Predicting Knee Femoral Component Failure Mechanisms and Designing Contemporary Implants to Avoid Fracture Failure

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INTRODUCTION

We set out to design a patient-specific knee femoral component that was bone preserving in comparison to standard total knee components. Fracture of the femoral component is not a common failure mode in total knee replacement, but we recognized that fatigue strength could be compromised when attempting to make condylar sections thinner than standard total knee components. We hypothesized that adding an additional facet would allow us to reduce the thickness of the component.

Understanding existing reported failures and building upon that knowledge should provide insight into improving the design. Scott[1] reported on 7 knee femoral fractures in his early PFC experience. Failure analysis of these components revealed that the fracture initiation site was on the inner bone surface at the intersection of the distal flat and posterior medial chamfer corner. This finding indicates that in these cases, femoral fracture was caused by the femoral component spreading apart in the anterior to posterior direction concentrating peak stress at the medial distal and posterior chamfer intersections.

METHOD

Using the knowledge of how the early PFC knee femoral components failed, we set out to simulate that failure mechanism in a FEA model. An extra small and an extra large knee femoral component were then tested in the model using both a 5-cut and a 6-cut design.

To design the patient-specific implants, CT scans are acquired on a patient's lower limb. The CT scan is converted into a segmented surface model with proprietary software and then imported into a design software system that creates a knee femoral component that closely matches the patient's natural medial 'J' curve, lateral 'J' curve and their natural trochlear 'J' curve. Each implant, therefore, has an individualized condylar geometry and thickness which can be optimized to fit each patient.

Two individual CT scans were used to design an extra small (XS) and an extra large (XL) knee femoral component. Knee components were designed in CAD in a 5-cut traditional design (**see Image 1**) in two sizes and then imported into ANSYS R11-SP1. The components were coupled to a bone model that was 0.5mm larger at the anterior flange region of the component, thus causing a wedge effect on the implant, theorizing that the wedge effect would concentrate stress in the region of the reported fracture failures of the PFC. 6-cut femoral components were also modeled and tested in the same method. The 6-cut design adds an additional posterior chamfer (**see Image 2**). The implant (contact) and femur (target) face connections were modeled as a frictional fit with the coefficient of friction set to 0.5. The surface to surface interface was set to 0mm offset so that the software would acknowledge and calculate the interference fit.

Loading was applied simulating a 15 degree flexion angle with 60% of the load being applied to the medial condyle, and the remaining load applied through the lateral condyle. The total load was adjusted for the size of the implant, where the XS got 1025 N and the XL received 4003 N. This loading regimen is based on accepted parameters as well as data collected from a clinical data base depicting patient weight according to femoral implant size.[2,3]

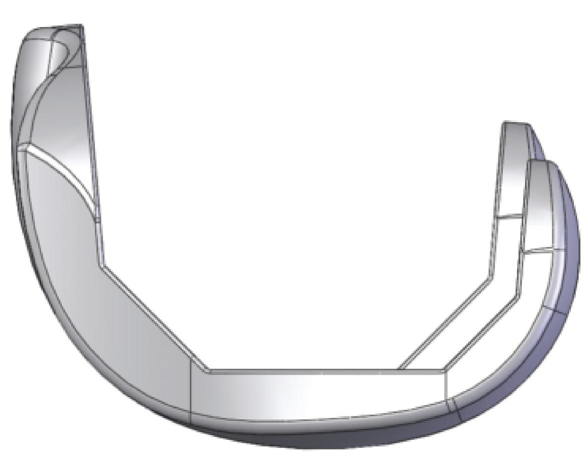

Image 1:
A patient-matched 5-cut femoral component.

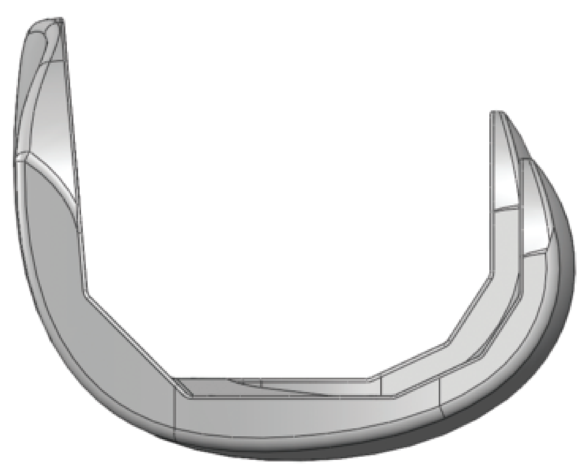

Image 2:
A patient-matched 6-cut femoral component; note, additional posterior chamfer cut.

RESULTS

The results for the maximum principal stress are tabulated in **Chart 1**. In all femoral components, the maximum principal stress occurred at the intersection of the distal medial and posterior chamfer intersection (**see Image 3**). In our FEA model, the 5-cut design increased the maximum principal stress on the femoral component by 24% in the XS size and by 32% in the XL size as compared to a 6-cut design.

	5-cut Design	6-cut Design
XS Femoral Component	201.4 MPa	161.8 MPa
XL Femoral Component	292.0 MPa	221.1 MPa

Chart 1: *Comparing maximum principal stress for both implant sizes.*

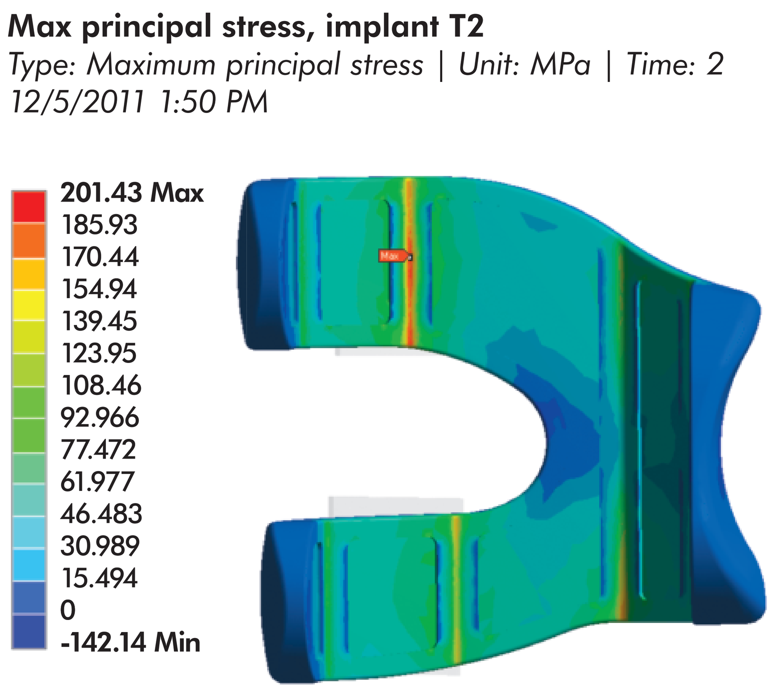

Image 3:
5-cut femoral component FEA image.

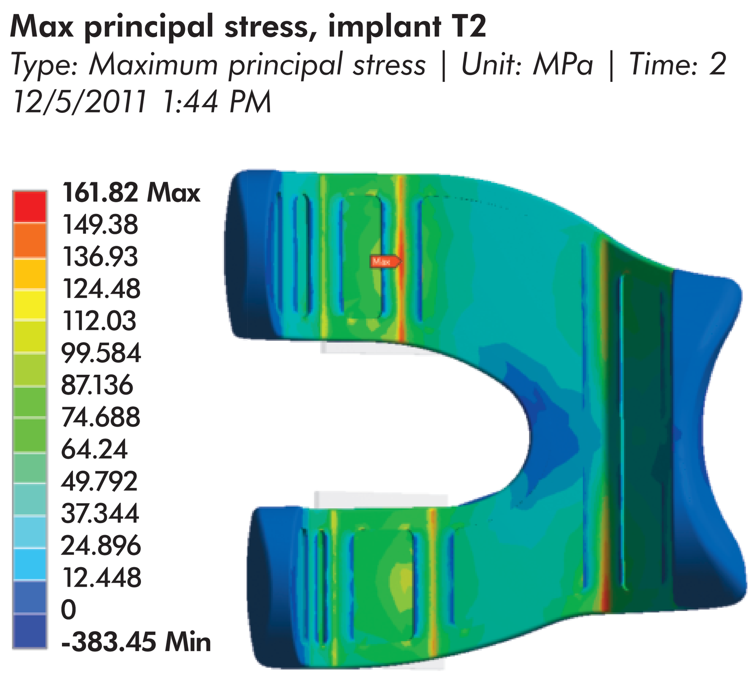

Image 4:
6-cut femoral component FEA image.

A dimensional comparison was made between 5 contemporary and commercially available total knee implant systems and a comparably sized patient-specific 6-cut design, looking at the thickness of the distal and posterior condyles. **Chart 2** shows the dimensions of the other commercially available implant systems, which were derived from radiographic templates. For a medium size femoral component, the 6-cut design is, on average, greater than 2.0mm thinner than standard competitive femoral component designs. In the posterior and distal condylar regions, the difference can be as much as 3.6mm and 3.2mm, respectively.

Medium Size

	Size	A-P Length	Medial Distal Thickness	Lateral Distal Thickness	Medial Posterior Thickness	Lateral Posterior Thickness
Zimmer NexGen	E	62	9	9	9.3	9.3
Johnson & Johnson PFC Sigma	3	61	9	9	8	8
Smith & Nephew Legion	5	62	9.5	9.5	9.3	9.3
Stryker Triathlon PS	4	62	8.5	8.5	8.5	8.5
Smith & Nephew Journey	5	62	9.5	7.0	9.5	7.4
ConforMIS—Serial #10535	**N/A**	**62**	**6.3**	**6.9**	**5.9**	**5.7**

Chart 2:
Comparative condyle thickness between several commercially available knee femoral components and the 6-cut design.

CONCLUSION

We have successfully demonstrated a finite element model and method that accurately reproduces the reported failure mechanism of an implant system with a long clinical history. In our model we were able to show the exact location of failure of the PFC femoral components as reported by Scott. Both sized implants showed maximum principal stress in the identical region as the failed PFC femoral components. Although the stress predicted in our model is below any reported endurance limit for a cast cobalt chrome implant, differences in actual implant thickness and/or magnitudes of the load applied could certainly raise the maximum principal stress above the endurance limit of the material, which clearly happened to the femoral component failures reported by Scott.

iTotal CR
A patient-matched Total Knee Replacement implant with 6 individualized faceted bone cuts.

We have also shown that the stress can be reduced substantially by adding an additional faceted cut. We hypothesize that the stress reduction in the 6-cut design is due to the additional corner imparted by the 6th facet, distributing the load over a greater area. The advantage of the additional cut is that the overall implant thickness can be reduced by an average of 2mm compared to the traditional 5-cut implant design. Berlin[4] showed the endurance limit of cobalt chrome as derived from a rotating beam test to be between 345 MPa and 480 MPa. This thickness reduction can be achieved because the 6-cut design shows a maximum principal stress substantially lower than the endurance limit for cast cobalt chrome as reported by Berlin. Any reduction in implant thickness can translate directly to bone preservation in total knee surgery, leaving more bone available in the event that a revision of the original implant is required.

References:

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