

Monovision, implants offer choices for presbyopia correction

by **Marilyn Haddrill** Contributing Editor

Patients likely will have the final word about whether current techniques using implants to address presbyopia are worth the financial investment and possibility that corrections could be short-lived. Monovision offers a different option, but potential depth-of-field loss is one downside.

Redesigned scleral expansion bands (SEBs) and monovision in laser in-situ keratomileusis procedures are among the newest techniques for correcting accommodation loss in an aging population forced to deal with presbyopia.

The method used must match the patient's lifestyle, said Warren D. Cross, MD, of Bellaire Eye and Laser Clinic in Houston. Depending on patient needs, Cross said, he performs LASIK monovision procedures or implants redesigned SEBs to restore accommodation.

Cross said that one patient who received SEBs is an ophthalmologist and a stunt flyer. The physician/pilot said reading instrumentation through bifocals while flying an airplane upside down was difficult, because the lenses are in the wrong place. Monovision was not an option, because of potential loss of depth-of-field.

"I have monovision, but I'm not landing an aircraft," Cross said.

Cross was among the first U.S. surgeons to implant SEBs, beginning with 16 patients in 1993 and 1994. These implants were done before a



The lamella blade is placed horizontally, to start making the belt loop, and has to completely exit the incision so that the segment can be easily inserted.



Check the thickness of the belt loop with the 1.4-mm wide spatula.



Future Intacs indications

A study detailing patient satisfaction with presbyopia and other corrections through monovision following laser in-situ keratomileusis was reported at the May 2000 American Society of Cataract and Refractive Surgery conference in Boston.

Daniel B. Goldberg, MD, of the Atlantic Laser Center in Little Silver, N.J., assistant professor at MCP Hahnemann University, Philadelphia, said reports regarding monovision in refractive surgery have been very limited, partly because of controversy about the break with traditional concepts that favor binocular seeing.

Goldberg quoted past studies showing success rates for contact lens monovision correction range from 50% to 75%, and up to 86% when other forms of contact lens failures are excluded.

“A strong sighting preference reduces monovision success,” Goldberg said.

Goldberg presented results of a retrospective study of 432 consecutive LASIK patients from January 1998 through October 1999, with follow-up from 6 to 29 months.

redesign by Presby Corp.

Cross, who owns some Presby stock, said SEBs were created from an extensive theory of how accommodation is lost in presbyopia, developed by Ronald A. Schachar, MD, PhD, Presby Corp. president and chief executive officer.

“Those [early procedures] were with 360° encircling bands. We recognized that there was quite possibly a problem with doing an encircling band,” Cross said. “We were concerned about anterior segment ischemic problems. Second, it was a 2- to 4-hour operation. And the third thing is that it was very hard to judge how tight or how loose [the bands] were. It was not necessarily a reproducible event from one patient to another.”

Two of the first patients still have accommodation with the original bands in place, he said. But since then, he said, the SEBs have been dramatically redesigned; they were converted to a four-piece design, still made of the PMMA used in the original implants.

The four segments are placed in scleral belt loops along 45° meridians. In a textbook chapter written by Cross and Gene W. Zdenek, MD, medical director, Valley Eye Center, Reseda, Calif., the procedure’s goal is described as re-establishing space between the lens equator and ciliary muscle. When ciliary muscle fibers are stretched, accommodation begins. The technique is undergoing Food and Drug Administration Phase I clinical trials.

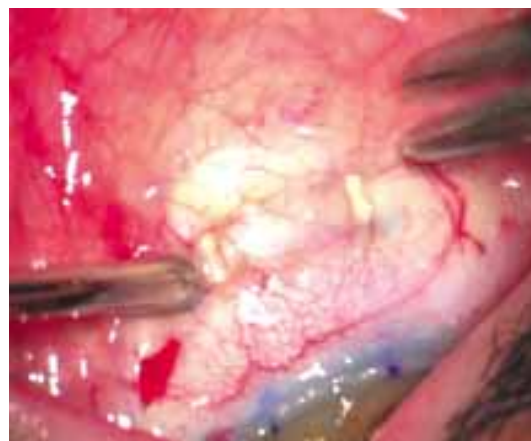
Meanwhile, Cross said, he flies patients to sites outside the United States to



Vertically introduce the segment into the incision, then proceed to horizontally insert the first third of the segment into the belt loop.



After inserting the first third of the segment, grasp the back third to insert the remainder of the segment.



Using the spatula, the surgical assistant may depress the sclera under the segment foot-plate to help it exit from the incision.

When given a choice of monovision or distance-only correction, about half the 233 patients over 40 opted for monovision. Women chose monovision 2:1 and men chose distance-only 2:1.

In the distance-only category, 99% of patients received 20/30 or better correction while 34% had 20/20 or better. In the monovision category, 100% had 20/40 or better correction and 50% had 20/20 or better.

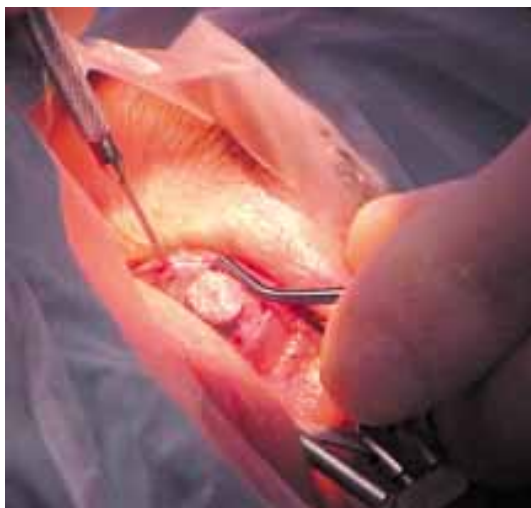
Most patients responded to a questionnaire asking for a subjective rating of the procedure, from a scale of 1 to 10. Thirty-five percent of the monovision group and 43% of the distance-only group rated the procedure a 10. Most respondents from both groups gave an 8 ranking or better to both procedures.

Twenty patients had tried monovision contact lenses and opted for LASIK distance correction only for both eyes, with 19 reporting dissatisfaction with monovision contact lenses. Of 18 patients who had tried monovision contact lenses and opted for LASIK monovision correction, 16 reported LASIK was superior to

perform the procedure. The approximately \$6,500 charge covers the procedure for two eyes, as well as airfare to the surgical site. Without airfare, the procedure would cost \$1,500 to \$2,000 per eye. Cross said he's performed the operation using the modern SEBs on about 85 eyes, while assisting with about another 125 eyes.



Insure that the belt loop is perfectly positioned with the calibrated marker.



Restorvision Reading Implant being inserted using patented Titanium Reading Implant Inserter. The globe is also fixated with a scleral pic.



Restorvision Reading Implant during surgery located within the scleral wall, before the conjunctiva is reapproximated

“It has worked on 100% of the patients,” Cross said. “The worst is 20/30 at 10 inches. Most are in the 20/20 or 20/25 range at 8 to 10 inches.”

Cross said he knows of only two complications involving the modern SEBs —

contact lenses. Two patients said contact lens monovision and LASIK were about equal.

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one involved a physician outside the United States who placed segments off axis about 20°, which, along with excessive cautery, produced significant anterior segment ischemic syndrome. Cross said that the case would be reported in the near future. He said a second complication involved an infection created when a sterilizer failed to cycle, which was not related to the operation.

“We’ve had two complications in 3 years,” Cross said.

Cross said patients are advised that the procedure is still too new to determine how long the implants will be effective.

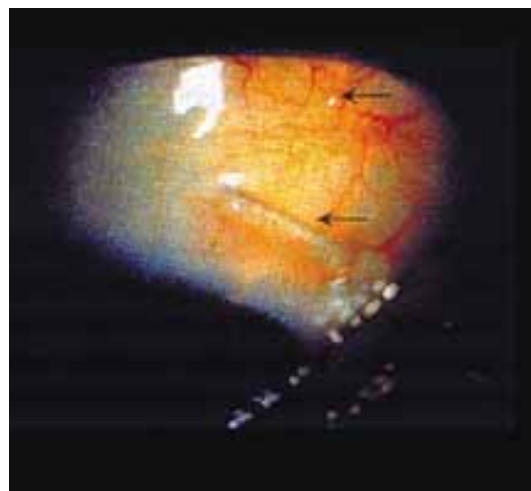
The first ophthalmologist in the world to receive Presby Corp. SEBs was F. Hampton Roy, MD, of Hampton Roy Eye Center in Little Rock, Ark., an associate professor at the University of Arkansas. Cross performed the procedure on Feb. 17. Roy also is a Presby Corp. stockholder.

“It seems to have maintained and I’m about 8 months out,” Roy told EyeWorld in mid-October. “It did not change my distance vision. It increased my accommodative ability 5 D. I had intravenous and topical anesthesia. Just the right eye was done. It was plano at distance and is still plano.”

Roy said patients need eye exercises to restore strength to weakened ciliary body muscles atrophied from lack of use when accommodation is lost. “I had to build up the ability to see up close,” Roy said. “I would look at a close object and bring it in until it blurred, then look at a distant object.”

Roy said implants with the earlier, now discarded, designs were associated with anterior segment necrosis and malignant glaucoma. With early promising results reported and his own experience with the redesigned SEBs, Roy said, he will incorporate the procedure in his own practice.

A second presbyopia reversal technology company, Restorvision, is based in Barbados and has marketing offices in Greenwood Village, Colo. The company’s Reading Implant procedure first was performed by Howard N. Straub, DO, clinical



Scleral expansion bands 1 month after surgery

professor of surgery/ophthalmology, Western University of Health Sciences, Pomona, Calif., associate clinical professor, Michigan State University, and an eye surgeon and director of the Colorado Eye Institute in Aurora.

“December [1999] was the first procedure. In January, we had the next group. It’s an ongoing thing. We’re putting data together for the FDA,” said Larry J. Deutsch, company president and cofounder.

Deutsch in October said that the FDA had requested sterilization testing on packaging materials used for the implant before submission of a final application and possible permission to begin the first phase of U.S. clinical trials.

Deutsch said he and Straub have financial interests in the company. Other Reading Implant procedures have been performed by Ricardo Guimaraes, MD, of Hospital de Olhos de Minas Gerias Clinica in Belo Horizonte, Brazil. Guimaraes has no financial interest in the company.

Guimaraes told EyeWorld that the basis of the Reading Implant procedure involves suspension of the ciliary muscle through scleral implants. “Until recently, we thought that the progressive decrease in accommodation with aging was due to a loss of lens flexibility, often referred to as lens sclerosis. This theory was developed by the German scientist Helmholtz in 1855 and has been accepted as true until 1994,” Guimaraes said. “In 1994, an American named Ronald Schachar proposed a new theory that there was no relaxation of the lens principal [equatorial] ligaments when accommodation occurred, and that the equatorial fibers of the ciliary muscles pull directly on the ends of the lens and cause it to thicken, thus allowing one to see more closely. He proposed that presbyopia could be corrected if the ciliary muscles could be stretched a small amount to allow them to function on the lens.”

Guimaraes said the Reading Implant procedure involves making a 3.5-mm incision in the sclera and placing a PMMA arched stent to stretch equatorial lens



Scleral expansion bands 6 months after surgery



Size of Presby Corp. implants

fibers. Four stents are placed around the eye in the sclera, approximately 3 mm away from the cornea and about 90° apart.

“These stents allow rapid restoration of accommodation and have proved to show good function and effectiveness in those patients done to this date,” Guimaraes said.

He said early presbyopia reversal procedures involved implants that were unstable and lost effectiveness, while Straub’s implant improves safety and stability.

“I liked this design much more, because of the stability,” Guimaraes said. “I have also seen Dr. Straub doing surgery, including in a fellow ophthalmologist. In June, we decided to operate on some patients and give a course in Brazil, when we called in ophthalmologists from all over South America. Dr. Straub assisted me in these surgeries.”

Of three implants, Guimaraes said, one had to be removed because of suspected anterior segment ischemic syndrome.

While an objective examination showed improvement in near vision for the other two patients, Guimaraes said, the patients themselves did not report functional improvement or satisfaction with the procedure.

“They were oriented to perform ciliary muscle exercises, but they admit they have not done any,” Guimaraes said. “It might be that we have not yet learned how to rehabilitate these patients, in spite of the improvement of muscle action.”

A Restorvision videotape features Straub with several patients who are seen reading 20/20 immediately after the procedure. On the tape, Straub explains that the stents used are aimed at elevating the eye’s sclera. He said the arch shape of the tapered stents provides stability within the eye, a feature developed in association with the Massachusetts Institute of Technology.

Time needed to perform presbyopia reversal implant procedures appears to vary, depending on the surgeon’s skill and experience.

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