Rayner

EYE SCIENCE by Rayner
SUPPORTING CLINICAL ADVANCES

OCT 2019

ESCRS Clinical Report

Reported by Saima Khokhar, Head of Eye Science

Rayner were pleased to exhibit at the 37th Congress of the European Society of Cataract and Refractive Surgeons (ESCRS) in the stunning city of Paris, France. Famous for world-renowned cuisine and its status as a global fashion hub, the city of love definitely left an impression on the Rayner team.

With thousands of delegates attending the ESCRS congress from all over the world, Rayner had a very strong presence, showcasing the complete patient pathway including three innovative new products:

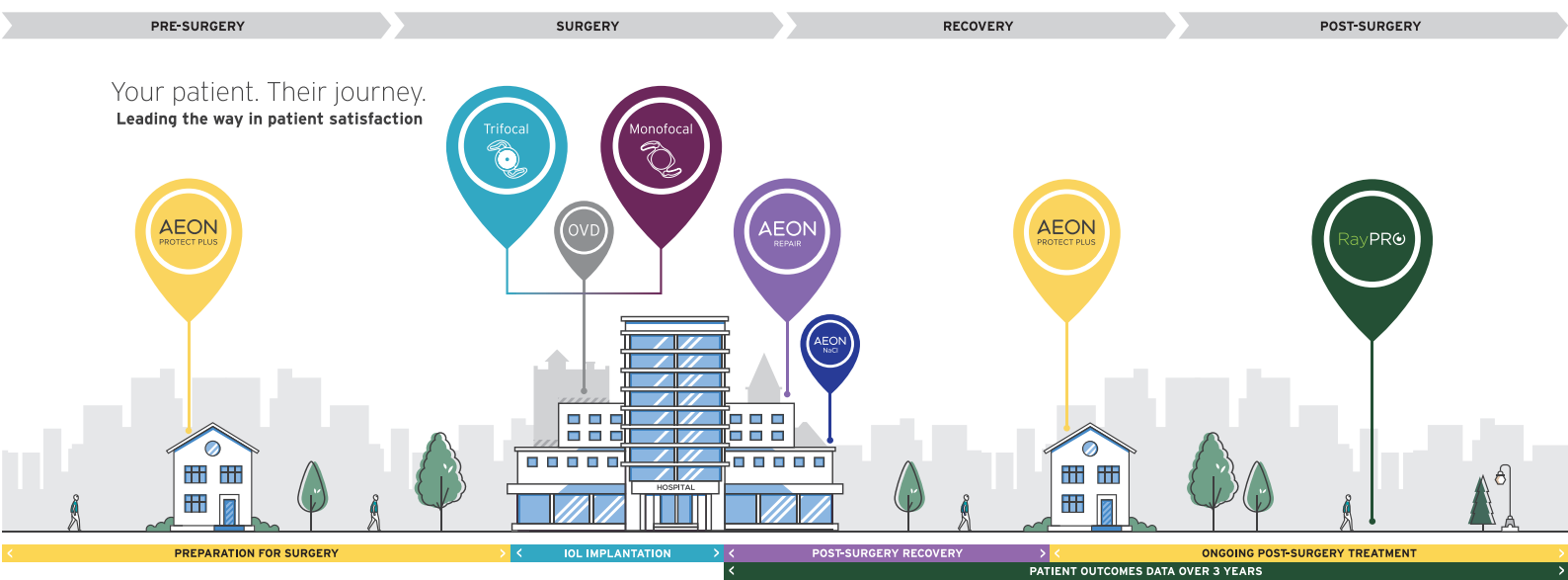
- **RayOne Trifocal Toric**, completing the Rayner family of trifocal IOLs, allowing surgeons to treat an even wider range of presbyopic patients. RayOne Trifocal Toric complements RayOne Trifocal launched at ESCRS 2017, which has since gained worldwide praise from surgeons for its predictive refractive outcomes combined with easy-to-use fully preloaded injector. This report brings you the early results from a multicentre study.

RayPRO

- **RayPRO**, a unique digital platform free for all Rayner IOL users, proactively collects patient-reported outcomes (PROs) over the three years following cataract surgery. Data is collected from patients through five simple email questionnaires on satisfaction, spectacle independence, refractive achievement, visual disturbances, and requirement for additional procedures and are automatically compiled into an intuitive dashboard. Surgeons can easily access the RayPRO dashboard on a dedicated smartphone app.

- **AEON**, the only eye drop family indicated for use before and after cataract surgery for the management of ocular surface disease. Up to 75% of cataract patients suffer from dry eye disease[1]. Dry eye disease changes the thickness and quality of the tear film and can cause a refractive power shift on the cornea by as much as 2 D[2]. AEON contains sodium hyaluronate (HA), the eye's natural lubricant, and is preservative and phosphate free. AEON Protect Plus contains 0.3% cross-linked HA, which provides longer lasting lubrication than traditional linear HA and AEON Repair is enhanced with vitamin A to support healing and vitamin E, an antioxidant, to protect cells from damage.

This report brings you highlights from Rayner's clinical activities at ESCRS 2019.



Rayner's Complete Trifocal solution - Sulcoflex Trifocal, RayOne Trifocal and RayOne Trifocal Toric

On the evening of Saturday 14th September at Le Tripot Régnier, five surgeons gathered to present and discuss Rayner's complete trifocal solution. We were thrilled to be joined by 100 international refractive surgeons from around the world.

"RayOne Trifocal yields very tight and accurate refractive results"

Dr Allon Barsam, MB, BS, MA, FRCOphth, Medical Director and Founder of Ophthalmic Consultants of London (UK), chaired the evening's clinical discussions and kicked off with an **introduction to Rayner's Trifocal technology** and his experience and clinical outcomes from over 250 implantations of RayOne Trifocal with two years' patient follow up since launch in 2017.

Dr Barsam was one of the first adopters of RayOne Trifocal technology and it has become his lens of choice for trifocal patients. His retrospective evaluation of 250 patients measured subjective refraction, visual acuity at all distances and patient satisfaction. He states *"a high percentage of my patients are achieving 6/6 distance vision and N5 reading vision unaided. 89% of patients are within +/-0.5D demonstrating how RayOne Trifocal yields very tight and accurate refractive results."* His early post-op observations are that *"vision tended to improve between one week and one month follow up, often patients accepted a refraction of -0.25 to -0.50 D in the first post-operative week which move closer to emmetropia as the capsule fibroses."* When discussing patient satisfaction and tolerance to dysphotopic phenomena, Dr Barsam states *"patients do report halos at night but none of them complained of this phenomenon as being more than mild, the halos are distinct and crisp. If they can see crisp and distinct halos around light sources, they will be less disturbed by quality of vision issues such as glare which distorts the overall quality of the image that they are trying to perceive especially at night. With RayOne Trifocal there are no complaints of glare at all which usually is more disabling and troublesome. Neuroadaptation was very fast, and patients were extremely happy at one week follow up. I have not yet had to perform laser on any of these patients as they are completely spectacle independent".*

Clinical Study Results

Dr Barsam, implanted the world's first RayOne Trifocal Toric on the July 15, 2019. He states, *"it is great to be the first centre in the world to implant Rayner's latest high technology offering. Ethical innovation requires a careful balance, ensuring patients have access to the latest and also safest technology once thorough R&D has been completed. Hugely grateful to be able to stand on the shoulders of giants and play a small role in this story."*

A prospective multicentre pilot study to assess subjective refraction, cylinder reduction, visual acuity for near, intermediate and far distances, patient and surgeon satisfaction after bilateral implantation of RayOne Trifocal Toric in 10 patients (20 eyes) took place across UK, Germany and Japan. One month data were presented at ESCRS.

Patients included into the study were aged 18 years and older, had age-related cataract and presented pre-operative corneal astigmatism of more than 1.0 D. Data from 20 eyes were analysed. The pre-operative mean absolute spherical equivalent was 2.73 ± 3.31 D (range -6.50 to 3.38 D) which reduced to 0.21 ± 0.23 D (range -0.50 to 0.25 D). Postoperatively 100% of patients were within ±0.50 SE and 57% were within ±0.25 SE (*Figure 1*). Additionally pre-operative mean cylinder was -1.44 ± 0.94 D (range -2.75 to -0.50) which reduced to -0.41 ± 0.27 D (range -0.75 to 0.00 D). 100% of patients were within 0.75 D of cylinder correction and 71% within 0.50 D of cylinder correction (*Figure 2*). Purkinje images demonstrate that the IOL centred very well (*Figure 3*). Just one degree of misalignment results in 3.5% loss of cylindrical correction and 10 degrees results in more than 34%[3]; results from a prospective study in 66 eyes at University of Aston (UK) demonstrate that the Rayner Toric platform has an average centration of only 0.08 mm and 1.83° mean IOL rotation 3 to 6 months after surgery[4].

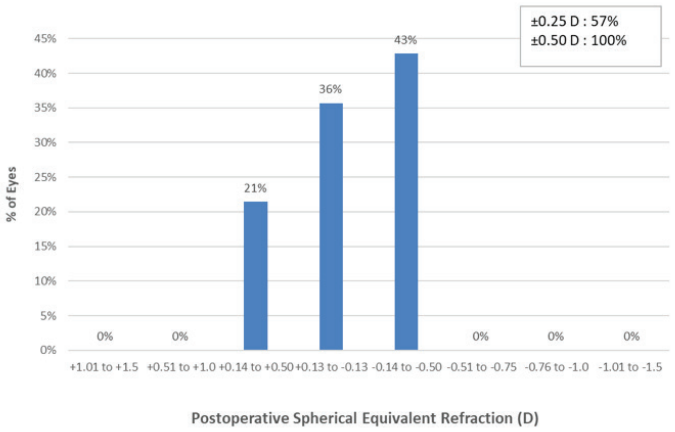


Figure 1: Postoperative Spherical Equivalent Refraction Accuracy

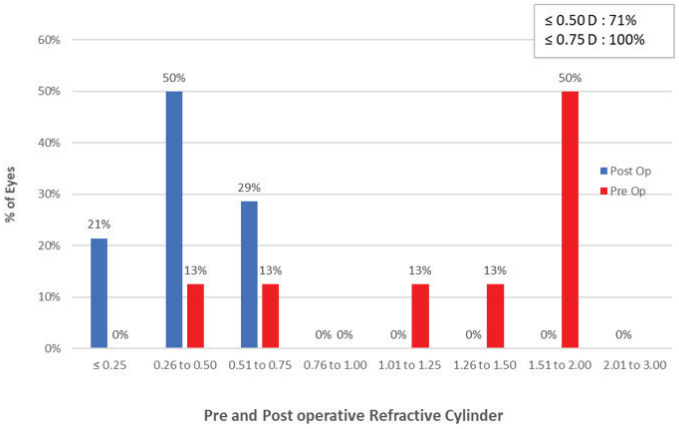


Figure 2: Pre and Post-operative Refractive Cylinder Accuracy

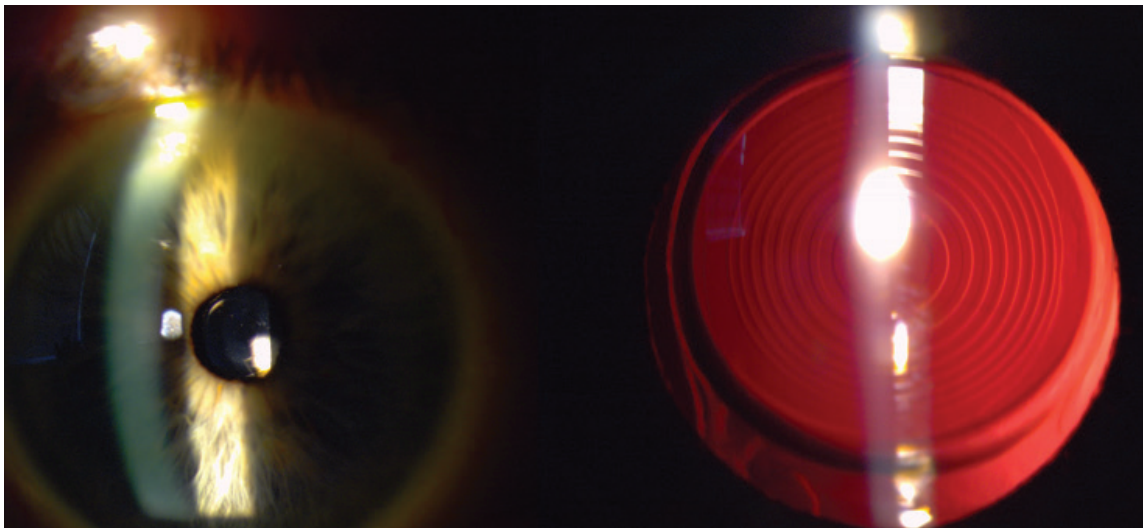


Figure 3: Centration of RayOne Trifocal Toric

There was high patient satisfaction and spectacle independence at all distances. The uncorrected distance visual acuity was reported as 0.00 ± 0.09 LogMAR, intermediate at -0.03 ± 0.05 LogMAR, and near at 0.05 ± 0.05 LogMAR. All surgeons involved in the study reported a high level of product satisfaction. The range of incisions used were from 1.9 mm to 2.4 mm and all implantations were delivered directly into the capsular bag using mini-incision. All five surgeons participating in the study would consider using RayOne Trifocal Toric again. 70% of surgeons said that RayOne Trifocal Toric is superior in usability and outcomes to their current Trifocal Toric of choice and the remaining 30% agreed that it was similar.

Dr Vinod Gangwani, FRCS, MRCOphth, MS, Consultant Ophthalmic Surgeon at Ashford and St Peter's hospital NHS Foundation Trust (UK), participant within the study states, "*having regularly used the RayOne Trifocal with excellent results, there was always a limitation on my patients with astigmatism. I have been using trifocal toric IOLs from other reputed providers, but was never comfortable with the injector systems, which are very cumbersome to use, RayOne Trifocal Toric is preloaded in the best injector system and provides excellent vision at all distances. This lens completes the portfolio for my patients seeking spectacle independence*."

"RayOne Trifocal had the shortest adaptation period with patients reporting excellent visual acuity and spectacle independence from day one"

Johan De Lange MB Ch. B, M. Med (Ophth), Medical Director and co-founder of Ocumed Eye & Laser Institute (South Africa), presented on his 20 years of experience with Presbyopia correcting IOLs and outcomes with RayOne Trifocal. Dr De Lange has evaluated a range of presbyopia correcting IOLs including accommodating, bifocal, trifocal, EDOF and most recently Hybrid IOLs. Sharing clinical pearls, he stated "*the most important factors when determining excellent multifocal IOL results are good patient selection, high patient communication and understanding the optic principles behind the multifocal IOL itself.*"

Patient Selection

He attributes his good results to good patient selection, "*patients who are easy going and either lose or are not using their spectacles are good candidates. It is important to avoid perfectionists and demanding personalities, patients who have high visual requirements such as those working at night and those undertaking meticulous activities (e.g. astronomers, photographers and bird watchers) should be selected with caution. The best patients have been those who are totally dependent on spectacles such as hyperopes who usually always depend on spectacles pre-op. Myopic eyes up to -3.5 D are not good candidates as they read without glasses and may lose some of their best corrected near visual acuity.*" Dr De Lange also discussed the surgeon's responsibilities and stated "*patient chair time is crucial, setting realistic expectations helps with the patient's neuroadaptation time, explaining the IOL's focal points using animations and pictures and explaining where they would expect to read after surgery helps with patient satisfaction. It is also important to explain the side effects such as dysphotopic phenomena thus setting the patient's expectations post-op*"

Patient Pathology

Ensuring the patient's ocular pathology is healthy prior to surgery is crucial. "*Pre-operatively, the patient's ocular surface should be treated if there are signs of dry eye disease, aim for a spherical equivalent of -0.5 D to +0.50 D and measure astigmatism accurately. Intraoperatively aim to eliminate astigmatism and consider using a Toric multifocal IOL if the patient presents more than 1.0 D astigmatism. Making a perfect CCC (I do 4.8mm) and using diagnostic equipment such as FLACS or Calisto Eye for accurate alignment is important. Avoid decentration (0 to 400μ is acceptable) or tilt (no more than 3°) of a multifocal IOL*"

Clinical Study Results

Dr De Lange has compared four of the most industry renowned Trifocal IOLs: RayOne Trifocal (Rayner, UK), PanOptix (Alcon, US), FineVision (PhysIOL, Belgium) and AT Lisa Tri (Zeiss, Germany). Results from his retrospective comparison study show that even though all four trifocal IOLs yielded excellent results, RayOne Trifocal had the best UDVA and UNVA results (*Figure 4*), best quality of vision under mesopic lighting conditions (*Figure 5*) and highest patient satisfaction (*Figure 6*). The RayOne Trifocal had the shortest adaptation period with patients reporting excellent visual acuity and spectacle independence from day one to two weeks. RayOne Trifocal patients had the fewest complaints of scatter of the four trifocals.

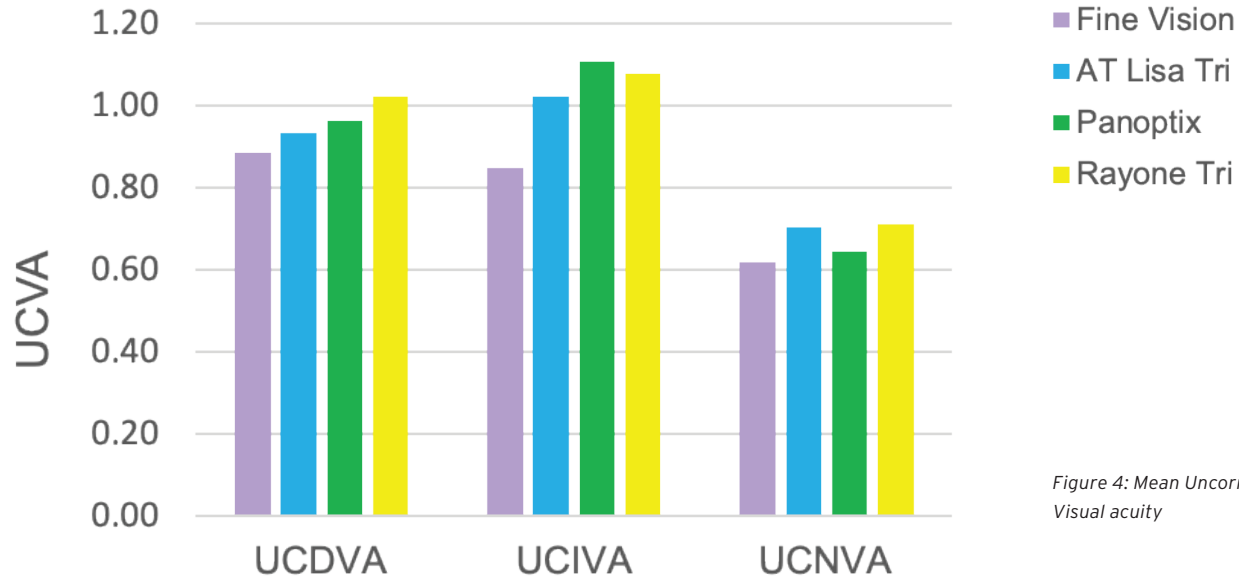


Figure 4: Mean Uncorrected Visual acuity

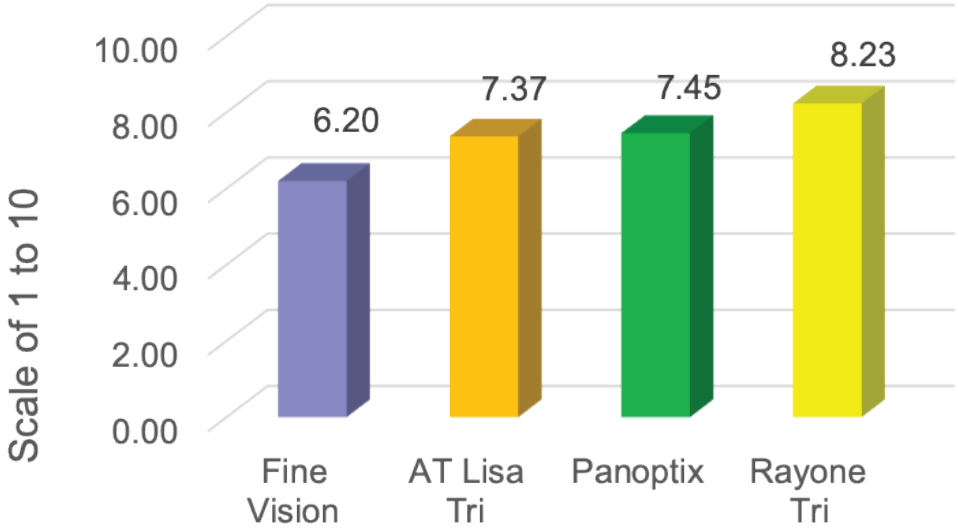


Figure 5: Quality of Vision under mesopic lighting conditions

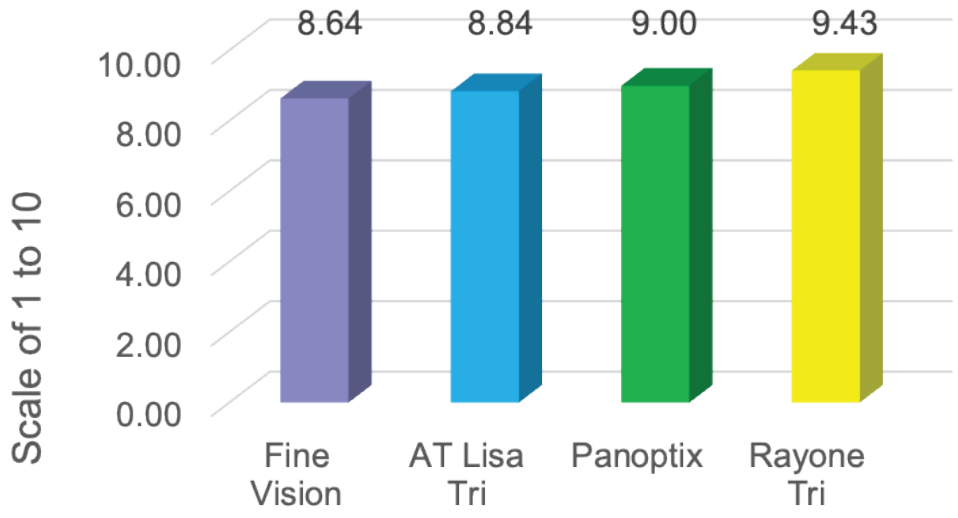


Figure 6: Patient satisfaction with Trifocal IOL using self administerd questionnaire

Gonzalo Muñoz, MD, Ph D, FEBO, Medical Director of Clinica Baviera- AIER Group (Spain) presented on his **Results with RayOne Trifocal in 1000 eyes**. The prospective multicentre study assessed subjective refraction, uncorrected and corrected monocular and binocular visual acuity for distance, intermediate and near vision, contrast sensitivity and patient satisfaction in 500 patients after bilateral implantation of RayOne Trifocal.

Inclusion criteria were cataract patients undergoing phacoemulsifcation aiming for emmetropia in both eyes, patients with corneal astigmatism of less than 1.25 D. The mean age was 60 years old and the mean follow up time was 4 months (range 3 to 14 months). Patients underwent biometry using IOLMaster, SRK/T and Barrett II formula were applied if the axial length was over 22.0 mm and Holladay II formula if the axial length was under 22.0 mm. Corneal topography (Pentacam) for posterior corneal assessment was used.

Clinical Study Results

Subjective refraction results demonstrate tight refractive accuracy as the mean postoperative spherical equivalent was -0.04 ±0.26 D (*Table 1*). Visual acuity results were reported monocularly and binocularly for uncorrected and corrected distance, uncorrected near and intermediate (*Table 2*). Defocus curve was measured using Qvision Multifocal Lens Analyser (*Figure 7*). Contrast sensitivty was measured using Topcon CSV-100 Test at far, intermediate and near distances (*Figure 8*). Patient satisfaction was measured using the Spanish Catquest-9SF self-administered questionnaire[5]. High patient satisfaction was recorded across all ten categories (*Figure 9*).

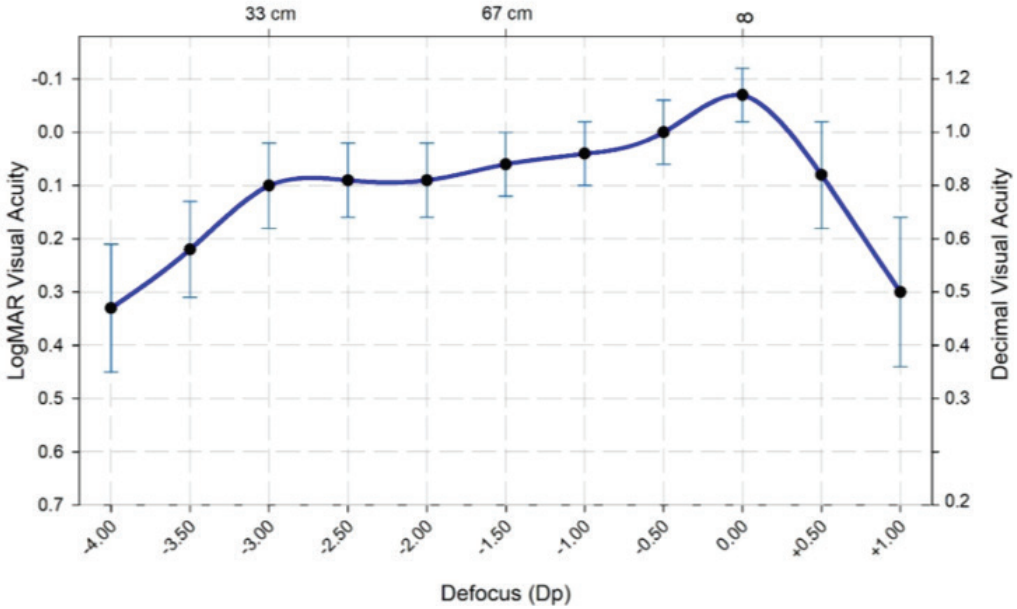
Table 1: Postoperative Subjective Refraction results N=1000

	Refractive result (D)				
	Sphere	**Cylinder**	**M**	**J0**	**J45**
Average	0.05	-0.19	-0.04	-0.04	0.02
S.D.	0.2	0.24	0.26	0.11	0.09

Table 2: Monocular and Binocular Uncorrected and Corrected Visual Acuity N=1000

		Monocular VA				Binocular VA		
		UCDVA	**DCVA**	**DCIVA (67)**	**DCNVA (40)**	**UCVA**	**UCIVA**	**UCNVA**
LogMAR	**Average**	**-0.02**	**-0.05**	**0.06**	**0.09**	**-0.07**	**0.01**	**0.04**
	S.D.	0.04	0.03	0.06	0.07	0.04	0.05	0.04
Decimal	**Average**	**1.05**	**1.13**	**0.87**	**0.81**	**1.18**	**0.98**	**0.92**
	S.D.	0.43	0.3	0.65	0.68	0.39	0.51	0.37

Figure 7: Defocus curve for RayOne Trifocal, N=1000



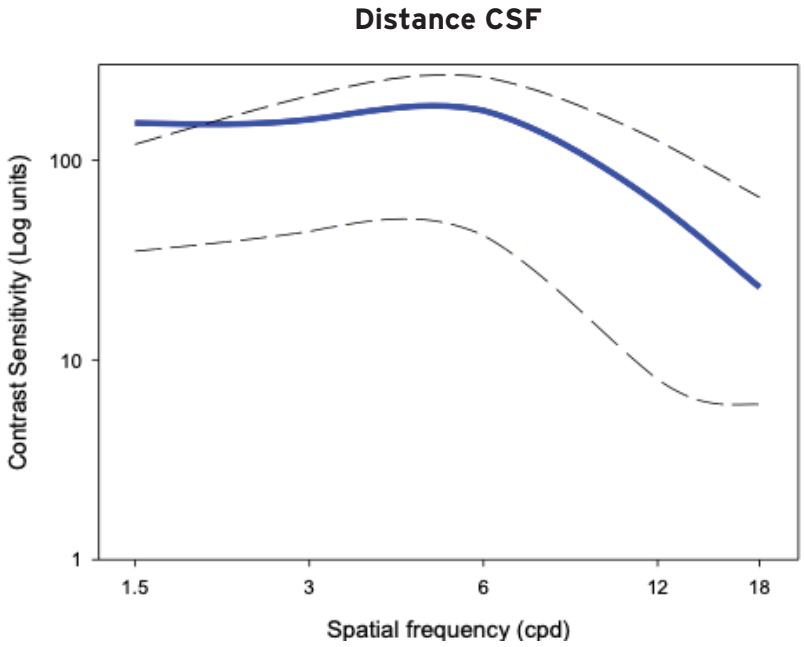
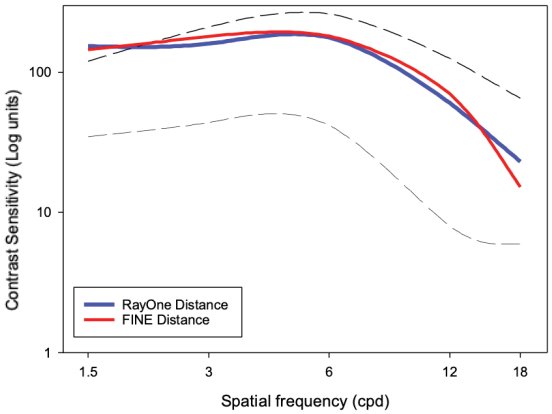
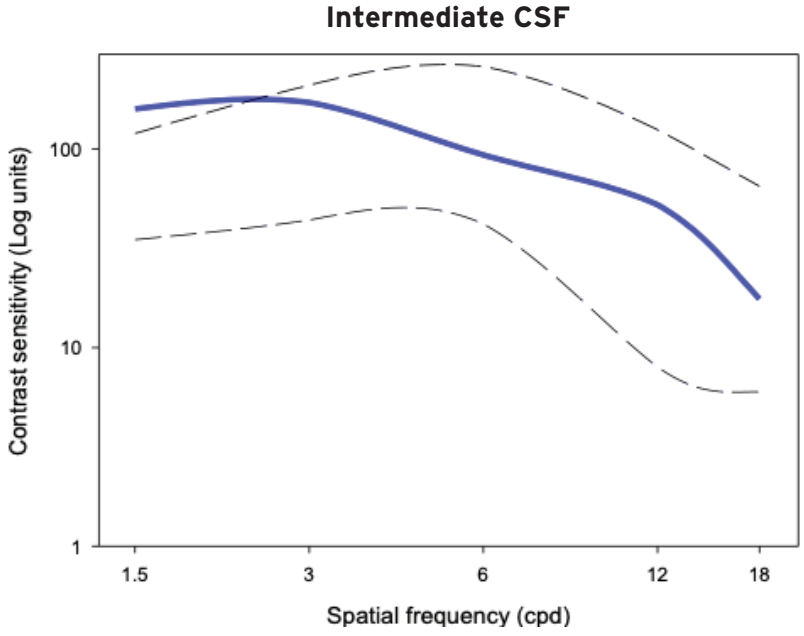
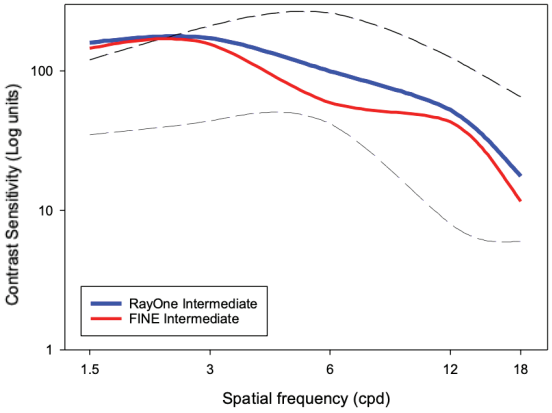
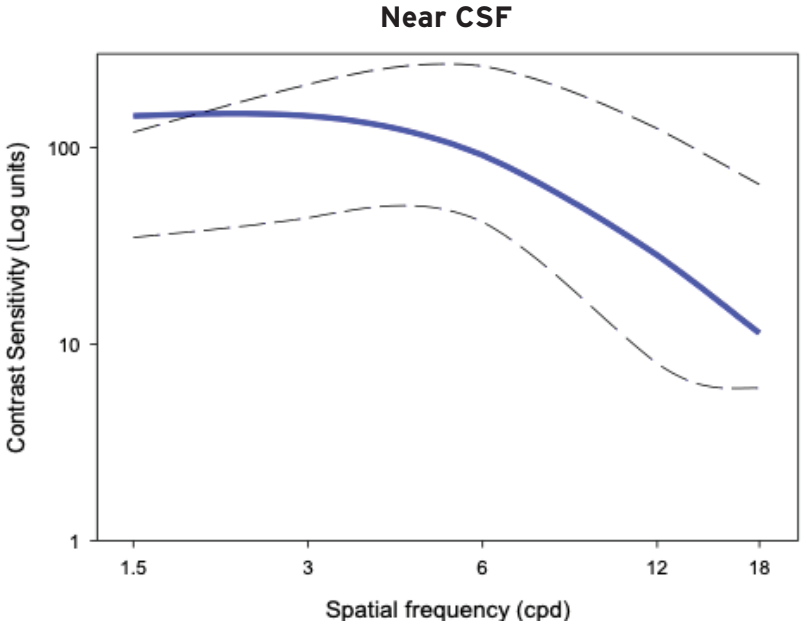


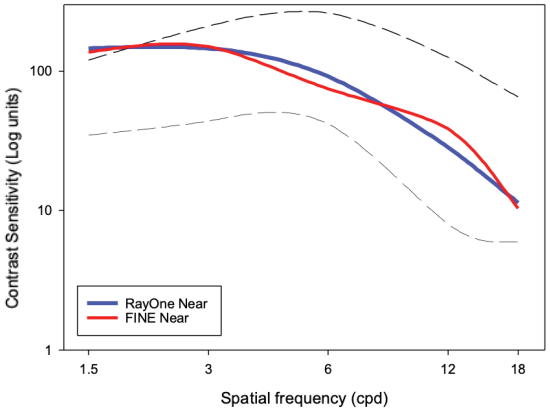
Figure 8: Contrast sensitivity measurements N=1000

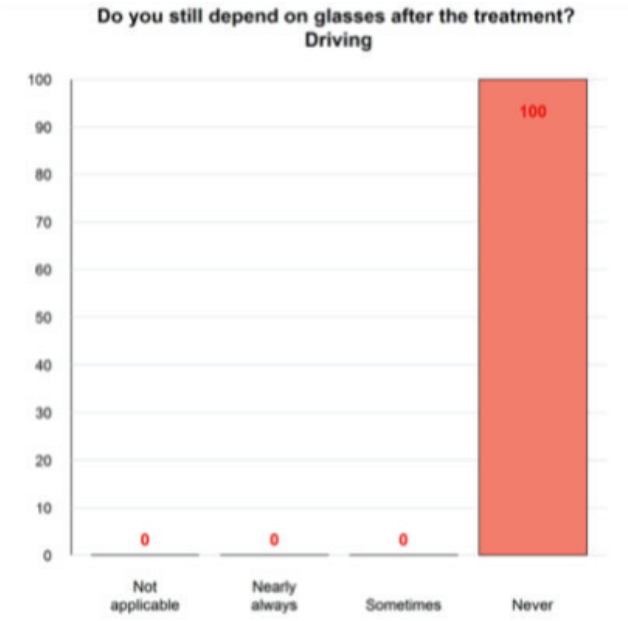











Do you still depend on glasses after the treatment?
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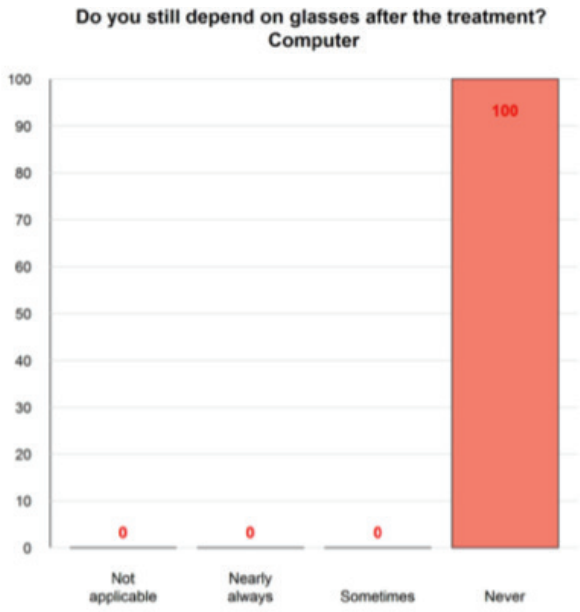
Nearly always
Sometimes
Never


Do you still depend on glasses after the treatment?
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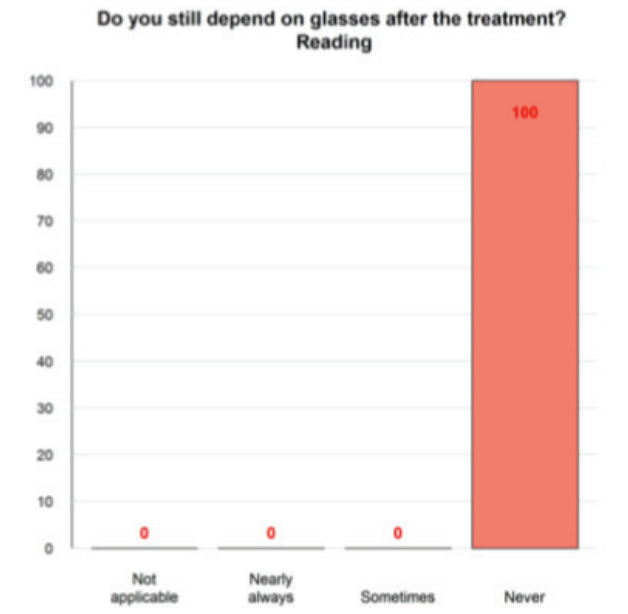
Not applicable
Nearly always
Sometimes
Never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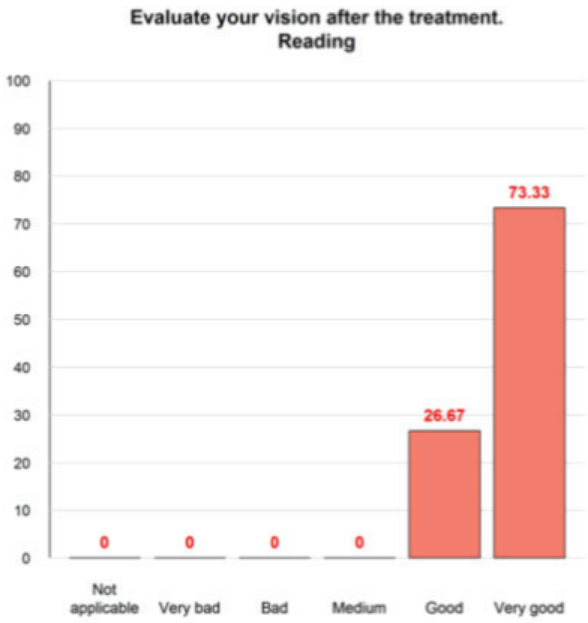
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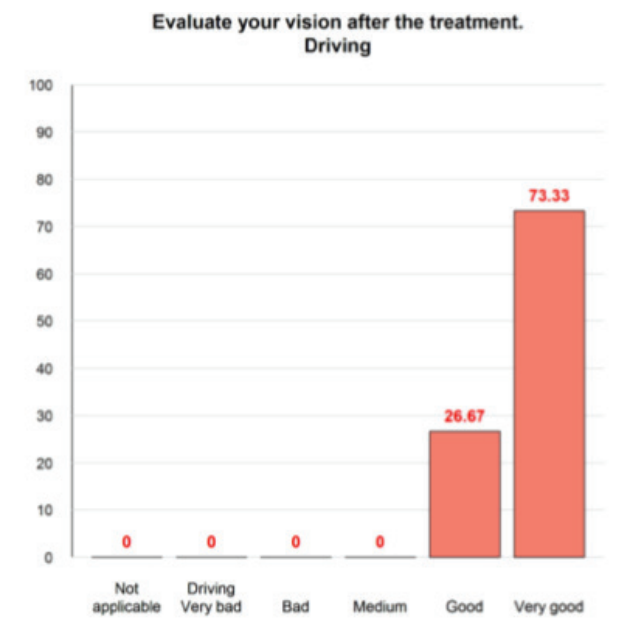
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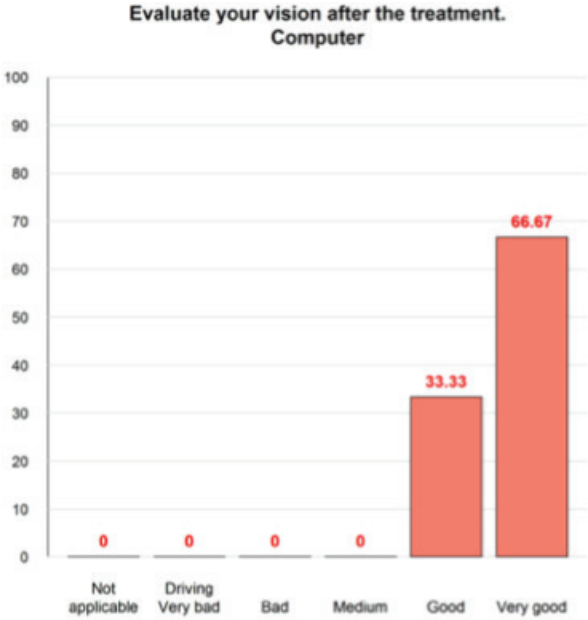
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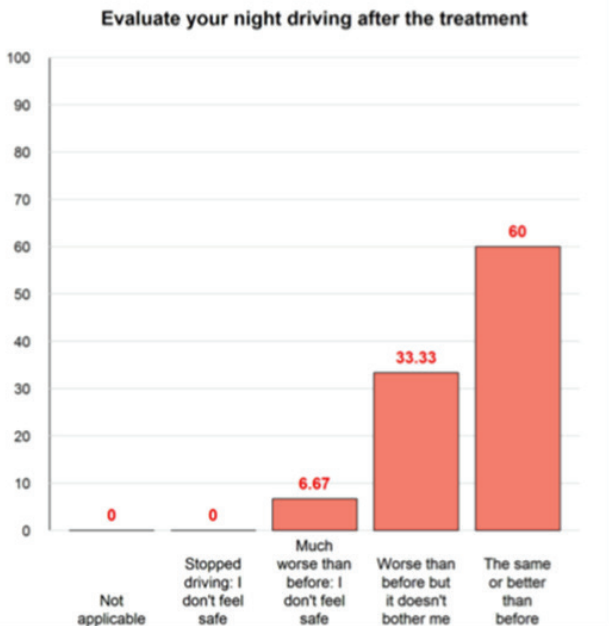
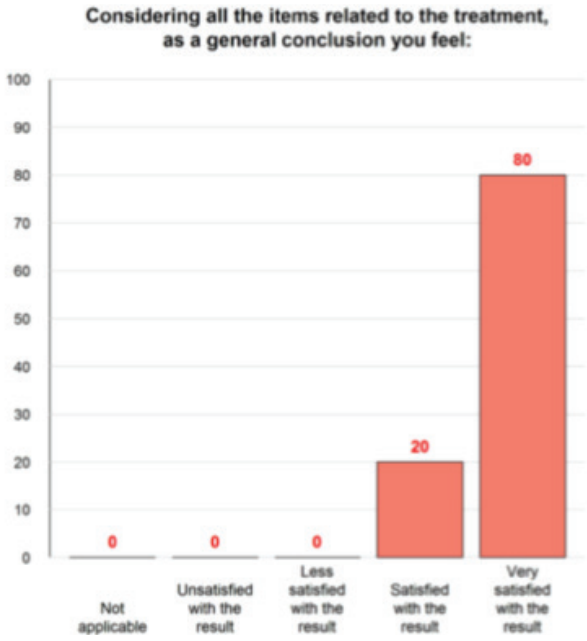
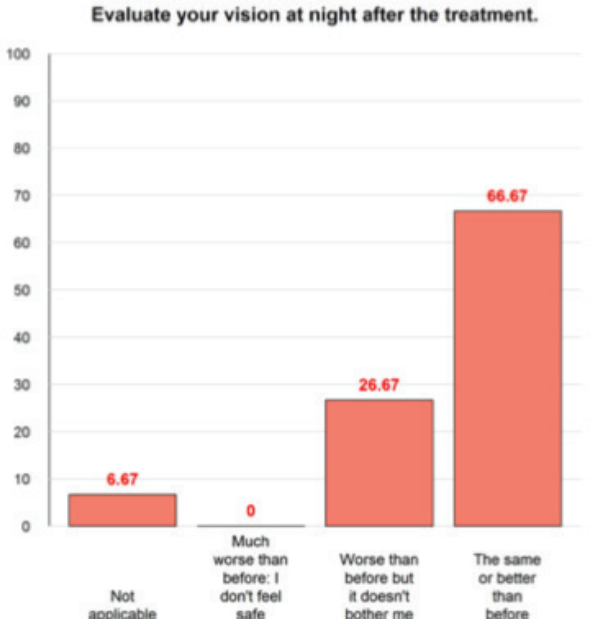
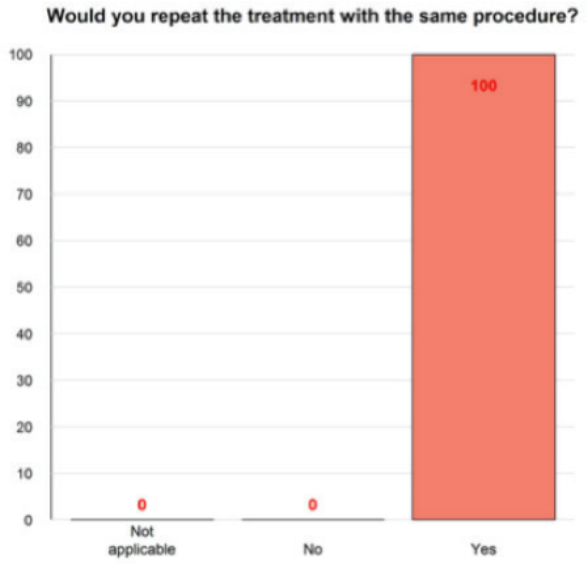








ARTICLE

Validation of the Spanish Catquest-9SF in patients with a monofocal or trifocal intraocular lens

Mats Lundström, MD, PhD, Fernando Llovet, MD, PhD, Andrea Llovet, MD, Mercedes Martinez del Pozo, MD, Blas Mompean, MD, José-Vincente González, OD, Konrad Pesudovs, PhD

Figure 9: Patient satisfaction recorded using Spanish Catquest-9SF questionnaire

Dr Fernando Llovet Osuna, MD, PhD of Clinica Baviera, also presented a free paper on the Multifocal IOL II session at ESCRS on Monday 16th September. His abstract excerpt is below.

First Author: F. Llovet Osuna SPAIN

Co Author(s): A. Llovet, J. Ortega-Usobiaga, R. Bilbao, G. Muñoz, M. Martinez-del-Pozo, M. Calvo

Purpose: To investigate visual outcomes, spectacle independence, and patient satisfaction after RayOne Trifocal intraocular lens implantation

Setting: Clinica Baviera - AIER Group. Madrid, Spain

Methods: A prospective study conducted on 222 patients (444 eyes) who underwent phacoemulsification and were implanted with a diffractive trifocal intraocular lens (RayOne Trifocal, Rayner, UK).

Results: Mean pre-operative cylinder –0.60 ± 0.57 D, sphere 1.77 ± 2.28, SE 1.47 ± 2.30 D; postoperative –0.37 ± 0.50 D, 0.02 ± 0.43, 0.20 ± 0.45 D; pre-operative monocular UDVA, UIVA, UNVA, CDVA values of 0.37 ± 0.25 (Snellen), 6.62 ± 1 (Jaeger), 6.26 ± 2.59 (Jaeger) and 0.91 ± 0.15 (Snellen), changed to 0.87 ± 0.17, 3.84 ± 1.58 , 2.68 ± 1.40 and 0.95 ± 0.13. Efficacy: 1.03 ± 0.97. Safety index: 1.12 ± 1.04. 95.28% UDVA same/better CDVA. High percentage satisfied and spectacle independence (never depend on glasses: 95.38% reading, 98.46% computer, 100% driving). 1.54% dissatisfied.

Variable	N	Min	Max	Mean	SD	Median	Q25	Q75
Sphere (D)		-2.50	1.75	-0.02	0.43	0.00	-0.25	0.00
Cylinder (D)		-3.50	0.00	-0.37	0.50	-0.25	-0.50	0.00
Spherical Equivalent (D)		-2.88	1.00	-0.20	0.45	-0.06	-0.50	0.00
UNVA	444	1.00	11.00	2.74	1.57	2.00	2.00	3.00
UIVA		0.00	11.00	3.65	1.89	3.00	3.00	5.00
UDVA		-0.08	1.00	0.07	0.12	0.05	0.00	0.10
CDVA		-0.08	1.00	0.03	0.09	0.01	0.00	0.05
Efficiency (distance)		0.10	18.00	1.03	0.97	1.00	0.86	1.03
Safety (distance)		0.10	19.00	1.12	1.04	1.00	0.98	1.09
UNVA Binocular		1.00	7.00	2.08	1.17	2.00	1.00	3.00
UIVA Binocular	222	1.00	9.00	3.24	1.51	3.00	3.00	3.00
UDVA Binocular		-0.08	0.32	0.02	0.06	0.00	0.00	0.03
CDVA Binocular		-0.08	0.18	0.00	0.04	0.00	0.00	0.01
Efficiency Binocular (distance)		0.54	3.00	1.01	0.24	1.00	0.95	1.02
Safety Binocular (distance)		0.69	3.00	1.06	0.24	1.00	1.00	1.11

Conclusions: The implantation of this model provided good visual performance in all distances, as well as high levels of spectacle independence and satisfaction.

Financial Disclosure: None

"In my opinion Sulcoflex is the only platform that makes it possible for the patient to upgrade safely"

Victor Antunes, MD, Senior Surgeon at the Institute of Ophthalmology of Assis (Brazil), presented on his **experience with the Sulcoflex Platform and early outcomes for Sulcoflex Trifocal**. To date, he has implanted more than 300 Sulcoflex Multifocal IOLs (a previous generation Sulcoflex IOL with refractive bifocal technology) with a long term follow up of seven years demonstrating high patient satisfaction and safety.

Clinical Study Results

In 2014, Dr Antunes performed a prospective study assessing visual outcomes and patient satisfaction after implantation of Sulcoflex Multifocal IOL in 145 cataract eyes. Sulcoflex Multifocal was implanted in DUET surgery with either a toric or monofocal IOL in the capsular bag. 62% of eyes in his study had pre-existing ocular pathology; however, the comfort of reversible multifocality in DUET surgery allowed Dr Antunes to include a larger range of patients into his inclusion criteria. Results from this study demonstrate 98% of patients achieved a postoperative sphere correction of between -0.5 D to +0.5 D and 100% of patients were within 0.75 D of emmetropia. 84% of patients achieved a monocular UDVA of 20/25 or better and 97% achieved a binocular UDVA of 20/25 or better.

Since the launch of Sulcoflex Trifocal IOL in 2018, Dr Antunes has upgraded his refractive bifocal supplementary IOL offering to the latest diffractive supplementary IOL, Sulcoflex Trifocal. He is currently undergoing a prospective study assessing visual outcomes and patient satisfaction after bilateral implantation of Sulcoflex Trifocal in DUET surgery with a monofocal (23% of eyes) or toric IOL (77% of eyes) in the capsular bag in cataract patients. The follow up time for preliminary results was 1 month. These early results demonstrate accurate and tight refractive results as 83% of patients achieved a postoperative sphere correction between -0.25 to +0.25 D and 92% of patients achieved a postoperative cylinder of less than 0.5 D (*Figure 10*).

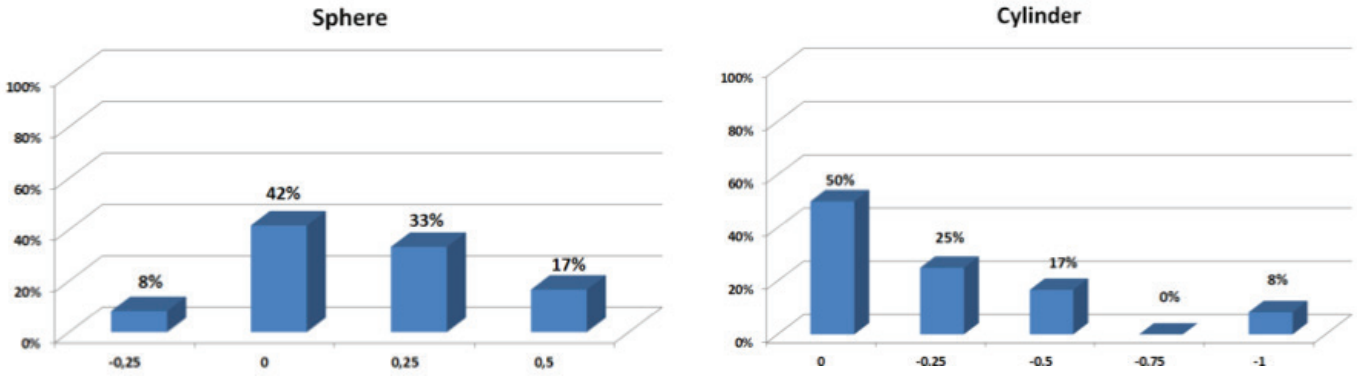


Figure 10: Postoperative Sphere and Cylinder correction

The study reports high visual acuity and patient satisfaction (*Figure 11*) with 94% of patients achieving monocular and 100% achieving binocular UDVA of 20/25 or better. 100% of patients achieved a binocular UNVA and 57% a binocular UIVA of J2 or better.

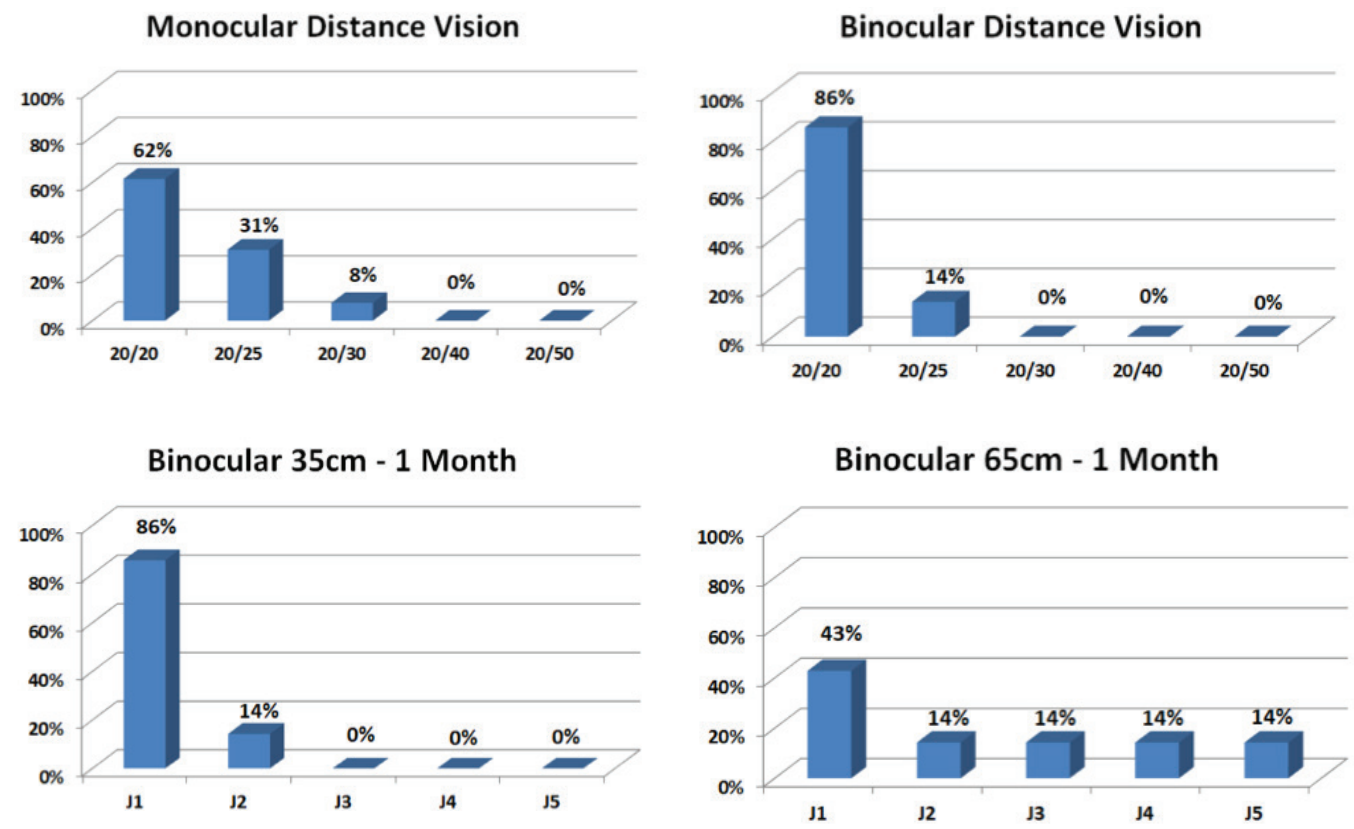


Figure 11. Visual acuity results for far, intermediate and near distances

Most importantly after implantation of Sulcoflex Trifocal is the measurement of intraocular pressure because of the concern that an elevated eye pressure may lead to glaucoma. Results from Dr Antunes' previous Sulcoflex Multifocal study demonstrate a stable postoperative IOP (*Figure 12*).

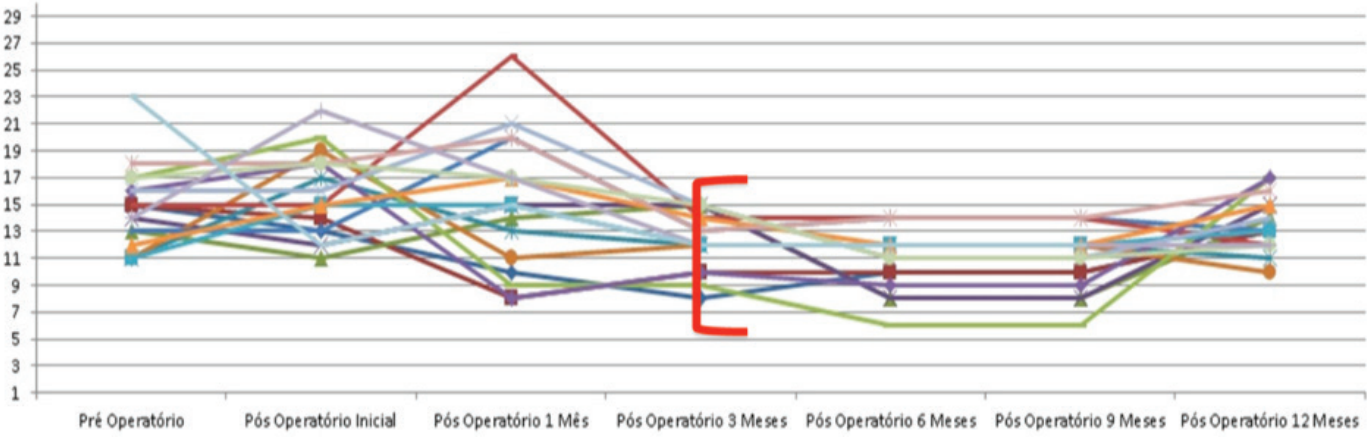


Figure 12. IOP Follow up after implantation of Sulcoflex Multifocal

Dr Antunes concludes "*the Sulcoflex platform has shown no safety issues in a long term follow up of over 300 eyes. Sulcoflex Trifocal has yielded great results for distance, intermediate and near visual acuities, at one month patients are reporting high levels of satisfaction. Early results demonstrate the Sulcoflex Trifocal provides better vision to the patient than the previous refractive multifocal version and there are no compromises on the excellent levels of safety. In my opinion Sulcoflex is the only platform that makes it possible for the patient to upgrade safely. The comfort that Sulcoflex can be removed and is reversible, means I can treat a wider range of patients with pre-existing pathologies that a trifocal IOL in the capsular bag could not to do otherwise. I have adopted the Sulcoflex Trifocal DUET approach for nearly all of my patients.*"

Sulcoflex Trifocal: A new opportunity for your refractive patients

On Sunday 15th September at Pavilion 7, Rayner hosted an ESCRS Eurotimes Satellite Symposium, a panel of five Sulcoflex experts participated in discussions around **Sulcoflex Trifocal: A new opportunity for your refractive patients** followed by a Meet the Expert session on the Rayner booth. The symposium welcomed 200 refractive surgeons.

"Sulcoflex Trifocal provides a reversible and exchangeable solution for the future"

Prim. Univ. Prof. Dr. Michael Amon, FEBO, MD (Moderator) - Head of Ophthalmology at the Hospital of St. John and Professor and Chair of Ophthalmology at Sigmund Freud Private University, Vienna (Austria) performed the first global implantation of Sulcoflex Trifocal on 30th July 2018 and presented on **Sulcoflex Platform: A journey through supplementary IOLs and 12 years of clinical history**.

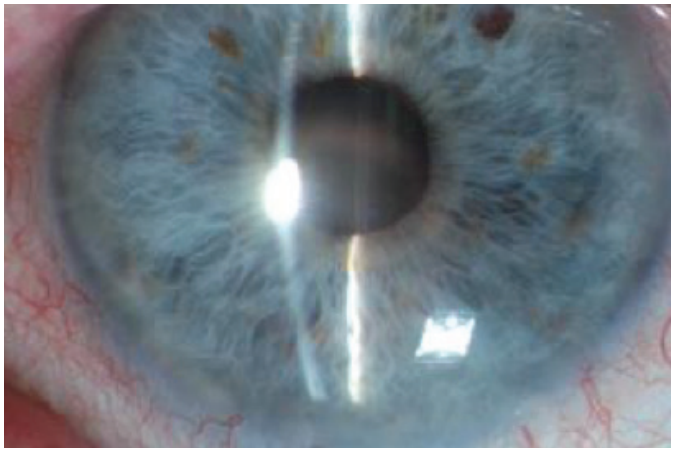
Material and Design

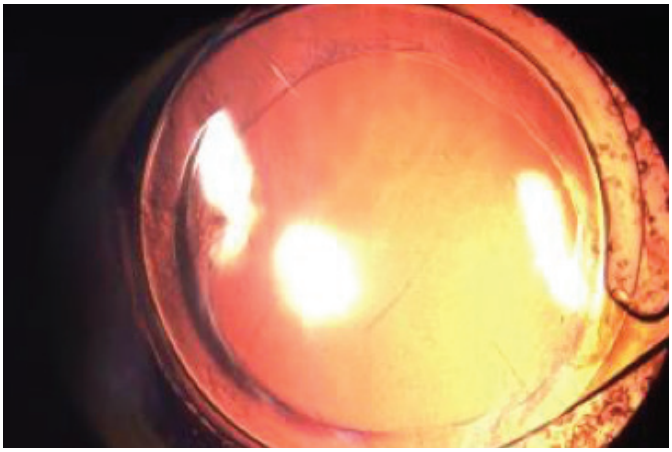
Professor Amon implanted the first Sulcoflex supplementary IOL in 2007 and has 12 years of clinical experience, safety and efficacy data in more than 300 eyes. Sulcoflex IOLs are made of a proprietary hydrophilic acrylic polymer (Rayacryl). As the Sulcoflex IOL is implanted into the sulcus, it is important for the material to have high biocompatibility with uveal tissue, research from studies performed in 2002 and 2007 confirm the hydrophilic Rayacryl material presents high uveal and capsular biocompatibility compared to hydrophobic acrylic or silicone[6,7] and most add on IOLs on the market are manufactured from hydrophilic acrylic material. Findings from a laboratory study examining pseudophakic human cadaver eyes report suitable sulcus fixation with limited interaction between uveal tissue or the IOL in the capsular bag[8]. Further data from an optical bench study investigating effects of surface reflections indicated that visual quality and optical performance is the same in a pseudophakic eye implanted with the Sulcoflex IOL compared with a pseudophakic eye with a single piece IOL in the bag[9]. A centration study on Sulcoflex demonstrates that there is statistically significantly improved

Continued...

centration of a ciliary sulcus fixated IOL compared to a capsular bag fixated IOL[10]. One potential explanation for this difference may be the effects of capsular contraction on the capsular bag fixated lens.

Reviewing his personal experience with Sulcoflex in 300 eyes, Professor Amon reports encountering no severe complications, severe pigment dispersion, iris trauma, interlenticular opacification, optic capture or significant pupil ovalisation. He states, "*there is a good distance between the iris and the IOL as Sulcoflex has a haptic angulation of 10°, the concave posterior surface of the IOL means there is no contact between the central zone of the two IOLs.*"

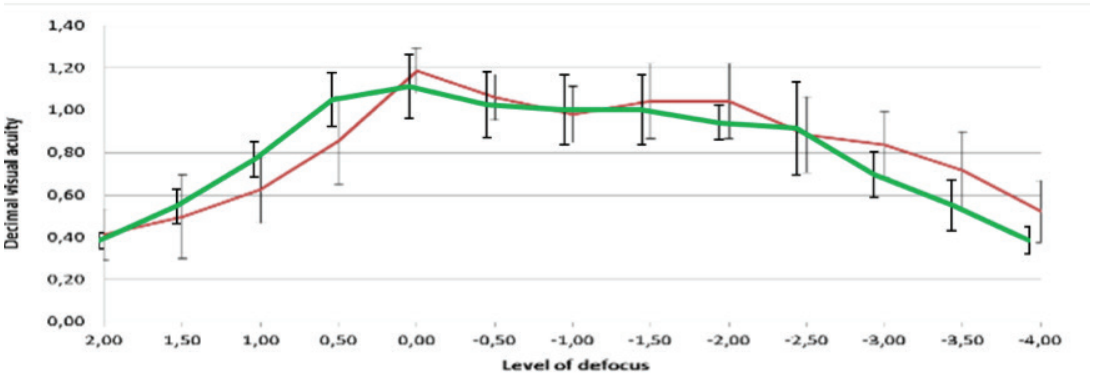




Clinical Study Results

Prof Amon reports his results from a prospective study assessing visual acuity, patient satisfaction and safety in 20 cataract patients after bilateral implantation of Sulcoflex Trifocal in DUET surgery with 6 months follow up. There was excellent visual acuity results across all distances, monocular UDVA reported was -0.04 ± 0.07, UIVA was 0.03 ± 0.16, UNVA was 0.04 ± 0.20. All patients reported high satisfaction and spectacle independence at all distances. There were no surgical or post-op complications. Comparisons to capsular bag RayOne Trifocal demonstrate similar defocus curve and visual outcomes (*Figure 13*).

Figure 13. Defocus curve comparing RayOne Trifocal and Sulcoflex Trifocal



Calculation

For pseudophakic patients presenting ametropia, the required Sulcoflex power can be calculated by multiplying the spherical equivalent of ametropia by 1.5 D for hyperopic patients and 1.2 D for myopic patients. If the refractive error is within a ±7.0 D margin, the Sulcoflex power is easy to calculate. Additionally the manufacturer's calculator Raytrace (Rayner, UK) performs Sulcoflex calculations and only requires the patient's postoperative spherical refraction. For DUET surgery in cataract patients, the distance power is corrected using a monofocal or toric IOL and a plano power (0 D) Sulcoflex Trifocal is added on top.

Surgical Technique

Sulcoflex Trifocal should be loaded into the Medicel Accuject 1.8 injector allowing a sub 2.2mm incision. When loading the injector (and throughout surgery), Prof Amon recommends to use a cohesive OVD, ensure the leading and trailing haptics are tucked under the optic to avoid haptic capture. During implantation, insert OVD behind the iris to lift it creating enough space to implant the IOL avoiding iris capture and/or pigment release. Professor Amon advises to insert the Sulcoflex Trifocal into the vertical plane of the sulcus as the ciliary sulcus diameter is typically wider vertically than horizontally. This can be measured with ultrasound biomicroscopy (UBM). During DUET surgery, remove the OVD entirely from behind the capsular bag IOL prior to placing the Sulcoflex IOL as access to the capsular bag can then become challenging. After implantation of Sulcoflex, OVD should be thoroughly removed between the two IOLs to prevent postoperative IOP increase.

Explantation, if necessary, can be performed through a 2.4mm incision without the need to cut the IOL. Insert OVD into the sulcus to create space and lift the optic, using a mushroom rotate the haptic out of the wound, the hydrophilic nature of the material means there are no adhesions present between the tissue and haptic material, using forceps the flexible IOL can then be removed out of the incision with no stress or stretch to the wound.

Professor Amon concluded "*the Sulcoflex Trifocal IOL is an effective solution for both secondary enhancement in pseudophakic patients seeking presbyopia correction and for DUET surgery in cataract patients. Sulcoflex Trifocal provides a reversible and exchangeable solution for the future, should a patient develop any ocular pathologies such as diabetic macular oedema, age-related macular degeneration or glaucoma, the Sulcoflex Trifocal can be easily removed returning the patient back to monofocal vision with excellent contrast.*"

"Sulcoflex Trifocal empowers the patient to upgrade their IOLs over the course of their life."

Dr Rakesh Jayaswal MBChB FRCS(Ed) FRCOphth, Consultant Ophthalmologist at Queen Alexandra Hospital and founding member of Laservision (UK), presented on **Sulcoflex Trifocal DUET offering Reversible Modular Multifocality** and the new opportunities this approach introduces for patient care.

Every year, there is a significant demand from patients seeking excellent distance and near vision and therefore new presbyopia correcting technology and IOLs are developed and introduced to the market, however despite all this new technology the amount of uptake amongst colleagues is variable and there is a nervousness about the quality of vision after surgery.

Patient selection is critical to success, however it is a complex process to determine patient suitability for multifocal IOLs. Some patient selection factors are quite static and don't change, however some factors are dynamic and do change over the course of a patient's life.

The eye is a very complex lenticular system and will change over time and if introducing a lens that aberrates light in the optical system, it is important to ensure the eye is in a good optical condition to allow good quality vision. If there are imperfections in the optical system, there is a chance of compounding aberrations resulting in poor quality vision.

Patient selection isn't black and white and there will be patients who may not tolerate a lens or certain types of multifocal technology. Previous IOL solutions which involve implanting a multifocal IOL in the capsular bag are very permanent which means its either all or nothing, however now there is the option of modulating this approach and reversing multifocality!

Sulcoflex Trifocal

Since the launch of Sulcoflex, approximately 40,000 IOLs have been implanted worldwide with an excellent safety record. Sulcoflex Trifocal, the most recent supplementary IOL model which applies the Rayner Trifocal technology onto the Sulcoflex optic, means there is now a possibility to treat two indications:

- Pseudophakic patients who may have had previous cataract surgery and are now seeking presbyopia correction. For example, in the UK, patients whom undergo monofocal cataract surgery especially within the NHS are sometimes disappointed they were not offered a multifocal IOL at the time of cataract surgery. Refractive enhancement with the Sulcoflex Trifocal allows them to upgrade their vision.

- Cataract patients who may not be suitable for a multifocal IOL in the capsular bag or there are concerns of neuroadaptation, or development of an ocular pathology later in life. These patients have the option of simultaneously implanting a monofocal IOL in the capsular bag with a plano powered Sulcoflex Trifocal IOL in the sulcus, called a DUET procedure.

Dr Jayaswal always explains to his patients that as their lens ages over time, rather than replacing the lens with a Trifocal IOL in the capsular bag, he can implant two IOLs either sequentially or simultaneously giving them plenty of time to adapt indefinitely. It is also possible to perform a YAG if required and if there are ocular changes over the course of their life, it is possible to reverse back to the monofocal IOL by removing the Sulcoflex Trifocal.

Clinical Study Results

In a prospective study performed at Laservision (UK), subjects underwent unilateral or bilateral cataract surgery with the RayOne Hydrophobic monofocal or RayOne Toric lens with a simultaneous Sulcoflex Trifocal IOL (Rayner, UK). Preoperative manifest refraction, and uncorrected visual acuity at far, intermediate, and near distances were compared with follow-up up to 10 months . Dysphotopsias, quality of vision issues and other adverse events were reported. 31 eyes of 17 patients with mean age 59.1 ± 12.3 years were included. One month following surgery, average binocular UCDVA was -0.07 ± 0.15 logMAR (*Table 3*) and UCNVA was 0.16 ± 0.06 logMAR (*Table 4*). All patients achieved an intermediate visual acuity of N6. 89% of patients achieved post-op refraction within ±0.5 D and 100 % within ±0.75 D spherical equivalent. All patients experienced mild night-time halos that were non-disabling. All patients were happy with the results.

Table 3: Distance Visual Acuity after Sulcoflex Trifocal implantation

Snellen	LogMAR	No. of Eyes	Cumulative %
6/4	-0.18	8	26%
6/5	-0.08	16	78%
6/6	0.00	5	93%
6/7.5	0.10	2	100%
6/9	0.18	0	100%

Table 4: Near Visual Acuity after Sulcoflex Trifocal implantation

Roman Chart	LogMAR	No. of Patients	Cumulative %
N4	0.10	12	38%
N5	0.20	14	84%
N6	0.30	5	100%
N8	0.10	0	100%
N10	0.18	0	100%

Why do these results outperform those from competitor capsular bag trifocal IOLs?

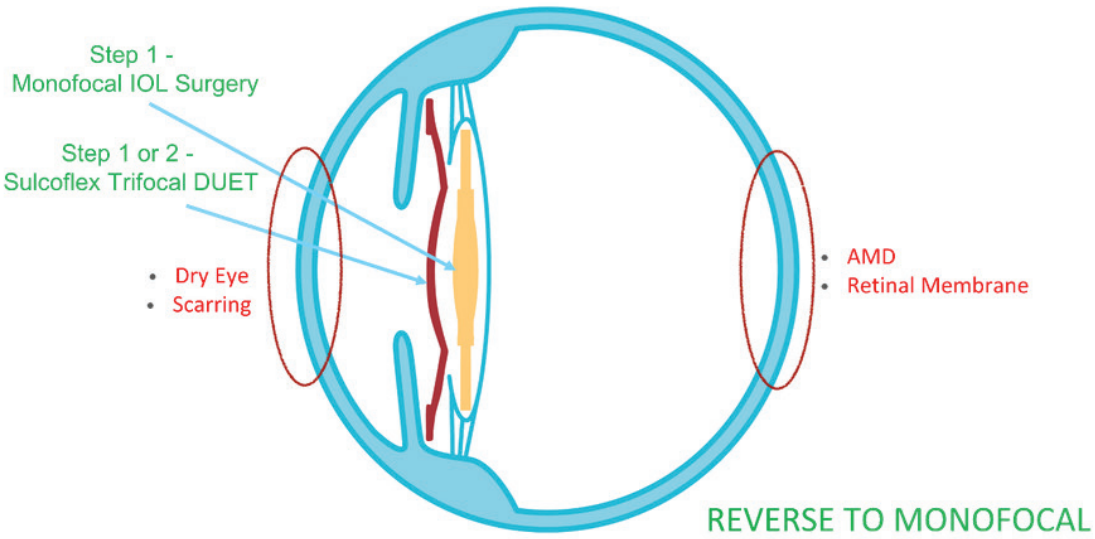
Comparisons made to capsular bag Trifocal IOL results demonstrate that Sulcoflex Trifocal outperforms at distance visual acuity (*Table 5*). Currently there are four patented trifocal optics on the market with different characteristics (*Figure 14*).

Snellen	LogMAR	DUET Sulcoflex	PhysIOL	PanOPTIX
6/4	**-0.18**	**26%**	**13%**	**14%**
6/5	-0.08	52%	44%	14%
6/6	0.00	16%	31%	54%
6/7.5	0.10	6%	12%	14%
6/9	0.18	0%	0%	6%

Table 5: Distance Visual Acuity Comparison to Capsular bag Trifocal IOLs

	PhysIOL FineVision	Zeiss AT LISA Tri	Alcon PanOptix	Rayner Trifocal
				
Diffractive Technology	Diffractive Apodized Trifocal across full optic surface	Diffractive Trifocal up to 4.34 mm thereafter bifocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal	Diffractive Trifocal up to 4.5 mm thereafter monofocal
Diffractive Steps	26 diffractive steps	29 diffractive steps 0.0 D	15 diffractive steps	16 diffractive steps
Diffractive Orders	0, 1, 2	0, 1, 2	0, 2, 3 (non-sequential)	-1, 0, 1
Light Loss 3.0 mm pupil	14%	14.3% (Ave.)	12%	11%
Light Energy Split 3.0 mm pupil	42% D / 15% I / 29% N	50% D / 20% I / 30% N	42% D / 24% I / 22% N (includes 12% light loss)	52% D / 22% I / 26% N
Optic Add Powers	+3.50 D Near add +1.75 D Intermediate add	+3.33 D Near add +1.66 D Intermediate add	+3.25 D Near add +2.17 D Intermediate add	+3.50 D Near add +1.75 D Intermediate add
Reading Distance	37.5 cm 75.0 cm	40.0 cm 80.0 cm	42.0 cm 60.0 cm	37.5 cm 75.0 cm
Aberration correcting	Biconvex aspheric (-0.11 SA)	Aberration correcting (-0.20 SA)	Aberration correcting (-0.20 SA)	Aberration Neutral
Lens Material	Hydrophilic	Hydrophilic	Hydrophobic	Hydrophilic
Dioptre range	+6.0 D to +35.0 D	+0.0 D to +32.0 D	+13.0 D to +34.0 D	+0.0 D to +30.0 D
Optic / Haptic Diameter	6.00 mm / 11.45 mm	6.00 mm / 11.00 mm	6.00 mm / 13.00 mm	6.00 mm / 12.50 mm
Haptic design	Double C loop	Plate	C loop	Closed C loop
PCO rate (estimated by review on studies stating YAG: caps rates on monofocal lenses)	Medium (24 months)	High (24 months)	Low (24 months)	Low (1.7% @ 24 months)

Figure 14: Characteristics of Trifocal IOLs and technology



Spherical Aberration

Positive spherical aberration (SA) is not considered all bad, the young capable eye tends to have modest amounts of positive SA (0.17±0.12 micron over 6 mm pupil)[11]. A natural degree of SA is beneficial and can increase depth of focus, which is especially important to patients with presbyopia (loss of accommodative amplitude) or those with pseudophakic eyes. All cataract patients are rendered presbyopic as soon as their natural crystalline lens is removed, so any small amount of flexibility in vision for monofocal patients is welcome.

The natural residual level of SA of the cornea creates a focus spread on the retina increasing the depth of field and defocus tolerance, while still offering excellent visual acuity (*Figure 15*). The spread of focus across each point explains the better unaided distance vision of 6/4 and good reading at N4. Rayner Trifocal IOLs have an aspheric, prolate anterior surface that creates no additional SA. The aberration neutral IOLs do not add or subtract from the natural level of SA in the ocular system and leaves the cornea as the sole source of SA.

An aberration-neutral lens leaves the pseudophakic eye with a modest amount of residual positive SA similar to a healthy young eye, preventing loss of contrast sensitivity and visual quality. No inherent SA in the IOL also improves the accuracy of lens power and optical quality measurement

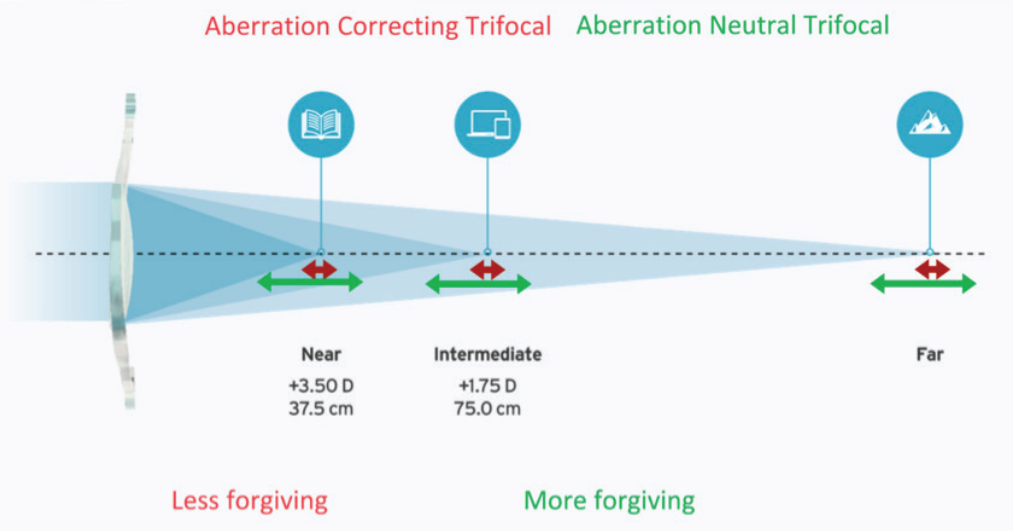


Figure 15: Depth of focus with aberration correction and neutral IOLs

Tolerance to tilt and decentration

The eye in its natural state has imperfect alignment as it is an optically asymmetric system. The visual axis is oblique and not aligned to the optical axis and the pupil is not centred on the optical or visual axis. A lens centred in the capsular bag is therefore likely to be misaligned with the visual axis.

Rayner Trifocal IOLs have a uniform refractive power from centre to edge, allowing them to work well in the imperfect alignment of the eye. With no negative "correction" designed at the periphery, deterioration of visual performances is minimised in conditions where centration and positioning of the IOL are compromised. Rayner Trifocal IOLs therefore produce predictable and reliable visual results.

Rayner Trifocal IOLs will not induce high order aberrations when decentred and will induce less HOA than a lens with a positive or negative spherical aberration when tilted such as FineVision, AT Lisa Tri and PanOptix.

Diffractive Orders

Multifocal IOLs work on the principle of diffraction, light scatters and interferes at certain points adjacent to the central axis causing interference patterns or halos. Trifocal IOLs use two different diffractive orders to create an intermediate and near focal point. *Figure 16* is a representation of diffraction of light with parallel positive and negative orders either side of the 0 order (non-diffracted light shining through an aperture). Each further order from 0 has more chromatic spread and is more diffuse due to the different colours travelling at different speeds. The first orders (-1 and +1) are the brightest and most focused.

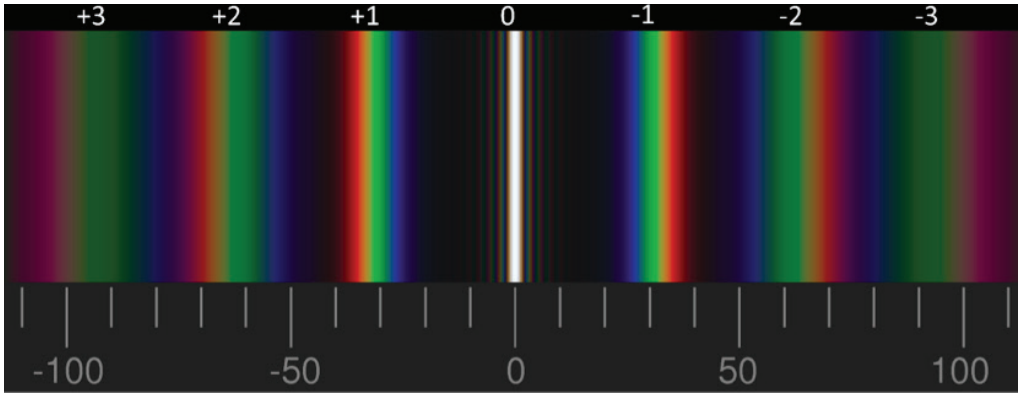


Figure 16: Principles of diffraction with parallel positive and negative orders

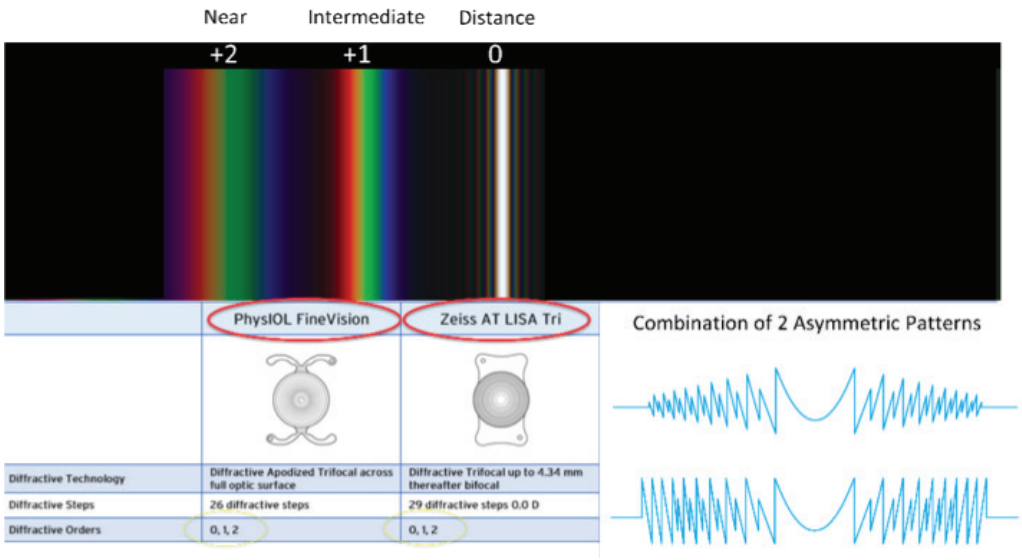


Figure 17 is a representation of the FineVision and AT Lisa Tri trifocal patent, 2 asymmetric patterns combined which use the 1st order for intermediate and 2nd order for near vision.

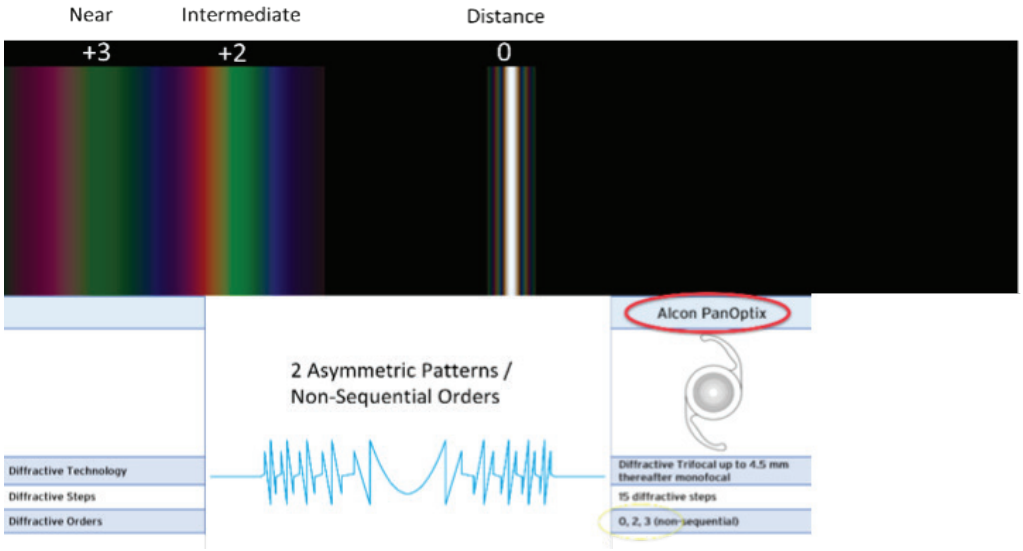
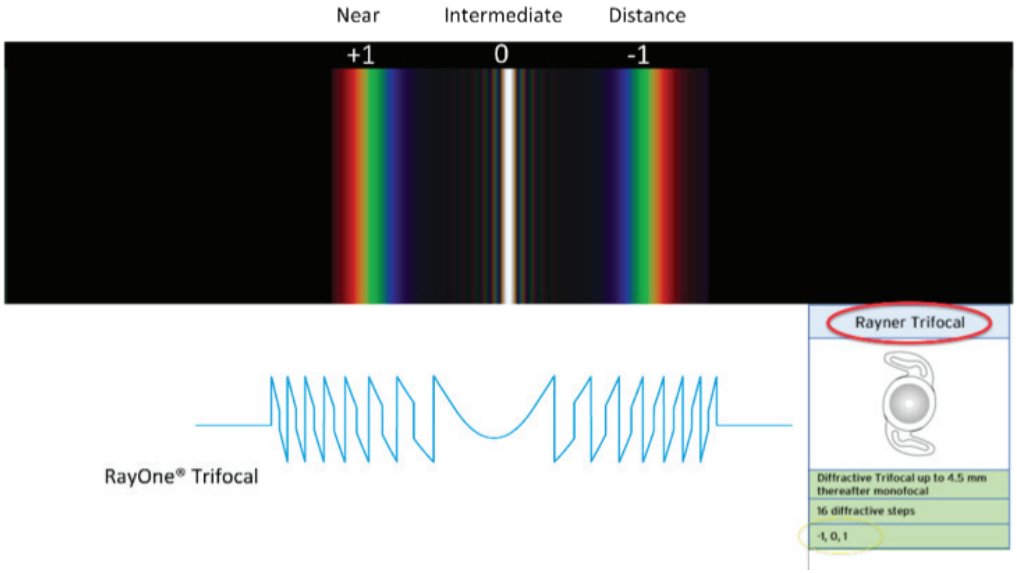


Figure 18 is a representation of the PanOptix Trifocal patent. Using the 2nd diffractive order for intermediate and 3rd diffractive order for near which are not sequential.

Finally Figure 19 is the representation of the RayOne Trifocal patent which uses the two clearest and sharpest first orders of diffraction. -1 order is used for distance, 0 for intermediate and +1 for near vision. Surgeons have reported that haloes are crisp and distinct making the adaptation process easier.



Dr Jayaswal concluded, *"the Trifocal optic from Rayner is very forgiving, the key subtle differences to other trifocal IOLs accumulatively have a better outcome for patients. Sulcoflex Trifocal allows us to customise our approach and offer patients reversible multifocality, we are no longer trapped to offer patients a permanent multifocal IOL into the capsular bag. Patients also understand and like the concept of reversibility especially as they present nervousness towards dysphotopic phenomena such as halo and glare. Patients are now driven, understand and want the latest technology. Sulcoflex Trifocal empowers the patient to upgrade their IOLs over the course of their life. The question we need to ask ourselves is, if we are going to be using an IOL that aberrates light, shouldn't we be placing it into sulcus to allow life- long reversibility?"*

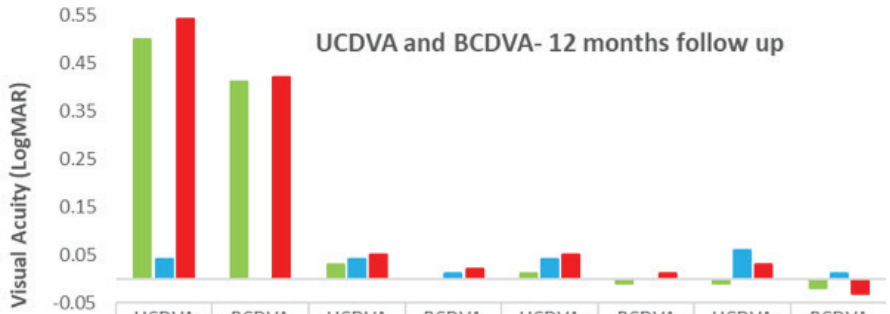
"Sulcoflex Trifocal ... demonstrated excellent centration and stability with no interaction with the capsular bag."

Dr Alessandro Mularoni, MD, Director of Laservision Centre in Bologna (Italy) presented on the Rayner Trifocal platform that performs on any optic. His prospective comparison study on RayOne Trifocal and Sulcoflex Trifocal (pseudophakic patients and DUET surgery) measured uncorrected and best corrected visual acuity for near, intermediate and far distances, contrast sensitivity, patient satisfaction and PCO and IOL stability. The average follow up time was 12 months.

In total 30 eyes of 15 patients were recruited for the study, 20 eyes received RayOne Trifocal and 10 eyes received Sulcoflex Trifocal. Of the Sulcoflex Trifocal group, 50% of eyes were pseudophakic patients and 50% of eyes were cataract patients undergoing monofocal IOL and Sulcoflex Trifocal under DUET surgery.

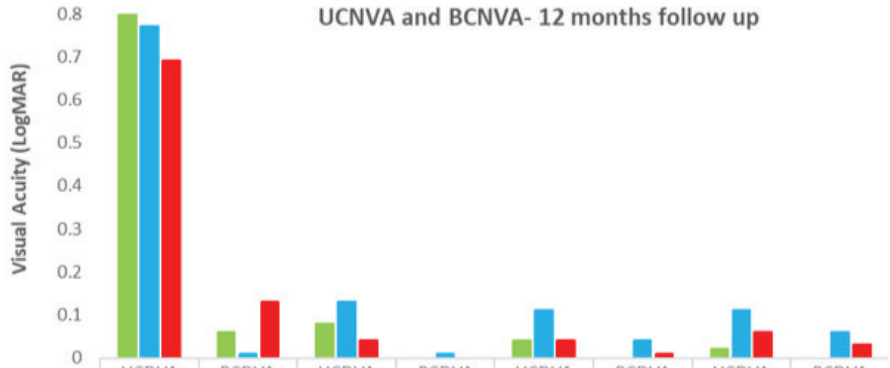
Clinical Study Results

Visual acuity results (*Figure 20*) show high visual outcomes across all three groups. 100% patients in the RayOne Trifocal group and 70% of patients in the Sulcoflex Trifocal group achieved monocular UCDVA of 0.1 LogMAR or better. 100% of patients in the RayOne Trifocal group achieved monocular UCNVA and UCIVA of 0.1 LogMAR or better. In the Sulcoflex Trifocal group, 70% and 100% of patients achieved monocular UCNVA and UCIVA of 0.1 LogMAR or better. There was no statistically significant differences between both groups across all visual acuities.

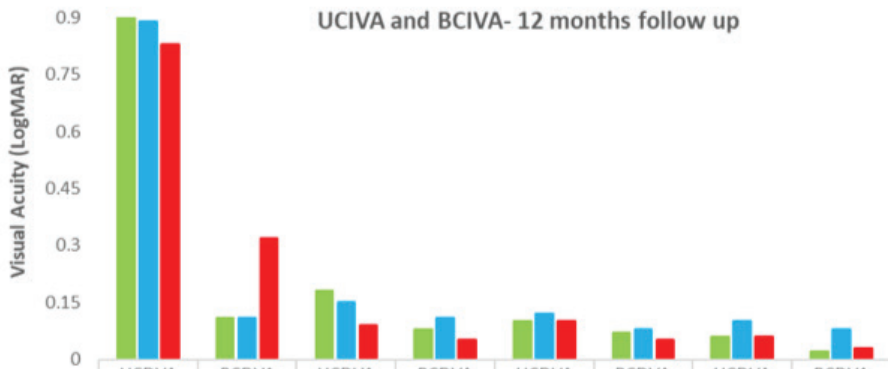


	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA
	PRE-OP		1 MONTH POST-OP		3 MONTHS POST-OP		12 MONTHS POST-OP	
RayOne Trifocal	0.5	0.41	0.03	0	0.01	-0.01	-0.01	-0.02
Pseudophakic Procedure	0.04	0	0.04	0.01	0.04	0	0.06	0.01
DUET Procedure	0.54	0.42	0.05	0.02	0.05	0.01	0.03	-0.03

Figure 20: Visual acuity results for distance, near and intermediate



	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA
	PRE-OP		1 MONTH POST-OP		3 MONTHS POST-OP		12 MONTHS POST-OP	
RayOne Trifocal	0.85	0.06	0.08	0	0.04	0	0.02	0
Pseudophakic Procedure	0.77	0.01	0.13	0.01	0.11	0.04	0.11	0.06
DUET Procedure	0.69	0.13	0.04	0	0.04	0.01	0.06	0.03



	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA
	PRE-OP		1 MONTH POST-OP		3 MONTHS POST-OP		12 MONTHS POST-OP	
RayOne Trifocal	0.91	0.11	0.18	0.08	0.1	0.07	0.06	0.02
Pseudophakic Procedure	0.89	0.11	0.15	0.11	0.12	0.08	0.1	0.08
DUET Procedure	0.83	0.32	0.09	0.05	0.1	0.05	0.06	0.03

Patient satisfaction was evaluated using a self-administered questionnaire (NEI RQL-42). High patient satisfaction was recorded in all patients who received either a RayOne Trifocal or Sulcoflex Trifocal IOL (*Figure 21*).

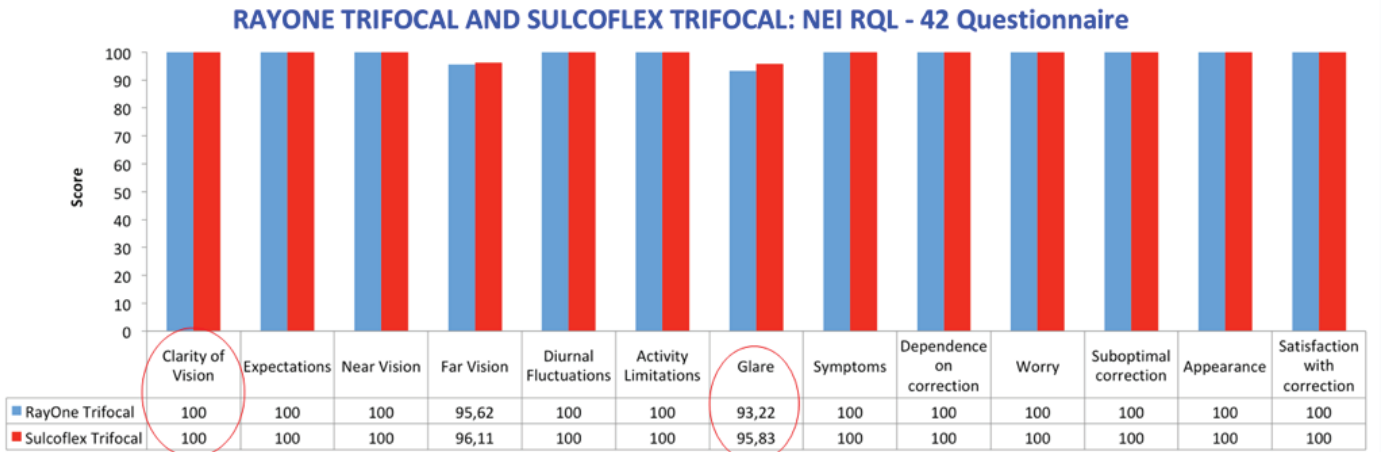


Figure 21: Patient satisfaction results from NEI RQL-42 questionnaire

Posterior Capsular Opacification (PCO) and IOL stability incidence was recorded using digital photos of anterior segment during the follow-up. No PCO was reported in any patients who received a RayOne Trifocal or Sulcoflex Trifocal IOL. No tilting or decentration was reported in any case (*Figure 22*)

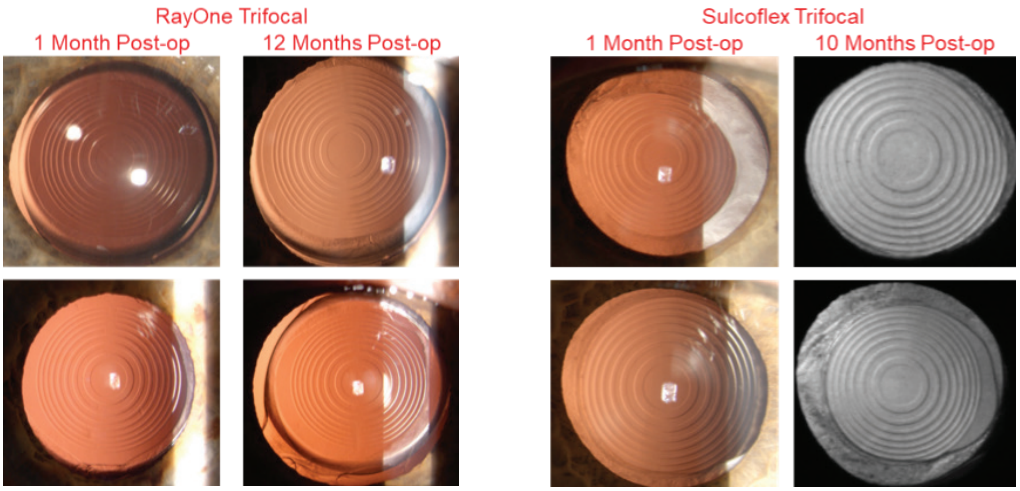


Figure 22: Digital photos of anterior segment showing no PCO

Dr Mularoni concluded "*when comparing the RayOne Trifocal and Sulcoflex Trifocal, both provide a very high level of spectacle independence and patient satisfaction. Both Trifocal IOLs showed similar results regarding visual outcomes, contrast sensitivity and internal aberrations. They both demonstrate long term stability, good centration and no PCO. Sulcoflex Trifocal also demonstrated excellent centration and stability with no interaction with the capsular bag IOL during all patient follow ups. The Rayner Trifocal technology performs very well on both optics whether implanted into the capsular bag or within the ciliary sulcus.*"

"Sulcoflex Trifocal opens up the opportunity to treat a larger number of patients..."

Dr Detlef Holland, MD, Director of the Ophthalmic service at nordBLICK Augenklinik Bellevue in Kiel (Germany) focused on the **unhappy pseudophakic patient: a new refractive opportunity with Sulcoflex Trifoca**l. There are approximately 25.3m monofocal IOLs implanted globally per year[12], which equates to 92% of all cataract surgeries. Dr Holland stated in Germany there are approximately 900,000 cataract surgeries performed a year, perfect pre-operative biometry at the time of cataract surgery means most of these patients are emmetropic, however only 3% may have received a multifocal IOL at the time of surgery and therefore could be still spectacle dependent for near vision. There is a huge population of pseudophakic patients that could benefit from this technology long after their cataract surgery. Dr Holland has been implanting Sulcoflex Trifocal in nearly all pseudophakic patients with a desire to become spectacle independent for near and intermediate distances.

Indications

In addition to pseudophakic patients who have a high drive to become spectacle independent, there are further interesting indications for which Sulcoflex Trifocal could now be suitable due to the nature of its reversibility. Dr Holland states that he now considers patients who wouldn't usually qualify for a multifocal IOL based on their lifestyle such as those that drive often. In Northern Germany, the days are very short with limited sunlight from October through to April, patients who drive a lot under challenging lighting conditions are usually very nervous to receive a multifocal IOL. Patients with moderate AMD and limited predictability on its progression over time would not have usually been considered for a capsular bag multifocal IOL, Sulcoflex Trifocal offers a great reversible solution to these patients. Patients with a reduced endothelial cell count as there are uncertainties on whether these patients will require future corneal intervention, these patients are now suitable candidates for a Sulcoflex Trifocal. Patients who may have had previous refractive laser surgery such as LASIK but did not achieve target refraction are great candidates as the IOL can be removed and replaced with another power. Patients with an extreme refraction are usually at a higher risk of a refractive surprise can also be considered for a sulcus placed Trifocal IOL. Finally, patients with borderline pupil sizes, sometimes patients with as little as 2.5 mm would like a multifocal IOL but surgeons are hesitant. If the pupil is too large or too small, the Sulcoflex Trifocal can be removed.

Dr Holland states, "*Sulcoflex Trifocal opens up the opportunity to treat a larger number of patients that we wouldn't usually consider giving a capsular bag trifocal IOL. It is important to look into your private practices and find these patients that can still benefit many years later.*"

There are multiple challenges on recruiting these patients, especially patients that had cataract surgery years ago and may be very happy with their distance vision. In order to offer a higher standard of care, these patients should be contacted from clinic directories, to create awareness to new technology that can offer complete spectacle independence even after cataract surgery. Emmetropic patients that are between 50 to 70 years of age are the best candidates. So how do we recruit these patients? Sharing information and educating colleagues on the performance and best practices of Sulcoflex Trifocal is vital. Congresses and educational symposiums are a good platform to do this. Training clinic staff to offer Sulcoflex Trifocal technology and educating every pseudophakic patients that returns for their check-up will help to create awareness. Holding patient evenings at your practice and a strong marketing campaign also helps. Listing your practice as an accredited provider on the dedicated Sulcoflex Trifocal patient website (www.sulcoflex.com) allowing patients to contact their surgeons if seeking this solution. These are all ways we can start to recruit these patients.

Figure 23: Postoperative spherical equivalent refraction

Clinical Study Results

A multi-centre prospective study assessing visual quality and patient satisfaction after bilateral implantation of the Sulcoflex Trifocal in pseudophakic eyes with a 1 month follow up demonstrates great results. A total of 34 patients (68 eyes) were recruited into the study. Subjective refraction results show that 100% of eyes were within ±1.00 D and 94% within ±0.50 D. Preoperative spherical equivalent of 0.39±1.27 reduced to -0.15±0.26 postoperatively (*Figure 23*).

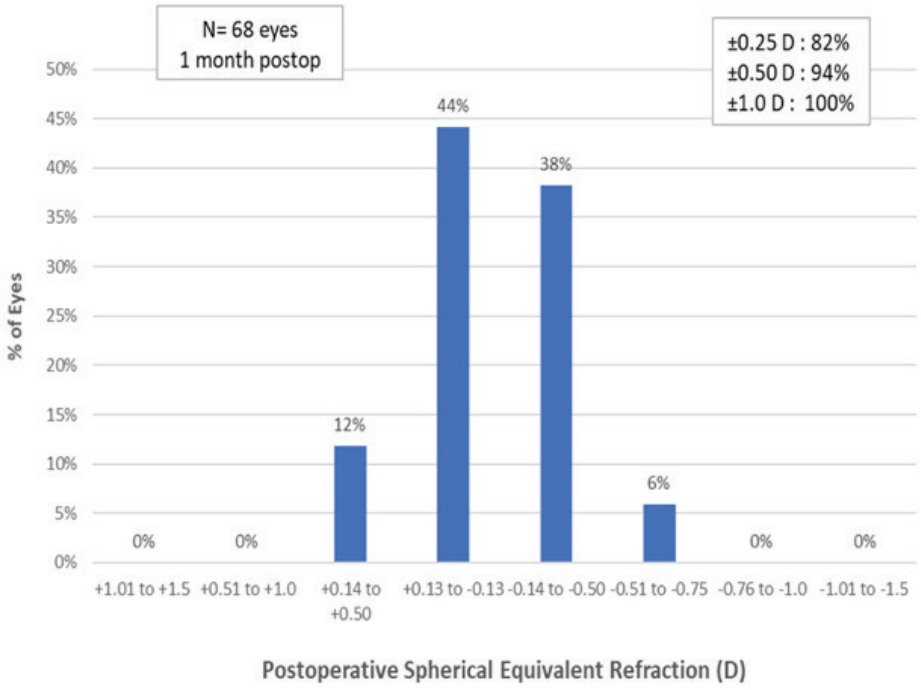
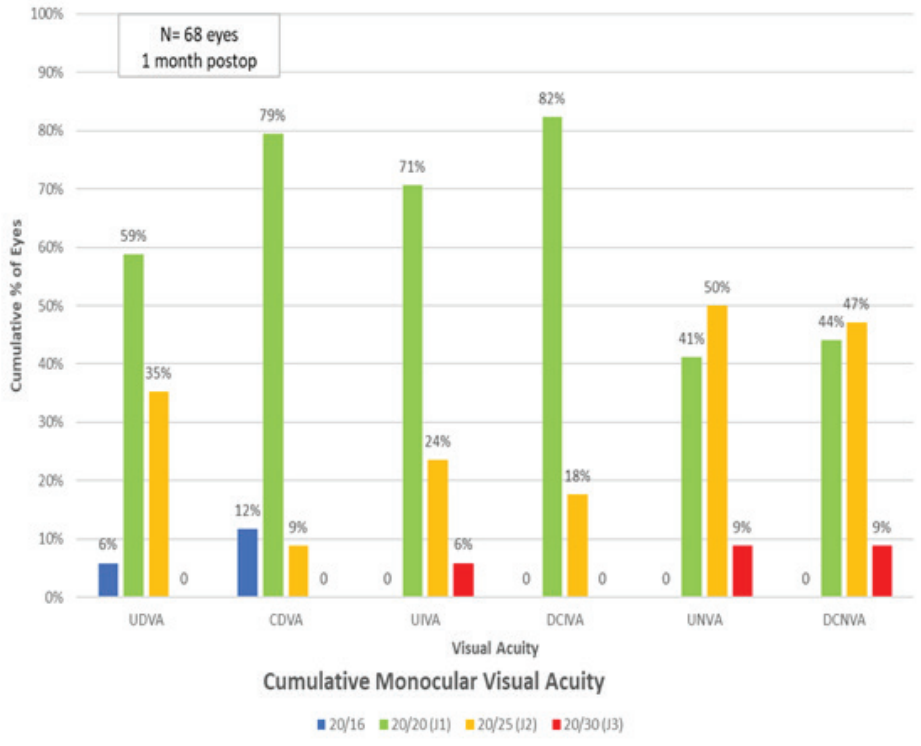


Figure 24: Visual acuity results for distance, near and intermediate

Visual acuity results for binocular UDVA were -0.02±0.04, UIVA 0.01±0.03 and UNVA 0.05±0.05. 100% of eyes achieved a UDVA of 0.1 LogMAR or better (*Figure 24*).



Patients reported high levels of satisfaction across all distances and 94% of patients were satisfied or extremely satisfied with their overall vision across all distances (*Figure 25*).

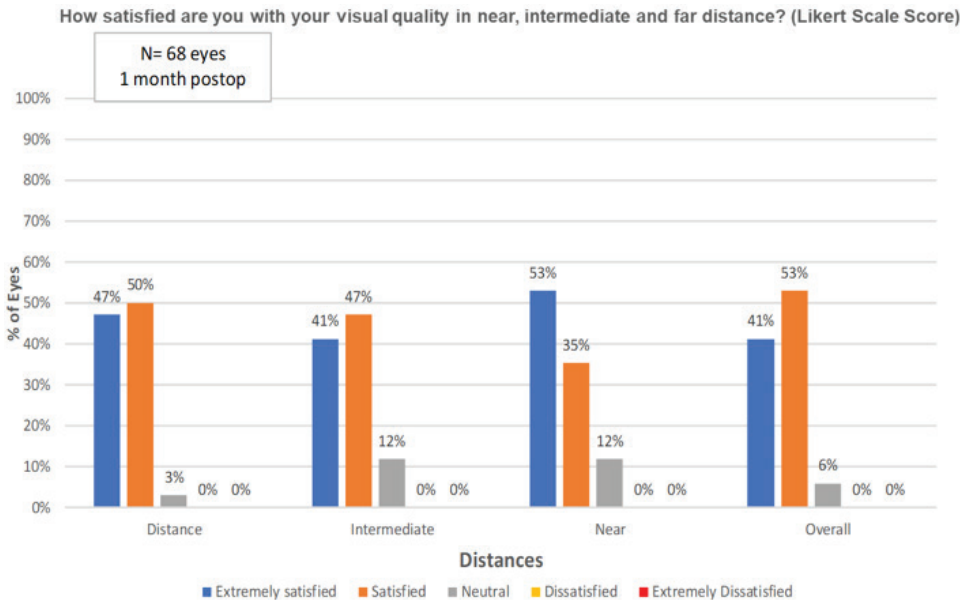


Figure 25: Patient satisfaction with overall vision

Dr Holland concluded that *"Sulcoflex Trifocal is a good solution to treat even more patients and grow our private practices, as it opens up a huge opportunity to bring back pseudophakic patients and stimulate a desire for presbyopia correction. Many of these patients may not have had a multifocal IOL implanted at the time of cataract surgery, in order to increase our standards of care, we should make them aware that they can still benefit from spectacle independence post cataract surgery. Sulcoflex Trifocal also allows us to treat patients who wouldn't usually be good candidates for a capsular bag trifocal IOL, the reversible concept of Sulcoflex Trifocal provides reassurance and confidence to these pseudophakic patients as it can be easily removed later in life."*

"Sulcoflex Trifocal opens up the opportunity to treat a larger number of patients..."

Professor Ramin Khoramnia, MD, FEBO, Associate Professor, Senior Physician and Head of Cataract and Refractive surgery Division at the University of Heidelberg and lead researcher in the David J Apple International Laboratory for Ocular Pathology (Germany) held a **Scientific deep dive: clinical results from in-vitro competitor analysis**. Results from a laboratory optical bench study were presented. Prof Khoramnia has previously used the Sulcoflex Bifocal Multifocal in DUET procedure to provide patients with reversible multifocality, results from the bifocal supplementary IOL were good but visual acuity at intermediate distance could be better.

Implantation of trifocal IOLs in the capsular bag has since become the standard of care in presbyopia treatment and therefore the introduction of Sulcoflex Trifocal has been very widely accepted by Heidelberg University who continue to provide reversible multifocality to many patients.

Professor Khoramnia states there are questions that are frequently raised around DUET surgery; **1)** if the visual optical quality might suffer and **2)** if there is increased light loss and reduced light transmission when two IOLs are implanted into the ocular system instead of one.

Optical bench evaluation is a well-known method to determine the optical quality of IOLs. David J Apple Labs and University Hospital of Heidelberg performed an assessment to measure the optical performance of two IOLs in a polypseudophakic combination. The first assessment was to examine the optical performance of the two IOLs (Sulcoflex Trifocal and RayOne Aspheric Monofocal) in DUET when placed in a model eye in the Trioptics OS IOL PRO 2 (with photopic and mesopic apertures/ pupil sizes). Optical quality measurements were made of the combined metrics of the lenses. The measurements taken were MTF, strehl Ratio; through focus MTF at 50lp/mm, lens power and USAF target images. The measurements recorded were then compared to the same of single, capsular-fixation multifocal IOLs; RayOne Trifocal (Rayner), PanOptix (Alcon), FineVision Pod F (PhysIOL) and AT Lisa Tri 839MP (Zeiss). Finally, a simple optical quality loss assessment ignoring light loss due to internal reflection from lens surfaces was calculated for the Sulcoflex Trifocal alone, the two IOLs in DUET and the four previously mentioned capsular-fixation multifocal IOLs.

In-Vitro Study Results

MTF curves through a 3.0mm aperture demonstrate that at far, intermediate and near distances, the RayOne Trifocal in the capsular bag and Sulcoflex Trifocal in DUET approach have similar optical quality across spatial frequencies. Strehl ratio is a measure of the quality of optical image formation, the comparison to competitor capsular bag IOL yields similar results. Light transmission results demonstrate that one IOL (monofocal RayOne) has a reflectance of 0.4% and a total light transmission of 99.6% and 2 IOLs (Sulcoflex Trifocal and monofocal RayOne) has a 0.8% reflectance and transmission of 99.2% therefore there are no disadvantages of an additional interface within the ocular system in terms of optical quality and performance (*Figure 26*). Results from this study are soon to be published.

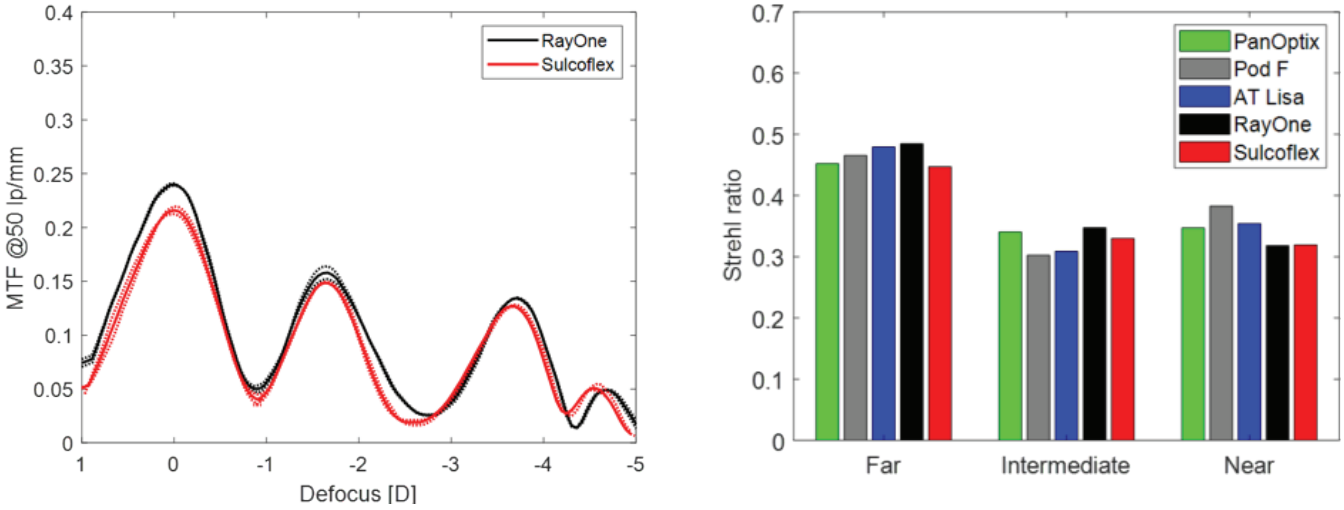
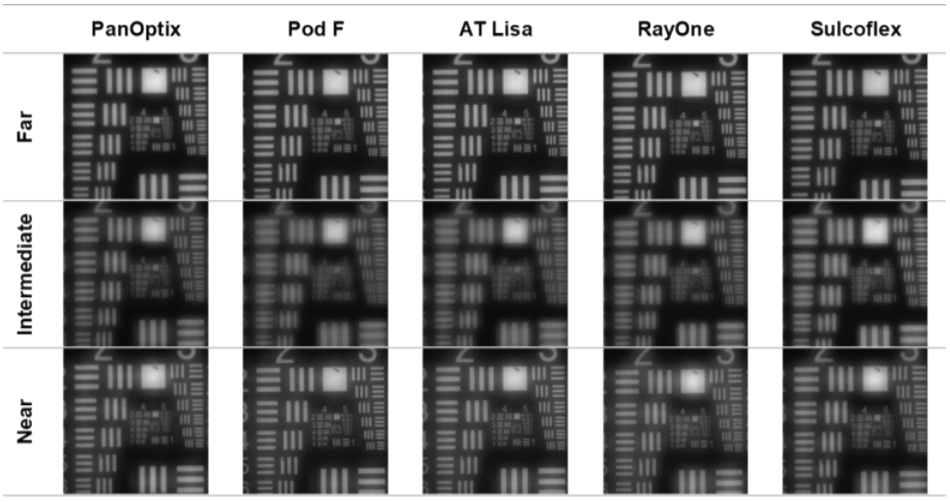


Figure 26: Preliminary results from a lab optical bench study



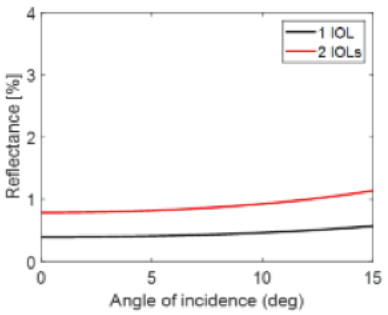
Light transmission: 2 against 1

	Reflectance [%]	Transmission [%]*
1 IOL±	0.4	99.6
2 IOLs†	0.8	99.2

*Transmission = 100 – Reflectance

±RayOne monofocal

†RayOne monofocal and Sulcoflex



For comparison: **1 AcrySof IOL** with a refractive index of 1.55

Reflectance = **1.1%**
Transmission = **98.9%**

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