Mechanical Testing of Functional Knee Braces:
An Evaluation of the BREG FUSION XT versus Selected Custom and Off-The-Shelf Functional Knee Braces

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INTRODUCTION

In a 1991 paper in the American Journal of Sports medicine, Cawley et al [1] noted that while there was little controversy regarding the use of functional knee braces in the management of ligamentous injuries to the knee, there was a great deal of controversy regarding the use of these braces following ligament reconstruction in the knee. Prior to 1991, a great deal of both functional and mechanical testing of functional knee braces was conducted. [2-24] However, despite a substantial evolution in both surgical and rehabilitation techniques, little mechanical/functional evaluation of these braces has been conducted since this 1991 review.

Between 1991 and the present, the primary application of functional knee bracing has also undergone a substantial change. The principal use of these braces today is prophylactic or protective in nature. Following ligament reconstruction in the knee, the principal application of functional knee braces is to provide protection to the healing/remodeling soft tissues in the knee. In the athletic setting, these braces are now widely employed to provide protection to the soft tissue stabilizers of the knee, primarily in football players but in other sports as well. While anecdotal reports from users would indicate that these braces do provide increased protection to the soft tissue structures of the knee, there is a dearth of mechanical data to substantiate this claim.

Accordingly, this investigation evaluated the mechanical effectiveness of a representative selection of both custom-made and off-the-shelf functional knee braces in the control of both valgus displacement at the knee and foot as well as anterior tibial displacement at the knee.

MATERIALS AND METHODS

A mechanical surrogate of the lower extremity was developed for this investigation. [Figure 1] In order to replicate physiologic conditions as closely as possible, this surrogate was designed as a weightbearing system. The musculature of this mechanical surrogate was simulated using a series of pneumatic actuators integrated with an accommodating cross-head at the top of the surrogate structure. When testing, this cross-head is unconstrained to rotation in both the frontal and sagittal planes and can translate freely vertically on linear bearings which form the vertical support structure of the mechanism. An axial load of approximately 125 lbs. (56.7 kg) is borne by the surrogate structure during testing. Flexion angle of the surrogate limb during testing was maintained by the muscle analogs. Cables attached to the pneumatic actuators in series with tensile load cells and which cross the knee joint replicate the normal axis of load application of the muscle analogs. A patella analog replicates force vectors in the quadriceps mechanism. Dimensions of the mechanical surrogate and forces generated by the muscle analogs were derived from standardized anthropomorphic data representing a 90^{th} percentile male. [25]

To simplify the system, the knee analog in this surrogate is symmetrical in design. In other words, the femoral condyle analogs are simulated using identical cylindrical shapes aligned parallel to one another but which are dimensionally similar to those from a human knee based on the anthropomorphic criteria listed above. In order to vary the dynamic response of the knee under load, additional actuators at the cross-head are interfaced with cables which cross the joint at the normal origin and insertion points of the anterior cruciate ligament, posterior cruciate ligament, and both the medial and lateral collateral ligaments. This permits variation of the dynamic response and dynamic stiffness of the knee analog to simulate either normal or pathologic conditions. The knee analog also incorporates individual medial and lateral meniscal analogs conforming in shape to the femoral condyle analogs. While not compliant in nature, these meniscal analogs are configured such that they are free to translate anteriorly and posteriorly in the sagittal plane and permit unconstrained rotation of the femoral condyles in the frontal plane. Each meniscal analog is constrained within the joint at four points by an elastomeric tether whose dynamic response can be changed to alter the overall dynamic response of the knee analog or alter dynamic response between knee compartments. Both medial and lateral plateaus of the tibial analog are instrumented with compression force sensors to characterize compressive load between compartments.

A limitation of this mechanical surrogate is the inability to replicate normal compliance in the soft tissue analog. In order to standardize testing across all braces, a soft tissue analog was molded from resilient polyurethane (Shore A 35) and skinned with latex. The mold was fabricated from a cast of a 95^{th} percentile male left lower extremity. To reduce the frictional resistance between braces and the limb analog during testing, a sleeve of cotton stockinette was applied over the limb before a brace was applied. The investigators assumed that the resilience of this soft tissue analog was a good approximation of the axial soft tissue of a well-conditioned athletic lower extremity with musculature contracted and allowed repeatable comparison of brace versus brace without the confounding variable of changing soft tissue compliance.

A selection of both custom-made and off-the-shelf braces was obtained for this investigation. [Table 1] Custom-made braces were obtained from casts molded on the mechanical surrogate to insure optimum fit. Off-the-shelf braces were sized according to the published guidelines of each manufacturer.

Custom Braces	Off-The Shelf Braces
Innovation Sports C.Ti.[2]	Innovation Sports Aspire
Omni Rage	Innovation Sports Edge
Townsend Premier	Generation II Paradigm
Lenox Hill (Seattle Systems)	Lenox Hill CrossTrainer (Seattle Systems)
Generation II 3DX	Bledsoe Ultimate
EBI® Alliance™	Townsend Rebel
DonJoy Defiance™	DonJoy 4titude™
BREG X2K	DonJoy Armor
Bledsoe Ultimate	BREG X2K
BREG FUSION™ XT (OTS)	BREG Women's X2K
	BREG FUSION XT

Table 1

All actuators on this mechanical surrogate were powered pneumatically. Each pneumatic circuit was controlled by a separate regulator with an integrated precision pressure gage. Muscle/ligament actuators and displacement actuators were controlled via separate manifolds to prevent lags or surges during testing. The cables on each muscle and ligament analog were connected in series with a tension force sensor (MLP-150, Transducer Techniques, Temecula, CA). Medial and lateral tibial plateaus were each instruments with a compression force sensor (LBO-500, Transducer Techniques, Temecula, CA). Actuators for both valgus displacement of the knee and foot as well as the actuator for anterior/posterior tibial displacement were instrumented with tension/compression force sensors (MLP-500, Transducer Techniques, Temecula, CA). Each of the force sensors was connected to an integrated signal conditioning and amplification module ((DP41-W-A, Omega Engineering, Stamford, CN). Anterior and posterior displacement of the tibia was measured using an LVDT (linear variable displacement transducer, LD-600- 50, Omega Engineering, Stamford, CN) which was interfaced with an integrated signal conditioning and amplification module (DP41-E-A, Omega Engineering, Stamford, CN). Both valgus displacement at the knee and foot were monitored using an RVDT (rotary variable displacement transducer, LX-PA-25, Unimeasure, Corvalis, OR) and each RVDT was also interfaced with an integrated signal conditioning and amplification module (Micro-p, Electro-Numerics, Temecula, CA).

Data from each of the signal conditioning and amplification units was retrieved in analog form via a data logging unit (Midi GL-400, Western Graphtec, Irvine, CA). This data was then acquired digitally via USB to a laptop computer for analysis. For each test condition, data for each sensor was acquired at a rate of 50 Hz for the duration of the test. For this investigation, an axial load of approximately 125 pounds was applied to the surrogate limb (weight of the cross-head and actuators). Tension loads to the muscle analogs was adjusted such that the limb maintained the chosen flexion angle. Tensile loads in the ligament analogs were arbitrarily chosen to provide moderate mechanical stiffness of the unbraced surrogate knee in all planes. Once selected, these same settings were used for all tests both braced and unbraced.

The unbraced condition was always tested first. Pneumatic pressures were first stabilized and the limb was subjected to five conditioning cycles without data acquisition. Data was then acquired for five subsequent displacements, insuring that pneumatic pressures and cable tension remained constant before each subsequent test. To insure that the knee analog returned to the "zero" or start point between valgus displacements of the knee, loads in the medial and lateral compartments were monitored and, if the knee analog did not return exactly to this position, it was reset to this zero position manually. For anterior displacements of the tibia, an anterior displacement force was applied, data was acquired, and then an equivalent posteriorly directed force was applied to reset the knee.

For braced testing, the unbraced limb was always tested first. A brace was then applied over a layer of cotton stockinette and the straps fastened in strict accordance with manufacturer instructions. A series of five "conditioning" displacements were then performed without data acquisition to allow the brace to seat on the limb. The brace straps were then re-fastened per manufacturer instructions and data was acquired on five subsequent tests, insuring a return to the zero or start position between tests. Initially, straps were fastened using a tensiometer, which quantified how much tension was applied to the straps before they were fastened. However, because of differences in brace design and strap location, this proved to be impractical. Subsequently, straps were tensioned to a level which was felt to be at the upper level of what a young athletic individual might tolerate.

For both anterior displacement and valgus displacement with the load applied at the knee and at the foot, a displacement force of 80 pounds (36.28 kg) was chosen. This was the maximum force which could be applied to the unbraced structure without either dislocation or mechanical disruption of meniscal analogs occurring. Anterior tibial translation was tested with the knee flexed 20 degrees and displacement forces were applied through a rigid link at the level of the tibial tubercle. [Figure 2] Valgus displacement with load applied at the knee was accomplished via the application of an 80 pound (36.28 kg) force applied directly on the lateral aspect of the brace with the knee in full extension. This test condition replicates an impact from an opposing player with the foot fixed. [Figure 3] In order to replicate the so-called "non-contact" injury in which a deceleration and directional change occurs with the foot fixed, a lateral displacement of the foot was produced by the application of an 80 pound (36.28 kg) force to the linear bearing representing the foot. [Figure 4] In this test, a rigid buttress at the upper cuff of the brace resists the tendency of the upper leg to translate medially. It is important to note that no axial rotation of the surrogate limb could occur during any of the valgus tests. Actual lateral displacement of the upper leg was characterized with an RVDT and this displacement (due to compressibility of the soft tissue analog) was subtracted from the total displacement measured at the foot.

All data was statistically analyzed using the Paired T-Test.

RESULTS

The results for valgus displacement test with the load applied at the knee are outlined in figures 5 and 6. For the tests of custom-made braces, all braces tested significantly reduced valgus displacement of the knee as compared to the unbraced knee. [Figure 5] Results are more variable for off-the-shelf braces. [Figure 6] The overall reduction of valgus displacement was substantially less for this category although, with four exceptions, most braces also significantly reduced valgus displacement of the knee relative to the unbraced condition. This difference in function is probably more a function of the material properties of the braces than of fit. Of note is that two of the off-the-shelf braces were substantially better than all other braces tested in this condition; the Armor and the FUSION XT.

The results for valgus displacement with the load applied at the foot are shown in figures 7 and 8. The presentation of the data for this category of testing is deceptive. While the differences between braced and unbraced conditions are not as strongly apparent for this category, it must be noted that all of the custom-made braces significantly reduced valgus displacement as compared to the unbraced knee [Figure 7] and, with only two exceptions, all of the off-the-shelf braces also significantly reduced valgus displacement relative to the unbraced condition. [Figure 8] A particular consideration for this test condition is that, while 80 pounds of force was applied at the foot, a torque or moment of 1120 inch/pounds was seen at the knee. This moment is well within the range of what would be considered a physiologic injury producing load in vivo. And, with two exceptions, all of the braces tested significantly reduced this displacement and increased the mechanical stiffness of the knee under this very high load.

Anterior displacement data is presented in figures 9 and 10. In this test condition, both the custom-made and off-the-shelf braces significantly reduced anterior displacement of the tibia as compared to the unbraced condition. Interestingly, when comparing the overall results, it would appear that the off-the-shelf braces actually provided slightly better resistance to anterior tibial translation suggesting that brace design rather than material properties may be the biggest contributor to function for this test condition.

DISCUSSION

As noted in the introduction, with the evolution of both surgical and rehabilitative technologies, the role of the functional knee brace has changed substantially over the last two decades. For conservative management of soft tissue injuries of the knee, functional knee braces continue to be used to provide mechanical stability to the knee and to increase the mechanical stiffness of the knee to permit the injured tissues to heal. Following surgical reconstruction of knee ligaments, functional braces are used primarily to protect the remodeling and healing soft tissues. This is a controversial issue within the orthopedic community with many surgeons contending that the reconstructive procedures have advanced to the point where post surgical protection is no longer required.[1] Increasingly these braces are also being widely employed in a purely prophylactic application in uninjured knees in football players. While there is abundant anecdotal evidence that this application is effective in reducing the number and/or severity of injuries there has been little recent research to validate this application.

In a predominantly prophylactic application, the primary role of the brace is to prevent or reduce a valgus moment or rotation of the knee in which the anterior cruciate ligament or ligament graft is impinged upon the lateral femoral condyle resulting in failure or stretching of the graft or ligament. The data presented here indicate that all of the braces tested provide substantial and, in most cases, a significant reduction in this valgus moment when loads are applied at the knee. While less pronounced, the same trend is noted when a valgus moment is generated at the knee by laterally displacing the foot, simulating the so-called non-contact injury. Again, the majority of braces tested provided a significant reduction in this valgus moment. For testing of anterior tibial translation, all of the braces in this investigation demonstrated a significant reduction in anterior tibial translation as compared with the unbraced construct.

Caution should be exercised when drawing direct corollaries with the potential in vivo performance of these braces as the test model used in this investigation is a mechanical surrogate that does not replicate the normal brace/limb composite interface and does not account for the normal dynamic responses of the athlete. However, these investigators would conclude that, based on this data set, the majority of the braces tested would provide increased mechanical stiffness to the knee for both valgus moments and anterior tibial translation in vivo. This response would be variable and would be based not only on the design and material properties of individual braces but also on the compliance of the composite structure formed when a brace is applied to the limb. This increased mechanical stiffness could contribute to the prevention or reduction of the severity of injuries resulting from valgus moments generated at the knee as well as anterior shearing forces imposed on the knee. This increased mechanical stiffness should also provide protection to remodeling soft tissues in the reconstructed knee.

What this investigation did not address are the subjective intangibles of functional knee bracing. Factors such as comfort, fit, migration and effect on performance will ultimately determine both patient compliance and satisfaction. These issues are being addressed in separate investigations.

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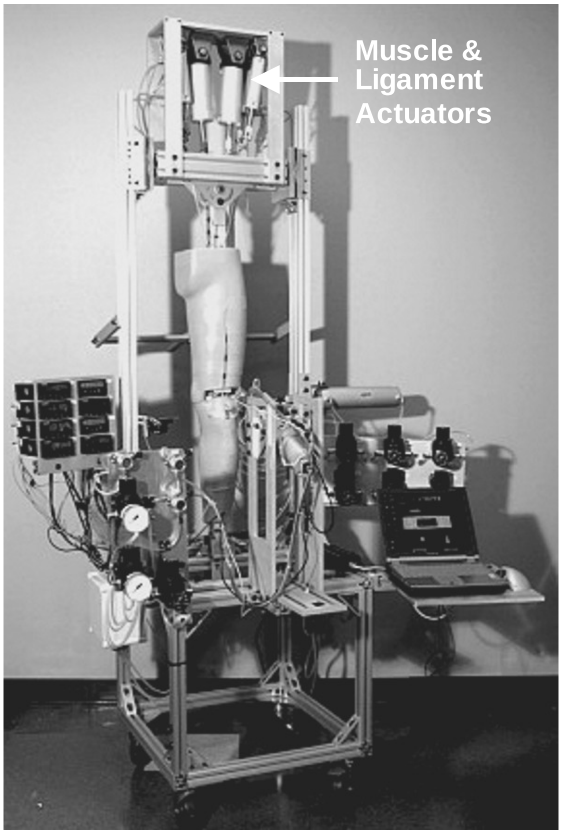

Figure 1

Figure 2

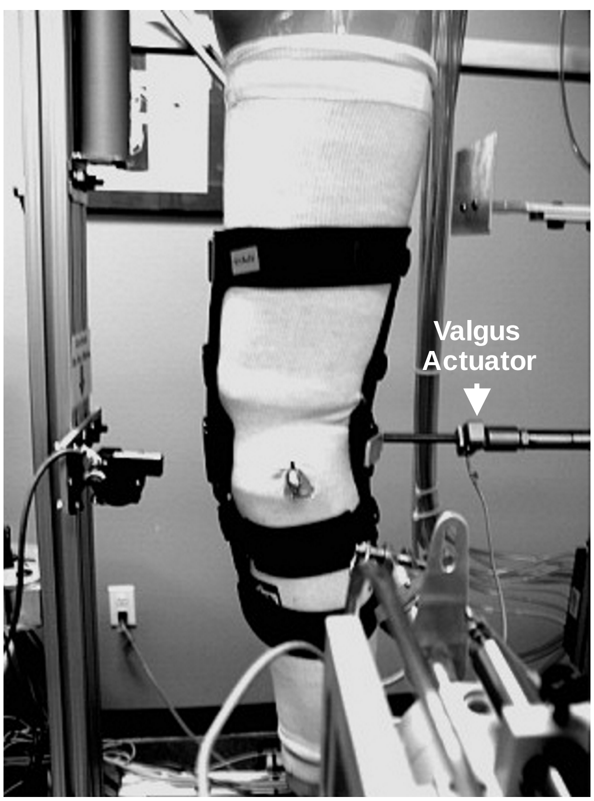

Figure 3

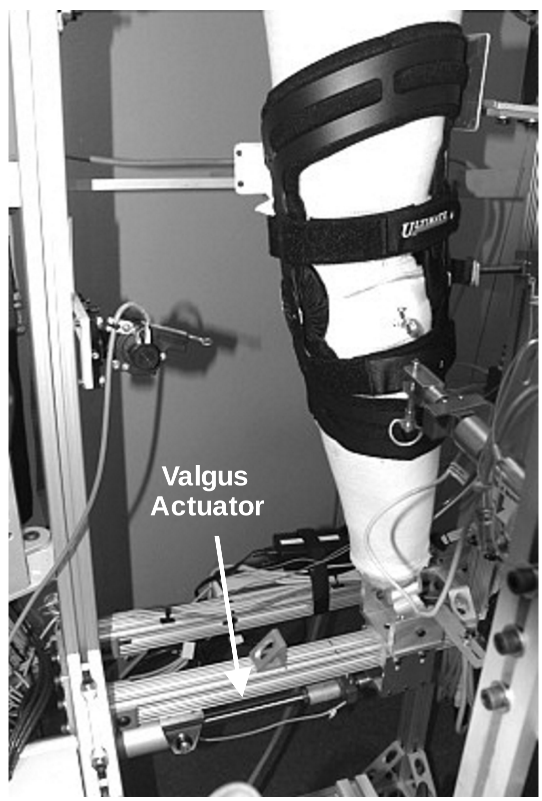

Figure 4

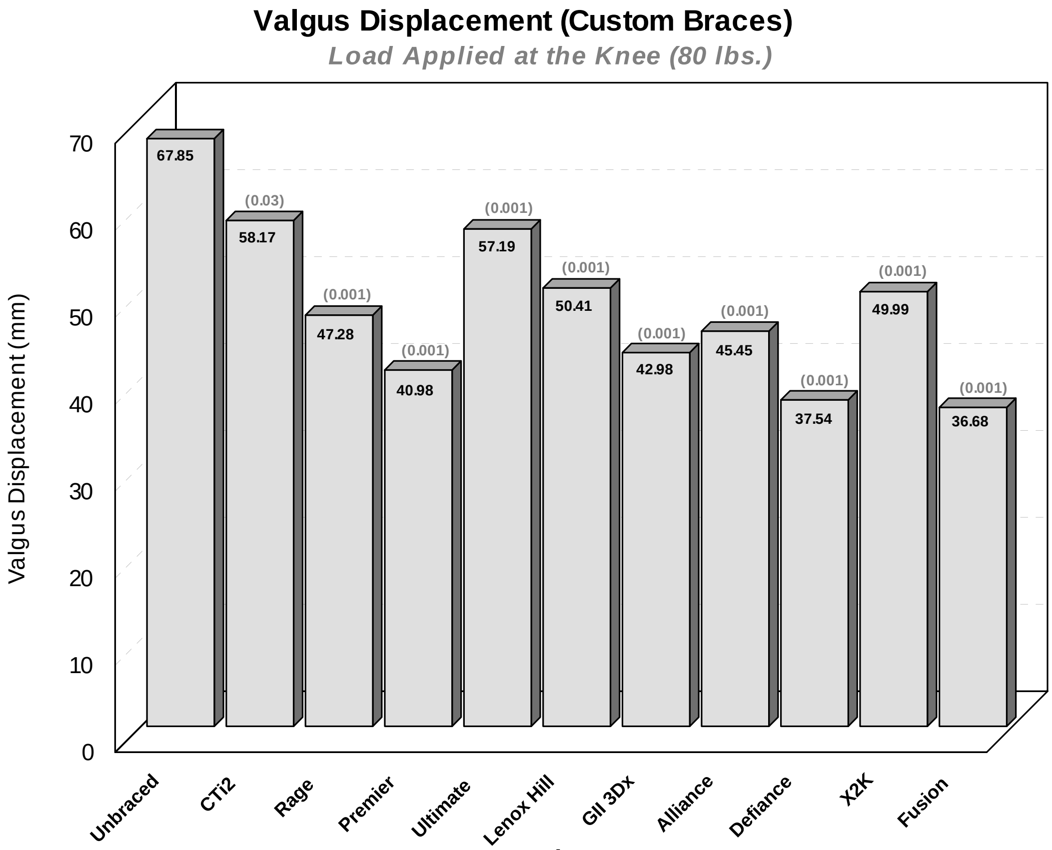

Figure 5

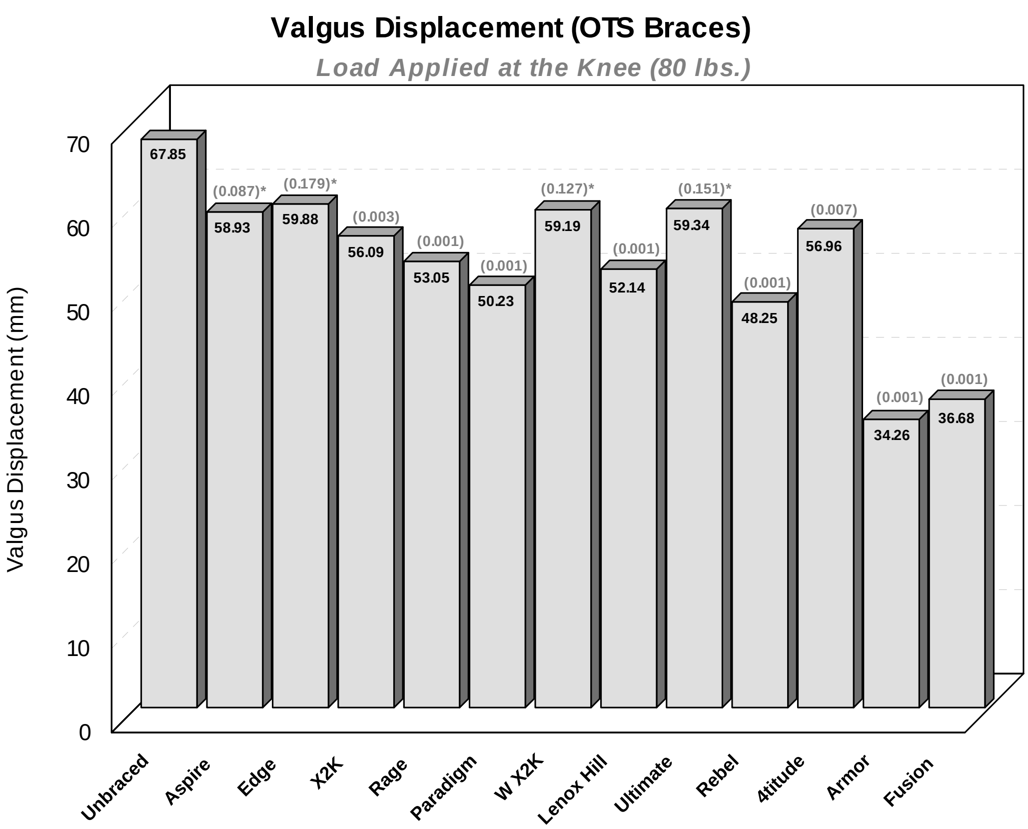

Figure 6

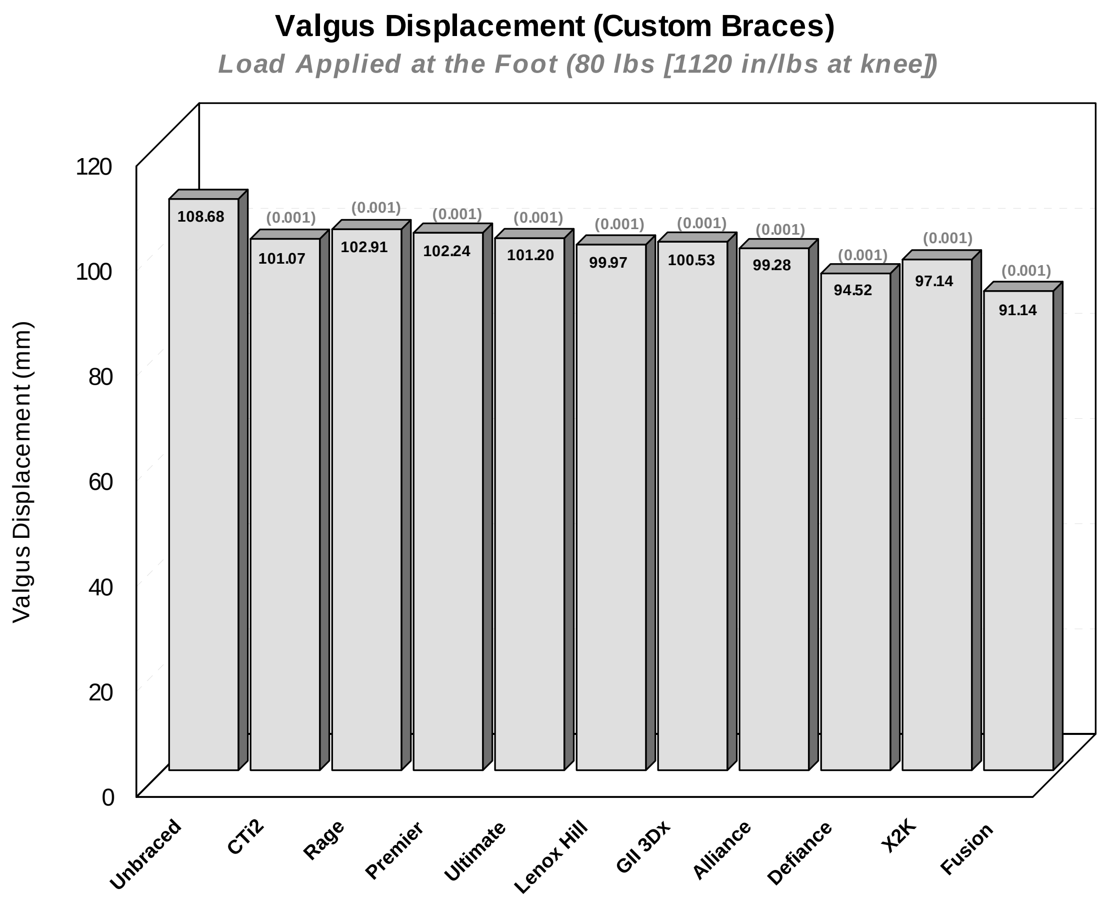

Figure 7

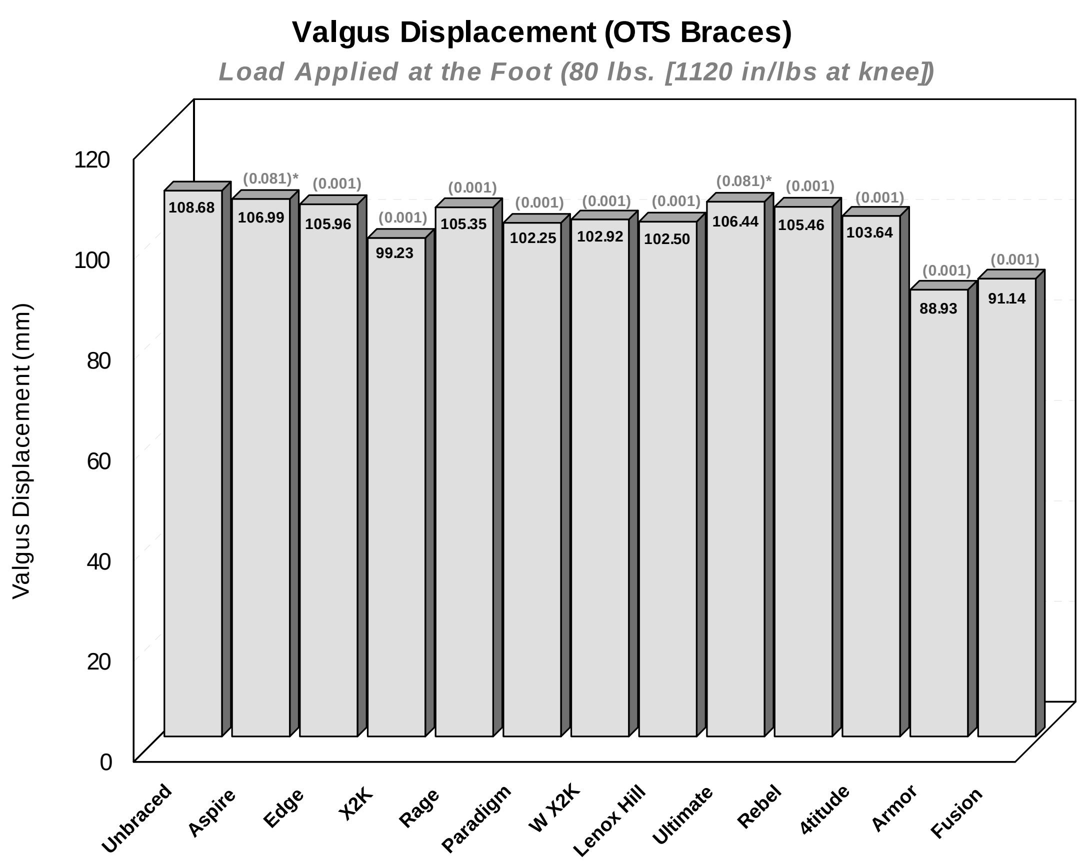

Figure 8

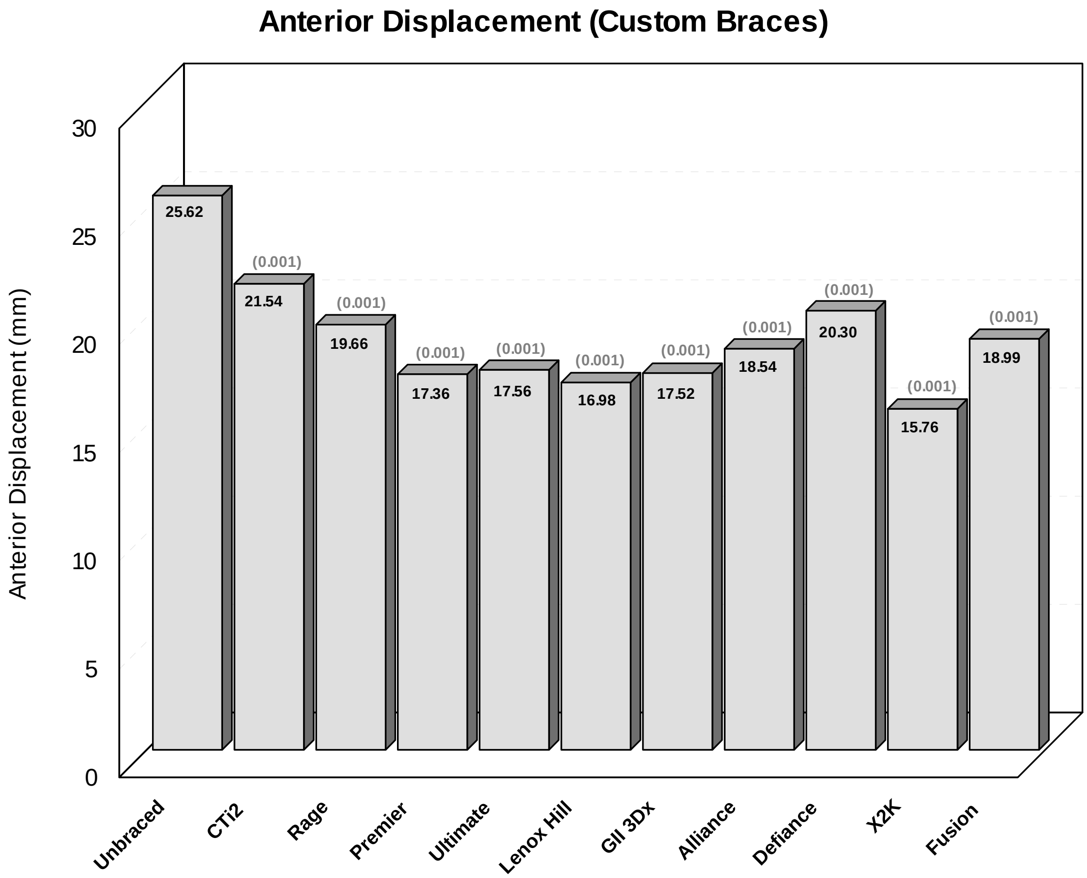

Figure 9

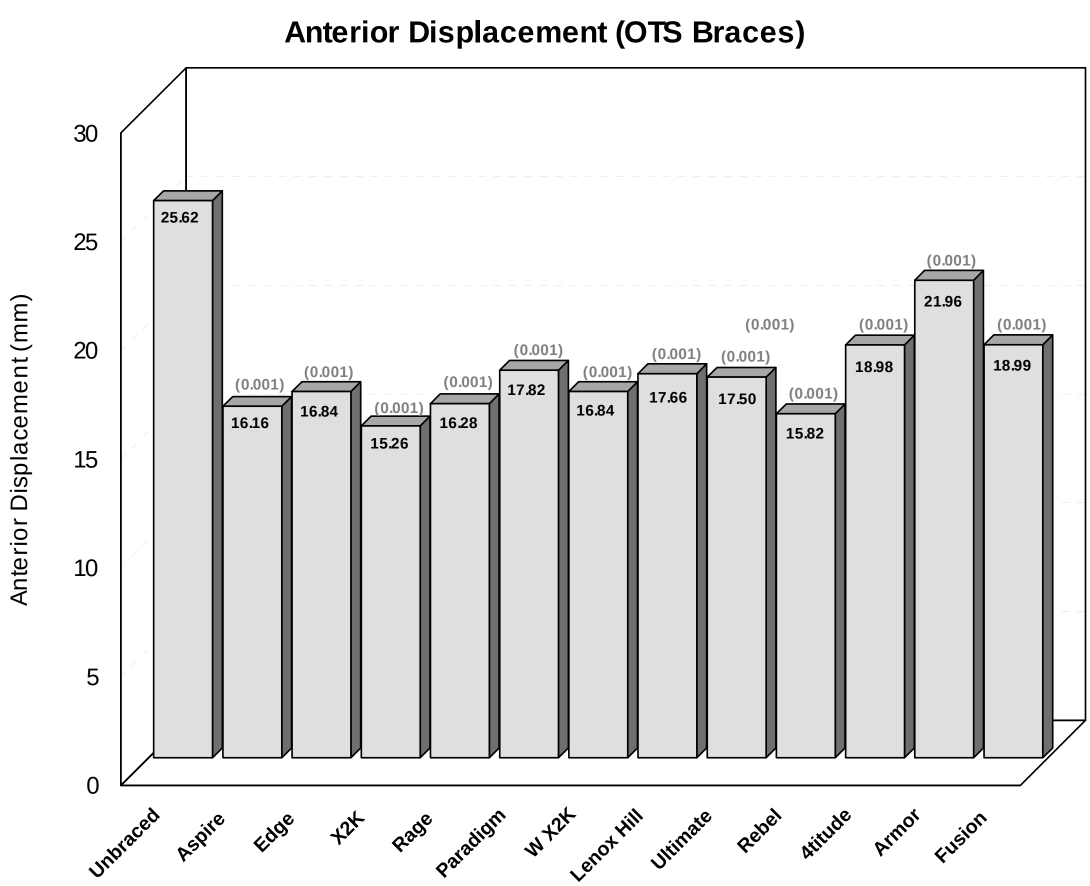

Figure 10