Micro-incision IOLs move toward the mainstream
Niche manufacturers see markets expand as technical barriers fall

Howard Larkin

The history of cataract surgery has been a steady march toward smaller incisions. With the advent of bimanual phaco techniques and equipment, typical incision sizes have dropped from 3.0 mm or more to about 1.5 mm. Even some coaxial phaco equipment can now be used through surgical wounds closer to 2.0 mm than 3.0 mm. That's good news for patients. As incision size shrinks, so do healing times - and the chances of complications including induced astigmatism and endophthalmitis.

But what good is a 1.5 mm phaco incision if it must be widened to 3.0 mm to insert an intraocular lens? To some minds, this necessity negates much of the advantage of micro-incision cataract surgery.

Overcoming this limitation requires extremely thin, flexible IOLs that can be rolled up small enough to insert through a sub-2.0 mm opening. In theory, ultra-thin lenses have the advantage not only of insertion through smaller incisions; they also are potentially more optically perfect, since optical aberrations increase with lens thickness.

But developing micro-incision lenses has been fraught with technical challenges. They must be soft enough to roll into a small tube, yet sturdy enough to resist decentration or other movement in the eye. Likewise, they must be thin enough to roll up small while retaining enough refractive power to be useful for a wide range of patients. All while offering optical performance and resistance to posterior capsular opacification comparable to existing standard lenses.

While these challenges are substantial, a handful of companies have set out to tackle them. As a result, a range of lenses are now available that can be inserted through a 2.2 mm down to a 1.5 mm micro-incision level. These lenses are gaining market acceptance as clinical trials continue to support their efficacy.

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Below are brief profiles of four manufacturers developing mini- and micro-incision lenses.

Acri.Tec

Founded in 1997 by Dr Christine Kreiner, Acri.Tec GmbH was one of the first manufacturers to develop a micro-incision lens. The rollable Acri.Smart lens was first implanted through a 2.0 mm incision in 2000, and was on the market in Europe in December 2001. The company, based in Henningdorf, Germany, now offers a wide range of lenses based on the original Acri.Smart design, including spheric, aspheric, optimised aspheric, bitoric and bifocal versions in powers from 0 to +32 dioptres, said Christian Lingenfelder, Acri.Tec’s head of marketing. The lens is typically implanted through incisions of 1.5 mm to 1.7 mm depending on the technique. ‘We are able to supply whatever type of optic is required through a small incision.’

Like other mini- and micro-incision IOls, Acri.Smart is made of a hydrophilic acrylic material with a high refractive index. This allows the manufacturer to make the IOL with almost standard thickness flexible enough to be rolled tight to fit through a small incision. However, the surface of the lens is a hydrophobic compound to discourage the growth of endothelial cells and calcification seen with earlier hydrophilic lenses, Lingenfelder said. “It is like a tomato. The surface is very resistant to water, but the interior is 25% water.”

Lingenfelder declined to provide sales figures for the Acri.Smart, but said demand is growing rapidly. “You are seeing a lot of interest in the scientific community whereas two years ago it was rather exotic. Some ophthalmologists are implanting as many as 2,500 a year. These are real high-volume surgeons. The main advantage is the security of the implant. You don’t need an additional instrument because you don’t have to rotate it. Some people have stopped using viscoelastics for their MICS procedures.

The lens is currently available in Europe, Asia, and South America. A large-scale trial is currently underway to gain approval in the United States.

Widespread availability of bimanual phaco equipment is a big driver in the growing popularity of the micro-incision lenses, Lingenfelder said. “The phaco technology is now ready to allow for smaller incisions and implantation of MICS IOLs. You can’t take advantage of the smaller lens when the phaco technology is not yet there.”

While more surgeons use a bimanual technique, the lens can be used with any surgical technique. “It’s a flexible design.”

PhysIOL

Founded by faculty members of the University of Liege in Belgium in 1986, PhysIOL began two years ago to introduce to the market a mini-incision IOL, the SlimFlex®, according to Dr Christophe Pagnoulle, research and development manager.

Based on the technology platform of the SlimFlex®, an advanced version known as the MicroFlex® was specifically designed to be injected through a sub-2.0mm incision. However, incision size can be as low as 1.5 mm depending on the surgical approach. Thanks to the modified square truncated edge design with 2step®, cell proliferation is also inhibited at the optic/haptic junction creating an effective barrier of 360° compared to other micro incision IOLs using a plate haptic design. Preliminary results from multicentre clinical studies have been extremely favourable especially as far as refractive stability and incidence of PCO is concerned.

The YellowFlex® offered by PhysIOL has a proprietary blue light filter, called BlueTec®, with adaptive properties to scotopic and photopic conditions which enhance contrast sensitivity specifically under low illumination and protection the retina under day light conditions. The YellowFlex® is provided in powers ranging from -10.0D to +35.0D and is compatible to incision sizes around 2.4mm using an injecting system.

The SlimFlex® with 2step® suitable for incisions of 2.4mm represents the majority of the companies sales and acceptance is gaining fast, Dr Pagnoulle said. It is believed that the widespread use of mini- and micro-incision IOLs like the MicroFlex® is dependent on the surgical technique and available equipment but it can be inserted through an astigmatically neutral phaco and is perceived to be very comfortable for the surgeon.

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**Xcelens**

Founded in 2003 by a group with long experience in IOL development, Xcelens S.A. entered the market with a mini-incision IOL in March 2004. Designed for insertion through a 2.2 mm incision, the Idea’ Lens is available in powers from -10 to +35 dioptres, said Stéphane Mendras, business development manager. “This lens can be used in 90% of cataract surgeries.” The company, which is based in Geneva, Switzerland, is now developing aspheric and yellow-tinted versions of the lens.

Providing a lens that would have broad use while reducing incision size was the goal for Xcelens, Mendras says. He noted that the Idea’ Lens is 13.0 mm in diameter, large enough to stabilise in virtually any eye with a patented elastic band design that accommodates to any size capsular bag. The lens is also designed with square edges to discourage posterior capsular opacification. “We knew it had to be as good as the gold standard on the market. It had to have stability and good PCO performance.”

With 80,000 lenses implanted in 40 countries around the world so far, the results are good – no posterior capsular opacification and no inflammation so far, Mendras said.

While the development of bimanual phaco stimulated the development of the mini-incision lens, Xcelens believes it has just as much to offer surgeons using a coaxial technique. To allow surgeons to use a coaxial technique while still benefiting from the smaller incision size, Xcelens has developed a complete range of products including a pre-calibrated knife, as well as a specific phaco tip and sleeve. With this concept of Coaxial Mini-Incision Cataract Surgery, surgeons can perform daily surgery through a 2.2 mm incision, a 30% to 40% reduction from standard coaxial incisions.

“This system combines the best aspects of bimanual and coaxial,” Mendras said. “You can introduce the smaller incision, but you don’t have to invest in new equipment or change your surgical habits. The learning curve is very low. This solution is open to any cataract surgeon… who is used to phacoemulsification and foldable IOLs.”

**ThinOptX**

After a long career in developing IOL manufacturing facilities, Wayne Callahan founded ThinOptX in 1995 with his son Scott, an engineer. “Our goal was to produce as close to an optically perfect lens as possible. That meant making it as thin as possible,” Callahan said. Using innovative design and machining techniques, the company, which is based in Virginia in the USA, produced a lens with a central thickness ranging from 50 to 300 microns, using concentric rings with slightly different radii to compensate for spherical aberrations. The lens is available in powers from -25 to +25 dioptres.

The lens was implanted though a sub-2.0 mm incision for the first time in Greece in 1999. As one of the first lenses available that could be inserted through incisions as small as 1.5 mm, the ThinOptX drew a great deal of attention and has been the subject of numerous studies comparing the optical qualities of the thinner lens with conventional IOLs.”

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A ThinOptX lens was approved for sale in Europe in September 2002 and commenced trials for US approval later that year. However, after about 8,000 lenses were produced, patients began reporting halos. Production was stopped until the problem was traced to a vibration in the lathe that polished the smooth side of the lens, highlighting the technical difficulty of manufacturing lenses to these tolerances. The problem was resolved and the lens is now available throughout Europe, Asia, South America and the Middle East.

Callahan has no plans currently to resume US trials.

Callahan believes the micro-incision market is dividing into segments. At one end, proponents of the phacoit process are looking for a lens that can be inserted through a 1.0 mm incision. Others who adhere to more traditional phaco techniques are looking for products in the 2.0 mm incision range.