A PERFECT VISION

To dramatically improve vision through customized patient-specific surgery, Optimeyes employs structural simulation in clinical ophthalmology.

By **Harald Studer**, Team Leader, Integrated Scientific Services AG, Biel, Switzerland

A cataract is a clouding of the lens of the eye that first blurs vision and can eventually lead to blindness if the lens becomes opaque. The World Health Organization estimates that nearly 18 million people worldwide are blind in both eyes because of cataracts, making this disease the cause of almost half of all cases of blindness. The main culprit is aging: Approximately half of all people older than 80 will suffer from cataracts to some extent.

The good news is that femtosecond laser surgery to remove the defective lens and replace it with an artificial intra-ocular lens is increasingly viable. In most cases, the surgery restores vision to the point that the patient has no need for glasses or contact lenses for vision correction. Still, about 30 percent of patients have to wear some form of corrective lens after the surgery. While this may seem like a reasonable outcome, the scientists and engineers at Integrated Scientific Services AG (ISS) knew they could do better.

Using knowledge of the structure and material properties of the various parts of the eye, especially the cornea, ISS teamed up with ANSYS to create Optimeyes — a clinical tool for ophthalmologists that runs ANSYS Mechanical in the background to produce patient-specific surgical strategies to improve results.

NONLINEAR MODELING FOR HEALTHCARE APPLICATIONS
ansys.com/91perfect
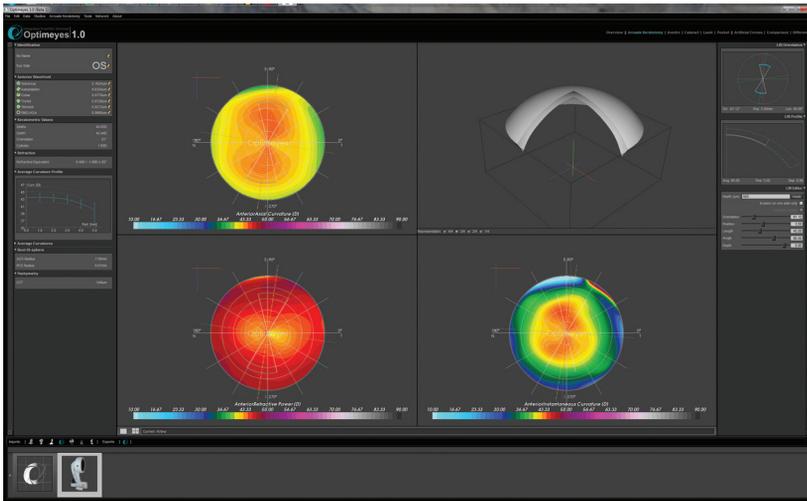
THE CORNEA IS THE KEY

The cornea is the transparent outermost layer of the front section of the eye, so virtually all eye surgeries, including the well-known LASIK procedure, involve cutting into the cornea to some degree. The details of where and how to make the laser incisions — the location, length, depth and angle of the cuts — are based largely on the doctor's experience, statistical information (so-called nomograms) and the properties of the average eye. The question is, what is the average eye?

The shape of the cornea is determined to a large extent by its stiffness and the internal pressure of the eye, also known as intra-ocular pressure. The cornea is a composite comprising collagen fibers in various orientations in a matrix of polysaccharides and cells called keratocytes. Ultraviolet light emitted by the sun causes crosslinks to form between the collagen fibers, adding shear stiffness to the cornea. Because our eyes encounter more UV light with time, our corneas — as any other
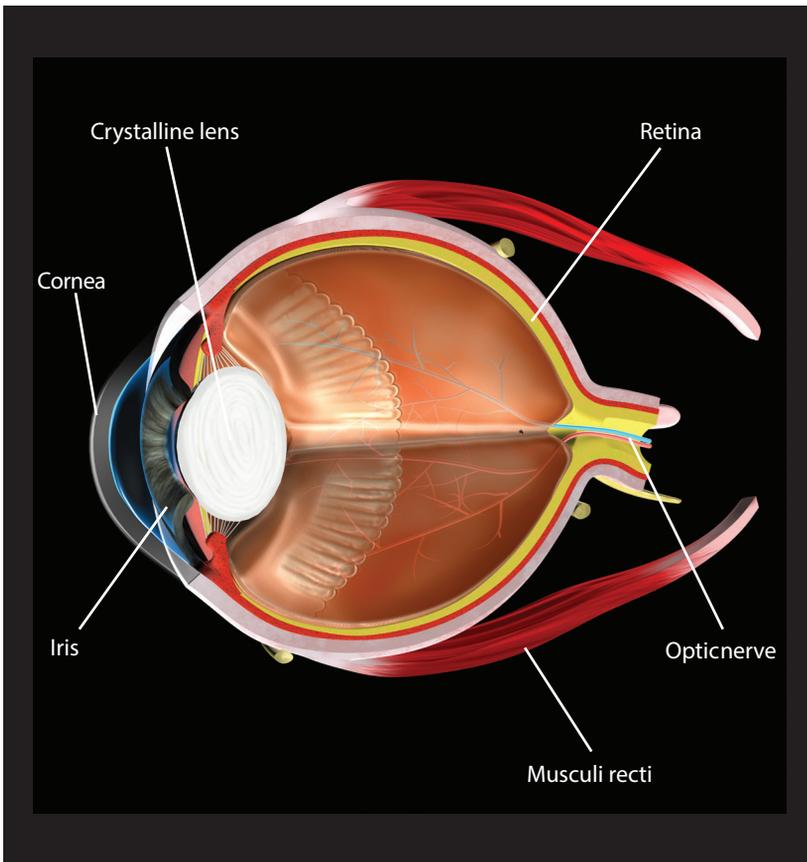
A clinical tool for ophthalmologists runs ANSYS Mechanical in the background.

▲ Optimeyes software user interface

Crystalline lens

Retina

Cornea

Iris

Opticnerve

Musculi recti

▲ The human eye

ANSYS Mechanical calculates the deformations of a patient-specific cornea for a given laser treatment.

soft biological tissue — become stiffer as we age. To model corneal biomechanics realistically, ISS implemented these distinct material properties in an inhomogeneous, nonlinear and anisotropic user-material Fortran function (usermat) in ANSYS Mechanical.

Intra-ocular pressure is caused by the amount of a clear fluid called the aqueous humor in the eye. This fluid is formed in the ciliary process behind the iris, and it then flows through the pupil and fills the space between the iris and the cornea. The combination of this internal pressure with the biomechanical stiffness of the eye tissue determines the unique shape, or how much an eye deviates from the average. The amount of deviation is critical in determining where and how to make incisions in the cornea to optimize the surgical outcome.

GETTING PATIENT-SPECIFIC

Optimeyes is a physician-friendly software product with a user interface that looks like other diagnostic software that ophthalmologists use routinely. This ensures the doctor's level of comfort with the product. The patient simply looks into a Pentacam® camera and the doctor sees a standard image of the cornea's front (anterior) and back (posterior) surfaces on the screen.

Meanwhile, a script starts ANSYS Mechanical, which works unseen in the background, using the camera image as the geometry for its finite element analysis (FEA) simulations. ANSYS Mechanical uses between 60,000 and 80,000 hexagonal mesh elements, organized in five layers, to produce a 3-D model of the cornea and part of the sclera (the white of the eye). The mesh is morphed to match the geometry of the patient's eye, and boundary conditions are applied to the clamped border of the sclera. The thickness of the cornea at any given point is measured as the normal distance between its anterior and posterior surfaces in the model. In this first step, the model produces a complete topography of the patient's eye without any intra-ocular pressure applied.

To account for the initial stress distribution in the cornea, caused by the intraocular pressure inflating it like a balloon, ANSYS Mechanical uses an inverse nonlinear process to determine the theoretical stress-free shape of the cornea. The difference between the stress-free shape

and the measured shape yields the actual 3-D stress distribution.

MAKING THE CUT

Even with all this modeling, another challenge remains: Laser surgery slightly deforms the cornea while cutting it, so this laser-induced deformation must be taken into account. Working together inside the clinical tool, ANSYS Mechanical calculates the deformations of a patient-specific cornea for a given laser treatment, and Optimeyes subsequently calculates surface curvatures and the length of the optical path of light rays passing through the cornea to predict the expected vision quality for the post-surgical eye.

To do this, ANSYS Mechanical simulates laser cuts in predefined areas of the mesh. When a standard intra-ocular pressure is applied to the model, the incision opens to reveal what kind of deformation will result from such a cut to the cornea. The result of the simulation appears on the Optimeyes screen for the doctor to review. An iterative, parametric workflow evaluates the impact of a given incision on the patient's post-surgical vision and adjusts the incision parameters to improve on the result. Ultimately, Optimeyes determines the optimized surgical procedure that will leave the patient with perfect vision. The complete process, from imaging the eye to optimized surgical model, currently takes about 20 minutes. The doctor then simply inputs the calculated optimized incision parameters — orientation, width and angle of incision — into the femtosecond laser instrument, and the instrument does the rest.

MOVING THE PRODUCT TO MARKET

As with any new medical instrumentation, Optimeyes has to go through very strict approval processes before it can be sold to ophthalmologists. ISS has started to perform clinical trials to demonstrate the effectiveness of Optimeyes in improving the post-surgical vision of cataract patients using this patient-specific approach compared to the currently used average-eye procedure. So far, Optimeyes has succeeded in correctly predicting surgical outcomes in all the cases studied. But more eye surgeries must be performed, and other steps taken, before approval can be granted.

The result of the simulation appears on the Optimeyes screen for the doctor to review. ▶
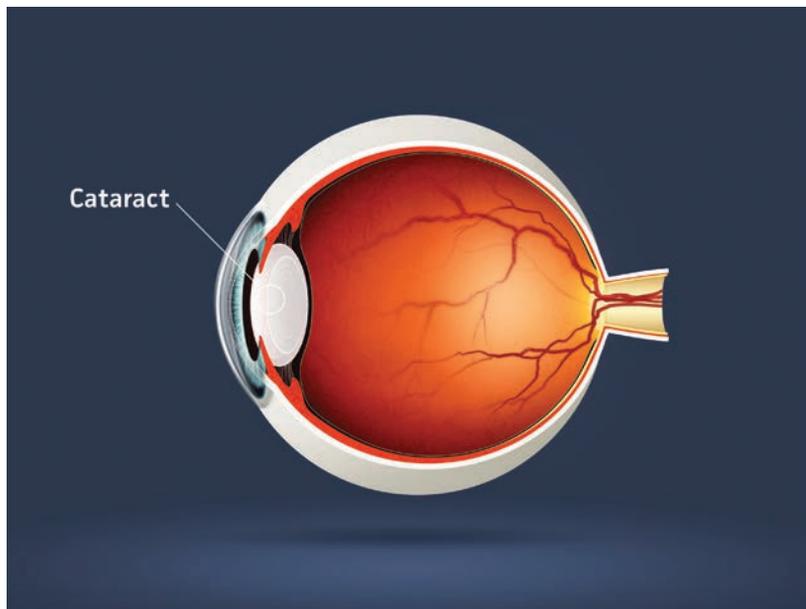
▲ Image of eye with cataract: opacification of eye lens

ANSYS specialists have been integral players on the development team every step of the way. The flexibility of ANSYS solutions and the cooperation of ANSYS technical personnel have been critical in achieving the progress made to date. ANSYS staff continue to work with ISS to improve Optimeyes as the company pursues the ultimate goal of selling the product to clinicians.

In the meantime, ISS offers Optimeyes Professional Service to R&D departments of other companies. Typically, they want to implant a device in a cornea and have questions about how deep to implant it to make sure that the cornea's anterior surface does not deform. ISS performs parametric sensitivity analysis simulations so they can answer their own questions.

A long-term goal is a project called Optimeyes Embedded, which will involve installing the software directly into a laser device so it does not have to run on a separate computer. Instead of having to connect it to a laptop, the laser instrument itself would make proposals for the optimized incision for the patient. This will require partnering with an ophthalmology device company.

ISS is excited about Optimeyes and its potential to provide perfect vision for millions of people around the world. Though the focus is on cataracts right now, Optimeyes has the power and capability to be adapted to many different types of eye surgeries to improve the precious gift of vision for so many people whose eyesight is impaired. ∧

Optimeyes has the potential to provide perfect vision for millions of people around the world.

▼