Deformable Surface Accommodating Intraocular Lens: Second Generation Prototype Design Methodology and Testing

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Purpose: Present an analysis methodology for developing and evaluating accommodating intraocular lenses incorporating a deformable interface.

Methods: The next generation design of extruded gel interface intraocular lens is presented. A prototype based upon similar previously in vivo proven design was tested with measurements of actuation force, lens power, interface contour, optical transfer function, and visual Strehl ratio. Prototype verified mathematical models were used to optimize optical and mechanical design parameters to maximize the image quality and minimize the required force to accommodate.

Results: The prototype lens produced adequate image quality with the available physiologic accommodating force. The iterative mathematical modeling based upon the prototype yielded maximized optical and mechanical performance through maximum allowable gel thickness to extrusion diameter ratio, maximum feasible refractive index change at the interface, and minimum gel material properties in Poisson's ratio and Young's modulus.

Conclusions: The design prototype performed well. It operated within the physiologic constraints of the human eye including the force available for full accommodative amplitude using the eye's natural focusing feedback, while maintaining image quality in the space available. The parameters that optimized optical and mechanical performance were delineated as those, which minimize both asphericity and actuation pressure. The design parameters outlined herein can be used as a template to maximize the performance of a deformable interface intraocular lens.

Translational Relevance: The article combines a multidisciplinary basic science approach from biomechanics, optical science, and ophthalmology to optimize an intraocular lens design suitable for preliminary animal trials.

Introduction

Natural accommodation is the eye's ability to change the shape of its lens, and thereby change its focal distance. This allows an individual to focus on an object at any given distance in their view with an autonomic nervous system feedback response. The person does this automatically, without thinking, by innervating their ciliary body muscle in the eye. The ciliary muscle adjusts radial tension on the natural

lens and changes the lens' curvature, which adjusts the focal distance of the eye in order that one may focus on a given object.¹

Without the ability to accommodate, lenses such as reading glasses must be relied upon to focus desired objects. Typically, cataract surgery will leave the individual with a fixed focal distance, typically greater than 20 feet. For activities such as computer work or reading, they need separate glasses.²

Several attempts have been made to restore accommodation with cataract surgery. The most

Figure 1. Bicameral design in intraocular configuration.

successful of these rely upon lenses with two or three discrete focal distances. The results has been fair, but the design compromises the overall quality of the vision and the continuous quality of natural accommodation.³

The concept of an extruded gel interface intraocular lens has been examined by several developers with successful animal and first stage human implantation.^{4,5} These concepts all incorporate a shape changing interface using the radial zonular tension provided by relaxation of the ciliary muscle. The zonular tension is then translated to provide an anterior vectored force on the accommodating lens allowing it to alter the curvature of the lens' interface and the overall lens power.^{4,5} The extruded gel intraocular lens (IOL) concept extrudes a gel material through a rigid circular aperture, which deforms in a more or less spherical shape. The increasing spherical deformation creates a variable lens that is directly proportional to the force applied to it by the zonular tension. Mechanically accommodating lenses rely upon the complex autonomic negative feedback control present in natural accommodation, which adjust the zonular tension to maximize the image clarity of a visual target.⁶ The amount of zonular actuation force on the intraocular lens is expected to reset via the negative feedback response just as it does with physiologic changes in the natural lens, provid-

ing the forces are in the possible physiologic range. In an effort to use the negative feedback accommodative control, a bicameral chamber was added to previous designs with a lower index of refraction silicone gel material in the posterior chamber and a higher refractive index silicone oil anterior chamber.^{4,5} In this manner, the gel interface is extruded through the internal rigid polymethyl methacrylate (PMMA) aperture and reduces the overall power of the lens in a physiologic manner.⁷ The anchoring haptic design provides a stationary support for the IOL, which prevents the whole lens from translating anteriorly during accommodation. The extruded gel design's efficacy has been shown in vivo, replicating accommodation with the eye's available natural accommodating force.^{4,5} Figure 1 illustrates the bicameral design of the extruded gel IOL in intraocular configuration.

The outer shell is that of a rigid spherical lens. When the ciliary muscle is relaxed (during distance focusing of the eye), tension is increased on the zonules and the lens capsule and applied pressure extrudes the gel through the aperture acting as a variable power lens directly proportional to the physiologic accommodative force. Conversely, during near focus the ciliary muscle contracts relaxing the tension on the zonules and the capsular membrane. The relaxed tension decreases the pressure and

Figure 2. Schematic of extruded interface testing prototype for examining interface characteristics.

reverses the extrusion increasing the power of the lens, equivalent to natural accommodation.¹

There is a small available force applied by the capsular membrane (~1 g) that must be sufficient to actuate the lens and alter its power sufficiently.⁸ The present study examines the ex vivo force requirements and image quality for this type of accommodating intraocular lens. Additionally, factors necessary to optimize the lens efficacy and quality are delineated for future developers and designers of accommodating intraocular lenses.

Methods

The extruded interface is recognized as the critical component of the gel accommodating lens. The other components fixate and maintain a base dioptric power to the lens, which have been shown effective in

prior studies.^{4,5} A prototype was constructed solely to examine the mechanical and optical properties of the extruded interface. The prototype was constructed from PMMA as a piston-cylinder mechanism pushing the silicone gel through a rigid aperture into a glycerin filled cavity. The glycerin had a higher refractive index at 1.47 than the silicone gel at 1.43, thereby creating an increasingly negative powered lens as the silicone gel is extruded. The modulus of elasticity of the silicone gel was approximately 1.0 KPa with a Poisson's ratio of 0.49. A bubble of gas was placed in the glycerin chamber to act as a compressible fluid allowing extrusion of the gel in the enclosed cylinder. The gas would be replaced by an equatorially expanding interface in the intraocular version of the IOL. Figure 2 depicts the interface prototype used to examine the extruded gel lens interface characteristics. Figures 3 and 4 are the full intraocular lens scaled prototype with an identical interface design.

A testing apparatus was constructed to apply measured force to the prototype lens while determining focal distance and taking images from an 8.0 MP CMOS F/2.4 camera (Sony, Tokyo, Japan) focused at infinity. Target objects were placed at various distances to determine imaging, focal length, and the corresponding force.

Topography of the interface extruded under pressure was measured with a Veeco profilometer (model NT9800; Veeco, Plainview, NY) using broadband optical interferometry. The measurement was used to verify predictive modeling with finite element analysis (FEA). Optical transfer function (OTF), modulation transfer function (MTF), and visual

Figure 3. Schematic of intraocular lens scaled prototype with an identical interface design.

Figure 4. Photograph of intraocular lens scaled prototype.

Strehl ratio have been used to measure optical quality of intraocular lenses.^{9–11} The MTF was measured by analyzing an image of a patterned test object in best focus through the actuated lens. The lens pupil was maintained at the central 3 mm of extruded interface. The image taken on the camera with and without the actuated lens in place was analyzed for the MTF intensity over spatial frequency using software from Quick MTF (model 2.04; Quick MTF, Kiev, Uk-

raine). The visual OTF was calculated by weighting the OTF obtained from the MTF by the Movshon formula for contrast sensitivity over the angular spatial frequency.¹² The measured visual Strehl ratio was calculated by the quotient of the integrated aberrated visual OTF to the integrated ideal visual OTF.

A model of the extruded gel accommodating lens was produced and verified with the measured lens extruded interface contour and found to have good correlation. The model's purpose was to run iterations examining the predicted performance (OTF and Strehl) of the lens while altering the mechanical and optical parameters in the lens' construction. The parameters examined were aperture diameter, gel thickness, ratio of aperture diameter to thickness, index of refraction change over the interface, pressure applied, gel elastic modulus, and gel Poisson's ratio.

The mechanical behavior of the interface was first modeled to determine the shape of the deformed interface. A finite element model (Algor; V23, Pittsburg, PA) was constructed based upon the posterior gel material. The model was constructed of three-dimensional brick elements, which maintain isotropic properties including a very low Young's and Shear modulus of elasticity. Lamellar boundaries were maintained and adjacent elements in overlying lamellae were fused. Figure 5 illustrates the wire mesh model of the actuated extruded gel surface creating the accommodating portion of the lens.

Silicone gel modulus of elasticity (Young's) was input approximately 1.0 KPa. Poisson's ratio was approximately 0.47. Nonlinear modulus of elasticity

Figure 5. Finite element model of the extruding gel surface through an aperture.

Figure 6. Accommodating image through the prototype focused at 3 m (A) and at 15 cm (B).

was used in development of the model. A 6-mm diameter gel disk of varying thickness (0.5–3 mm) was modeled and a uniform pressure (1–15 dynes/cm²) was applied to the back surface with constraints on the opposing surface except over the aperture (2- to 5-mm diameter) through which the gel is extruded. The surface of the extruding gel was unconstrained and no modeling of the compressible gas in the fluid chamber was included.

The lens power of the extruded surface was calculated by the closest spherical fit of the predicted deformation and the index of refraction difference. Closest poly line fit equations were used in modified spherical wave-fronts through a circular aperture to determine the OTF on the retina while varying parameters.

A spherical wave-front propagating from a point source at 150 mm was used for near simulation and a planar wave-front was used to simulate infinity objects. The anterior and posterior surfaces, which comprise the shell of the lens negate the quadratic term in the Fresnel propagation function at the image plane. This effectively reduces the calculations to a Fraunhofer transfer function at the image plane on the fovea of the retina. The aperture was modeled at 2- to 5-mm diameter through the extruded interface.

In order to model the asphericity of the extruded gel, the approaching wave-front was modified by the surface curvature predicted by the FEA model above. The index of refraction scaled aspheric surface was subtracted from the approaching wave front, which was then propagated to the image plane at the fovea.

A Hankel transform was applied (Matlab v2007a; MathWorks, Natick, MA) to the modified wave front with a zero order Bessel function. The square modulus

was then taken of the transform to produce the point spread function (PSF) and a second Hankel transform was taken to obtain the MTF and the OTF. Also included for comparison were the unaberrated wave-fronts. The model assumes a perfect lens with the exception of aberration induced by the extruded interface. A direct comparison to the measured OTF of the first generation prototype is difficult as numerous other aberrations are induced by imperfections in the various surfaces including the camera system.

The model predicted visual OTF was calculated by weighting the OTF obtained from the MTF by the Movshon formula for contrast sensitivity over the angular spatial frequency.¹² The model predicted visual Strehl ratio was calculated by the quotient of the integrated aberrated visual OTF to the integrated ideal visual OTF. To evaluate the multiple parameters for an optimal configuration, a standard root sum squared (RSS) evaluation was used to maximize the merit function output measured by visual Strehl ratio.

Results

The prototype image quality showed some attenuation at high spatial frequencies but gross large aberrations were not seen at the various focal distances. This high frequency attenuation is likely due to the optical quality of the various surfaces in the prototype. Figures 6A and B shows the actual accommodating image obtained at both 3 m and 15 cm.

The OTF of the actuated prototype accommodating to 3 diopters (D) was measured as well as the OTF of the camera system alone in Figure 7. The visual Strehl ratio was measured for the extruded gel accommodat-

Figure 7. Log visual OTF of the prototype lens compared with an ideal lens, and the camera system.

ing lens and found to be 0.64, with mostly high spatial frequency loss. This Strehl ratio seems to correspond well with images produced in Figure 6.

The force required to actuate the prototype lens to various degrees of accommodation was measured. Also, the force required to actuate the lens to various diopter lens powers was predicted by the finite element model with a closest spherical fit to the extruded interface shape. The measured and model predicted accommodation force curves are shown in Figure 8. Note 1 dyne/cm² is equivalent to 1 g of force in the prototype and the model. The actual lens prototype appeared to have some static friction in the low range of actuation pressure and added resistance to actuation in the in the high range of pressures due

to continued compression of the gas in the fluid chamber. The predictive model did not include these factors nor viscosity.

The profile of the prototype's extruded interface was accurately measured with optical profilometry and was found to be consistent with the predictive model. Both the measured data and FEA data best fit to a cubic polynomial as shown in Figure 9. The model was then used with varied parameters to examine trends and possible limitations of this type of lens.

Since the construction and testing of several hundred prototypes was not feasible, parameters such as aperture diameter, gel thickness, Poisson's ratio, index of refraction, and Young's modulus were varied in the model. The interface's radial profile was

Figure 8. Force required for accommodation; both actual prototype and model predicted.

Figure 9. Extruded gel interface lens profile; both prototype measured and model predicted.

predicted by the model and used to produce the wave-front aberration and ultimately a visual Strehl ratio. **Figure 10** is an example of extruded lens' radial profile while varying the gel's axial thickness and keeping all other parameters constant. Note that the altered parameters greatly affect the shape and that

the profile can easily become a lens producing very poor image quality by producing superimposed higher orders of spherical aberration. **Figure 10** indicates design optimization should include maximizing parameters such that the interface approximates a spherical deformation.

Figure 10. Predictive model radial profile of the extruded gel interface with decreasing axial gel thickness.

Figure 11. Visual Strehl image quality verses the ratio of gel thickness to aperture diameter for 3 D of accommodation.

Individual parameters were examined for their effect on image quality measured by visual Strehl ratio. Also, these parameters were examined for their effect on the force requirement needed to actuate the lens to the desired 3 D of accommodation. The force is depicted in percent of maximal force the design goal is to minimize the required force to less than 1 g. [Figure 11](#) is an example of many iterations examining image quality measured by visual Strehl ratio. [Figure 12](#) is an example of the force required to achieve 3 D of accommodation. These curves are valuable in illustrating the trends and limits to optimize the design of any extruded gel interface accommodating lens.

The RSS evaluation of the examined parameters yielded maximum performance of the lens with: a ratio of gel thickness to aperture diameter of 0.62, an aperture diameter of 3.1 mm, minimizing the gel's Poisson's ratio, maximizing the interface refractive index change, and minimizing the elastic modulus of the gel material.

Discussion

The extruded gel accommodating lens incorporates an extruded internal gel to create an interface of increasingly negative power with physiologic pressure provided by relaxation of the ciliary body muscle. The optimum design attempts to produce a spherical interface to minimize aberrations. A deformed solid cannot create a truly spherical surface and instead produces an oblate asphere. As a result the aspheric aberrations create a broadening of the incoherent PSF and a decrease in the image quality. This is seen by patients as decreased visual acuity and contrast sensitivity.

The design prototype performed well operating

Figure 12. Percent of maximal pressure required to achieve 3 D accommodation with varied extruded gel thickness.

within the physiologic constraints of the human eye. The parameters that optimized optical and mechanical performance were delineated as those which minimize asphericity and actuation pressure. Identified design parameters can be used as a template to maximize the performance of any deformable interface intraocular lens. The temporal response of the lens to pressure actuation was immediate (<1 second) and stable, but it was not measured.

The natural force available from the eye's ciliary body muscle contraction and zonular/capsular tension is minimal.⁸ Therefore, any design must incorporate a minimal force required to actuate the lens while not exceeding its elastic limits.

Factors that optimize the performance of an extruded gel interface type accommodating intraocular lens in vivo include:

1. Maximizing the ratio of axial gel thickness to aperture diameter of the extruded area. This ratio is limited by available space for an implanted lens. A desirable large diameter optical zone limits radial discontinuities in the lens, which result in glare and aberrations, but also increases the asphericity of the interface. Increasing the thickness/diameter ratio also decreases the force necessary to actuate the lens;
2. Maximizing the refractive index change at the extruded interface will minimize the force necessary and modestly improve the optical performance;
3. Poisson's ratio of the gel material should be minimized to improve the spherical deformation at the interface and modestly reduce the force requirement. Unfortunately, the Poisson's ratio of gel materials almost invariably approaches 0.50; and
4. The elastic (Young's) modulus and total disk area

to be compressed have the greatest effect on the force requirement. A low elastic modulus and gel disk diameter minimize the force requirement to actuate the lens.

Important design parameters not examined in this study would include: biocompatibility of the material in inflammation and material property stability, its ability to pass through a small incision in the eye, minimal refractive discontinuities in the lens optic to minimize scatter, lens anchoring system exhibiting stability and able to actuate lens and prevent creep and migration through tissue, ability to use pupillary meiosis during actuation for near focus, posterior capsular opacification, and the need for extruded gel displacement of the incompressible anterior liquid to expand elsewhere. It should be clear that the IOL design presented is an optimized prototype in need of in vivo animal model study before human clinical study.

The optimization methodology outlined here can be extrapolated to the design of any deformable interface intraocular lens. The method takes a basic concept to produce a 'best guess' prototype. It then incorporates a mathematical model based upon the prototype's optical, mechanical, and ophthalmic properties to optimize the design. Optimization involves varying the input design properties to produce maximized merit output functions, in this case: maximum visual optical quality and minimum actuation force. The optimized design is then able to be used in initial animal implantation studies and as a basis for further revision based upon those in vivo trials.

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