Presbyopia Correcting IOLs for Phakic & Pseudophakic Eyes

EPS Technology\(^1\): A Special Concept with Multiple Applications

\(^1\) patent pending
Cataract surgery patients today are increasingly interested in reducing their dependence on spectacles across a full range of vision. Created using optical principles and knowledge of ocular physiology, the Liberty trifocal (677MY / 677MTY) presbyopia correcting trifocal IOL from Medicontur was engineered to meet the functional needs of the modern cataract surgery patient population and optimise quality of vision.

**Revolutionary Optical Design (EPS)**

The Liberty trifocal IOL is distinguished from other commercially available trifocal IOLs by unique features in its optic which are equally utilised on the 1stQ AddOn IOL designed for placement in the sulcus. Both lenses make use of Medicontur’s proprietary, patented Elevated Phase Shift (EPS) technology - a novel optical concept for trifocal performance and efficient light energy utilisation.

A brief review of visual optics is helpful for understanding the performance and benefits of this optical design and how EPS compares with other trifocal technologies, said Alexandra Kontur MD, PhD, Scientific Director, Medicontur.

**Light Propagation – Diffraction**

The optics of multifocal IOLs (MIOLs) are based on a diffractive paradigm that takes advantage of the wave nature of light. A wavefront of light consists of waves that have the same amplitude in their crest and trough. Diffraction describes the physical phenomenon that occurs when a wavefront meets an obstacle (surface). When a wavefront encounters an obstacle, it changes its wavefront. As waves emanate through, the waves can overlap, causing their amplitude to change, becoming equal to the sum of the amplitudes of the individual waves.

The overlapping waves can reinforce each other (Fig. 1a), which is known as constructive interference, or cancel each other out, which is known as destructive interference. (Fig. 1b)

"Through EPS we are able to create a third focal point for an intermediate peak with only seven rings within the central 3mm of the optic, leaving 75% of the lens surface as refractive"

**Tuning Light Interference**

Diffractive optics modify the interference of light, but the level of light interference depends on the design of the diffractive structure. Every lens manufacturer has the same amount of light to play with.

When developing a diffractive MIOL, it is the job of the optical physicist to tune the light interferences that are generated by the diffractive design in order to achieve the desired optical properties while also using the incoming light as efficiently and effectively as possible so as to optimise visual function and minimise compromises.

"With those goals in mind and based on our knowledge of ocular physiology, at Medicontur we took a very conservative approach to designing a trifocal IOL," said László Kontur, MD, CEO, Medicontur.

"By using the proprietary Elevated Phase Shift (EPS) technology that causes constructive interference at the wavefront arriving to the intermediate region, we can use only one diffractive array to create two additional diffractive focal points (Fig.2).

In contrast, other trifocal IOLs generate an intermediate focus by combining two bifocal diffractive profiles on a single surface or by using a trifocal diffractive profile combined with a bifocal diffractive array."

Through EPS we are able to create a third focal point for an intermediate peak with only seven rings within the central 3mm of the optic, leaving 75% of the lens surface as refractive.

From Theory to Clinical Trials

A series of careful evaluations were conducted in the laboratory to evaluate the performance of this unique technology. The studies included special simulations, 3D modulation transfer function (MTF) measurements, and testing in a proprietary anatomic eye model.

"The simulations were developed to help us predict the light distribution of different diffractive optical patterns at different pupil apertures. With the use of these simulations, it was possible to easily identify how the distribution of light intensity would vary based on pupil aperture. “ said László Kontur.
“This allows us to apply knowledge of ocular physiology to design the optic. In other words, our goal was to create an IOL that would distribute light intensity according to where it is most needed depending on the size of the pupil for different vision tasks.”

The results of the laboratory testing demonstrated that the light intensities allocated at different aperture sizes provide excellent performance for far and near vision and seem to deliver enough light intensity for the intermediate peak. (Fig 5)

Findings from prospective clinical trials have confirmed the observations made in the laboratory simulations. As reported by different investigators, studies evaluating patients implanted with the Liberty trifocal IOL showed that its innovative optic design translates into excellent far and near vision and very good, competitive intermediate vision.

In a prospective study that included 50 cataract patients (100 eyes) who underwent bilateral implantation with the Liberty trifocal IOL, József Győry MD and colleagues performed monocular and binocular defocus curve measurements in patients followed for up to 24 months postoperatively.1 (Fig 6a)

The data from evaluations performed at 12 and 24 months showed that the trifocal IOL provided good levels of functional vision from +0.50D to -3.00D.

Similar findings were reported by Joaquín Fernández MD, PhD, and colleagues in an investigation where binocular defocus curve measurements were obtained at three months after surgery.2 In the study that included 24 patients, mean visual acuities were -0.05 ±0.11 logMAR at far, 0.15 ± 0.15 logMAR at intermediate, and 0.01 ±0.11 logMAR at near. Fig 6b shows the defocus curve they obtained at a later time increasing the sample size up to 66 subjects.

Light scattering contributes to loss of contrast sensitivity and the development of dysphotopsias with MIOLs. Therefore, the potential for a diffractive optic to reduce contrast sensitivity and cause bothersome dysphotopsias is a consideration when contemplating implantation of a MIOL.

“It should not be forgotten, however, that loss of media transparency causes an increase in light scattering. Therefore, decreased contrast sensitivity and symptoms of dysphotopsia are already experienced by patients who have cataract,” Dr Fernández said.

**Contrast Sensitivity & Dysphotopsia**

In a cohort of 192 subjects (unpublished data), Dr Fernández and colleagues showed that in subjects with a clear crystalline lens, median contrast sensitivity was 0.9 logCS and more than 50% of patients with a clear lens had a contrast sensitivity below the mean. The proportion of subjects with contrast sensitivity below the mean exceeded 75% in a group of patients with early cataract (grade 1 nuclear cataract on the LOCS III scale). These findings were in agreement with...
those reviewed in previous publications.6

“One of our main worries relating to the use of a MIOL was to determine the proper age and preoperative degree of cataract that can lead to the highest positive experience after surgery. When we are performing cataract surgery and implanting a presbyopia-correcting IOL, we not only want to improve visual performance at the close and intermediate distance range but we also want to provide a positive experience for the patient with respect to contrast sensitivity as well as dysphotopsia,” said Dr Fernández.

“According to our analyses, 50% of patients who are around age 60 or with early cataract will actually improve their contrast sensitivity after implantation of the Liberty IOL. They will also experience less dysphotopsia in comparison to their preoperative vision with best spectacle refraction,” Dr Fernández said.

In their study of 50 patients (100 eyes) who had bilateral implantation of the Liberty trifocal IOL, Dr Győry et al. measured contrast sensitivity at three, six, 12, and 24 months postoperatively using a standardised chart (CSV 1000).1

“We found that the contrast sensitivity values were in the upper third range of age-matched normal values. There was significant improvement of contrast sensitivity in all light conditions, compared to the preoperative status (p<0.0001). The mean values at low, medium, and higher spatial frequencies remained unchanged until one year postoperatively. At two years, however, the mean values were reduced at low spatial frequencies under mesopic conditions, mainly because of onset of PCO development” Dr Győry reported (Fig.7)

“...There was significant improvement of contrast sensitivity in all light conditions, compared to the preoperative status

Dysphotopsia

“Ray tracing simulations were done by researchers at Medicontur to visualise the out-of-focus light intensity for different optical patterns representing different MIOL designs in order to evaluate the potential for dysphotopsia. The simulations were done by a Zemax extension for calculation of light propagation after creating the custom defined diffractive surface and were run on a 4.5mm aperture setting that corresponds with the average size of the mesopic pupil for driving at night. The results showed that the intensity of out-of-focus light at both near and far distances was least with the seven rings Liberty IOL compared with optical patterns including a larger number of rings. By minimising the amount of out-of-focus light at far, the Liberty IOL diffractive design was also associated with the smallest diameter halo, which would be expected to be least noticed by or disturbing to patients” (Fig. 8)

“Although dysphotopsia with MIOLs is a topic that needs more relevant scientific evidence, theoretical simulations confirmed our expectations of reduced glare and haloes with the Liberty IOL compared with other trifocal IOLs,” Dr Fernández said.

Clinical experience with the Liberty trifocal IOL seems to be consistent with the evidence obtained in the ray tracing simulations, said Dr Győry.

He stated: “We analysed data on haloes and glare in our prospective study of 50 patients (100 eyes) who had implantation of the Liberty IOL after bilateral cataract surgery. We found that these visual disturbances were rarely reported. Furthermore, patients who noticed halo and glare generally found their severity was tolerable.” All patients in the cohort completed the VFQ-25 visual functioning questionnaire, on which 96% of patients reported no to mild haloes and 96% reported no to mild difficulty with night driving.

“This high level of patient satisfaction with minimal postoperative visual symptoms might be attributable to the minimal diffractive steps limited to the central 3mm on the optic of the trifocal IOL,” said Dr Győry.

“In our experience, symptoms of dysphotopsia that are experienced by some patients after cataract surgery is often a short-term phenomenon,” said Dr Fernández.

Efficiency Through Using Ocular Physiology

Manufacturers and surgeons have gotten used to labelling IOLs as pupil-dependent or pupil-independent. However, it is against physiology to design “pupil-independent” IOLs because the IOL design should adapt as closely as possible to the pupil size required by the tasks carried out by patients, which are not pupil-independent”, said Dr Fernández, QVision, Department of Ophthalmology, Vithas Virgen del Mar Hospital, Almería, Spain.

“Pupil size plays an important role in the performance of trifocal IOLs because it controls the intensity of light that goes through the specific lens zones. Surgeons should not forget that there is relative miosis during intermediate and near vision tasks because the Near Triad reflex remains intact in pseudophakic patients. Although the speed with which the pupil responds to changes in vision tasks slows with age, the Near Triad reflex is not lost with increasing age or after cataract surgery with IOL implantation,” he said.

The Liberty trifocal IOL is designed to provide high light distribution in the near and intermediate foci at the different pupil apertures that are associated with near and intermediate vision tasks. Conversely, it maintains high light distribution for far vision under low mesopic or scotopic conditions, such as occur when driving at night. Dr Fernández observed that spectacle independence is the most important factor for determining the success of premium cataract surgery. “This is the reason why we believe that, secondary to distance vision, we have to prioritise near vision in order to achieve the highest rate of satisfaction in our patients,” he said.

The useful light distribution plot for trifocal IOLs shows how at the 3mm aperture, the Liberty IOL gives the highest priority to near vision (37.7%).

“According to our clinical measurements from 180 subjects ages 45 to 85 years old, photopic mean pupil for subjects older than 50 years is below 3mm. If we add the Near Triad reflex, we can see that the Liberty IOL is designed to achieve the highest rate of spectacle independence for conducting near-tasks such as reading,” Dr Fernández said.

...theoretical simulations confirmed our expectations of reduced glare and haloes with the Liberty IOL compared with other trifocal IOLs
Because the pupil changes with different tasks, an IOL should adapt the light distribution according to the main needs of the patient for conducting these tasks. At low light conditions, such as when driving at night, patients might be surrounded by point sources of light. In this situation, it does not make sense to maintain near light distribution. Rather it is better to enhance distance light distribution and to reduce the number of diffractive rings, resulting in better distance vision and low incidence of dysphotopsia, said Dr Fernández.

“Again, the Liberty IOL is responsive to the light required for tasks when the pupil is bigger (4.5mm), and compared with competitors, it has the highest light distribution (79.3%) for distance vision in mesopic pupil size conditions,” he said. “It is easy to understand why we say that the Liberty design is not pupil-dependent, we prefer to say that its design is responsive to the pupil-dependent tasks conducted by the patient.”

Design Matters

The Liberty IOL is manufactured of a time-tested 25% hydrophilic copolymer material and built on the Bi-Flex platform that incorporates multiple design features for ensuring proper fixation, preventing posterior capsule opacification (PCO), and maintaining positional and refractive stability.

The Bi-Flex design is characterised by a double C-loop haptics that have a large contact angle (2 × 88.8°) with the capsular bag equator that allows for proper positioning but also for flexibility, which confers stability through resistance against compressive forces from capsular bag contraction. (Fig 9). As another key aspect of the Liberty IOL design, its optic has a 360° sharp square edge (≤10 microns) that includes the optic-haptic junction zone for protection against lens epithelial cell migration.

“We designed this platform to excel in rotational and refractive stability, and we are continuing to see great results through clinical experience,” said László Kontur.

Posterior Capsule Opacification

Dr Fernández analysed data on PCO in a series of 21 eyes implanted with the Liberty trifocal IOL. He reported that at 12 months post-implantation, PCO was grade 0 in 83% of eyes and grade 1 in the remaining 17% of eyes. In contrast, data collected after 12 months in eyes implanted with another hydrophilic IOL showed grade 0 PCO in 44%, grade 1 in 29%, and higher grades in 27%.

“Both biomaterial and edge design are important factors for the development of PCO. Based on our data we realised that not all hydrophilic IOLs are associated with the same rate of PCO. In short, by using the Liberty trifocal IOL, we have reduced the rate of PCO we are seeing at 12 months after,” said Dr Fernández.

Prof Zoltán Nagy MD, Chair, Department of Ophthalmology, Semmelweis University, Budapest, Hungary, collected data on PCO development with the Liberty trifocal IOL in a prospective comparative study. The investigation included 48 patients who underwent cataract surgery and had bilateral implantation of either the Liberty IOL or a hydrophobic acrylic bifocal diffractive IOL (AcrySof IQ ReSTOR SN6AD1). By the end of 24 months of follow-up, the PCO rate was lower in the Liberty trifocal group than in eyes with the AcrySof IQ ReSTOR IOL (22.9% vs. 28.3%)1.

“PCO remains a potential long-term complication of cataract surgery that can reduce contrast sensitivity and decrease vision, especially in patients with a multifocal IOL. Patients who choose a presbyopia-correcting lens have high expectations to achieve and maintain spectacle dependence. Therefore, the rate of PCO is an important characteristic to consider,” said Prof Nagy. “Because it has been reported that PCO rates are lower after implantation of hydrophobic acrylic lenses, we were somewhat surprised to find no significant difference in PCO development between the two lenses in our study. Our data support the hypothesis that IOL design might be a more important factor for preventing PCO than IOL material.”

Data on PCO development in patients implanted with the Liberty trifocal IOL were also collected in the prospective clinical study published by Dr Győry and colleagues. “We found that PCO was surprisingly low,” he said.

All of the 50 patients included in the study were seen after one year and 48 patients (96 eyes) were evaluable after two years1. At the one-year visit, none of the eyes implanted with the Liberty IOL had undergone YAG capsulotomy. Nine eyes had undergone YAG capsulotomy by two years. “Only three of the patients who had YAG capsulotomy had visual complaints that could be related to PCO while in the other cases, the suggestion was made to have the YAG laser treatment based on the findings of the slit-lamp examination,” Dr Győry said.

Refractive Stability

Data on refractive outcomes collected by Prof Nagy in his two-year study demonstrate refractive predictability and stability in patients implanted with the Liberty IOL, but a shift toward negative values in the group of eyes implanted with the AcrySof IQ ReSTOR IOL.

“The change in refraction with the competitor MIOL was slightly manifested in the visual outcomes for patients implanted with the AcrySof MIOL, and a more obvious change was observed in the defocus curve with time,” said Prof Nagy (Fig. 10)

He hypothesised that differences in design and biomaterial explain the superior stability of the refractive and visual outcomes with the Liberty IOL compared with the AcrySof MIOL.

“The Liberty IOL has a higher degree of haptic contact with...
Clinical experience with the 1stQ AddOn® IOLs show that these supplementary IOLs, which use the same EPS technology as the Liberty trifocal IOL, are well-designed to provide safe and effective presbyopia correction in patients previously implanted with a monofocal IOL, agree surgeons who have used the technology.

Translating Features Into Benefits

The hydrophilic material used for the 1stQ AddOn® has proven uveal biocompatibility to avoid inflammatory reactions and also a high Abbe number (low chromatic aberration) that confers high image quality. Its four flexible haptics and concave – convex optic design provide good fixation and a stable sulcus fit for protection against endothelial damage, iris chafing, and iris pigment release. Long-term rotational stability is assured by the implants anti-torque design. (Fig.11)

“Findings from a study that we conducted in pseudophakic cadaver eyes confirms that there is good clearance between the 1stQ AddOn® IOL and the primary pseudophakic lens3” said Sathish Srinivasan FRCS(Ed), FRCOphth, FACS, University Hospital Ayr, Ayr Scotland.

Clinical Perspectives

“Based on the reliable stability of the 1stQ AddOn® Lens, I use it often in clinical practice for increasing my options for refractive upgrades or correction,” said Prof Srinivasan. The opportunity for creating a dual-lens system with the 1stQ AddOn lens enables me to increase the size of my satisfied patient pool.”

Dr Erik L. Mertens said that “the 1stQ AddOn® IOL allows him to bring patients into their visual comfort zone. Some cataract surgery patients who have a monofocal IOL implanted will tell me they did not realise how handicapped they would be in daily life when performing tasks involving near and intermediate vision,” said Dr Mertens, CEO and Medical Director, Medipolis Antwerp Health Centre, Antwerp, Belgium.

“Using the 1stQ AddOn® IOLs helps me to have more happy patients. Implanting the 1stQ AddOn® Lens is also much easier than performing IOL exchange, especially if the patient has already had YAG laser capsulotomy. The ease of handling and implantation also minimises risk of iatrogenic trauma and endothelial cell loss.”

Fig. 10: Showing a significant difference at near and intermediate distances in favour of Liberty 677MY at 3 months post-op, the curves plotted throughout the postoperative course remained identical in case of Liberty (p=0.5119), however a significant decrease in the results could be observed with the Alcon ReSTOR lens

Fig. 11: Sulcus fit through 4 flexible haptics and non-torque AddOn® design

Dr Fernández observed: “The large size of the Liberty IOL and its double-loop haptic design are considered to be very important features for maintaining postoperative stability, and that is important for providing good long-term results with all multifocal IOLs and particularly for toric versions.”

Elevated Phase Shift Technology for the Sulcus

Clinical experience with the 1stQ AddOn® IOLs show that these supplementary IOLs, which use the same EPS technology as the Liberty trifocal IOL, are well-designed to provide safe and effective presbyopia correction in patients previously implanted with a monofocal IOL, agree surgeons who have used the technology.

Translating Features Into Benefits

The hydrophilic material used for the 1stQ AddOn® has proven uveal biocompatibility to avoid inflammatory reactions and also a high Abbe number (low chromatic aberration) that confers high image quality. Its four flexible haptics and concave – convex optic design provide good fixation and a stable sulcus fit for protection against endothelial damage, iris chafing, and iris pigment release. Long-term rotational stability is assured by the implants anti-torque design. (Fig.11)

“Findings from a study that we conducted in pseudophakic cadaver eyes confirms that there is good clearance between the 1stQ AddOn® IOL and the primary pseudophakic lens3” said Sathish Srinivasan FRCS(Ed), FRCOphth, FACS, University Hospital Ayr, Ayr Scotland.

Clinical Perspectives

“Based on the reliable stability of the 1stQ AddOn® Lens, I use it often in clinical practice for increasing my options for refractive upgrades or correction,” said Prof Srinivasan. The opportunity for creating a dual-lens system with the 1stQ AddOn lens enables me to increase the size of my satisfied patient pool.”

Dr Erik L. Mertens said that “the 1stQ AddOn® IOL allows him to bring patients into their visual comfort zone. Some cataract surgery patients who have a monofocal IOL implanted will tell me they did not realise how handicapped they would be in daily life when performing tasks involving near and intermediate vision,” said Dr Mertens, CEO and Medical Director, Medipolis Antwerp Health Centre, Antwerp, Belgium.

“Using the 1stQ AddOn® IOLs helps me to have more happy patients. Implanting the 1stQ AddOn® Lens is also much easier than performing IOL exchange, especially if the patient has already had YAG laser capsulotomy. The ease of handling and implantation also minimises risk of iatrogenic trauma and endothelial cell loss.”

...they did not realise how handicapped they would be in daily life when performing tasks involving near and intermediate vision
or diabetic retinopathy, are also not appropriate candidates for the 1stQ AddOn®. "It is not a problem, however, if a patient develops one of these pathologies later in life because the 1stQ AddOn® can be easily explanted," Dr Mertens said. The 1stQ AddOn® can be inserted through a 2.2mm self-sealing clear cornea incision. Offering a few tips, the surgeons said to take care not to apply downward force on the primary IOL in an eye that has undergone YAG laser capsulotomy. To avoid postoperative IOP spikes, the 1stQ AddOn® Lens should be lifted at the end of the case to enable complete removal of viscoelastic from the interface.

Positive Outcomes

Prof Srinivasan reviewed results achieved by Prof C Palomino Bautista MD, Head, Department of Ophthalmology, Quirón University Hospital, Madrid, Spain, using the 1stQ AddOn® IOL in 16 eyes that had a monofocal IOL.

Data collected at six months demonstrated the safety, predictability, and efficacy of the procedure. Mean sphere, cylinder, and spherical equivalent were -0.32 ± 0.18D, -0.61 ± 0.21D, and -0.015 ±0.09D, respectively. Mean uncorrected logMAR VA at far, intermediate, and near were 0.02 ±0.08, 0.22 ±0.12, and 0.14 ±0.06, respectively. Defocus curve measurements showed mean logMAR VA was ≥0.22 over the range from -3.0 to +0.5D.

"The defocus curves showed nice peaks for near and distance along with a broad flat zone of good intermediate vision (Fig.12). The defocus curve was similar to that seen with Liberty trifocal IOL," Prof Srinivasan said.

Measurements obtained with specular microscopy showed minimal change in endothelial cell density (ECD). Mean ECD was 2200 ± 55 cells/mm² preoperatively and 2024 ±96.3 cells/mm² at six months after 1stQ AddOn® Lens implantation.

"Preservation of endothelial cell function is an important concern when implanting an 1stQ AddOn® Lens in the ciliary sulcus. The anterior chamber depth measured from the corneal endothelium to the anterior surface of the lens should be at least 2.8mm. Most eyes meet that threshold," said Prof Srinivasan.

Imaging with anterior segment OCT showed the angle structure was unchanged, and with biomicroscopy the 1stQ AddOn® Lens was seen to be stable in the sulcus. None of the patients required a peripheral iridotomy or iridectomy, and IOP was not increased.

"There is no change to the iris configuration after implantation of the 1stQ AddOn® Lens because of its convex-concave optic, and the stability of IOP is also no surprise considering the IOL's design," Prof Srinivasan said. (Fig.13)

Response to a questionnaire for evaluating satisfaction and functional performance showed that all patients were generally satisfied.

References

5. Fernández J, Rodríguez-Vallejo M, Martínez J, Burguera N, Piñero DP. Prediction of visual acuity and contrast sensitivity from optical simulations with multifocal intraocular lenses. J Refract Surg. 2019; Accepted for publication
9. Palomino Bautista C. Long term experience with the 1stQ AddOn supplementary IOL. ESCRs (free paper), Paris 2019
A special thank you to our valued scientific partners for sharing their long-term clinical data and experiences with our Liberty trifocal IOL and the 1stQ AddOn lens.

M. Assouline, MD, PhD (France)
J. Fernández, MD, PhD (Spain)
J. Győry, MD (Hungary)
E. Mertens, MD, FEBOpht (Belgium)
Z.Z. Nagy, MD, PhD, Med Habil, DSc. (Hungary)
C. Palomino Bautista, MD, FEBO (Spain)
S. Srinivasan, FRCS(Ed), FRCOphth, FACS (UK)