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SULCUS-BASED
enhancement of visual quality

1stQ AddOn®



Introduction

Patient interest in reducing spectacle-dependence after cataract surgery is growing, and new technologies have emerged that enable surgeons to deliver on this goal by providing excellent refractive outcomes. Yet, concerns about visual quality have remained an obstacle to the greater adoption of presbyopia-correcting intraocular lenses (IOLs).

Despite new generations of advanced capsular bag IOL technologies being available, certain limitations still exist especially considering special occupations or the chance of future ocular pathologies. Given its reversible nature, the AddOn may provide further options to address those. Moreover, even with careful surgical planning using modern biometry devices and IOL formulas, residual refractive error that compromises postoperative vision and therefore patient satisfaction remains an issue in the current era of cataract surgery.

The portfolio of 1stQ AddOn® supplementary IOLs, which includes refractive, toric, trifocal, and trifocal toric models, stands out as a solution that surgeons can rely on to provide high quality vision whether patients are seeking to reduce spectacle-dependence for distance or for a full range of vision. As described in this supplement, findings from a growing number of clinical studies investigating the 1stQ AddOn IOLs confirm their outstanding clinical performance characterised by predictable and durable refractive results, visual outcomes, and safety.

The Evolution of a Tailor-Made Sulcus Platform

The 1stQ AddOn supplementary IOL was designed by German Engineer Rüdiger Dworschak, founder and CEO of 1stQ. Although he created his first sulcus lens in 1998, Mr Dworschak continued to make refinements in the design. In 2008, his work culminated in the platform that is the current patented design for the 1stQ AddOn lens.

The current version of the 1stQ AddOn IOLs was first implanted in Europe in 2010. Now, this line of supplemental IOLs is available in 48 countries – for more than a decade in most – and the number of markets is increasing.

After the lens exchange with a monofocal IOL, a trifocal AddOn lens was also implanted in the same surgical setting. He said: "With the 1stQ AddOn lens I am able to see without glasses in 99% of situations. My vision is sharp with excellent contrast, and the colours are true."

Form Follows Function

Sulcus is not the physiological site for IOL implantation, and insertion of an IOL in the ciliary sulcus poses numerous risks, including iris chafing, pigment dispersion syndrome, pupillary block, secondary angle closure and secondary glaucoma. The 1stQ AddOn platform was designed to overcome these issues.

Four main features describe the salient qualities of the 1stQ AddOn platform: specially designed for sulcus implantation, rotational stability, preservation of anterior segment physiology, and clearance with the capsular bag IOL (Figure 1).

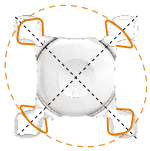
"The stability of the AddOn lenses with their four-point fixation and their minimal potential for ciliary body touch are some of the key features of this platform," said Brian Harrisberg MD, an expert in cataract and refractive surgery practicing in Sydney, Australia.

"I highly recommend the 1stQ AddOn lenses as a supplemental sulcus-based platform that is associated with excellent visual acuity outcomes and no long-term adverse sequelae."

Key Attributes of the 1stQ AddOn IOLs

Versatility

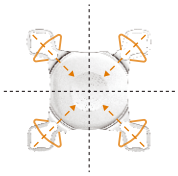
The 1stQ AddOn IOLs can be used with any type (monofocal, multifocal) and power of primary capsular bag IOL. There are four main applications for implanting a 1stQ AddOn IOL: refractive correction, astigmatism correction, trifocal upgrade, and planned dual procedure for potentially reversible multifocality (Figure 2).



Variation in sulcus size & shape requires an adaptive design

The unique 4-flex haptic configuration by 1stQ ensures independent anchorage on four pressure points as opposed to C-loop type sulcus lens designs.

The 1st AddOn Trifocal IOL maintains a stable position in eyes with a wide variety of axial lengths.



High rotational stability with the 1stQ AddOn non-torque design

To date, no cases (0%) have been reported in which 1stQ AddOn Toric IOLs needed repositioning.

The mean absolute change in IOL – position was below 5°.

This confirms a remarkably higher stability than that was published on C-loop type sulcus lens designs.

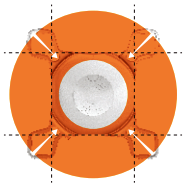
Maintaining iris function and anterior segment physiology

The square optic design of the 1stQ AddOn Trifocal was engineered to prevent iris capture, independent of pupil aperture.

The rounded edges of the optic and haptics help avoid iris chafing and iris pigment dispersion, thereby preventing secondary glaucoma.

To date no reports of iris chafing, pupillary rupture or pigment dispersion syndrome have been published.

Intraocular pressure (IOP) after 1stQ AddOn Trifocal implantation remains in the physiological range, hence it helps to maintain normal ocular conditions.



Maintaining IOL clearance

With the convex - concave optic design of the 1stQ AddOn Trifocal IOLs sufficient interienticular space is created to avoid IOL touch and to minimize the development of interienticular opacification.

Preserved endothelial cell integrity and function Endothelial cell loss is much less, than during a routine cataract surgery with phacoemulsification.

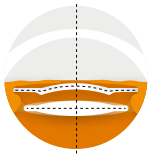


Figure 1. Design features of the 1stQ AddOn® IOLs



Figure 2. Primary applications of the 1stQ AddOn® IOLs

"The 1st Q AddOn lenses have become a versatile adjunct for achieving success in my refractive lens exchange and cataract surgery population," said Dr Harrisberg.

In addition to the indications listed above and because of their proven reliability, many surgeons also use the 1stQ AddOn IOLs for special applications. These latter situations include correction for patients whose refractive error exceeds the range available with capsular bag IOLs and for the temporary or permanent correction of refractive error that occurs following penetrating keratoplasty or pars plana vitrectomy.

Reversibility

The reversible nature of the 1stQ AddOn IOL supports its use in temporary applications. It is also appealing to surgeons who are interested in separating trifocality from the functions of the primary capsular bag lens because it allows a simple solution for patients who are unhappy with the results of a trifocal IOL or go on to develop pathology that is incompatible with multifocality.

Dr Harrisberg says that reversibility of presbyopia correction with the 1stQ AddOn Trifocal IOL is an attractive feature. He notes that he initially gained exposure to the AddOn platform when he became the first Australian surgeon to implant the SML (Scharioth Macula Lens) AddOn lens.

"The success I had using this technology in eyes with stable macular diseases gave me confidence to expand its use in my practice," he said.

Subsequently, Dr Harrisberg began using the 1stQ AddOn Trifocal IOL for patients who were interested in presbyopia correction but reluctant to proceed with primary implantation of a multifocal IOL.

"Multifocal lenses comprise 25% or more of my cataract and refractive lens surgeries, but there has always been a cohort of patients who lacked confidence to consent to a multifocal implant. A planned dual procedure using the 1stQ AddOn Trifocal IOL with a monofocal or monofocal toric IOL in the bag for distance correction allows for reversibility of multifocality. This flexibility is reassuring for patients and allows me to offer them an opportunity for restoring near vision that would otherwise be lost," he said.

Having performed the planned dual lens procedure in more than 35 eyes, Dr Harrisberg reports that both he and his patients have been very pleased with the results.

"To date, I have not yet needed to remove an add-on lens, thus confirming the good outcomes and patient satisfaction," he said.

Francesco Carones MD, Medical Director, Carones Vision, Milan, Italy, also considers reversibility a key feature of using the AddOn Trifocal/Trifocal Toric lenses for presbyopia correction and notes it can give patients confidence in choosing presbyopia correction.

"I am finding the AddOn IOLs are a great choice because the implantation is very easy and straightforward, potential surgical complications are minimal and any medium or long-term potential complications may be reversed by removing the implant," Dr Carones said.

"Patients who are already pseudophakic and are offered the lens as an upgrade do not see the secondary procedure as challenging. The refractive results, visual outcomes and level of spectacle independence achieved with the AddOn IOLs has been very high, matching that of conventional trifocal IOLs, and patient satisfaction has also been very high," Dr Carones added.

Physical Stability as a Base for the Toric Model

Results from both cadaver and clinical studies confirm that the 1stQ AddOn® IOLs remain positionally stable in eyes across a wide range of axial lengths. Rotational stability of the AddOn platform makes it suitable as a base for a toric IOL.

To date, there are no reports that any 1stQ AddOn Toric IOLs have needed repositioning. Evidence of the long-term stability of the 1stQ AddOn Toric IOL is available from a study reported by Kjell Gundersen MD and Rick Potvin MD.[1] The study included 18 eyes followed for between 43 days and 4.5 years after their secondary IOL surgery. Analyses of changes in the position of the AddOn Toric IOL showed a mean difference of -0.1 +/- 6.3 degrees between actual and intended lens orientation. In 16 eyes (89%), lens orientation was within 10 degrees of intended (Figure 3).

"Residual spherical or toric refractive error > 0.5D will significantly reduce patient satisfaction after cataract surgery and should be treated. Laser surgery might induce or worsen ocular surface disease that is already highly prevalent in the cataract patient population. I believe that a 1stQ AddOn lens is a much better option for refractive fine-tuning," said Dr Gundersen.

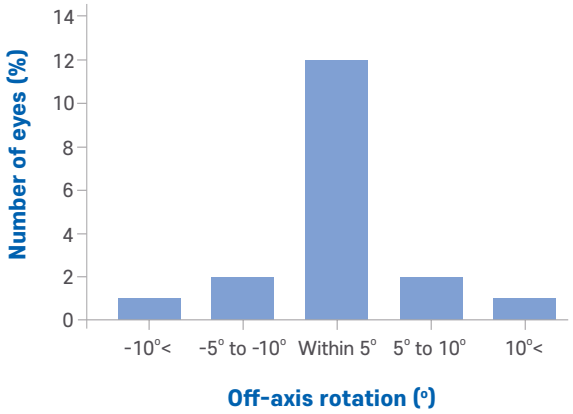


Figure 3. Distribution of difference in lens orientation from intended[1]

"The first generations of supplementary toric IOLs rotated in more than 30% of cases. The 1stQ AddOn toric IOL is the first supplementary IOL platform that has the rotational stability needed to achieve and maintain accuracy and precision. Furthermore, it is easy to implant and has not been associated with any iris irritation or inflammation postoperatively."

Dr Carones also observes that the toric versions of the AddOn lenses show excellent rotational stability post-surgery. At the same time, the lens is easy to rotate during implantation.

"The rotation is smooth and so axis alignment is very easy," he said.

Clinical Outcomes

Refractive predictability

A study conducted by Dr Harrisberg that compared a group of 57 eyes implanted with a trifocal/trifocal toric capsular bag IOL (Liberty 677MY/Liberty 677MTY) against a cohort of 15 eyes that underwent a planned dual lens procedure with a monofocal/monofocal toric IOL (Bi-Flex 877PA/BiFlex 677TA) + a plano supplementary trifocal (1stQ AddOn Trifocal) provides evidence on the predictability of refractive outcomes with the dual lens approach (Figure 4).[2]

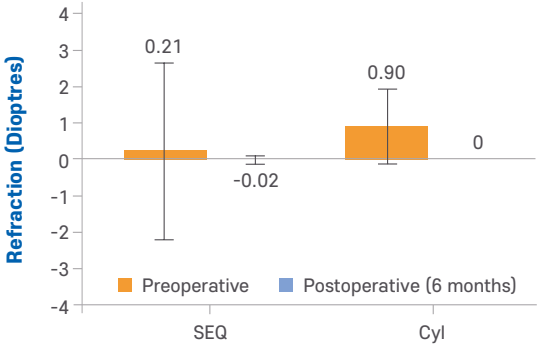


Figure 4. Refractive error before and after 1stQ AddOn Trifocal implantation in the dual lens approach[2]

Superior Visual Acuity and Quality

The potential of glasses-free vision can increase quality of life for many pseudophakic patients. The 1stQ AddOn Trifocal is proven to provide spectacle independence, therefore improving visual comfort for pseudophakic patients while they are performing a wide range of everyday activities. Trifocal performance following the implantation of the 1stQ AddOn IOLs has been confirmed by multiple clinical investigations that show it is associated with similar visual acuity results compared to a conventional trifocal in-the-bag lens (Figure 5).[2-4] In Dr Harrisberg's series, 100% of

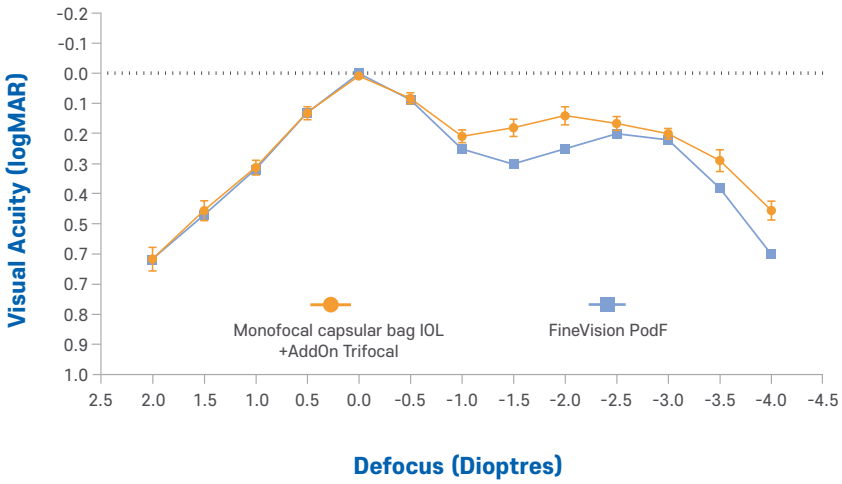


Figure 5. Defocus curve of the add-on IOL shows superior visual acuity in intermediate and near ranges compared to the trifocal capsular bag intraocular lens. Depth of focus is identical in eyes implanted with each of these lenses. Monocular defocus curve (n=12 eyes) with the supplementary IOL compared to the binocular defocus curve (n=20 eyes) of a trifocal capsular bag intraocular lens

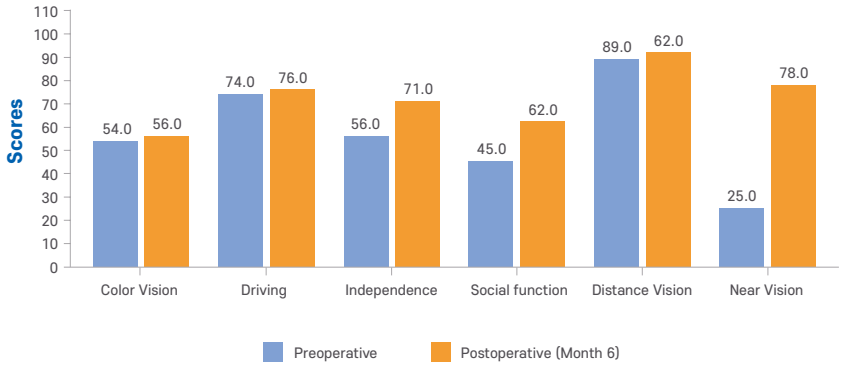


Figure 6. Mean scores for visual function and quality before and six months after implantation of the 1stQ AddOn Trifocal IOL as a secondary procedure[4]

patients implanted with the AddOn Trifocal achieved spectacle independence for all distances.[2]

Furthermore, a study by Albayrak et al. showed that in addition to their near vision gains, patients with a monofocal lens who underwent secondary implantation of the 1stQ AddOn Trifocal IOL achieved improvements in other visual skills as well as in social functioning (Figure 6).[4] [Albayrak] These patients enjoyed the benefits of the AddOn lens without any negative effects on distance vision, contrast sensitivity, or colour perception.

Safety

Studies of eyes implanted with the 1stQ AddOn IOLs show no statistically significant difference in IOP before and after the secondary IOL implantation. In addition, data show that the convex-concave geometry of the 1stQ AddOn IOLs helps to maintain endothelial structure and function. Unlike other supplementary sulcus platforms, the 1stQ AddOn IOLs have not been associated with such problems as dislocation, iris capture, iris chafing, pigment dispersion syndrome, pupillary rupture, angle closure (secondary glaucoma), or change in material of the capsular bag or AddOn IOL. In Dr Harrisberg's study, none of the patients undergoing a dual lens procedure with a 1stQ AddOn Trifocal IOL reported bothersome glare or halo.[2]

Dr Harrisberg says that meticulous attention to technique is needed for insertion of the AddOn lens to avoid complications. In a planned dual procedure, the 1stQ AddOn is inserted immediately after the capsular bag IOL is positioned and after taking care to remove all of the viscoelastic from behind and in front of the primary lens. Dr Harrisberg advises delivering the AddOn lens into the anterior chamber with each haptic rotated into the sulcus via a diagonal approach rather than working with downward pressure or behind the wound. In addition, he said a miotic should be used to constrict the pupil, allowing the surgeon to check that no haptic has popped out through the pupil.

"I have not done any peripheral iridotomies prophylactically and I have not yet seen any case of pupillary block glaucoma. I insert the lens through a 2.2mm incision using a Medicel cartridge injector, and the wound size is unchanged after the procedure," Dr Harrisberg said.

Adding to the AddOn Evidence Base

Clinical impressions and published results from single centres support the efficacy and safety of the 1stQ AddOn IOLs. Soon, a prospective, multinational clinical trial will be launched to gather further evidence on outcomes achieved in patients receiving this supplementary lens technology to correct residual spherical refractive error, astigmatism and presbyopia.

Sathish Srinivasan MD, Consultant Ophthalmologist, University Hospital Ayr, Ayr, UK, is the principal investigator for the study that is investigating the visual, refractive and safety outcomes following implantation of the 1stQ AddOn Trifocal or Trifocal Toric IOL in previously pseudophakic eyes. Six centres located in Scotland, Spain, Portugal, France, Germany, and Belgium are participating.

Prof Srinivasan notes that a study of this kind has never been done before. "There are no prospective, multi-centre clinical trials investigating piggyback IOLs. A human cadaver eye study we performed showed this platform achieved appropriate centration and interlenticular distance with different primary in-the-bag IOLs.[5] My personal clinical experience with the 1stQ AddOn lenses has been consistently positive," Prof Srinivasan said.

References

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