Clinical & Refractive Optometry is pleased to present this continuing education (CE) article by Dr. George Beiko entitled **Innovations in Intraocular Lenses.** In order to obtain a 1-hour Council of Optometric Practitioner Education (COPE) approved CE credit, please refer to page 298 for complete instructions.

Innovations in Intraocular Lenses

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Abstract

The newest intraocular lenses (IOLs) attempt to provide better vision for cataract surgery and refractive lens exchange patients. Great strides have been made in understanding and designing lenses to address IOL-related problems such as posterior capsular opacification, dysphotopsia (unwanted images), and higher-order wavefront aberrations. New IOLs include the Technis Z9000 (Pharmacia) that was conceived to correct spherical aberration and improve contrast sensitivity and the Light Adjustable Lens (Calhoun Vision) that can correct hyperopia, myopia, and astigmatism. Other novel IOLs include small-incision IOLs such as the ThinOptix lens (ThinOptix) and the SmartLens (Medennium) that can be inserted in a 1.5 mm incision. Accommodative lenses such as the AT-45 CrystaLens (C&C Vision), diffractive bifocals — such as the CeeOn 811e (Pharmacia), the M4 (IOL Tech), and the MA60D3 (Alcon) IOLs — and the refractive multifocal Array (AMO) IOL are designed to make patients less dependent on spectacle use.

Introduction

IOL designs have evolved greatly over the past few years, but even better advancements are "in the pipeline." Some of these novel IOLs will potentially make a huge difference in vision and quality of life following cataract and refractive surgery. New developments include designs to reduce visual quality problems caused by posterior capsular opacification (PCO), dysphotopsia (unwanted images), and wavefront aberrations, especially higher-order aberrations.

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Based on a presentation which was made at the OPTOMETRY 2003 meeting held on June 8, 2003, in Montreal, Quebec.

Posterior capsular opacification, dysphotopsia, and wavefront aberrations

Posterior capsular opacification

PCO is the proliferation of epithelial cells in the capsular bag, which is part of the eye's wound healing response after cataract surgery with implantation of an IOL. The condition appears between 3 months to 4 years after surgery, and usually causes decreased visual acuity by direct blockage of the visual axis. PCO is the most common complication of cataract surgery, and is seen on retroillumination digital slit-lamp photographs. When PCO is clinically significant, cataract patients require a neodymium yttrium-aluminum-garnet (Nd:YAG) laser capsulotomy. Improved surgical techniques and IOL designs are reducing the incidence of PCO.

A square-edge IOL design has been shown to reduce the incidence of PCO. Okihiro Nishi, MD (Osaka, Japan) demonstrated in a rabbit model that a square posterior edge stops migration of epithelial cells, which is associated with decreased PCO. This barrier effect of a square edge was shown in three lenses made from different materials: a polymethylmethacrylate (PMMA) lens, a silicone CeeOn 911 (Pharmacia) lens, and an acrylic AcrySof (Alcon) lens. Later clinical studies confirmed these results.

IOLs with smaller haptics have a better shrink-wrap effect (shrinkage of the capsular bag around the IOL) compared to those with larger haptics. In a rabbit study, Nishi showed that this improved shrink-wrap effect was associated with lower rates of PCO. In a clinical study, Randall Olson, MD (Salt Lake City, Utah) found more Nd:YAG capsulotomies were required with the large-haptic one-piece SA-30 AcrySof (Alcon) IOL compared to the smaller-haptic three-piece AcrySof IOL (MA-30).

Dysphotopsia

Unwanted images can be either positive flashing images or negative shadows. Dysphotopsia has been shown to be reduced in IOLs with a rounded edge. The OptiEdge (AMO) design features a rounded anterior edge to minimize glare (as well as a sloping side edge to minimize internal reflection and a squared posterior edge to minimize PCO). A study comparing a silicone lens with

Table I Wavefront aberrations		
Category	**Order**	**Aberration types**
Lower-order	0	piston
	1st	tip, tilt, prism
	2nd	defocus (myopia, hyperopia), astigmatism
Higher-order	3rd	coma, trefoil
	4th	spherical, secondary astigmatism, quadrafoil
	5th	secondary coma
	6th	secondary spherical

OptiEdge versus the acrylic AcrySof (Alcon) lens that has a square edge found no dysphotopsia when pupil size was 3 mm. With a 5 mm pupil, however, the square edge of the AcrySof IOL allowed light to be reflected, forming a secondary arc of light. With the OptiEdge design, dysphotopsia was reduced by 66%.

Higher-order wavefront Aberrations

Wavefront analysis using an aberrometer evaluates how a plane of light is transformed as it passes through the eye. When a plane of light passes through a normal eye, some parts of the light are speeded up and other parts are slowed down, which results in a wavy beam of light leaving the eye. In a myopic eye, the central portion of a plane of light is slowed down, so the light beam that exits the eye is concave. In a hyperopic eye, the central portion of the plane of light is speeded up and the exiting light beam is convex.

About 85% of wavefront aberrations in the normal eye are lower-order sphere and cylinder aberrations. These include 0 order piston, 1st order tip or tilt, and 2nd order defocus (myopia, hyperopia), or astigmatism aberrations. Higher-order aberrations include 3rd order coma and 4th order spherical aberrations. Types of wavefront aberrations are summarized in Table I.

In the Zywave (Bausch & Lomb) aberrometer, which is based on the Hartmann-Schack principle, a flat wavefront is projected on the retina and reflected light deviations from equally spaced points of light are determined. These aberrations are expressed as the root mean square (RMS) of the variance of the wavefront. Figure 1 shows the wavefront aberrations. Figure 2 shows the effect of these aberrations on an image. Spherical aberration looks like a Mexican hat (Figure 1).

A study of patients who received the silicone CeeOn 911 (Pharmacia) IOL in one eye and the acrylic AcrySof (Alcon) or the silicone SI40 (AMO) IOL in the other eye found no difference in the total wavefront RMS in the two groups.

In another study, I investigated individual higher-order aberrations in 100 patients. I implanted the silicone LI61U (Bausch & Lomb) IOL in one eye. Patients were then randomized to receive one of five IOLs in the second eye: the silicone SI40 (AMO) IOL, the silicone ClariFlex (AMO) IOL with OptiEdge, the square-edged silicone CeeOn 911 (Pharmacia) IOL, the acrylic AcrySof SA60AT (Alcon) IOL, or the silicone multifocal Array (AMO) IOL. The RMS was approximately 0.1 for all lenses except the Array. The Array was associated with a higher degree of trefoil aberration. The AcrySof IOL was linked with a small, but significantly larger degree of 5th order secondary coma aberrations, which might explain dysphotopsias seen with this lens.

In the healthy human eye, most aberrations come from the cornea and about 25% to 30% come from the lens, provided there is no induced astigmatism. In an aphakic eye, 98% of the aberrations come from the cornea. With age, the cornea does not change, but the lens changes. In a young individual, the cornea has a positive spherical aberration and the lens has negative spherical aberration. With age, the lens has increasing positive spherical aberrations, which when combined with the positive spherical aberration from the cornea results in a loss of contrast sensitivity. Coma aberrations increase with age and with pupil size. Some aberrations might be desirable for optimal vision. A study of fighter pilots, who have excellent vision, found that those with 6/3.6 (20/12) Snellen visual acuity had a small amount of coma and spherical aberration.

Some of the newest IOLs

Correcting spherical aberration

The Technis Z9000 (Pharmacia) has a modified prolate anterior surface designed to produce negative spherical aberrations to compensate for positive corneal spherical aberration. Ulrich Mester, MD (Sulzbach, Germany) studied 45 patients who received the Technis Z9000 IOL in one eye and the silicone SI40 (AMO) IOL in the other eye. In eyes with the Technis Z9000 IOL, spherical aberrations were reduced, while low-contrast visual acuity and mesopic contrast sensitivity were significantly better. Roberto Bellucci, MD, Lucio Buratto, MD, and Antonio Scialdone, MD (Verona, Italy) compared the Technis Z9000 with the acrylic AcrySof SA60AT IOL. They reported that contrast sensitivity was better with the Technis Z9000 IOL in all lighting conditions.

Light-adjustable lens

The Light Adjustable Lens (LAL, Calhoun Vision) is composed of monomers that are sensitive to UV light. A surgeon can use a noninvasive beam of light to adjust the IOL power 2 to 4 weeks after the LAL has been implanted, when the eye has healed and the refractive error has stabilized. For example, if the IOL proves to be slightly underpowered, the surgeon can irradiate the

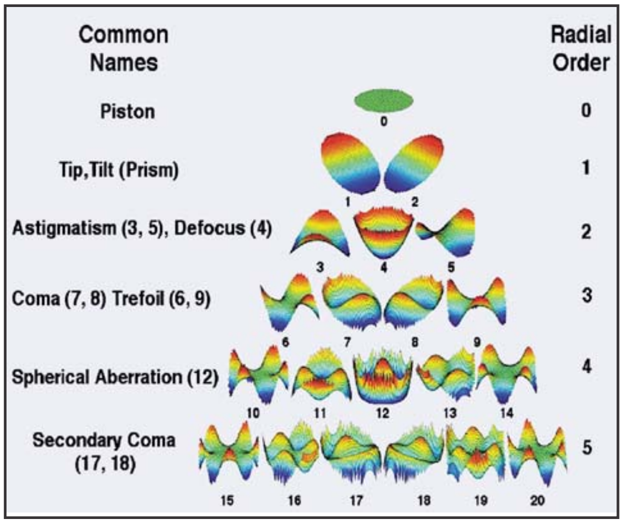

Fig. 1 Wavefront aberrations

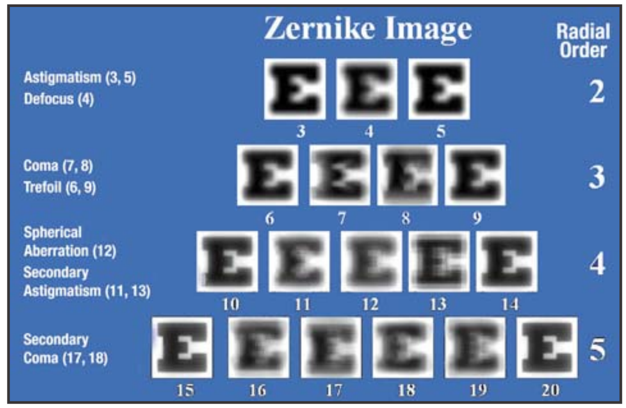

Fig. 2 Effect of wavefront aberrations on an image

center of the lens. By polymerizing the light sensitive molecules of the LAL in that area, a concentration gradient is formed that prompts the remaining non-irradiated molecules to diffuse across the lens. This thickens the lens in the center and increases its power. Astigmatism can be treated by applying UV light in a cylindrical pattern across one axis.

Nick Mammalis, MD (Salt Lake City, Utah) demonstrated in a rabbit model that a 4 D adjustment is possible. Since most of cataract patients are usually within 1 D or 2 D of where they should be, this would give surgeons a lot of ability to correct hyperopia, myopia, and astigmatism. Earlier this year, a patient in Mexico was the first person to be implanted with this IOL.

Small-incision IOLs

Cataract surgeons now have the technology to perform bimanual phacoemulsification through a 1.5 mm incision. IOLs that are currently available in North America, however, do not fit through such small incisions. In Europe, small-incision IOLs such as the ThinOptix lens (ThinOptix) and the Aerismart are already in use. The ThinOptx IOL is 50 microns thick at the footplate and 400 microns thick in the central portion. It has a 5.5 mm optic, is foldable, and can fit through a 1.5 mm incision. The Health Protection Board of Canada gave me permission to implant this lens in an 80-year-old woman with dementia. This first North American patient to receive this IOL is doing very well.

Another small-incision IOL, the SmartLens (Medennium) is currently being tested in laboratory studies. The SmartLens is made from the same thermoplastic material as the SmartPlug that is used for punctal occlusion. The IOL comes as a compact 2-mm diameter rod that can be inserted into the eye through a smaller than 3-mm incision. Once inserted, it warms to body temperature and opens into a full-sized lens that fills the capsular bag. This IOL is expected to prevent PCO because it fills the capsular bag. It might offer some accommodation, because the material remains pliable.

Accommodative lenses

Since a normal lens is about 5 mm thick and an IOL is about 1 mm thick, some clinicians and researchers hypothesized that the IOL had space to move and could be designed to provide accommodation. J Stewart Cummings, MD (Aliso Viejo, CA) and Jochen P. Kammann, MD (Dormund, Germany) investigated several accommodative IOL designs. The seventh design, the AT-45 CrystaLens (C&C Vision) IOL just received pre-market approval in the United States. This IOL features hinged haptics with a silicone optic. It was created to maximize anterior-to-posterior axial movement and restore accommodation in pseudophakic patients. As the ciliary muscle contracts the lens moves forward, allowing near objects to become focused on the retina. With relaxed ciliary muscles, the lens is pulled back, so that distant targets become focused on the retina. The amount of movement depends on the individual's accommodative effort.

One advantage of the CrystaLens is that it is not preset to a particular distance. With the CrystaLens, patients can focus at various near, intermediate and far away distances by making greater accommodative efforts.

The 1CU Akkomodative IOL (Human Optics), which is already available in Europe, features an axial movement design similar to that of the CrystaLens.

Diffractive bifocals

Diffractive bifocals include the 1-piece PMMA CeeOn 811e (Pharmacia) lens and the foldable, hydrophilic acrylic M4 (IOLTech) lens, which are available in Europe. Clinical trials are underway in the United States for the three-piece MA60D3 AcrySof (Alcon) lens, which is similar to the company's 3-piece AcrySof lens, but has a clear periphery with a central 3-mm zone that has diffractive optics. With diffractive bifocals, light entering the eye is focused for distance and near, but about 20% of the light is lost.

Multifocal IOLs

The Array (AMO) IOL is the only multifocal IOL currently approved for use in North America. To qualify for Array implantation, patients should be motivated to decrease dependency on glasses, and should be counseled carefully so that they understand and accept the prospect of seeing halos at night. Pupil size should be larger than 2.5 mm when reading, in order to be able to use the near portion of the Array lens. IOL power should be accurately determined. For patients outside the available range of 6 D to 30 D, piggyback IOL implantation can be considered. Preoperative astigmatism should be corrected either preoperatively or postoperatively.

The Array is a silicone lens, with a 1.46 refractive index. It has five zones and is distance dominant. Odd zones 1, 3, 5 are for distance vision. Even zones 2 and 4 are for near vision. The Array was designed to give 6/6 (20/20) distance vision, 6/21 (20/70) or better intermediate vision, and J3 or better near vision, and 75% of patients implanted with this IOL can read without spectacles.

Patients have reported that they can read fine print (in magazines, phonebooks, and labels), work at hobbies, and perform grooming tasks (such as putting on makeup or shaving) without wearing glasses. A golfer implanted with this lens can see where their drive lands, sink the putt, and write the score without having to put glasses on. Patients implanted with monofocal lenses may see where the ball lands, but would have to put on glasses to do the other things.

A study that compared the Array IOL versus the CeeOn 811e (Pharmacia) IOL confirmed that the Array provides significantly better intermediate vision. Another study comparing the Array IOL with the MA60D3 (Alcon) IOL found comparable intermediate and distance vision with the two lenses, but more glare and haloes were reported by patients implanted with the Array. A third study comparing the Array IOL with the M4 (IOL Tech) lens found that patients were more satisfied with the Array lens than with this diffractive bifocal IOL. Since the Array is a refractive multifocal lens, all of the incoming light is utilized. The Array IOL is currently used for motivated patients with hyperopia and is the gold standard for treatment of pseudophakic myopia.

Conclusion

The newest IOLs on the market attempt to mimic the natural human lens to provide sharp vision. Ongoing innovations in IOL technology are likely to increase the number of FDA-approved lenses for cataract surgery and refractive lens exchange patients. Clinicians will be able to offer their patients more choices. Patients will benefit from better quality vision and in some cases will enjoy less dependence on spectacles with a better quality of life. ❑