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**Rocky Mountain Musculoskeletal
Research Laboratory**

AN IN VIVO DETERMINATION OF CONDYLAR SEPARATION IN SUBJECTS WEARING AN OSTEOARTHRITIC KNEE BRACE DURING STANCE PHASE AND HEEL STRIKE OF GAIT

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INTRODUCTION

Previous kinematic studies on the effects of knee braces have concentrated primarily on the anterior cruciate ligament (ACL) and the effects of knee bracing to stabilize the patient with deficiency of this ligament^{1-3,5-9,11-14,16-21,23,28,31,35-37,40}. The majority of these studies have concentrated on the analyses of functional knee braces using the arthrometers^{3,5,8,11-13,29,31,35-36,40}. Other studies have concentrated on the analysis of femorotibial translation through the use of roentgen stereophotogrammetric analyses (RSA) techniques^{1,6,18,22}, subjective evaluation of bracing by categorizing pain and functional ability^{2,14,19,28}, and the determination of the effectiveness of braces such as cast bracing^{23,30,33,39}. Minimal research evaluating the efficiency of off-loading braces for treatment of unicompartamental arthritic degeneration has been performed²⁰.

Presently, multiple nonoperative techniques are available to alleviate pain in patients with unicompartamental arthritis including medication, physical therapy, heel wedges^{31,41} and off-loading knee bracing. Previously, we analyzed fifteen subjects using video fluoroscopy to determine if an osteoarthritic knee brace actually separates the medial condyle at heel strike²⁸. The objective of this study was to analyze forty subjects with symptomatic unicompartamental osteoarthritis under in vivo, dynamic, weight-bearing conditions using video fluoroscopy^{16,38} to determine if off-loading knee braces provide separation of the femoral condyle from the tibial plateau at both heel-strike and mid-stance of gait, thus avoiding excessive loads on the degenerated compartment.

METHODS

Forty subjects with symptomatic unicompartamental osteoarthritis were studied under fluoroscopic surveillance in the frontal plane while performing normal gait on a treadmill (Figure 1a). Medial joint space narrowing was demonstrated in all patients on standing anteroposterior radiographs. Initially, each subject was asked to walk on a level treadmill under fluoroscopic surveillance in the frontal plane. A Bledsoe Thruster osteoarthritic knee brace (Bledsoe Brace Systems, Grand Prairie, TX) was then applied to the osteoarthritic knee joint. Five other subjects, also having osteoarthritis, were utilized in the study as a control group. These five subjects were analyzed while wearing a brace that was not properly fitted to offload the degenerated compartments. These five subjects were included in the study to ensure that subjects were not subjectively believing their pain was minimized after brace application. All of the subjects (forty study subjects and 5 control subjects) were then asked to walk on level ground while wearing the brace to rate the effectiveness of the brace in alleviating pain. The subjects were then asked to perform normal gait on a treadmill while wearing the brace (Figure 1b). Successive fluoroscopic images of each patient's stance phase of gait (with and without a brace) were downloaded to a workstation computer. The captured images, just after heel strike and at mid-stance, were analyzed using 2D digitization methods. Previous studies utilizing mathematical model-



Figure 1. Subject performing normal gait on a treadmill (a) without a brace and (b) with a brace.

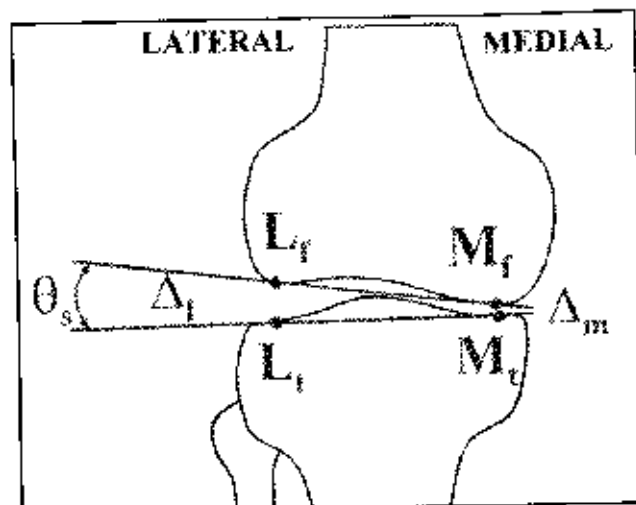


Figure 2. Schematic of the digitized points on the femur and the tibia.

and L_t (Δ_l) and M_f and M_t (Δ_m) were measured using the software package SigmaScan™ (SPSS, Inc., Chicago, IL). The angular difference between the distal femur and the proximal tibia was denoted to be the condylar separation angle (θ_s). The actual amount of change in condylar separation (Δ) was determined using the following equation:

$$\Delta = \Delta_l (\text{brace}) - \Delta_m (\text{no brace}),$$

The actual amount of change in condylar separation angle (θ_s) was determined from the equation:

$$\theta = \theta_s (\text{brace}) - \theta_s (\text{no brace}).$$

Each patient was initially asked to subjectively assess the level of their pain before brace application. Following brace application, they were asked if the brace provided little to no relief in pain versus pain relief considered substantial enough to merit routine use of the osteoarthritic brace.

An error analysis was also conducted using a fresh cadaver and ten spacers having known thicknesses (Figure 3). While a spacer was inserted between the medial femoral condyle and the tibial plateau, the cadaver was fluoroscoped in the frontal and oblique planes (Figure 3). These images were downloaded to the workstation computer and analyzed. The predicted values were compared with known condylar separation values to determine the average error of the process.



Figure 3. Spacers (left) of known thickness were inserted into a cadaver (center) and were then fluoroscoped (right) and analyzed to determine the error.

ing techniques have determined that the maximum force exerted at the knee joint occurs just after heel strike and a varus thrust occurs at mid-stance^{12,34}. Therefore, since the maximum vertical force at the knee joint occurs just after heel-strike and a varus thrust is induced at mid-stance, it was assumed that these positions of stance phase would provide the most meaningful data regarding brace function. The most inferior points (L_f , M_f) on the femoral condyle, and the most superior points (L_t , M_t) on the tibial plateau were digitized (Figure 2). Digitization has been used effectively in previous fluoroscopic studies^{16,17,27}. The studies have shown that in plane measurements can be made with accuracy of 0.5 mm. The vertical distances between L_f

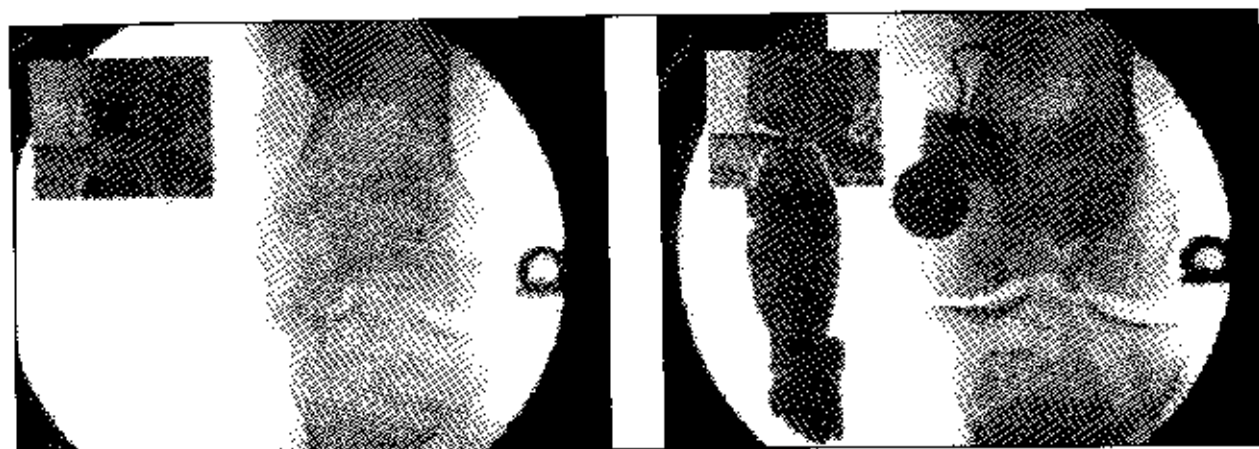


Figure 4. Fluoroscopy of a randomly selected subject at heel strike (left) without a brace and (right) with a brace.

RESULTS

Thirty-four of forty subjects (85%) that were analyzed while wearing a properly fixated brace judged the off-loading knee brace to be effective in reducing knee pain. Thirty-one of forty subjects (78%) experienced condylar separation of the narrowed, degenerated knee compartment at heel-strike, (Figure 4) while 28/40 (70%) of the subjects experienced separation at mid-stance (Figure 5). Six of the forty subjects (15%) received no subjective pain relief following brace application and demonstrated no condylar separation following brace application. Interestingly, all six of these patients were judged obese (greater than 20% above ideal body weight) resulting in suboptimal brace fixation. Three other subjects determined the brace reduced their knee pain, but the analysis did not reveal medial condyle separation at heel-strike. We hypothesize that these subjects may have experienced condylar separation, but the amount was less than our error of 0.5 mm for this process. Condylar separation did not occur in any of the five subjects that were included in the placebo group. Therefore, it can be concluded that the osteoarthritic brace was the reason for the subjects experiencing joint separation.

The average amount of change in condylar separation (Δ) was 1.7 mm (0-6.4 mm) at heel-strike and 1.9 mm (0-7.9) at mid-stance. Since the accuracy for this digitization method is 0.5 mm, an average separation value of 1.7 mm and 1.9 mm can be concluded to be clinically significant. The average amount of change in angle θ_s was 2.0 degrees (0.0-7.9 degrees) at heel-strike and 1.6 degrees (0-

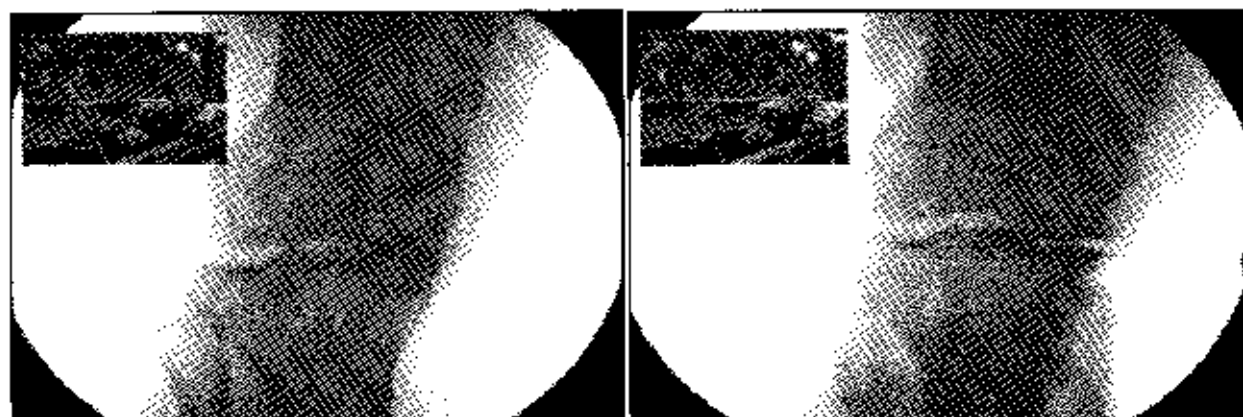


Figure 5. Fluoroscopy of a randomly selected subject during mid-stance (left) without a brace and (right) with a brace

in condylar separation before and after a brace ($p=0.015$). The standard deviation for the forty subjects that received a properly fixated brace was 1.79. Using the fresh cadaver, it was determined that the average error for the digitization process was 0.4mm.

DISCUSSION

Numerous treatment modalities are available for the patient with symptomatic unicompartmental osteoarthritis. Nonoperative measures include management with nonsteroidal anti-inflammatory drugs, physiotherapy, injections (corticosteroid, hyaluronic acid), heel wedge insoles, and off-loading knee braces. Operative options include arthroscopic debridement, high tibial or distal femoral osteotomy, unicompartmental arthroplasty, or total knee replacement.

The goal of treatment with off-loading braces is to reduce loads on the degenerative compartment of the knee by application of peri-articular forces applied distant from the knee joint. By transferal of loads to the normal or at least less diseased compartment of the knee, pain from the narrowed, arthritic compartment may be reduced.

Numerous analyses have been conducted on the abduction and adduction moments at the knee during normal gait. An abduction moment occurs at early heel strike, but quickly reverses to an adduction moment throughout the remainder of stance phase¹⁵. This adduction moment has been shown to have a magnitude of between thirty-six to fifty Newtons, increasing if co-existing deformity is present^{4,10}. During the midstance phase of gait in subjects with normal knees, the medial compressive loads increase to a range of 70-75% of the load at the knee, secondary to the adduction moment occurring at midstance^{22,24,25}. In order to reset the adduction moment, numerous physiologic compensatory mechanisms are active at the knee joint including: (1) the redistribution of condylar loads, (2) contraction of antagonist muscle groups, (3) increased tension in the lateral convex soft tissues and cruciate ligaments, (4) increased body sway in the lateral direction, (5) decreased stride length, and (6) decreased inversion moment at the ankle accomplished by out-toeing. If these compensatory mechanisms become inadequate, excessive medial compartment loads and subsequent medial knee pain may result.

Using an in vivo, weightbearing fluoroscopic analysis, the present study supported the findings of our initial study conducted on fifteen subjects. The results from our previous fluoroscopic study determined that 12/15 subjects (80%) experienced medial condyle separation at heel-strike. These results lead us to conduct this follow-up study on forty subjects, analyzed at heel-strike and mid-stance to determine if our initial findings will be supported by a larger group of subjects and if the findings at heel-strike will be similar at mid-stance. The results from our present study supported our previous study, demonstrating that use of off-loading knee braces can be effective in providing condylar separation of narrowed and degenerative knee compartments with a corresponding subjective relief of medial knee pain. It is assumed that braces of this design function through transferal of load to the contralateral, less diseased compartment, thereby reducing pain in the arthritic compartment. It can be theorized that they also lessen the adduction moment occurring throughout the majority of stance phase.

Lack of subjective pain relief correlated with the absence of condylar separation viewed fluoroscopically in this study. This occurred in patients with substantial obesity in which optimal brace fixation was difficult to obtain. This suggests that off-loading braces, which provide maximal benefit in subjects with reduced soft-tissue girth in the affected lower extremity, allow for a more direct transfer of the externally applied forces to the underlying femur and tibia.

Osteoarthritic knee braces have been developed to lessen loads in the degenerative compartment while subsequently reducing knee pain in patients with unicompartmental arthritis. The present study has demonstrated that articular separation of a degenerated knee compartment can be achieved at heel-strike and mid-stance of gait with the Bledsoe Thruster knee brace with subsequent subjective relief of knee pain in the majority of patients tested. Although these knee braces seem to be very effective devices for pain management, they may have limited effectiveness to offload and relieve pain in heavier patients.

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REFERENCES

Furnished upon request.