PRECLINICAL COMPUTATIONAL MODELS: *PREDICTORS OF TIBIAL INSERT DAMAGE PATTERNS IN TOTAL KNEE ARTHROPLASTY*

Orthopaedic Research Laboratories
Cleveland, Ohio

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

INTRODUCTION

Manufacturers and regulatory agencies share a common goal of having safe and effective total knee arthroplasty (TKA) products available in the global marketplace. Several preclinical methods of testing TKA designs, inclusive of virtual computational models and physical laboratory wear simulations, are employed to predict polymer tibial insert damage patterns. However, the latter is criticized for poor clinical correlation, long testing times, large expense and the difficulty in providing meaningful comparisons with other clinically successful designs.

This exhibit describes a computational modeling experience dating back 16 years for over 45 TKA designs where predicted polymer insert damage patterns have correlated well with **physical contact area and stress measurements**, **laboratory wear simulation and clinical retrievals**, suggesting an alternative pre-clinical pathway of evaluating these systems.

COMPUTATIONAL MODELING

Two computational modeling algorithms are described. The finite element method (Figure 1) provides snapshots of surface and subsurface stress states for tibial inserts at prescribed positions during activities of daily living (ADL). The kinematic method (Figure 2) extends our understanding by providing a continuous simulation of TKA component motion and contact areas during an entire activity cycle.

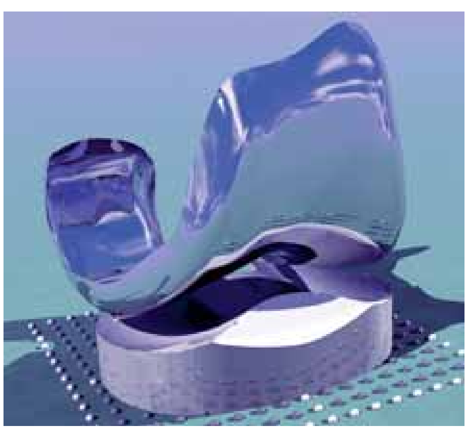

Figure 1 - Finite element model

Both methods derive component geometries measured from the articular surfaces of implantable quality components employing a three dimensional laser scanner, rather than relying on idealized computer aided design (CAD) models. The benefit from this reverse-engineering procedure is a determination of actual component fit which directly relates to the accuracy of the manufacturing process.

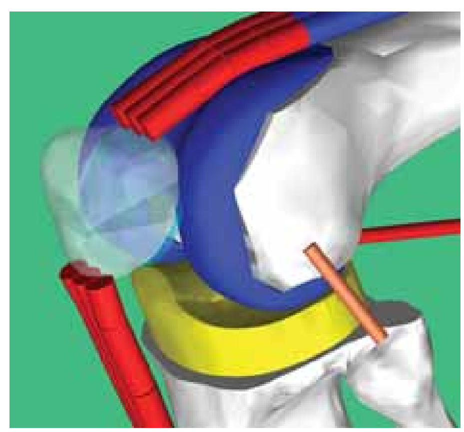

Figure 2 - Kinematic model

The Finite Element Method

The finite element (FE) method allows a bridge to be constructed between the known *in vivo* loading environment of the normal knee and the location and magnitudes of both surface and subsurface stress states associated with polymer insert damage for a given TKA design. A repeatable method of building FE models[1,2,3] was developed using MARC software (MSC.Software, Santa Ana, CA), with validation checks on multiple, clinically utilized TKA designs.

Direct **physical contact area and stress measurements** employing Fuji pressure sensitive film are an accepted industrial and regulatory agency methodology for predicting tibial insert polymer damage. Comparison between the contact stress results predicted by the FE model and the Fuji film analysis for the Genesis Total Knee System (Smith + Nephew, Memphis, TN) are shown in Figures 3a and 3b. The magnitude and shape of the contact areas and stress levels compare favorably.

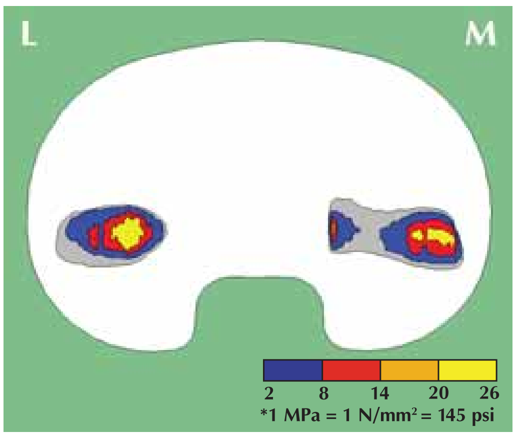

Figure 3a - Contact Stress as measured by Fuji Film

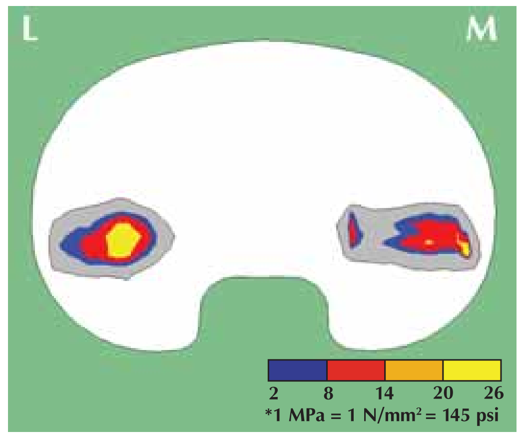

Figure 3b - Contact Stress as predicted by Finite Element

An example of the consequence of poor fit between the femoral component and the proximal surface of a mobile bearing plateau as predicted by its FE model is appreciated in Figure 4a. The poor proximal fit propagates to the distal interface creating contact patterns along the edge (Figure 4b). The amplifying effect of prescribed kinematics in a **laboratory wear simulation** specimen[4] can be appreciated in a photograph of the distal surface of the same design (Figure 4c). Comparison of Figures 4b and 4c indicates that the FE model is capable of accurately predicting locations of abrasion even in an extreme case of poor component fit.

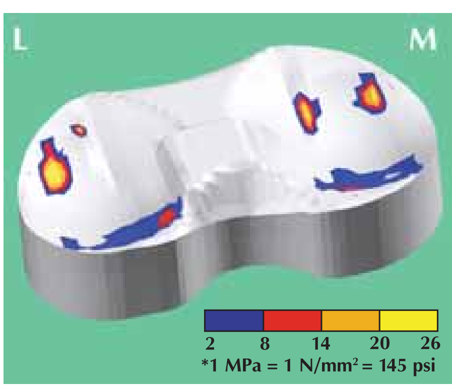

Figure 4a - Proximal contact stress as predicted by Finite Element visualizing poor proximal component fit

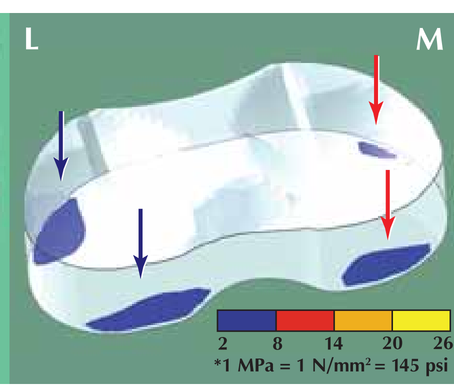

Figure 4b - Distal contact stress as predicted by Finite Element visualizing unusual perimeter contact

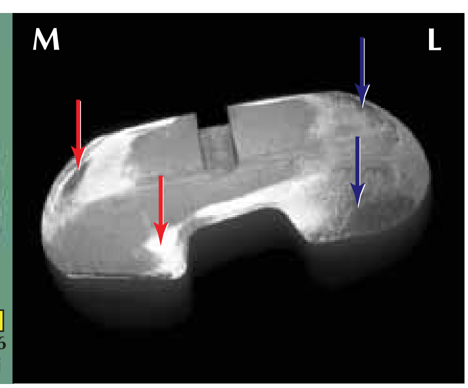

Figure 4c - Distal abrasive wear from laboratory wear simulation visualizing unusual perimeter abrasion

Similarity between an FE model result and **clinical retrievals** for the Duracon Total Knee System (Howmedica, Rutherford, NJ), a long enduring, clinically successful design, further increases confidence in the validity of the computational methodology. Figure 5a is a proximal view of the contact areas predicted by the FE model for the heelstrike portion of walking gait. The image in Figure 5b is an overlay plot that visualizes all damage pattern measurements from a series of 17 retrieved tibial inserts of this design[5]. The progressive darkening of areas suggests a commonality of damage locations amongst the retrievals. It is apparent that if the measured contact areas in Figure 5a were swept by typical patient kinematics that a simile of the wear pattern visualized in Figure 5b would emerge. Comparison of these images indicates, again, that the FE model reasonably predicted distinctive tibial insert polymer damage patterns.

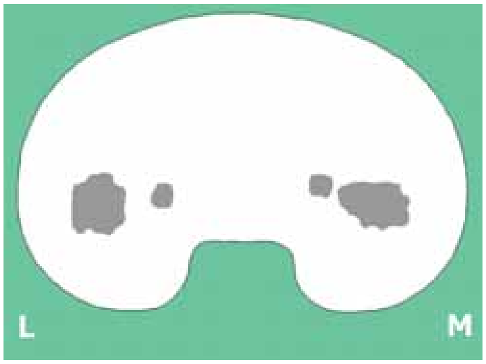

Figure 5a - Contact area predicted by Finite Element

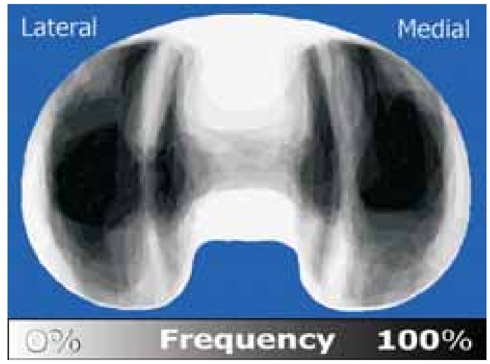

Figure 5b - Abrasive wear scar from 17 clinical retrievals

The Kinematic Method

A computational kinematic model for this Duracon Total Knee System was created using KneeSIM (LifeModeler, Inc., San Clemente, CA), which offers a constraining soft tissue envelope with active flexor and extensor muscle groups driving activity. The ADL of walking gait and deep knee bend were simulated and animations of resulting component motion and contact areas sweeping across the tibial insert recorded.

Figure 6a visualizes an accumulation of contact areas during the activity cycles of walking gait and deep knee bend. This data is overlaid on Figure 5b for comparison and visualized in Figure 6b. It clearly demonstrates that the dynamic KneeSIM model, which predicts patient kinematics, closely matches the abrasive wear scar seen in the clinical retrieval data.

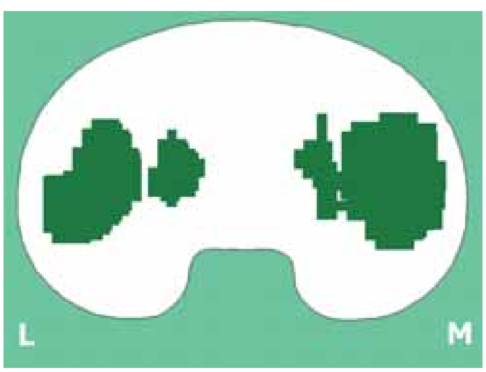

Figure 6a - Accumulated contact areas swept out by KneeSIM activities of daily living

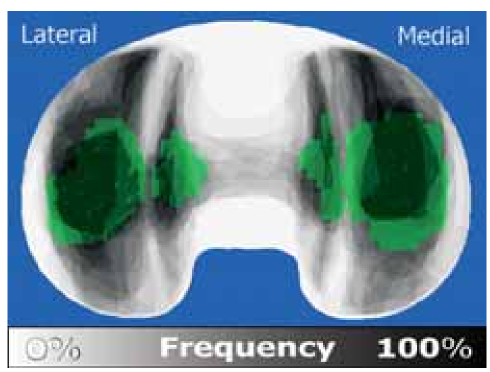

Figure 6b - Figure 6a KneeSIM data (green) overlaid on Figure 5b clinical wear scar data

CONCLUSION

This exhibit demonstrates that computational finite element and kinematic modeling tools offer an effective alternative for predicting the *in vivo* performance of TKA designs. The computational results compare favorably to industry and regulatory agency accepted evidences of **contact areas and stress measurements, laboratory wear simulation and clinical retrievals.**

These contemporary tools will prove most useful in the product development stage to vet design concepts computationally prior to the time and expense required for prototype production and subsequent physical laboratory testing.

TAKE HOME MESSAGE

In the emerging healthcare environment where minimizing expense is a predominant theme, the utilization of contemporary tools to reduce the cost burden of bringing new products to market is important. This information assists both medical device manufacturers and regulatory agencies in providing safe and effective products for the global marketplace while meeting the above challenge.

Orthopaedic Research Laboratories has a searchable compendium of over 45 contemporary TKA designs with directly comparable results for both physical and computational testing. (http://orl-inc.com/search_device/)

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2310 Superior Avenue East
Cleveland, Ohio