

## Trends in Cataract Surgery

a report by

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Members of the baby boom generation, born following World War II, are entering their senior years. They are a generation accustomed to technological change and adopting it into their work and personal lives. As they age they are encountering presbyopia and are, we believe, eager to take advantage of surgical options for managing it. At the same time, the ophthalmic industry and ophthalmic surgeons are developing new surgical techniques and products to meet the demands of these patients and their active lifestyles.

Cataract surgery, while mostly confined to those in their 1960s and 1970s, has been the surgical venue in which the basic techniques and products have been developed that will serve as the foundation providing presbyopia artificial lenses.

### Cataract Surgery Fundamentals

Cataract removal is generally accomplished through a procedure called phacoemulsification. In this procedure, a probe is inserted through an incision in the cornea, through the dilated pupil, and into the capsule that holds the lens of the eye. The probe, or hand piece, has a rapidly oscillating tip that emulsifies the lens and a tube that aspirates the nuclear material until the lens is completely removed.

Following lens removal, the probe is withdrawn. A syringe-like device with a cartridge holding a folded artificial lens is inserted through the incision and the artificial lens, called an intraocular lens (IOL) is inserted into the capsule where it unfolds. Other instruments are used to position the lens within the capsule. Centering of the typically circular IOL lens is accomplished by 'haptics'—tiny arms extending from the sides of the lens—that extend to the sides of the capsule.

Until recently, monofocal IOLs were the only lenses available and typically they provided cataract patients with good distance vision, but reading glasses were needed for near vision function. Recent innovations in IOL technology have just begun to offer patients good distance and near vision. This article will review some of those surgical and lens innovations that are setting

the stage for a greatly expanded field of ophthalmic surgical practice that aims to give cataract patients—as well as younger, pre-cataract presbyopic patients—greater spectacle independence.

### Surgical Innovations

The OZil hand piece recently introduced by Alcon Laboratories is regarded by many American surgeons as a genuine and valued innovation in the design of the phacoemulsification probe and it is gaining wide popularity here. Unlike other instruments, the probe uses oscillating torsional ultrasonic movement of the emulsifying tip rather than longitudinal movement. This has the effect of increasing cutting efficiency, decreasing friction of tip against the cataract-damaged lens which reduces the possibility of an incisional burn. Its chief advantage is that it does not repel nuclear material from the probe tip during the emulsifying process. Surgeons who have adopted this new instrument have been impressed with its increased safety and improved efficiency. On the negative side, the use of the instrument's angled tip requires a learning curve, which most surgeons can manage in a short time.

In the area of lens removal and implantation technology, using a new product called an 'ultrasleeve' has allowed a reduction of the required corneal incision size to approximately 2.2mm with the concept of coaxial micro-phacoemulsification—introduced by Alcon Laboratories—and it is expected that within a short time other manufacturers will offer similar devices. The advantage of reduced incision size is a smaller amount of surgically induced astigmatism. Also, the wound stability is likely to be stronger, as there are fewer tendencies to leak fluid from the anterior chamber of the eye following surgery.

### New Intraocular Lenses for Astigmatism

One of the shortcomings of traditional IOLs has been their inability to correct for astigmatism, the blurriness of vision caused by irregularities in the shape of the cornea. Special astigmatism correcting lenses, called 'toric IOLs' have been developed to address this need and give



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patients greater spectacle independence. This year, the US Food and Drug Administration (FDA), the government agency that must approve medical devices and drugs before they can be used in the US, has approved an Alcon Laboratories manufactured toric IOL. From various studies, this device appears to be a more effective strategy for the reduction of astigmatism than combining corneal relaxing incisions with cataract surgery.

### Aspheric IOLs

A problem encountered with the use of some of the more powerful traditional IOLs is spherical aberration. This year saw the continuing development of aspheric IOLs designed to improve contrast sensitivity and functional vision following cataract or lens replacement surgery. This has come from an improved understanding of corneal curvature and its relationship to vision quality following laser vision correction. Wave front analysis of the eye has made us aware that the cornea induces positive spherical aberrations and, in the youthful eye, the natural lens counteracts the spherical aberration of the cornea. As we age, the natural crystalline lens hardens, changes shape, and no longer neutralizes the spherical distortion of the cornea. By using an artificial lens that mimics the optics of the youthful natural lens, we are achieving better quality of vision for patients following surgery. This understanding has contributed to the increased interest and use of these lenses in the US. Currently there are three aspheric lenses that have been approved by the FDA on the US market: the Technis made by Advanced Medical Optics, the IQ lens made by Alcon Laboratories, and the Bausch and Lomb SofPort Advanced Optics lens.

### Lens Implant-based Refractive Surgery

In addition to lenses which replace the crystalline lens of the eye, implantable lenses are being used to correct nearsightedness, which is primarily associated with the cornea. They are called 'phakic IOLs' because patients retain their normally functioning lenses. These are typically being used to correct moderate to extreme myopia (-5 to -20 diopters) in patients who are not candidates for laser vision correction. There two phakic IOLs available in the US. In 2005, the FDA approved the Verisyse Artisan lens, and this year the Starr Vision Implantable Contact Lens (ICL) was approved. The Verisyse is placed in front of the pupil and attaches to the iris. The Starr Vision ICL is placed behind the pupil directly in front of the lens.

We have seen a continuation of the theme of increasing use of IOLs to manage refractive errors including presbyopia or the loss of accommodation.

### Presbyopia—The Last Frontier

There is great excitement in the profession, the ophthalmic industry, and in the middle-aged public that implantable lenses can be used for presbyopia and that these devices that will lead to elimination of dependence on spectacles and contact lenses.

Simply put, presbyopia is caused by the normal, age-related hardening of the lens. This hardening results in the loss of the ability of the eye to change the shape of the lens, thus limiting its ability to change focus from distant to intermediate or near objects. The ability to change focus is called accommodation.

Presently, there are three presbyopia correcting lenses that have been approved by the FDA. Two of these are 'pseudo-accommodative:' the ReStor by Alcon Laboratories, and the ReZoom by Advanced Medical Optics. Approved by the FDA as an 'accommodating' lens is the CrystaLens from Eyeonics.

A pseudo-accommodating lens is essentially a disc with concentric rings of different optical power. Thus, light entering the eye from distant and near sources is divided by the rings and focused on the retina simultaneously. The brain selects which one to focus on, that is, which one to pay attention to. As light is divided, there is always a loss of image quality. While they work well, especially relative to the vision of a cataract patient before surgery, they are not perfect.

By contrast, accommodating lenses achieve their visual effects dynamically. True accommodation requires a transient and rapidly reversible change in the power of the visual system. In keeping with the Helmholtz theory of accommodation, the lens must change its shape or move forward and backward in the eye to change its power and focus. Either the lens moves within the eye, or additional power is added to it by some other means. To do that accurately, a complex series of actions must be initiated by muscles in the eye.

Few ophthalmologists today believe that any of the above mentioned lenses are adequate enough in their performance to use them for surgery when the patient only needs reading glasses. However, if the patient has cataracts, which require the removal of the natural lens, then these lenses offer an excellent alternative to traditional mono-focal IOLs. They are also indicated for patients without cataracts who want reduced dependence on reading glasses, but most ophthalmologists do not feel that 45- to 50-year-old presbyopic patients who have normal distance vision in both eyes should be subjected to surgery in hopes of keeping their distance vision normal and eliminating their need for reading glasses.

## Products in the Pipeline

One means of increasing the optical power of an IOL lens is to use a device with two lenses that can be moved closer or farther apart by the muscles of the eye to change focus. One such dual optic telescoping device is the Visiogen Synchrony, which is in FDA trials at this time. Another dual optic lens, the Sarfarazi, is under development by Bausch and Lomb, but it is not yet in FDA trials.

The next series of lenses illustrate the different mechanisms by which lenses can make an accommodative increase in power.

The LiquiLens by Vision Solutions Technologies has two liquids that alter position in the lens as the eye looks down. It provides normal distance vision and three or more diopters accommodation for low vision patients.

Another lens of this type is made by Power Vision, which also incorporates new 'applied fluidic' technology in a single piece IOL. As the muscles in the eye flex to provide accommodative stimulation, fluid is pumped reversibly, altering the radius of the curvature of the lens, affecting an increase in power for near vision purposes.

The NuLens accommodating IOL, being developed in Israel, increases optical power by a compression plate acting against a semi-liquid silicone optic.

Many ophthalmic surgeons look forward with anticipation to an injectable, full-size lens that fills the capsular bag. Medennium Inc. and Advanced Medical Optics (AMO) are in various stages of developing such lenses.

The AMO product is an optical polymer that, when warmed, takes the form of a semi-liquid that can be injected through a syringe-like instrument into the lens capsule. As it cools to body temperature it assumes the shape of a lens that will flex to allow for accommodation.

Medennium Inc. is developing a lens made of hydrophobic acrylic with thermodynamic properties such that the lens can be warmed, shaped into a tiny rod, and then cooled to keep the rod shape. When it is inserted into the capsule of the eye and warms to body temperature it assumes its predetermined lens shape with a specific optic power. As it is pliable, the muscles of the eye can alter its shape to provide greater power and accommodation, thus mimicking the behavior of the natural crystalline lens.

The AcuFocus Corneal Inlay is an ultra-thin disc placed

under a flap created on the surface of the cornea, similar to the flap created for laser-assisted *in situ* keratomileusis (LASIK) surgery. It is based on small optical aperture or 'pin hole' effect. It is an opaque biocompatible polymer similar in appearance to a metal washer. Placed in the non-dominant eye, it increases depth of focus but does not reduce distance visual acuity.

LASIK and other laser-based vision correction procedures are also being used to provide solutions for presbyopia. A presbyopic excimer laser algorithm is being developed to address the needs of post cataract and eventually middle-aged presbyopic patients. In effect, this approach uses the laser to sculpt a multi-focal prescription on the cornea. The VISX division of AMO is investigating this technology.

## Adjusting the Outcome

The power of lenses to be implanted is determined by certain formulas. While these formulas work well, we cannot always predict with absolute exactitude the post-operative power for the lens. Therefore, the ability to adjust the optical outcome of surgery is necessary. Two of these means of adjustment are laser vision correction of the cornea and incisional surgery on the cornea to relieve astigmatism.

The light adjustable lens by Calhoun Vision Inc. uses a polymer whose properties are such that the lens power can be changed post-operatively by exposing the lens to a certain type of laser. The concept of post-operative adjustment in lens power can, hopefully, be adaptable to a wide variety of lens types.

Ophthalmic surgeons are excited about this emerging technology. They hold the promise of offering pre-cataract as well as post-cataract patients a series of surgical options for dealing with presbyopia and enhancing their quality of life. However, surgeons will need to invest time and effort to develop proficiency with these new lenses and vision correction strategies and develop means for appropriate patient selection. From a business perspective, they will also have to learn how to integrate these products into their practices and how to market their services.

To help surgeons make the transition to this expanded field of practice the American Society of Cataract and Refractive Surgery (ASCRS) is developing courses and symposia for its various meetings. They will also provide information through the peer-reviewed *Journal of Cataract and Refractive Surgery*, and their scientific and socio-economic news magazine *EyeWorld*, and will fund research through the ASCRS Foundation and make information available on their various websites. ■