29 Accommodative Intraocular Lenses: Crystalens

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29.1 Overview of the Crystalens Platform

Crystalens was approved by the Food and Drug Administration in 2003 as the first accommodating intraocular lens (IOL) and, to date, remains the only FDA-approved accommodating IOL in the United States. The Crystalens platform comprises a single 5 mm silicone optic with adjacent hinged plate haptics and four terminal polyimide loops. It was designed to produce dynamic changes in IOL optic shape and/or axial movement to provide an active range of distance, intermediate, and functional near vision (Fig. 29.1). Currently in its fifth generation, the Crystalens AO has an aspheric design with uniform power across the optic and is considered "aberration-free," in that it neither adds nor decreases fourth order spherical or other higher-order aberrations to the eye and is immune from the optical effects of IOL decentration. This design also makes Crystalens AO an attractive option in post-refractive surgery patients with lens opacity, particularly post-hyperopic LASIK, where the cornea typically already has high amounts of negative spherical aberration and where image quality would decrease if additional amounts of negative spherical aberration were further compounded by

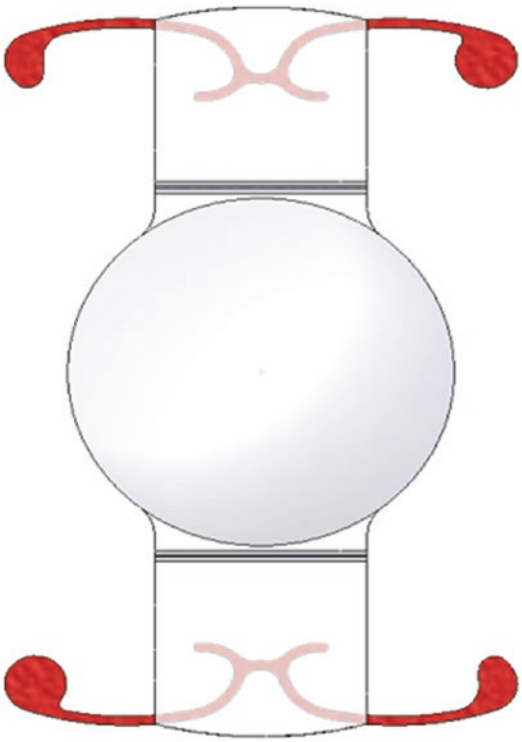

Fig. 29.1 The Crystalens AO has a 5 mm aspheric zero aberration optic with adjacent hinged rectangular-shaped plate haptics and four terminal polyimide loops. When this IOL is inserted, it is important that the leading polyimide haptic on the right is the round one to ensure that the IOL is properly oriented

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an IOL. Unlike multifocal, extended depth of focus (EDOF), or bifocal IOLs, Crystalens does not statically split light among various focal points and thus provides a high contrast retinal image of 100% light energy, as seen in a comparison of through-focus image sharpness with other lens designs using a model eye/camera assembly [1]. Crystalens has gone through a number of iterations since the approval of Crystalens 4.5 in 2003, expanding from a 4.5-mm- to a 5-mm-diameter optic, which is aspheric on both lens surfaces and also modifying its haptic design to increase surface area contact with the capsular bag (compare Fig. 29.1 with Fig. 29.2). Initial trials of the Crystalens 4.5 parent IOL for the FDA showed the equivalent of 1.12 D of "accommodation," based on a study comparing the add needed to achieve best corrected near visual acuity in Crystalens versus standard monofocal IOL [2].

Fig. 29.2 The parent Crystalens 4.5 had a 4.5 mm spherical optic, tapered hinged plate haptics and terminal polyimide loops

29.2 Evidence Regarding Proposed Mechanism of Action

By definition, an accommodating IOL must show an objective, dynamic change in dioptric power associated with an effort to view objects at near or intermediate vergence. It is possible for an IOL to provide enhanced intermediate or near vision by pseudoaccommodative mechanisms either alone or in concert with accommodation. Improved near and intermediate vision with Crystalens was initially thought to be achieved through contraction of the ciliary body decreasing zonular tension and allowing posterior pressure from the vitreous to move the optic anteriorly. Early meta-analysis partially supported these claims of some small anterior axial movement; however, the methods used to assess accommodation and the results of these studies varied widely [3]. The initial FDA approval was based on decrease in the reading add required to achieve best corrected vision and did not include objective measurements of accommodation [2]. Marchini et al., using high-frequency ultrasound biomicroscopy (UBM), measured the average axial shift to be 0.33 mm [4]. Mean axial shift was found to be even lower in a study by Marcos and colleagues using 3-D spectral domain OCT. In their study, 9 lenses moved anteriorly, while 11 shifted posteriorly, with a mean change of 0.09 mm [5]. Neither of these studies found nearly enough anterior axial movement of the optic to explain the 1.12 D of accommodation seen in the FDA study [6].

Pseudoaccommodative mechanisms have been noted in the Crystalens. Perez-Merino observed no more than 0.4 D of axial accommodation using laser ray tracing aberrometry. However, they did note changes in astigmatism, spherical aberration, and trefoil, reflecting geometrical and alignment changes in the IOL that can increase depth of focus via pseudoaccommo-

dative mechanisms [7]. Pseudoaccomodation may thereby explain some or most of the enhanced depth of focus experienced by some Crystalens patients.

29.3 Comparison of Crystalens Outcomes to Extended Depth of Focus and Multifocal IOLs

While there is significant controversy over whether Crystalens or its toric version, Trulign, truly accommodates, there is substantial and consistent evidence that this platform provides enhanced distance-corrected intermediate (DCIVA) and distance-corrected near vision (DCNVA) as compared to a non-presbyopia-correcting monofocal IOLs [8–10]. As seen in Fig. 29.3, at a near distance (30–40 cm), the non-presbyopia-correcting monofocal AcrySof SN60WF IOL (Alcon Laboratories, Inc.) and CeeOn 911A IOL (Abbott Medical Optics, Inc.) were reported to provide a mean DCNVA of 20/100 and 20/72, respectively [11, 12]. In comparison, the all-diopter Trulign group had a mean DCNVA of 20/40. At intermediate (70–80 cm) distances, the AcrySof SN60WF and CeeOn 911A were reported to provide a DCIVA of 20/40 and 20/38, respectively [11, 12]. In comparison, the all-diopter Trulign group had a mean DCIVA of 20/23 (similar to reports with Crystalens, which is close to double that of the monofocal IOLs that do not correct presbyopia) [8–12]. These acuities were measured with optimum distance correction; thus, the improved near and intermediate acuities were not a reflection of the residual refractive error but rather of the inherent attributes of the IOL.

In addition, the better dynamic through focus at intermediate and near with the Trulign toric IOL and the Crystalens IOL than with monofocal IOLs that do not correct presbyopia are reflected in the respective lower required add (~1.5 D ver-

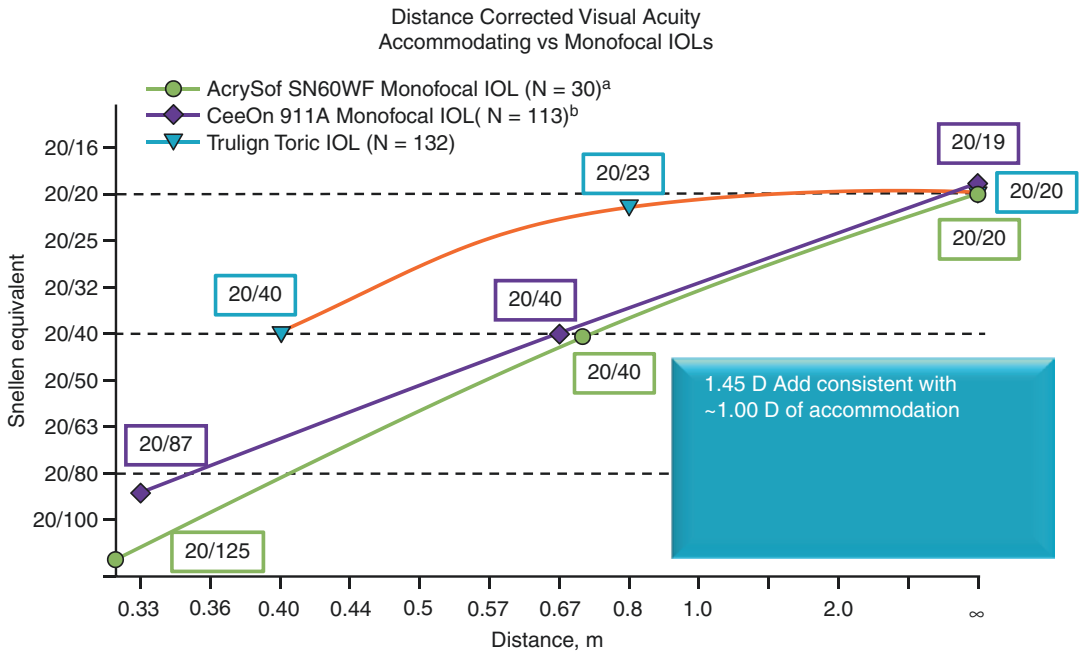

Fig. 29.3 Defocus curves of the toric Trulign version of the Cyrstalens platform compared to two non-presbyopia-correcting monofocal IOLs. Note the enhanced distance-corrected near and distance-corrected intermediate vision of Trulign compared to the non-presbyopia-correcting IOLs. [a]Hayashi et al. [12]. [b]Packer et al. [11]

sus 2.5 D). Since the equivalent of approximately 1 D of accommodation (i.e., the FDA label of Crystalens) is not sufficient for unaided reading at 40 cm, patients should be aware of the need for low power reading glasses or a strategy of targeting monovision or mini-monovision in the nondominant eye.

Crystalens does have some specific benefits over traditional bifocal or multifocal IOLs in respect to providing high quality, high contrast vision, low rates of photic phenomenon, and excellent intermediate vision and, thus, is worth considering as an EDOF IOL. In fact, given the new FDA standards that require objective evidence of accommodation with instruments, such as the Grand Seiko refractometer (Grand Seiko Co. Ltd., Hiroshima, Japan) or i-Trace aberrometer (Tracey Technologies, Houston, Tx), it is likely that given today's standards, Crystalens might be classified as an EDOF IOL [13, 14]. The FDA requirements for an EDOF IOL is that its peak performance BSCVA must be less than one line different from the monofocal control based on a sample providing a 95% confidence interval of 100 eyes. The defocus curve for the EDOF of IOL needs to be 0.5 D greater than the defocus curve for the monofocal IOL control at logMar 0.2 (20/32). EDOF lenses must have at least 50% of eyes BSCVA or better than or equal to logMAR 0.2 (20/32) at 67 cm.

In a three-arm randomized evaluation of three presbyopia-correcting IOLs, Crystalens tested better than the ReSTOR 3.0 or Tecnis Multifocal +4D at intermediate vision at 80 cm, but worse at near vision at 40 cm [10]. As evidenced by the comparative defocus curves in Fig. 29.4, monocular functional range of vision (20/40 or better) was continuous for Crystalens across 2.5 D, for Acufocus IC-8 across 4 D, and for Tecnis Symfony across 3.0 D and was noncontinuous across 4.5 D for ReSTOR 3.0 and 4 D for Tecnis MF + 4.0, respectively. Considering these data, the Crystalens can be used as an EDOF in patients where diffractive optics are problematic such as patients with retinal disease or excessive higher-order aberrations or who are adverse to photopsias (Fig. 29.5).

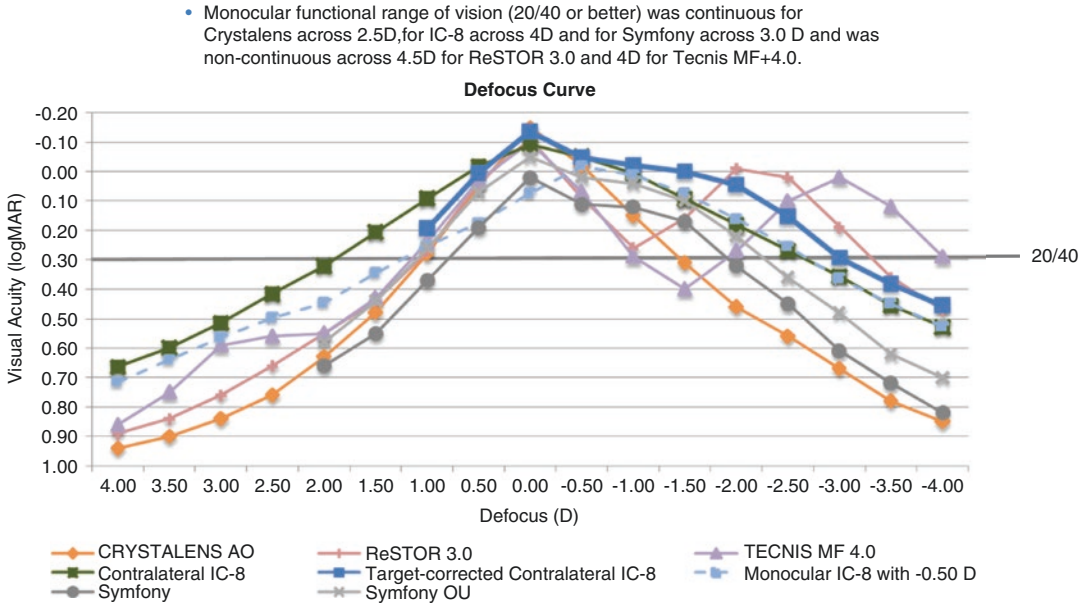

Fig. 29.4 Comparison of defocus curves of Crystalens vs two EDOF IOLs (Tecnis Symfony and Acufocus IC-8) and two bifocal IOLs (ReSTOR 3.0 and Tecnis Multifocal +4D)

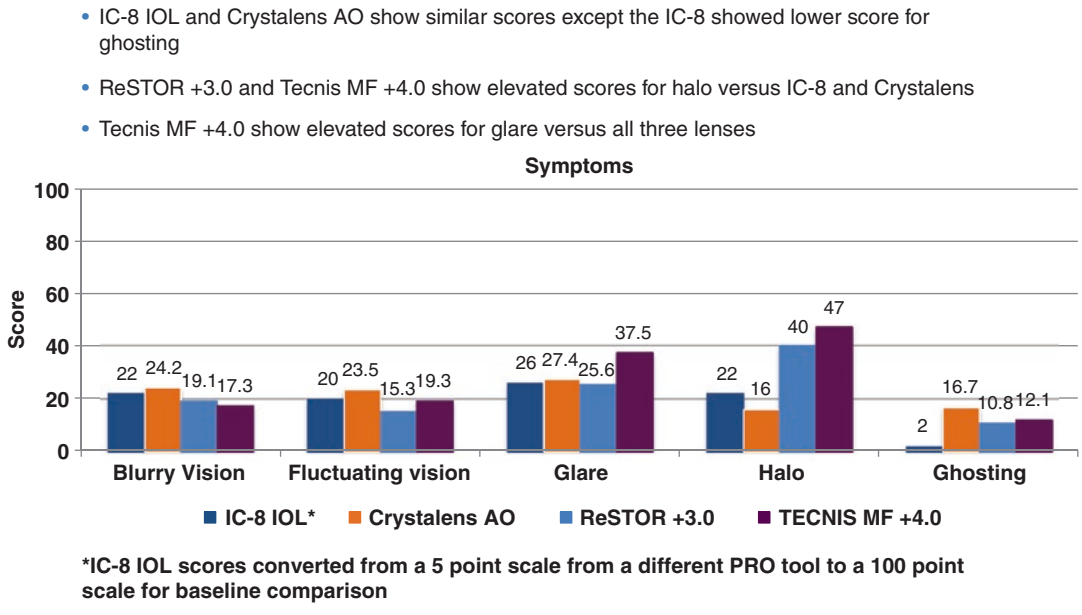

Fig. 29.5 Comparison of quality of vision and photic phenomenon metrics associated with Crystalens AO, IC-8, and ReSTOR 3.0 and Tecnis Multifocal 4D

29.4 Techniques to Minimize and Treat Capsular Contraction Syndromes

Capsular contraction syndrome describes a post-surgical complication unique to hinged haptic IOLs. When capsular phimosis creates inward force on the IOL, the hinge at the optic haptic junction can rotate anteriorly or posteriorly, and, if the rotation occurs in opposite directions, Z syndrome occurs with one optic haptic junction flexed anteriorly and one posteriorly, resulting in optic tilt (Fig. 29.6). This is often accompanied by noncorneal astigmatism along the long axis of the IOL and posterior capsular striae. Options for mitigating the risk of Z syndrome include meticulous rhexis size and centration, capsular polish including the underside of the anterior capsular leaflets, rotating the IOL to ensure equatorial fixation in the bag, and avoiding implantation in patients with unstable (e.g., pseudoexfoliation) or compromised capsules. The incision should be tested at the end of phacoemulsification and demonstrated to be Seidel test negative, and there should be a low threshold for suture or sealant placement to avoid wound leakage that can affect the position of the IOL. Consideration should be given for using a capsular tension ring in short or large eyes. In addition, the IOL is available in 11.5 or 12 mm length over a range of dioptric powers, and the longer IOL may be indicated for eyes with axial length over 25 mm, which tend to have larger capsular bags. This can be an important consideration in patients who had previous myopic LASIK or have long axial lengths, but IOL calculations are calling for a higher power IOL given the previous refractive surgery. A lengthy course of topical corticosteroids may also reduce capsular fibrosis, and patients should be cautioned to wear a shield at night and avoid eye rubbing. Postoperatively, careful ND:YAG laser treatment of fibrosis posterior to the hinged areas and the optic can be performed to lessen contractile forces of the capsular bag, while severe cases may require operative repositioning or exchange [15]. The best course is prevention and avoiding the most common causes of Z syndrome which include (1) a large, asymmetric capsulorrhexis; (2) one haptic out of bag; (3) haptic pinched on capsule, not extended to fornix; (4) capsular contraction syndromes, especially in smaller eyes; (5) capsular rent in which case

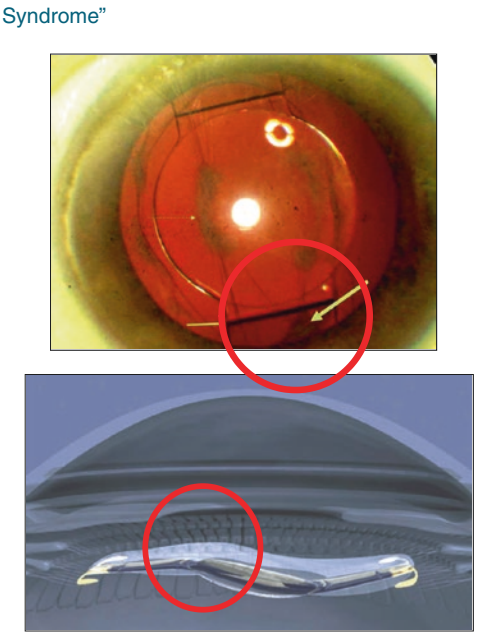

Fig. 29.6 A Z syndrome is a complication specific to hinged plate haptic IOLs, where one footplate hinge is flexed anteriorly toward the cornea and the other is flexed posteriorly, resulting in optic tilt

Crystalens should not be implanted; and (6) possible mismatch between capsule and IOL diameter.

29.5 Conclusions

To date, Crystalens remains the only accommodating IOL approved by the FDA and delivers an active range of high contrast vision. Crystalens is labeled as providing functional distance, intermediate and near vision via the equivalent of approximately 1 Diopter of monocular accommodation. It provides an alternative to non-presbyopia-correcting monofocal IOLs and may be particularly useful in patients with other reasons for reduced contrast vision, such as mild AMD, epiretinal membranes, or highly aberrated corneas, as it does not split light to multiple foci nor lose light to higher diffractive orders. It also has a low reported incidence of photic phenomenon, such as glare and halos.

Advantages

1. Aberration-free IOL that provides the equivalent of approximately 1 Diopter of accommodation and enhanced distance-corrected intermediate vision and distance-corrected near vision compared to a non-presbyopia-correcting monofocal IOL.
2. 100% of light energy is provided at any vergence, producing a high contrast retinal image and low incidence of photic phenomena in comparison to diffractive multifocal IOLs that split light energy to discrete foci.
3. The aberration-free optical design is immune to effects of IOL decentration and a good option to consider in post-refractive patients, particularly following hyperopic LASIK, or in patients with mild or moderate retinal macular pathology or glaucoma.

Limitations

1. The evidence supporting accommodation as the principal mechanism of action of Crystalens is limited and it might be better classified as an extended depth of focus IOL.
2. The defocus curve at near vergence and the required +1.5D add to read over distance correction indicates that patients will likely

require some low power readers for some near tasks, limiting total spectacle independence.
3. The potential for capsular contraction and Z-syndrome is peculiar to hinged plate haptic IOLs and requires careful monitoring and meticulous surgical technique to mitigate its occurrence.

Compliance with Ethical Requirements Mujtaba Qazi and Caleb Morris have no conflicts of interest. Jay Pepose is a consultant for AcuFocus, Bausch + Lomb, and Johnson and Johnson Vision.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

No animal studies were carried out by the authors for this article.

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