Meeting Higher Patient Expectations With the Softec HD

The major advantages of this lens are its 0.25 D increments and stated manufacturing tolerances.

BY PETER STEWART, MD, MBBS (QLD), FRACO

Every successful refractive surgeon needs to deliver on three benchmarks: highly accurate results, high quality vision, and low complication rates—and all must be approaching best practice levels. These axiomatic standards apply equally to excimer laser treatments and cataract/lensectomy surgeries. If unaided vision after lens surgery is augmented by secondary procedures (eg, LASIK for astigmatism), then the rate of unplanned enhancements must be low as well.

Approximately 12 to 15 million patients receive an IOL implantation each year. Our patients are increasingly sophisticated, internet-savvy, and more demanding of higher quality vision. Advances in surgical technique, better biometry, fourth-generation IOL calculation formulae, and latterly, advances in IOL design and manufacture have enabled us to routinely achieve a high standard of outcome. Ironically, these good results are something of a two-edged sword: The better we become, the more our patients expect.

The largest recent thrust in IOL technologies has been the advent of aspheric optics. These may be divided into two broad groups. The first group employs a negative asphericity in an attempt to actively compensate for the typical positive corneal asphericity. The second group more modestly chooses to remain aspherically neutral. Both groups seek to create less overall aberrations, increase contrast sensitivity, and provide better image quality. Although a near-neutral aspheric result for every patient would be ideal, the negative aspheric IOLs needed to achieve this are more sensitive to the effects of decentration and tilt, and so some surgeons elect to use the more forgiving neutral aspheric lenses.

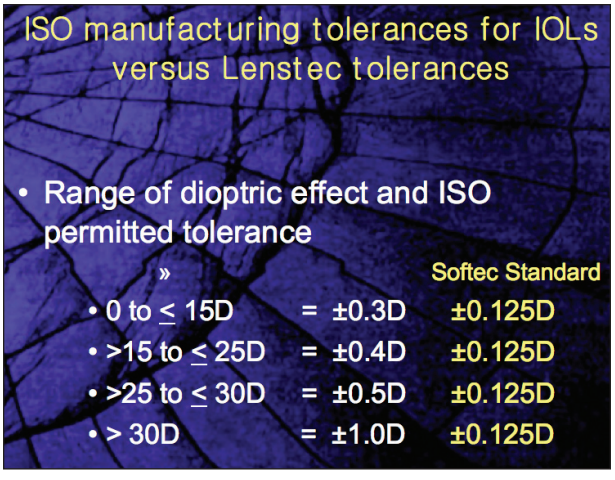

Figure 1. ISO benchmarks (center column) for IOL manufacturing tolerances are outdated and surprisingly lax. The Softec standard (right column) is much lower than that of the ISO.

Before we engage in this debate, however, it is far more salient to remember the need to correct sphere and cylinder before we have the luxury of chasing after higher orders of aberration. To achieve this, not only does a refractive surgeon needs to employ the full suite of advances available, but IOL manufacturers need to play their part as well. The International Organization of Standardization (ISO) has aided by setting standards for

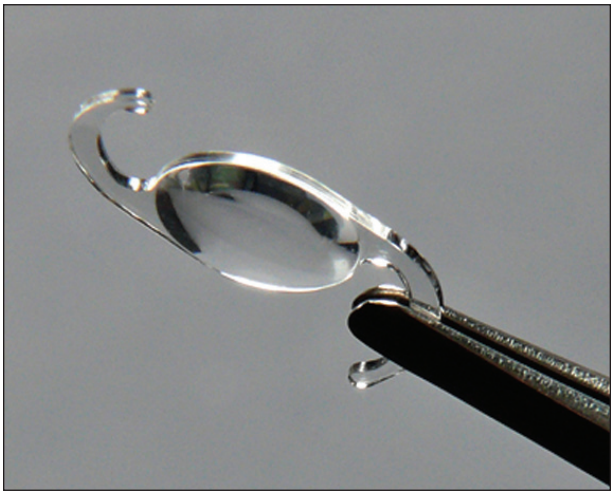

Figure 2. The Softec HD is a one-piece hydrophilic acrylic lens suitable for microincisional insertion.

IOL manufacturing tolerances. The ISO benchmarks, however, are outdated and surprisingly lax (Figure 1). All manufacturers claim to exceed these tolerances, but they are reticent to go on the record with actual data. The difference with the Softec HD aspheric lens (Lenstec, Inc., St. Petersburg, Florida) (Figure 2) is that its manufacturer actually publishes manufacturing tolerances (Figure 1), thus creating the most accurate aspheric IOL advertised on today's market.

The Softec HD is a one-piece hydrophilic acrylic lens suitable for microincisional insertion. It is aspherically neutral, has a square-edged optic, and utilizes a patented equiconic aspheric design that splits the asphericity equally between the front and back surface of the lens to create crisper and sharper vision.

AVAILABLE IN SMALLER INCREMENTS

Another advantage of the Softec HD is that it is available in 0.25 D increments from 18.00 to 25.00 D. It is also available in 0.50 D increments from 10.50 to 29.50 D and 1.00 D increments from 5.00 to 36.00 D.

Since August 15, 2006, I have implanted 393 Softec HD lenses. We use the IOLMaster (Carl Zeiss Meditec AG, Jena, Germany) for biometry and the Professional Edition of the Holladay IOL Consultant (Holladay Consulting, Inc., Bellaire, Texas) for IOL calculations. We refract our patients postoperatively on day 1 and at 1 and 5 weeks. We were familiar with a very predictable and minor myopic shift seen from day 1 to week 1 with our previous IOL, the Tecnis Z9000 (Advanced Medical Optics, Inc., Santa Ana, California). An early clinical observation with the Softec HD was that over the same period, the refractive shift was more variable and could be plus, minus, or absent. Initial concerns that this variability would translate to poor dioptric accuracy proved to be unfounded, with the 5-week results being equivalent to our Tecnis Z9000 results (ie, ±0.50 D accuracy in 90% of cases). A refractive surgeon needs to strive for this level of accuracy to have parity with good LASIK surgery accuracy. Both lenses offer similar predictabilities, and hence it might be considered that the actual refractive results are the same. A predictable result, however, is not the same as a desired result. Because the Softec HD is available in 0.25 D steps through the most popular range of powers, you can choose a lens power to give a predicted result closer to the desired refraction. The Softec HD offers less compromise of choice and excellent results.

We found that employing entrapment to the capsulorrhexis offered additional benefit to the accuracy of outcomes. It is hard to achieve a 360º closure around an optic, as the pupil center is not necessarily the same as the center of the capsular bag. With this series of Softec HD lenses, however, we achieved between 270º and 360º closure in all cases. This is probably one of the most significant surgical maneuvers to ensure dioptric accuracy.

SMALL LOOPED DIAMETER

Another advantage of the Softec HD is its looped diameter, which is smaller than other acrylic lenses. If a small tear in the posterior capsule occurs during implantation, it is still possible to place the lens in the bag without extending the tear. This is due to the relatively small amount of peripheral push of the haptics. Although not the classic textbook answer to handling a posterior capsule tear, this method allows the skilled surgeon to still center the lens. In these cases, I continue to place the leading haptic into the capsular bag with the injector, but I do not attempt to follow with the trailing haptic. Instead, I very gently use a manipulator to get the second haptic into the bag while it is still opening. Overall, it is a low-damage and robust lens, providing that the haptics do not catch in the loading system.

The Softec HD is a safe option for those surgeons just learning to use aspheric IOLs, because it is not as sensitive to tilt and decentration as other aspheric models. I like this lens because aspheric IOLs that correct for positive spherical aberration on the cornea, such as the Tecnis range and the AcrySof IQ (Alcon Laboratories, Inc., Fort Worth, Texas), use a single aspheric value based on population averages and do not always accurately correct the total aberration for an individual. Corneal Q-values sourced from placido-based topography are not helpful indictors of corneal

asphericity. Using the Softec HD allows me to be sure—without doing a routine aspheric examination of the cornea—that the correction will provide quality vision to the patient.

FUTURE PRODUCTS

Many aspheric IOL models are available in Europe, and all offer similar spherical aberration corrections. Companies including Bausch & Lomb (Rochester, New York) and Advanced Medical Optics, Inc. intend to either produce a family of aspheric-powered IOLs that will depend on corneal asphericity or customize aspheric lenses to a patient's pupil and corneal values. Until this industry moves more toward that direction, I choose to implant the Softec HD because it is—to my knowledge—the only aspheric IOL that advertises the accuracy of its production, which is within ±0.125 D. Other companies have chosen to not disclose this information.

We are in an age where we strive to obtain emmetropia in our patients by attacking on many fronts. We use gold standard biometry technology such as the IOLMaster. We employ latest-generation IOL power calculations with personalized constants. We modify our surgical techniques according to our latest understanding. All of this would be pointless if we were to use lenses that were manufactured to just meet the ISO standards, which are too forgiving. I do not think that it is sufficient for manufacturers to state that their individual lenses exceed the standard. I believe that surgeons—and patients—deserve to know the spherical manufacturing tolerances of these increasingly expensive IOLs. Each company should be required to disclose the lens' tolerance on the box. The Softec HD aspheric IOL has excellent manufacturing tolerances across the entire power range, gives very predictable results, and with its range of 0.25 D lenses lets me walk up to a desired refraction. For these reasons, I choose to implant it in any patient where a zero aberration aspheric IOL is indicated. ■

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