

Adjustable IOLs showing results in clinical trials

Cheryl Guttman
in Fort Lauderdale,
Florida

ACCORDING to surveys from the ESCRS and ASCRS, incorrect lens power is the second most common indication for removal of a pseudophakic foldable IOL. To address that problem, various groups have been working to develop novel IOLs that would allow precise in situ modulation of refractive status either through a minimally invasive or a completely non-invasive procedure.

"Despite the best biometry and keratometry, there remain a number of patients who do not achieve optimum vision after cataract or refractive lens exchange surgery. Currently, a leading cause of that problem is the absence of any precise way to correct astigmatism, but in the future as more patients come to cataract surgery after having a keratorefractive procedure, its occurrence is likely to increase," said Arturo Chayet MD, Codet Aris Vision Institute, Tijuana, Mexico.

Light Adjustable Lens

Dr Chayet is currently conducting a clinical trial investigating the Light Adjustable Lens (LAL™, Calhoun Vision). The LAL is designed to allow non-invasive power adjustment after implantation using low-level ultraviolet irradiation to induce polymerisation changes of its proprietary photoreactive silicone macromer material. Irradiation of the optic

in a specific pattern induces localised polymerisation of the silicone macromers.

As a result of the concentration gradient that arises between polymerised and non-polymerised macromers, macromer diffusion occurs and leads to a change in lens shape and power. The new power is "locked in" with a second irradiation procedure. Patients with an accurate refractive outcome and no need for power adjustment undergo only the lock-in treatment.

The irradiation procedures are performed at the slit-lamp with placement of a contact lens, similar to Nd:YAG laser capsulotomy. They were originally performed with an analogue light system, but in September 2004, a digital light delivery device developed in partnership with Carl Zeiss-Meditec Inc was introduced for use in clinical trials.

Postoperative adjustment

That instrument uses Digital Mirror Device chip technology to generate beam spatial profiles with a resolution less than 1.0 micron. The adjustment and lock-in procedures each take less than two minutes. The adjustment can be performed about one week after the implantation surgery, and the lock-in is done at least 20 hours later.

At the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), Dr Chayet and colleagues reported results achieved with LAL

power adjustment in 17 eyes, including 15 treated for spherical errors (+2.25 D to -1.75 D) and two that underwent astigmatic correction for -0.75 D of cylinder.

Their analyses indicated that it is possible to achieve precise, postoperative adjustment of spherical and astigmatic power and that the patients benefited with improvement in UCVA without experiencing changes in BCVA or contrast sensitivity.

"When I was first shown the concept of the LAL, it seemed like science fiction to me.

However, based on my clinical trial experience, I believe this technology affords a very safe and precise method to easily and noninvasively correct myopia, hyperopia, and/or astigmatism. It is truly incredible to see these patients achieve 20/20 UCVA by the day after the adjustment procedure, and we are looking forward to further studies, including use of this approach to treat higher order aberrations at the level of the IOL," said Dr Chayet.

The 15 eyes with spherical refractive errors included eight eyes with hyperopia and seven eyes with myopia. All had been intentionally implanted with a lens power that would leave a residual refractive error.

In all 15 eyes, the achieved spherical power changes after the adjustment procedure were within 0.25 D of attempted, and there was no shift in power after the lock-in procedure. Refractions measured in two eyes that did not require any adjustment in lens

power and underwent the lock-in procedure only confirmed that the lock-in itself has no effect on lens power.

The two eyes that underwent astigmatic power adjustments had pre-existing cylindrical error. In those eyes, the achieved correction on the cylindrical axis was within 10 degrees of the target.

Excellent biocompatibility

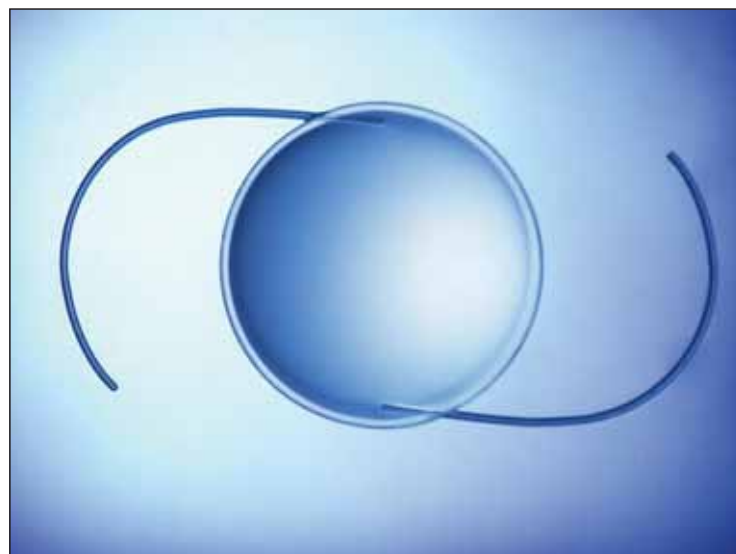
The LAL also continues to demonstrate excellent biocompatibility. No eyes have developed any significant inflammation with more than 24 months of follow-up now available from the first human eye implantation.

The LAL has a three-piece design. It has an overall length of 13.0-mm, a 6.0-mm, square-edge optic, and blue PMMA modified-C loop haptics.

"The LAL is implanted similarly to a conventional three-piece foldable silicone IOL, and it centres beautifully in the eye," Dr Chayet said.

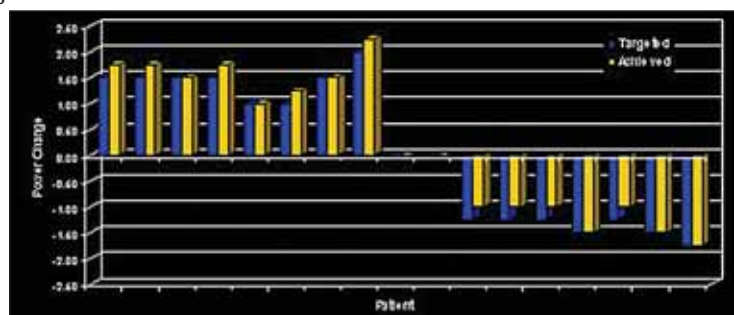
Mechanically adjustable IOL

Also at the ARVO meeting, Claus E Jahn MD, Kempen, Germany, reported results from a phase I clinical trial evaluating a prototype of his power adjustable IOL concept -- a posterior



The Light Adjustable Lens

Courtesy of Shiao Chang MD



Targeted vs. achieved power adjustments. Data for 15 spherical adjustment patients demonstrate all corrections are within ±0.25D of target refraction.

chamber IOL with a



Patient eye implanted with LAL and treated for power adjustment/lock-in at 15 months.

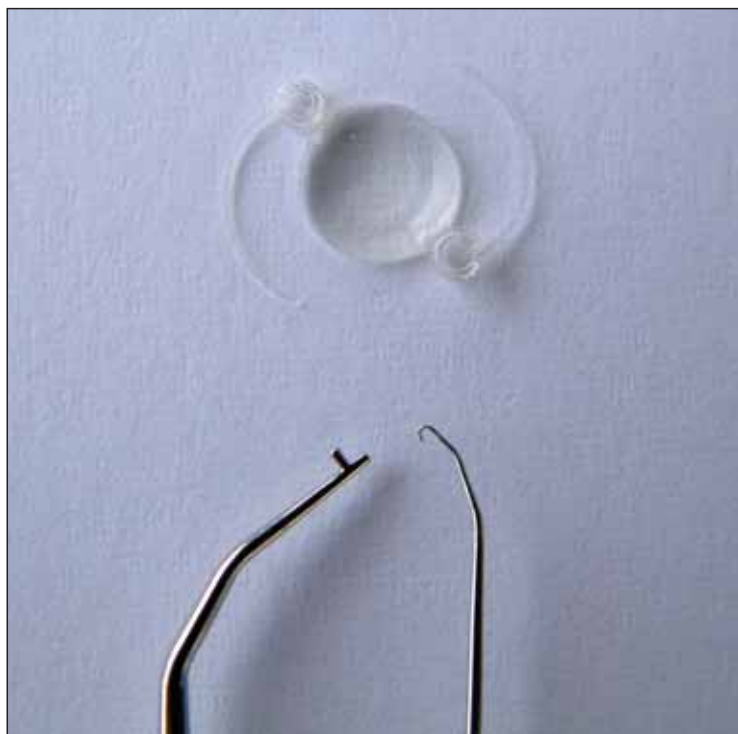
reversibly adjustable focus that is modified mechanically during a secondary procedure by manipulating an element incorporated within the haptics. The IOL is being developed by Acri.Tec GmbH as the Acri.Tec AR-1 PC/IOL.

Dr Jahn presented experience from 15 eyes that were implanted with the investigational IOL after removal of senile cataracts. Patients who needed bilateral surgery received the adjustable implant in one eye and either a PMMA Acri.Tec 23 CS PC/IOL with a 6.5-mm optic or a foldable acrylic Acri.Tec 43 TS PC/IOL with a 5.8-mm optic in the fellow eye.

The study is

designed primarily to evaluate the clinical safety of the IOL, but refractive adjustment was performed in one eye at 2 weeks post-implantation for correction of a +1.0 D error. In total, 30 of the adjustable focus IOLs have been implanted to date, with several eyes now being followed for more than one year.

Dr Jahn reported that the IOL could be easily implanted into the posterior capsular bag without damaging the posterior capsule or causing inadvertent movement of the adjustment element. The corneas were clear on the first day after surgery, and induced astigmatism



Courtesy of Claus Jahn MD

The mechanically adjustable IOL.

was ≤ 0.5 D.

The adjustable IOLs have maintained good position over time with no decentration or tilting, and refraction has also been stable from the first month on after the initial healing process was completed, indicating the position of the adjustment element is not subject to unpredictable movement intraocularly.

Compared with implanted fellow eyes, there were no differences in outcome with respect to visual acuity, refractive stability, slit-lamp appearance, or IOP changes, Dr Jahn said.

"This novel implant appears to be as safe as any conventional IOL, and our initial experience with adjustment also indicates that the refraction can be effectively changed with surgery that is both simple and safe," he commented.

The prototype being studied is constructed of PMMA and has a 5.5-mm optic. It has been implanted into the capsular bag through a scleral tunnel incision after crystalline lens removal by phacoemulsification.

Cylinder-piston mechanism

The adjustable element for changing lens focus uses a cylinder-piston mechanism integrated into the haptic. A 1.0 mm cylinder is attached to the optic and contains a piston attached to the outer part of the haptic. By moving the cylinder and the piston in

relation to each other with the use of a forceps or two hooks specially designed for the procedure, the IOL optic moves along the optical axis of the eye, Dr Jahn explained.

"The principle of the adjustment mechanism is

"This prototype PC/IOL design would offer the opportunity to completely correct residual refractive errors in almost every case."

analogous to that of the lens on a slide projector where the focus is changed by moving the objective lens back and forth," he said.

Every millimetre of optic displacement induced by the adjustment translates into a 1.5 D change in refraction. Between 2.0 and 2.5 D of refraction adjustment is possible using this technology.

"Our studies indicate that about 97% of all deviations of post-operative refraction from the predicted value fall within an interval of 2.0 D. Therefore, this prototype PC/IOL design would offer the opportunity to completely correct residual refractive errors in almost every case," Dr Jahn said.

To investigate the amount of space available for the adjustment element, the IOL was implanted in the Phase I trial with the adjustment element pointing towards the iris in some eyes and towards the vitreous in others. The experience with implantation was similar regardless of the orientation of the adjustment element.

"The ability to orient the adjustment element towards the front and back of the eye will allow the manufacture of versions with a longer, bidirectional adjustment element, which may be necessary in myopic eyes," Dr Jahn said.

Secondary surgery for power adjustment

In the one eye that underwent power adjustment, the secondary surgery was performed using topical and intracameral anaesthesia with bupivacaine 0.5% and viscoelastic (Acrihylon) instilled into the anterior chamber for endothelial protection. The patient had a small pupil, and so dilator hooks were needed for sufficient intraocular access.

The adjustment was performed with a bimanual technique using the specially designed hooks and was completed without any complications intra- or postoperatively. The surgery produced an emmetropic result without any trauma to the posterior capsule or other complications. The refraction has remained stable during follow-up that now extends to three months.

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Nick Mamalis MD will be presenting an update on the Light Adjustable Intraocular Lens at the ESCRS Congress in Lisbon in a free paper session (Tuesday, September 13, 8:00-10:30, Auditorium VI-VII) and in a video presentation, viewable in the video library (Pavilion 3, behind registration desk). Claus Jahn MD will provide an update on the implantation and adjustment of the Acri.Tec AR-1 PC/IOL in a poster presentation.