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ENHANCING PSEUDOPHAKIC VISION WITH THE RAYNER SULCOFLEX LENS

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INTRODUCTION

By Kenneth J Rosenthal MD, FACS

The first IOLs designed by Sir Harold Ridley and produced by Rayner were poly(methyl methacrylate) lenses placed behind the pupil, probably some place in the sulcus, in a second-stage procedure after removing the cataract and allowing the capsular bag to fibrose. The location of IOL placement corresponded to the method of cataract removal, which was an extracapsular technique, and in which the capsulotomy was insufficiently predictable to hold a well-centred, stable IOL.

In the 1960s and 1970s, cataract surgery was often done as an intracapsular procedure, and, following that surgical trend, iris-supported and anterior chamber IOL models predominated. When extracapsular cataract extraction re-emerged in the 1980s, IOLs were once again placed in the sulcus because in-the-bag implantation was too unreliable given capsulotomy was done using a can-opener technique.

Interestingly, however, work by David Apple MD, and colleagues showed that more than 50 per cent of the sulcus-placed lenses were, unintentionally, half in and half out of the capsular bag, and therefore they were often tilted and decentred. Furthermore, the implants frequently incited prolonged inflammation because they were constructed of materials, and were of a design not well suited for use in the sulcus.

Concerns about the problems associated with sulcus-placed IOLs diminished after the introduction of continuous curvilinear capsulorhexis that allowed for secure and predictable in-the-bag lens implantation. However, sulcus placement of a supplementary lens in the ciliary sulcus remained desirable in a variety of situations, such as in eyes with a postoperative refractive surprise, a change in refractive error over time, or with a monofocal IOL where the patient desires multifocality or toric correction to reduce spectacle dependence.

As discussed in the proceedings of this symposium, those issues and more, including management of negative dysphotopsia, can be addressed safely and effectively today by performing a DUET procedure using a Sulco*flex*® supplementary IOL (Rayner Intraocular Lenses Limited, East Sussex, United Kingdom), a lens specifically intended, by virtue of a unique design and biocompatible materials, for the sulcus.

Dr Rosenthal moderated the symposium. He is an associate professor of ophthalmology at the John A Moran Eye Center, University of Utah Medical Center, Salt Lake City, UT, US, and in private academic practice at the New York Eye and Ear Infirmary, New York, NY and in Great Neck, NY.

He has received travel support from Rayner, and is a consultant for AMO, Bausch + Lomb, Alcon and Ophtec USA.

SULCOFLEX: DESIGN, RESULTS AND INDICATIONS

Michael Amon MD

Sulco*flex* DUET procedures with sequential implantation of a primary capsular bag IOL and a supplementary Sulco*flex* sulcus-based lens offer a safe and effective means for enhancing the surgical result in a range of pseudophakic eyes, according to Michael Amon MD.

Dr Amon is the inventor of the Sulco*flex* IOL and professor of ophthalmology, Academic Teaching Hospital of St John, Vienna, Austria. He discussed design features of the Sulco*flex* lenses, the indications and approaches for using the various Sulco*flex* models in a DUET procedure, considerations for surgical technique and outcomes.

Highlighting the advantages of Sulco*flex* DUET, Dr Amon said, "Sulco*flex* implantation, whether performed simultaneously with placement of the primary IOL or as a secondary intervention, is a safe procedure that provides predictable, stable refractive outcomes. As a means for pseudophakic enhancement, Sulco*flex* implantation is less traumatic than IOL exchange, and unlike laser vision correction, it is also easily reversible as supplementary lens explantation can be performed at any time."

Sulco*flex* Multifocal Toric Lens

DESIGN OBJECTIVES

Explaining his goals in designing the Sulco*flex* IOL platform, Dr Amon said it was developed with the past problems of piggybacked and sulcus-placed IOLs in mind. He referred to the development of interlenticular membranes, hyperopic defocus, pigment dispersion, inflammation, elevated IOP and even haemorrhage.

In addition to focusing on safety, versatility was another of his objectives in designing a modern additive IOL. The main concepts were to create a reversible option that could be used in secondary interventions to treat refractive surprises or enhance the optical results, but also for primary add-on procedures.

All of these design aims are met by the portfolio of Sulco*flex* IOLs that includes four models: monofocal aberration-neutral aspheric (653L), multifocal (653F), toric (653T), and multifocal toric (653Z). All of the Sulco*flex* IOLs are single-piece lenses made of a hydrophilic acrylic material (Rayacryl) demonstrated to have high uveal biocompatibility. The IOL optic has a large, 6.5mm diameter that covers the whole circumference of the capsular bag IOL and reduces risks of pupillary block and photic effects. The optic also features round edges to reduce dysphotopsia risk and a concave posterior surface to avoid contact with the capsular bag IOL and induction of hyperopic defocus.

Undulated 14.0mm haptics optimise IOL centration and rotational stability. A 10° posterior haptic angulation prevents iris touch and contributes to uveal clearance, and round haptic edges also reduce the risk of iris trauma.

> "SULCOFLEX IMPLANTATION, WHETHER PERFORMED SIMULTANEOUSLY WITH PLACEMENT OF THE PRIMARY IOL OR AS A SECONDARY INTERVENTION, IS A SAFE PROCEDURE THAT PROVIDES PREDICTABLE, STABLE REFRACTIVE OUTCOMES"

INDICATIONS

Scenarios for using the Sulco*flex* IOL include primary DUET implantations, where the supplementary IOL is implanted at the same time as the capsular bag IOL in order to correct high refractive errors or to provide potentially reversible multifocal vision. Alternatively, the Sulco*flex* IOL can be placed in a secondary implantation where it can be used for spherical or astigmatic correction, to convert a patient from monofocal to multifocal vision. Specific indications for secondary implantation of a Sulco*flex* IOL include patients experiencing a dynamic change of refraction, such as those with a history of paediatric cataract surgery, a buckling procedure, silicone oil filling or corneal changes (eg, keratoconus or post-keratoplasty).

IMPLANTATION AND OUTCOMES

Dr Amon described implantation of the Sulco*flex* IOL as straightforward. Although he initially implanted the supplementary IOL through a 2.75mm incision, he now routinely places it through a 2.4mm incision and has even inserted it through a sub-2.0mm incision.

"The sulcus is first prepared with instillation of a cohesive ophthalmic viscosurgical device (OVD). The IOL unfolds gently and in a very controlled manner in the eye, and then it is rotated behind the iris. Careful aspiration of all OVD is important at the end of the case," he said.

Dr Amon reviewed clinical outcomes from a series of 108 eyes he implanted with a Sulco*flex* IOL. The series included eyes implanted with all optic models of the Sulco*flex* IOL and having primary capsular bag IOLs constructed of a variety of materials. Mean patient age was 53.4 years, but the population included four paediatric patients.

Analyses of a variety of endpoints confirmed the safety of the procedures. Postoperative IOP was not elevated in any eye, while

intraocular inflammation determined by laser flare cell meter measurements was minimal (5-30 photon counts/ms) and lower than after routine phacoemulsification.

During a mean follow-up of 54 months, no problems were encountered with iris trauma, pigment dispersion, interlenticular opacification, or optic capture. Analyses of Scheimpflug images showed uniform maintenance of a safe distance between the two IOLs as well as between the supplementary IOL and the iris.

"We also saw no cases of pupil ovalisation. However, this problem has been reported by others and underscores the importance of implanting the supplementary IOL precisely in the sulcus, avoiding the area of the iris root," Dr Amon said.

Measurements of rotational stability showed that the sulcus-placed IOL maintained its position overall, but rotated by more than 10° in three per cent of eyes.

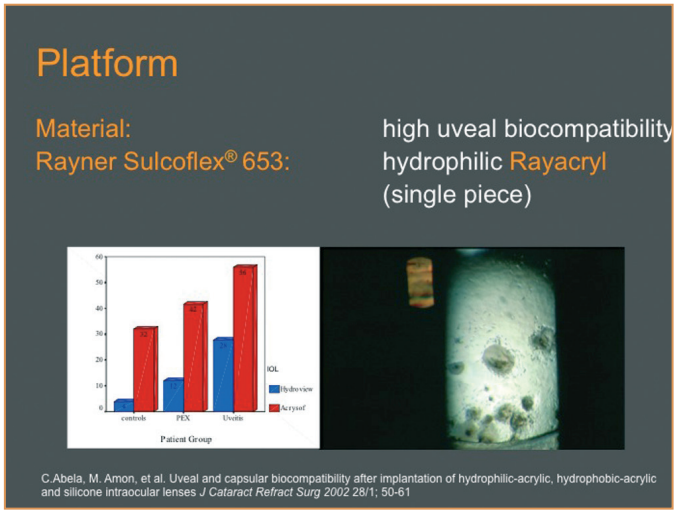
"Rotational stability is an important issue when using one of the toric versions of the Sulco*flex* IOL as10° of rotation off-axis results in a 30 per cent loss of toric power," noted Dr Amon.

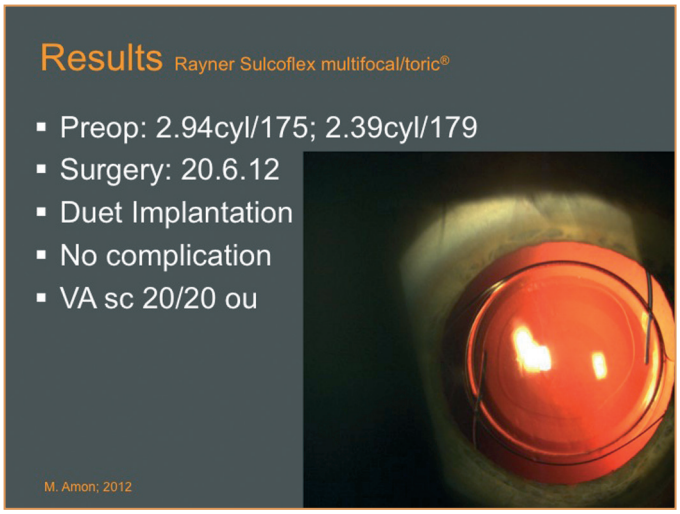
"In my opinion, it is not possible to guarantee stable fixation with any kind of sulcus-placed IOLs, because of their anatomical position. However, it can be suture-fixated, and in the three eyes where I have done that, the supplementary IOL remained stable."

Dr Amon also reported that he performed the first implantation of the recently introduced multifocal toric Sulco*flex* IOL in June, 2012, in a patient with preoperative cylinder measurements of 2.4 and 2.9 D. The procedure was a primary DUET implantation in which both the capsular bag and sulcus lenses were implanted in a single procedure. The sulcus IOL was not sutured and did not rotate. There were no complications, and the patient was very happy with the outcome.

Dr Amon noted that over the years, he has explanted a Sulco*flex* IOL in a single eye, and he presented a video to demonstrate the procedure and illustrate its simplicity.

"A Sulco*flex* lens can be easily removed through an astigmatism-neutral small incision without any need for cutting or folding the IOL in the eye," Dr Amon said.





FINAL THOUGHTS

In concluding, Dr Amon acknowledged that there are some limitations to keep in mind when considering a Sulco*flex* DUET procedure. In addition to the possibility of IOL rotation, he noted that implantation of the supplemental IOL in a secondary operation is intraocular surgery so that antibiotics are needed. He also recommended iridotomy in short eyes to minimise the risk of pupillary block.

Finally, Dr Amon observed that Sulco*flex* DUET is a new concept for which peer-reviewed reports are limited.

"However, tens of thousands of Sulco*flex* lenses have been implanted to date, and we can expect more publications will come."

Dr Amon is a consultant to Rayner.

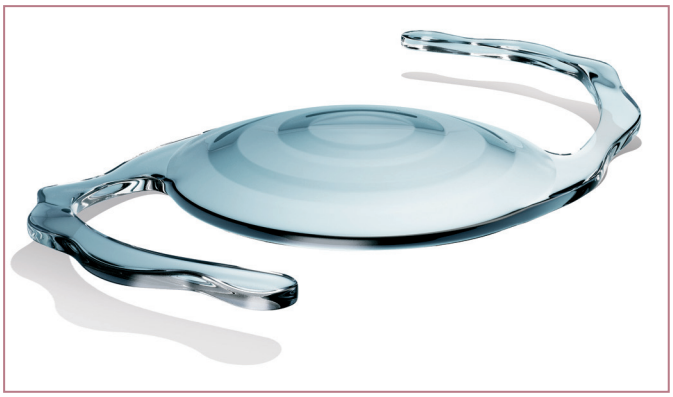
THE DUET PROCEDURE — HOW AND WHEN TO USE SUPPLEMENTARY IOLS

Charles Claoué MD

A rational classification scheme for Sulco*flex* DUET operations can help surgeons appreciate the multiple opportunities for improving patient outcomes using supplementary IOL technology, according to Charles Claoué MD.

Dr Claoué explained that the Sulco*flex* IOL can be implanted in two types of primary surgeries, termed Primary DUET and the DUET deconversion, and in two secondary operations, known as DUET correction and DUET conversion. He also underscored use of the term DUET procedures.

"Surgeons need to think about these supplementary IOL operations as DUET procedures and not refer to them as piggybacking. Piggybacking pertains to surgery performed using older lens platforms that were never designed for sulcus implantation," said Dr Claoué, senior consultant ophthalmic surgeon, Queen's Hospital, London, UK.



Sulco*flex* Multifocal Lens

PRIMARY DUET

The primary DUET procedure involves implanting a primary IOL in the capsular bag and a Sulco*flex* aspheric or toric IOL in the sulcus during the primary cataract surgery session. Its purpose is to provide pseudophakic correction for eyes with extreme refractive errors (high myopia, hypermetropia, or astigmatism) that cannot be fully corrected using a single, commercially available IOL implanted in the capsular bag.

"We also know that the eyes with high ametropia are the ones where biometry remains least accurate and where there is an increased possibility of being faced with a refractive surprise and need for IOL exchange. Whereas removing an IOL from the capsular bag is difficult and dangerous, refractive adjustment after a primary DUET procedure by exchanging only the supplementary IOL is much safer and easy," Dr Claoué added.

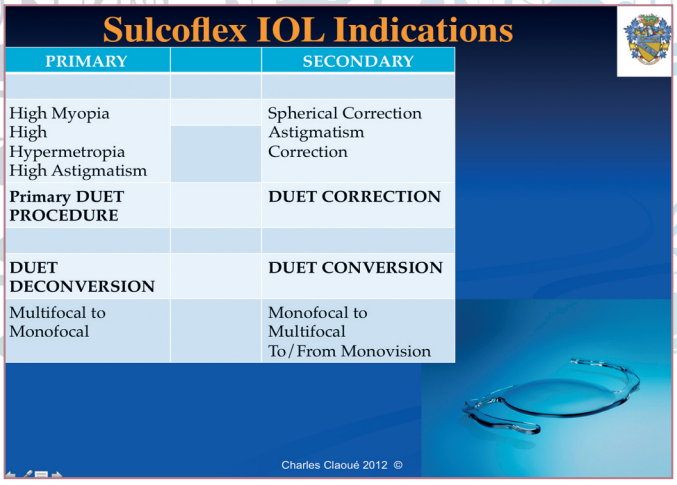
Eyes with high astigmatism that would need additional toric correction with a supplementary IOL often are those with keratoconus or that are post-penetrating keratoplasty. Recognising the possibility that these eyes may need a future repeat graft procedure leading to a change in astigmatism, Dr Claoué proposed that when performing a primary DUET procedure in these eyes, surgeons should preferably implant a purely spherical lens in-the-bag and use the toricity of the Sulco*flex* IOL to correct all of the astigmatism, if possible.

DUET CORRECTION

This category of Sulco*flex* IOL procedures involves secondary implantation of the supplementary IOL to correct residual spherical and/or astigmatic errors in the pseudophakic eye. The candidate pool includes a surgeon's own cataract surgery patients with a postoperative refractive surprise as well as those operated on by others.

"Compared with implantation of the Light Adjustable Lens (Calhoun Vision) to allow fine-tuning of the postoperative refractive outcome, correction of residual refractive errors using a Sulco*flex* IOL is cheaper and easier," said Dr Claoué.

The DUET Correction procedure is also a good option for managing patients with changing refraction, such as paediatric cataract surgery patients. In the latter population, secondary implantation of a Sulco*flex* IOL offers a method to correct any residual myopia in the pseudophakic eye once it is full-grown (>age 18). Alternatively, Dr Claoué noted that the supplementary IOL can be implanted at the time of cataract surgery together with a capsular bag IOL powered so that it alone will make the eye emmetropic once the child has grown. Upon maturity, removal of the Sulco*flex* IOL allows for safe and easy correction to emmetropia, he explained.



DUET CONVERSION

These are secondary procedures where the supplementary IOL is used to convert the optics of existing pseudophakic eyes. "DUET conversion procedures have immense potential for practice enhancement," Dr Claoué said.

Situations encompassed in the DUET conversion include implanting a multifocal or multifocal toric, Sulco*flex* IOL to correct presbyopia and/or astigmatism in pseudophakic patients with an existing monofocal IOL. The DUET conversion category also includes procedures where an aspheric supplementary IOL is implanted to change a patient to or from monovision.

"I am not a big believer in monovision for presbyopic correction," stated Dr Claoué. "However, implanting a monofocal Sulco*flex* IOL offers a method for moving emmetropic patients to monovision as well as for eliminating monovision if a patient desires."

DUET DE-CONVERSION

Describing this as the newest concept for using the Sulco*flex* IOL, Dr Claoué explained that in this primary DUET procedure, a C-*flex* monofocal IOL is implanted in the bag and a Sulco*flex* multifocal IOL is placed in the sulcus. The purpose of DUET de-conversion is to provide a safe trial of multifocal vision to cataract surgery patients who are hesitating to choose a multifocal IOL.

"Since 1997, there have been advances in the technique and IOL technology, including introduction of multifocal IOLs with design modifications that enhance stability, reduce posterior capsule

opacification, and minimise problems of contrast sensitivity loss and haloes. There have also been increases in understanding of neuro-adaptation and the rate of immediate sequential bilateral cataract surgery (see ***www.isbcs.org***)," said Dr Claoué.

"Performing DUET de-conversion using a Sulco*flex* multifocal IOL is a new advance as it permits a reversible procedure."

To understand the Presby-DUET procedure, Dr Claoué suggested surgeons consider patients who say they do not want to be presbyopic, but are concerned about potential haloes. The multifocality provided by the Sulco*flex* IOL allows these individuals to experience multifocal vision without facing the risks of removing a capsular fixated IOL.

Dr Claoué added that if a patient is dissatisfied after Presby-DUET, a decision about explanting the sulcus IOL should not be made for at least six months in order to allow sufficient time for neuro-adaptation. Even then, patients who are not entirely happy may change their mind about having the multifocal Sulco*flex* IOL removed if they are shown what their reading vision will be like while wearing trial frames with a -3.0 D add.

"If the patient is finding multifocal vision intolerable and also understands absolute presbyopia, the multifocal Sulco*flex* IOL can be removed easily through an astigmatism-neutral small incision," he said.

Dr Claoué noted that he routinely performs a peripheral iridotomy when implanting a Sulco*flex* IOL, and he suggested that other surgeons consider this adjunctive procedure as well.

"DUET CONVERSION PROCEDURES HAVE IMMENSE POTENTIAL FOR PRACTICE ENHANCEMENT"

Dr Claoué is a consultant to Rayner.

BIOMETRY OF SUPPLEMENTARY IOLS

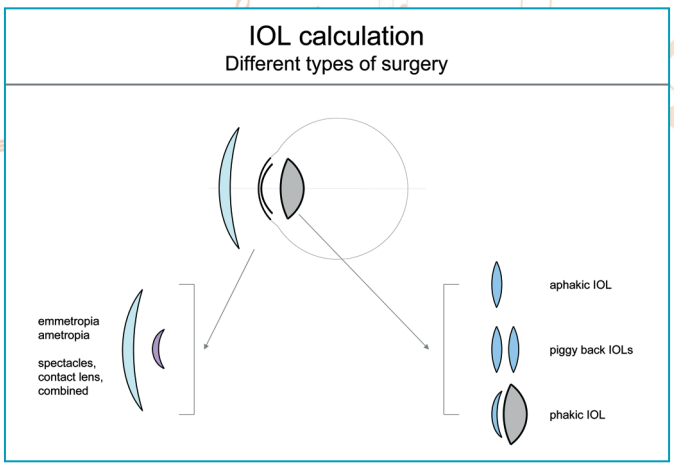
Wolfgang Haigis MS, PhD

Surgeons implanting an add-on Sulco*flex* IOL in the pseudophakic eye are achieving good refractive results. However, users must keep in mind that the accuracy of power calculation for the supplementary IOL depends on careful determination of the existing refraction, according to Wolfgang Haigis MS, PhD.

Discussing biometry for supplementary IOLs, Dr Haigis explained that free online calculators for determining the power of a supplementary Sulco*flex* IOL are available through his own website (***www.augenklinik.uni-wuerzburg.de/rayn***) and as a service through the manufacturer's online ordering system (***www.raytrace.net***). Dr Haigis's power calculation is based on classical Gaussian optics, whereas the Rayner calculation uses a ray-tracing based approach.

With either option, the only input data needed are sphere and cylinder from the current refraction, vertex distance, pseudophakic anterior chamber depth, measured corneal radii and target refraction.

"Axial length is required when calculating pseudophakic IOL power for the aphakic eye, and error in axial length measurement is the major source of inaccuracy in the postoperative refractive outcome," said Dr Haigis, head of the biometry laboratory and professor of ophthalmic biometry, University of Wuerzburg, Germany.



"In contrast, axial length is not used when calculating IOL power for a supplementary IOL in the pseudophakic eye. However, surgeons do need to take care in obtaining an accurate refraction."

Dr Haigis reported findings from a Sulco*flex* user evaluation that showed almost 2,200 power calculations were performed through Dr Haigis's online service between September 2008, and June 2012, representing an average of about 40 uses per month. While outcomes data were submitted by only about 20 surgeons, the results were excellent using the classical Gaussian optics method, with the mean (± standard deviation; range) spherical equivalent post-implantation being -0.15 D (± 0.70; -1.68 to +1.31).

"Although the vast majority of users did not report their results, I believe we can assume they were also good as it is likely we would be getting feedback from surgeons who were obtaining less than satisfactory outcomes," Dr Haigis said.

In addition, he found that the two methods for power calculation performed equally well with the mean difference in the classical Gaussian optics and manufacturer's ray tracing technique for power calculation being only +0.02 D (± 0.27; -0.62 to +0.66).

Discussing the impact of inaccuracies in the variables used for calculating the power of a supplementary IOL, Dr Haigis presented analyses for a sample eye to demonstrate that precision in measuring the existing refraction has the greatest influence on refractive outcome accuracy. Assuming an eye with an anterior chamber depth of 3.00mm, vertex distance of 12mm, corneal radii of 7.8mm, preoperative SE of -8.0 D, and a target refraction of emmetropia, an error in vertex distance of ±1mm would have a negligible effect on the accuracy of IOL power selection (<±0.1 D). With inaccuracy ±1mm in determining corneal radii, the IOL power would be changed by just ±0.2 D, and if there was a 1mm discrepancy in the accuracy of the anterior chamber depth measurement, the selected IOL power would be off by about 0.5 D, which is still not of major significance, said Dr Haigis.

"However, a 1.0 D error in measurement of current refraction would result in almost a 1.0 D error in selected power for the supplementary IOL," he explained.

Dr Haigis is a consultant to Carl Zeiss Meditec.

MARKETING PEARLS FOR SUPPLEMENTARY IOL USE: SERVING UNDEREXPLORED PATIENT POPULATIONS

Thomas Homscheid PhD

The Sulco*flex* IOL is one of the first ever implants designed specifically for placement in the ciliary sulcus, and its availability is a win-win situation for surgeons and patients alike, according to Thomas Homscheid PhD.

"The Sulco*flex* IOL is a different implant technology from a standard pseudophakic posterior chamber IOL and it is not a piggyback solution. Rather it was designed so that it will be stable and safe when implanted in the sulcus without causing inflammation or interlenticular opacification. Experience accumulated over the past six years since Prof Michael Amon MD, implanted the first Sulco*flex* IOL proves it has achieved these goals," said Dr Homscheid, marketing consultant, Nürnberg, Germany.

"Now, with four different versions available, the Sulco*flex* IOL is a very versatile tool. Moreover, it is a cost-efficient addition to the armamentarium of cataract surgeons that enables an increase in practice volume and delivery of refractive solutions to current and past cataract patients without investing in expensive new equipment."

The original target population for the Sulco*flex* IOL was patients with residual ametropia, and data recently reported by Anders Behndig MD, [*J Cataract Refract Surg 2012;38:1181-6*] showing that 55 per cent of all cataract patients are left with refractive error worth correcting indicates this is a large and important market.

"Surgeons should not overlook that previous cataract surgery patients may also be re-invited back for an enhancement using a Sulco*flex* IOL," Dr Homscheid said.

However, with the different optic designs available, surgeons can also use the Sulco*flex* IOL to target a broader variety of patient groups. Implanted as a primary or secondary intervention, a Sulco*flex* IOL can be used to eliminate residual astigmatism. With use of a multifocal or multifocal toric Sulco*flex* IOL, surgeons can offer patients presbyopia correction with several advantages, said Dr Homscheid.

He explained, "No matter how careful surgeons are in selecting patients for multifocal IOL implantation, a small percentage of these individuals do not tolerate multifocality because of a lack of neuroadaptation or problems with haloes or glare. Sulco*flex* IOL removal is still a surgical procedure, but it is done quickly and is far less complicated than explanting an IOL from the capsular bag.

"This ease of reversibility offers patients peace of mind in choosing a Sulco*flex* multifocal or multifocal toric IOL for correction of presbyopia, and the supplementary IOL technology also has particular appeal as an alternative to a multifocal posterior chamber IOL in markets where co-payment is now allowed. Considering the benefits offered for presbyopia correction and as patient awareness of the technology increases, we expect particular growth in multifocal Sulco*flex* IOL procedures," said Dr Homscheid.

With its various optic models, a Sulco*flex* IOL also can be used to target patients who are unhappy with their refractive outcome after laser vision correction, those who request or are not tolerating monovision, patients seeking an enhancement after refractive or presbyopic lens exchange and patients with dynamic change of refraction over time.

"THE SULCOFLEX IOL IS A DIFFERENT IMPLANT TECHNOLOGY FROM A STANDARD PSEUDOPHAKIC POSTERIOR CHAMBER IOL AND IT IS NOT A PIGGYBACK SOLUTION"

Delivering an optimum of precision to the cataract patient

- 55% of all cataract patients are left with an ametropia worthwile correcting.*
- A secondary intervention can elimininate residual presbyopia and / or astigmatism.
- Historic cataract patients may be reinvited for an enhancement.
- A planned sequence of capsular bag and sulcus lens implantation is also possible.

*Anders Behndig et al., JCRS 2012; 38:1, 1181-6.

"SURGEONS SHOULD NOT OVERLOOK THAT PREVIOUS CATARACT SURGERY PATIENTS MAY ALSO BE RE-INVITED BACK FOR AN ENHANCEMENT USING A SULCOFLEX IOL"

"By overcoming the problems of piggybacking and with its ease of reversibility, the Sulco*flex* series of IOLs has converted supplementary lens use in cataract surgery from being just a makeshift solution in special cases of patients with intolerable residual refractive error to a planned, standard procedure in a variety of indications," said Dr Homscheid.

"Bringing the Sulco*flex* lenses to market is evidence that Rayner continues to be the spearhead of innovation in IOL technology, just as it was when it manufactured the first IOL implanted by Sir Harold Ridley more than 60 years ago."

Dr Homscheid is a marketing consultant to Rayner.

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