



Supplement
February 2015



Maximising Treatment Outcomes with Premium IOL Technology

Saturday 13 September 2014
XXXII Congress of the ESCRS
London, UK

Sponsored by

 **Rayner**
Your skill. Our vision.

Introduction

Thanks to advances in lens technology, a growing number of premium intraocular lenses (IOLs) are becoming available for the treatment of cataracts. Intraocular lenses vary according to optic and haptic design, material, and approach to aberrations. IOL designs also include toric lenses for the correction of astigmatism and multifocal IOLs to provide freedom from reading glasses. Unlike corneal surgery (whether performed with incisions or laser ablations), IOLs leave the cornea virtually untouched from an optical point of view. Moreover, some IOLs that are specifically designed for implantation in the sulcus offer reversible results.



The C-flex® Aspheric and the Superflex® Aspheric: the benefits of aberration-neutral technology

Gerd U Auffarth MD, FEBO

Monofocal IOLs are the mainstay of cataract surgery and, regardless of optical features such as multifocality or toricity, the predictability of the position of a lens is central to determining an IOL's performance following implantation. Therefore a lens platform must perform especially well in terms of refractive predictability with monofocal optics if it is to also deliver a good performance with premium optic lenses.

One of the requirements to achieve predictable outcomes is the secure positioning of the haptics in the capsular bag. The Rayner platform addresses this issue by incorporating two designs, the hydrophilic C-flex® and Superflex® IOLs, which differ in their dimensions. The C-flex®, with an overall length of 12.0mm and an optic diameter of 5.75mm, is suitable for normal eyes. The Superflex®, with overall length of 12.5mm and an optical diameter of 6.25mm, is particularly well-suited to large eyes with large capsules, such as those of myopic patients.

The predecessor of the C-flex® Aspheric and Superflex® Aspheric lenses was the 570C developed by Rayner in the late 1990s and early 2000s. The C-flex® 970C lens has the additional special feature of having an aspheric, aberration-neutral optic. Optical bench test comparisons show that the newer lens provides a considerable improvement over the older lens. In fact, its modulation transfer function closely approximates the theoretical upper limit of resolution achievable with an artificial lens.

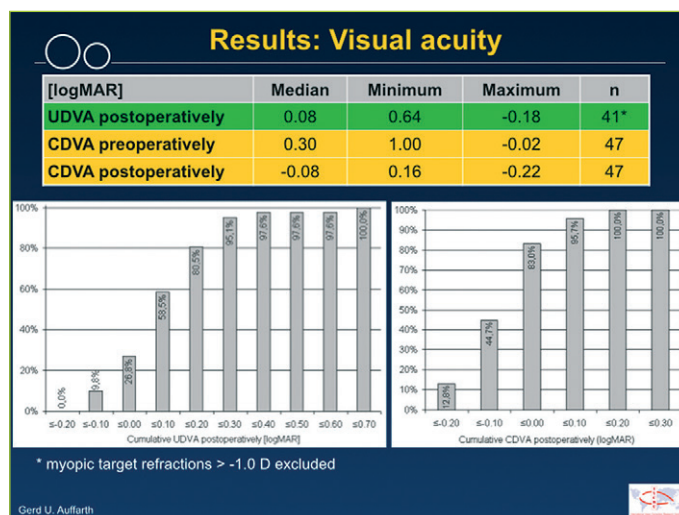
“One of the requirements to achieve predictable outcomes is the secure positioning of the haptics in the capsular bag”

Encouraging results with aberration-neutral design

We now have three- and four-month results of a prospective trial that we conducted for the clinical evaluation of the aberration-neutral lenses. Our study involved 47 eyes of 34 patients (median age, 68 years; range, 43 to 80 years) who underwent implantation of the C-flex® Aspheric or Superflex® Aspheric IOL between October 2011 and May 2012.

The study included a typical cross-section of cataract surgery patients i.e. myopes as well as some hyperopes. The dioptric power of the IOLs ranged from 16.0D to 24.0D (median, 21.0D).

With so many new options to consider, cataract surgeons must have a thorough knowledge of which lens will work best, to provide their patients with optimal results. At a EuroTimes educational symposium, sponsored by Rayner and held at the XXXII Congress of the ESCRS in London, a panel of leading innovators in the field of cataract surgery met to discuss key factors to consider when choosing a premium IOL, the indications for each type of lens, the results that can be expected, and the challenges that remain in order to achieve optimal visual outcomes.



Patients had a median preoperative corrected distance visual acuity of 0.30 logMAR. In terms of manifest refraction, their preoperative sphere ranged from -6D to 3.5D (median, +0.25D) and their preoperative cylinder ranged from -3.0D to 0.0D (median, 0.75D).

At the most recent follow-up, median manifest refraction spherical equivalent was -0.25D, compared to a median target refraction of -0.2D, calculated with the Holladay 1 formula. Although there was some variation, owing largely to astigmatism, approximately 75 per cent of patients were within 0.5D of the target refraction and almost 90 per cent were within 0.75D. In addition, 46 of 47 eyes were within 1.0D; the remaining eye was within 1.25D of target.

In terms of visual outcomes, when eyes with a target refraction greater than -1.0D were excluded, the median uncorrected distance visual acuity (UDVA) was 0.08 logMAR, which is somewhere between 20/25 and 20/20 in Snellen visual acuity terms. Furthermore, UDVA was 0.2 logMAR or better in 80.5 per cent of patients. Additionally, the postoperative median corrected visual acuity was -0.08, or higher than 20/20, compared to 0.3 logMAR preoperatively, and was 0.1 or less i.e. 20/40 or better, in 95.7 per cent of patients.

Wavefront analysis with the Zywave® II (Bausch and Lomb) aberrometer indicated that the aspheric, aberration-neutral design of the lens delivered on its promise. The lens appeared to induce almost no aberration and the amount of spherical aberration was about the average value for the Caucasian population in Europe.

The stray light performance of patients who received *C-flex*[®] or *Superflex*[®] Aspheric IOLs, as measured with the C-Quant machine (Oculus), was roughly the same as age-matched patients with clear crystalline lenses and somewhat better than pseudophakes in general.

In addition, contrast sensitivity values, as measured with the FACT (Functional Acuity Contrast Test) chart with the Functional Vision Analyzer, were very good for monofocal patients, and were within the normal distribution, whether measured under photopic or mesopic conditions with or without glare.

There was also a very high level of satisfaction among patients who received *C-flex*[®] or *Superflex*[®] Aspheric IOLs. In response to a questionnaire, 97 per cent of patients said they would recommend the *C-flex*[®] or *Superflex*[®] Aspheric to friends and relatives, and would have the surgery again with the same lens if they had to do it over again. Moreover, when questioned

about visual symptoms, including halos, glare, double images, or difficulty with vision under different lighting conditions, the average score for most symptoms (on a scale from zero to four) was between zero, for “no symptoms”, to one, for “slightly”. Only sensitivity to glare by day and vision problems in bright light conditions had a mean score exceeding one. No visual symptoms had mean scores of two (“moderately”), three (“considerably”) or four (“strongly”).

Regarding spectacle use, patients said that they used reading glasses often but only needed glasses for intermediate distances sometimes, and almost never need glasses for distance vision.

These results indicate that the *C-flex*[®]/*Superflex*[®] Aspheric IOLs provide predictable refractive outcomes with good visual acuity. This lens platform therefore fulfils all the requirements on which to build premium lenses with advanced optics for patients with corneal astigmatism and presbyopia.

Long-term performance of Toric IOLs vs LRIs in the management of astigmatism

Oliver Findl MD



For cataract patients with large amounts of corneal astigmatism, toric IOLs will always outperform incisional techniques. However, for those with more moderate amounts of astigmatism, there is still some debate as to which technique will provide the most predictable results.

A significant proportion of the general population have some astigmatism, as illustrated by a German study of 23,239 eyes which showed that while very high levels of astigmatism were relatively rare, over a third of eyes had a dioptre or more of astigmatism (*Hoffmann et al, J Cataract Refract Surg 2010; 36:1479–1485*). It is in eyes with lower amounts of astigmatism that both toric IOLs and incisional techniques should be most effective.

A crucial factor in the treatment of corneal astigmatism is correctly defining the meridian of cylinder. In the case of toric IOLs, a misalignment of the lens by one degree will reduce the anti-astigmatic effect by three per cent, while a misalignment of about 10° will reduce the effect by approximately 30 per cent. There are numerous techniques available to determine the astigmatic meridian, including the IOL Master and other optical biometers that feature keratometry, placido disc topography and Scheimpflug and optical coherence tomography (OCT).

Discrepancies between the measurements obtained with the different devices can be a contraindication for either toric IOLs or incisional techniques, as they are indicative of irregular astigmatism and possibly forme fruste keratoconus.

Ensuring stability

Ideally a toric IOL should have good safety and biocompatibility, good predictability of axial position for the spherical component, and rotational stability for its cylinder component. The ideal toric IOL should also perform well in terms of posterior capsule opacification prevention, and should have an aspheric surface to provide optimal visual function.

The Rayner *T-flex*[®] Aspheric Toric IOL fulfils these criteria through its hydrophilic acrylic material, special Anti-Vaulting Haptic (AVH) Technology[®] which conform very well to the capsular bag, and aspheric sharp-edged optic. Like the non-toric monofocal *C-flex*[®]/*Superflex*[®] Aspheric lenses, the *T-flex*[®] is available in two different sizes. One model, the 573T for normal sized eyes, has an overall length of 12.0mm and an optic diameter of 5.75mm. The larger model, the 623T, has an overall length of 12.5mm and an optic diameter of 6.25mm.

It has been my experience with several different toric IOLs on the market that in highly myopic eyes, or any eyes that require a lens with less than 10D of spherical power, the lens may rotate quite freely in the bag during surgery because of the large capsular bag diameter. My clinical impression was that the Rayner toric IOLs remain very stable in large capsular bags and is my IOL of choice for these astigmatic myopic eyes. The lenses are also available in a broad range of dioptric powers; spherical powers ranging from -10D to +34D in 0.5D steps and cylindrical powers from +1D to +11D in 0.5D steps. This range is split (at a SE power of around 25D) between the higher powers on the smaller 573T platform and the lower powers on the larger 623T platform.

Furthermore, Rayner has provided an online IOL calculator (*Raytrace*[®]) which, in addition to the usual parameters, also takes into account the postoperative anterior chamber depth. That makes it particularly advantageous in eyes that are highly myopic or highly hyperopic.

The challenge of predictability

A review of results achieved in 250 eyes of 200 patients with currently-available toric IOLs shows that they consistently reduce the astigmatic error. However, the nearness to target cylindrical refraction that they achieve is somewhat unpredictable, owing to factors that are, as yet, poorly understood.

Incisional approaches, meanwhile, are much more limited in terms of the amount of astigmatism they can correct, although they can produce good results in cases of mild to moderate astigmatism. However, as with toric IOLs, results can vary from the target in an unpredictable manner.

We carried out a study in which we compared the astigmatism-correcting effect of three different incisional techniques, namely limbal relaxing incisions and clear corneal main surgical incision on the steep meridian, either alone or combined with an additional matching clear corneal incision on the opposite side of the eye.

The study showed that limbal relaxing incisions, performed with a 600 micron blade using the Donnenfeld algorithm, reduced the astigmatism by a mean of 0.69D, compared to a mean of 0.44D in eyes that underwent clear corneal and opposite clear corneal incisions, and 0.27D in eyes that underwent a single clear corneal incision. However, with all three techniques there was considerable variation in the outcomes.

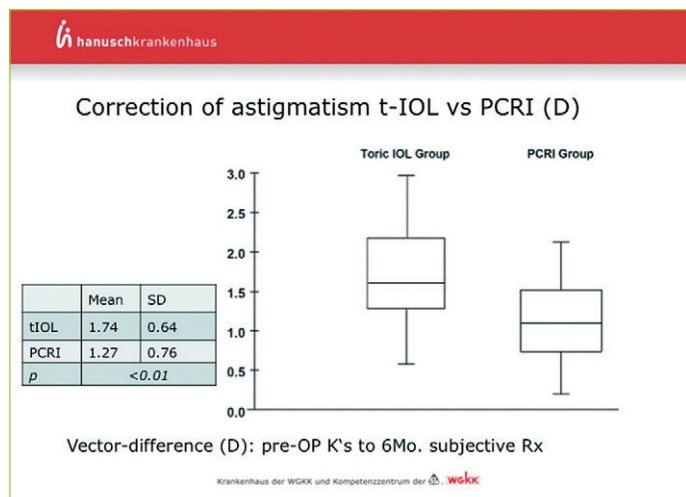
Incisions vs toric IOLs

In a subsequent study, we compared the astigmatism-reducing effect of the T-flex® IOL with that of limbal relaxing incisions, which I prefer to call peripheral corneal relaxing incisions (PCRIs), as I believe that is a more accurate term.

The randomised, double-masked study involved 56 eyes of 28 cataract patients with corneal astigmatism of at least 1.0D but not exceeding 2.5D. All eyes underwent phacoemulsification. A T-flex® IOL was then implanted in one eye, while the fellow eye underwent PCRIs and implantation of a C-flex®/Superflex® IOL.

In all eyes we performed preoperative marking at the slit-lamp. In the T-flex® group we used the online toric IOL calculator and placed the cataract incision on the steep meridian or temporally. For the PCRI group we used the Donnenfeld nomogram for the incisions, placing the clear corneal incision (CCI) on the steep axis and making an opposite PCRI with a 600 micron guided blade. Alternatively, we placed the CCI temporally and two PCRIs opposite to each other.

At a follow-up of six months, the mean difference between the preoperative keratometric cylinder and the postoperative subjective astigmatism was 1.74D in the toric IOL group and 1.27D in the PCRI group. The difference between the groups was statistically significant ($p < 0.01$).



In terms of rotational stability (as measured with retro illumination photographs), there was essentially no rotation or only very little between one hour and six months post-surgery.

On the other hand, when initial misalignment and rotation were taken into account there remained some variability in terms of astigmatic correction - though less than in the PCRI group. Potential sources of postoperative residual cylinder error include: incorrect determination of the meridian of astigmatism, incorrect corneal topography, intraoperative misalignment of the IOL marking, and surgically-induced astigmatism.

Among the currently available marking systems for the alignment of toric IOLs, the slit lamp marker and the pendulum marker seem to provide the most reproducible results. Automated systems are likely to be introduced in the near future. We have been involved in a trial using a prototype system that imports images of the conjunctival vessels taken during preoperative biometry and then imported into the operating system of the surgical microscope and provides an overlay with which to guide the orientation of the lens during surgery.

“We believe this is due to inaccuracies in the measurement of corneal astigmatism before surgery”

However, even when we correct alignment and biometric errors, there is still a degree of scatter in our results. We believe this is due to inaccuracies in the measurement of corneal astigmatism before surgery. Newer systems that provide information regarding the posterior corneal surface, such as the Scheimpflug photography and spectral domain and swept-source OCT, appear to improve the accuracy of those measurements. However, among the systems we have tested and compared thus far, there remains some noise that we cannot account for.

In summary, the Rayner T-flex® Aspheric Toric IOL showed very good rotational stability and provided more predictable results than peripheral corneal relaxing systems in the range of 1.5D to 2.5D of preoperative cylinder. However, some challenges remain in the preoperative measurement of astigmatism.



Supplementary IOLs effective for secondary enhancement of surgical results

Michael Amon MD

The original additive IOLs were conventional bi-convex lenses that were implanted piggyback-style along with the primary lens together in the capsular bag. This type of procedure was introduced in the early 1990s and was performed as a secondary procedure in cases of refractive surprise, or as a primary procedure for highly ametropic eyes.

However, this approach had two essential problems: first, there was interlenticular opacification, a complication that resulted from the formation of membranes between the lenses caused by the migration of lens epithelial cells from the capsular bag. The second problem was that the anterior surface of the posterior lens pressed against the posterior surface of the anterior lens, resulting in a hyperopic defocus.

The alternative was to place the second implant in the sulcus. However, this approach had its own problems including the risk

for pigment dispersion and haemorrhage. Moreover, it did not eliminate the problem of contact between the two lenses.

The solution was therefore to develop an IOL specifically designed for implantation in the ciliary sulcus, and that lens is the Rayner Sulcoflex® 653L Aspheric. The Sulcoflex® is a one-piece IOL composed of a highly biocompatible hydrophilic acrylic material that does not irritate uveal tissue. For example, our research shows that hydrophilic material is much better tolerated than hydrophobic material in uveitis patients (*Abela-Formanek C, et al. J Cataract Refract Surg 2002;28:50-61*).

In addition, the Sulcoflex® has a large (6.5mm) diameter optic so that it will overlap the primary lens and avoid iris/optic-capture. Furthermore, the optic has an aspheric shape with a rounded edge to reduce dysphotopsia and its posterior

surface is concave so as to prevent contact with the primary IOL in the capsular bag.

The haptics are large to ensure secure placement with good centration and rotational stability, and have a 10 degree angulation to provide clearance from the iris. The haptics also have a rounded edge to reduce tissue reactions.

The IOL calculation for secondary lens implantation of the Sulcoflex® is straightforward. In patients with 7.0D of ametropia following the primary surgery, all that is necessary is to multiply the amount of ametropia by 1.5 in hyperopic eyes and by 1.2 in myopic eyes.

Implantation of the Sulcoflex® is also very easy and straightforward. I usually use a 2.5mm incision, but the lens can also be implanted through a micro-incision. It is best to inject ophthalmic viscosurgical device (OVD) behind the iris and then, following injection of the lens, be sure to aspirate all of the OVD, not only that which is anterior to the Sulcoflex® but also the OVD between the two lenses. Iridotomy is optional. I generally reserve it for very short eyes. I always use an antibiotic.

Our five-year results in a series of 178 eyes indicate that the Sulcoflex® lens provides a high degree of safety and predictability. The patients in the series had a mean age of 53 years and included 35 eyes receiving the toric version of the lens and 10 eyes treated with silicone oil.

Throughout the follow-up period there have been no instances of pigment dispersion, interlenticular opacification, or iris trauma. Intraocular pressure remained within normal limits, ranging from 11-22 mmHg, and laser flare cell meter counts were within the 5-30 photon counts/ms which is less than after phacoemulsification.

In addition, there was a positive optic-to-optic and optic-to-iris distance and there were no cases of optic capture or pupil ovalisation. Furthermore, among those undergoing secondary implantation to correct refractive surprises, which ranged from -7.0D to + 6.0D, the mean postoperative uncorrected visual acuity was 0.9, and 96 per cent of eyes were within 0.25D of target refraction. In the remaining eyes, some visual acuity was lost owing to secondary interventions unrelated to the implants.

In our study, there was a postoperative rotation of over 10° in 10 per cent of our cases. Therefore, with astigmatic patients I tend to put the toric lens in the capsular bag and place the monofocal or multifocal lens in the sulcus. However, I will implant a toric Sulcoflex® in astigmatic patients who already have an IOL in the capsular bag. But in cases with rotation, I will secure the haptics with a 10/0 prolene suture to prevent later rotation of the lens.

In general, the lenses appear to behave in accordance with their design. A cadaver eye study presented by Liliana Werner at the 2011 ESCRS Winter meeting in Istanbul showed a very nice sulcus fixation and centration of the Sulcoflex® lens, with minimal interaction with the uveal tissue. In addition, an in vitro study in artificial eyes showed that the modulation transfer function curves in eyes with a supplementary IOL were identical in those having just one IOL. Therefore the optical quality of two lenses is similar to the optical quality of one lens (*Schrecker J et al, J Cataract Refract Surg. 2012 ;38:1650-1656*).

“Our five-year results in a series of 178 eyes indicate that the Sulcoflex® lens provides a high degree of safety and predictability”

Duet and secondary implantation

I use primary implantation of the two lenses, which I call the Duet procedure, in eyes with ametropias that cannot be corrected with one IOL, those with astigmatism, and in patients who wish to be multifocal.

The multifocal Duet procedure has an important advantage of being easily reversible. You can implant the standard monofocal lens in the capsular bag, then implant the multifocal Sulcoflex® in the sulcus and let the patient decide if they like it. If, after time has been allowed for neuroadaptation, the patient complains of visual disturbances like glare and halos, the lens can be removed, very easily and non-traumatically. The same is true if the patient should develop retinal diseases, like diabetic macular oedema or age-related macular degeneration that might make pseudophakic multifocality undesirable.

The indications for secondary implantation of Sulcoflex® IOLs include eyes with refractive surprises following cataract surgery and monofocal pseudophakic patients who would like to give multifocality a try. Another potential indication is eyes with negative dysphotopsia, a condition which, according to some anecdotal reports, may be ameliorated by secondary implantation of a zero power Sulcoflex® lens.

Generally speaking, the primary Duet procedures are preferable to the two-stage procedure because only a small minority of patients will have unsatisfactory outcomes requiring exchange of the sulcus-fixated lens.

In conclusion, supplementary IOLs are effective for secondary enhancement of surgical results. The main reasons to use Sulcoflex® are multifocal Duet implantation and to correct pseudophakic ametropia.





Visual outcomes after implantation of a multifocal supplementary lens

Victor A Antunes MD

There are many technologies available today for providing cataract patients with multifocality, but none of them are perfect. Therefore, it is in the patient's best interest to have the option of upgrading to new and better technologies as and when they become available. This is especially true of younger patients (50 to 55 years in age), who are increasingly undergoing lens surgery for the treatment of presbyopia.

The aim of the Sulcoflex® Multifocal IOL is to provide a reversible form of multifocality. The Sulcoflex® Multifocal IOL has essentially the same design features as the monofocal Sulcoflex® Aspheric but its optic also has a +3.5D add-on for near vision.

Like the monofocal and toric versions, the Sulcoflex® Multifocal lens can be removed easily and with minimal trauma. Its use, therefore, involves little additional risk for patients who postoperatively change their mind about having the multifocal implant, whether due to a failure in neuroadaptation, retinal pathology or the desire of a less compromised near or distance visual acuity.

Predictable outcomes with high patient satisfaction

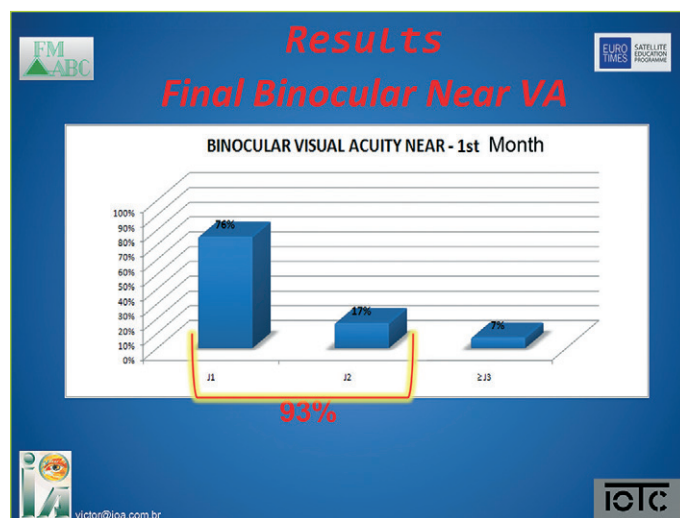
We recently carried out a retrospective study to assess visual outcomes and patient satisfaction following implantation of a multifocal sulcus IOL and primary capsular bag lens in a single surgical procedure.

The study involved 145 eyes of 75 cataract patients with a mean age of 65 years. The inclusion criteria were age greater than 45 years of age, hyperopia of 1.50D or more and potential visual acuity measurement of at least 20/30. Exclusion factors for the study were manifest corneal and retinal pathologies.

The primary IOLs implanted in the capsular bag were aspheric in 80 per cent of eyes and toric in 20 per cent of eyes. Nearly all patients underwent implantation of a C-flex® or Superflex® IOL in the capsular bag and a Sulcoflex® multifocal IOL with a +3.5D near add in a same surgical session. The main exceptions were patients who had undergone previous corneal refractive surgery, constituting six per cent of eyes. Instead they underwent implantation of the multifocal lens three weeks after receiving the primary IOL in order to correct any residual ametropia.

At the one-month follow-up visit, monocular distance visual acuity was 20/25 or better in 84 per cent of eyes and 20/20 or better in 39 per cent of eyes. Final binocular distance visual acuity was 20/25 or better in 97 per cent of eyes and 20/20 or better in 75 per cent of eyes.

Monocular near vision at one month was J2 or better in 94 per cent of eyes and J1 in 75 per cent of eyes. Final binocular near visual acuity was J2 or better in 93 per cent of eyes and J1 or better in 76 per cent of eyes. However, nine patients (6.2 per cent) required reading glasses in order to improve their reading speed.



Predictability was high with the double-lens procedure; 98 per cent of patients were within 0.5D of the targeted spherical refraction, and all eyes were within 0.75D of the targeted spherical and cylindrical refraction. Furthermore, 59 per cent of patients were within 0.5D or less of targeted cylinder value and 22 per cent were within 0.25D or less. Moreover, because we performed limbal relaxing incisions, the mean surgically induced astigmatism was also only 0.11D.

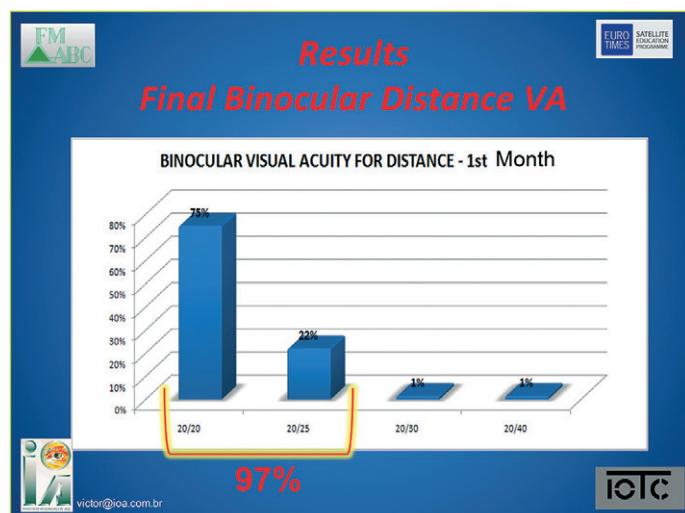
To simulate the movement of the Sulcoflex® lens under different lighting conditions, we measured the changes in distance occurring between the two lenses and between the sulcus-fixated lens and the cornea during dilation of the pupil. We found that the IOL moved only 25 microns towards the cornea and only 15 microns closer to the intracapsular IOL during pupil dilation.

Regarding the safety of the procedure, none of the patients had pigment dispersion. Specular microscopy showed very normal endothelial cell loss. However, IOP was elevated in 19 eyes (13 per cent), although it returned to normal levels following reduction of their steroid regimen. There was also one case of anterior capsular rupture but we were still able to perform implantation of the Sulcoflex® lens in that eye in the same procedure without any problems.

There is a slight learning curve involved with implanting Sulcoflex® lenses. In six of our early cases, we had to explant the multifocal lens because we broke the 14.0mm haptics when loading the lens into the cartridge. However, we were able to replace the IOL in the same procedure.

In terms of satisfaction, 91 per cent of patients said that they were satisfied, with 41 per cent rating their outcomes as good, and 50 per cent as excellent. Among the remaining nine per cent of patients, the chief sources of complaint were glare and halos.

In conclusion, visual results of the Sulcoflex® Multifocal IOL are similar to conventional multifocal IOLs. Patients with good visual potential show good tolerance to the multifocality they provide and it is a safe and reversible procedure.



Contacts:

Gerd U Auffarth MD, FEBO

Chairman, Dept of Ophthalmology, University of Heidelberg, Germany
Director (Head) of the International Vision Correction Research Centre (IVCRC)

Gerd.Auffarth@med.uni-heidelberg.de

Oliver Findl MD

VIROS – Vienna Institute for Research in Ocular Surgery,
a Karl Landsteiner Institute, Hanusch Hospital, Vienna, Austria
Moorfields Eye Hospital NHS Foundation Trust, London, UK

oliver@findl.at

Michael Amon MD

Academic Teaching Hospital of St John, Vienna, Austria

amon@augenchirurg.com

Victor A Antunes MD

Instituto de Oftalmologia de Assis, Assis, Brazil

Victor@ioa.com.br



Supplement
February 2015

Sponsored by

 **Rayner**
Your skill. *Our vision.*