In Vivo Three-Dimensional Determination of OA Brace Effectiveness: A Multiple Brace Analysis

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INTRODUCTION

Presently, multiple nonoperative techniques are available to alleviate pain in patients with unicompartmental arthritis including medication, physical therapy, heel wedges and off-loading knee bracing. 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. The majority of these studies have concentrated on the analyses of functional knee braces using arthrometers. Other studies have concentrated on the analysis of femorotibial translation through the use of Roentgen Stereophotogrammetric Analyses (RSA) techniques, subjective evaluation of bracing by categorizing pain and functional ability and the determination of the effectiveness of braces such as cast bracing. Although minimal research evaluating the efficiency of off-loading braces for treatment of unicompartmental arthritic degeneration was previously performed, an initial fluoroscopic analysis determined that osteoarthritis (OA) bracing is an effective treatment for non-obese patients under weight-bearing conditions.[23] Using a two-dimensional fluoroscopic evaluation, 80% of the subjects evaluated experienced medial condyle separation during stance-phase of gait.[1] In this single brace study results were not assessed for three-dimensional motion and it did not determine if OA braces would perform well under similar conditions.

The objective of this study was to analyze subjects with symptomatic unicompartmental osteoarthritis under *in vivo*, dynamic, weight-bearing conditions using video fluoroscopy to determine if off-loading knee braces provide separation of the femoral condyle from the tibial plateau, thus avoiding excessive loads on the degenerative compartment. Specifically, this study assessed and compared the effectiveness of off-loading the medial condyle for five different commercially available OA braces.

METHODS

Five subjects with substantial unicompartmental osteoarthritis were studied under fluoroscopic surveillance in the frontal plane while performing treadmill gait (Figure 1). Medial joint space narrowing was demonstrated in all patients on standing anteroposterior radiographs. Subjects were patients of one surgeon and were all clinically diagnosed to have marked unicompartmental degenerative joint space narrowing. Initially, each subject was asked to perform gait without the assistance of an off-loading brace (Figure 1a). Then, to evaluate a placebo effect, each subject was asked to perform the same activity while wearing an ACL brace. Finally, each subject was fitted with five different off-the-shelf OA braces and performed normal gait while under fluoroscopic surveillance (Figure 1b). Each brace manufacturer was contacted and asked to send a representative to the evaluation site. The representative fit their brace on each patient to ensure each brace was fitted properly. The five OA braces were the Bledsoe Thruster 2, DJ OAdjuster, Breg Tradition X2K, Innovation Sports OAsys, and the Generation II Unloader Spirit. In addition, each subject was asked to undergo a CT scan in order to reconstruct the three-dimensional femoral and tibial bones (Figure 2). Since the skeletal geometry varies between subjects, CAD models of the femur, tibia, and fibula were needed for each subject. In order to create these CAD models, the normal knee was imaged using computed tomography (CT) at intervals of one to three millimeters

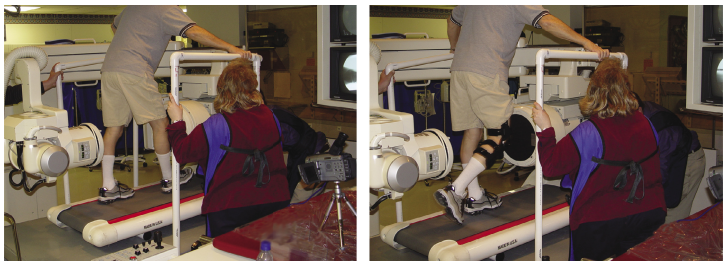

Figure 1. Subject performing normal gait on a treadmill with a brace

over a range of approximately 12 centimeters superior/inferior of the knee (approximately 90 - 140 total slices). The CT slice interval was set at one millimeter near the joint interface and three millimeters further from the interface to minimize radiation exposure to the patient, while providing enough data from which to create accurate CAD models. The three-dimensional bone density data was then loaded into the Amira™ software package (San Diego, CA) in order to segment the femur, tibia and fibula from the surrounding muscle and supportive tissues. Segmentation was achieved by applying a threshold operator to the CT data. Since the densities of the bone and muscles differed significantly, a threshold value was selected between them to remove soft tissue while retaining the femoral, tibial and fibula bone data. Once segmented, the exterior edges of the femur and tibia were identified in each CT datum slice and designated with an IGES curve (Figure 2).

An iterative interpolation is performed between each of the adjacent IGES curves for both patella and femur. Upon completion of the interpolations, the resulting data was used to create full three-dimensional surface models for the distal femur, tibia and fibula (Figure 3).

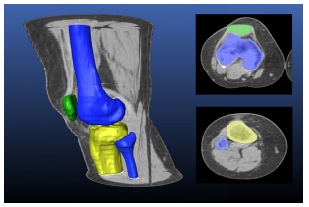

Figure 2. CT scan of the normal knee

Using a 3D to 2D registration technique, the three-dimensional bones were overlaid onto the fluoroscopic images to determine the amount of medial condyle off-loading.[2,3] Successive fluoroscopic images of each patient's stance phase, without a brace and while wearing the ACL brace and the five OA braces, were downloaded to a workstation computer. Images were captured at five instances during stance-phase of gait: heel strike, 33% of stance phase, mid-stance, 66% of stance-phase and toe-off. A comparative analysis was conducted for each subject while wearing all five OA braces with their non-braced test. Then, the amount of medial condylar separation was assessed for each subject and compared for all five subjects while wearing the five different braces to determine which brace is the most effective. The process error for the 3D fluoroscopic process used in this study was 0.3 mm.[4]

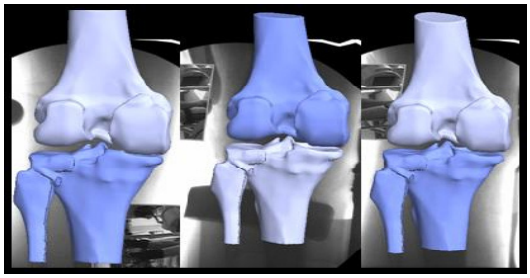

Figure 3. Subject without a brace (left), while wearing an effective brace (center) and a non effective brace (right).

RESULTS

Initially, the ACL brace was analyzed and on average, revealed no medial compartment separation during mid-stance or toe-off and an average of only 0.2 mm at heel-strike, which is below our error threshold of 0.3 mm (Table 1). Analysis of the OA braces revealed variable results (Tables 1-5). On average, subjects experienced their largest magnitude of medial condyle separation at heel-strike, leading to an assumption that all of these braces were most effective at heel-strike, compared to mid-stance and toe-off (Table 1). The Bledsoe (average = 1.3 mm) and DJ (average = 1.2 mm) braces achieved the greatest amount of separation at heel-strike compared to the other three braces (Table 1). At mid-stance the Bledsoe brace was the only brace to produce an average separation value greater than our process error (Table 1). The DJ brace achieved an average mid-stance value of 0.3 mm, equal to our process error, while the other three braces experienced average values less than 0.3 mm (Table 1). At toe-off the average amount of separation was 1.3 mm for the subjects wearing a Bledsoe brace, 0.4 mm while wearing a DJ brace and less than our process error of 0.3 mm for the other three braces (Table 1).

Table 1.
The average amount of medical condyle separation for all five subjects at three different locations during stance-phase of gait.

SUBJECT	Heel-Strike	Mid-Stance	Toe-off
Bledsoe	1.3	0.7	1.3
DJ Ortho	1.2	0.3	0.4
Breg	0.7	0.1	0.2
Isports	0.7	0.0	0.0
Gen II	0.7	0.2	0.1
ACL	0.2	0.0	0.0

Although the average values were quite variable, the maximum amount of medial condyle separation was very good for all of the braces (Table 2). All five braces achieved a maximum separation value (for one subject) greater than 2.0 mm at heel-strike. Four of the five braces achieved a maximum separation value greater than 1.0 mm at mid-stance, and two of the five braces had greater than 1.0 mm at toe-off (Table 2). The values in Table 2, which are significantly higher than the values in Table 1, may suggest that only one out of five subjects achieved desirable results, while the other four subjects achieved minimal or no separation.

Table 2.
The maximum amount of medical condyle separation for all five subjects at three different locations during stance-phase of gait.

SUBJECT	Heel-Strike	Mid-Stance	Toe-off
Bledsoe	2.3	1.6	2.1
DJ Ortho	2.7	1.0	1.5
Breg	2.7	1.3	0.7
Isports	2.1	0.8	0.2
Gen II	3.4	1.3	0.9
ACL	0.4	0.2	0.2

The braces were then evaluated to determine their effectiveness to off-load the medial condyle. Two evaluations schemes were used to determine the brace effectiveness in separating the medial condyle by more than 0.0 mm and 0.3 mm. It was determined that using both of these comparative tests would reveal a better assessment of brace effectiveness. The first test would reveal the effectiveness to separate the condyles by any amount. The second test would reveal absolute occurrence of separation as the process error was introduced into the equation as the threshold to determine effectiveness of each brace.

Table 3.
The percent separation greater than 0.0 mm for all five subjects at three different locations during stance-phase of gait.

SUBJECT	Heel-Strike	Mid-Stance	Toe-off
Bledsoe	80%	80%	80%
DJ Ortho	80%	80%	60%
Breg	60%	40%	40%
Isports	80%	60%	60%
Gen II	60%	40%	40%
ACL	60%	60%	60%

Table 4.
The percent separation greater than 0.3 mm for all five subjects at three different locations during stance-phase of gait

SUBJECT	Heel-Strike	Mid-Stance	Toe-off
Bledsoe	80%	60%	80%
DJ Ortho	80%	60%	40%
Breg	60%	20%	40%
Isports	60%	20%	0%
Gen II	40%	40%	20%
ACL	60%	0%	20%

The Bledsoe brace was 80% effective to separate the medial condyle more than 0.0 mm at heel-strike, mid-stance and toe-off (Table 3). The DJ brace was the next most effective, while the other three braces achieved mixed results, at times being less effective than the ACL brace. At mid-stance, the ACL brace achieved 60% effectiveness to off-load the medial condyle more than 0.0 mm, while the Breg and Generation II braces were only 40% effective. As stated previously, this same test was then conducted using our process error of 0.3 mm as the threshold to determine brace effectiveness. During this evaluation the Bledsoe and DJ braces were again the most effective (Table 4). At heel-strike both of these braces were 80% effective and at mid-stance both were 60% effective. At toe-off, the Bledsoe brace was 80% effective, while the DJ brace was 40% effective. The ACL brace demonstrated a greater effectiveness at heel-strike than the Generation II brace; the Isports brace was more effective at heel-strike and as effective as the Generation II brace at toe-off (Table 4).

The final evaluation was to determine the average amount of separation throughout stance-phase for each subject. This average value was produced for each subject by summing the amount of separation for all five instances during stance-phase of gait (heel-strike, 33% of stance-phase, mid-stance, 66% of stance-phase and toe-off) and then dividing the total amount by five (Table 5). For Subjects 1, 2 and 3, the Bledsoe brace achieved the highest amount of separation and the Isports and Generation II braces achieved the least amount of separation. All five braces were ineffective in off-loading the medial condyle for Subject 4. The Bledsoe and Breg braces were the only braces to achieve an average medial condyle separation greater than 0.0 mm. Subject 5 produced the largest average, which was 1.6 mm while wearing a Bledsoe brace. The Generation II brace was least effective for Subject 5 (Table 5).

Table 5.
Average amount of medial condyle separation for all five subjects.

SUBJECT	Bledsoe	DJ Ortho	Breg	ISports	Gen II	ACL
Subject 1	0.9	0.4	0.3	0.2	0.2	0.1
Subject 2	0.6	0.4	0.5	0.0	0.0	0.1
Subject 3	0.8	1.0	0.4	0.0	0.0	0.2
Subject 4	0.1	0.0	0.1	0.0	0.0	0.0
Subject 5	1.6	0.8	0.9	0.5	1.0	0.1
AVERAGE	0.8	0.5	0.4	0.2	0.2	0.1

DISCUSSION

Numerous treatment modalities are available for treatment of patients with symptomatic unicompartmental osteoarthritis. Nonoperative measures include management with nonsteroidal anti-inflammatory drugs, physiotherapy, injections (corticosteroid and 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 phase. This adduction moment has been shown to have a magnitude of between 36 to 50 Newtons/meter, increasing if coexisting deformity is present. 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. 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.

Previously, we used a 2D *in vivo*, weight bearing fluoroscopic analysis and determined that 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.[1] It was 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 was then 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 previous, limited study.[1] 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 more direct transfer of the externally applied forces to the underlying femur and tibia.

This present study is the first study to analyze the OA knee in three-dimensions and to conduct an impartial analysis of multiple braces, designed by five different manufacturers. There was a noticeable variability between the five braces. At times, the OA braces were less effective than the ACL brace that was used for a placebo effect. In this study, the Bledsoe brace produced the best results followed by the DJ brace. The other three braces demonstrated more variable and less optimal results. The braces were most effective in off-loading the knee at heel-strike and least effective at mid-stance. Four of the five subjects achieved off-loading of their medial condyle, while one subject did not experience any benefit from the five OA braces. In conclusion, this study revealed that OA bracing is an effective mode of treating unicompartmental degeneration, especially in younger patients. Although this is an effective treatment, variable results are evident for the different types of braces.

SUMMARY

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 consistently with two braces, but not as effectively with the other three braces tested in this study. Therefore, there is a difference in the results produced by off-the-shelf OA braces.

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