ORIGINAL RESEARCH

Efficacy of a Secondary Trifocal Sulcus IOL in Providing Near and Intermediate Vision in Patients with Prior Myopic Laser Vision Correction and Cataract Surgery

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Purpose: To evaluate the visual function of patients with a history of prior laser vision correction and cataract surgery with implantation of a monofocal primary IOL after subsequent implantation of a secondary sulcus trifocal intraocular lens (IOL). **Setting:** One clinical practice in Haugesund, Norway.

Design: Prospective, single arm, non-interventional unmasked study.

Methods: Eligible subjects who had previous laser vision correction and cataract surgery involving implantation of a monofocal IOL in the capsular bag of one or both eyes were subsequently implanted with a secondary IOL in the sulcus. Postoperative uncorrected and best distance-corrected visual acuities (VAs) were measured at distance (4 m), intermediate (60 cm), and near (40 cm), along with low contrast visual acuity and the monocular distance corrected defocus curve.

Results: Twenty-five eyes were evaluated from 7 to 24 months after trifocal implantation. The mean monocular uncorrected VAs were 0.06, 0.21 and 0.10 logMAR at distance, intermediate and near, respectively. Uncorrected near VA was 0.2 logMAR or better in 80% of eyes (20/25). VA of 0.2 logMAR or better at all test distances was achieved in 15/25 eyes (60%) in the uncorrected state and 17/25 eyes (68%) when corrected for distance vision. Binocular uncorrected distance visual acuity was 0.1 logMAR or better in all subjects while binocular uncorrected near visual acuity was 0.1 logMAR or better in all but one subject. The defocus curve showed a range of functional vision from distance to 30 cm. No adverse events were identified.

Conclusion: The trifocal sulcus IOL provided excellent distance and near vision and a good range of functional vision, similar to results obtained when a primary trifocal IOL is implanted. It is a viable option to provide better intermediate and near vision to patients with a prior history of refractive surgery and a monofocal IOL implanted.

Keywords: LASIK surgery, post-LASIK cataract surgery, trifocal IOL, intraocular lens, sulcus IOL, secondary IOL, 1stQ AddOn®

Plain Language Summary

Cataract surgery involves the removal of the cloudy crystalline lens from the eye and implantation of an artificial intraocular lens (IOL). Modern measurement methods have increased the likelihood that patients will not need glasses for distance vision after surgery, but for patients with previous refractive surgery (eg, "LASIK"), results are less predictable. This can make multifocal IOLs (which provide the ability to see at various distances) less attractive, because their success depends on predictable calculation results. However, some patients are interested in reducing their dependence on glasses for near, intermediate and distance work. A possible approach here is to correct the eye with an IOL designed for good distance vision, and then add a secondary multifocal IOL afterwards to provide better intermediate and near vision. The secondary IOL can also correct any refractive errors to improve distance vision if necessary. This study was designed to determine if a secondary trifocal IOL could effectively improve the range of vision in such patients, while also correcting residual refractive error if necessary. Results obtained suggest that the secondary trifocal IOL is as effective as a primary trifocal IOL in this regard, providing a functional range of vision from distance to near.

Introduction

Modern cataract surgery planned with up-to-date intraocular lens (IOL) power calculation formulas may be considered a refractive procedure, with a high percentage of eyes expected to have a residual spherical equivalent refraction within 0.50 D of the intended target. With uncomplicated surgery, the rate may be 80% or better.^{1,2} Eyes with shorter and longer axial lengths may be more problematic, but the most challenging cases remain those eyes that have had previous refractive surgery.³ In the case of laser assisted in situ keratomileusis (LASIK), IOL power calculations are most affected by the change in the anterior corneal curvature, though predicting the effective lens position and use of the standard refractive index of the cornea are also contributing factors.⁴ A number of formulas to address this have been designed and implemented, with limited success. To date, no clear "best" formula has been identified.

The lower predictability of refractive outcomes may make surgeons less inclined to use a multifocal or extended depth of focus (EDOF) IOL in these eyes because uncorrected distance vision is one of the major factors influencing satisfaction with these lenses.⁵ Consistent with this finding is that postoperative residual refractive error has been reported as the major cause for dissatisfaction of patients who have had a presbyopia correcting IOL implanted.⁶ While studies reporting clinical results after primary multifocal IOL implantation after refractive surgery are limited, the percentage of eyes within 0.50 D of emmetropia ranges from 48% to 70%.^{7–9}

One approach to the challenges presented by eyes with previous refractive surgery is to implant a primary monofocal IOL. If, after surgery, a patient expresses an interest in greater overall spectacle independence (ie, better near and intermediate vision), a secondary IOL may be implanted. The advantage of this approach is that any residual refractive error after the primary surgery might also be corrected by adjusting the base power of the secondary IOL. In addition, the sulcus IOL can be easily removed if the patient experiences unacceptable visual disturbances.

Secondary multifocal IOL implantation was first described in 1999,¹⁰ but saw limited adoption because of concerns with interlenticular opacification when both lenses were in the bag.¹¹ Secondary lenses were then moved to the sulcus,¹² which increased the potential for iris chafing and the potential for pigmentary glaucoma.¹³ Subsequent advances in lens design and materials have addressed these issues, making sulcus IOL implantation a generally safe and effective procedure.¹⁴

The AddOn[®] trifocal sulcus IOL (1stQ GmbH, Mannheim, Germany) was designed to provide patients who have been previously implanted with a monofocal IOL targeted for distance the ability to see better at intermediate and near, while also correcting any residual refractive errors. Figure 1 shows the main features of the lens. It is made from a hydrophilic acrylic material and has a convex anterior and concave posterior to reduce the potential for contact with the primary IOL – a pseudophakic anterior chamber depth > 2.8 mm is required. The lens has a 13.0 mm overall diameter, with a 6.0 mm optic zone. The central 3.0 mm contains the diffractive component of the IOL. The square design reduces



Figure I The AddOn® trifocal sulcus lens (courtesy IstQ GmbH, used with permission).

the likelihood of iris capture and the 4 closed loop haptics provide a rotationally stable position in the sulcus. Previous studies have demonstrated predictable clinical outcomes with both monofocal toric and non-toric configurations, with or without a trifocal component, with no iris chafing.^{15–17} The spherical IOL is available with a base power of \pm 5.0 D, while the toric IOL has a sphere range of \pm 3.0 D with from 1.0 to 4.5 D of cylinder at the IOL plane. Power calculations for post-refractive eyes are performed in a standard fashion using the manufacturer's online calculator. There is no requirement for a separate calculator for post-refractive eyes because after primary IOL implantation the only relevant parameters are the eye biometry and the residual refraction. A proprietary diffractive technology is used to provide the trifocal effect, with a near add of 3.0 D and an intermediate add of 1.5 D at the IOL plane.

This study was designed to evaluate refractive outcomes, visual acuity at a range of distances and visual function after secondary sulcus implantation of the AddOn[®] trifocal IOL in eyes with a history of prior refractive surgery and cataract surgery with a monofocal IOL implanted. We believe this is the first study of its kind.

Methods

This study was a prospective unmasked non-interventional single-arm study of refractive and visual outcomes after implantation of a trifocal sulcus IOL. Subjects must have had prior laser vision correction and prior cataract surgery in the enrolled eye, with subsequent implantation of a trifocal sulcus IOL in one or both eyes at least 1 month before their evaluation visit. Planned enrollment was 30 eyes, dependent on availability. The study was reviewed and approved by the Regional Committee for Medical and Health Research Ethics (REK) in Norway (ref. no. 2019/768). All enrolled subjects signed an informed consent document. The study was conducted in accordance with the tenets of the Declaration of Helsinki, International Harmonization (ICH) Guidelines and good clinical practice. The study did not involve an intervention, so registration with a clinical trial registry was not required. Data are not available for sharing.

All subjects were post-LASIK patients implanted with a monofocal IOL who had a subsequent desire to improve their intermediate and near vision, achieved through implantation of a trifocal sulcus IOL. Patients who had uncomplicated cataract or refractive lens exchange surgery followed by uncomplicated secondary sulcus trifocal IOL implantation in one or both eyes were invited to participate. The sulcus IOL surgery had to be at least 1 month prior to their scheduled study visit. They had to have good ocular health, with no pathology that would compromise visual acuity, outside of residual refractive error. There were no specific exclusion criteria. All primary and secondary cataract surgeries were completed by one surgeon (KGG) at one site.

The study visit included a manifest refraction and measurement of both monocular and binocular visual acuities at distance (4 m), intermediate (60 cm) and near (40 cm), in the uncorrected state and with a distance correction in place. The primary outcome measure of interest was the uncorrected near VA. Additional measures included a distance corrected monocular defocus curve and photopic corrected low contrast (10%) visual acuity at distance. The defocus curve testing was conducted from maximum defocus (+1.00 D or -4.00 D) down towards 0.00 D using 3 separate ETDRS charts at 4 m to reduce the potential for memorization. A slit lamp examination and anterior optical coherence tomography (OCT) were used to check for iris chafing and/or lens displacement at the study visit. Subjects were screened for adverse events. All VA measures were made using logMAR charts with chart luminance >80 cd/m². In addition, the intraocular pressures (IOP) before and after sulcus IOL implantation were extracted from the clinical records.

Relevant data related to the refractive surgery, primary surgery and secondary surgery were extracted from the subjects' clinical records. Diagnostic visit data were collected on a spreadsheet. Statistical analyses were performed using an analysis of variance (ANOVA), with a level of significance (alpha) of 0.05 being considered statistically significant.

Results

Twenty-five eyes of 13 subjects implanted with the trifocal sulcus IOL were evaluated. In one eye of one subject, the trifocal sulcus IOL was implanted but there had been no prior refractive surgery. There were 8 male subjects and 5 female subjects. Average age was 57 ± 5 years, with a range of 51 to 68 years. Primary surgery was refractive lens exchange (RLE) in 17 eyes and cataract surgery in 8 eyes. Sixteen eyes were implanted with a primary toric IOL, the remainder had a monofocal spherical IOL implanted. All primary lens materials were AcrySof[®], a hydrophobic acrylic, and all primary IOLs were implanted in the bag. Table 1 shows demographic data and prior LASIK/cataract history

		n	Average	SD	Minimum	Maximum
Prior to LASIK	Sphere	21	-3.42	1.70	6.50	-1.25
	Cylinder	10	-0.60	0.45	1.35	-0.25
	Spherical equivalent	21	-3.57	1.67	6.50	-1.50
Primary IOL	Sphere	25	20.6	2.1	16.5	24.5
	Cylinder	16	1.22	0.26	1.00	1.50

 Table I Demographics and LASIK/Cataract History (25 Eyes of 13 Subjects)

Abbreviations: SD, standard deviation; LASIK, laser in situ keratomileusis.

where available. Four eyes of two subjects had no refractive surgery history available, but the low keratometry and high axial length recorded highly suggest the eyes were initially myopic. The mean time between primary and secondary IOL implantation was 5 ± 3 months, ranging from 2 to 16 months. The mean time after sulcus trifocal IOL implantation to the study visit averaged 17 ± 4 months, ranging from 7 to 24 months.

Fourteen sulcus lenses were trifocal only, with no additional sphere or cylinder power. Two had only a toric primary component and the remaining nine ranged in base sphere power from -0.50 D to +0.75 D; 8 of these 9 had plus power.

Table 2 contains summary refractive data from before and after sulcus IOL implantation. There was a statistically significant increase in the mean magnitude of refractive cylinder but the clinical significance of this was likely to be nominal (<0.25 D). In 21 of 25 cases (84%) the difference in refractive cylinder magnitude was 0.50 D or less. The spherical equivalent was statistically significantly lower after sulcus IOL implantation, reflecting the use of slight plus power in a third of the lenses.

Figure 2 shows the mean monocular visual acuity by distance and correction status. The mean monocular uncorrected VA was 0.1 logMAR (20/25, 0.8 decimal). Distance corrected near VA was about a half line better. Table 3 summarizes the categorized VA data by distance and correction. Twenty of 25 eyes (80%) had a UNVA of 0.2 logMAR (20/32) or better. Seventeen of 25 eyes (68%) had a distance corrected VA of 0.2 logMAR or better at all test distances, while 15/25 eyes (60%) had uncorrected VA of 0.2 logMAR or better at all test distances.

As noted previously, one eye of one subject had the trifocal sulcus IOL implanted but did not have prior refractive surgery. Table 4 shows the binocular visual acuity results. Binocular uncorrected distance visual acuity was 0.1 logMAR or better in all subjects and the binocular uncorrected near visual acuity was 0.1 logMAR or better in all but one subject. Monocular corrected low contrast distance visual acuity was 0.24 ± 0.13 logMAR, with a range of 0.02 to 0.46 logMAR.

Figure 3 shows the distance-corrected monocular defocus curve. Mean distance VA was $-0.05 \log MAR (20/20 + 2)$ while mean near VA was 0.05 logMAR (20/20 - 2). Mean acuity was better than 0.3 logMAR (20/40) from distance to -3.00 D vergence (~ 33 cm viewing distance).

Given the range of follow-up times in this study, all VA and refractive data were checked for correlation to the time of follow-up. Distance corrected intermediate vision was the only statistically significant correlation (p < 0.05), suggesting better intermediate vision over time. However, a detailed examination of the data showed the correlation was driven by one outlier with lower (worse) intermediate VA and the shortest follow-up time (7 months), so it was not deemed clinically important.

		Mean	SD	Minimum	Maximum	p value
Refractive cylinder (D)	Before After	-0.21 -0.40	0.25 0.35	-0.75 -1.25	0.00 0.00	0.02
Spherical equivalent (D)	Before After	0.13 0.11	0.24 0.34	-0.25 -1.25	0.75 0.38	0.01

Table 2 Refractive Data Before and After Trifocal Sulcus IOL Implantation

Abbreviations: D, diopter; SD, standard deviation.



Figure 2 Monocular visual acuity by correction and distance. Abbreviation: logMAR, log of the minimum angle of resolution.

Slit lamp examination and OCT imaging of the eyes in this study showed no evidence of intralenticular opacification or iris chafing/depigmentation. There was no statistically significant difference in the IOP measured before and after sulcus IOL implantation (11.9 \pm 4.1 mm Hg before and 12.9 \pm 3.2 mm Hg after, p = 0.07). No eye post sulcus IOL implantation had an IOP higher than 19 mm Hg. There were no adverse events observed in the study population.

Discussion

The visual acuity and refractive results obtained in this group of subjects indicate that the trifocal sulcus IOL implanted provides the expected functionality of such a lens. Results appear comparable to those reported in a separate study of the same lens.¹⁷ Distance and near VA appear slightly better in the current study while intermediate vision appears slightly worse. The monocular defocus curves in both studies are also very similar, again with the slight differences noted above. Comparison of

		Cumulative Visual Acuity							
	Snellen	20/16	20/20	20/25	20/32	20/40	20/63	20/80	
	logMAR	-0.I	0	0.1	0.2	0.3	0.4	0.5	
Uncorrected	Distance (4 m) Intermediate (60 cm) Near (40 cm)	12% 0% 0%	36% 0% 32%	76% 24% 60%	88% 60% 80%	92% 72% 92%	96% 96% 100%	100% 96% 100%	
Distance corrected	Distance (4 m) Intermediate (60 cm) Near (40 cm)	32% 4% 0%	76% 8% 44%	92% 40% 84%	100% 68% 92%	100% 72% 96%	100% 100% 100%	100% 100% 100%	

 Table 3 Cumulative Monocular Visual Acuity Results by Distance and Correction (n = 25)

Abbreviation: logMAR, log of the minimum angle of resolution.

Status	Distance	logMAR Acuity (Lower is Better)					
		Mean	SD	Minimum	Maximum		
Uncorrected	Distance (4 m)	-0.05	0.11	-0.2	0.1		
	Intermediate (60 cm)	0.09	0.10	-0.1	0.26		
	Near (40 cm)	0.04	0.09	-0.08	0.22		
Distance Corrected	Distance (4 m)	-0.08	0.10	-0.22	0.1		
	Intermediate (60 cm)	0.10	0.15	-0.18	0.32		
	Near (40 cm)	0.02	0.09	-0.12	0.2		

Table 4 Binocular Visual Acuity Results (n = 13)

Abbreviations: SD, standard deviation; logMAR, log of the minimum angle of resolution.

the reported defocus curve results for an "in the bag" primary trifocal in that previous study indicate that the trifocal sulcus IOL is providing equivalent or better performance.¹⁷ The previous study did not include eyes with prior refractive surgery.

A 2014 study of a different sulcus multifocal IOL indicated similar performance of that IOL to one implanted in the bag as the primary lens.¹⁸ The studied lenses were both bifocal designs. The uncorrected and distance corrected near visual acuities observed in the current study were better than those reported for the sulcus IOL and equivalent to those of the primary IOL in the previous study. The intermediate vision in the current study was better than reported for either lens in the previous study, a confirmation of the trifocal effect of the IOL studied here.¹⁸ Distance and near binocular visual acuities found here were also as good or better than those reported for several diffractive sulcus bifocal IOLs.^{12,19} One recent study evaluated a trifocal sulcus IOL of a different design; binocular visual acuity results in the current study.²⁰ The trifocal sulcus IOL studied here also showed comparable visual acuities to a primary trifocal IOL made with the same material and incorporating the same design properties.²¹ Visual performance was also similar to results reported for several different primary trifocal IOLs in both recent randomized



Figure 3 Monocular defocus curve. Abbreviations: logMAR, log of the minimum angle of resolution; D, diopter.

prospective studies,^{22,23} and a recent retrospective study.²⁴ As always, comparisons between studies will be affected by inclusion/exclusion criteria, test conditions and testing procedures. It should be noted again that none of the studies referenced above included eyes with a prior history of refractive surgery.

This study has limitations. The study size was limited by the rather specific inclusion criteria. Only patients with prior myopic LASIK were included. The range of follow-up time after trifocal implantation was relatively long. Because the primary IOL implanted was a monofocal, no prior intermediate or near VA data were available. The defocus curve was measured only once – monocularly and with the eye corrected for distance. Subjective data regarding quality of vision or visual disturbances were not collected.

A final comment is that the intermediate vision with the IOL implanted was similar to, but slightly lower than, some alternative trifocal designs. This has been observed for this lens in the past. The manufacturer has advised us that the diffractive design of the lens has been modified to address this, but we have no clinical experience with the modified IOL.

In conclusion, the trifocal sulcus IOL implanted provided excellent distance and near visual acuity, with functional intermediate acuity and a good overall range of vision in these eyes with a history of previous refractive surgery and a monofocal IOL implanted. There were no evident safety concerns with sulcus implantation. The trifocal sulcus IOL provides visual performance that appears equivalent to that which can be obtained with a primary trifocal IOL implanted in the bag.

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Disclosure

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