FEA of Prosthetic Lens Insertion During Cataract Surgery

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Abstract: Cataract surgery is the most common surgery in America today. Modern surgeries require the opacified crystalline lens to be removed and for a prosthetic lens to be inserted through a suture-less incision during a 5-10 minute outpatient procedure. The industry is driving for smaller incisions by redesigning the lens and insertion device geometry in addition to new materials. Typical lens dimensions are 6mm diameter with a center thickness of 1mm which is inserted through a 2.8mm incision. For the insertion the lens is folded and elongates while advancing down a tapering tube. Abaqus Explicit was chosen for this analysis because of its capability to solve large deformations and difficult self contact. During the insertion the lens can experience strains in excess of 60%. The purpose of this model is to increase our understanding of the mechanical response of existing products to aide in the design of our future products.

Keywords: Biomechanics, Biomedical, Contact, Self Contact, Abaqus/Explicit, Hyperelasticity, Implantable Medical Device, Large Deformation, Optics, Visualization, quasi-static.

1. Introduction

Cataracts develop as part of the natural aging process. The crystalline lens which is located behind the iris and is responsible for the focusing of light becomes hardened and opaque. If left untreated blindness would inevitably result. Insertion of a prosthetic lens following cataract removal began with a rigid PMMA intraocular lens (IOL) which required an incision roughly half way around the cornea. The medical community has made significant strides in the improvement of this procedure by improving outcomes, reducing recovery time and simplifying surgical techniques.

Current surgeries employ a highly deformable silicone or acrylic lens utilizing an inserter instead of forceps. The lens is loaded into the inserter and pushed with a plunger down a tapering tube. Internal areas of the inserter are filled with viscoelastic (viscous aqueous substance) to lubricate the surface and to prevent the introduction of air bubbles into the eye. The end of the tube is placed through an incision in the eye and the lens is allowed to bloom inside of the eye behind the iris. The driving factors in reducing the incision size to 3mm and below removes the need for sutures to seal the wound and reduces surgically induced astigmatism. Now the driving factor is to further improve visual outcomes. The size of the incision is directly related to optical aberrations that will remain after healing. Incisions less than 1mm have been proposed which is currently the limit of the additional surgical instruments used in the procedure.

The design of the inserter and the lens directly affects the incision size during surgery. A smaller lens allows for a smaller incision however a smaller optic can create glare and halos for the patient if the pupil dilates larger than the optic diameter. Because of this and many similar tradeoffs lens and inserter design ideally are created in tandem. A convenient metric for assessing the performance of the inserter lens system is to divide the cross sectional area of the lens by the inserter's area. The currently available lens inserter system which is presented in this paper has a 2.2 compression ratio. To achieve a 1mm incision a 3.3 compression ratio is needed.

2. Model

SolidWorks was used to create all of the solid CAD geometry. This data was imported utilizing the SolidWorks Associative Translator. Abaqus/CAE was used for finite element model creation. Abaqus/Explicit was selected as the solver to employ it's robust contact algorithms and tolerance of extremely large deformations.

Geometry

The IOL geometry consists of 2 discrete parts, the optic body and the haptics as shown in Figure 1. The haptics are used to stabilize the lens in the eye. They press onto the equator of the capsular bag which held the now removed cataract.

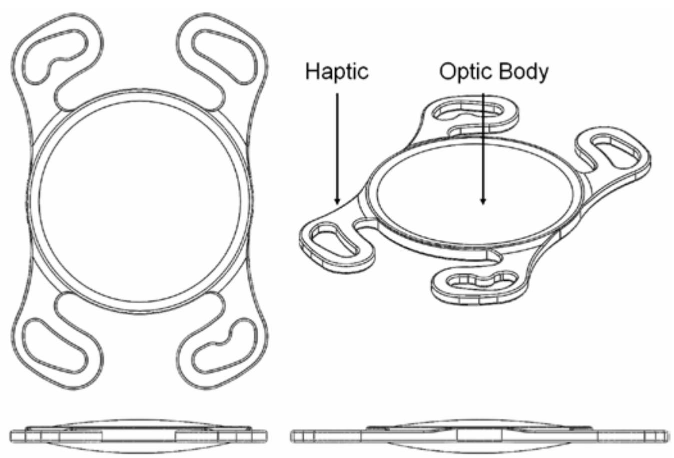

Figure 1. Lens geometry.

The critical features of the inserter are the plunger, loading area and tip as shown in Figure 2. The IOL is placed in the loading area. The tip is snapped over the loading area. The inserter tip is inserted through a corneal incision. Then the IOL is then advanced by the plunger down the tip.

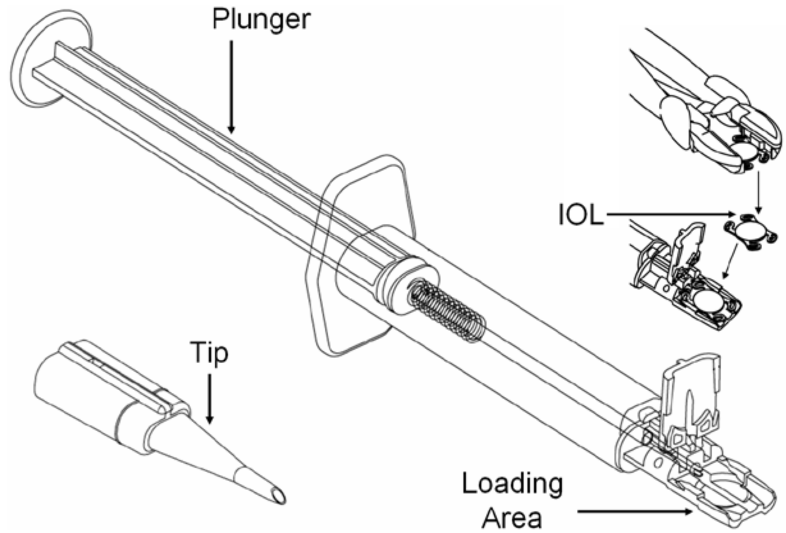

Figure 2. Inserter geometry.

Materials

The lens material has been tested by compressing buttons with a load frame. The material has been fitted with a hyperelastic Neo Hooke material model. Rayleigh damping which utilizes Equation 1 has been applied to the material model to reduce low frequency oscillations. For this application only • (mass proportional) damping was utilized. • (stiffness proportional) damping was not used because it reduces the stable time increment and in turn increases the solution time. Since • damping was not used, the second half of the equation can be negated. The first natural frequency of the lens was predicted with a separate modal analysis. The damping value selected was 5% which is very conservative for this application because of the visco-elastic fluid filling the loading area and tip. Linear elastic vendor data is being utilized for all inserter parts.

Equation 1. Rayleigh damping.

$$\xi_i = \frac{\alpha_R}{2\omega_i} + \frac{\beta_R \omega_i}{2}$$

Boundary Conditions

In use the inserter remains relatively stationary while the surgeon pushes on the plunger. The insertion velocity was chosen to deliver in 2 seconds, which is the fastest that delivery would be performed in practice. The choice of the fastest delivery allows for a reduced step time and in turn less computational time. General contact has been applied to the model with zero friction because of the smooth surfaces and the lubricant used. A nonlinear pressure-overclosure relationship was used to reduce contact penetration.

Step Properties

Due to the quasi-static nature of this analysis mass scaling was utilized to greatly reduce the solve time. This is accomplished by artificially increasing the mass of all elements with stable time increments below the specified value. The kinetic energy of the lens was less than 4% of its internal energy throughout the step. This value is deemed acceptable and is a desirable trade off for the 10x reduction in solution time.

3. Results

Several images of the deformed geometry can be viewed in Figure 3 - Figure 6.

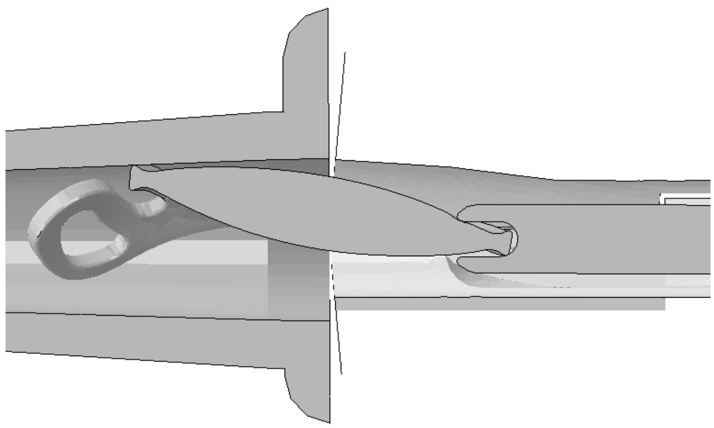

Figure 3. Strain of sectioned geometry (0-60%).

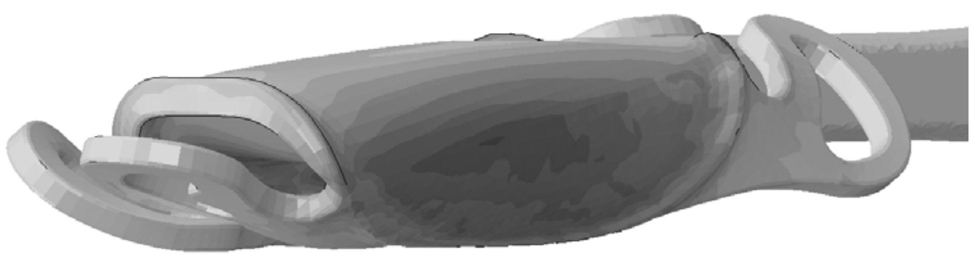

Figure 4. Strain of lens and plunger (0-60%).

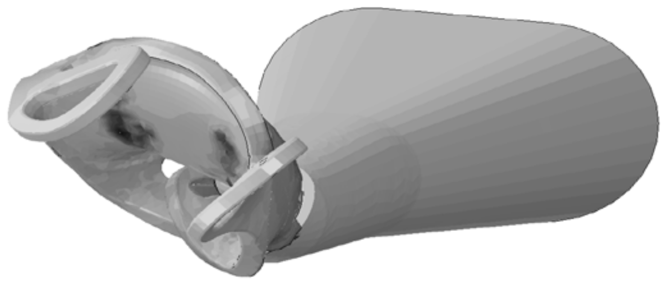

Figure 5. Strain of final deformed geometry (0-60%).

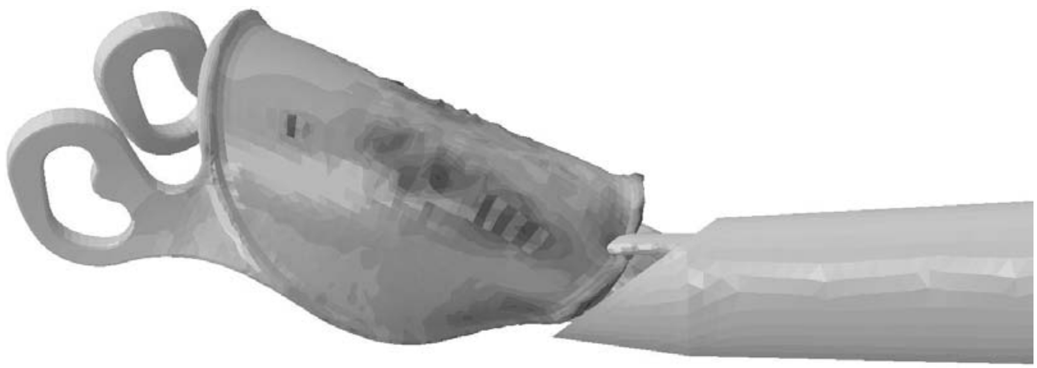

Figure 6. Strain of final deformed geometry (0-60%).

A critical design feature of an inserter system is the force required by the surgeon to deliver the IOL. Test data is plotted with the FE predicted data in Figure 7. The test results are the thin lines. The unfiltered data is the diamonds. The thick line is the filtered data. The FE data needs to be filtered with a moving average to remove some noise inherent in an Explicit analysis. It can be seen that the FE results predict within roughly 10% of the test data. This disparity is likely due to the absence of friction and visco-elastic in the model. At the end of the data set there is a significant divergence which attributed to a spring that retracts the plunger which was not modeled.

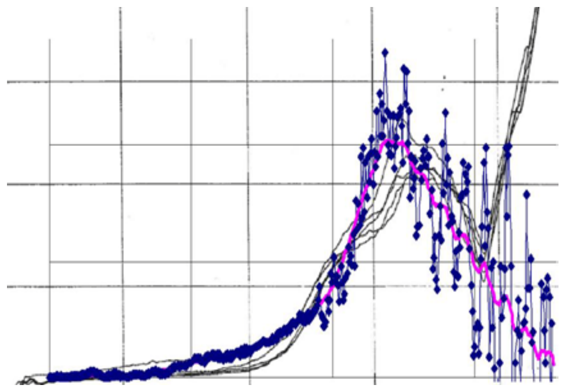

Figure 7. Test and FE comparison of Plunger Force vs. Displacement.

There are several extremely rare, failure modes of the system: tip fracture, lens tear and lens scratches. Tip fracture occurs in the most compressed region of the inserter. The fracture usually propagates from just inbound of the inserter end. The maximum strain in the tip across all time steps is shown in Figure 8. The deformed geometry with the lens fully compressed is shown in Figure 9. This location agrees well with historical failure modes.

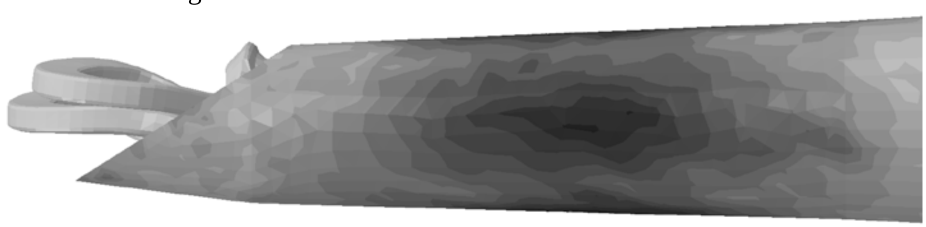

Figure 8. Strain of maximum compression (0-0.3%).

Figure 9. Strain at maximum compression of lens (0-60%).

Lens tear typically occurs where the plunger contacts the IOL or on the trailing haptics. Figure 10 shows the maximum stress in the lens across all time steps. There is a significant stress concentration and localized deformation where the plunger is pushing the IOL.

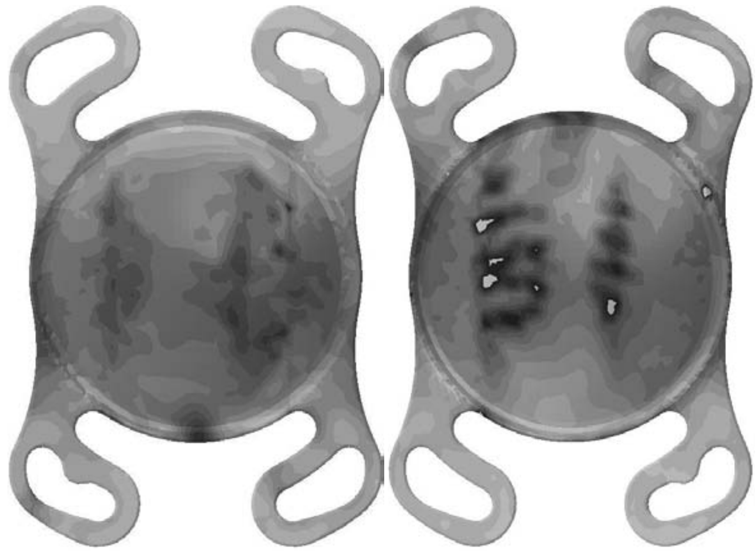

Figure 10. Maximum strain in IOL across all time points, anterior and posterior respectively (0-100%).

The optic body can become scratched during delivery. This is expected to occur where contact pressures are highest as shown in Figure 11. Large strain values also could increase the susceptibility of scratching as shown previously in Figure 9. These locations agree well with historical locations where scratches occur.

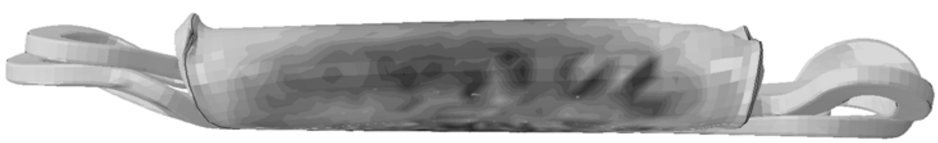

Figure 11. Contact pressure on the IOL in fully compressed state with contours (0-1.5MPa).

4. Conclusion

Abaqus/Explicit is able to model this highly nonlinear event with sliding self contact and large deformations. The model has accurately predicted insertion force and likely failure locations where peak stresses are developing. This validated model is being used to help develop the next generation of IOLs and inserters which will experience much more demanding loading conditions.