ENCOURAGING results achieved so far with a keratophakia approach for the treatment of hyperopia and presbyopia are expected to be further enhanced by future developments in the design of the intracorneal inlay and placement technique.

At the annual ASCRS Symposium on cataract, refractive and IOI surgery, researchers described experiences with various versions of the novel intracorneal lens (PresbyLens, ReVision Optics) as a stand-alone approach for the treatment of hyperopia and presbyopic hyperopia and for presbyopia correction in conjunction with myopic LASIK.

"Keratophakia, or placing a lens within the cornea to change refraction by altering the anterior corneal curvature, was the first refractive surgery procedure ever investigated by Dr Jose Barraquer. My personal experience with it so far using this innovative technology has been extremely fascinating, and I believe keratophakia offers unique advantages for treating presbyopia compared with other modalities," said Stephen G Slade MD, Houston, Texas.

Unlike multifocal IOIs, this approach does not involve intracorneal surgery and offers the potential for well-controlled centration by placement within a customised flap. In contrast to LASIK, the inlay is removable, exchangeable, and does not require stroma removal. Perhaps only conductive keratoplasty matches the ease and safety of this minimally invasive procedure, he commented.

Optimised biocompatibility

The PresbyLens is constructed of a proprietary, microporous hydrogel material that has been engineered to have physical and chemical properties that optimise biocompatibility and mimic the cornea. It is optically clear and matches the cornea with respect to water content (78%) and refractive index (1.376), but allows even higher rates of fluid and glucose diffusion. Therefore, nutrient flow is not impeded and corneal tissue integrity is maintained. Central thickness depends on inlay power and type, but all iterations have a very thin edge of about 5.0 microns.

In the US FDA Phase II trial of the 5.0mm hyperopia implant, Dr Slade treated 11 eyes with MRSE ranging from +1.00 to +6.00 D and cylinder up to 1.0 D. In all cases, the inlay was placed under a flap created with the femtosecond laser (IntraLase). At one month, UCVA at distance was 20/20 or better in three eyes (27%) and 10 (91%) achieved 20/40 or better uncorrected distance acuity. All eyes were also seen at six months, and the results were even better. Among seven eyes followed to 18 months, six (86%) had uncorrected distance acuity of 20/20 or better and all were able to see 20/25 or better at distance without correction.

The refractive predict-ability and stability have also been excellent. At one month, six (55%) eyes were within 0.50 D of the intended target and 10 (91%) were within 1.0 D. At 18 months six (86%) were within 0.50 D and all were within 1.00 D.

"These outcomes did meet the FDA grid for approval," Dr Slade said.

Safety with the inlay technology has been excellent. There have been no problems with adverse corneal responses, infiltrates or acute inflammation, nor have patients experienced edge glare or halos. Best-corrected acuity has been maintained in about 90% of eyes, although one patient lost two lines of BCVA.

Multifocal version

In Mexico, Arturo S Chayet MD has been studying a 4.0mm inlay for treating hyperopic presbyopia and a 1.5mm presbyopic-correcting inlay that is placed on the stromal bed after myopic LASIK.

In one study, Dr Chayet implanted the 4.0mm inlay in six eyes with hyperopic presbyopia. That device has an elevated 1.5 to 2.0mm central add zone to produce multifocality and provides add power of +1.25 to +2.50 D.

After one year of follow-up, mean uncorrected distance acuity improved from 20/42.5 to 20/32.8 and mean uncorrected near acuity improved from 20/143.3 to 20/39. All patients were spectacle independent at distance and 88% were spectacle independent at near. One-third of patients used correction for intermediate vision tasks.

"This inlay is exciting technology for its potential to expand the LASIK market. It can be used in presbyopes who are undergoing LASIK, but can also allow refractive surgeons to treat new onset presbyopia in their new LASIK patients who had refractive surgery at a younger age. Furthermore, because it is removable, this inlay can also be exchanged for a different power as needed to compensate for hyperopic drift or presbyopia progression that occurs with age," said Dr Chayet, director, CodoAris Laser Vision Institute, Tijuana, Mexico.

Dr Chayet also reported results from a study evaluating placement of the 1.5mm inlay after LASIK. It enrolled eight presbyopic myopes who underwent LASIK targeted for emmetropia in both eyes and had the inlay placed in the non-dominant eye after the ablation.

Mean pre-operative MRSE was nearly identical in the dominant and non-dominant eyes, -3.29 D and -3.14 D, respectively. For the eyes that underwent LASIK only, mean pre-operative values for UCVA at distance, intermediate, and near were 20/167, 20/84, and 20/39, respectively. They achieved excellent uncorrected distance acuity (mean 20/22), an improvement in intermediate UCVA (mean 20/41), but mean near uncorrected acuity worsened to 20/75.

In contrast, the eyes with the inlay showed significant improvements across the entire range of vision. Mean distance UCVA improved from 20/170 to 20/41, mean intermediate UCVA improved from 20/78 to 20/24, and mean near UCVA improved from 20/43 to 20/28.

Dr Chayet reported that safety has also been excellent with the 1.5mm inlay. Compared with the 5.0mm hyperopia lens, its mass is reduced about 50%, and so any potential influence on corneal biomechanics is also greatly reduced.

Femtosecond injector system

Ongoing studies include research being performed in collaboration with IntraLase using that company's femtosecond laser to develop an insertion technique in which the inlay would be placed into an intrastromal pocket through a very small incision using a one-step injector system.

"Use of the femtosecond laser to create a pocket and entrance channel would further reduce the invasiveness of this procedure, optimise positioning and predictability, hasten visual recovery, and eliminate any concerns about migration," Dr Slade said.

Dr Slade has been working with collaborators at IntraLase to develop that approach. Its benefits are suggested by the experience of one hyperopic patient who underwent that procedure and achieved UCVA of 20/25 on the first postoperative day.

Various optics designs are also being developed with the idea that the inlay could be customised to a patient's visual needs, eg, creation of a near-dominant presbyopia correcting inlay for individuals whose occupation involves reading or computer work.

"This technology can be created with any optics design, but if patients aren't satisfied with their vision, the inlay can be easily removed," Dr Slade said.

Clinical trials with the intracorneal inlay technology began in the US about two years ago using a 5.0mm device designed to treat hyperopia. That technology is about to enter US FDA Phase III trials. Studies will be undertaken evaluating that same device in patients who had previously undergone LASIK and have since developed presbyopia. The inlay material is CE-marked and studies in Europe with various lens types are expected to begin toward the end of 2006.

Both Dr Slade and Dr Chayet are investigators for ReVision Optics and members of that company's Scientific Advisory Board.

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Keratophakia shows promise for hyperopia and presbyopia

Stephen Slade