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Contact Stress Evaluation for the K1 Unicompartmental Knee Replacement Design: A Finite Element Study

Report submitted to BodyCAD on July 29, 2015
by:

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> *The K1 unicompartmental knee design was submitted by BodyCAD to the Orthopaedic Research Laboratories (ORL) for confidential evaluation as a Category A (private) device. The results presented in this report will not be released into the public domain by ORL or BodyCAD without written approval of the other party.*

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ABSTRACT

The computational finite element method was utilized to determine the magnitude and location of contact stresses on the polymer tibial insert bearing surface for a medium and small size BodyCAD K1 medial unicompartmental design. The methods and results of the study are discussed in detail, and a graphical comparative analysis with a clinically successful predicate unicompartmental design is made. Physical contact stress results are compared to computational stress results to validate the finite element model. Test results indicate that the computational model is valid and that both medium and small K1 unicompartmental designs consistently have lower peak contact stresses and more favorable stress distributions than the predicate design.

INTRODUCTION

There is an interest in the use of unicompartmental knee replacement (**Figure 1**) as a remedy of choice for isolated compartment disease. The popularization of mini-incision surgery with claims of reduced pain, shorter hospitalization, more rapid rehabilitation, more normal knee function and decreased cost are positive arguments for the procedure.

The durability of ultra high molecular weight polyethylene (UHMWPE) tibial insert bearing surfaces is considered a factor limiting the clinical longevity of unicompartmental knee arthroplasty[1,2]. Polyethylene abrasion and burnishing observed in component retrievals are the result of high cycle loads that act on the UHWMPE tibial insert during activities of daily living. These damage modes contribute to wear debris generation, the initial step in the sequence leading to osteolysis[3,4,5].

Many researchers[6,7,8] have linked specific states of stress that arise when a femoral component articulates with a tibial insert to damage modes observed in UHMWPE. Abrasive wear is related to the magnitude and distribution of compressive normal (contact) stresses on the surface of the tibial insert. Several methods of determining stresses in knee designs have been used in the past, including experimental and computational approaches.

Experimental methods to measure surface contact stresses include interposing Fuji pressure sensitive film between components[9]. This approach has the advantage of measuring actual geometries, but has the disadvantage of not being able to measure highly conforming articulations before film crinkling occurs. Fuji film experiments also cannot be done with components at body temperature.

Computational finite element models have the ability to determine surface and subsurface stresses for flat or highly conforming contact geometries and can employ material models using polymer data gathered at body temperature[10].

Figure 1 - An example of a generic unicompartmental knee replacement for the medial compartment of the left knee.

MATERIALS

Three-dimensional Computer Aided Design (CAD) geometry files, inclusive of a tibial insert and femoral components for a left knee, were provided by BodyCAD (Quebec City, Canada) for the K1 medial unicompartmental design in two sizes, medium and small. CAD files for a small sized predicate unicompartmental knee design, ZUK, a Zimmer product (Warsaw, IN USA) were also provided for predicate comparison. All CAD files were built from "cloud of points" measurements of manufactured components, utilizing blue light scanner data gathered by an ATOS II Triple Scan Rev.02 system (GOM mbH, Braunschweig, Germany) in BodyCAD's lab.

METHODS

A three-dimensional, non-linear, finite element model was created of each design submitted using MARC (MSC Software Corporation, Newport Beach, California USA). CAD geometries representing the "as manufactured" tibial insert and femoral components were imported into a baseline finite element model to simulate a successful surgery. A sophisticated non-linear Ogden material model of UHMWPE at body temperature of 37^{o} Celsius was assigned to the tibial insert to accurately calculate stress. Six load cases were created for investigation, each representing the most highly loaded portion of a walking gait or high flexion activity cycle. Values for total joint loads were determined via a literature search, and 60% of the compressive total joint loads[11] were applied to the medial compartment. Six instances of the femoral component were also created, each corresponding to the appropriate degree of knee flexion for each load case.

A specific load case in the baseline model was selected for analysis, activating only the appropriately flexed femoral component and incrementally applying the selected compressive load. Contact developed between the components until the full amount of force was applied and the femoral component settled into its preferred alignment without friction. Contact area and stress associated with polymer surface burnishing and abrasion (compressive normal stress) was calculated and the magnitudes and locations imaged photorealistically. The details of the finite element modeling process are described in **Appendix A - Finite Element Methods**. The above methods were repeated for the ZUK predicate device, with the exception that the femoral component was posed near the middle of the tibial insert without frictionless settling, due to the very flat tibial insert geometry that lacked a discernible sulcus point to settle into.

The validity of the finite element model for calculating stress was established by comparing physical measures of contact area and stress using a pressure sensitive Fuji film technique. Comparison to the computational results of the finite element model under the same loading conditions for heel strike and chair rise activities are found in **Appendix B - Validation Results**.

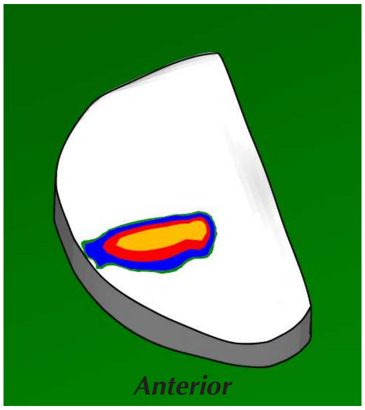
RESULTS

The resulting images of the contact stresses on the proximal surface of the tibial insert on the following two pages are appreciated from a superior, anterior view of the medial compartment of the left knee. Contact stress images give an indication of areas where surface abrasion caused by contact with the femoral component would occur. The higher the contact stresses, the greater the propensity for abrasive damage. In all load cases investigated the BodyCAD K1 Unicompartmental designs exhibit larger contact areas and lower peak stresses than the clinically successful predicate design ZUK.

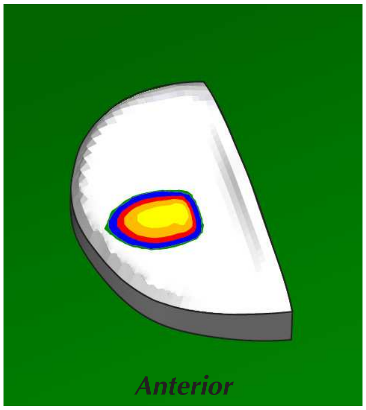
Left Knee Medial Unicompartmental Contact Stress

K1 - Medium Size | **K1 - Small Size** | **ZUK - Small Size**

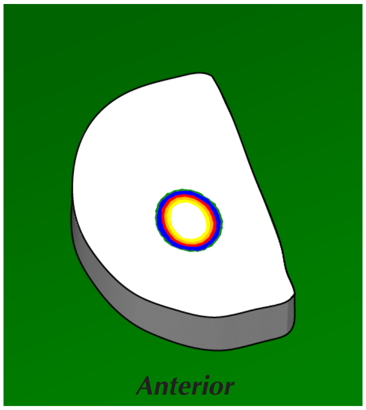
Activity: Heel Strike, Knee Flexion Angle: 0 deg, Applied Compressive Force: 1,170 N



Contact Area: 129 mm²
Peak Contact Stress: 20.3 MPa

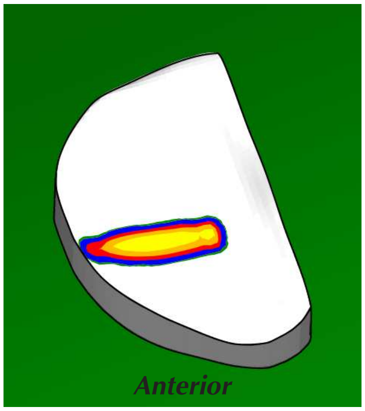


Contact Area: 100 mm²
Peak Contact Stress: 24.8 MPa

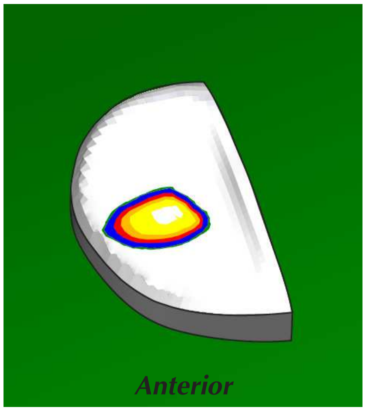


Contact Area: 73 mm²
Peak Contact Stress: 35.4 MPa

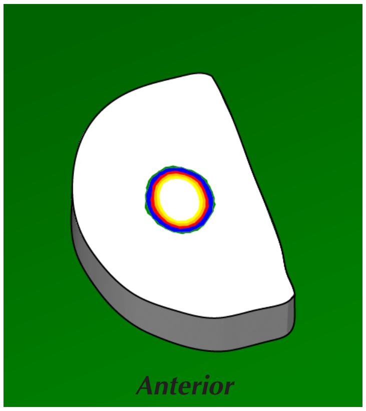
Activity: Toe Off, Knee Flexion Angle: 15 deg, Applied Compressive Force: 1,404 N



Contact Area: 119 mm²
Peak Contact Stress: 24.1 MPa

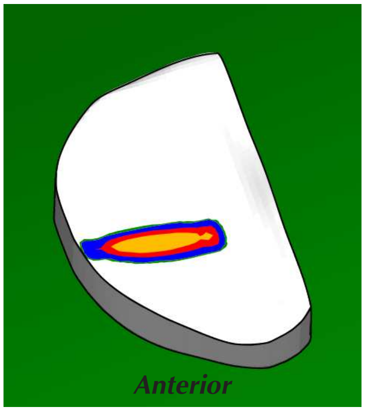


Contact Area: 104 mm²
Peak Contact Stress: 27.4 MPa

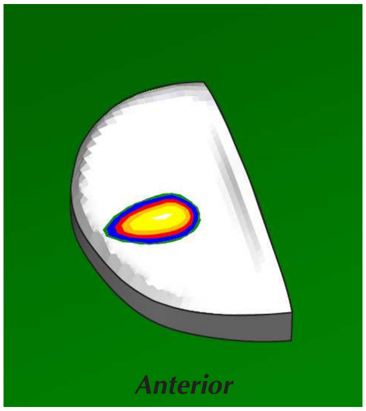


Contact Area: 80 mm²
Peak Contact Stress: 39.9 MPa

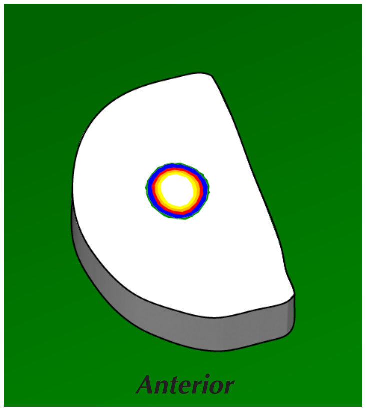
Activity: Mid Stance, Knee Flexion Angle: 20 deg, Applied Compressive Force: 936 N



Contact Area: 102 mm²
Peak Contact Stress: 19.1 MPa



Contact Area: 78 mm²
Peak Contact Stress: 26.8 MPa

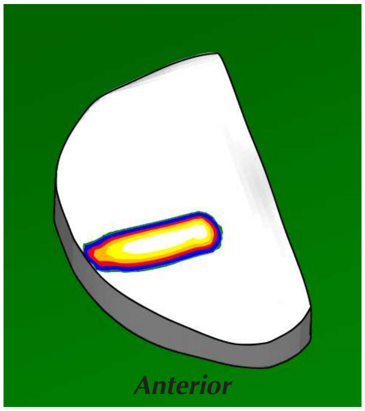


Contact Area: 61 mm²
Peak Contact Stress: 35.6 MPa

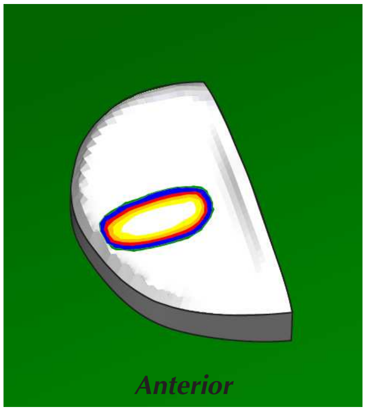
Left Knee Medial Unicompartmental Contact Stress

K1 - Medium Size **K1 - Small Size** **ZUK - Small Size**

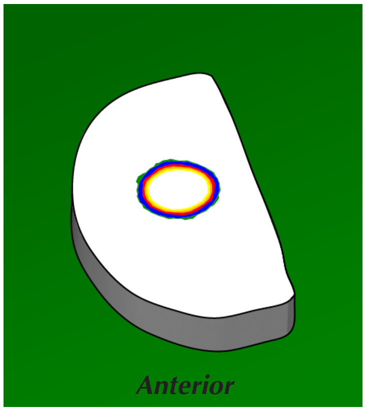
Activity: Stair Descent, Knee Flexion Angle: 60 deg, Applied Compressive Force: 1,818 N



Contact Area: 123 mm^2
Peak Contact Stress: 30.3 MPa

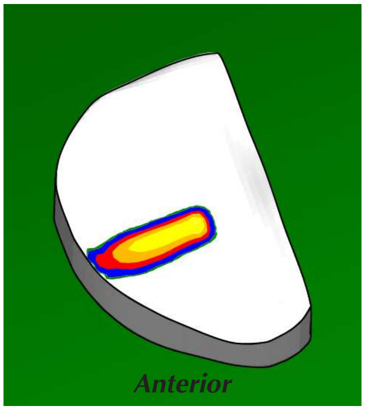


Contact Area: 115 mm^2
Peak Contact Stress: 33.4 MPa

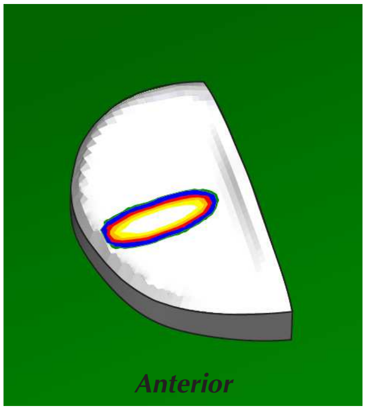


Contact Area: 85 mm^2
Peak Contact Stress: 54.2 MPa

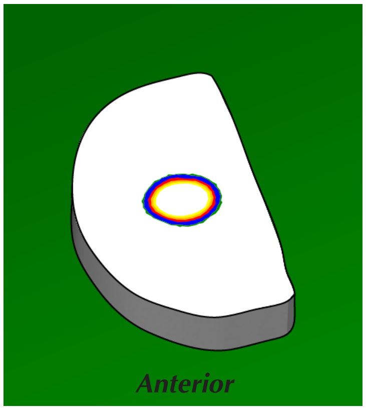
Activity: Chair Rise, Knee Flexion Angle: 90 deg, Applied Compressive Force: 1,368 N



Contact Area: 118 mm^2
Peak Contact Stress: 26.5 MPa

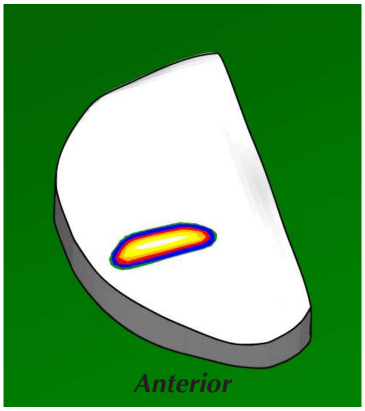


Contact Area: 93 mm^2
Peak Contact Stress: 34.5 MPa



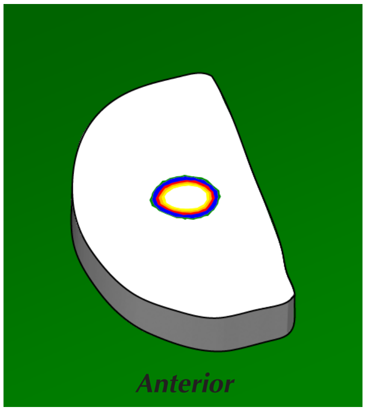
Contact Area: 72 mm^2
Peak Contact Stress: 46.4 MPa

Activity: Kneel Rise, Knee Flexion Angle: 120 deg, Applied Compressive Force: 840 N



Contact Area: 69 mm^2
Peak Contact Stress: 29.3 MPa

Contact Area: 75 mm^2
Peak Contact Stress: 26.2 MPa



Contact Area: 51 mm^2
Peak Contact Stress: 44.4 MPa

RESULTS (continued)

The validation tests documented in **Appendix B - Validation Results** were performed with heel strike and chair rise load case conditions for both the medium and small sized K1 designs for a total of four validation comparisons. Peak stresses matched very closely in three of the four tests conducted. The finite element method predicted higher peak stresses in the most highly loaded case of chair rise for the small K1 design. Measurements of contact area are sensitive to differences in component positioning and may slightly account for some of the differences seen between the physical and computational methods. Contact areas predicted by the finite element model were larger than Fuji film in all cases, and may be attributed to the softer material response expected from UHMWPE at body temperature.

DISCUSSION

This study attempts to closely simulate conditions found in an implanted tibial insert during daily patient habitus using methodology employed consistently over the last two decades to objectively evaluate and compare total and unicompartmental knee arthroplasty designs[12,13]. Toward that goal, a complex material model of UHMWPE at physiological temperatures was used, and the applied loading conditions simulated the most highly loaded portions of activities of daily living. Design features, which are known to affect stress magnitudes and distributions; inclusive of polymer thickness and UHMWPE material response, were modeled for each design in the same manner. By holding these aspects of the design constant, the role that articular surface geometry plays in the development of damaging stresses acting on the tibial insert was isolated.

The ZUK results are an example of the effect of a rounded femoral component articulating with a nearly flat tibial insert. These results are similar to classic total knee designs such as the Duracon and NexGen that were evaluated using a similar testing protocol[12]. Contact stresses are very high for the ZUK design in all load cases investigated. Contact stresses for both K1 designs are lower than the ZUK but also relatively high during the demanding activities of stair descent, and the smaller K1 design during chair rise. Both the medium and small sized K1 results are indicative of a medium conforming design, where the femoral curvature meets a tibial insert that offers a geometry with a sulcus point to settle into[14]. This generally increases the opportunity for congruity, increasing contact areas and lowering contact stresses.

CONCLUSION

When comparing the small sized K1 and ZUK designs, the K1 exhibits larger contact areas and lower peak stresses than the clinically successful predicate design ZUK in all loading cases investigated. In general, the medium sized K1 further improves with larger contact areas and lower stresses than its smaller K1 counterpart.

Overall, the multi-flexion walking gait and high flexion results from this study suggest a hypothetical long-term retrieval for the small size K1 unicompartmental knee would present with less surface damage and a lower volume of wear debris than a small sized ZUK predicate design.

REFERENCES

1. Collier, J. P., Mayor, M. B., McNamara, J. L., Surprenant, V. A., Jensen, R. E., "Analysis of the Failure of 122 Polyethylene Inserts from Uncemented Tibial Knee Components", Clinical Orthopaedics and Related Research, 273 pp 232-242, 1991.

2. Landy, M. M, Walker, P. S., "Wear of Ultra-high-molecular-weight Polyethylene Components of 90 Retrieved Knee Prostheses", Journal of Arthroplasty, 3 pp S73-S85, 1988.

3. Dannenmaier, W. C., Haynes, D. W., Nelson, C.L., "Granulomatous Reaction and Cystic Bony Destruction Associated with High Wear Rate in a Total Knee Prosthesis", Clinical Orthopaedics and Related Research, 198 pp 224-230, 1985.

4. Goodman, S. B., Chin, R. C., Chiou, S. S., Schurman, D. J., Woolson, S. T., Masada, M. P., "A Clinical-Pathologic-Biochemical Study of the Membrane Surrounding Loosened and Nonloosened Total Hip Arthroplasties", Clinical Orthopaedics and Related Research, 244 pp 182-187, 1989.

5. Willert, H. G., Bertram, H., Buchhorn, G. H., "Osteolysis in Alloarthroplasty of the Hip: The Role of Ultra-High Molecular Weight Polyethylene Wear Particles", Clinical Orthopaedics and Related Research, 258 pp 95-107, 1990.

6. Bartel, D. L., Bicknell, M. S., Wright, T. M., "The Effect of Conformity, Thickness, and Material on Stresses in UHMWPE Components for Total Joint Replacement", The Journal of Bone and Joint Surgery, 68A:7 pp 1041-1051, 1986.

7. Rose, R. M., Goldfarb, H. V., "On the Pressure Dependence of the Wear of Ultrahigh Molecular Weight Polyethylene", Wear, 92 pp 99-111, 1983.

8. Rostoker, W., Galante, J. O., "Contact Pressure Dependence of Wear Rates of Ultra High Molecular Weight Polyethylene", Journal of Biomedical Materials Research, 13 pp 957-964, 1979.

9. Heim C. S., Postak P. D., Greenwald A. S., "Factors Influencing the Longevity of UHMWPE Tibial Components", Instructional Course Lectures, American Academy of Orthopaedic Surgeons, 45:34 pp 303-312, 1996.

10. Anderson, D. D., Rullkoetter, P. J., Hillberry, B. M., "Viscoelastic Response of UHMWPE in Finite Element Analysis of TKR Components", Transactions of the Orthopaedic Research Society, 20:2 p 762, 1995.

11. Daley, R. E., "Measurement of the Distribution of Forces at the Human Knee Joint", Ohio State University Ph.D. Thesis 75-19, 426, 1975.

12. Morra, E. A., Postak, P. D., Greenwald, A. S., "The Effects of Articular Geometry on Delamination and Pitting of UHMWPE Tibial Inserts: A Finite Element Study", Orthopaedic Transactions, 20:66, 1996.

13. Morra EA, Heim CS, Greenwald AS. "Preclinical Computational Models: Predictors of Tibial Insert Damage Patterns in Total Knee Arthroplasty", J. Bone Joint Surg. Am. 2012; 94:e137(1–5).

14. Morra EA and Greenwald AS "The Effects of Walking Gait on UHMWPE Damage in Unicompartmental Knee Systems: A Finite Element Study.", J Bone Joint Surg [Am] 85(Suppl. 4):111-114, 2003.

Appendix A - Finite Element Methods

MOTIVATION

Historically, stresses in a material are determined in order to predict where a material failure may occur. When evaluating stress in knee arthroplasty polymer components, computational finite element models have several unique features; including the ability to evaluate highly conforming articulations, determine surface and sub surface stresses, use material models that capture the experimentally observed nonlinear behavior of ultrahigh molecular weight polyethylene (UHMWPE) at body temperature, and are sensitive enough to detect small differences between "as designed" component geometries and measured "as manufactured" ones.

The three dimensional, finite element model in this study utilizes these advantages to offer fair comparison between different knee arthroplasty designs. Physical measurements of actual articulating surface geometries are used to build a computational model that can determine complex stresses that arise in the UHMWPE tibial insert during activities of daily living.

MATERIALS

Three-dimensional Computer Aided Design (CAD) geometry files, inclusive of a tibial insert and femoral components for a left knee, were built from "cloud of points" measurements of manufactured components, utilizing blue light scanner data gathered by an ATOS II Triple Scan Rev.02 system (GOM mbH, Braunschweig, Germany) in BodyCAD's lab. Scanner validation experiments demonstrated an accuracy of 1.5 micrometers and repeatability of 0.1 micrometer.

Subsequent surface fitting of a slightly relaxed non-uniform rational basis spline (NURBS) surface was performed through the cloud of points. Quality test indicated the surface passed within plus or minus 7 micrometers or less of the measured point cloud data, about nine times more precise than manufacturing tolerances. This ensured that a very accurate "as manufactured" CAD file representation of each design was captured using this method. BodyCAD provided an assembly CAD file with the tibial insert and multiple femoral components posed in various degrees of knee flexion (0, 15, 20, 60, 90 and 120 degrees) for each design submitted.

The medium sized components were analyzed to provide nominal results. The smallest component sizes were selected to represent what is deemed to be the worst case for stress analysis and allow fair predicate comparison. All tibial insert components were modeled with a 6 mm minimum polymer thickness. The submitted CAD file component assemblies are summarized in **Table A1-1** below.

Product	Component Size	File Name	File Date	File Size
K1	Medium	Bodycad U1-UGM01.x_t	March 4, 2015	2,633 KB
K1	Small	Bodycad_U1-SM03_R02.x_t	March 16, 2015	6,646 KB
ZUK	Small	ZUK.x_t	March 10, 2015	2,516 KB

Table A1-1 Summary of solid model CAD files submitted for finite element stress analysis.

TIBIAL INSERT: NURBS SURFACE TO 3D HEXAHEDRAL MESH

The NURBS surface representing the proximal articulating surface of the tibial insert was imported into a finite element preprocessor Mentat 2014.0.0 (MSC Software Corporation, Newport Beach, California USA) and positioned such that its lowest sulcus point was 6 mm above a “floor” reference plane. A flat, two dimensional, tiled mesh of quadrilateral elements with an average edge length of 1 mm was projected onto the NURBS surface such that the nodes at their vertices rested on the surface. Manual adjustments were made to the location of nodes near edges or other sharp geometry transitions to insure that these important features would be modeled accurately.

The resulting three dimensional quadrilateral elements were then expanded distally to form tall and narrow hexahedral (brick) elements with distal faces resting on the floor reference plane, effectively flattening the distal surface of the tibial insert. The tall narrow hexahedral elements were then subdivided along their height into ten equal sized bricks, creating a finished 3D hexahedral mesh of the tibial insert with a minimum polymer thickness of 6 mm and a typical brick element size of 1x1x0.6 mm (**Figure A1-1**).

FEMORAL COMPONENT: NURBS SURFACE TO RIGID BODY

The NURBS surface representing the articulating surface of the femoral component was also imported into the preprocessor as a basis for creating a rigid body to articulate against the 3D hexahedral mesh of the tibial insert. The goal was to define the femoral articulating surface as a NURBS in the finite element model, not to create a mesh of that surface. A NURBS surface offers a single, continuous mathematical description of the complex femoral curvatures. This allows a continuously defined surface normal to be established, which increases efficiency and accuracy of the finite element contact algorithm. No meshing was required of the femoral NURBS, thus reducing the finite element model’s degrees of freedom, file size, and time to converge on a solution.

FINITE ELEMENT MODEL ASSEMBLY

A finite element model was created for each load case investigated. The 3D hexahedral mesh of the tibial insert was combined with the femoral NURBS surface that was rotated to the appropriate flexion angle. For each position the corresponding normal joint force was applied, bringing the femoral surface and tibial insert mesh together for a complete stress analysis.

The loads were applied and the virtual femoral component was allowed to settle into its preferred alignment without friction or consideration of soft tissue constraints, generally seeking to settle in the lowest sulcus point of the tibial insert. Contact area and peak stress results were gathered. Photorealistic images of the resulting stresses were generated for illustration and comparison.

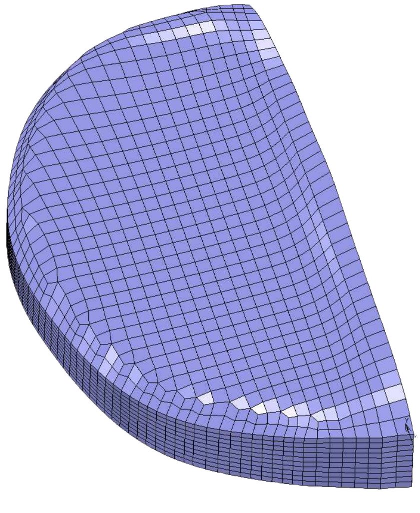


Figure A1-1 A typical mesh of a uni-compartmental knee replacement tibial insert.

The finite element model incorporated a nonlinear elastic Ogden formulation to describe the mechanical response of the UHMWPE material. Full integration (eight gaussian points plus a ninth hydrostatic pressure point), first-order, isoparametric, hexahedral elements were employed for highest accuracy. The tibial tray locking mechanism was simulated by fully constraining the perimeter of the distal surface of the tibial insert. The remainder of the distal surface was free to slide in the transverse plane. The femoral component had compressive force applied, but was allowed to move in the transverse plane, and balance as needed in the varus or valgus direction while its prescribed flexion angle was maintained.

LOADING CONDITIONS

The weighted average of available information in the literature regarding knee flexion angles and total joint loads was compiled and summarized in **Table A1-2** below. In all six cases 60% of the compressive total joint loads[1] were applied to the medial compartment.

Testing Condition	**Walking Gait Activity**			**High Flexion Activities**		
Activity	Heel Strike	Toe Off	Mid Stance	Stair Descent	Chair Rise	Kneel Rise
Knee Flexion Angle (degrees)	0	15	20	60	90	120
Average Total Joint Force (Newtons)	1,950	2,340	1,560	3,030	2,280	1,400
Applied Medial Compartment Force, 60% of Average (Newtons)	1,170	1,404	936	1,818	1,368	840

Table A1-2 Summary of knee flexion angles and total joint forces at the most highly loaded positions of an activity cycle. Sixty percent of these compressive loads are applied to the medial compartment for subsequent stress analysis of the medial unicompartmental knee design.

The normal joint forces are average values of results reported by Morrison[2,3], Paul[4], Smith[5] and Hirokawa[6]. The knee flexion angles are average values of results reported by Murray et al.[7], LaFortune et al.[8] and Apkarian et al.[9]

UHMWPE MATERIAL MODEL

The mechanical response of UHMWPE is overall viscoelastic in nature; it exhibits creep behavior[10] and rapid stress relaxation[11] in compression at 37 degrees Celsius. However, it has been observed at this laboratory that the mechanical response of a typical total knee device to loading is nonlinear and repeatable after the tenth step, because the short term time dependent effects of UHMWPE have dissipated to an equilibrium point. This suggests that after an initial preconditioning, the response of UHMWPE to a given rate of loading can be modeled in a nonlinear elastic manner.

Figure A1-2 illustrates a recasting of the uniaxial, compressive, viscoelastic experimental data gathered by Waldman and Bryant[11] on gamma sterilized in air, UHMWPE samples at 37 degrees

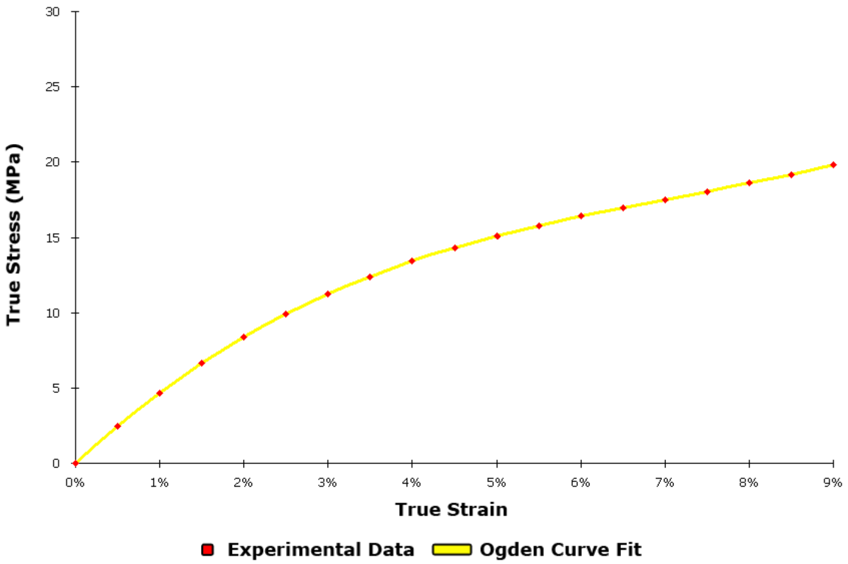


Figure A1-2 UHMWPE mechanical response; experimental data and Ogden curve fit.

Celsius, for the loading rate that occurs during heel strike of level walking gait. The Ogden material formulation was adjusted until its single element response matched the experimental data. The Ogden formulation utilizes an energy-based model, which creates a continuous, elastic nonlinear material model that considers the polymer's bulk modulus and nearly incompressible properties.

MODEL VALIDATION

The Fuji film methodology developed in this laboratory over the past 22 years[12], which experimentally measures surface stresses, was used to validate the computational model. Heel strike and chair rise loading conditions applied to the computational model were applied experimentally to the tibial insert by utilizing a uniaxial, closed loop, servo-hydraulic, materials testing system Model 810.442 (MTS Systems Corporation, USA) in a 22 degrees Celsius laboratory environment. The resulting imprint is photographed, digitally scanned and the contact area calculated with a calibrated pixel counting algorithm. The experimental results are compared to the finite element results for the same loading conditions at 37 degrees Celsius.

ERROR ANALYSIS

There are several sources of error in this analysis: measurement error, NURBS surface fitting error, contact algorithm threshold error and finite element mesh accuracy. Worst case volumetric measurement error associated with the blue light scanner is less than 3 micrometers and is considered negligible in this analysis. NURBS surface fitting error is held to 15 micrometers for articulating surfaces, but was typically less than 7 micrometers. The contact algorithm is set to detect contact within a window height of 50 micrometers and biased 80% into the tibial insert mesh, effectively adding 10 micrometers of cushion on the proximal surface of the tibial insert. These values are quite low in perspective, as good modern machining tolerances are typically +/- 60 micrometers, so the worst case aggregate of these errors would only be 20 micrometers, about one third of the variation we might expect in a given lot of manufactured components.

Finite element mesh accuracy is determined by mesh density, the order of the interpolating function that describes the stress field within the element, and the method of integration across the volume of the element. Accuracy can be increased by using full integration (eight point gaussian), higher order interpolating functions (quadratic), and increasing mesh density (smaller elements). Full integration was computationally expensive but deemed necessary for this nonlinear problem. Because the non-linearities associated with contact make quadratic interpolative functions impractical, linear functions were chosen. As a consequence, smaller elements were required to accurately model strain and stress fields in the tibial insert.

A parametric analysis showed the relationship between mesh density and component strain was examined in this study. The results indicated that full integration, linear isoparametric hexahedral elements with 1 mm edge lengths and 0.6 mm thickness accurately captured component strain within 8% error of its asymptotic value. Doubling the mesh density, so that each brick element was divided into eight smaller bricks, marginally increased accuracy by 3% at the expense of greatly reduced computational efficiency and was deemed unnecessary for this analysis.

REFERENCES

1. Daley, R. E., “Measurement of the Distribution of Forces at the Human Knee Joint”, Ohio State University Ph.D. Thesis 75-19, 426, 1975.
2. Morrison, J. B. “The Mechanics of the Knee Joint in Relation to Normal Walking”, Journal of Biomechanics, 3 pp 51-61, 1970.
3. Morrison, J. B. “Function of the Knee Joint in Various Activities”, Bio-medical Engineering, 4 pp 573-580, 1969.
4. Paul, J. P., “Forces Transmitted by Joints in the Human Body”, Proceedings of the lnstitute of Mechanical Engineers, 181:358, 1967.
5. Smith S. M., Cockburn R. A., Hemmerich A., Li R. M., Wyss U. P., “Tibiofemoral Joint Contact Forces and Knee Kinematics During Squatting”, Gait & Posture, 27:376–86, 2008.
6. Hirokawa S, Fukunaga M. “Knee Joint Forces When Rising from Kneeling Positions”, Journal of Biomechanical Science and Engineering, 8:1 pp27–39, 2013.
7. Murray, M. P., Drought, A. B., Kory, R. C., “Walking Patterns in Normal Men”, Journal of Bone and Joint Surgery, 46:A pp 335-360, 1964.
8. LaFortune, M. A., Cavanaugh, P. R., Sommer, H. J., Kalenak, A., “Three-Dimensional Kinematics of the Human Knee During Walking”, Journal of Biomechanics, 25:4 pp 347-357, 1992.
9. Apkarian, J., Naumann, S., Cairns, B., “A Three-Dimensional Kinematic and Dynamic Model of the Lower Limb”, Journal of Biomechanics, 22:2 pp 143-155, 1989.
10. Little, E. G., “Compressive Creep Behaviour of lrradiated Ultra-High Molecular Weight Polyethylene at 37° C”, Engineering in Medicine, 14:2 pp 85-87, 1985.
11. Waldman, S. D., Bryant, J. T., “Nonlinear Viscoelastic Behaviour of lrradiated Ultra-High Molecular Weight Polyethylene at 37° C”, UHMWPE workshop, ASTM Annual Meeting, 1994.
12. Heim C. S., Postak P. D., Greenwald A. S., “Factors Influencing the Longevity of UHMWPE Tibial Components”, Instructional Course Lectures, American Academy of Orthopaedic Surgeons, 45:34 pp 303-312, 1996.

Appendix B - Validation Results

BodyCAD Contact (Normal) Stress Validation for K1- Medium Size

Flexion Angle: 0 degrees **Flexion Angle: 90 degrees**

Physical Contact Stress as Measured by Fuji Prescale Film - Trial #1

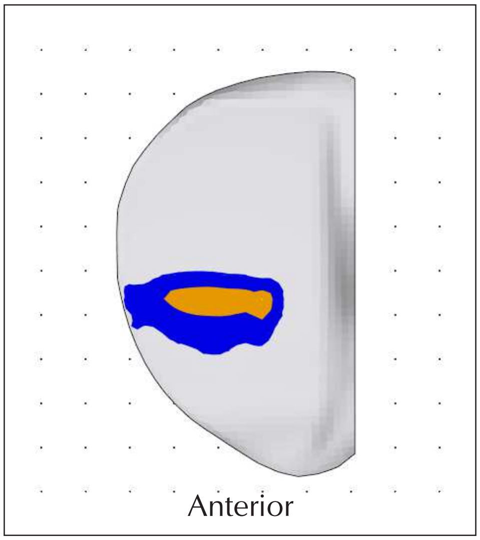
	0 deg	90 deg
Contact Area (mm^2)	105	98
Peak Stress (MPa)	18.6	29.7
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	22	22

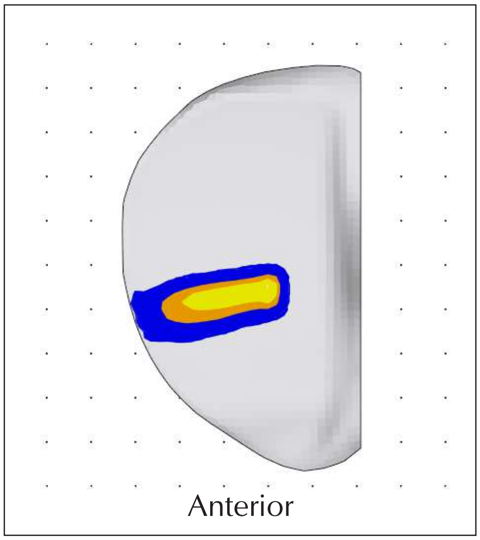
Physical Contact Stress as Measured by Fuji Prescale Film - Trial #2

	0 deg	90 deg
Contact Area (mm^2)	92	94
Peak Stress (MPa)	19.2	30.5
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	22	22

Virtual Contact Stress as Measured by Finite Element Method

	0 deg	90 deg
Contact Area (mm^2)	129	118
Peak Stress (MPa)	20.3	26.5
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	37	37





BodyCAD Contact (Normal) Stress Validation for K1- Small Size

Flexion Angle: 0 degrees | **Flexion Angle: 90 degrees**

Physical Contact Stress as Measured by Fuji Prescale Film - Trial #1

	0 deg	90 deg
Contact Area (mm²)	77	59
Peak Stress (MPa)	23.8	26.2
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	22	22

Physical Contact Stress as Measured by Fuji Prescale Film - Trial #2

	0 deg	90 deg
Contact Area (mm²)	77	56
Peak Stress (MPa)	26.5	24.7
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	22	22

Virtual Contact Stress as Measured by Finite Element Method

	0 deg	90 deg
Contact Area (mm²)	100	93
Peak Stress (MPa)	24.8	34.5
Applied Force (Newtons)	1,170	1,370
Material Temp (Celsius)	37	37