Presbyopia technologies include IOL and scleral approaches

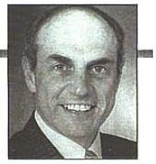
Time will tell whether lenses, scleral expansion or something else will be proved safe and effective.

NEW ORLEANS, U.S.A. – Several promising refractive surgical procedures are available to surgeons for treatment of simple presbyopia. However, none has been proved safe and effective at present. These technologies and surgical approaches were discussed at the American Academy of Ophthalmology meeting here.

Surgical techniques for presbyopia correction fall into two categories: IOL or scleral approaches. The IOL technologies include multifocal IOLs and accommodative IOLs. The most successful multifocal IOL is the Allergan Array. Several accomodative IOLs are in development.

The three principal scleral surgical techniques currently in either U.S. or international clinical trials were described by Australian refractive surgeon **Noel A. Alpins, MD.**

"The first involves scleral expansion techniques such as anterior ciliary sclerotomy with refinements such as silicone or titanium expansion plugs that are sutured into place to reduce regression over time. The second, laser presbyopia reversal (LAPR), is a technique analogous to the incisional technique, with the ablative properties of the laser creating incisions, occurring under lifted conjunctival flaps. Finally, the mode of action of intrascleral segment surgery as described by Schachar is also purported to be by scleral expansion. All these techniques claim to improve accommodation by relative movement of the ciliary body that changes zonular tension in one way or another," he said.



"All these techniques [anterior ciliary sclerotomy, laser presbyopia reversal and intrascleral segment surgery] claim to improve accommodation ... that changes zonular tension in one way or another."
— Noel A. Alpins, MD

In the past decade, intracorneal hydrogel bifocal lenses (Bausch & Lomb) that employ a multifocal concept of a central plus lens for near vision (2-mm diameter) and a peripheral area for clear distance vision have had some success, according to Dr. Alpins. Also, anterior chamber multifocal phakic IOLs described by George Baikoff, MD, work with a tripod Kelman-style lens with a median donut zone for near vision.

"The lens is a multifocal foldable anterior chamber lens with an acrylic optic and PMMA haptics. It has been reported that at 6 months iris necrosis and pupil ovalization is not an observed complication," Dr. Alpins said.

Observations on presbyopia

"As a cataract surgeon, one notices a proportion of patients who seem to gain near vision with a monofocal lens and coexisting emmetropia. The potential for a lens with enhanced ability to flex at the optic-haptic junction, such as C&C Vision's AT-45 silicone lens with polyamide haptics, would seem to have the greatest potential to aid pseudophakia-induced presbyopia," Dr. Alpins said.

Theoretically, the accommodative mechanism of the IOL works when ciliary muscle contraction reduces the volume available to the vitreous body initiating forward movement of the IOL optic aided by a hinge at the optic/haptic junction.

"The mechanism would favor the likely forward movement of the lens by less than 1 mm. An implant of average power of around 20 D for a pre-cataract emmetropic eye would be needed to achieve an effective 2 D addition for near vision," he said.

According to Dr. Alpins, the accommodative pseudophakic implant has many advantages over monofocal vision, including better depth perception.

"As the surgery is incorporated in conventional small-incision cataract surgery, it is likely to have the most rapid uptake of refractive cataract surgeons and the widest acceptance if it is shown to be consistent and effective. The procedure depends on stability of the haptics in the bag with established fibrotic reaction, with an optic well situated posteriorly in the capsular bag," he said. Outcomes have been tracked for more than 1 year with promising results, Dr. Alpins said.

"The Allergan SI18 looped lens acts on a similar principle to the AT45. The progressive multifocal Array lens has multifocal properties but does not exploit the process of anterior movement of the lens on attempted accommodation. The patient can encounter difficulties with haloes and night vision," he said.

Many U.S. ophthalmic surgeons rely on monovision for presbyopia correction.

"At present, with current U.S. limitations, monovision is my principal approach," said **Roger F. Steinert, MD,** at the AAO Subspecialty Day Refractive Surgery meeting.

Dr. Steinert reported that a review of data from his LASIK patients over age 45 showed that 67% selected monovision and have been successful with that arrangement.

"The principal downside to monovision is an increased rate of enhancement procedures in the distance eye, because the monovision patients are entirely dependent on that one eye for their distance vision and therefore are very critical of the quality of their LASIK result in the distance corrected eye," he said.

Laser option

LAPR using the SurgiLight IR-3000 laser is an exciting laser-based option. **Oscar Mallo, MD,** of Argentina, described the infrared fiber-coupled laser technique as a safe and effective method for correction of presbyopic patients' near vision with minimum regression. LAPR is based on a hypothesis that attributes increased ciliary muscle functional range to increased elasticity of the scleral ring resulting from the laser ablation.

Dr. Mallo and J.T. Lin, PhD, shared outcomes of an international study of LAPR with OCULAR SURGERY NEWS at the AAO meeting. The patients ranged in age from 42 to 60 years (mean age 53); 17% were men and 83% were women. Of 41 patients and 82 eyes, only four patients did not achieve outcomes as good as expected.

"We believe this is due to either thin scleral thickness or to shallow ablation during our learning stage," Dr. Mallo said.

Of the 78 remaining cases, postoperatively 74% were J2 or better and 81.5% were J3 or better in near vision without glasses.

"Our results improved significantly, if we exclude those patients with thin sclera or shallow ablations," he said.

Of the 78, 44% have near vision of J1 or better, 84% are J2 or better and 93% are J3 or better.

"The general observation is that subjective near-vision improvement was noticed about 2 to 3 days after the procedure. It continued to improve over 2 to 4 weeks. No myopic shift and no regression were noted during the follow-up period, with a maximum of 14 months," he said.

No significant change in refraction for distance was noted. There was no induced astigmatism. In general, there was a tendency for lower intraocular pressure readings postop, which became normal after a few days to a few weeks, and no significant complications were encountered.

"The advantages of performing presbyopia surgery on the sclera, avoiding the cornea and the anterior segment, consist of unchanged performance on distance visual acuity and contrast sensitivity. Patients who have undergone this technique acknowledge the added benefit of much better vision at the intermediate range, for example, seeing the food while they eat," Dr. Mallo said.

Theories and controversy

Among several competing theories regarding accommodation and presbyopia correction, the most controversial appears to lie in the mechanism of action of scleral expansion. According to Dr. Alpins, Helmholtz' theory of accommodation claims that scleral expansion works by creating more space to enable the zonules to be more actively tensioned during distance vision.

"Active accommodation by ciliary muscle contraction relaxes the zonules enabling the crystalline lens to become more spherical," Dr. Alpins explained. "Schachar promotes a theory that differs from this; accommodation tightens the zonules' tension, flattens the lens equator but also increases anterior and posterior crystalline lens curvatures. However, work by Matthews appears to contradict the explanation."

Work by Glasser and Kaufman disputes the idea that scleral expansion in any form contributes to accommodation if testing techniques are carried out in a proper manner, according to Dr. Alpins.

"They claim the mechanism of action is more likely to be due to favorable ocular aberrations or lenticular multifocality. If presbyopia is, in fact, principally due to the aged human lens becoming hardened, it is then unable to undergo shape changes with the dynamic necessities of the accommodation process that surgery is attempting to influence," he said.

Dr. Steinert said the overwhelming majority of refractive surgeons seem to believe the Helmholtz theory.

"However," he said, "data that show good results from any technique that reverses presbyopia will be of great interest, regardless of theories." OSN

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