the wide range of body mass indices and disease severity increase the generalizability of these results to those for whom bracing is typically prescribed. With more patients, however, perhaps other relationships with secondary variables would emerge in the regression analysis to help to determine how changes in pain and function are predicted by muscle cocontraction. Quantifying the explained variance of these relationships will produce a better understanding of these mechanisms.


The brace order was not randomized. This was intentional because the basis for our protocol was to examine the

subtle influences of bracing on pain relief and neuromuscular function between the neutral setting and the valgus setting of the braces. Conventional wisdom suggests that the setting in 4° of valgus alignment would produce the greater decrease in symptoms. Changing from a valgus alignment to a neutral setting might have masked benefits of wearing the brace in the patient's normal alignment. The patients served as their own controls with the analysis focusing on the differences between brace conditions. As the data suggested, the two-week wash-out period between the neutral and valgus force conditions was sufficient; therefore, it is unlikely that the order affected the clinical interpretations of the data.

The benefits of this study lie with the potential that the positive effects of the neutrally aligned brace may lead to an increased use of braces for the treatment of osteoarthritis as a method to reduce pain and improve function. Bracing is a cost-effective intervention⁵⁴, although greater access in response to clinical need appears appropriate. Among a group of patients with osteoarthritis who were questioned about their health status, use of medications, various nonsurgical treatment modalities, and use of health-care resources, only 11% were informed of bracing and only 12% of those who were informed tried them⁵⁵. The efficacy of the use of braces in maintaining higher levels of activities has been shown⁵⁶, and compliance with long-term use is encouraging^{4,15,56}.

Our results could impact the treatment of patients with symptomatic medial compartment osteoarthritis of the knee. Without the need to induce the valgus correction, patients with varied body morphologies could be managed with braces. Reduction in morbidity for this widespread chronic condition could have a positive impact on health-care costs and on the economic productivity of the affected individuals.

Appendix

 A table showing demographic data on all study subjects is available with the electronic versions of this article, on our web site at jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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