VIRTUAL GEOMETRIC CONSTRAINT OF TOTAL KNEE ARTHROPLASTY DESIGNS: *ADDRESSING PATIENT NEEDS*

Orthopaedic Research Laboratories
Cleveland, Ohio

Edward A. Morra, M.S.M.E
Alon Katz, M.Sc.
Christine S. Heim, B.Sc.
A. Seth Greenwald, D.Phil.(Oxon)

INTRODUCTION

Restoration of normal knee joint function through surgical reconstruction is dependent upon load sharing between the implant and surrounding ligamentous and other supporting structures. Pathological weakening or surgical excision of these structures imposes an increased dependency upon the implant for stability. In this context, functional stability is defined as the ability of femoral and tibial component geometry, acting in concert with surrounding soft tissues, to limit anterior-posterior (A-P), medial-lateral (M-L) and internal-external (I-E) motion within normal physiologic limits.

To assist implant selection for addressing various patient needs to maintain a stable knee joint, the U.S. Food and Drug Administration (FDA) pre-clinical assessment for total knee arthroplasty (TKA) designs[1] requires evidence of expected tibial-femoral interface constraint. The American Society for Testing and Materials (ASTM) suggests that this testing be performed in accordance with ASTM F1223-08, "Standard Test Methods for Determination of Total Knee Replacement Constraint"[2,3]. While this document appears as a straightforward physical/mechanical test, it is increasingly difficult to perform due to the large number of predicate devices needed for comparison to new designs, resulting in a resource-demanding evaluation.

A modern, virtual alternative to the physical ASTM F1223-08 test was developed to determine the geometric constraints of four contemporary TKA designs, representing three styles of constraint. Cruciate retaining designs Duracon (Howmedica) and Triathlon (Stryker Orthopedics), medial pivot design Saiph (MatOrtho Ltd.), and Vanguard posterior stabilized design (Biomet Orthopedics) are all fixed plateau and cleared for clinical use in the United States.

METHODS

A virtual version of the physical ASTM F1223-08 testing standard was developed using ADAMS (MSC Software Corporation). The software allows general contact between Computer Aided Design (CAD) geometries of arbitrary shape. Such files were obtained for the left knee of each TKA design studied, with sizing selected to represent a nominal North American population.

A virtual testing environment was built and calibrated to match a physical testing environment. The femoral component was rotated to a flexion angle of interest, compressed together and allowed to settle into its neutral alignment (Figure 1). The tibial insert was then propelled beneath it in the direction of interest (A-P, M-L and I-E) and the force required to do so was recorded.

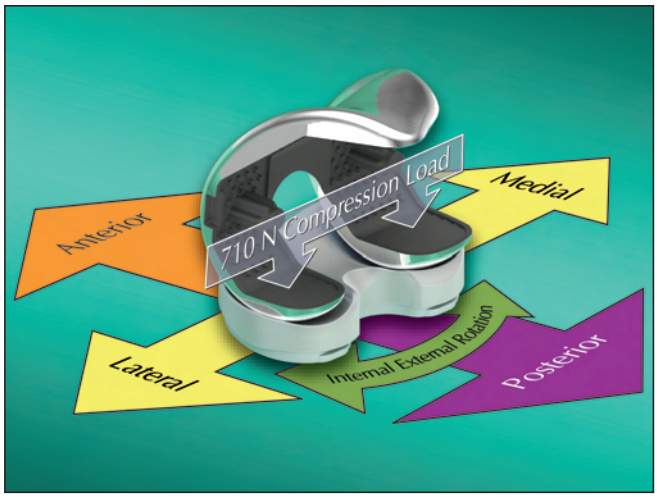

Figure 1: The virtual testing environment where Anterior-Posterior translation, Medial-Lateral translation and Internal-External rotation were simulated under a 710N compressive load for a left knee TKA design.

COMPUTATIONAL MODELING

Surgical Alignment

The tibial insert and femoral components for each design were imported into a SolidWorks (Dassault Systèmes SolidWorks Corporation) CAD modeling environment and arranged into an assembly representing the respective, prescribed surgical procedure. The surgically arranged components were then transferred into the virtual testing environment presented in Figure 1.

Determination of the Final Neutral Position

When determining the neutral position at each flexion angle of interest, the tibial insert was fully fixed (locked) while motions were applied to the femoral component. A constant compressive load of 710N was applied to the femoral component in the inferior direction, allowing full contact to develop with the tibial insert. Three steps were required to determine the final neutral position; a natural settling of the femoral component onto the tibial insert, an initial exploration of the extents of constraint when more than one preferred alignment was possible, and selecting the middle position between the extents of constraint to determine the final neutral position.

Virtual Constraint Testing

The resulting final neutral-aligned component positions, loaded at a constant 710N of compression, were the starting points for the subsequent A-P, M-L and I-E constraint tests. For each flexion angle of interest the femoral component was fixed during testing, except for the Varus-Valgus (V-V) and Superior-Inferior (S-I) directions which could move freely. For the A-P and M-L constraint tests, the position of the tibial insert component was driven along the axis of the test with all other directions fixed. For the I-E rotation constraint test, the tibial insert was allowed to translate in the A-P and M-L directions while rotation was driven. This allowed the axis of I-E rotation to move freely to its preferred location during testing, an important consideration in total knee designs with asymmetrical geometries.[4] The table below summarizes the constraints of both the femoral and tibial insert components during the three constraint tests.

	Femoral Component Constraint						**Tibial Insert Component Constraint**					
Testing Condition	FLX	V-V	I-E	A-P	M-L	S-I	FLX	V-V	I-E	A-P	M-L	S-I
Anterior-Posterior Translation	L	F	L	L	L	F	L	L	L	D	L	L
Medial-Lateral Translation	L	F	L	L	L	F	L	L	L	L	D	L
Internal-External Rotation	L	F	L	L	L	F	L	L	D	F	F	L

Component constraints during virtual ASTM F1223-08 testing are prescribed for the three rotations of flexion (FLX), varus-valgus (V-V), internal-external (I-E) and three translations of anterior-posterior (A-P), medial-lateral (M-L) and superior-inferior (S-I). Depending on the testing conditions, these degrees of freedom are either locked (L), able to move freely (F), or driven (D).

According to ASTM F1223-08, the extent of motion for each test should be bounded by one of the following: a mechanical stop, dislocation of the components, or if a dangerous or unrealistic situation may occur. The extents of testing were selected beyond the clinically relevant constraint of the device, but before full component dislocation, assuring that all relevant data was captured. If a mechanical stop was encountered, it was noted in the results.

RESULTS

Animations of the full complement of testing results for A-P, M-L and I-E motions at multiple flexion angles of interest for each design were generated. For brevity, only the results of the A-P test performed at 90° of knee flexion are presented here in a distilled graphical format in Figure 2. This result was selected for presentation due to its similarity to the clinically familiar A-P drawer test.

For each design, the photorealistic rendering of the gray tibial insert represents the starting point of the A-P test. The sulcus reference points of each compartment are marked with a small gray circle and connected by a black horizontal line to the zero mark of a millimeter scale, indicating the starting position. The orange representation of the tibial insert indicates the amount of force and the distance traveled before component dislocation occurs as it is pulled in the anterior direction. Conversely, the purple representation of the tibial insert indicates the force and distance traveled in the posterior direction prior to dislocation, or in the case of the Vanguard PS design, the mechanical stop provided by the tibial insert post and femoral cam mechanism, indicated by the graphical purple block. Designs are presented in alphabetical order.

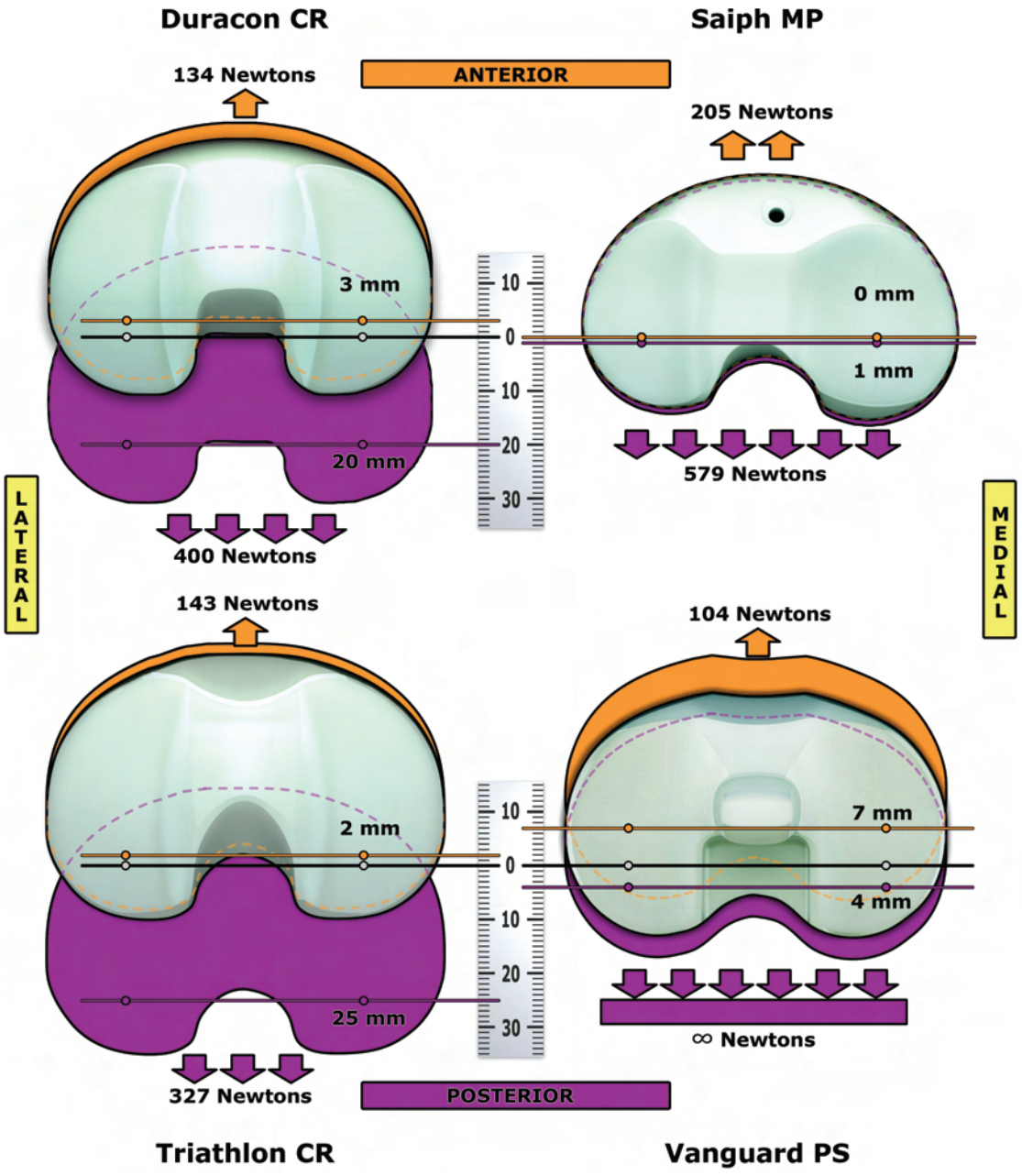

Figure 2: The results of the Anterior-Posterior test performed at 90° of knee flexion are presented here in a distilled graphical format.

DISCUSSION

For the A-P test at 90° of knee flexion, the cruciate retaining designs, Duracon and Triathlon, allow the largest amount of excursion, due to their relatively flat tibial insert geometry. The Vanguard PS constrains motion between the tibial insert post and femoral cam mechanism when the insert is pulled posteriorly and the posterior lip of the tibial insert when pulled anteriorly. The Saiph medial pivot design greatly constrains the A-P motion by employing a ball and socket like geometry in the medial compartment. The F1223-08 test prescribes that I-E rotation of the insert should be constrained, so the entire insert A-P motion is effectively constrained by the medial compartment geometries. These data assist implant selection for addressing various patient needs to maintain a stable knee joint and reduce mid-flexion A-P instability as reported in the clinical literature.[5]

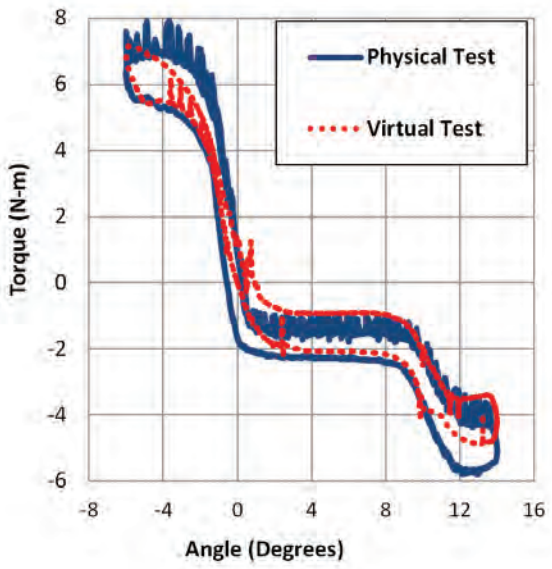

Figure 3: Comparison of virtual and physical ASTM F1223-08 testing results during internal-external rotation.

VALIDATION

A comparison between a physical constraint test and a virtual constraint test was needed to anchor the virtual testing model to a physical reality. A physical tibiofemoral I-E rotational constraint test was performed using a closed loop, servohydraulic, axial/torsional materials testing system (MTS Systems Corporation) that generated torque versus angulation data during several cycles of motion. The components were loaded to 710N of compression and lubricated with distilled water at room temperature during the test. A virtual model of the same test was created using ADAMS software and the torque versus angulation data was overlaid on the physical results for comparison. Virtual model parameters including component contact and friction were adjusted until a closer match was obtained between the numerical simulation and the physical test results (Figure 3).

CONCLUSION

The virtual test method described is able to discern differences in performance between TKA designs, is faster and less expensive than physical methods, solves the contemporary problem of obtaining predicate designs for comparison and has been accepted by the FDA[6].

Clinical longevity of knee arthroplasty is enhanced by attaining the correct balance between the intrinsic stability provided by plateau geometry and the presenting soft tissue structures. Patient selection, surgical proficiency and implant design are the three factors that shape clinical outcome. This evaluation assists the selection of the appropriate geometric constraint to assure a stable knee joint reconstruction.

REFERENCES

1. Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA. 2003:3.
2. ASTM. F 2083 - 11; Standard Specification for Total Knee Prosthesis.
3. ASTM. F 1223 - 08; Standard Test Method for Determination of Total Knee Replacement Constraint.
4. Haider H, Walker PS. Measurements of Constraint of Total Knee Replacement. J Biomech. 2005;38:341–348.
5. Dennis DA, Komistek RD, Colwell CE, et al. In Vivo Anteroposterior Femorotibial Translation of Total Knee Arthroplasty: A Multicenter Analysis. Clin Orthop Relat Res. 1998;356:47–57.
6. FDA 510K approval letter. http://www.accessdata.fda.gov/cdrh_docs/pdf14/k140222.pdf accessed on February 23, 2015.

2310 Superior Avenue East
Cleveland, Ohio