



# Berlin

EuroTimes Educational Symposium

The Role of Premium IOLs  
in Modern Lens Surgery

XXVI CONGRESS OF THE ESCRS, BERLIN, GERMANY  
September 2008



Rayner

[www.rayner.com](http://www.rayner.com)

ESCRS **EUROTIMES**<sup>™</sup>

Supplement March 2009

# Introduction

Since Harold Ridley first implanted an intraocular lens into a human eye in 1949, Rayner's original biconvex disk design has undergone an array of transformations to meet the need for safer surgery and more satisfactory visual outcomes. In more recent years there has been development of a revolutionary new platform and optic designs in intraocular lenses, promising multifocality and aberration-free vision. At a EuroTimes Educational Symposium held at the XXVI Congress of the ESCRS, a panel of leading ophthalmologists from around the world met to discuss some of the new options that are available which enable cataract surgeons to choose IOLs based on a patient's specific requirements. Gerd Auffarth MD, Germany, and I Howard Fine MD, US, chaired the session.



**Charles Claoué,  
MD, FRCS, FRCOphth**

Charles Claoué MD, FRCS, FRCOphth commenced the symposium by noting that customised optics will provide little benefit to patients unless they are delivered on a standardised platform that will ensure easy injection with predictable and stable positioning and orientation of the lens within the eye with minimal complications.

"The Rayner philosophy is a standard lens platform and customised optics. If you do not have a stable platform, you can't have

complex optics, they simply do not work," said Dr Claoué, the Queen's Hospital, London, UK.

The platform of an IOL includes the material it is made of, its optic edge and its haptic design. Such design factors all have an important bearing on an IOL's predictability and long-term safety, Dr Claoué pointed out. He noted that Rayner has applied the growing understanding of intraocular dynamics and physiology to every aspect of its IOL platform.



*Rayner C-flex®*

A primary requirement of an IOL platform is that the IOL material should be foldable, so that it may be placed through a small, astigmatically neutral incision, he noted. Additionally, the smaller incisions also induce less inflammation and provide a more rapid visual recovery.

The foldable materials now available for IOLs include silicone and the hydrophobic and hydrophilic acrylic materials. Of these, the hydrophilic acrylics, such as are used in the Rayner platform, may be the most suitable because they present much less of a problem to patients who subsequently undergo silicone oil injection, Dr Claoué said.

He pointed out that silicone oil adheres strongly, with 100 per cent coverage, to the surface of silicone IOLs. It adheres somewhat more weakly to hydrophobic IOLs, with only 35 per cent coverage, but silicone oil coverage is lowest with hydrophilic IOLs at only five per cent. Silicone IOLs also have the disadvantage of having been associated with an increased rate of endophthalmitis in the ESCRS Prophylaxis of Endophthalmitis Study.

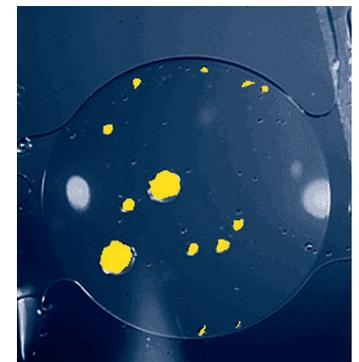
"If the ESCRS study's findings are confirmed by another study, then I think that silicone will have to be abandoned," he added.

An additional advantage of hydrophilic acrylic material is that it is the only IOL material currently available which is capable of absorbing drugs and delivering them into the eye. Agents that may be incorporated into hydrophilic IOLs include antibiotics, anti-inflammatory agents, and agents designed to prevent PCO. Furthermore, in their dehydrated state, hydrophilic materials can be machine-lathed into customisable optical shapes that would not be feasible with injection-moulding.

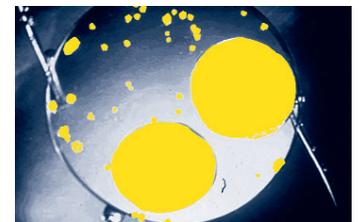
Another essential requirement for the success of customised optics is rotational and centration stability, which the Rayner IOL platform provides through its closed-loop anti-vaulting haptics. Dr Claoué noted that in his own practice, IOLs based on the Rayner platform have remained very well-centred and rotationally stable, with a mean of less than 0.2mm decentration and less than two degrees of rotation at six months' follow-up.

An ideal IOL platform should also have design features which reduce PCO. To this end, the Rayner platform includes an optic with an Amon-Apple Enhanced Square Edge. The edge of the optic

*Computer-enhanced images  
of silicone oil adherence*



*Rayner Rayacryl® IOL five per cent*



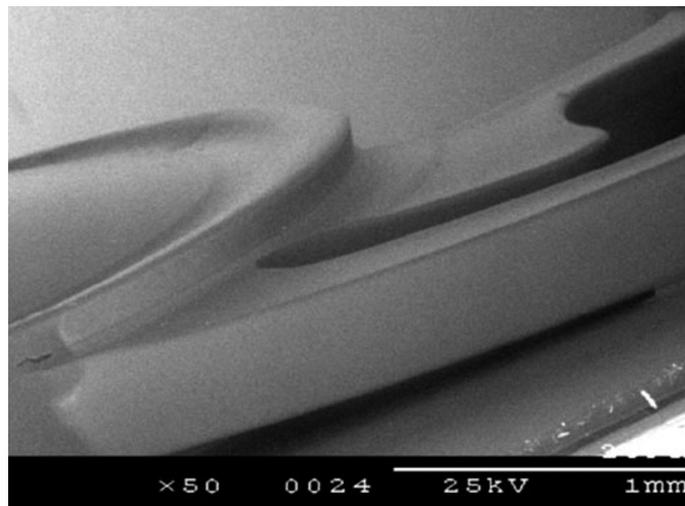
*Hydrophobic acrylic IOL 35 per cent*



*Silicone IOL 100 per cent*



AVH Technology - note the progressive postoperative capsular compression of the C-flex® haptics with excellent centration and stability



SEM of Amon-Apple Enhanced Square Edge (courtesy D J Apple)

remains square throughout its circumference, including the optic/haptic junctions. Since there is no route of entry for the spread of epithelial cells across the capsule, there is a lower rate of PCO, Dr Claoué said. He noted that his rate of Nd:YAG capsulotomies with IOLs based on the Rayner platform is only 1.8 per cent after 30 months of follow-up.

To facilitate implantation, Rayner IOLs are supplied together with a single-use injector. The device has a soft plunger tip that completely occludes the lumen. The lumen has a round profile and the outer diameter of the nozzle tip is 2.0mm, allowing surgery with ultra-small incisions.

Rayner's C-flex® Family of intraocular lenses now includes the C-flex® and C-flex® Aspheric for normal Eyes, the Superflex® and Superflex® Aspheric for Myopic Eyes, the T-flex® for correcting astigmatism, the M-flex® Refractive Aspheric Multifocal for correcting presbyopia, and most recently the M-flex® T, a Refractive Aspheric Toric Multifocal.

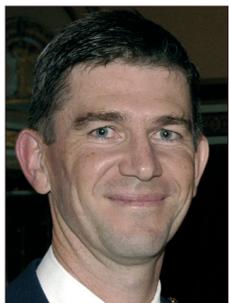
"The hydrophilic acrylic material, the assured centration and rotational stability, the anti-vaulting haptic technology and the lowest Nd:YAG capsulotomy rate are what give us the opportunity to use customised optics and has given Rayner FDA approval," Dr Claoué added.

Charles Claoué, MD, FRCS, FRCOphth  
charles@dbcg.co.uk



Rayner Single Use Soft-Tipped Injector

# The emerging importance of toric IOLs

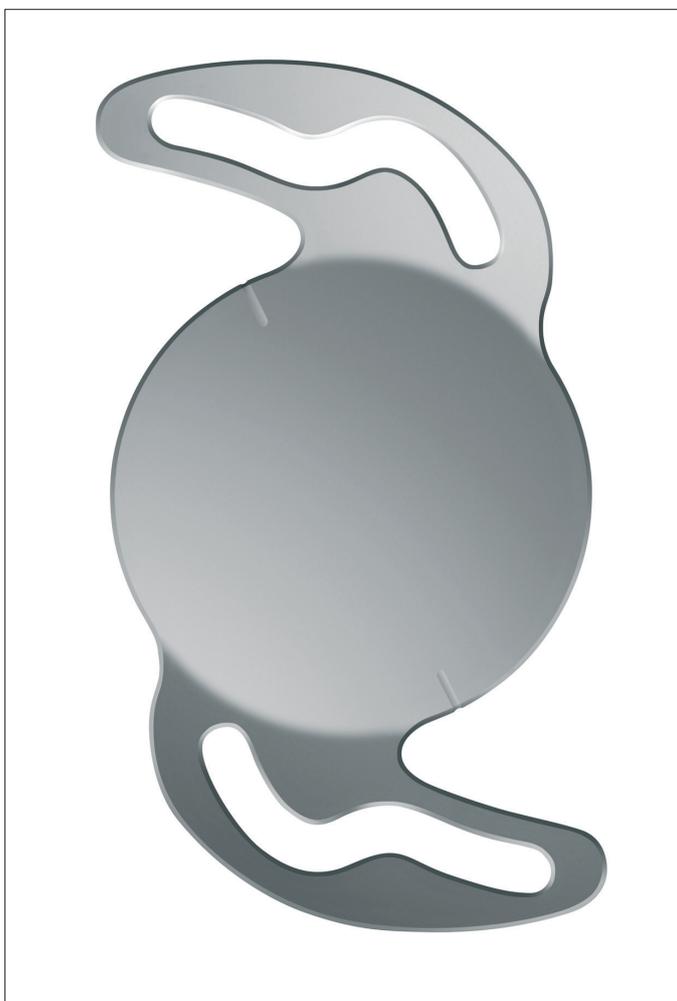


**Daniel A Black, MD**

The Rayner toric IOL provides an effective solution for astigmatic cataract patients because of the stability of its axis alignment and its broad range of refractive powers. Furthermore, since it is implantable through a 2.3mm incision, patients receiving the lens will have minimal amounts of surgically-induced astigmatism, said Daniel A Black MD, Sunshine Coast, Queensland, Australia.

"The T-flex® is effective over a large range of cylindrical and spherical corrections and it is very easy to load

and implant. These lenses have increased my surgical workload. I now have many patients who have been specifically referred to me for astigmatic correction," Dr Black added.



*Rayner T-flex® Toric*

Dr Black noted that the Rayner toric IOL is available in two different sizes depending on the dioptric power. The 623T, which is especially suitable for myopic eyes, has a 6.25mm optic and an overall length of 12.5mm while the 573T, for normal and hyperopic eyes, has a 5.75mm optic and an overall length of 12.0mm. The model selection is made automatically by Rayner so that the largest possible diameter optic is supplied for any particular sphere/cylinder/injector nozzle combination.

The lens is also available in both a standard range and extended range of refractive powers, he noted. The standard range has spherical powers from +6.0 D to +26.0 D, in 0.5 dioptre steps, and cylindrical powers from +1.0 D to +6.0 D, in 1.0 dioptre steps and an extended range with spherical powers from -5.0 D to +35.0 D in 0.5 dioptre steps and cylinder +0.5 to +11.0 in 0.25 dioptre steps.

For IOL power calculations, he uses Holladay IOL Consultant software, which includes a special algorithm for toric calculations. Rayner will also perform the IOL calculations upon request, based on the biometry data it receives. An online IOL calculator is also imminent, Dr Black said.

While Dr Black and his associates do not keep a stock of Rayner toric IOLs, they have no trouble obtaining the lenses in their practice in Australia. Orders shipped from the UK on a Friday generally arrive by Wednesday of the following week, Dr Black said.

Dr Black presented the results of a consecutive series of his first 40 patients to receive the toric IOL. The patients had a preoperative sphere ranging from -5.0 D to +5.0 D and a mean preoperative cylinder of 2.2 D.

At a follow-up of at least one month, UCVA was 6/6 or better in 30 per cent of eyes, 6/7.5 or better in 60 per cent, 6/9 or better in 70 per cent and 6/12 or better in 80 per cent. In addition, postoperative cylinder had a mean value of 0.3 D and was 0.5 D or less in 70 per cent of eyes. The mean postoperative spherical error was 0.28 and the maximum spherical error was 0.66 D.

Moreover, slit-lamp examination showed that in 35 of 40 eyes the toric axis of the lens was within five degrees of its intended rotation and no lens rotated by more than 10 degrees.

## Easy implantation

Prior to implanting the lens, Dr Black uses a special marker from ASICO to make two well-defined marks at the limbus for the orientation of the lens. Following phacoemulsification, he puts a small amount of viscoelastic into the injector cartridge and then eases the lens into the loading bay. He then inserts the nozzle through a 2.3mm phacoemulsification incision and injects the lens.

"The material is very easy to handle. The wings of the cartridge close and lock into position and, because of the transparency of the cartridge, it's very easy to observe the lens travelling down the shooter to be certain that everything is okay. I provide a little counter traction with a viscoelastic cannula and then the lens implant will come out very slowly in a controlled fashion into the capsular bag," he said.

**Daniel A Black, MD**  
[daniel.black@blacksmith.net.au](mailto:daniel.black@blacksmith.net.au)

# Clinical experience with M-flex® Multifocal and the M-flex® T Multifocal Toric IOLs



Julián Cezón, MD

By combining a stable and predictable IOL platform with unique multi-zoned refractive aspheric optic technology, Rayner's M-flex® Multifocal IOL can provide sharp visual acuity for both near and distance vision. In addition, the new toric multifocal, the M-flex® T may at last provide an all-in-one solution for astigmatic cataract patients and presbyopes who seek freedom from spectacles, said Julián Cezón MD, CIMO, Seville, Spain.

The new multifocal IOLs also reduce the compromises encountered with earlier multifocal IOLs, such as reduced contrast sensitivity and increased glare and haloes, Dr Cezón said. The new lenses may therefore add to the increasing popularity of multifocal IOLs. He noted that in Spain the proportion of IOLs implanted that were multifocal increased from 5.2 per cent to 12 per cent between the years 2006 and 2007.

The M-flex® lens is manufactured in the same successful platform as Rayner's

C-flex® and T-flex® IOLs. It is composed of the same highly biocompatible hydrophilic acrylic material, which has low silicone oil adherence and the optic has the Amon-Apple enhanced square edge design, which provides low PCO. It also has the platform's anti-vaulting haptics, which provide good centration and stability of the IOL within the capsular bag.

The lens has a large 6.25mm optic and an overall length 12.5mm. It is available in a standard range with powers from +14.0 D to +25.0 D, in 1.0 D increments, and a premium range from +18.5 D to +23.5 D, in 0.5 D increments. Furthermore, depending on a patient's visual requirements, surgeons may now choose between near focus powers of +3.0 D or +4.0 D at the IOL plane. That is equivalent to a near add of +2.25 D or +3.0 D at the spectacle plane.

## Trial verifies M-flex® efficacy

Dr Cezón noted that in a study he and his associates carried out involving 43 patients who underwent implantation of the M-flex® IOL (630F), over three-quarters of patients had a postoperative uncorrected distance visual acuity of 0.6 or better and half had a near visual acuity of J3 or better.

The prospective non-randomised observational study involved 36 men and seven women with a mean age of 65 years who underwent implantation of the M-flex® IOL during the period from April 2006 to April 2008. Preoperatively, they had a mean spherical equivalent of 1.47 D, a mean sphere of 2.11 D and a mean preoperative cylinder of -1.27 D. In addition, preoperative UCVA was 0.4 or worse in 90 per cent.

Among eyes with one year of follow-up, postoperative UCVA was 1.0 or better in 41 per cent, 0.8 in 33 per cent, 0.6 in 19 per cent and 0.5 in seven per cent. Among eyes with two years of

follow-up, UCVA was 0.8 in 33 per cent, 0.6 in 44 per cent and 0.5 in the remaining 22 per cent. As regards safety, no eyes lost any lines of BSCVA, while 35 per cent gained more than two lines, 12 per cent gained two lines, 23 per cent gained one line and 27 per cent remained unchanged.

At one year, the defocus equivalent was 0.5 D or less in 74 per cent and 1.0 D or less in 96 per cent and 2.0 D or less in all eyes. At two years, the defocus equivalent was 0.5 D or less in 56 per cent but 1.0 D or less in 89 per cent and still 2.0 D or less in all eyes.

As regards intermediate vision, when viewing charts at a distance of 65.0cm, over 80 per cent had an intermediate visual acuity of 0.6 or better at one and two years after surgery, whereas none were 0.6 or better prior to surgery. In addition, around half of patients had a near visual acuity of J3 or better and all were J5 or better. At one year 60 per cent were J3 or better, at two years 50 per cent were J3 or better and all were J5 or better.

"At one and two years all patients have a near visual acuity of J5 or better no one has J1. That means that with the +3.0 D version of the lens, most patients will need a 1.35 addition to read J1. However, the lens will perform well for social reading," he said.

## Good results with toric multifocal



Rayner M-flex® T Multifocal Toric

Dr Cezón noted that his initial experience with Rayner's new toric multifocal M-flex® T (638F) has also been promising. He has so far implanted the lens in six eyes of three patients.

He described the results achieved with the lens in two of his patients bilaterally implanted with the lens. The first was a 51-year-old man who was a pottery-maker by profession with a spherical error of +4.5 D in both eyes and a cylinder of -5.0 D at 25° in his right eye and 4.25 D at 165° in his left eye.

At 12 months' follow-up, distance visual acuity in his right eye improved from 20/25 with best correction to 20/20 without correction, and it improved from 20/25 with correction to 20/25 without correction in his left eye. In addition, he achieved a near distance visual acuity of J1 in his right eye and J2 in his left eye.

"With uncorrected visual acuity of 20/25 and J2 as you can imagine, the patient was delighted and we were so excited with these very impressive results that we decided to operate on a myopic patient," Dr Cezón said.

His second patient was a 61-year-old woman with spherical errors of -7.5 D and -6.0 D in her left and right eye, respectively, and cylinder of -1.75 D and -3.0 D in her right and left eye, respectively. At a year's follow-up after implantation of M-flex® T (638F), she had an uncorrected visual acuity of 20/30 for distance and J1 in both her eyes. Furthermore, she had no problems with haloes or other photopic phenomena in either eye.

"The M-flex® T is an amazing lens. The very good alignment and extreme stability of this IOL platform is what makes the T-flex® and M-flex® T very effective in correcting astigmatism," he added.

Julián Cezón, MD  
drcezon@cimo.es

# Sulcoflex®: a platform for customised supplementary IOL optics



Michael Amon, MD

A new sulcus-fixated IOL, the Sulcoflex®, provides a safer and optically superior alternative to piggy-back IOLs in patients who do not achieve satisfactory vision with their primary IOL, said Michael Amon MD, Medical University of Vienna, Vienna, Austria.

“The concept behind this lens is to answer the demand for an exact refractive result after cataract surgery or refractive lens exchange and to establish an alternative to laser enhancement, while providing

additional benefit to the patient and avoiding contact and distortion of the two optical zones as after conventional polypseudophakia,” he added.

There are many cases where one IOL provides inadequate visual acuity and where the addition of a second lens may be preferable to IOL exchange, Dr Amon noted. They include patients with very high preoperative refractive errors and cases where biometry errors have resulted in refractive surprises and an IOL exchange procedure might be excessively traumatic.

One approach to deal with such cases has been to implant a piggy-back IOL into the capsular bag. However, implanting a second IOL into the capsular bag has in the past resulted in a high incidence of interlenticular opacifications and other capsule-related problems. It is possible to avoid such complications by placing the lens in the sulcus but if both the primary and secondary IOL are convex, an area of contact between the lenses will result in a hyperopic defocus.

Rayner has therefore designed its new sulcus fixated IOL, the Sulcoflex®, with an optic that has a concave posterior surface which emphasises rather than distorts the optics of the primary IOL. The sulcus-fixated IOL is available in both monofocal and multifocal versions. It is manufactured from the well-known hydrophilic acrylic, Rayacryl®, which is highly compatible with the uveal tissue, a factor so important in sulcus-fixation.

The optic of the lens has a large, 6.5mm diameter so that it covers the whole of the primary lens. It also has a more optically ideal round edge resulting in less in the way of dysphotopsia. Since the lens is not in the capsule but in the sulcus, the round edge does not entail any risk of capsular opacification.

In addition, the IOL's haptics also have soft round edges which reduce the chance of tissue interaction. The unique, undulating haptics also ensure centration and rotational stability, providing the possibility for their use as a toric design in patients with astigmatism. In addition, the 10 degree angulation of the haptics ensures uveal clearance and prevents pigment dispersion and optic capture.

## Secondary IOL performs well in trial

Dr Amon presented results of a study involving 12 eyes that were ametropic following implantation of their primary IOL and which underwent implantation of monofocal or multifocal Sulcoflex® IOLs. It showed that the new lenses were very stable in the sulcus and that they provided very satisfactory visual results with no complications.

The study involved 12 eyes of patients with mean age of 56 years. Their preoperative ametropia ranged from +5.0 D to -2.0 D. In all eyes, Dr Amon implanted the secondary IOLs using a standard

3.0mm clear corneal incision with the application of an OVD and using a standard injector for inserting the lens into the sulcus.

In six eyes, he implanted monofocal versions of the Sulcoflex® lens over conventional monofocal IOLs, while in three eyes multifocal Sulcoflex® lenses were placed over multifocal IOLs and in the remaining three eyes monofocal Sulcoflex® IOLs were implanted over multifocal IOLs. In addition, four eyes had undergone Nd:YAG capsulotomies and one eye had uveitis prior to Sulcoflex® implantation.

At a follow-up of 18 months, the patient's mean visual acuity was 0.9 and all eyes were within 0.25 D of intended refraction. Moreover, all eyes with a multifocal Sulcoflex® and a multifocal primary IOL achieved complete independence from spectacles, Dr Amon said.

There were no intraoperative complications and the procedure appeared to be only minimally traumatic. Intraocular pressure at final follow-up

ranged from 11.0 mmHg to 22.0 mmHg and laser flare cell metre counts ranged from 5-30 photon counts/ms, which was less than after phacoemulsification during the primary IOL procedure. In addition, there was no evidence of iris trauma, pigment dispersion, or fibrin in the aqueous.

Dr Amon noted that he would be implanting the first toric version of the lens within a few weeks. He added that sulcus-fixated IOLs may in the future have a broad range of additional applications. The lens might be used in cases where refraction changes may have occurred

some time long after implantation of a conventional IOL; such cases could include paediatric cataract patients and patients who have undergone treatment with silicone oil.

“This lens has many interesting possible indications. The surgery for implanting it is safe and easy and is less traumatic than an IOL exchange procedure. The postoperative refraction is stable and predictable, rotational stability is high so toric applications are feasible. There were no severe complications, it is a reversible procedure and I think this sulcus-fixated IOL represents a very promising new IOL concept,” Dr Amon said.

Michael Amon, MD  
amon@augenchirurg.com



Rayner Sulcoflex® Aspheric



Rayner Sulcoflex® Multifocal



Rayner Sulcoflex® Toric

# Novel design prismatic IOL for treatment of advanced age-related macular degeneration: initial clinical experience



**Frik Potgieter, MD, FRCS**

**A** new prismatic IOL which can redirect light from a degenerated macula to healthier parts of the retina may be able to improve the vision of patients with advanced age-related macular degeneration (AMD), said Frik Potgieter MD, FRCS, Pretoria, South Africa.

Dr Potgieter noted that while treatment and prevention strategies are available for patients in the early stages of exudative and dry AMD, the options for advanced AMD are few and problematical. In patients with early exudative AMD, PDT and anti-VEGF treatments are available which have been shown not only to prevent further visual loss but actually restore some vision. In patients with early-stage dry AMD, several large trials have shown supplements containing vitamins and antioxidants can slow or even halt progression of the disease.

However, ophthalmologists generally regard patients with late-stage AMD as outside their remit, and refer them to low vision clinics. There are surgical interventions which have shown promise in such cases, but they are highly invasive and are often of questionable benefit.

One such approach is the miniaturised intra-ocular Telescope, but this device is very bulky and its implantation requires a very large incision. It also runs the risk of inducing corneal decompensation. Macular translocation is another approach that has some advocates, but it requires a highly trained surgeon, is very time-consuming and some patients end up with no light perception.

Therefore, instead of placing healthy retina tissue where the light is focused, a better approach might be to redirect the focus to where the healthy retina tissue is already. That is the concept behind the Rayner P-flex®, an investigational prototype IOL, which includes a Fresnel prism on the posterior surface.

The new lens design is based on the standard Rayner IOL platform. It is a single piece IOL composed of a hydrophilic acrylic material with anti-vaulting closed loop haptics and the 360° Amon-Apple square edge design. It has an optic diameter of 6.0mm and an overall length of 12.5mm. The Fresnel component of the optic deviates the image by six degrees.

Preliminary results of a pilot study involving two eyes of two patients implanted with the new IOLs showed that although the lenses did not improve visual acuity in these particular cases, visual field testing showed that the location of their scotoma had changed.

In addition, there was no occurrence of diplopia, which had been a theoretical concern with such a lens. There was also no tilt or axial rotation of the lens. The only complication to occur was a small but insignificant damage to the Fresnel edges on the periphery of the lens, Dr Potgieter said.

“Our results show that it is possible to manufacture a Fresnel prism IOL which can displace the central scotoma. Candidates for the lens should have acuity in the better eye worse than 6/60 i.e. hand movements or counting fingers. Although surgery and IOL implantation is essentially for cataract patients, it can be undertaken in all eyes even with no significant cataract,” he added.

**Frik Potgieter, MD, FRCS**  
fjp@lasik.co.za

## The Video Atlas of Eye Surgery



**Brian Little, Bsc, MA, DO, FRCS, FRCOphth**

**S**urgeons now have a valuable new teaching tool available to them in the form of a new DVD series, The Video Atlas of Eye Surgery (published by EyeMovies), said Brian Little, Bsc, MA, DO, FRCS, FRCOphth, London, UK. The Video Atlas is the result of a collaborative effort of an international group of experienced ophthalmologists who are also committed teachers and surgeons. The DVDs are designed to provide an enduring high-quality educational resource for teaching eye surgery, using high-quality video together with graphics and 3D animations.

A measure of its success is that it is now licensed by the AAO and for use by over 50 per cent of US ophthalmology residents. The material is regularly used during instructional courses at national and international level.

“The concept has been to pool the knowledge and experience of an international group of ophthalmologists in order to provide a comprehensive and non-individual view of the best methods and techniques for performing surgery. The publishers will also donate a portion of profits from this to provide support for ophthalmology training in the developing world,” Dr Little said.

The topics covered by the series will ultimately include phacoemulsification, vitreoretinal surgery, glaucoma surgery and lid surgery. The catalogue at present includes four DVDs about phacoemulsification techniques, including one which Rayner sponsored on capsulorhexis and hydrodissection. The EyeMovies team have also produced a DVD on the basics of vitreoretinal surgery. The training structure of each DVD series starts with basic techniques and then moves on to more challenging cases before moving on to complications and their prevention and management.

The videos compress not only over 150 man-years of pooled experience of surgery and teaching, but also thousands of hours of video footage. For example, in the video, “Vitreoretinal Surgery: Basic Techniques”, 600 hours of captured footage were used to produce just under two hours of tightly edited and scripted educational video.

Another production from the EyeMovies team is a computer program, the “Eyemodel” strabismus modelling software. This program for PCs provides a physiologically accurate simulated view of eye movements and their control. The virtual Eyemodel has parameters which the user can modify to simulate a wide variety of scenarios relating to squint development and squint surgery. In this way, surgeons can use it to compare the results predicted by computer simulation with those obtained in actual surgery.

Dr Little predicted that the Video Atlas of Eye Surgery and the profits arising from it could have an important role to play in reducing the rate of blindness in developing countries, where expert training in eye surgery is very difficult to obtain.

“A cataract procedure can be performed for as little as €25. All that’s needed is to make training accessible to where it is most needed and that’s what this is all about,” Dr Little said.

**Brian Little, Bsc, MA, DO, FRCS, FRCOphth**  
brianlittle@blueyonder.co.uk



*Video Atlas of Eye Surgery*

