Introduction: Valgus bracing has been used as a treatment for patients with medial compartment OA for several years. It has met with considerable success, which is reflected in the increased number of manufacturers offering valgus bracing. The basic biomechanical philosophy is to apply a valgus load or correction about the knee to partially offset the varus moment that is present in the knee with the brace on and the stance phase of gait. In doing so, some of the joint compressive load is shifted from the medial compartment to the lateral compartment.

The efficacy of valgus bracing using the Generation II Unloader brace has been previously documented in an instrumented study of the brace in subjects with isolated medial compartment osteoarthritis[1]. Patients reported a decrease in pain and improvement in the performance of functional activities. The degree of pain relief and functional improvement varied across subjects, however, as did changes in the mechanical joint loads.

There is a need to better understand this conservative treatment, especially in light of the broad range of costs for these braces, the differences in design, and the current climate for reimbursement. It is important to assess and document these brace factors that are effective in controlling pain and allowing a return to function. As the indication for referrals has expanded to include patients with ligamentous instability, it becomes more critical to objectively quantify the changes in gait seen with the use of the brace and determine those factors that influence successful outcome.

The common denominator in the design of these braces is that, in theory, they apply a valgus load about the knee. It is unclear, however, whether or not the applied valgus load is actually a factor responsible for the clinical success of valgus bracing. Other factors, e.g., the additional stability offered by the brace or increased proprioception, may be responsible for the success of the treatment. The purpose of this study is to examine the hypothesis that valgus loading is responsible for the success observed clinically. This is accomplished by comparing clinical outcomes of patients treated with valgus bracing versus outcomes of those treated with sham bracing (no valgus correction).

Methods: To date, thirty subjects with a mean age of 49 ± 11 years, mean height of 1.8 ± 0.1 m and mean weight of 91 ± 20 kg have been tested. Inclusion criteria were: males and females 21 years of age or older; medial compartment knee arthritis; and physician referral for unilateral valgus bracing. Exclusion criteria were: fixed knee flexion deformity greater than 5°; leg length discrepancy greater than 2 cm; other neuromuscular deficits; skin or peripheral vascular disease preventing brace application; and current orthopaedic deficits in lower extremity joints except for the contralateral knee. All had a physician referral for valgus bracing and received an off-the-shelf, adjustable hinging correction, Bledsoe Thruster brace at no charge.

The braces were fit from the same orthotic department according to the manufacturer’s suggested protocol. Treatment was randomized to one of two groups. The treatment group received the prescribed amount of valgus correction applied to the brace. A sham group was fit with the same model brace with no valgus correction applied. This group of subjects served as a “no valgus correction group”. Upon completion of the gait analysis, the braces for these subjects were adjusted to the prescribed amount of correction. The treatment group assignment was known only to the orthotist who fit the patient with the brace. The patients and the laboratory personnel were blinded with respect to the assignment.

Randomization was done with a block design. Each of five blocks consists of two treatment cells that contain five subjects each, so that a block comprises 20% of the study population. Subjects are randomly assigned to a cell when recruited for the study. At that time the leg is measured for the brace, informed consent is obtained and each participant completes the initial questionnaire. Included in the questionnaire were visual analog scales (VAS) for pain at rest, during walking, stair negotiation and usual sports activity.

Subjects used the brace according to physician referral when needed during activities of daily living, walking, exercising and sports. After two weeks, but less than eight weeks, of using the brace, a gait analysis was conducted. The subject unbraced and braced. Time-distance parameters, knee joint kinematics and kinetics, brace loads from instrumented braces and calculated knee joint compartment loads were determined. A follow-up questionnaire was also completed at the time of testing.

Each of the braces is instrumented to record bending moments. Three-dimensional video based gait analysis using a six-camera system (Motion Analysis Corporation. Santa Rosa, CA) and two force platforms (Bertec, OH) was completed at self-selected free speed walking. A minimum of three trials of force platform contacts was collected for each of two conditions: braced and unbraced free speed walking. A 2m by 1m volume was calibrated and a standard unilateral lower extremity 11 marker set (Cleveland Clinic configuration) was used. Hip, knee and ankle joint center coordinates were calculated according to standardized methodology. Pelvis and unilateral lower extremity (hip, knee and ankle) joint kinematics, and unilateral lower extremity (hip, knee and ankle) joint kinetics were determined. Only the affected lower extremity was measured.

Average kinematics, kinetics and brace loads for each subject, for three trials at each condition were calculated. In order to measure similarity between treatment groups, analysis of variance and chi square analysis (p < 0.05) were used to compare: demographics; time-distance parameters (velocity, cadence, and stride length); and the pre-braced questionnaire results. To assess the differences in gait pattern between treatment groups, differences between loads for the braced and unbraced conditions were compared across treatment groups. The results were analyzed to determine whether or not clinical success as measured by pain relief was associated with treatment. In addition, the degree of load sharing by the brace was analyzed for the two groups. A significance level of 0.05 was used.

Results: For the thirty subjects tested, there were no differences between groups with respect to demographics. The time-distance parameters were no different for 12 subjects analyzed, to date. The unbraced and braced velocities for the sham group were 125 and 124 cm/s, respectively. For the treatment group these values were 133 and 130 cm/s, respectively. For six subjects in the sham group and eight subjects in treatment group the changes in pain score were -1.5 ± 2.2 and -1.0 ± 2.8, respectively. A two sample t-Test demonstrated no difference in the pain relief for the two groups (p = 0.74).

The average varus moment taken up by the brace during the stance phase for six subjects in the sham group was 0.004 ± 0.019 Nm/kg versus 0.032 ± 0.027 Nm/kg for the treatment group. A test of the difference between these means yielded p = 0.07.

Discussion: The population is representative of the spectrum of patients treated with valgus bracing. The results, to date, suggest that load sharing by the brace is different for the two groups. The large variability in pain scores resulted in the measured amount of pain relief not being different in this preliminary group.

Acknowledgments: The authors gratefully acknowledge the support of Bledsoe Brace Systems and the Clark, Dana and Frose Foundations.