PRECLINICAL COMPUTATIONAL MODELS: *PROMISE AND PROGRESS IN TOTAL KNEE ARTHROPLASTY DESIGN*

Orthopaedic Research Laboratories
Cleveland, Ohio

Edward A. Morra, M.S.M.E
A. Seth Greenwald, D.Phil.(Oxon)

INTRODUCTION

Clinicians, manufacturers and regulatory agencies share a common goal of having safe and effective total knee arthroplasty (TKA) products available in the global marketplace. Preclinical computational modeling of new, innovative knee designs allows dynamic visualization of anticipated *in vivo* performance during activities of daily living. Comparison is possible with established, clinically successful designs determining relative performance differences.

This exhibit presents fluoroscopic and clinical range of motion evidence for a variety of fixed bearing knee designs, suggesting computational modeling can be predictive of *in vivo* performance. The modeling environment is extended to include mobile bearing designs and smaller patients, validated through comparison with an Asian clinical report.

What emerges from these studies is the promise that preclinical computational modeling offers a first line tool for contemporary knee design.

COMPUTATIONAL MODELING

KneeSIM software (LifeModeler, San Clemente, California) provides a dynamic, physics-based, musculoskeletal modeling environment of a nominal sized, male, Caucasian virtual patient (Figure 1). Activities of daily living, such as deep knee bend, are propelled by flexor and extensor muscle groups and restrained by the capsular and ligamentous structures surrounding the knee. A generalized contact algorithm allows the TKA components to articulate in a natural manner during a full activity cycle. Animations of component motions and quantitative data plots are generated to characterize the resulting kinematics.

Component geometries are derived from the measured articular surfaces of implantable quality components employing a three dimensional laser scanner, rather than relying on idealized computer aided design 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.

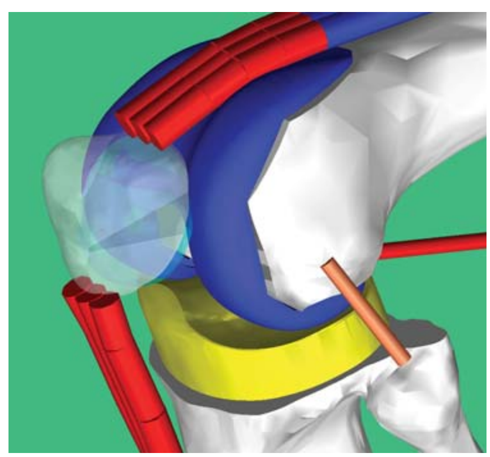

Fig 1 Kinematic knee model

CLINICAL EVIDENCE

The results from several video fluoroscopy studies, inclusive of the Duracon [Banks] and Journey BCS knees [Victor] have demonstrated that *in vivo* component motions for a given activity are very similar to those results predicted by the computational model [Morra].

The maximum weight bearing flexion angle is a further measure of clinical performance predicted by the computational model. Impingement of the posterior femoral bone cut surface (Figure 2a) with the tibial insert (Figure 2b) defines this angle. Model predictions for a variety of contemporary TKA designs are compared with values reported from recent clinical studies in the peer reviewed literature and are summarized in the table below:

TKA DESIGN NAME	POSTERIOR STABILIZED?	MAXIMUM FLEXION ANGLE (degrees)	
		MODEL PREDICTION	CLINICAL AVERAGE
Triathlon	No	104	108 [Banks]
MRK	No	104	105 [Mannan]
Duracon	No	105	105 [Penington]
Vanguard	Yes	117	111 [Lombardi]
Journey BCS	Yes	139	118 [Laidlaw]
Legacy LPS-Flex Fixed	Yes	144	135 [Kim TH]

Model predictions for non-posterior stabilized designs are very similar to clinical results. The maximum flexion angles reported for the posterior stabilized designs are less than model predictions, possibly due to early thigh to calf contact in patients with a higher body mass index (BMI).

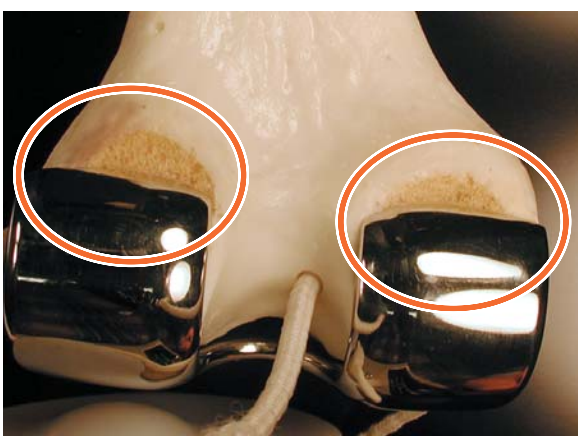

Fig 2a Posterior femoral bone cut surface.

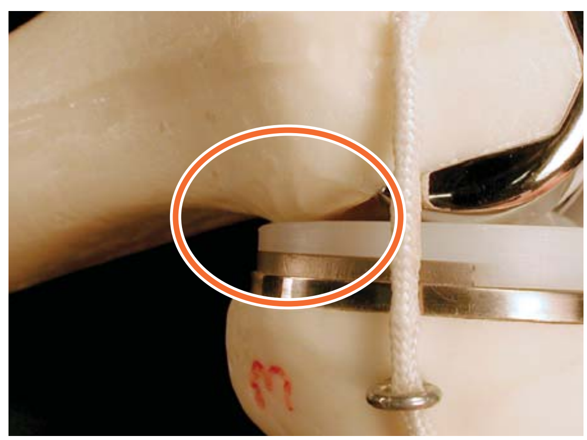

Fig 2b Maximum flexion in computational model is defined by bony impingement.

MOBILE BEARING SOFT TISSUE ENVELOPE

Mobile bearing TKA designs pose several additional challenges to the computational modeling environment. The soft tissue envelope surrounding the TKA components required refinement to accommodate the rotary motion of the tibial insert in deep flexion activities. A survey of functional knee anatomy literature yielded a comprehensive cadaveric study [Markolf] that accurately measured the rotational stiffness of the unloaded knee joint capsule at various knee flexion angles. Values for torsional stiffness and damping for the joint capsule were derived from these measurements, overcoming the soft tissue challenge.

TIBIAL BASEPLATE FRICTION

A second challenge to creating a realistic mobile bearing TKA model was determining a useful representation of friction between the tibial insert and tibial baseplate. A "stick-slip" description of friction was employed due to the low relative velocities and rotational reversals between these components. Appropriate values for the mobile bearing KneeSIM friction models were unknown, and a survey of the computational model literature generated a variety of dynamic friction values that appeared either arbitrary or model specific [Easly, Sathasivam].

A high quality clinical study reported external rotation of small sized mobile bearing knee components during deep flexion activities [Watanabe]. A KneeSIM model was created to replicate clinical conditions of the study, by employing small mobile bearing components placed in a small virtual patient. The KneeSIM model was then used to determine optimal "stick-slip" friction parameters that yielded component motions closely matching those reported. Figure 3a allows comparison of the external femoral component rotation predicted by the KneeSIM model with the clinical data. When compared to the use of simple dynamic friction (green line), model prediction was improved by employing "stick-slip" friction (blue line) between the tibial baseplate and polyethylene insert.

PATIENT AND COMPONENT SIZE MATTERS

Once the challenges of a refined soft tissue envelope and mobile bearing friction were overcome, the question of the effect of virtual patient and component size was investigated. The optimized "stick-slip" friction Watanabe KneeSIM model was repeated using a medium sized male Caucasian patient with medium sized TKA components. Figure 3b allows comparison of external femoral component rotation with a medium sized patient KneeSIM model (orange line) to the small patient model and clinical data. The medium sized virtual patient externally rotates less than the small sized patient.

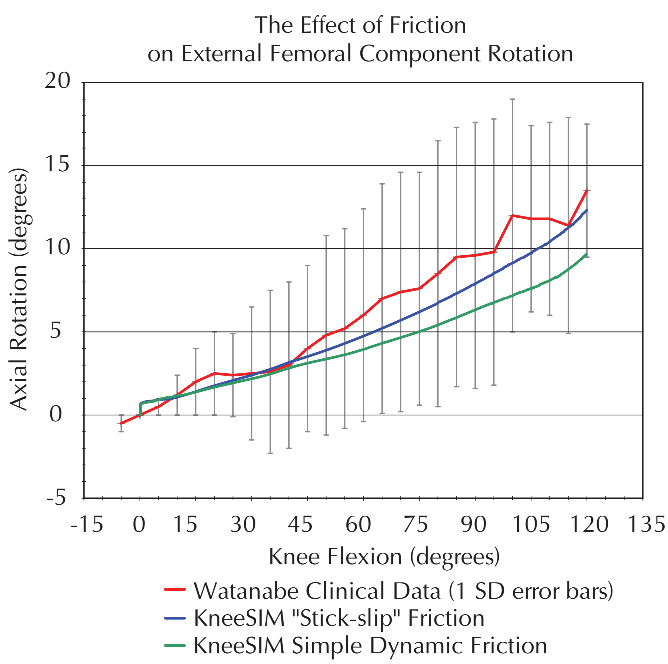

Fig 3a *An improved "stick-slip" friction model (blue) better replicates clinical results (red) than a simple dynamic friction model (green).*

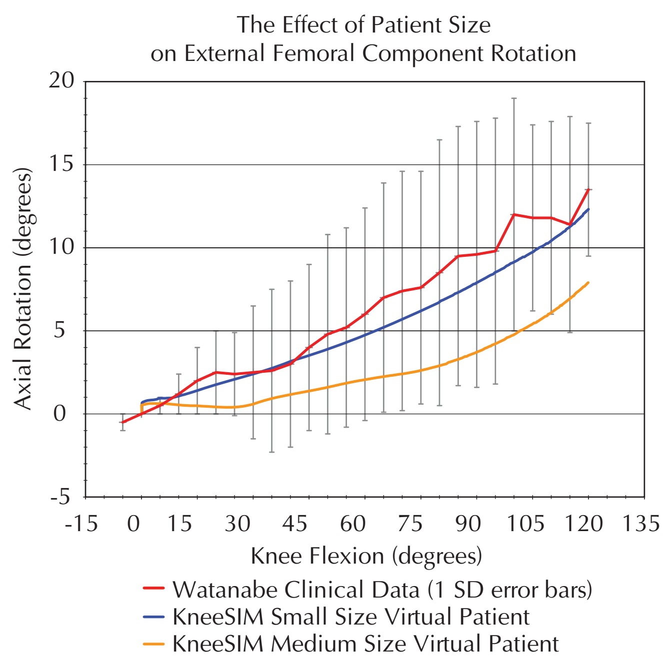

Fig 3b *A smaller virtual patient size (blue) better replicates clinical results (red) than a medium sized virtual patient (orange).*

CONCLUSION

This exhibit provides further clinical validation that computational kinematic modeling tools offer an effective preclinical pathway for predicting the *in vivo* performance of fixed and mobile bearing TKA designs, inclusive of physically smaller patient populations.

Orthopaedic Research Laboratories has a searchable compendium of directly comparable results for both physical and computational testing at http://orl-inc.com/search_device/ for contemporary knee designs.

REFERENCES

Banks SA, Hodge WA, "2003 Hap Paul Award Paper for International Society for Technology in Arthroplasty. Design and Activity Dependence of Kinematics in Fixed Mobile-bearing Knee Arthroplasties", J Arthroplasty, (7):809-816, 2004.

Easley S, Rullkoetter P, "Efficient Finite Element Model Prediction of TKR Constraint", 52nd Annual Meeting of the Orthopaedic Research Society, Paper No: 0591, 2006.

Kim TH, Lee DH, Bin SI, "The NexGen LPS-flex to the Knee Prosthesis at a Minimum of Three Years", J Bone Joint Surg Br, 90B(10):1304-10, 2008.

Laidlaw MS, Rolston LR, Bozic KJ, Ries MD, "Assessment of Tibiofemoral Position in Total Knee Arthroplasty Using the Active Flexion Lateral Radiograph", The Knee, 17(2010) 38-44, 2009.

Lombardi AV, Viacava AJ, Berend KR, "Rapid Recovery Protocols and Minimally Invasive Surgery Help Achieve High Knee Flexion", Clin Orthop, (452):117-122, 2006.

Mannan K, Scott G, "The Medial Rotation Total Knee Replacement: A Clinical and Radiological Review at a Mean Follow-up of Six Years." J Bone Joint Surg Br, 91-B:750-6, 2009.

Markolf KL, Mensch JS, Amstutz HC, "Stiffness and Laxity of the Knee --The Contributions of the Supporting Structures. A Quantitative In Vitro Study", J Bone Joint Surg Am, 58A:583-594, 1976.

Morra EA, Rosca M, Greenwald JFI, Greenwald AS, "The Influence of Contemporary Knee Design on High Flexion: A Kinematic Comparison with the Normal Knee", J Bone Joint Surg Am, 90(4):195-201, 2008.

Pennington J, Quinlan J, Doyle T, Bayan A, Theis J, "Results of Porous-Coated Anatomic and Duracon Total Knee Arthroplasty", J Knee Surg 23(4):181-186, 2010.

Sathasivam S, Walker PS, "A Computer Model with Surface Friction for the Prediction of Total Knee Kinematics", J Biomech, 30(2):177-184, 1997.

Victor J, Mueller JKP, Komistek RD, et. al., "In Vivo Kinematics after a Cruciate-substituting TKA", Clin Orthop, 468(3):807-814, 2009.

Watanabe T, Yamazaki T, Sugamoto K, et. al., "In Vivo Kinematics of Mobile-Bearing Knee Arthroplasty in Deep Knee Bending Motion", J Ortho Res 22:1044–9, 2004.

2310 Superior Avenue East
Cleveland, Ohio