

SCIENTIFIC REPORT

A dual optic accommodating foldable intraocular lens

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Aim: To design an accommodating intraocular lens with extended accommodative range that can be adapted to current standard phacoemulsification and endocapsular implantation technique.

Method: Ray tracing analysis and lens design; cadaver eye implantation.

Results: Ray tracing analysis indicated that axial movement of an exaggerated converging anterior optic linked by spring loaded haptics to a compensatory static diverging posterior optic produced greater change in conjugation power of the eye compared to axial movement of a single optic lens. A dual optic one piece foldable silicone lens was constructed and implanted via a 4 mm corneal incision into the capsular bag of two cadaver eyes.

Conclusion: A dual optic intraocular lens design can increase the optical effect of a given displacement and suggests improvements for accommodating intraocular lenses.

Accommodation in the youthful, phakic human eye is accomplished by contraction of the ciliary body and subsequent release in the resting tension of the zonular fibres by which the crystalline lens is suspended, resulting in increased lens curvature.^{1–3} Presbyopia is defined by the progressive loss of accommodation amplitude producing compromised near function, and has been attributed to mechanical changes in the lens and capsule including changes in elastic property¹ and progressive circumferential enlargement of the crystalline lens,^{2,3} weakening of the ciliary muscle,⁴ and loss of zonular and ciliary body effectiveness and elasticity.^{5,6} An excellent review of the variety of proposed mechanisms has been presented by Atchison.⁷

Although the mechanism of presbyopia remains incompletely understood, the weight of current evidence seems to suggest that although some loss of ciliary body action might contribute to reduced accommodation,⁸ significant ciliary body function persists into advanced maturity, and that loss of lens and capsule elasticity in concert with changes in the geometry of zonular attachments are probably most culpable in producing the distress of presbyopia.⁹ If so, then replacement of the crystalline lens with a lens that responds to ciliary body contraction should restore accommodative function. Attempts have been made to replace the crystalline lens by refilling the capsular bag with appropriately deformable gels.^{8,10,11} However, this approach is limited by the intrinsic mechanical instability of such materials that cannot be expected to retain a specific shape (and thus optical power) over time while sustaining a rapid, constant, and predictable response to equatorial tension as demanded by the dynamics of accommodation.

Recognising these limitations, Hara *et al* proposed refilling the capsular bag with a rigid shell, described as two lenses 8 mm in diameter connected by a polypropylene coil spring.⁸ This design was later replaced by a pair of inflexible polymethylmethacrylate optics, 6 mm in diameter, connected

by four peripheral closed polyvinylidene fluoride flexible loops separating the optics by 3.0 mm. The posterior optic was assigned no optical power, and change in the conjugation power of the eye was achieved by anterior and posterior movement of the anterior lens to which was assigned the full optical power of the lens system.¹²

The principle of axial lens movement has been adopted by more recent accommodating IOL designs. For example, the AT-45 (C&C Vision Corporation, Aliso Viejo, CA, USA) is a hinged single optic intraocular lens that is intended to be implanted with posterior vault. Cumming *et al* recently reported the results of early clinical trials in which varying degrees of near function was described in subjects following implantation.¹⁰ Near function was ascribed to anterior axial displacement of approximately 0.7 mm (Cumming; unpublished data, 1989) and corresponding conjugation power change postulated by the authors to result from increased vitreous pressure. Kuchle and co-workers¹¹ have recently reported clinical results of a more anteriorly positioned posterior chamber lens also designed to undergo anterior axial displacement with accommodative effort. A mean retinoscopic accommodative range of 1.2 (SD 0.4) D was achieved in these patients, and pharmacologically induced accommodation by instillation of pilocarpine produced a mean change of 0.63 (0.16) mm in anterior chamber depth.

Ray tracing analysis, however, suggests that such designs are expected to produce varying degrees of accommodation depending upon the power of the lens implanted. The degree of conjugation change produced by axial movement of an intraocular lens is proportional to the magnitude of excursion as well as the power of the lens, as linearly approximated by the following formula:

$$\Delta Dc = (Dm/13)\Delta s$$

where ΔDc is change in conjugation power of the eye, Dm is the dioptric power of the moving lens, and Δs is the change in lens position expressed in millimetres.

Measures of intraocular lens movement in pseudophakic eyes suggest that the expected range of axial optic displacement is in the order of 0.25–1 mm,^{13,14} and thus the degree of accommodation that is expected to result for an optic in the range of the most common powers implanted (+15 to +25 D) varies from 0.3 D for lower powers with limited movement to a theoretical maximum of 1.9 D. Therefore, we sought to better define the optical effect of lens displacement, and to design an IOL that would provide more robust and consistent accommodative performance. We also sought a design that would incorporate predictable optical and mechanical properties, and that would allow implantation through a standard phacoemulsification incision.

METHODS

Ray tracing analysis software (ZEMAX, Focus Software Inc, Tucson, AZ, USA) using a theoretical model eye¹⁵ was used to analyse the expected optical effect of axial movement of a single intraocular lens (IOL) located at the plane of the posterior capsule. For example, based on the assumptions listed in Table 1, the theoretical model eye would predict that a 19 D IOL with

Table 1 Constants applied to the theoretical model eye

| | |
|---|----------|
| Cornea index of refraction | 1.3771 |
| Aqueous index of refraction | 1.3374 |
| Lens index of refraction | 1.42 |
| Vitreous index of refraction | 1.336 |
| Cornea aspheric anterior vertex radius | 7.8 mm |
| Cornea aspheric posterior vertex radius | 6.5 mm |
| Cornea thickness | 0.55 mm |
| Anterior chamber depth | 3.05 mm |
| Second nodal point, posterior to corneal apex | 7.51 mm |
| Axial length | 23.86 mm |

lens thickness 1.0 mm and posterior surface located 5.3 mm posterior to the corneal apex would be required to produce emmetropia in this eye. Conjugation power change was calculated as change in refraction at the spectacle plane with vertex distance to the posterior spectacle surface of 12 mm. Anterior displacement of 1 mm was calculated to produce a change in conjugation power of approximately 1.2 D. However, 1 mm movement of a 32 D IOL at that location would produce a change in conjugation power of approximately 2.6 D.

Having confirmed that in a model of the human eye, object distance change per unit axial movement increased with lens power, we investigated alternative scenarios whereby a dual optic lens system was created in which an anterior converging lens was assigned a high plus power well beyond that required to produce emmetropia, but a posterior diverging lens was assigned the minus power required to return the eye to emmetropia. Applying the assumptions listed above, the optical effect of axial movement of the anterior optic in this dual optic lens system was modelled.

In order to respond to ciliary body action, energy must be stored and released in the system. To that end, a lens complex was designed whereby the optics are linked by articulations that, at rest outside of the confines of the capsular bag, produce an outward force separating the axes of the optics by approximately 4.0 mm. When implanted within the capsular bag, bag tension should compress the optics reducing the interoptic separation—that is, the resting ciliary body maintains zonular tension that is transmitted to the bag producing outward circumferential movement of the equator, axial shortening of the capsular bag, and thus compression of the lens complex resulting in the storage of strain energy in the connecting arms. Elements are incorporated to control minimum separation, thus setting the resting distance refraction at emmetropia. With accommodative effort, the zonules relax, releasing the tension on the capsular bag, thus allowing release of the strain energy stored in the interoptic articulations and anterior displacement of the anterior optic (Fig 1) The posterior element is designed with a significantly larger surface area than anterior, thus reducing the tendency toward posterior axial excursion.

Based on the optical analysis and mechanical design considerations as described above, we proceeded to design and fabricate a prototype lens. Human cadaver eyes were used to investigate ease of folding and manipulation through a clear corneal wound and into the capsular bag.

RESULTS

Ray tracing analysis suggested that anterior movement of the anterior optic of a dual optic IOL design with a high power anterior converging lens and a compensatory posterior diverging lens produces significantly greater change in object distance compared similar displacement of single optic IOL. For example, as described earlier, based on the assumptions listed in Table 1, a 1 mm anterior axial movement of a single

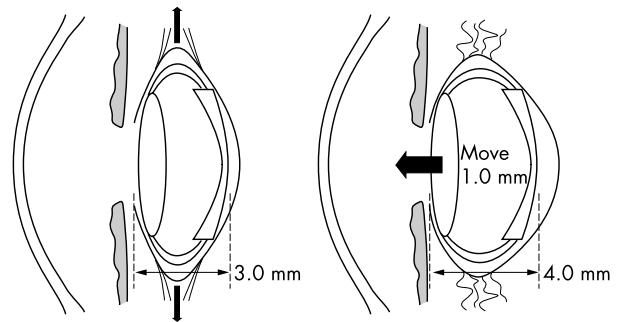


Figure 1 Accommodative function of the dual optic IOL. At ciliary body rest, the zonules are put on stretch producing axial shortening of the capsular bag, thus pulling the optics together and loading the haptic springs. With accommodative effort, zonular tension is released, compressive capsular tension on the optics and spring haptics is released and thus the anterior optic moves forward.

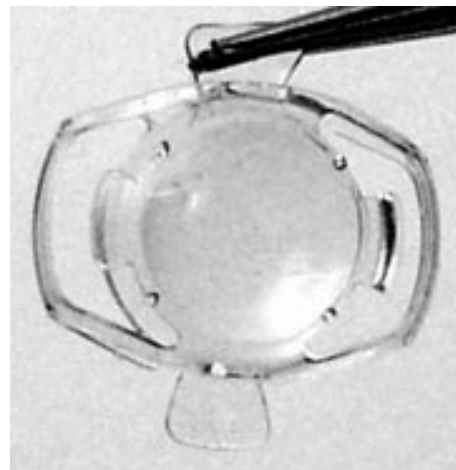


Figure 2 Photograph of the single piece silicone lens consisting of an anterior convex and posterior concave optic linked by haptics with spring action.

optic 19 D IOL would produce a change in conjugation power of the eye of approximately 1.2 D. However, for a dual optic system placed in the same model eye, assuming an anterior +32 D lens separated by 0.5 mm from a posterior -12 D lens, 1 mm forward displacement of the anterior convex lens is calculated to produce a change in conjugation power of approximately 2.2 D.

This model was used in the fabrication of prototype lenses (Fig 2) The lens as shown is a single piece design constructed of silicone in order to facilitate folding. Five mm diameter optics are connected by haptics with spring function. The device has length 9.5 mm and width 9.8 mm. When compressed, the total lens thickness is 2.2 mm. Based on the optical calculations described above, it is evident that a greater change in conjugation power per unit axial displacement can be generated by choosing a more powerful anterior lens, but the advantages of increased accommodative range must be weighed against the increased optical sensitivity of the system. Thus, at present our power choice for the anterior lens is within a range of 30 D and 35 D, and the posterior lens assigned a variable diverging power as required to produce emmetropia for a given eye. The optics are connected by arms, the length and thickness of which can be varied to produce a range of response to capsular bag tension.

Folding and introduction into a human cadaver eye via a 4 mm clear cornea wound was demonstrated. In one such experiment, a standard phacoemulsification clear corneal incision was created in a cadaver eye. A metal blade was used

to create a 4.0 mm groove at the limbus and a shelved 2 mm entry into the anterior chamber created using a metal 3.2 mm keratome. This opening was then widened to approximately 4.0 mm by side to side motion of the keratome, and the dimensions of the opening confirmed with calipers. Without removal of the crystalline lens, viscoelastic material was introduced to deepen the anterior chamber. The two optics of the prototype lens were brought together in lens forceps, the lens depressed and folded around the forceps into a taco configuration, and then guided through the wound into the anterior chamber. The wound width was then remeasured with calipers, and found to be approximately 4.0 mm. In two subsequent experiments, phacoemulsification was performed on cadaver eyes, and using the procedure described above, the lens unfolded within the capsular bag via a 4 mm clear cornea wound.

DISCUSSION

Following cataract surgery and IOL implantation, options to extend depth of field allowing distance and near function include monovision (that is, the assignment of one eye to distance activities and the other eye to near), multifocal intraocular lens implantation and, most recently, accommodating intraocular lens implantation. The advantage of multifocal or accommodating IOL implantation over the monovision approach is that of the potential for binocular function at all distances. Multifocal lenses are designed to produce at least two axially separated focal points that create the functional equivalent of accommodation. The design of such lenses is rendered challenging by the demands of minimising loss of incident light to higher orders of diffraction, minimising optical aberration, and balancing the brightness of the focused and unfocused images.¹²

Current accommodating intraocular lenses might be expected to provide superior image quality compared to multifocal lenses, since competing retinal images are avoided, but as described above, the accommodative range of a single rigid optic design that depends upon axial displacement of the optic is limited by the range of excursion generated. The design that we have described has the potential to allow the extremes of distance and near focus characteristic of multifocal designs, but additionally should offer improved function at intermediate distance, and improved image quality at all object distances.

While this design is optically robust and describes a device that is amenable to surgical manipulation, other features critical to clinical application warrant further investigation. Although the IOL was readily placed within the capsular bag of cadaver eyes, it cannot be assumed that in the living eye this lens complex that has significant axial dimension will remain stable within the capsular bag early after surgery. The action of the lens is dependent upon ciliary body function as translated

by the capsular bag, and the evolution of capsular fibrosis following cataract extraction and implantation might alter this relation over time. In order to address these and other issues, vivo studies in an animal model are in progress.

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