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Implant technology

Monofocal IOL sets new standard

By Cheryl Guttman Krader

Reviewed by James P. Gills, MD

Tarpon Springs, FL—With the April 12 FDA clearance of a new monofocal pseudophakic posterior chamber IOL (Softec HD, Lenstec Inc.) comes the availability of a novel implant designed with a host of features that result in outstanding clinical outcomes and that make the lens a premier option for most cataract surgery patients, said James P. Gills, MD.

The new IOL is a single-piece lens with a bi-aspheric (zero spherical aberration), 5.75-mm, 360° square-edge optic. It is constructed of a unique hydrophilic acrylic material (26% water content), and as part of the company's "precision series" of implantable IOLs, the lens also offers tight tolerance for power errors along with power options in 0.25-D steps across the +18 to +25 D range.

The material, manufacturing, and optic design features of the newly available IOL provide unsurpassed refractive outcome predictability, extended depth of focus, excellent quality of vision, and extremely low rates of posterior capsule opacification (PCO), explained Dr. Gills, founder and president, St. Luke's Cataract & Laser Institute, Tarpon Springs, FL.

"Considering patients we enrolled in the FDA clinical trial and those operated on since the lens was approved, we've implanted the Softec HD in about 300 eyes at St. Luke's," Dr. Gills said. "Our results are incredible, with the majority of patients achieving spectacle-independent vision across the full range of distance, but without the visual side effect problems and need for adaptation that can occur with mul-

Take-Home Message

A novel monofocal posterior chamber IOL (Softec HD, Lenstec Inc.) offers a number of unique features that contribute to excellent outcomes. The foldable hydrophilic acrylic, bi-aspheric, single-piece IOL provides extended depth of field and is manufactured with tighter tolerance for power errors along with finer power increments relative to other IOLs so that it delivers more precise refractive outcomes.

tifocal IOLs. With its many benefits, this new technology will be rapidly adopted by surgeons aiming to satisfy patients who want to see clearly at both distance and near."

Dr. Gills said he already has decreased his use of multifocal IOLs by more than 50% because he considers the new implant to be a better lens.

"The [device] is great technology that delivers more for less money, and that makes it a valuable option in today's economy," he said.

The newly approved IOL has been available in countries outside of the United States since 2005, and worldwide, there is experience with more than 1 million implants. Increased precision in refractive outcomes using the lens compared with other marketed IOLs is achieved because it is manufactured with a tighter tolerance (difference between the labeled and actual power of just 0.125 D) and in finer power increments with 0.25-D steps for the range representing the most common implant powers.

Putting those specifications into perspective, Dr. Gills said that current standards for IOL tolerances published by the International Organiza-



The monofocal pseudophakic posterior chamber IOL (Softec HD, Lenstec) provides extended depth of field. (Photo courtesy of Lenstec)

tion for Standardization allow for variances of ± 0.3 to ± 1 D, depending on the dioptric power of the implant.

"Considering IOLs with powers ranging from 15 to 24.50 D, the [new lens] cuts down on labeling error by 3-fold because of its more rigorous manufacturing tolerance," he said. "Combined with the availability in 0.25-D increments, there is the opportunity to provide a much more precise refractive outcome."

For example, if a patient requires a 24.25-D implant for optimal vision, the potential variance using the lens is only 0.125 D compared with up to 0.65 D of error using another IOL.

"Residual refractive error has a much greater impact on vision performance than spherical aberration," Dr. Gills said.

The bi-aspheric design of the IOL reduces higher-order aberrations for good quality vision. In addition, it accounts for the implant's ability to deliver good uncorrected vision across a full range of distances for the majority of patients because with the bi-aspheric design, light rays are better focused on the retina independent of where they enter the visual axis. The bi-asphericity allows the point of focus to be over a greater distance, thus increasing the depth of focus, Dr. Gills said.

"Just as with any monofocal IOL, patients that are more farsighted will achieve the best



Dr. Gills

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Studies of exact-power-labeled IOLs suggest that tight tolerance for power errors may offer higher accuracy in visual outcome. See OphthalmologyTimes.com/exact

near vision with the [new lens] because of the depth of focus effect," he said. "While there are other commercially available IOLs that feature a bi-aspheric optic design, the combination of the bi-asphericity with the right material and predictable refractive outcomes provided only by the [new lens] delivers the near vision benefits to some [patients with myopia] as well.

"While [about] one-third of our patients do not need glasses after implantation of the [lens], these are generally [those with hyperopia and emmetropia]," Dr. Gills said. "Occasionally, however, we do see [patients with myopia and] J1-J2 and perfect distance vision, but it is much more likely with [emmetropia] and [hyperopia] to have excellent uncorrected visual acuity for both distance and intermediate ranges."

Material benefits

The hydrophilic acrylic material of the lens enables smooth implantation and is highly biocompatible, which accounts for its excellent intraocular performance profile. Dr. Gills described the ease of implantation as being equal to or better than any other IOL he has used.

"Many hydrophobic acrylic IOLs take a long time to unfold, but the [new lens] opens quickly, centers well, and fits within the capsule without causing a lot of capsular bag striae that can be seen with other implants," he said.

A pre-loaded injector with the IOL is pending FDA approval and will further improve case efficiency while reducing the potential for handling-related lens damage and contamination.

Since the hydrophilic acrylic has a low refractive index, complaints of glare and halos are minimized. Problems with glistenings and vacuoles also are avoided with this material, and PCO rates have been very low. Considering 390 eyes with implants in the FDA study, Nd:YAG capsulotomy rates at 6, 12, and 18 months were 4.4%, 7.7%, and 10%, respectively.

Other data from the FDA study show that outcomes for best-corrected visual acuity (BCVA) and adverse event rates surpassed FDA grid standards. BCVA was 20/40 or better in 98.4% [95% CI, 96% to 99%] of eyes with the IOL implanted, which is statistically significantly better than the FDA grid value of 92.5%. BCVA outcomes were best in the youngest patients, because almost 92% of those aged <60 years achieved BCVA of 20/25 or better.

However, 78% of patients in the 70- to <80-year-old age bracket achieved BCVA of 20/25 or better. Analyses of cumulative adverse events through 1 year in 366 eyes showed incidences of cystoid macular edema (CME) and secondary interventions of only 0.8% each (FDA PCIOL grid values for these events are 6.0% and

2.6%, respectively). Persistent adverse events at 6 months and/or 1 year included only CME (0.8%), iritis (0.3%), and elevated IOP requiring treatment (0.3%); there were no cases of hypopyon, endophthalmitis, dislocated lenses, pupillary block, or retina detachment, Dr. Gills concluded. **OT**

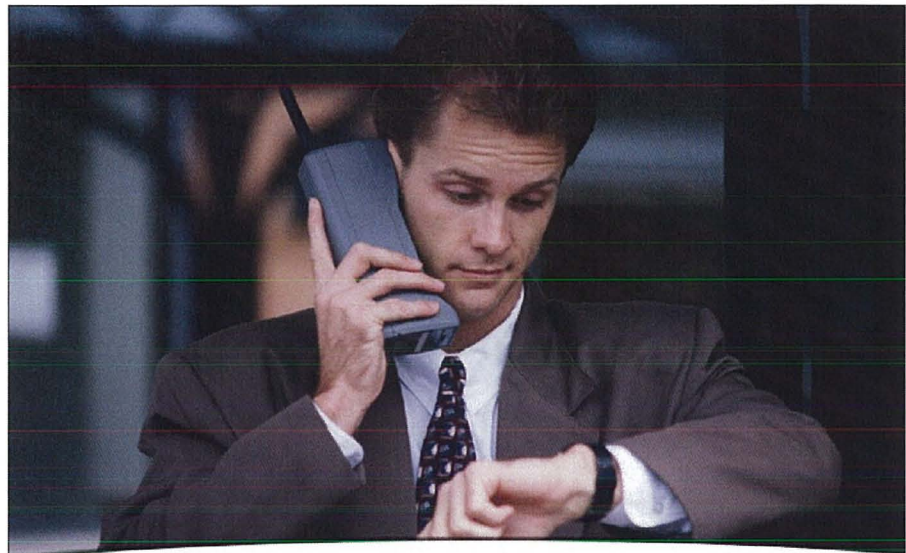
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Dr. Gills has an investment interest in Lenstec Inc.

Pit Gills, MD, was the investigator for St. Luke's in the FDA trial, but has no financial interest in Lenstec.



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