

KEYS

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Success



WITH TODAY'S



PRESBYOPIA

and

Toric Lenses

TECHNOLOGIES



Assessing baseline trends and shifts in the treatment of refractive surgery patients

Oliver Findl MD, PhD – oliver@findl.at

Chief of the Institute and Department of Ophthalmology, Hanusch Hospital, Vienna, Austria

Conducted for the sixth time at the 39th Congress of the European Society of Cataract and Refractive Surgeons (ESCRS), the 2020 ESCRS Clinical Trends Survey comprised 145 questions and received responses from nearly 400 doctors.

In terms of trends in the use of intraocular lenses (IOLs) in routine practice, survey responses suggested that implantation of presbyopia-correcting IOLs during cataract surgery has remained stable over the past five years. However, in the same period, the use of toric IOLs during cataract procedures has doubled from 7% to 14% (Figure 1). Interestingly, survey respondents reported that if ‘cost were not an issue’, 38% of patients with clinically significant astigmatism would receive a toric IOL. In regions where reimbursement is available for toric IOLs, such as Australia, the reported use of these lenses is much greater (60–70%).

Trifocal IOLs remain the most frequent lens choice in managing presbyopia, with over half of respondents using them in the majority of their appropriate patients (Figure 2). In the past two years, the popularity of extended depth-of-focus IOLs has increased, from 20% to 32%, and it will be interesting to see if this trend continues.

Doctors and their patients must assess the potential benefits and limitations with any IOL-implanting procedure. The most common concerns associated with presbyopia-correcting procedures were the ‘cost to the patient’ (65% of respondents), the ‘quality of night-time vision’ (52%) and the potential ‘loss of contrast visual acuity’ (39%). These concerns could lead to the procedure not being performed.

In routine practice, optical biometry and corneal tomography were the primary preoperative measurements used to evaluate astigmatism; since 2019 the use of optical biometry has

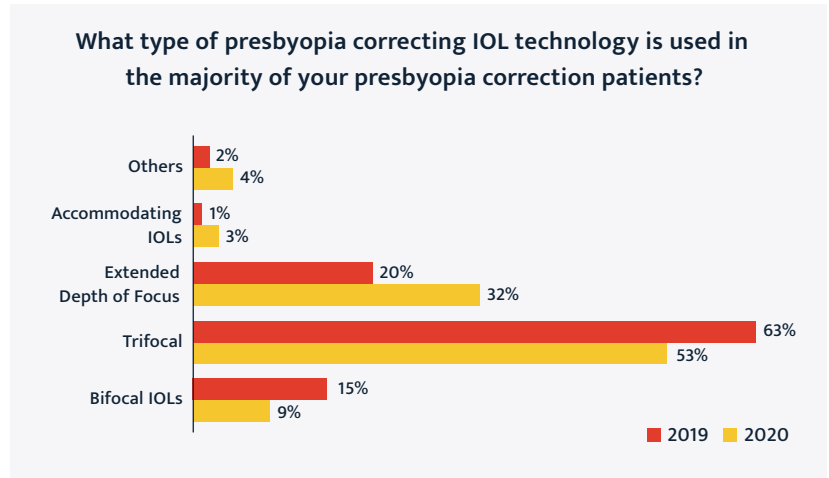


Figure 2. Reported use of IOL type from 2019–2020 for patients requiring presbyopia correction¹

“Trifocal IOLs remain the most frequent lens choice in managing presbyopia”

increased by 12%, and the use of tomography by 6%. Over the same period topography and optical coherence tomography (OCT) were only used in 35% and 17% of preoperative measurements for astigmatism.

For doctors who were implanting toric IOLs, 45% believed that more than 5 degrees of postoperative rotational error was acceptable before degradation of visual acuity and visual quality occurred. The slight majority (55%) would ideally only accept a rotational error of less than 5 degrees.

The 2020 ESCRS Clinical Trends Survey results will be available at forum.escrs.org this autumn. The ESCRS looks forward to conducting the seventh Clinical Trends Survey at the 39th annual meeting, later in 2021.

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Author financial disclosures:
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What percentage of your CURRENT cataract procedures involve presbyopia correcting or toric IOLs in qualified patients?

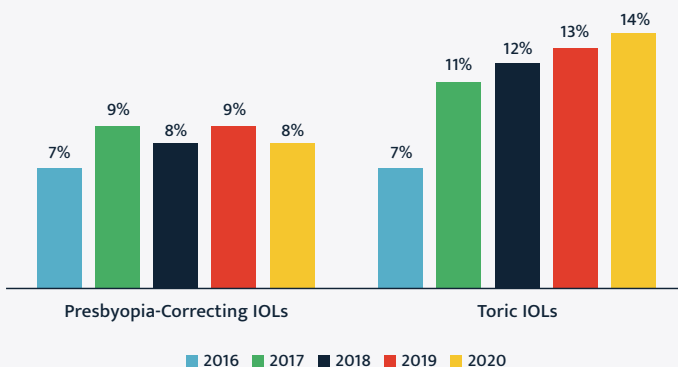


Figure 1. Reported average of presbyopia-correcting IOLs and toric IOLs from 2016–2020¹



The importance of functional and intermediate vision

Filomena Ribeiro MD, PhD, FEBO – filomenajribeiro@gmail.com

Head of Ophthalmology Department, Hospital da Luz, Lisbon, Portugal. Professor at University of Lisbon, Portugal

In essence, cataract surgery is performed to restore the principal function of the eye: the ability to see.

In recent years, cataract procedures have seen major developments that provide benefits beyond the restoration of basic sight, and now astigmatism correction and relatively small residual refractive error are routinely achieved. These visual outcomes can be accurately predicted, following advances in optical biometry and intraocular lens (IOL) power calculation. It might be considered that in modern practice, it is no longer an option to correct presbyopia, but a mandatory step in improving visual outcomes.

Beyond the measurements of visual acuity, when assessing IOL options with the patient, optimal outcomes must consider several dimensions: visual function, quality of vision, the degree of functional vision in every-day life, and how these factors combine to improve a patient's quality of life.



Figure 3. Intermediate vision is important in a patient's overall functional vision, which affects many aspects of daily life and overall quality of life

Interaction with the daily environment is key to patients' post-surgery experience, and the ultimate goal of cataract procedures should be to improve performance in daily life and work activities. Critical to achieving this goal is to look beyond only near and far vision

outcomes, and consider the change in intermediate vision, which is of growing relevance considering modern lifestyles, increasing periods of active years, and an ageing workforce.

Functional vision is therefore the most relevant post-surgery outcome for patients, and should be assessed pre-surgery, to determine outcome goals, and post-surgery, to measure treatment success. Physicians should discuss real-life aspects of functional vision including: walking on uneven ground or stairs,

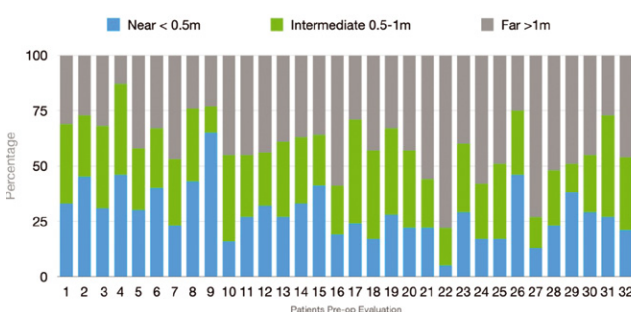


Figure 4. Vision needs in patients at pre-cataract procedure evaluation (proportion of distance viewing over 3 days, n=32)

“ The maintenance of the functional ability must be the main indicator for cataract surgery...”

cooking, driving, shopping and computer use, to understand the impact of intermediate vision on the patient's quality of life (Figure 3). The 'Catquest-9SF QoL' questionnaire is a useful tool in assessing intermediate vision, and it would be desirable to have more questionnaires focusing on this aspect of sight in both clinical trials and routine practice.

Analysis of recent data (n=32; 53% female) from the Vivior Monitor register, which captures real-world vision use by patients, suggests that 30% of daily vision needs fall into the intermediate vision category (average data collection of 10 hours per day over three days; Figure 4). Furthermore, 30% of daily work was conducted in low-light conditions, which should inform the choice of IOL to reduce the risk of night-time dysphotopsia.

In practice, following surgery with corrective monofocal IOLs, patients are generally less satisfied with their intermediate vision outcomes than they are with their near and far vision.¹ Several new IOL technologies are in development or have recently launched in some markets, that aim to improve intermediate vision, and therefore functional vision.

These updates on the importance of understanding and assessing the multi-dimensional aspects of functional vision have been published by the ESCRS Functional Vision Working Group. Key findings included:²

- Functional ability must be the main outcome for cataract surgery and, also, the main reason for performing the intervention.
- There is a need to conjugate objective and subjective outcome data.
 - Questionnaires in current use assess intermediate vision to some degree, but there is room to improve.
- Patient-reported data are key to understanding multi-dimensional outcomes.
- The concept of functional vision should help in optimising clinical procedures to promote patient satisfaction and improve quality of life.

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Enhanced monofocals: minimising dysphotopsia and maximising visual quality

Gerd U. Auffarth MD, PhD, FEBO – Gerd.Auffarth@med.uni-heidelberg.de

Chairman of the Department of Ophthalmology at the Heidelberg University Eye Hospital, Germany;
Head of the David J. Apple Center for Vision Research

Common to all intraocular lenses (IOLs), including the newest generation of developments, is the issue of night-time dysphotopsia.

Some dysphotopsia phenomena, for example halo, are attributed to the optics of an IOL. Other effects, including starburst, glare, and flare, are associated with refractive error or ocular surface diseases.

of use suggest promising improvement with minimal side effects.

In developing new IOL technology, the balance between depth of field, quality of vision and optical side effects is critical. When aberrations are reduced, quality of vision is maximised. Increased multifocality leads to decreased quality of vision and night vision dysphotopsia. Therefore, incorporating a small increase of multifocality or range minimises worsening of quality of vision and night vision symptoms.

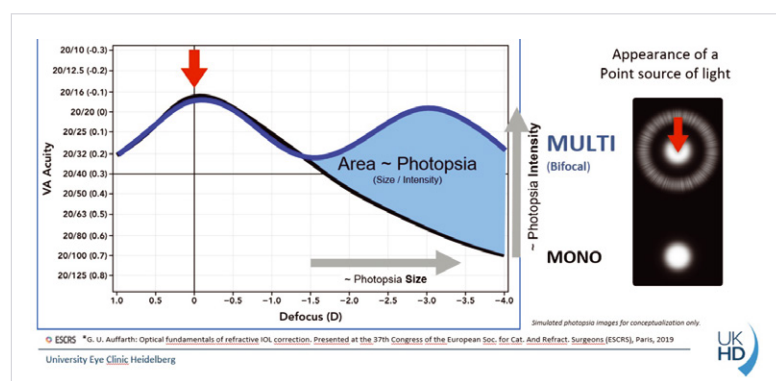


Figure 5. The size and intensity of dysphotopsia relate to depth of field and can be predicted with the area under the curve

Considering optical principles, greater levels of dysphotopsia can be expected with multifocal IOLs compared with monofocal IOLs (Figure 5). At a defocus of 0, the point of light will appear the same with a monofocal and multifocal IOL; however, at the first defocus 'valley' (1.5D, Figure 5), a black halo will form with the multifocal IOL, followed by a diffuse halo appearing with greater defocus. Photopsia size and intensity can be predicted with the visual acuity–defocus area under the curve when comparing the two lens types. In summary, depth of field and intensity of dysphotopsia are directly related.

Monofocal IOLs continue to be the most commonly implanted type of lens in cataract surgery, and they provide high quality vision and minimal incidence of photic phenomena. However, most patients still require reading glasses for focal points other than pure distance. The treatment goal with enhanced monofocal IOLs is to achieve uncorrected distance acuity and a low severity of dysphotopsia, as with normal monofocal lenses, but with improved depth of focus, more predictable refractive calculation, and, ultimately, more freedom from spectacle use – or complete spectacle independence.

There are now several enhanced monofocal IOLs available. The Eyhance™ (Johnson & Johnson Vision) lens has the same base geometry and material as a normal monofocal IOL and the associated minimal dysphotopsia effects; however, it provides power changes continuously from the centre of the lens to the periphery, and with a greater power profile. Recent studies have shown these properties correlate to significant improvements in intermediate vision versus a standard monofocal IOL, while having a similar rate of halo, glare, or starburst to the normal lens.²

Extended depth-of-field (EDOF) IOLs strike a compromise between mono- and multi-focal lenses, with an expectation of less severe dysphotopsia compared with the multifocal IOL. The Vivivity® (Alcon) is a next-generation non-diffractive lens based on Wavefront-Shaping technology, and which uses an extended focal range instead of multiple focal points. Data from 6 months

“ Enhanced monofocal IOLs aim to provide improved depth of focus compared with standard monofocal lenses, but without an increase in dysphotopsia effects”

| Dysphotopsias | | |
|---|--------------------|--------------------------------|
| ENHANCED MONOFOCAL | EDOF-ERV | TRIFOCAL |
| Older patients | All ages | All ages |
| Quality of vision | Quality of vision | Spectacle independence |
| Distance w/ some intermediate | Intermediate | Full range |
| Sedentary or Active | Active | Active |
| Frequent driving | Frequent driving | Occasional driving |
| Light PC, laptop, tablet | PC, laptop, tablet | PC, laptop, tablet, smartphone |
| Infrequent reading or okay wearing near vision spectacles | Light reading | Reading |

Figure 6. Understanding the expectations and objectives of a patients is essential to selecting an appropriate IOL and balancing the relative benefits and limitations of that lens

Another new 'monofocal plus' IOL is the LuxSmart™ (Bausch & Lomb), which creates a depth of focus by using a combination of 4th order spherical aberration and 6th order spherical aberration with the opposite side, which increases the depth of focus by 118%. With some personal positive experiences implanting this IOL, more post-surgery data from launch markets are eagerly awaited.

The ISOPURE (PhysIOL) is a premium monofocal IOL with a polynomial complex surface design across the full optic, which increases depth of focus compared with a normal monofocal IOL.

To date, this IOL appears to offer similar depth of focus benefits, with no increase in dysphotopsia effects versus standard lens, to the other enhanced monofocal IOLs.

It is important to consider for which patients this new generation of enhanced monofocal IOLs is suited. Suitable candidates might have a high demand for distance vision, significant activity using intermediate vision, an active and dynamic lifestyle and a desire for some degree of spectacle independence. Physicians are already reaching a point, with the amount of IOL options available, that patient selection has become complicated, and new developments are constantly adding to these options. Understanding a patient's objectives, lifestyle and expectations is key to deciding on a treatment path (Figure 6).



Keys to customising presbyopia IOL selection for the individual patient's needs

Francesco Carones MD – fcarones@carones.com

Medical Director and Physician CEO at Carones Vision @ Advalia, Milan, Italy

There are several ways to define the characteristics of intraocular lenses (IOLs). When considering presbyopia-correcting IOLs, it can be useful to group them by range of focus; broadly, IOLs fall into one of four groups. Single focus lenses typically provide range of focus of around 0.5D; enhanced monofocal IOLs offer up to 1.0D of range of focus; then we have increased range of focus IOLs providing up to 1.75D; and full range of focus IOLs (trifocal and hybrid lenses) that can provide more than 3.0D.

However, personalising presbyopia-correcting IOL selection is a process that begins with a mindset related to not only the surgeon, but to the practice, and specifically to the patient. The journey to selecting the appropriate IOL for a patient's needs and expectations can be divided into 13 steps across four phases (Figure 8). Of these, the third phase, where patients come into the practice in preparation for their IOL selection surgery, is key. While each practice will differ in approaches to diagnostics, the staff performing measurements and explaining available IOL products, the critical step is always providing clear information on treatment options and open discussion around expectations.

The benefits and limitations of each IOL category need to be illustrated, and these can be compared with a patient's visual behaviour data. It can be useful to share examples and outcomes from previous patients who have similar lifestyles, preferences (e.g. spectacle independence), visual needs and treatment goals.

The ophthalmologist's role at this stage is to interview the patient and assess their visual behaviour, before discussing the key

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“No single IOL meets all the needs and expectations, and there are always some compromises associated with presbyopia-correcting IOL selection”

compromises with IOL selection, particularly the balance between range of vision and quality of vision (Figure 7). It is important to reinforce that no single IOL can meet all expectations – depth of focus, quality of vision during the day or night, spectacle independence – and that compromise is necessary, after understanding the patient's priorities.

The more the physician understands the individual patient, the more accurate they can be in IOL selection. This can be challenging when the patient is visiting for the first time, or there is a short existing relationship. Key factors to explore might include: age and relative presbyopia, pre-existing refractive error, lifestyle and daily activities, status of the lens, acceptable visual compromise, cost of the procedure and any surgically associated risks.

The balance between financial cost and benefit, and the consequent value proposition to the patient must be considered as part of meeting treatment expectations. For patients choosing presbyopia-correcting IOLs, the value of spectacle independence may be a key factor, and for some patients may be of greater priority than quality of vision compromises or procedure cost.

There are several things that can aid the ophthalmologist in supporting the patient through the decision-making process. Questionnaires to assess goals

| Lens type | Range of distances | Dysphotopsia profile |
|----------------------|----------------------------------|----------------------|
| Monofocal | Distance or intermediate or near | No compromise |
| Enhanced Monofocal | Distance and useful intermediate | No compromise |
| Refractive EDOF | Distance to great intermediate | Almost no compromise |
| Diffraction EDOF | Distance to great intermediate | Some compromise |
| Diffraction Bifocal | Distance plus one distinct near | Compromise |
| Diffraction Trifocal | Distance to near | Compromise |
| Diffraction Hybrid | Distance to near | Compromise |

Figure 7. All IOLs require compromise between range of focus and quality of vision

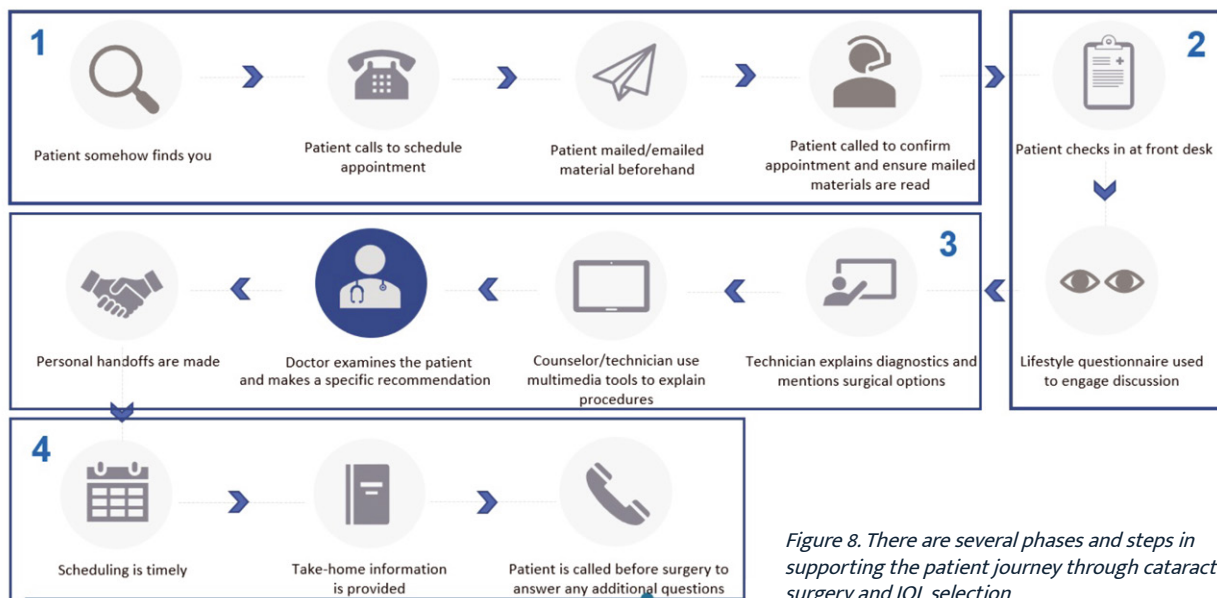


Figure 8. There are several phases and steps in supporting the patient journey through cataract surgery and IOL selection

and preferences can be useful, and interviewing the friends and relatives of some patients could be of great value. Objective vision behaviour monitoring can provide real-world insight into a patient's daily life and vision needs and provides objective data that can be discussed alongside subjective preferences.

The patient will require the ophthalmologist's expert opinion in many cases, for example where there are complicating factors (e.g. previous LASIK, or high orders of correction needed). Furthermore, it is important to identify individuals for whom presbyopia-correcting IOLs are not the most appropriate

option. For example, in patients who work or drive frequently or professionally at night, implanting any IOL that could cause or worsen dysphotopsia would not be of benefit when addressing their cataracts. In these cases, other options, such as normal monofocal lenses, should be discussed.

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Managing residual refractive error in the presbyopia IOL patient

Thomas Kohlen MD, PhD, FEBO – kohlen@em.uni-frankfurt.de

Professor and Chairman of the Department of Ophthalmology, Goethe University, Frankfurt

Multifocal intraocular lenses (IOLs) are increasingly being used to correct presbyopia. To guarantee patient satisfaction, the properties of different IOLs and patient inclusion criteria need to be understood; further appropriate patient selection needs to be performed. Optimised preoperative and postoperative management is also necessary to drive positive treatment outcomes and patient satisfaction.

The ESCRS Clinical Trends Survey assessed reports of patient dissatisfaction with vision outcomes, one-year post-operation, in those who received monofocal lenses or presbyopia-correcting IOLs (Figure 9).¹ Patients with monofocal lenses were consistently more dissatisfied than those with presbyopia-correcting IOLs, which were associated with a low reported rate (<2%) of serious dissatisfaction.

However, presbyopia-correcting IOLs are a premium-cost intervention, and patients' expectation of satisfaction with their selection is high. It is therefore important to identify potential issues and their causes in order to optimise outcomes.

There are numerous sources of postoperative dissatisfaction in patients who have received an IOL during their cataract procedure. These are both objective and subjective. Objective factors include residual refractive error, dysphotopsia, problematic near-point

focus and posterior capsule opacification. Comorbid conditions can also contribute to dissatisfaction, and examples could include corneal irregularities, Fuchs' dystrophy and retinal disease. Subjective dissatisfaction revolves primarily around unrealistic expectations that then manifest as unmet expectations; there may also be dissatisfaction during the period of neuroadaptation following the procedure.

Preoperatively, it is critical to assess the anatomy of the eye, the behaviour of the eye (for example, any ocular surface disease or dry eye), any previous LASIK treatment and to perform all necessary measurements. At this time, of course, the key factor in providing postoperative satisfaction is the preoperative discussion of expectations, goals, preferences and compromises with the patient ahead of their IOL selection.

Preparation of the ocular surface prior to cataract surgery is key to optimising outcomes, and there is support in the literature for aggressive treatment of dry eye disease prior to cataract surgery.² This is especially important, because cataract surgery can exacerbate existing dry eye disease (including subclinical disease) and can lead to poor satisfaction with treatment.

Preoperative IOL calculation also plays a key role in achieving the

desired outcome – this is usually emmetropia. Current optimised formulae, ray tracing formulae and, in the future, artificial intelligence-driven calculations should now be used over older methods.

Examining the posterior surface to determine any source of refractive error is important. Posterior surface measurements need to be incorporated in any calculations because any difference in curvature between steep and flat posterior corneal surface would have to be about 10 times greater at the posterior surface; accurate calculations are therefore pivotal in treatment outcomes and satisfaction.

Measurement of astigmatism is also critical to optimal outcome. The lens can have an impact on the astigmatism, but this will be removed, so the main consideration should be post-implantation residual astigmatism. It has been demonstrated that if astigmatism is increased from 0D to 2D, both near and distance visual acuity are compromised.³ Ideally, astigmatism should be below 0.5D.

Uncorrected axis of astigmatism correction reduces the effect of treatment, so toric IOLs need to be placed accurately on the correct axis. Management of misaligned toric lenses is best carried out after 7–14 days postoperatively and can be achieved with precise femtosecond laser treatment or even postoperative measurement of the patient.

In cases where IOL power is incorrect, glasses or contact lenses can be considered, although this will often be associated with patient dissatisfaction. Corneal refractive surgery can be used three months postoperatively to make adjustments; add-on IOLs may also be an option in some markets, and these too should be used in a three-month postoperative window.

Finally, there is the need for education and discussion around neuroadaptation, and the fact that visual cortex activity is increased three weeks postoperatively. Many unhappy patients can be bothered by the superimposed image-reduced contrast because neuroadaptation has not yet taken place.

While there are several postoperative options to address patient dissatisfaction with an IOL procedure, much can be done

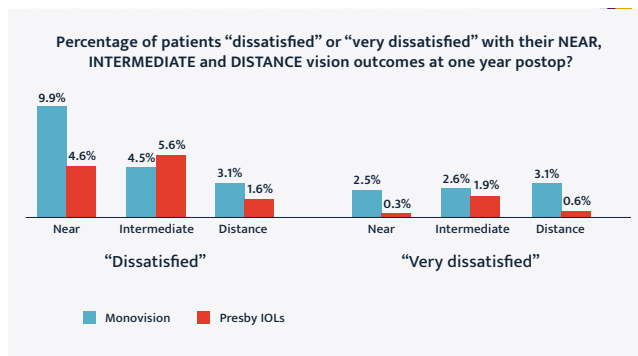


Figure 9. The rate of dissatisfaction with near vision outcomes is consistently higher in patients who received monovision lenses

preoperatively to optimise outcomes and satisfaction, including preparing the ocular surface, using modern IOL calculations and performing accurate measurements, particularly of the posterior surface and of astigmatism.

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Why we should consider refractive intraocular lenses in patients with comorbidities

Béatrice Cochener-Lamard MD, PhD – beatrice.cochener@ophthalmologie-chu29.fr

Professor and Chairman of the Ophthalmology Department at the University Hospital, Brest, France

Comorbidities are common in patients considering the implantation of a premium IOL during cataract surgery. These include ocular surface disease, corneal abnormalities, prior refractive surgery, glaucoma and patients whose retina is at risk.

Here we will examine why it is critical to address comorbid conditions, and that they will not necessarily exclude patients from being considered for refractive IOLs.

Physicians are aware of the impact of some comorbidities; the European Society of Cataract & Refractive Surgeons (ESCRS) Clinical Trends Survey 2020 revealed that 82% of respondents thought that mild-to-moderate dry eye disease would affect keratometry and IOL calculations (Figure 10). However, 22% of physicians reported that they did not routinely check the ocular surface during their preoperative examinations for cataract surgery.¹

Thorough examination of the ocular surface is essential because subclinical disease can still affect outcomes and is likely to be

“Considering ocular surface disease, it is best to: detect; pre-treat before surgery; and inform the patient. Prevention is better than cure”

exacerbated during surgery. More than half of patients are likely to have meibomian gland dysfunction (MGD) that is ‘not obvious’, but that will subsequently be revealed or aggravated by surgery.^{2,3}

How strongly do you believe that mild to moderate dry eye significantly impacts keratometry and IOL calculations?

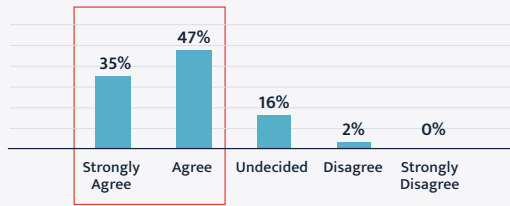


Figure 10. Most physicians recognise that ocular surface disease impacts keratometry and IOL calculations prior to cataract surgery and IOL implantation¹

Early management with lubricant and anti-inflammatory eye drops will be sufficient in most cases and suitably prepare the patient's ocular surface for IOL implantation. In patients with unresolved ocular surface disease, it may be unwise to use a multifocal IOL, and extended depth-of-focus (EDOF) or enhanced monofocal IOLs should be carefully considered. The status of tear film stability is also critical in assessing suitability of toric IOLs.

Corneal abnormalities, including opacities like pterygium, leucoma and anterior corneal dystrophy can induce irregularities, compromise the ocular surface and affect visual quality. In patients with these comorbidities, refractive IOLs should not be considered because reliable measurements, IOL calculations and determination of astigmatism for the use of toric IOLs will not be possible. Physicians should consider whether these patients are more suited to excimer laser phototherapeutic keratectomy (PTK) or keratoplasty.

Other corneal irregularities, such as keratoconus or post tissue-graft will induce coma and spherical aberration. If measurement of topography, biometry and cylinder suggest a stable condition, implantation of toric IOLs can be considered. The 'piggyback' IOL format is particularly valuable for these patients because there is an opportunity for lens exchange in the case of inadequate results. It is recommended to avoid refractive IOL implantation on an irregular cornea, although in some cases a pinhole IOL might be considered.

Endothelial dystrophy raises the question of whether a refractive IOL should be implanted during a combined surgery, or after the cataract has been resolved satisfactory first. It is important to assess pachymetry and visual fluctuations in the morning as well as cell density in the examination stage. Multifocal IOLs are not recommended because the patient needs to achieve emmetropia. A cautious approach may be to perform Descemet's membrane endothelial keratoplasty (DMEK) and then consider an EDOF or enhanced monofocal IOL.

Glaucoma may be present in around 11% of cataract patients.¹ In cases of glaucomatous neuropathy there will be pre-existing visual field defects and low contrast sensitivity, both of which will reduce intended effects of some lenses, and therefore limit the suitability of multifocal or EDOF IOLs. Enhanced monofocal and aspherical

What is your confidence in treating post-laser vision correction cataract patients?

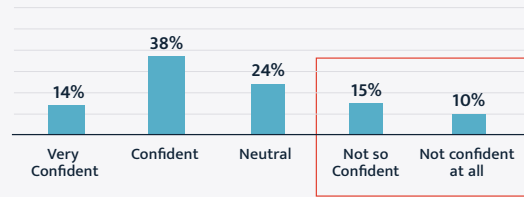


Figure 11. The 2020 ESCRS Clinical Trends Survey reports that a quarter of physicians are not confident in treating cataract patients with previous laser-corrected vision¹

IOLs can be considered in most cases, as can toric monofocal lenses if the central visual field is still normal. In patients with a controlled increase in intraocular pressure, multifocal and EDOF IOLs can be considered. However, decisions need to be made on a case-by-case basis, taking into account the potential risks, including family history of glaucoma, high degrees of ametropia and the stability of the visual field, and the benefits of IOL implantation.

Secondary glaucoma can occur post-implantation and will present a decrease in visual performance and a loss of contrast sensitivity. To date, no cases of IOL exchange have been reported, but there is a need for a longer follow up period to understand this fully.

Patients may also present with comorbid risk to the retina. No refractive IOL is indicated in the presence of retinal disease, diabetic retinopathy or age-related macular degeneration, especially if the disease is progressive or there is an abnormal optical coherence tomography (OCT) finding.

For patients with only a family risk of retinal disease, EDOF or enhanced monofocal IOL can be considered.

Finally, the 2020 ESCRS Clinical Trends Survey reported that a quarter of respondents are not confident in treating cataract patients who have had previous refractive laser treatment (Figure 11).¹ This is a difficult situation because patient expectations of treatment will be high. They have already paid for spectacle independence and their previous surgery may reduce vision quality with the implanted IOL. Extensive consultation and discussions with the patient are needed to agree on expectations before surgery.

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