Personalized Medical Devices: Contact Lens

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Optimal Device

1.1 Abstract

Personalized medical devices require 3 enabling technologies: biometric measurements, automated simulation and customized manufacture. Every customized device be it an external prosthetic or an implantable device will follow a similar workflow. For the purpose of this paper, a customized contact lens design will be investigated. A contact lens in essence is an optical suction cup which corrects the abnormalities of the patient's vision. The lens interfaces with the anterior surface of the cornea by way of a suction pressure. This suction pressure is balanced by the energy stored in the deformed shape of the contact lens. The lens is free to move on the cornea finding its equilibrium position which will be unique for each eye.

Many patients can be served by off the shelf lenses however for some patients this does not work. There are a variety of conditions that could cause this. Trauma can cause irregularities. Severe astigmatism, where, the optical power of the eye is different as you go around the eye is likely. Keratoconis is where the cornea thins and sags. The current standard of care, for these cases, has an eye care practitioner either optometrists (O.D.s) or ophthalmologists (M.D.s) measure the refraction error and the central corneal curvature with a keratometer. Working with custom contact lens labs, who CNC each lens individually with a diamond tool. They will design a contact lens for each unique patient through diagnostic fitting lenses, intuition and trials. In this study we are investigating the use of corneal topographer data, simulation and optimization to improve the outcomes and reduce the iterations. Point cloud data from an Eaglet-Eye ESP corneal topographer has been imported into Catia using Digitized Shape Editor. NURBS geometry for the clear cornea and white scelera were created with Quick Surface Reconstruction also within Catia. Various contact lens geometries have been modeled in Catia, SolidWorks and Abaqus/CAE. This simulation includes multiple non-linearities such as hyperelastic material properties, large deformation and sliding contact. Isight has been used to automatically modify lens geometry, optimizing comfort and fit of the contact lens.

1.2 Background

There are many ocular conditions that require the use of corrective lenses. The most common ones are myopia, hyperopia, astigmatism and presbyopia. Myopia is commonly referred to as nearsightedness and in this condition light is focused in front of the retina. Distance vision suffers and near vision can be good. To correct this minus powered lens are used. Hyperopia is commonly referred to as farsightedness and in this condition light is focused behind the retina. Near vision suffers and distance vision can be good. To correct this plus powered lens are used. With astigmatism light is focused differently with rotating angle. To correct this toric lens are used and they typically also correct myopia or hyperopia. With presbyopia the body's ability to adjust focus called accommodation. The crystalline lens behind the pupil becomes less elastic and thicker. Around the age of 40 the symptoms are usually noticed.

These conditions can typically be corrected with spectacles, contact lenses, refractive surgeries such as LASIK or with intraocular lenses. This paper will focus on contact lenses. There are also options for each lens to be uniquely designed and machined for the patient's specific needs. The specific design is sent to a specialized lathing process called a Single Point Diamond Turning (SPDT) where the lens is cut by rotating the lens while in contact with a sharp diamond cutter.

1.3 Methods: Biometric Measurements

An Eaglet-Eye ESP ocular topograph was used to create scans of the eyes. The ESP can measure the corneal and scleral surfaces up to 20mm. It can measure the cornea limbus and scleral part of the eye. The technology is called Fourier profilometry. To obtain an image it is necessary to instill fluorescein to make the sclera reflective for light.

Figure 1 Eaglet-Eye ESP ocular topograph utilizing Fourier profilometry

Several different eyes were scanned and have been renamed with generic descriptive names such as: average, steep and flat for patient privacy. Steep and flat refers to a smaller or larger radius of curvature respectively. These scans were exported as CSV text files from the ocular topogropher.

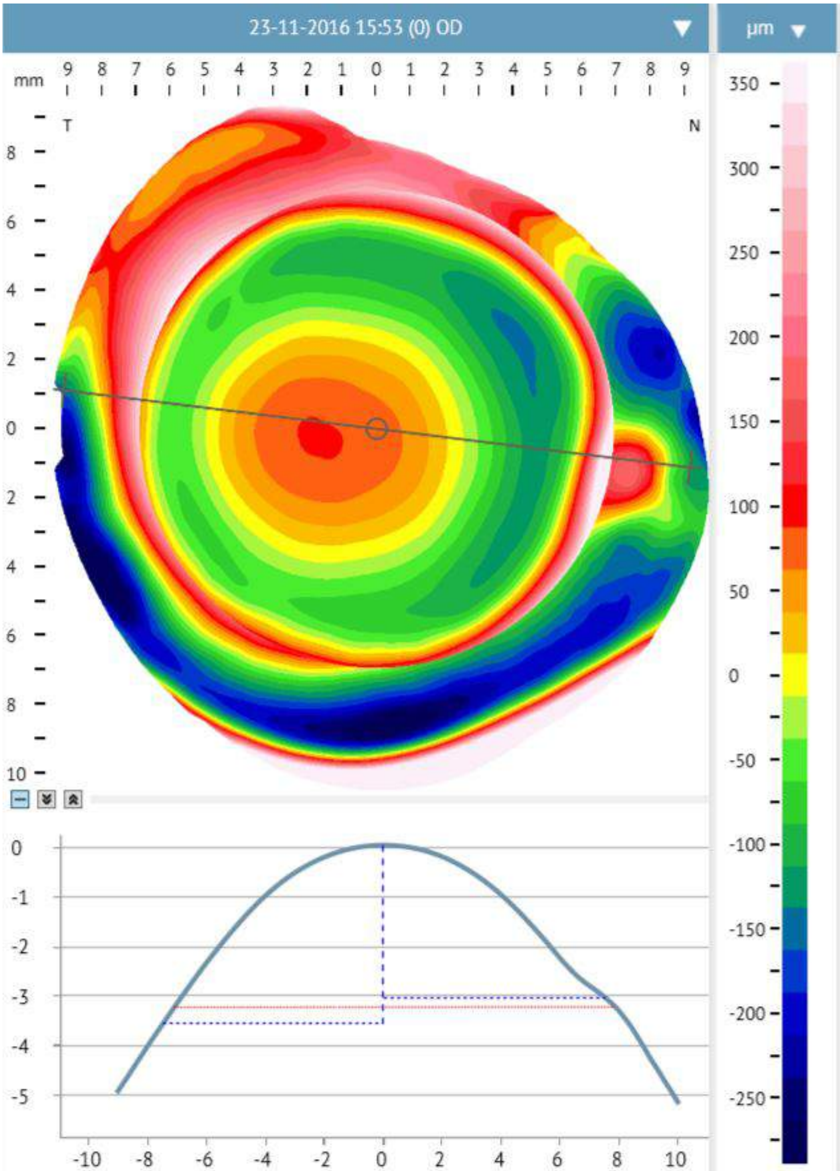


Figure 2 Outputs from Eaglet-Eye ESP of an eye with a pinguecula. The contour plot depicts deviation from a bi-sphere

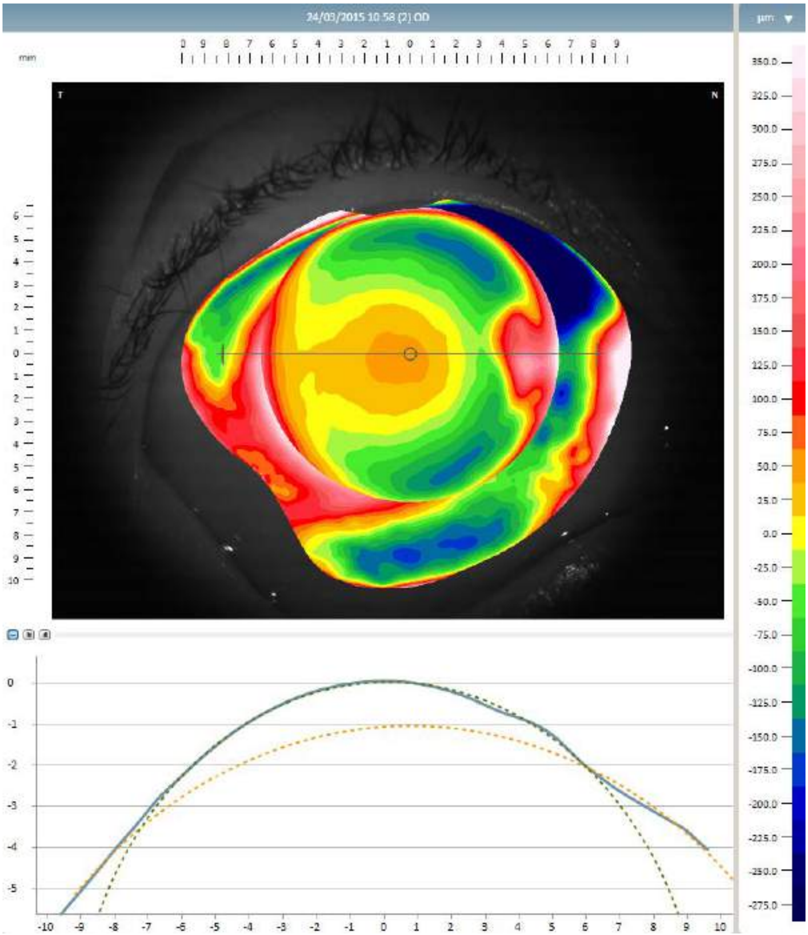


Figure 3 Outputs from Eaglet-Eye ESP of an eye with a pteryium. The contour plot depicts deviation from a bi-sphere

1.4 Methods: CAD

In Catia the digitized shape editor workbench was used to import the point cloud data. Also, in Catia the quick surface reconstruction workbench was used to create a mesh which is the first step in going from point cloud to NURBS geometry and should not be confused with an FEA mesh. Healing and smoothing operations were performed as needed to create the NURBS surface of the anterior surface of the patient’s eye. These steps are detailed in the figures below.

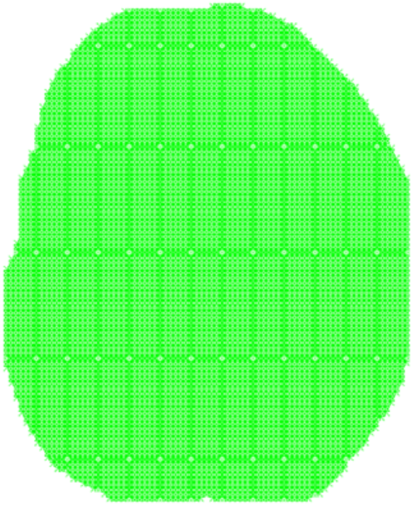


Figure 4 Point cloud imported with Catia's Digitized Shape Editor

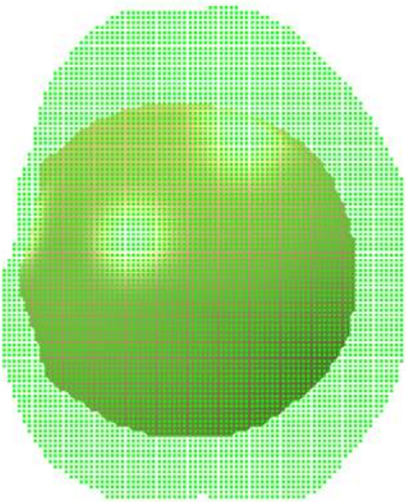


Figure 5 Mesh created with Catia's Quick Surface Reconstruction

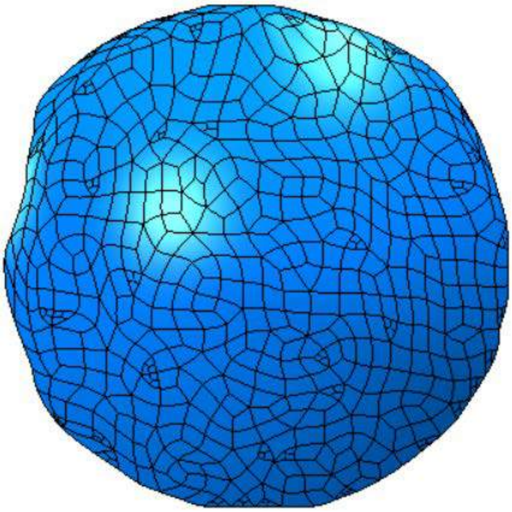


Figure 6 NURBS surface created with Catia's

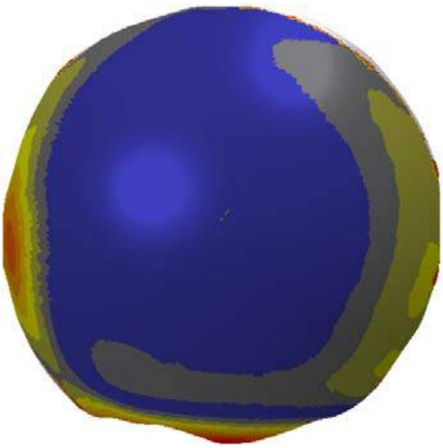
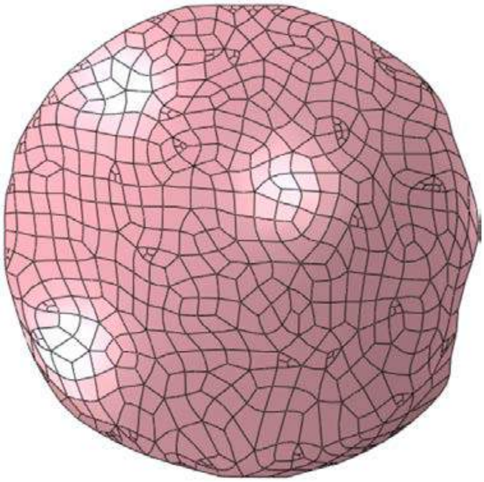


Figure 7 Catia Distance Analysis Eye vs. Best Fit Sphere to visualize the unique topography of this patient's eye



1.5

Figure 8 Exported STEP file

Contact lenses were modeled in SolidWorks. Due to the proprietary nature of the designs generic lenses have been created. Several lenses were created corresponding to different lens powers. They will be called mid, high and low power. They were exported as SAT files because this format is the native format of Abaqus/CAE.

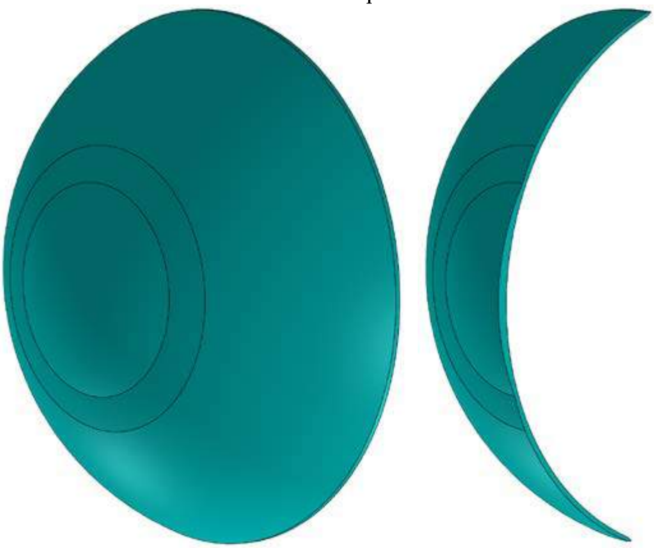


Figure 9 SolidWorks models of generic contact lenses

1.6 Methods: FEA

Patient specific Eaglet Eye Scans were imported as Rigid Bodies and meshed with R3D4 elements.

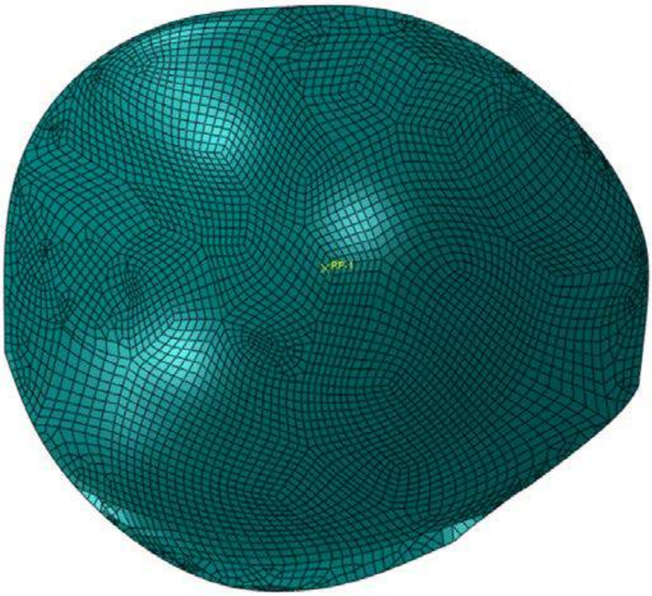


Figure 10 FEA mesh on eye

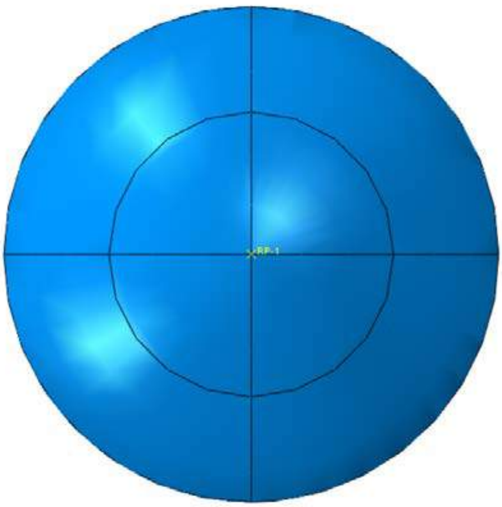


Figure 11 Imported contact lens sectioned to allow for a hex mesh

The lenses were imported as STEP files and meshed with C3D8R elements.

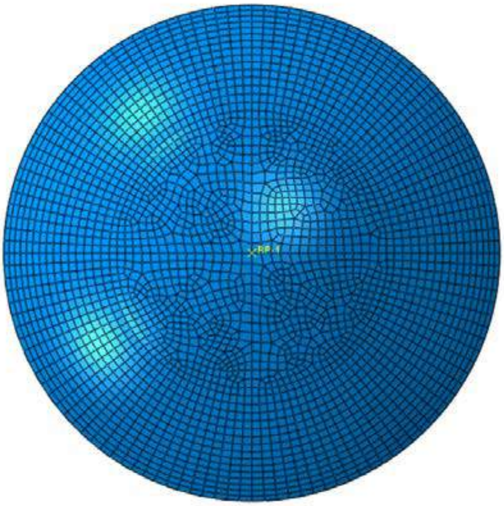


Figure 12 Meshed contact lens

Hyperelastic material properties were used for the lens. Calibration for the material properties was presented in the 2013 Simulia Customer Conference in the paper titled 'Reverse-Engineering of Contact Lens Mechanical Properties from an In Situ Compression Test'. In this

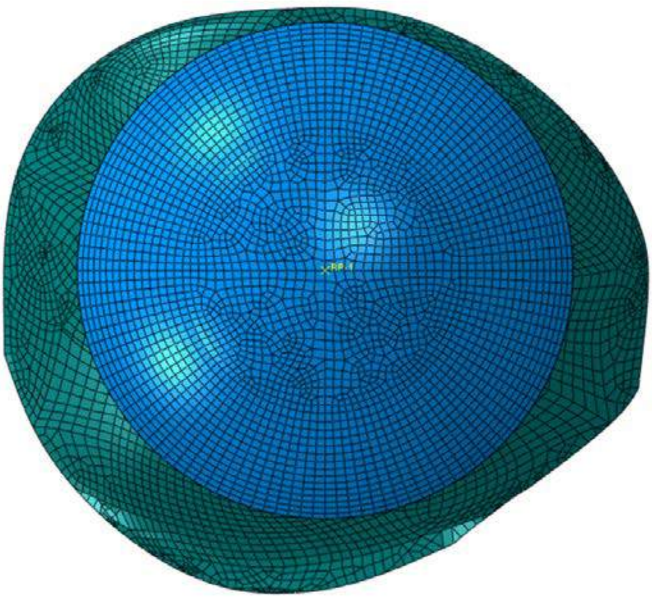


Figure 13 Assembly of contact lens on positioned near the eye ####UPDATE###

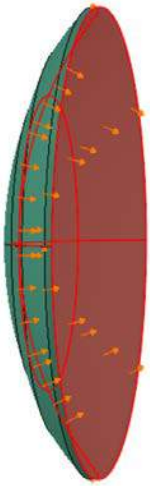


Figure 14 Suction pressure on contact lens posterior surface

Figure 15 Surface to surface contact with finite sliding between the lens and eye

Note that due to the non-uniform geometry of the eye scans that the contact lens initially has a gap between it and the eye scan.
Nlgeom has been turned on and incrementation has been changed to a Maximum number of increments of 1e5 an initial increment size of 1e-3 and minimum of 1e-8 and a maximum of 0.1. The author has found these to be good initial settings for sliding contact problems with large deformations.

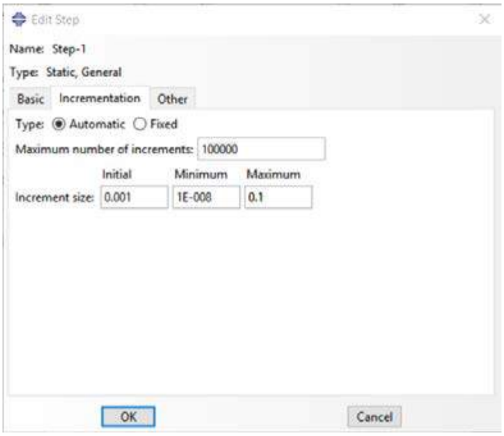
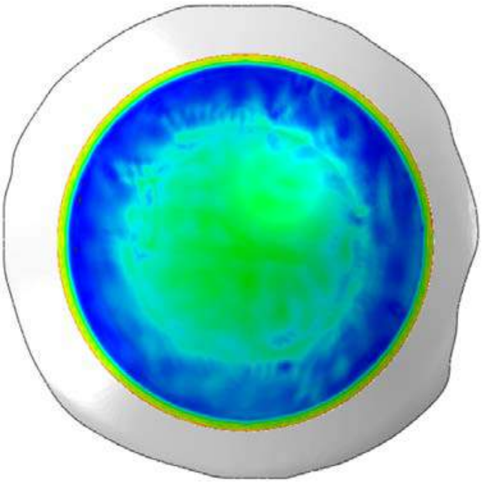


Figure 16 Step definition

1.7 Results



1.8

Figure 17 VonMises Stress upon full conformation

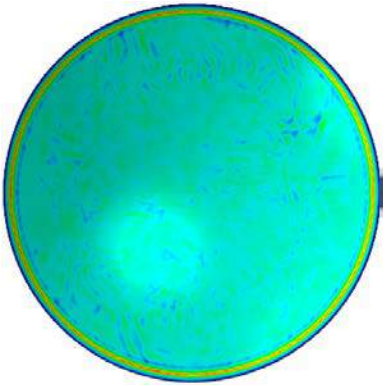


Figure 18 Contact pressure on the posterior surface of the contact lens

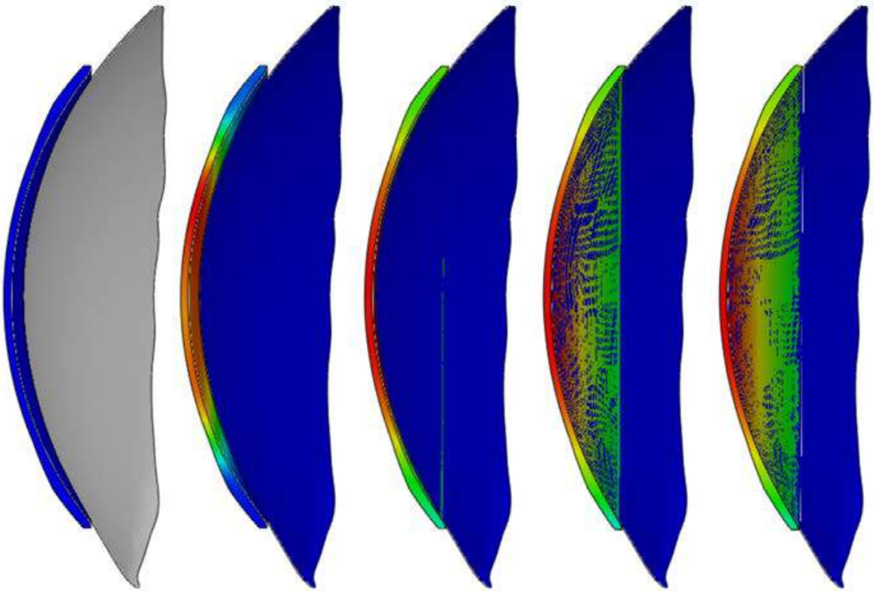


Figure 19 Progression through steps of right section cut of conformation with displacement contour plotted

1.9 Conclusion

The use of patient specific biometric data along with realistic simulation has proved to predict and improve clinical outcomes. For this system to work 3 things are needed

1. High resolution biometric scans of the cornea and scelera, which are provided by Eaglet-Eye ESP
2. Robust non-linear finite element solver to provide realistic in silico modeling of the conformation of a contact lens on a patient specific eye

3. Rapid manufacturing to make time and cost a viable product which is provided by Single Point Diamond Turning SPDT

This methodology can be applied to a wide range of problem sets and the author plans on expanding this workflow to these. Hearing aids, performance monitors and headphones can all be customized with scans and 3D printing. In this case comfort is critical. Footwear is being customized based on customer specific scans and could be further enhanced by including expected loading to maximize comfort or performance. In conclusion, with the convergence of simulation, scanning, and rapid manufacturing customized products can be realized to improve key performance attributes and differentiate in an otherwise commoditized market.

1.10 References

Blog post for this work "Personalized Medical Devices Contact Lens"
http://optimaldevice.com/blog/personalized-medical-devices-contact-lens
G. Richardson and R. Stupplebeen SCC2013 "Reverse-Engineering of Contact Lens Mechanical Properties from an In Situ Compression Test"
http://www.allaboutvision.com/contacts/custom-contact-lenses.htm