In Vivo Three-Dimensional Determination of the Effectiveness of the Osteoarthritic Knee Brace: A Multiple Brace Analysis

Matthew C. Nadaud, Richard D. Komistek, Mohamed R. Mahfouz, Douglas A. Dennis and Matthew R. Anderle
J Bone Joint Surg Am. 2005;87:114-119. doi:10.2106/JBJS.E.00482

In Vivo Three-Dimensional Determination of the Effectiveness of the Osteoarthritic Knee Brace: A Multiple Brace Analysis

By Matthew C. Nadaud, MD, Richard D. Komistek, PhD, Mohamed R. Mahfouz, PhD, Douglas A. Dennis, MD, and Matthew R. Anderle, BS

Introduction

Previous kinematic studies on the effects of knee braces have concentrated primarily on the anterior cruciate ligament and the effects of bracing to stabilize the knee that has a deficiency of this ligament[1-23]. The majority of those studies have concentrated on the analysis of functional knee braces with use of arthrometers[2,3,5-8,10-15]. Other studies have concentrated on the analysis of femorotibial translation through the use of roentgen stereophotogrammetric analysis techniques[4,9,16,17], subjective evaluation of bracing by categorizing pain and functional ability[18-22], and the determination of the effectiveness of different types of knee braces, such as cast bracing[23-26]. Although minimal research evaluating the efficiency of off-loading braces for the treatment of unicompartmental arthritic degeneration has been performed, a previous study with an initial fluoroscopic analysis determined that bracing is an effective treatment for osteoarthritis of the knee in nonobese patients under weight-bearing conditions[27]. In that investigation of a single type of brace, the results were not assessed for three-dimensional motion and the study did not determine whether different types of osteoarthritic knee braces would perform well under similar conditions.

The objective of the present study was to analyze subjects with symptomatic unicompartmental osteoarthritis under in vivo, dynamic weight-bearing conditions with use of video fluoroscopy[28,29] to determine whether five different off-loading knee braces provide separation of the medial femoral condyle from the tibial plateau, thus avoiding excessive loads on the degenerated compartment.

Materials and Methods

With institutional review board approval, five subjects with substantial medial compartment osteoarthritis of the knee who had provided consent to participate were studied with fluoroscopic surveillance of the knee in the frontal plane while they performed a normal gait on a treadmill (Fig. 1, *a* and *b*). Medial joint space narrowing was demonstrated in all patients on standing anteroposterior radiographs. The subjects were the patients of one surgeon (M.C.N.) and all were clinically diagnosed as having marked unicompartmental de-

Fig. 1

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

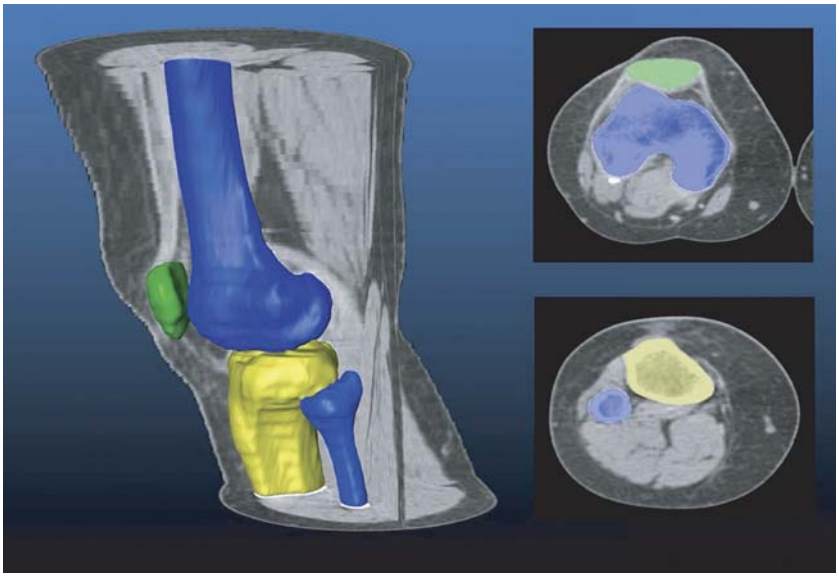

Fig. 2

Reconstruction of the normal knee based on computed tomographic scanning images.

generative joint space narrowing. Initially, each subject was asked to walk without the assistance of an off-loading brace (Fig. 1, *a*). Then, to evaluate a placebo effect, each subject was asked to perform the same activity while wearing an anterior cruciate ligament brace. Finally, each subject was fitted with five different off-the-shelf osteoarthritic knee braces and performed with a normal gait while under fluoroscopic surveillance (Fig. 1, *b*). To ensure that each brace was fitted properly, all companies were contacted and were asked to send one of their sales representatives to the evaluation site. Therefore, if they chose to participate, the sales representatives for each company were asked to fit their brace on each of the patients. The five osteoarthritic knee braces evaluated were the Bledsoe Thruster 2 (Bledsoe Brace Systems, Grand Prairie, Texas), Breg Tradition X2K (Orthofix International, Huntersville, North Carolina), DJ OAdjuster (dj Orthopedics, Vista, California), GII Unloader Spirit (Generation II; Richmond, British Columbia, Canada), and the OAsys (Innovation Sports, Foothill Ranch, California).

Each subject also underwent a computed tomographic scan to allow three-dimensional reconstruction of the distal aspect of the femur and the proximal aspect of the tibia (Fig. 2). Since the skeletal geometry is different for every person, computer-aided design models of the normal femur, tibia, and fibula were created for each specific subject. In order to create these models, the normal knee was imaged with use of computed tomography at intervals of 1 to 3 mm over a range of approximately 5 in (12.7 cm) superior and inferior to the knee joint line (approximately ninety to 140 total slices). The computed tomography slice interval was set at 1 mm near the joint interface and 3 mm farther from the interface to minimize radiation exposure to the patient, while providing enough data from which to create accurate computer-aided design models. The three-dimensional bone density data were then loaded into the MIMICS software package (Materialise, Ann Arbor, Michigan) in order to segment bone and the surrounding soft tissues. Segmentation was achieved by applying a threshold operator to the computed tomography data. Density values of the bone and muscles differed substantially; therefore, a threshold value was selected between them in order to remove the soft tissue while retaining the bones. Once segmented, the exterior edges of the femur and tibia were identified in each computed tomography datum slice and designated with an Initial Graphics Exchange Specification (IGES) curve (Fig. 2).

These curves were loaded into a software package (Pro/ENGINEER; Parameteric Technology; Waltham, Massachusetts), and iterative interpolations were performed to create full three-dimensional surface models for the distal aspect of the femur and the proximal aspects of the tibia and fibula (Fig. 3).

With use of a model-fitting technique, the three-dimensional bones were overlaid onto the fluoroscopic images to determine the amount of medial off-loading[30,31]. Successive fluoroscopic images of each patient's stance phase, without a brace and while wearing the anterior cruciate ligament brace and the five osteoarthritic knee braces, were downloaded to a computer workstation. Images were captured at five instances during the stance-phase of gait: heel strike, 33% of stance phase, midstance, 66% of stance-phase, and at toe-off. A comparative analysis of the findings while each of the five osteoarthritic knee braces was worn and during the test performed without a brace was conducted for each subject. Then, the amount of medial condylar separation was assessed for each subject and was compared with that for all five subjects while each of the five different braces was worn, to determine which brace proved to be most effective.

The process error for the three-dimensional fluoroscopic analysis used in this study was 0.3 mm[32].

TABLE I Average Amount of Medial Condylar Separation for All Five Subjects at Three Different Locations During Stance Phase of Gait

Type of Brace	Heel-Strike *(mm)*	Midstance *(mm)*	Toe-off *(mm)*
Bledsoe Thruster 2	1.3	0.6	1.3
DJ OAdjuster	1.2	0.3	0.4
Breg Tradition	0.7	0.1	0.2
OAsys	0.7	0.0	0.0
GII Unloader Spirit	0.7	0.2	0.1
Anterior cruciate ligament	0.2	0.0	0.0

Results

Initially, the analysis of the anterior cruciate ligament brace revealed, on the average, no medial compartment separation during midstance or toe-off and an average separation of only 0.2 mm at heel-strike, which is below the error threshold of 0.3 mm (Table I). Analysis of the osteoarthritic knee braces revealed variable results (Tables I through V). On the average, the largest magnitude of medial condylar separation occurred at heel-strike, leading to an assumption that all of these braces were most effective at heel-strike compared with midstance and toe-off. The Bledsoe braces (average, 1.3 mm) and DJ braces (average, 1.2 mm) achieved the greatest amount of separation at heel-strike compared with the other three braces (Table I). At midstance, the Bledsoe brace was the only brace to produce an average separation value greater than our process error. The DJ brace achieved an average midstance value of 0.3 mm, equal to our process error, while the other three braces had average values of <0.3 mm. At toe-off, the average amount of separation was 1.3 mm when the subjects wore a Bledsoe brace, 0.4 mm when they wore a DJ brace, and less than our process error of 0.3 mm for the other three braces (Table I).

Although the average values were quite variable, the maximum amount of medial condylar separation was very good for all of the braces (Table II). All five braces achieved a maximum separation value (for one subject) of >2.0 mm at heel-strike. Four of the five braces achieved a maximum separation value of ≥1.0 mm at midstance, and two of the five achieved a maximum value of >1.0 mm at toe-off. Therefore, when the average values in Table I are considered, a high maximum value in Table II may suggest that only one of the five subjects achieved desirable results, while the other four subjects achieved minimal or no separation.

The braces were then evaluated to determine their effectiveness in off-loading the medial condyle. Two evaluations were conducted to determine the ability of the brace to separate the medial condyle from the tibial plateau by >0.0 mm and 0.3 mm. It was determined that use of both of these comparative tests would provide a better assessment of brace effectiveness because the first test would reveal separation by the condyles of any amount and the second would reveal absolute

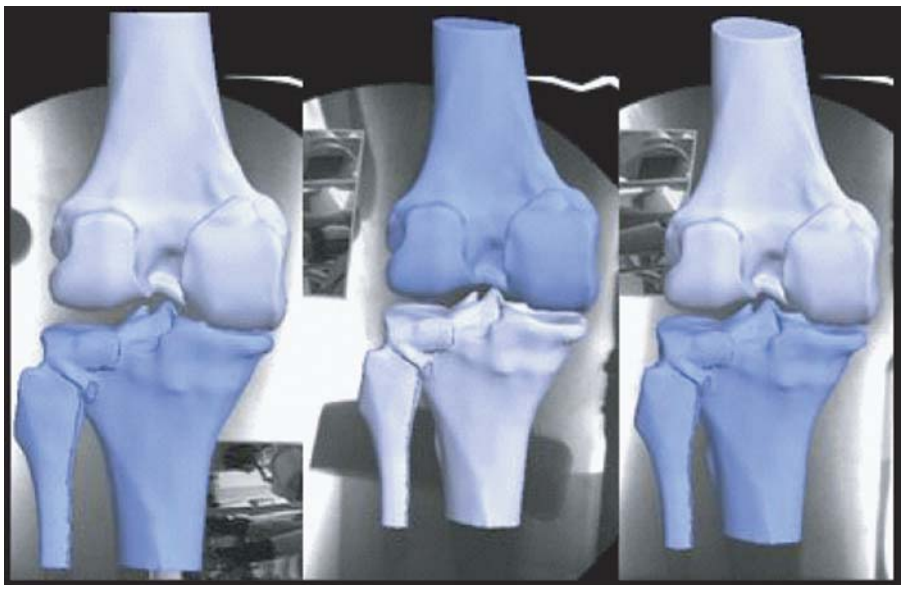

Fig. 3

A knee in a subject without a brace (left), with an effective brace (center), and with a noneffective brace (right).

TABLE II Maximum Amount of Medial Condylar Separation for All Five Subjects at Three Different Locations During the Stance Phase of Gait

Type of Brace	Heel-Strike *(mm)*	Midstance *(mm)*	Toe-off *(mm)*
Bledsoe Thruster 2	2.3	1.6	2.1
DJ OAdjuster	2.7	1.0	1.5
Breg Tradition	2.7	1.3	0.7
OAsys	2.1	0.8	0.2
GII Unloader Spirit	3.4	1.3	0.9
Anterior cruciate ligament	0.4	0.2	0.2

TABLE III Knees That Attained Medial Condylar Separation of More Than Zero Millimeters in All Five Subjects at Three Different Locations During Stance Phase of Gait

Type of Brace	Heel-Strike *(No. of Knees)*	Midstance *(No. of Knees)*	Toe-off *(No. of Knees)*
Bledsoe Thruster 2	4	4	4
DJ OAdjuster	4	4	3
Breg Tradition	3	2	2
OAsys	4	3	3
GII Unloader Spirit	3	2	2
Anterior cruciate ligament	3	3	3

separation since the amount would be greater than our process error of 0.3 mm.

The Bledsoe brace was effective in four of five subjects with respect to creating separation of the medial condyle from the tibial plateau by >0.0 mm at heel-strike, midstance, and toe-off (Table III). The DJ brace was the next most effective, while the other three braces achieved mixed results, at times demonstrating effectiveness similar to that of the anterior cruciate ligament brace. At midstance, the anterior cruciate ligament brace was effective in off-loading the medial condyle by >0.0 mm in three of five subjects, while the Breg and GII braces were effective in only two of five subjects. This same test was then conducted with use of our process error of 0.3 mm as the threshold. This may be the best measure of brace effectiveness because the brace must off-load the medial condyle by 0.3 mm, which is an absolute separation. During this evaluation, the Bledsoe and DJ braces were again the most effective (Table IV). Both of these braces were effective in four of five subjects at heel-strike and effective in three of five subjects at midstance. At toe-off, the Bledsoe brace was effective in four of five subjects, while the DJ brace was effective in two subjects.

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 summating the amount of separation for all five instances during stance phase of gait (heel-strike, 33% of stance phase, midstance, 66% of stance phase, and toe-off) and then dividing this amount by five (Table V). For Subjects 1, 2, and 3, the Bledsoe brace achieved the highest amount of separation and the OAsys and GII 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

TABLE IV Knees That Attained Medial Condylar Separation of More Than 0.3 Millimeter in All Five Subjects at Three Different Locations During Stance Phase of Gait

Type of Brace	Heel-Strike *(No. of Knees)*	Midstance *(No. of Knees)*	Toe-off *(No. of Knees)*
Bledsoe Thruster 2	4	3	4
DJ OAdjuster	4	3	2
Breg Tradition	3	1	2
OAsys	3	1	0
GII Unloader Spirit	2	2	1
Anterior cruciate ligament	3	0	1

TABLE V Average Amount of Medial Condylar Separation (in Millimeters) for All Five Subjects

Subject	Bledsoe Thruster	DJ OAdjuster	Breg Tradition	OAsys	GII Unloaded Spirit	Anterior Cruciate Ligament
1	0.9	0.4	0.3	0.2	0.2	0.1
2	0.6	0.4	0.5	0.0	0.0	0.1
3	0.8	1.0	0.4	0.0	0.0	0.2
4	0.1	0.0	0.1	0.0	0.0	0.0
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

only braces to achieve an average medial condylar separation of >0.0 mm in all five subjects. The largest average amount of separation, which was 1.6 mm, was achieved by Subject 5 while wearing a Bledsoe brace. The OAsys brace was least effective for that subject (Table V).

Discussion

The goal of the treatment of osteoarthritis of the knee with off-loading braces is to reduce loads on the degenerated compartment. By the transfer 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 it quickly reverses to an adduction moment throughout the remainder of stance phase[33]. This adduction moment has been shown to have a magnitude of between 36 and 50 N, increasing if a coexisting deformity is present[34,35]. During the midstance phase of gait in subjects with normal knees, the medial compressive loads increase to a range of 70% to 75% of the total load at the knee, secondary to the adduction moment occurring at midstance[36-38]. 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.

While the use of osteoarthritic knee bracing has been shown to be effective clinically, the long-term effectiveness and the rate of patient compliance have not been well established. Giori followed patients for a minimum of two and a half years and found that patient compliance was greatest in younger age-groups[39]. Perhaps younger patients are more motivated than their older counterparts to avoid operative treatment; however, the reasons for discontinuing braces and subsequent treatments were not identified. Other studies have demonstrated the ability of load-shifting braces to reduce the varus moment[40]. Pollo et al. reported improvement in pain and activity levels with valgus bracing[41]. Bracing in that study reduced the varus moment by an average of 13% and the medial compartment load by an average of 11%[41]. To our knowledge, no previous study has used three-dimensional fluoroscopic analysis.

In a previous study, we used a two-dimensional in vivo, weight-bearing fluoroscopic analysis and determined that an off-loading knee brace can be effective in providing condylar separation of narrowed and degenerated knee compartments with a corresponding subjective relief of medial knee pain[27]. It was assumed that braces of this design function through the transfer of load to the contralateral, less diseased compartment. It was then theorized that they also lessen the adduction moment occurring throughout the majority of stance phase. The lack of subjective pain relief was found to be correlated with the absence of condylar separation viewed fluoroscopically in the previous, limited study[27]. This occurred in patients with substantial obesity in whom optimal brace fixation was difficult to obtain. These findings suggest 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.

To our knowledge, the present study is the first to analyze the osteoarthritic knee in three dimensions under in vivo conditions and to conduct an impartial analysis of multiple braces designed by five different manufacturers. There was a noticeable variability among the five braces. At times, the osteoarthritic knee braces were less effective than the anterior cruciate ligament brace that was used for a placebo effect. In the present study, the Bledsoe brace produced the best results and the DJ brace, the next best results. The other three braces demonstrated more variable and less optimal results. All braces were most effective in off-loading the knee at heel-strike and least effective at midstance. Four of the five subjects achieved at least some off-loading of the medial condyle, while one subject did not experience any benefit from the five osteoarthritic knee braces.

Since the present study had a small sample size, we hope to add another ten subjects to determine whether there is a significant difference among the braces. We also hope to analyze the custom osteoarthritic knee braces to determine whether they are more effective in off-loading the medial femoral condyle than off-the-shelf braces are. The present study addressed only varus

gonarthrosis. To our knowledge, no study to date has examined similar treatment for lateral compartment disease. In conclusion, our study revealed that osteoarthritic knee bracing is an effective mode of treating unicompartmental disease, especially in a younger patient. Although this is an effective treatment, variable results are evident for the different types of braces. ■

Corresponding author:
Richard D. Komistek, PhD
The University of Tennessee, 301 Perkins Hall, Knoxville, TN 37996.
E-mail address: rkomiste@utk.edu

The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

doi:10.2106/JBJS.E.00482

References

1. Beynnon BD, Johnson RJ, Fleming BC, Peura GD, Renstrom PA, Nichols CE, Pope MH. The effect of functional knee bracing on the anterior cruciate ligament in the weightbearing and nonweightbearing knee. Am J Sports Med. 1997;25:353-9.

2. Bagger J, Ravn J, Lavard P, Blyme P, Sorensen C. Effect of functional bracing, quadriceps and hamstrings on anterior tibial translation in anterior cruciate ligament insufficiency: a preliminary study. J Rehabil Res Dev. 1992;29:9-12.

3. Beck C, Drez D Jr, Young J, Cannon WD Jr, Stone ML. Instrumented testing of functional knee braces. Am J Sports Med. 1986;14:253-6.

4. Beynnon BD, Pope MH, Wertheimer CM, Johnson RJ, Fleming BC, Nichols CE, Howe JG. The effect of functional knee-braces on strain on the anterior cruciate ligament in vivo. J Bone Joint Surg Am. 1992;74:1298-312.

5. Branch TP, Hunter R, Donath M. Dynamic EMG analysis of anterior cruciate deficient legs with and without bracing during cutting. Am J Sports Med. 1989;17:35-41.

6. Cawley PW, France EP, Paulos LE. The current state of functional knee bracing research. A review of the literature. Am J Sports Med. 1991;19:226-33.

7. Colville MR, Lee CL, Ciullo JV. The Lenox Hill brace. An evaluation of effectiveness in treating knee instability. Am J Sports Med. 1986;14:257-61.

8. Cook FF, Tibone JE, Redfern FC. A dynamic analysis of a functional brace for anterior cruciate ligament insufficiency. Am J Sports Med. 1989;17:519-24.

9. Jonsson H, Karrholm J. Brace effects on the unstable knee in 21 cases. A roentgen stereophotogrammetric comparison of three designs. Acta Orthop Scand. 1990;61:313-8.

10. Martin RC, Steadman JR. Quantitative analysis of anterior tibial translation using the MVP brace. Am J Knee Surg. 1992;5:129-34.

11. Mishra DK, Daniel DM, Stone ML. The use of functional knee braces in the control of pathologic anterior knee laxity. Clin Orthop Relat Res. 1989;241:213-20.

12. Pettrone FA, Rood C. A comparative study of brace effectiveness in the anterior cruciate ligament-deficient knee. Am J Knee Surg. 1992;5:117-22.

13. Rink PC, Scott RA, Lupo RL, Guest SJ. Team physician #7. A comparative study of functional bracing in the anterior cruciate deficient knee. Orthop Rev. 1989;18:719-27.

14. Romash MM, Henningsen HJ, Claybaugh J. Knee braces—comparative functional testing. Orthop Trans. 1989;13:501.

15. Wojtys EM, Loubert PV, Samson SY, Viviano DM. Use of a knee-brace for control of tibial translation and rotation. A comparison, in cadavera, of available models. J Bone Joint Surg Am. 1990;72:1323-9.

16. Acierno SP, D'Ambrosia C, Solomonow M, Baratta RV, D'Ambrosia RD. Electromyography and biomechanics of a dynamic knee brace for anterior cruciate ligament deficiency. Orthopedics. 1995;18:1101-7.

17. Feller J, Bartlett J, Chapman S, Delahunt M. Use of an extension-assisting brace following anterior cruciate ligament reconstruction. Knee Surg Sports Traumatol Arthrosc. 1997;5:6-9.

18. Harilainen A, Sandelin J, Vanhanen I, Kivinen A. Knee brace after bone-tendon-bone anterior cruciate ligament reconstruction. Randomized, prospective study with 2-year follow-up. Knee Surg Sports Traumatol Arthrosc. 1997;5:10-3.

19. DeVita P, Torry M, Glover KL, Speroni DL. A functional knee brace alters joint torque and power patterns during walking and running. J Biomech. 1996;29:583-8.

20. Alexander AH. In search of the perfect ACL brace. Am J Orthop. 1995;24:328-36.

21. Decoster LC, Vailas JC, Swartz WG. Functional ACL bracing. A survey of current opinion and practice. Am J Orthop. 1995;24:838-43.

22. Helfet AJ, Manley MT, Vaughan CL. The helicoid knee brace: a lightweight but effective support for the damaged knee. Injury. 1983;15:189-92.

23. Veldhuizen JW, Verstappen FT, Koene FM, Greep JM. Effects of cast-bracing of the knee on physical performance in healthy subjects. Int J Sports Med. 1994;15:520-4.

24. Odenbring S, Lindstrand A, Egund N. Early knee mobilization after osteotomy for gonarthrosis. Acta Orthop Scand. 1989;60:699-702.

25. Matsuno H, Kadowaki KM, Tsuji H. Generation II knee bracing for severe medial compartment osteoarthritis of the knee. Arch Phys Med Rehabil. 1997;78:745-9.

26. Jawad AS, Goodwill CJ. TVS brace in patients with rheumatoid arthritis or osteoarthritis of the knee. Br J Rheumatol. 1986;25:416-7.

27. Komistek RD, Dennis DA, Northcut EJ, Wood A, Parker AW, Traina SM. An in vivo analysis of the effectiveness of the osteoarthritic knee brace during heel-strike of gait. J Arthroplasty. 1999;14:738-42.

28. Dennis DA, Komistek RD, Hoff WA, Gabriel SM. In vivo knee kinematics derived using an inverse perspective technique. Clin Orthop Relat Res. 1996;331:107-17.

29. Stiehl JB, Dennis DA, Komistek RD, Keblish PA. In vivo kinematic analysis of a mobile bearing total knee prosthesis. Clin Orthop Relat Res. 1997;345:60-6.

30. Mahfouz MR, Komistek RD, Dennis DA, Hoff WA. In vivo assessment of the kinematics in normal and anterior cruciate ligament-deficient knees. J Bone Joint Surg Am. 2004;86 Suppl 2:56-61.

31. Komistek RD, Dennis DA, Mahfouz M. In vivo fluoroscopic analysis of the normal human knee. Clin Orthop Relat Res. 2003;410:69-81.

32. Mahfouz MR, Hoff WA, Komistek RD, Dennis DA. A robust method for registration of three-dimensional knee implant models to two-dimensional fluoroscopy images. IEEE Trans Med Imaging. 2003;22:1561-74.

33. Dennis DA. Patellofemoral complications in total knee arthroplasty. In: Callaghan JJ, Dennis DA, Paprosky WG, Rosenberg AG, editors. Orthopaedic knowledge update: hip and knee reconstruction. Rosemont, IL: American Academy of Orthopaedic Surgeons; 1995. p 283-9.

34. Burstein AH. Biomechanics of the knee. In: Insall JN, editor. Surgery of the knee. New York: Churchill Livingstone; 1984. p 21-39.

35. Bartel DL, Burstein AH, Santavicca EA, Insall JN. Performance of the tibial component in total knee replacement. J Bone Joint Surg Am. 1982;64:1026-33.

36. Johnson F, Leitl S, Waugh W. The distribution of load across the knee. A comparison of static and dynamic measurements. J Bone Joint Surg Br. 1980;62:346-9.

37. Hsu RW, Himeno S, Coventry MB, Chao EY. Normal axial alignment of the lower extremity and load-bearing distribution at the knee. Clin Orthop Relat Res. 1990;255:215-27.

38. Noyes FR, Schipplein OD, Andriacchi TP, Saddemi SR, Weise M. The anterior cruciate ligament-deficient knee with varus alignment. An analysis of gait adaptations and dynamic joint loadings. Am J Sports Med. 1992;20:707-16.

39. Giori NJ. Load-shifting brace treatment for osteoarthritis of the knee: a minimum 2 ½-year follow-up study. J Rehabil Res Dev. 2004;41:187-94.

40. Self BP, Greenwald RM, Pflaster DS. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. Arthritis Care Res. 2000;13:191-7.

41. Pollo FE, Otis JC, Backus SI, Warren RF, Wickiewicz TL. Reduction of medial compartment loads with valgus bracing of the osteoarthritic knee. Am J Sports Med. 2002;30:414-21.