History and Function of the Crystalens

Details from the inventor of this accommodating IOL.

BY J. STUART CUMMING, MD, FACS, FRCOPHTH

In 1989, a few of my elderly patients who received plate haptic lenses that were 10.5 mm long reported that they could read, even though they were close to emmetropia. When sitting behind the phoropter and given their maximum distance correction, they could still read J3 or better in dim light. I was also at that time implanting the three-piece SI18 lens (Allergan, Inc., Irvine, CA) and noticed at the slit lamp that the plate haptic lens optic appeared to vault much farther posteriorly in the capsular bag space than did the posterior-vaulted, loop SI18 lens. The A-constants of the plate haptic and SI18 lenses were 119.0 and 117.2, respectively (Figure 1). The more posteriorly vaulted lens design, however, would be expected to have the higher A-constant.

These findings suggested that forces within the eye tended to move the plate haptic optic posteriorly and the loop lens optic anteriorly. It seemed possible that these forces might also move the plate lens optic anteriorly with accommodation.

FURTHER STUDY

Alan Ritter, an ultrasound engineer, and I pre- and postoperatively measured the length of patients' vitreous cavities (Figure 2). This small study[1] disclosed that the plate haptic lenses consistently moved to the posterior part of the capsular bag and shortened the vitreous 50% of the time, with the most anterior location only 0.77 mm in front of the original location of the posterior capsule. By contrast, the loop lenses shortened the vitreous cavity only 20% of the time and lengthened it as much as 2.17 mm. The spread of the plate haptic lens along the axis of the eye was 1.45 mm, whereas that of the loop lens was 3.15 mm. Both of these 6-mm silicone optic lenses had the same refractive index and center thicknesses of 1.3 mm, and they were implanted in patients in their 70s to replace crystalline lenses approximately 5 mm thick. Fibrosis with ensuing shrinkage of the anterior capsule caused posterior vaulting of the optic of the plate haptic lens and pulled the posterior capsule tightly against the posterior surface of the optic.

As expected, subjects in the plate-lens group had superior UCVAs, because they had a much shorter range of location along the axis of the eye compared with subjects in the loop-lens group.[2] Additionally, the IOLs of the former group fit tightly against the posterior capsule, thus stabilizing the vitreous by maintaining it at close to its preoperative volume. This appeared to significantly reduce the incidence of retinal detachment[3] and posterior capsular opacification,[4-7] which was less than 5% at 1 year in the referenced studies.

I then measured the vitreous cavity lengths and anterior chamber depths in the patients who received plate lenses—first, after instilling pilocarpine and, later, after instilling cyclopentolate. I found a 0.7-mm average anterior movement of the optic in 10 eyes.

THE LITERATURE

In 1986, Thornton[8,9] published what I believe was the first evidence of movement of an IOL optic along the axis

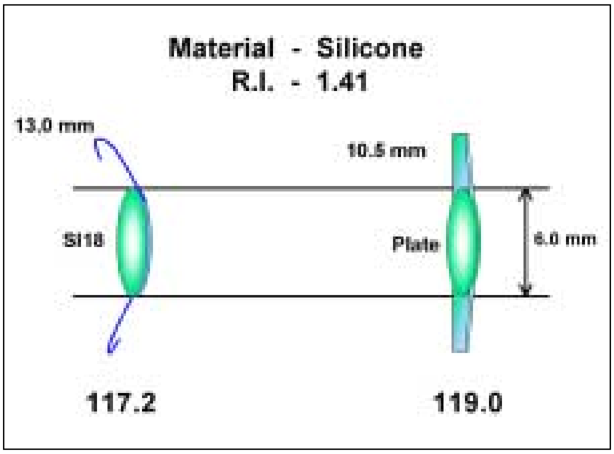

Figure 1. The plate haptic and SI18 lenses are compared.

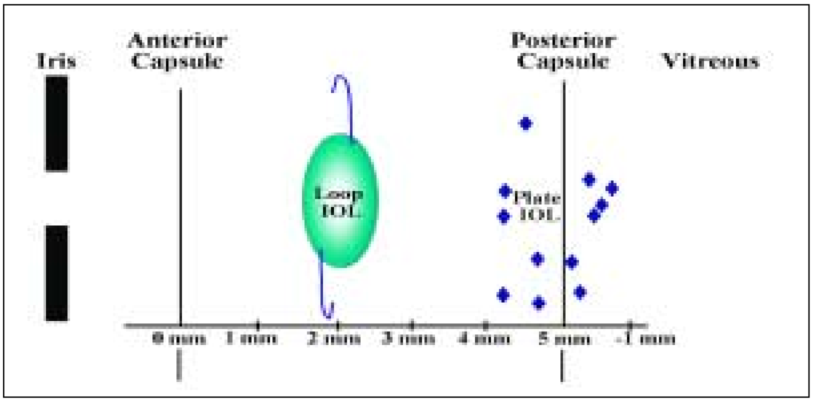

Figure 2. This diagram shows the location of the optics of the SI18 and plate haptic lenses along the axis of the eye.

of the eye with accommodation. He demonstrated movement in 20% of the eyes implanted with a loop lens that he designed by measuring a significant reduction in the depth of the anterior chamber upon constriction of the ciliary muscle.

During the same year, Coleman[10] published an article demonstrating an increase in vitreous cavity pressure with a simultaneous decrease in anterior chamber pressure upon constriction of the ciliary muscle in 10 primates. An earlier study by Busacca[11] using gonioscopy documented the changes in the ciliary muscle's shape and how they related to the zonules and lens after the use of parasympathomimetic and parasympatholitic drops in a young anaridic patient. Busacca's meticulous drawings revealed that the ciliary muscle, upon constriction, redistributed its mass to bulge posteriorly, thereby impinging upon the peripheral vitreous. This change in the ciliary muscle's mass explained the increased pressure in the vitreous cavity upon accommodation, as demonstrated by Coleman, and could account for the anterior movement of the optic upon accommodation first disclosed by Thornton.

These observations indicated to me that a functioning ciliary muscle was the only mechanism that could account for my findings and those published in the literature and could explain why the optic could move in these elderly patients' eyes. By reducing the optic's diameter, the length of the plates could be increased, thereby increasing the ability of the optic to move. Thus, I hoped to design an accommodating lens that would consistently move along the axis of the eye.

THE FIRST DESIGN

The first lens design had an overall length of 10.5 mm and an optic diameter of 4.5 mm. To maximize the anterior movement of the optic, a hinge was placed across the plate haptics adjacent to the optic, which, as a result, became the least resistant component of the vitreous cavity to an increase in its pressure. I chose a 4.5-mm optic after measuring the optical zones of standard loop lenses, for which the effective optical zone (the distance between the loops staked into the optic) is less than 5 mm in all designs.[12] Loop lenses are located farther anteriorly along the axis of the eye, as signified by their lower A-constants.

The first accommodating lens was designed in 1990 (Figure 3) and implanted in the eye of an 85-year-old lady in England on March 12, 1991. When I examined her on July 25, 1991, she demonstrated significant accommodation with fogging. I then performed A-scans, first with her looking at distance and, then, after the instillation of pilocarpine. Three independent scans showed an average increase in the vitreous cavity's length of almost 2.5 mm and shallowing of the anterior chamber by approximately the same amount. These findings conclusively showed that the ciliary muscle still functioned in an elderly person and strongly suggested that it would be possible to develop an IOL that would consistently accommodate.

Subsequent Designs

In 1990, I was fortunate enough to meet Professor Jochen Kammann, MD, from Dortmund, Germany, with whom I cooperated over the next 9 years. During that

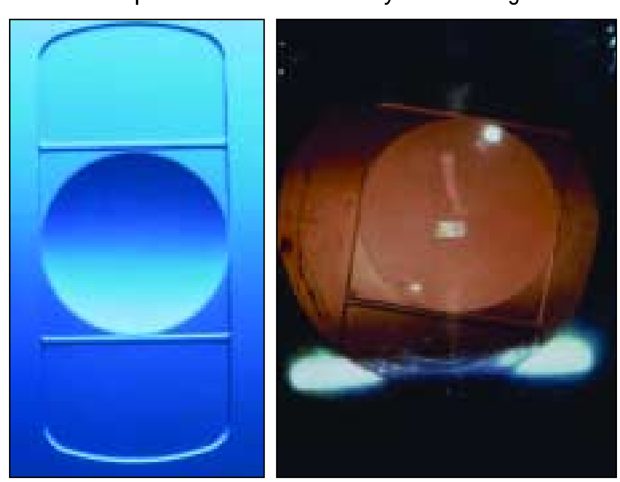

Figure 3. The first accommodating lens design was implanted in 1991. Atropine was used during surgery and on the first postoperative day to allow the lens to fixate in the distance position.

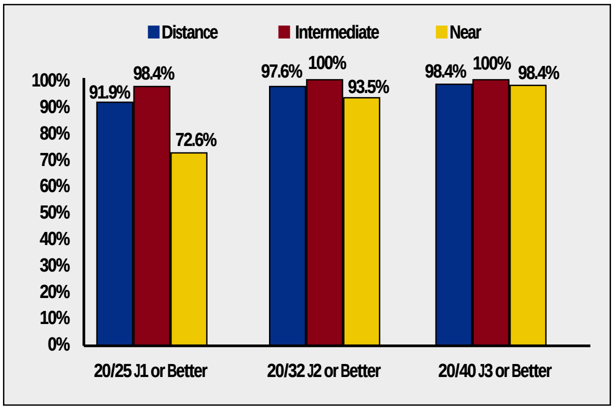

Figure 4. This graph shows the 1-year results of 74 patients implanted bilaterally with the Crystalens via the Vision Enhancement System. Their refractions were ±0.50 D of emmetropia in each eye.

time, we implanted seven lens designs, the first six of which all demonstrated accommodation, both through subjects' ability to read at near through their distance correction and by demonstrating optic movement by means of A-scans with cycloplegia and, later, pilocarpine. The optic of two of the lens designs moved approximately 1 mm anteriorly after the administration of pilocarpine. The designs were evaluated sequentially. It took well over 12 months to change the design to make new molds, manufacture lenses of different powers, sterilize and package them in Europe, implant them, and observe patients for possible complications. The patients were carefully followed for a period of 3 months. The seventh and current Crystalens design (Eyeonics, Inc., Aliso Viejo, CA) was first implanted in 1998. The plates are 10.5 mm long, and the diameter from loop tip to loop tip is 11.5 mm, with a hinge across the plate adjacent to the optic.

RESULTS

The current Crystalens has been implanted in more than 2,000 eyes, and objective evidence of the optic's movement has been demonstrated by A-scan, wavefront analysis (Tracey Technologies, Houston, TX), and dynamic retinoscopy. The ability of the vast majority of patients to read J2 through their distance correction provides subjective evidence of optic movement. In the monocular FDA study comparing the Crystalens with standard lenses, at 6 months, 89.3% of the Crystalens-implanted eyes and 35.9% of eyes implanted with standard lenses read J3 through distance correction. With the Crystalens, the number increased to 90.1% monocularly and 100% binocularly at 12 months.

Meticulous monitoring by Eyeonics, Inc., of the preoperative measurements, comparisons of the actual versus the expected postoperative results, and monitoring of the surgical techniques used in more than 2,000 eyes led to the development of the Vision Enhancement System (Eyeonics, Inc.). This system requires surgeons to measure axial lengths with immersion biometry or interferometry and to perform manual keratometry. The A-constant is 119.24. The SRK-T formula is used for axial lengths of 22.0 mm or longer, and the Holladay II formula is employed for shorter eyes. The use of a scleral tunnel incision is strongly recommended to avert wound leaks that can cause anterior vaulting of the optic. The recommended capsulorhexis size is 5.0 to 5.5 mm. Atropine should be administered on the day of surgery and 1 day postoperatively.

In the FDA clinical trial, 74 patients were implanted bilaterally with the Crystalens following the Vision Enhancement System. Their postoperative refractions were ±0.50 D of emmetropia in each eye, and Figure 4 documents their results. These patients have excellent, seamless vision from distance to near at 40 cm.

Both the surgeons and the patients have been highly satisfied with the results. The Vision Enhancement System must be followed meticulously, however. Additionally, it is essential to construct a leak-free wound (single-plane, clear corneal wounds leak) and to have adequate cycloplegia postoperatively. ■

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