September 1, 2010
VOL. 35, NO. 17

Ophthalmology Times

All the Clinical News in Sight

www.ophthalmologytimes.com
Part of the ModernMedicine NETWORK

Inside:

Acrylic IOL combines performance, value

By Cheryl Guttman Krader
Reviewed by James C. Loden, MD

St. Petersburg, FL—Cataract surgeons have a new IOL in their armamentarium with the July 26 announcement of the FDA approval of a single-piece, spherical hydrophilic acrylic implant with modified C-loop haptics (Softec 1 IOL, Lenstec Inc.).


Dr. Loden

The device's features—highly surgeon-friendly, excellent patient outcomes, and value-priced—make the lens an attractive alternative when selecting a monofocal IOL for cataract surgery patients, according to **James C. Loden, MD.**

"The [lens] is a great single-piece acrylic platform that is easy to load, injects effortlessly through a 2.5-mm incision, and unfolds quickly in the eye," said Dr. Loden, in private practice, Loden Vision Centers, Nashville, TN. "Positioning is easy as well, because with its uniplanar design and equal biconvex spherical optic, there is no need to figure out if the IOL is 'right-side up.'

"Clinical experience shows the [lens] gives excellent and stable visual acuity," he said. "On top of all of these performance features, the [IOL] is available at a very economical cost."

After the FDA approval, Dr. Loden was the first surgeon in the United States to implant the lens. Aside from his offices in the greater Nashville area and Paris,

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Complex cases

'Telling it like it is'

Inaugural meeting to cover cataract surgery without limits

By Beth Thomas Hertz
Reviewed by Robert H. Osher, MD

Cincinnati—Frustrated by the restrictions placed on most continuing medical education (CME) events, longtime cataract surgeon **Robert H. Osher, MD**, has decided to launch his own course devoted entirely to managing challenging cataract cases and surgical complications.

The inaugural meeting of "Cataract Surgery: Telling It Like It Is!" will be held at the Ritz-Carlton in Sarasota, FL, from Jan. 20 to 23, 2011. *Ophthalmology Times* will provide the official news coverage of the event.

"I have always wanted to organize a unique and completely innovative teaching event that will set a new standard in ophthalmic surgical education," said Dr. Osher, professor of ophthalmology, University of Cincinnati College of Medicine, and medical director emeritus, Cincinnati Eye Institute (CEI). "I guarantee this will be the finest educational program in the world, in large part because I have invited faculty members whose expertise in managing complex cases is unparalleled."

That faculty includes:

- Richard Mackool, MD, medical director of the Mackool Eye Institute, Astoria, NY, and senior attending surgeon at The New York Eye and Ear Infirmary

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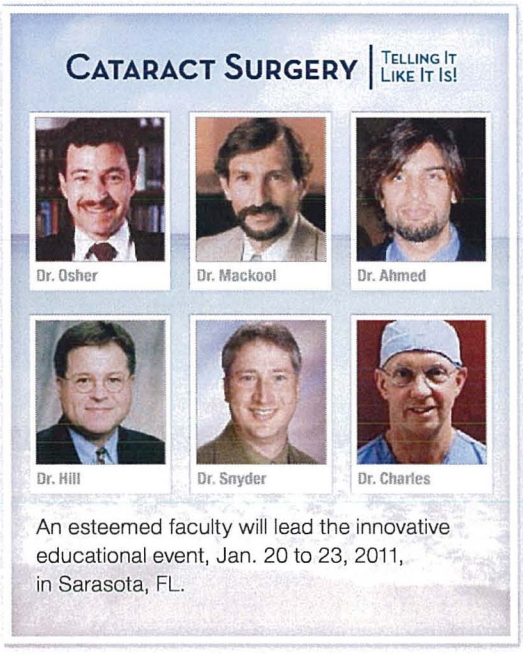

An esteemed faculty will lead the innovative educational event, Jan. 20 to 23, 2011, in Sarasota, FL.

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IOL

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TN, and he also owns two ambulatory surgery centers where he performs about 3,500 cataract surgery cases annually.

Dr. Loden said that his criteria for choosing an IOL are based on his desire to provide excellent immediate and long-term visual outcomes for patients. As a high-volume cataract surgeon and business owner, he also considers IOL handling ease and cost.

The new IOL easily meets all of these needs, he said.

The lens has been available outside of the United States for 10 years. In international experience, which encompasses several million eyes, the implant has demonstrated outstanding results that reflect its design and high-quality acrylic material, Dr. Loden said.

"One of the key features of the hydrophilic material of the [lens] is that it is not prone to the development of inclusions," he said. "These intralenticular vacuoles or 'glistenings' have been associated with a competitor's hydrophobic acrylic material and have been shown to have vision-degrading consequences."

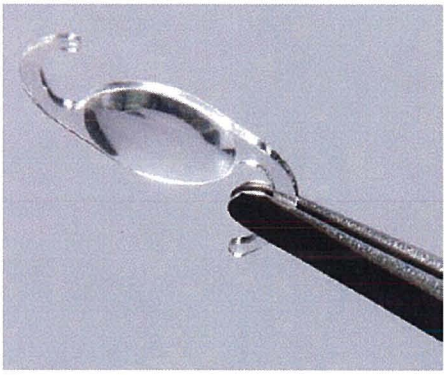

Figure 1 The uniplanar design and equal biconvex spherical optic of the new lens (Softec 1, Lenstec) are designed to ease implantation by allowing surgeons to insert the lens without regard to whether it is "right-side up." The design is based on that of another lens (Softec HD, Lenstec) cleared by the FDA earlier this year.
(Photo courtesy of Lenstec)

Workflow efficiency

As a surgeon who performs about 40 to 45 cataract surgery cases in an average day in the operating room, Dr. Loden said he also wants an implant that will not hamper workflow efficiency.

The IOL fills this requirement because it unfolds quickly in the eye and without any problems with sticking haptics. These intraoperative performance features also set the lens apart from hydrophobic acrylic IOLs.

"Once we started using the [lens], the technicians also found they were up and running quickly with loading the IOL into the cartridge and injector system," Dr. Loden added.

Dr. Loden acknowledged that the lens lacks two of the more recent innovations in IOL technology—asphericity and yellow tinting. However, he said he does not consider the absence of these features as a detriment to the lens because he is not convinced, based on available studies, that either offers proven benefits.

According to Dr. Loden's review of the literature, studies comparing aspheric and spherical IOLs show a statistically significant difference in contrast sensitivity favoring the aspheric design only when the pupil size exceeds 5 mm. However, the average pupil size in the older population of cataract surgery patients is about 3.5 mm.

In addition, in studies involving implantation of spherical and aspheric IOLs in fellow eyes, patients have generally not perceived any differences in vision, he said.

"The need to consider carefully whether an aspheric IOL truly offers superior quality of vision will take on greater importance in February 2011, when per current CMS guidelines, the increased Medicare reimbursement for new technology-IOL status will be eliminated," Dr. Loden said.

He also observed there is no solid scientific evidence proving whether adding a yellow chromophore to a pseudophakic IOL offers a safety benefit or poses any risks. However, Dr. Loden said that his personal bias is against the presence of a yellow tint.

"I do more than 1,000 cases of LASIK a year, and in operating on a large number of young adult patients, I never see anyone with a yellow crystalline lens," Dr. Loden said. "Therefore, it would seem to make more sense to me to replace the aged crystalline lens in a cataract surgery patient with an IOL that is the same color of the lens in a 20-year-old rather than a 50-year-old person."

FDA approval of the lens was not based on a U.S. clinical trial but rather on its equal features to its "parent" model (Softec HD, Lenstec) that was approved by the FDA in April 2010. The two IOLs share the same hydrophobic acrylic material (26% water content), haptic design, and overall dimensions—both have a 5.75-mm biconvex optic with a 360° square edge and a 12-mm overall length.

Take-Home Message

A newly approved monofocal, spherical hydrophilic acrylic IOL (Softec 1, Lenstec) offers excellent intraoperative handling characteristics, functional and biocompatibility advantages of a high-quality acrylic material, and is well-priced relative to competitor implants.

> **'One of the key features of the hydrophilic material of the [lens] is that it is not prone to the development of inclusions.'**
>
> James C. Loden, MD

The main differences between the two implants are that the new IOL has a spherical optic and is available in 0.5-D power increments. The "parent" model lens has an aspheric optic, is available in 0.25-D power steps for the range representing the most common implant powers, and is manufactured with tighter tolerances (difference between the labeled and actual power of just 0.125 D). **OT**

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Dr. Loden was an investigator for Lenstec in a clinical trial evaluating its investigational accommodating IOL (Tetraflex), but has no other proprietary or financial interests to disclose relevant to the products discussed.