



Trifocal Intraocular Lenses for Presbyopes

WRITERS **Clinical Associate Professor Michael Lawless and Dr. Rick Wolfe**

New trifocal intraocular lenses (IOLs) are delivering excellent visual results at different distances.

The importance of near, intermediate and distance vision in modern society cannot be under-estimated, particularly in the face of an ageing population with a rising prevalence of presbyopia. Several studies have reported that the loss of reading skills, for instance, can reduce a presbyopic patient’s quality of life. Poor intermediate vision can impact many professional and domestic tasks, especially the use of computers.

Progressive spectacles and contact lenses are examples of nonsurgical procedures used to correct for presbyopia. Surgical methods used to correct presbyopia include scleral expansion and sclerotomy, corneal procedures (presbyopic laser in situ keratomileusis), corneal inlays, conductive keratoplasty, monovision, and multifocal intraocular lenses (IOLs).

Classic multifocal IOLs are bifocal. They are dependent on two focal points, representing far and near working distances, at which they produce a sharp image on the retina. However because the intermediate viewing distance falls between these two focal points, patients fitted with these IOLs typically require spectacles for purposes such as computer use.

Lens designers have now introduced a third focal point in the IOL optic aimed at providing better visual acuity at the intermediate distance while maintaining good far and near vision. Results from four studies have been promising.

COMPARISON OF DIFFRACTIVE BIFOCAL AND TRIFOCAL INTRAOCULAR LENSES

One study¹ lead by Czech Republic’s Dr. Peter Mojzis compared a Carl Zeiss diffractive bifocal (AT LISA 801) with a Carl Zeiss trifocal intraocular lens (AT LISA tri 839 MP). Both lenses were made from the same material and haptic design.

Sixty eyes of 30 patients with cataract or presbyopia / pre-presbyopia participated in this prospective comparative study, with each eye randomly assigned to one type of implant. The same type of IOL was implanted in both eyes of each patient and visual, refractive, contrast sensitivity and aberrometric outcomes were evaluated.

The study found that significantly better intermediate vision was experienced by

“The use of three foci provided significant intermediate visual results without sacrificing near or distance vision”

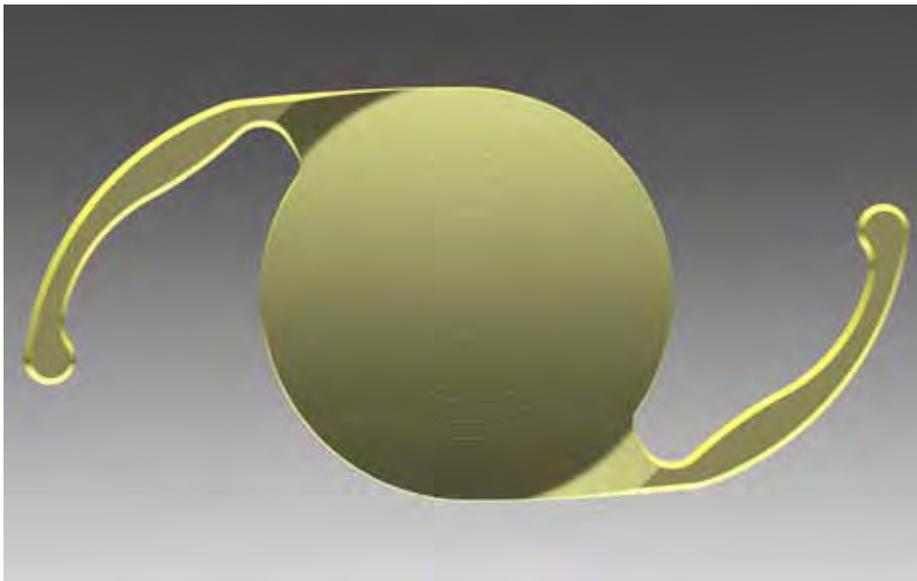
those implanted with trifocal diffractive IOLs, with equivalent postoperative levels of visual and ocular optical quality across both groups. The study authors wrote, “the trifocal IOL seems to be a better option over the bifocal diffractive IOL in terms of visual outcome. The generation of a third focal point with a diffractive trifocal design does not imply a detriment in the distance and near visual acuity or in the visual and ocular optical quality.”

BEHAVIOUR OF AT LISA TRI 839 MP IOL

Another study² by Dr. Mojzis analysed the behaviour of the Carl Zeiss trifocal intraocular lens AT LISA tri 839 MP when implanted post cataract surgery. The study evaluated results obtained for distance, intermediate, and near visual acuity. Defocus, contrast sensitivity curves and quality of vision were also analysed and surgical complications evaluated.

Sixty eyes of 30 patients (mean age 57.9 years \pm 7.8 [SD]; range 42 to 76 years) had bilateral refractive lens exchange and multifocal diffractive IOL (AT Lisa tri 839 MP) implantation. At a six-month follow up, researchers observed statistically significant improvement in uncorrected distance visual acuity (UDVA); uncorrected intermediate visual acuity (UIVA), uncorrected near visual acuity (UNVA), corrected distance visual acuity, and distance-corrected intermediate and near visual acuity.

They reported that the postoperative refractive status was within the range of +1.00 to -1.00 diopter. Total internal aberrations decreased significantly (P<.001). There were no serious



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complications recorded at the follow-up and patients reported that “the final result, as a whole, was excellent or very good”. All reported they were comfortable performing intermediate-distance tasks. Although 10 per cent of patients reported severe halos during the follow-up, they also reported a significant improvement over time.

The researchers concluded that, “The trifocal IOL improved near, intermediate, and distance vision in presbyopic patients. The use of three foci provided significant intermediate visual results without sacrificing near or distance vision”.

LISA TRI 839 MP IOL VS. A FINEVISION MICRO IOL

Another study³ compared phacoemulsification with bilateral implantation of the AT LISA tri 839 MP IOL with that of a Finevision Micro IOL. Each group comprised 30 eyes from 15 patients.

The lenses were described in the article as follows:

“The Finevision Micro F is a single-piece aspheric trifocal IOL of hydrophilic acrylic material with a 25 per cent water content at the equilibrium and a blue- and

ultraviolet-light filter. It is compatible with microincision cataract surgery (incision size 1.8 mm). The total diameter is 10.75 mm and the optic diameter, 6.15 mm. The haptic angulation is 5 degrees. The available powers are between C10.00 D and C35.00 D in 0.50 D increments. The addition (add) powers at the IOL plane are C3.50 D for near vision and C1.75 D for intermediate distance. The optic is apodized and designed to increase the distance vision dominance with increasing pupil size. The light-energy distribution for a 20.0 D IOL and a 3.0 mm pupil diameter is 42 per cent, 29 per cent, and 15 per cent for distance, near, and intermediate vision, respectively.

“The AT Lisa tri 839 MP is a single-piece aspheric trifocal IOL of hydrophilic acrylic material (25 per cent) with a hydrophobic surface. It is compatible with injection through a 1.8 mm incision. The total diameter is 11.0 mm and the optic diameter, 6.0 mm. The haptic angulation is 0 degrees. The available powers are 0.00 to C32.00 D in 0.50 D increments. The add powers are C3.33 D for near and C1.66 D for intermediate vision. The light distribution is 50 per cent, 20 per cent, and 30 per cent for distance, intermediate, and near foci, respectively.”

Led by Dr. Eduardo Marques in two clinical centres; Lisbon and Portugal, this prospective comparative case-series study determined that both trifocal IOL models provided excellent distance, intermediate and near visual outcomes; although monocular distance corrected intermediate visual acuity and distance corrected near visual acuity appeared slightly better in the patients who received the Finevision Micro F IOL. They wrote that predictability of the refractive results and optical performance were excellent, and similar between the two IOLs and that all patients achieved spectacle independence.

PATIENT SURVEY OF TRIFOCAL FINEVISION IOL

The final results from a pilot observational study⁴ of 198 eyes of 99 patients also demonstrated that the trifocal Finevision IOL was safe to implant and able to restore near, intermediate and distance visual function under both photopic and (to a lower extent) mesopic lighting conditions. Patients enrolled in this study were scheduled to undergo cataract surgery, had expressed a desire to be spectacle independent and had a corneal astigmatism of less than 1.75 D and no ocular comorbidity.

This was the largest group of patients to use the novel trifocal IOL and the first study to report on patients' subjective outcomes with the Finevision IOL one year post-surgery. The researchers noted that less than half of the 99 patients participated in the follow up survey, “probably due to the absence of comorbidity, which does not motivate patients to return for follow-up visits”.

Of those who attended the one-year follow up, 31 per cent reported some symptoms of glare, 40 per cent reported ghost images; 49 per cent reporting halos and 80 per cent reporting problems with night driving.

Post-operatively 4 per cent required spectacle correction for distance and intermediate vision; 20 per cent needed reading glasses to read small characters and 7 per cent needed reading glasses for the newspaper. When asked whether they would undergo implantation of the FineVision IOL again, 98 per cent answered ‘yes’.

Based on these results, the researchers concluded that “the FineVision IOL provides patients with near, intermediate, and distance vision with a reduced need for spectacle correction and fewer reports of visual disturbances.”

Comment



**Clinical Associate
Prof. Michael Lawless**

2015 has seen, and will continue to see, the introduction of intraocular lenses not previously available in Australia. Specifically these four articles in *mivision* examine the efficacy of two different trifocal intraocular lenses. The LISA tri839 from Carl Zeiss has been available in Australia for some time and ophthalmologists have had ample opportunity to explore the use of this lens.

The study by Mojzis specifically compares the Carl Zeiss bifocal (AT LISA 801) with the Carl Zeiss trifocal (AT LISA tri839). This is a good comparison as both lenses are made from the same material and have the same haptic design. Not unexpectedly, the better intermediate vision was obtained with the trifocal version, but with equivalence in other measured parameters. Not unreasonably, the authors suggest that given the improved intermediate with no observable untoward effects, why would we not use this trifocal design?

Mojzis, in a further study using the Carl Zeiss AT LISA tri829 implanted bilaterally, found good functional vision at near, intermediate and distance. Ten per cent of this cohort did report severe halos during the follow-up, although the authors mentioned this improved over time. So, the trifocal designs are likely to improve the range of vision and functionality... patients will be grateful for this but the jury is out on whether it will have an impact for good or bad on the troublesome photic phenomena, well known with multifocal intraocular lenses.

INTERMEDIATE VISION

Good intermediate vision is increasingly important in a world that has moved from printed spreadsheets to mobile devices and tablets.

The new lens available in 2015 is the FineVision micro-IOL and Marques' study compared this lens with the LISA tri839. They found no real difference in the visual results but there was a suggestion that the FineVision was slightly better in unaided near acuity although this was not significant.

A reality check occurs in the last paper by Cochener et al, which looks specifically at the FineVision trifocal intraocular lens. It is hard to make comment on a paper where less than half of the 99 patients participated in follow-up but of those that

did attend follow-up at one year, 31 per cent had glare symptoms; 40 per cent ghosting images; 49 per cent reported halos and an alarming 80 per cent reported problems with night driving. Bizarrely, when asked whether they would undergo implantation of the FineVision intraocular lens again, 98 per cent answered "yes". Further work is required to tease out the significance of these reported unwanted side effects.

What to make of this? Well, go back a step and realise that modern multifocal intraocular lenses have been available in Australia for well over a decade. They have undergone some iteration e.g. the Alcon ReSTOR began with a high powered add, the equivalent of +4.0, which was reduced in the subsequent versions to a +3.0 and more recently, the addition of a +2.5. Surgeons quickly abandoned the +4.0 version as the near range was too close and the unwanted photic phenomenon too troublesome. The +3.0 version was clearly an improvement in visual quality and had a more acceptable range of vision. Bringing out the +2.5 gave some surgeons a comfort level because this was almost a mini-multifocal, with a modest multifocal capability. That meant patients who were more demanding and did not want to have unwanted photic phenomenon could have the lens implanted bilaterally and achieve better intermediate vision than they would with a standard monofocal lens, although they would almost always require reading glasses to some extent. The iterated Alcon ReSTOR extended the options available and this lens has been readily accepted in Australia, even among surgeons who would normally not have used a multifocal lens in the past.

Alcon is releasing the PanOptix trifocal version in Australia, which will be their answer to the Zeiss and FineVision trifocal. The PanOptix received its European CE mark in June 2015 and TGA registration in Australia has also just been obtained.

In 2015 surgeons have the opportunity to explore and consider for their patients

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three versions of a trifocal design. It will be interesting to see whether this shifts the percentage of multifocal lenses beyond the 6 per cent where it has sat for some time i.e. in 6 per cent of cataract procedures done in Australia a multifocal intraocular lens of some type is used. This percentage has remained fairly constant for the last few years – although there has been some movement as different versions have become available, the total number of multifocal lenses as a percentage of all lenses implanted has remained fairly steady, reflecting a number of things. Firstly, many surgeons would never consider a multifocal intraocular lens either because they had prior bad experience years ago or they just do not see that it adds value for their particular patients. Some ophthalmologists will consider a multifocal lens in very specific circumstances and other ophthalmologists, with perhaps more refractive type practices, are more willing to offer these to patients.

THE GOLDEN RULE APPLIES

The golden rule still applies though. Any type of multifocal lens, whether it be a newer version trifocal or the bifocal type, needs everything to be right to work well. By that, I mean the tear volume and quality have to be normal with no significant dry eye or unstable tear film; and the biometry and intraocular lens power selection must be accurate. You need a mechanism for dealing with astigmatism, generally within the toric version of these intraocular lenses; you have to pay attention to the posterior capsule and you need to make sure that the macular function is healthy. Anything that can decrease the quality of vision from the front, middle or the back of the eye, needs to be addressed before surgery if possible. If it cannot be addressed then these patients should probably not be offered a multifocal intraocular lens.

If issues arise post-operatively such as residual refractive error, in particular small amounts of astigmatism, mild

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PCO or ocular surface problems related to the post-operative recovery, these have to be addressed aggressively in order to have a happy patient outcome. These are demanding lenses, that are often most appealing to demanding patients and require much more work on the part of the ophthalmologist and his or her team when dealing with patients. The rare possibility of needing to exchange a lens also needs to be part of the preoperative counselling.

AN INTERESTING FUTURE

If we think this has been an interesting year with new trifocal intraocular lens options for ophthalmologists, optometrists and their patients, the next few years are going to be even more interesting. With lenses such as the light adjustable lens where the intraocular lens power can be modified post-operatively in a relatively non-invasive way; the coming availability of extended depth of focus lenses as an alternative to

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mini monovision and finally, lenses such as the ClarVista-Harmoni lens. This lens has a removable optic so that it can be adjusted post-operatively, for alterations through

the patient's life to adjust for refractive error, toricity, multifocality or indeed, to accommodate new lens designs as they become available.

It is going to be a most interesting period and we need as always with new technology to sit back and consider are they safe and effective in a way that they can reasonably be offered to patients when there are good alternatives already.

Clinical Associate Professor Michael Lawless is one of Australia's most experienced vision correction surgeons. He has been involved in laser eye surgery for many decades, performing the first LASIK procedure in Sydney. He is the first eye surgeon in the Southern Hemisphere to perform laser cataract surgery. Clinical Associate Professor Michael Lawless practices at Vision Eye Institute in Chatswood, Sydney.

Associate Clinical Professor Michael Lawless is to be involved in a trial of the Alcon PanOptix IOL.

Comment



Dr. Rick Wolfe

Dr. Lawless, in his excellent editorial, points to the need these days for good intermediate vision to see computers and hand-held devices. Trifocal IOLs have the ability to reliably provide total spectacle independence – not so reliably provided by any other means – by ensuring reading vision and vision at 60–80 cm. The papers presented detailed visual outcomes of implantation as well as negative effects of these lenses.

Bifocal IOLs work well, but there are few patients these days who don't want intermediate vision as well as reading vision. Low add multifocals, such as ReSTOR +2.5 (Alcon) and Symphony (Abbott), whilst giving improved depth of focus with minimal photic symptoms, are poor choices when we are aiming for spectacle independence.

In all four papers¹⁻⁴ implantation of trifocal IOLs results in excellent uncorrected distance, intermediate and near visual acuities. Mojis¹ demonstrates the trifocal superiority with LogMAR distance corrected intermediate visual acuity (DCIVA) for the bifocal and trifocal IOL at 0.25 (±0.15) and 0.03 (± 0.08) respectively. The defocus curve contrasts the two IOLs with maintenance of good vision from 0.00D defocus to -2.50D defocus for the

trifocal, but a dip in the curve with the bifocal, where vision at 60–80 cm, is mostly inadequate.

PATIENT SATISFACTION NOT OBVIOUS

What is not obvious from the data is the remarkable patient satisfaction a surgeon sees after implantation of a trifocal IOL. The ideal patient for a trifocal IOL is one who wants total spectacle independence. Low hyperopic presbyopes are ideal patients whether they have cataract or not.

Several factors prevent many surgeons from adopting multifocal, and in particular trifocal IOLs. Mostly they point to the high rate of photic symptoms; in particular they point to night halos and glare. They also point to the concern over lower contrast sensitivity. Just how bad are these problems really?

In fact contrast sensitivity was normal for healthy phakic individuals aged 55–70 years in all papers that tested it.¹⁻³ That multifocals always cause reduced contrast sensitivity, and this loss correlates to particular symptoms, is a myth in my view. It is repeated in the literature but never referenced. The only study⁵ I know of that measures contrast sensitivity before and after healthy lens extraction in hyperopes showed no change. What is true is that, in comparison to monofocal IOLs, there is statistically less contrast sensitivity at high spatial frequency⁷ but still generally within normal range. Having said that I have seen one patient who had a significant reduction in contrast sensitivity at 18cpd only and noted what were probably related symptoms. It required explanation. This is one case in 10 years and is certainly not the rule.

The incidence and severity of halos will depend upon the question asked. The

interpretation of the result however is not really easy without a monofocal control. A Cochrane Review⁶ looking at differences between multi and monofocal IOLs found BCVA the same but halos were twice as common in multifocals. Interestingly the review could come to no conclusion about glare in multifocals, as glare was always included with halos in papers reviewed. Glare means different things to different people anyway.

Marques³ reported one patient (6.7 per cent) with an AT Lisa Tri with “considerable trouble” with glare and halos, but none with “overwhelming trouble”. A similar study⁶ of ReSTOR +3.0 by the same group had only one patient (2.6 per cent) with “considerable trouble” or worse for halos, but average scores for halos and starburst were worse than for the trifocals. I am uncertain how to interpret these findings, but at least trifocals are unlikely to be worse than bifocals in this regard. The surgeon must tell the patient that halos are very likely. In 10 years of implanting multifocal IOLs I have not had a single patient I have explanted for night halos! I put this down to patient selection and patient information.

Cochner,⁴ in 60 of the original 99 patients found: “Thirty-one percent of patients reported that they had some symptoms of glare, with 40 per cent reporting ghost images, 49 per cent reporting halos, and 80 per cent reporting problems with night driving”. Dr. Lawless thought it bizarre that in this cohort, though many were apparently unhappy, only one patient would not have the procedure all over again. It should be remembered these patients are in the half that returned for review and possibly have, in their numbers,

the worse patients. There is no monofocal control and but for one patient, all these fell into the “minimal” or “annoying” categories. It is also known these symptoms lessen with time. Satisfaction is usual even with mild to moderate photic phenomena.

“The Happy Patient Study”⁸ addressed patient satisfaction. It found in a study of 183 patients implanted with a variety of multifocal IOLs that: “Overall satisfaction with the procedure was correlated to low astigmatism, good visual function, low spectacle dependence, and less halos or glare. The personality characteristics of compulsive checking, orderliness, competence, and dutifulness were statistically significantly correlated to subjective disturbance by glare and halos”.

ATTENTION TO SPHEROCYLINDRICAL OUTCOMES

I agree the golden rule is that everything has to be in place for a multifocal to work well, with no ocular pathology, including dry eye, which might affect results. Also great attention to spherocylindrical outcomes is required. With the best IOL prediction protocol, refractive errors of say 0.75D of cylinder will still result and will reduce spectacle independence and satisfaction. It is not enough to say to the patient it is too bad it didn't work because of their residual astigmatism, but rather laser refractive surgery must be offered. This requirement puts off many surgeons. Multifocal IOLs are well established. If a patient desires spectacle independence and is suitable for one, referral to a surgeon skilled in their use is appropriate.

The future is of continued improvement. Alcon's PanOptix will bring the ACRYSoF platform to trifocals. Like the FineVision it has a blue-violet filter. The risk of advancing AMD by cataract surgery has been suggested and good evidence⁹ is accumulating that a blue-violet filter in an IOL slows age related macular degeneration progression with reference to a standard IOL.

“Overall satisfaction with the procedure was correlated to low astigmatism, good visual function, low spectacle dependence, and less halos or glare”

This is of additional importance as many trifocal recipients will be hyperopic presbyopes in their early fifties. I think their possible four decades of blue light risk mandates an IOL with a filter. The promise of the accommodative IOL providing spectacle independence seems further off than ever with such modest success over many years.

Dr. Rick Wolfe MB BS FRACS FRANZCO is one of Australia's most experienced cataract and refractive surgeons. He has performed more than 10,000 cataract procedures and over 17,000 LASIK procedures during the past 25 years while practising as an ophthalmic surgeon. Dr. Wolfe has given more than 20 years service to the Royal Australian Navy Reserve, where he holds the rank of Lieutenant Commander. In 2004 he performed live laser surgery in front of 2,000 of his colleagues at The American Society of Cataract and Refractive Surgeons (ASCRS) in San Diego. Dr. Wolfe regularly speaks at conferences, including ASCRS, AUSCRS (Australasian Society of Cataract and Refractive Surgeons) and Alcon in Hong Kong. His private practice at Peninsula Eye Centre, Mornington, Victoria and his laser eye surgery practice at VISTAeyes Elsternwick Victoria is limited to cataract and refractive surgery.

Dr. Rick Wolfe is a paid speaker for Alcon and Bausch+Lomb. He is an investigator for AcuFocus.

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IOL Lens Design

The four types of IOLs currently available are: refractive, diffractive, refractive-diffractive, and accommodating.

Refractive design is based on light rays shifting in direction as they are transmitted through materials, due to the material thickness, curvature, and optical density. The main disadvantage of refractive multifocal IOLs is their pupil dependence.³

Diffractive design is based on light scattering in different directions as it encounters an edge in the material.

Diffractive IOLs have been shown to result in good distance and near visual acuities. Dependence on spectacles is reduced when compared with monofocal IOLs. Additionally patients fitted with diffractive IOLs experience better optical quality, better contrast sensitivity, and less photic phenomena than those fitted with refractive IOLs. The main disadvantage of diffractive designs is loss of energy.

In recent years, achieving spectacle independence has become an objective of cataract surgery. Multifocal intraocular lenses (IOLs) have different depth-of focus capabilities within the optical zone and are an effective way of achieving good visual acuity for far, intermediate, and near distances with spectacle independence.

Great variability in uncorrected intermediate visual acuity (UIVA) associated with different commercial IOLs, along with a growing presbyopic population has inspired the development of diffractive trifocal intraocular lenses.

Eduardo F. Marques, MD, Tiago B. Ferreira, MD. Comparison of visual outcomes of two diffractive trifocal intraocular lenses. *Journal of Cataract Refractive Surgery* 2015; 41:354-363