

MicroPort

Life Sciences Case Study



Challenge

Shanghai MicroPort Orthopedics wanted to expand into new orthopedic products. They were looking for a cost-effective, accurate means to compare the performance of fixed-bearing and mobile-bearing designs for total knee replacement (TKR) implants.

Solution

The SIMULIA Abaqus Knee Simulator (AKS) from Dassault Systèmes provided tools to semi-automatically model and simulate both TKRs in dynamic analyses.

Benefits

The AKS offered valuable insights into the merits of each implant type. This saved considerable time and costs by reducing the need for physical prototyping and mechanical testing. Use of the AKS may also shorten clinical trial times for MicroPort products in the future.

Knees can perform extraordinary tasks. They can spin while withstanding the loads of a triple axel in figure skating, or brace against the forces of a hip check in hockey. They also endure the mundane loads and stresses of daily life: stair climbing, walking, standing, sitting, and bearing body weight. When all that activity takes too great a toll over time, Total Knee Replacement (TKR) surgery may be advisable [see the sidebar, "Knee Replacement: Past, Present, Future"].

But before the surgeon goes to work, product developers and manufacturers have to create TKR implants that will perform as long as possible. Realistic simulation with finite element analysis (FEA) software has now become vital to that process. "Simulation helps us reduce physical prototyping and shorten mechanical and fatigue testing times," says Wind Feng, R&D Engineer at Shanghai MicroPort Orthopedics. "More importantly, it helps us evaluate the biomechanics performance of our design without conducting expensive and lengthy physical tests."

With the goal of cutting time and improving efficiency, MicroPort chose the SIMULIA Abaqus Knee Simulator (AKS) (See Figure 1), from Dassault Systèmes' 3DEXPERIENCE technology.

As China's leading developer and supplier of orthopedic medical devices and implants, MicroPort is taking the first steps in exploring TKR implants to augment their already successful line of spinal products. "There is a huge market for orthopedic implants, especially knee replacements," Feng says. "We want to be a major part of that." During their initial proof-of-concept phase MicroPort is evaluating what kind of TKR implant model to focus on going forward. The team

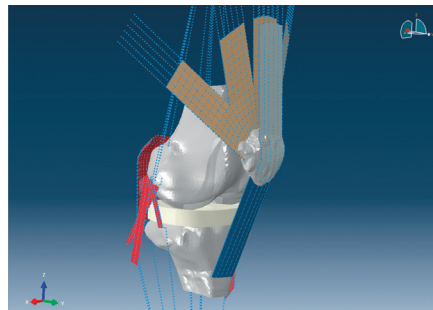


Figure 1. Designer and analyst applications guide users from model creation to results interpolation with the Abaqus Knee Simulator.

has been looking at the two most commonly used implant types: fixed bearing (FB) and mobile bearing (MB) (See Figure 2). Both designs involve a metal tibial tray that is inserted into the upper end of the large lower leg bone. An ultra-high-molecular-weight polyethylene bearing, taking the place of the meniscus, rests on the tray. The metal femoral component sits on the bearing. In the FB implant, the bearing is attached to the tibial tray; the mobile bearing, on the other hand, is free to rotate slightly in the tray. "Both FB and MB implants have their proponents," Feng says, "but we wanted to compare them for ourselves. We strongly believe in conducting our own research and development to bring out innovative products." Among other comparisons, MicroPort is particularly interested in seeing if the rotation freedom of the MB increased TKR performance by any measurable degree.

The AKS not only offered tools to thoroughly evaluate the FB and MB configurations—it established a new, shorter path at MicroPort for testing and analyzing designs.



Figure 2. Above are views of fixed (left) and mobile (right) bearing total knee replacements (TKRs).

Taking FEA modeling in stride

Prior to widespread acceptance of simulation, much of the industry-wide test data on TKR performance came from a bench-top device called the Kansas Knee Simulator (KKS). This is a complex mechanical device that provides dynamic loading similar to what human knees do during normal activities. The simulator generally uses a cadaver knee joint. Testing is done with an eye toward regulatory requirements, particularly ISO standards. "The Kansas Knee Simulator provides accurate data," Feng says, "but testing prototype designs in the lab is costly and time-consuming. Anything we can do to minimize its use is a great benefit to product development." One reason that FEA can be substituted for the KKS and other physical tests is precisely because a wealth of information has already been collected on knee implants, both from labs and from the field. In October of 2012, the Abaqus Knee Simulator was introduced to the market to take full advantage of the available data. The software is a validated tool that can conduct basic-to-advanced knee implant analyses. "We chose the AKS for this research because it semi-automatically creates advanced explicit analyses," Feng says. "That significantly increases our simulation efficiency."

Among the built-in analyses that AKS includes are:

- **Tibiofemoral contact mechanics** at varying static positions during flex
- **Implant Constraint**, measuring laxity between femoral and tibial implant components, ignoring soft tissue
- **Tibiofemoral Constraint**, measuring laxity but this time including soft tissue
- **Wear Simulator**, predicting wear on the lower (tibial) component over gait cycles
- **Basic TKR Loading**, evaluating the complete mechanics of the artificial joint under the basic muscle-load conditions of daily activities (walking, squatting, and so forth)

Putting the AKS through its paces

The FB and MB simulations concentrated on dynamic analyses of physiological loading and used the Basic TKR Loading function. The objectives of the simulation were to evaluate tibiofemoral and patellofemoral kinematics, contact mechanics between implant parts (and the leg itself), and component stresses, all under the physiological loading conditions of normal daily activities. "We primarily analyzed gait," Feng says, "but because these products are intended for the Asian market, we were also particularly interested in modeling squatting—a very common stress load in these cultures."

Gait and squatting sound simple, but they are actually highly complex physical processes involving bone, muscles, tendons and, of course, motion. Accordingly, the models that accurately capture them in a nonlinear analysis are also complicated, as they must incorporate muscle force control, realistic data from in vivo testing, and rigid bodies for bone structure. To model the implants, engineers imported MicroPort's own TKR geometries for FB and MB TKRs. The AKS



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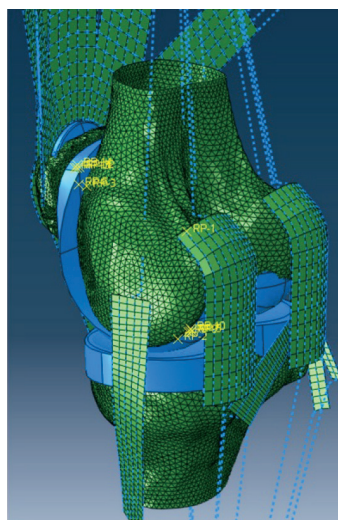


Figure 3. This meshed finite element model of a TKR is ready for analysis in the Abaqus Knee Simulator (AKS). The 2D rectangular strips and the vertical lines are tendons. The TKR components are in blue. The two large green knobs are the tibia (bottom) and the femur (top).

meshed each component automatically in the process and assembled them together in the AKS along with the distal femur, proximal tibia, patella, and the soft tissues surrounding the knee. The ligaments can be represented in 1D or 2D.

The realistic nature of the model would be difficult to achieve without the AKS, which sets up loading, boundary condition, and interactions. "Because of their complexity and loading conditions, setting up these two models could easily have taken a week by hand," Feng says. "Instead, it took a day or two. The AKS makes it practical for product development companies to perform simulations as thorough as those at research institutes."

The savings continued once the analyses were running. The AKS can perform most analyses in hours to a few days, depending on the complexity of the model and the available computational power. By contrast, physical testing of even one implant prototype could have taken months.

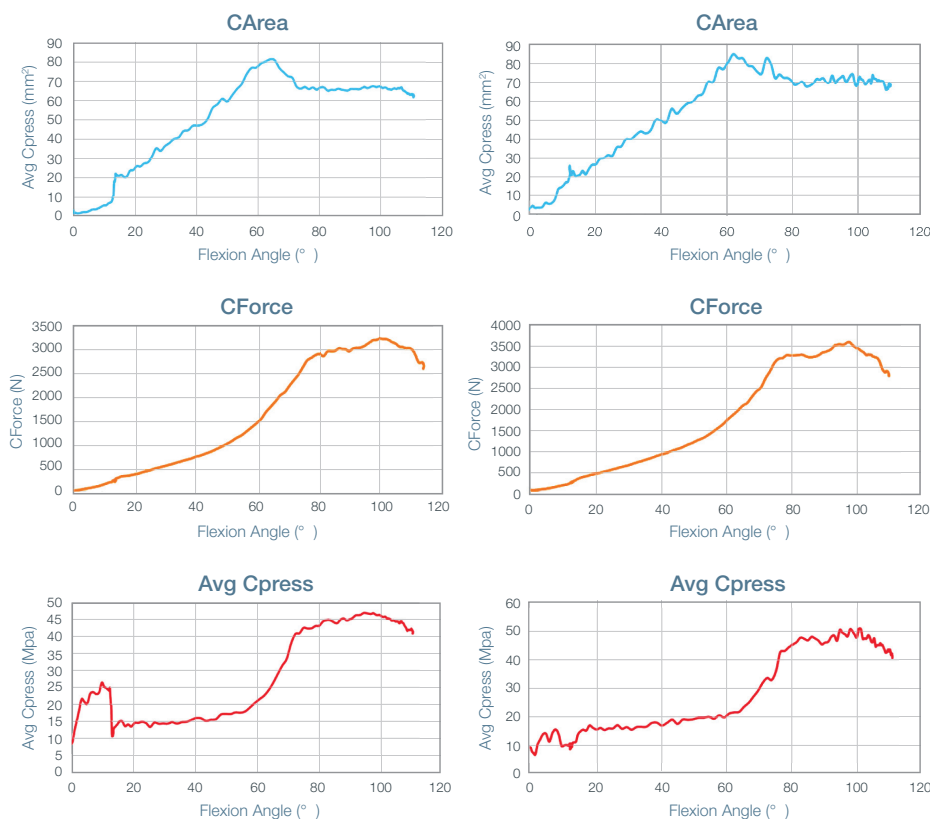
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Further steps with AKS

The simulations provide insight into the merits of both fixed and mobile bearing knee implants. Not surprisingly, the MB provided more rotation—but only slightly more. With behavior under squat loading conditions, little difference was observed. "We didn't find any significant evidence that suggests mobile bearings performed better than conventional fixed ones, a result supported in the literature as well," Feng says. "We'll continue researching both designs with hospitals and universities—and we'll definitely keep using the AKS."

MicroPort's work with the AKS has shown that FEA is not just good for design development—it's good for business. "Simulation has saved us considerable development time and money by reducing physical prototyping and mechanical testing, so that engineers could concentrate on product design and optimization," Feng says. "It may even help us to reduce clinical trial times in the future."



Charts 1-6. The graphs above show patellofemoral analysis results for squat. The analysis did not find significant evidence that mobile bearings (right) performed better than conventional fixed ones (left), a result supported in the literature as well.

Knee Replacement: Past, Present, Future

For as long as humans have had joints, we've had joint problems. The first knee arthroplasty was probably performed by French orthopedic surgeon Verneuil in the 1860s. Then in the 1890s, a German doctor explored the idea of using elephant ivory to replace damaged knee components. Over time, advancements in materials and techniques helped physicians better serve orthopedic needs. Almost a century and numerous trials after the basic idea arose, many design challenges of early artificial knee parts had been overcome, leading to more successful surgeries: In 1968, the first fully artificial knee was implanted in a total knee replacement (TKR) procedure. Today, there are more than 600,000 TKR surgeries using metal and plastic annually in the U.S. alone. Over 90 percent of patients

who have the surgery experience significantly improved knee function, pain relief, and restored ability to perform most daily activities. In most cases, the implants are effective for ten to twenty years. As knee replacements become more common, the technology surrounding them continues to advance. What began as a pre-surgery guessing game now properly assesses the issue with a comprehensive orthopedic evaluation. This in-depth analysis of the condition and abilities of the knee—via medical history, physical examination, x-rays, MRIs, and so on—determines the necessity and the plan for the TKR. The evaluation process can take several weeks. By 2030, the demand for artificial knees, including full replacements, is anticipated to reach about 3.5 million patients in the U.S.—a nearly fivefold increase in less than twenty years.



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Europe/Middle East/Africa

Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific

Dassault Systèmes
Pier City Shibaura Bldg 10F
3-18-1 Kaigan, Minato-Ku
Tokyo 108-002
Japan

Americas

Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

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