Customer Story

Bausch + Lomb

Visualizes cataract surgery with SIMULIA

Without a doubt, it has helped us shorten our time to market, decrease our development costs, and improve our product performance.

Robert Stupplebeen
Bausch + Lomb
Design Engineer and Analyst

Challenge

To understand the design engineering issues involved in the highly complex cataract surgical process in order to improve products, procedures, and post-surgery visual acuity.

Solution

Abaqus FEA from SIMULIA solves large nonlinear deformations and difficult self-contact issues, helping engineers visualize a complex biomedical application that cannot be measured physically.

Benefits

Simulation of cataract surgical lenses, tools, and processes has shortened product design cycle iterations, decreased development costs, and improved product performance and surgical outcomes.

DASSAULT SYSTEMES

As populations age, the number of people with cataracts increases. By age 80, more than 50 percent of all Americans will have developed a cataract; every year, more than 3 million undergo eye surgery to correct it. The success rate is phenomenal: 95 percent of patients have vision restored to within a 20/20 (normal) to 20/40 (good) range.

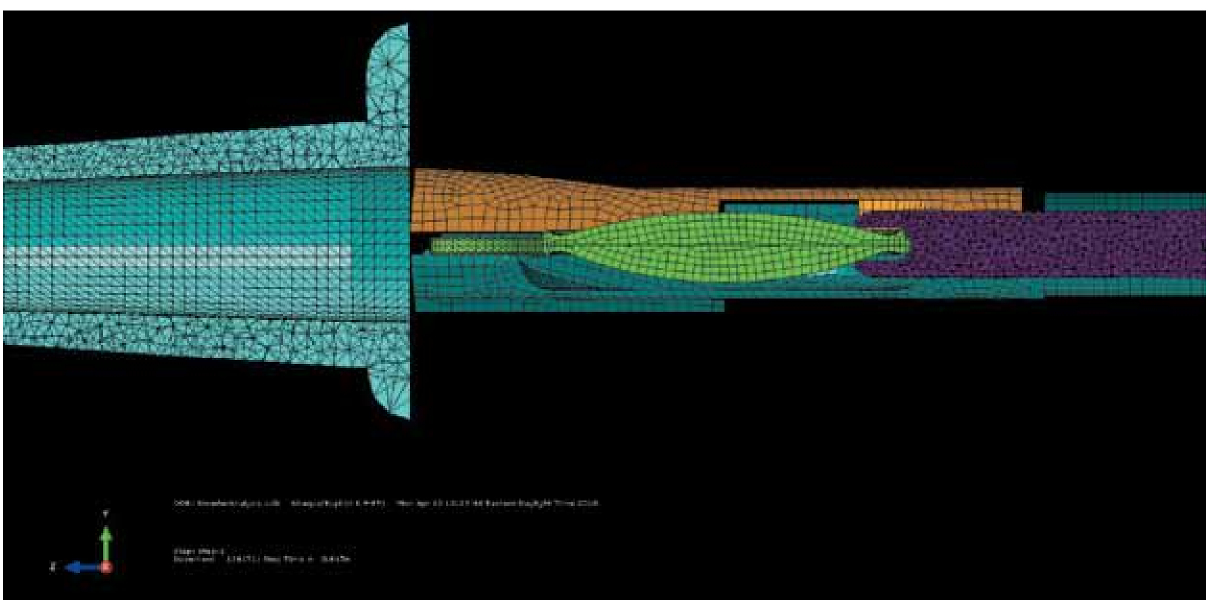
Modern cataract surgery was first performed in the late 1960s. Because the first prosthetic intraocular lens (IOL) was rigid, however, the incision required to insert it into the eye was large, required sutures, and made recovery long. Outcomes varied widely.

These outcomes are largely due to the development of deformable materials, including hydrophobic acrylic and silicone. When these materials became available in the early 1990s, incision size decreased dramatically and positive outcomes skyrocketed. The new materials could be rolled, folded, and bent during insertion. As materials evolved, the insertion process did, too, shifting from forceps to a tapering tube – similar to a syringe – that pushed the lens into the eye. Lenses are now being delivered through incisions as small as 1.8 mm.

With the size of the incision directly related to post-surgical vision aberrations, engineers at Bausch + Lomb in Rochester, N.Y., have recently set an ambitious goal of enabling incisions as small as 1 mm incision goal – nearly half the current minimum incision size. To achieve this, ongoing research and development is focused on new lens materials, improved lense geometry, and better inserter designs. Finite element analysis (FEA), with its ability to realistically simulate a wide variety of physical phenomena, is critical to this effort.

Simulation sees what can't be measured

Engineers at Bausch + Lomb have been using Abaqus FEA from SIMULIA, the Dassault Systèmes brand for realistic simulation, in biomedical applications for about a decade. It was first employed to model the conformation and deformation of contact lenses on the cornea; this helped predict lens



Section view of the FEA model used to simulate lens (IOL) insertion during cataract surgery. The IOL (green) is being pushed by the plunger (purple) and is about to enter the inserter tip (blue) through which it is delivered into the eye. The lens, tip, and plunger are modeled using deformable elements; the loading door (brown) and loading area (dark green) are modeled using rigid elements.

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> Robert Stupplebeen, *Design Engineer and Analyst at Bausch + Lomb*

performance, including optical properties. FEA also has been applied to improve cataract surgery tools and model manufacturing procedures.

“We use FEA in our iterative design process to shorten development time by analyzing each design or by developing design rules-of-thumb,” explains Robert Stupplebeen, design engineer and analyst at Bausch + Lomb. In short, FEA helps Bausch + Lomb test more designs, more quickly to arrive at optimized solutions.

To create its FEA models, the Bausch + Lomb team generally starts with 3D models created in SolidWorks, the Dassault Systèmes CAD brand for professionals, and then uses the software’s Associative Interface to import the model into SIMULIA Abaqus. From there, simulations are often coupled with other programs, such as SigFit, an optomechanical pre- and post-processor (developed by Abaqus Integration Program partner Sigmadyne), and ZEMAX, a comprehensive optical design software package.

When starting a new product design project, “getting sufficient biological test data can be problematic,” Stupplebeen says. “With just about any biomedical product or process development, a lot of assumptions need to be made.”

In the case of cataract surgery, the Bausch + Lomb product development team is focused on two primary modeling issues that can be confirmed by testing: the insertion force required to implant the lens, and the geometry of the lens as it emerges from the inserter. They also are studying what can’t be measured in real life, including the geometry and internal stresses placed on the lens by the inserter.

“We validate our model on the things we do know and then utilize the rest of what the model tells us to gain a better understanding of the physical behavior,” Stupplebeen says. “Without FEA, all of these things are just unknowns.”

The cataract surgery simulation setup requirements are stringent. “The analysis is highly non-linear with large deformations, difficult self-contact, sliding contact and hyper-elastic material properties. To handle all this in one model, we chose Abaqus/Explicit.”

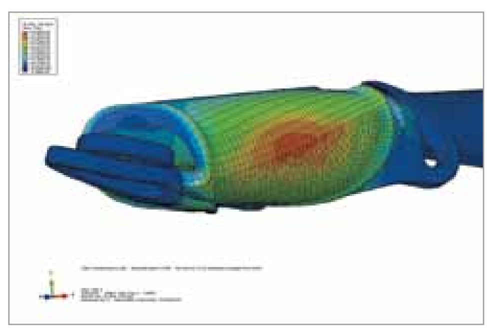
The model: lens, inserter, incision

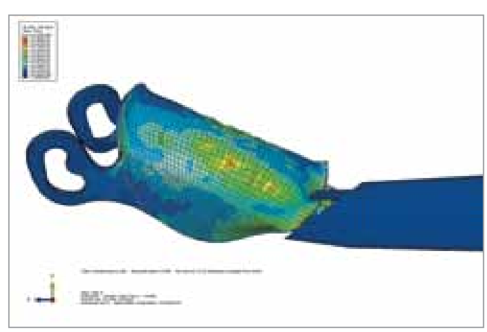
From an ophthalmologist’s point of view, the cataract surgical procedure is relatively simple: take a standard IOL, which consists of a circular lens with four appendages (haptics) that stabilize the lens in the eye; load the lens in the inserter and fill the inserter tube with a viscoelastic lubricant; make a small corneal incision and remove the damaged crystalline lens using an ultrasonic device; then place the inserter in the incision and push the plunger, inserting the IOL. The surgery typically takes less than ten minutes.

From an engineering perspective, however, the procedure is quite challenging due to the geometry: an industry-standard precision lens has a 6 mm diameter, a center thickness of 1 mm, and four haptics; an average incision is 2.8 mm.

“It’s like trying to suck a Frisbee through a vacuum,” Stupplebeen says. “During the insertion, the lens can experience strains in excess of 60 percent.”

To simulate the lens insertion process, the Bausch + Lomb team modeled an acrylic lens,





(Top) Lens strain is illustrated as the IOL is being pushed by the plunger inside the inserter during a cataract surgery simulation. Rare lens tear has been observed to occur at points of stress where the plunger contacts the IOL or on the trailing haptics.

(Bottom) Strain on the lens is shown as the IOL emerges from the tip of the inserter. The areas of highest stress correlated with the location of rare lens scratching. Values represent 0-60% strain.

with average lens and inserter dimensions, and applied several parameters to the model: hyper-elastic Neo Hooke material properties; Rayleigh damping to reduce low-frequency oscillations; general contact with zero friction (because of the smooth surfaces and lubricant); a nonlinear pressure-overclosure relationship to reduce contact penetration; and mass scaling to reduce solve time by a factor of ten.

The loading area of the inserter was treated as rigid and modeled using R3D4 elements; the lens, plunger, and tip were all treated as deformable using C3D8R and C3D4 elements. The model of the lens and inserter, which are designed in tandem because of their close interrelationships, is highly complex, with approximately 250,000 elements with more than 100,000 increments. To run the five-hour analysis, the team used a Cray CX1 with Windows HP Server 2008.

Validating lens strain and inserter forces

By using Abaqus, the team was able to calculate the force applied on the inserter versus the displacement experienced by the lens and then compare it with physical test data. The analysis yielded results that correlated well with the tests, which validated the simulations. The team was also able to measure strain on the lens while visualizing its deformation as it traveled through the inserter. These peak strain measurements correlated well with extremely rare failure modes (tip fracture, lens tear, and lens scratches) and were also found to occur in the same locations where past, real-world failures had occurred.

"Given the agreement between simulation results, physical tests, and observations, the validated model is being used to reduce the likelihood of failure modes, reduce insertion force, and develop the next generation of IOLs and inserters," Stupplebeen says. "As surgeons strive for smaller incisions, we have to develop a more compressible material, thinner lenses, and/or new inserter geometries."

FEA benefits are clearly visible

Whatever the product development direction, Abaqus FEA from SIMULIA is helping its designers and engineers reliably predict what will work. Since cataract surgery product design cycle time is typically about a year and a half, with an additional year for clinical trials, accelerating prototyping with realistic simulation provides tremendous bottom-line benefit.

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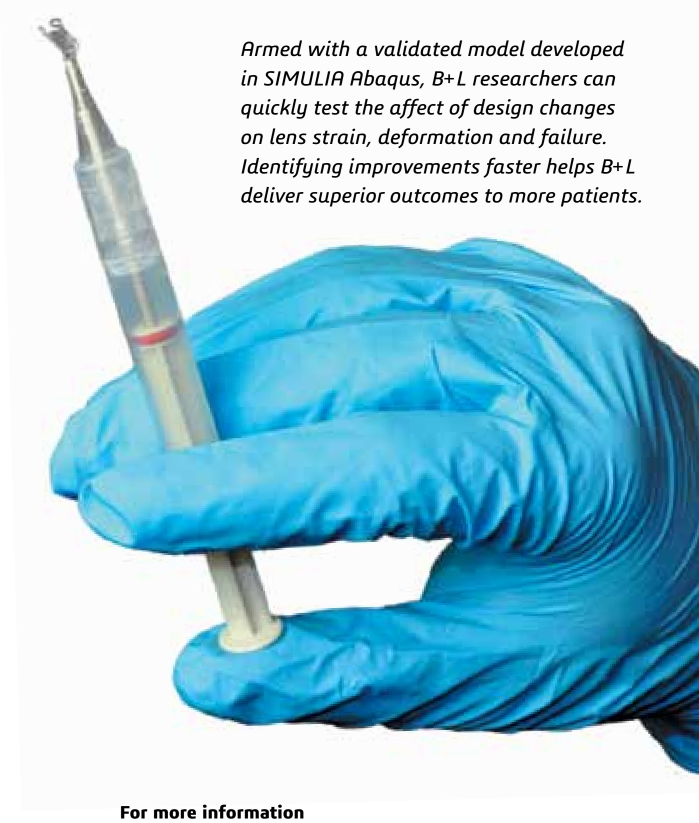

Armed with a validated model developed in SIMULIA Abaqus, B+L researchers can quickly test the affect of design changes on lens strain, deformation and failure. Identifying improvements faster helps B+L deliver superior outcomes to more patients.

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