

PRESBYOPIA



Astigmatism

correcting

IOLs:

*Key clinical opinions
& practice patterns*

Introduction

The objectives of the ESCRS Consensus Roundtable were to explore the current state of presbyopia- and astigmatism-correcting intraocular lenses and exchange clinical opinions and practice patterns. Discussions included the importance of correcting astigmatism in patients seeking spectacle independence, best practices in acquiring precise preoperative measurements and strategies to avoid and manage postoperative rotational or

residual refractive error, along with insight to help increase patient satisfaction with their procedure.

The 2020 ESCRS Consensus Roundtable on Refractive IOLs was comprised of the following faculty: Dr Kohnen, Dr Ribeiro, Dr Reus, Dr Srinivasan, Dr Carones and Dr Cummings. All faculty members completed multiple consensus survey questions to help assess agreement on the key issues discussed.

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Intraocular Lenses for the Correction of Presbyopia & Astigmatism

Trends in the use of premium intraocular lenses

Recent developments in intraocular lens (IOL) technology have provided physicians with the tools to address multiple refractive errors for their patients. Refractive correction with modern premium IOLs goes far beyond what was achievable with earlier implantable lenses, and management of presbyopia and astigmatism, along with increased independence from spectacles, is attainable for many patients.

Recent data from the 2019 ESCRS Clinical Survey have shown that around 9% of cataract surgeries implant a presbyopia-correcting lens, and this percentage has not changed markedly

over the past few years.¹ The ESCRS Consensus Roundtable survey reported that the faculty use presbyopia-correcting lenses more frequently, with a split between 11–20%, and over 30% of their patients (Figure 1). Overall, presbyopia-correcting IOLs are only used in a minority of patients.

The faculty suggest that side-effects of presbyopia-correcting lenses, particularly halos around lights, and dysphotopsia may limit uptake by patients. Dr Reus commented that, “There are many people in my practice who don’t want these side-effects, and they choose a monofocal lens.” The ESCRS Consensus Roundtable faculty noted that this highlights the importance of discussing available options with patients.

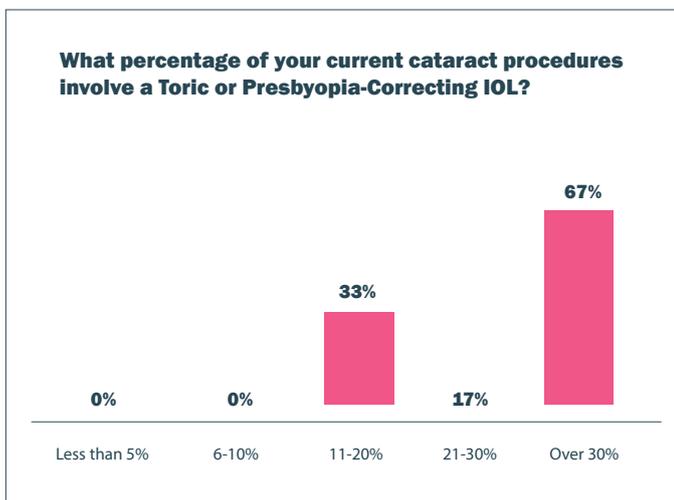


Figure 1. ESCRS Consensus Roundtable survey: Faculty use of presbyopia-correcting lenses during cataract procedures is split between 11–20%, and over 30% of their patients

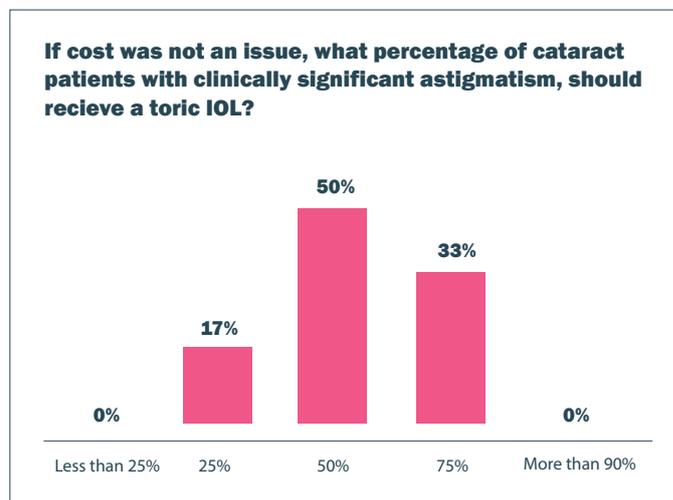


Figure 2. ESCRS Consensus Roundtable survey: If cost wasn't an issue, more patients would receive astigmatism-correcting IOLs during cataract surgery

According to the faculty, many patients will choose the lens that offers the best visual quality overall and will use reading glasses as needed, whereas some people would accept a balance between not having to use reading glasses with experiencing some dysphotopsia. Dr Kohnen questioned whether this reported use of presbyopia-correcting IOLs was too low, and asked how it might be increased. Dr Ribeiro suggested that more experience with presbyopia-correcting IOLs would encourage greater use and that uptake might mirror the increased use of toric lenses that has been observed as physicians have become more confident with them.

ESCRS Clinical Survey findings show a sharp increase in the use of toric IOLs to correct astigmatism during cataract surgery over the period 2016-2019, with implantation doubling from 7% to 14%.¹ The faculty considered that this increase was driven by several factors: relatively low associated side effects, effective pre-operative measurements and calculations, and predictable treatment outcomes. Dr Reus commented that, if astigmatism was addressed in each patient undergoing cataract surgery, implantation numbers would be much higher; however, there are several key barriers to the use of premium IOLs in routine surgery.

“ If astigmatism was addressed in each patient undergoing cataract surgery, implantation numbers would be much higher

Dr Nic Reus, MD, PhD

Limitations in the use of premium refractive IOLs

Dr Srinivasan reinforced that the major factor determining use of premium IOLs is the socioeconomic burden, with considerations both in private and public practice.

In private practice, patient expectations with premium IOLs are high and there is considerable demand on the physician to understand the attributes and comparative benefits of each product, as well as determine the surgical requirements and purchase the supporting devices to enable optimal outcomes. Dr Ribeiro commented that, “Another limiting factor is the processing of all this information and then transferring it to the patient...This is time demanding, too.”

In public practice, time and cost pressures are increased by the volume of patients and healthcare budget constraints. Dr Kohnen observed that in most cases: “It’s not that surgeons don’t want to use

premium IOLs. It’s just that the structure in which they work doesn’t allow them to invest either in technology or in the time required.”

While noting that each country has specific structures, constraints, and requirements, the ESCRS Consensus Roundtable faculty found that certain newer approaches for access to premium IOLs were proving beneficial. A shift in some countries to allow physicians to charge for premium IOLs in public practice has increased access to toric lenses for patients. Where, previously, patients faced an “all or nothing” approach to premium IOLs, systems now exist where a person will have their cataract surgery reimbursed by their national healthcare system or insurer, and then have the option to choose a premium IOL.

Dr Reus concluded that in his public practice: “I think being able to charge the patient for implanting these lenses has grown the amount of people who have now toric lenses or presbyopia-correcting lenses.” Essentially, an upcharge system ensures patients receive essential surgery and then allows additional options to suit their objectives. Dr Kohnen feels that the upcharge model could be the future of all cataract procedures: “I think, from my perspective, we have to change the whole system from normal cataract surgery to premium IOL surgery. You just have to have more personnel, time and resources, and give more information to the patient.”

The ESCRS Consensus Roundtable survey showed that, should cost become less of an issue, more of the faculty’s patients would likely receive astigmatism-correcting IOLs during cataract procedures (Figure 2). It is striking that the survey finding that 25-75% of patients would be considered for toric IOLs is markedly higher than the 14% currently receiving this treatment option.¹

Dr Srinivasan observed that: “It’s very cost effective to correct astigmatism, and the first step, even in the public system, is offering good solutions to achieve this.” This position is supported by studies suggesting a public health benefit in resolving astigmatism, particularly in avoiding a healthcare burden associated with falls.^{2,3} In older people, astigmatism is a leading factor in gait change and foot placement; astigmatic corrections may reduce the risk of falling.² Such findings may lend support to development of upcharge models for premium IOLs in public practice.

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3. Kim SY, et al. Changes in falling risk depending on induced axis directions of astigmatism on static posture. *J Phys Ther Sci*. 2015;27:1971–3

Patient Selection & Preoperative Measurements

Selecting the most appropriate intraocular lens for a patient

The ESCRS Consensus Roundtable faculty unanimously agreed that the preferences and objectives of the patient should be central to discussions around selection of an IOL. It was noted that in some countries a comprehensive explanation of all available and unavailable treatment options must be provided, by law. However, even where this is not a legal requirement, a full and open discussion maximises the chances of an acceptable outcome and minimises the chances of patient dissatisfaction. Dr Ribeiro felt that: "It is an obligation for us, as doctors, to inform our patients of the options they have or do not have and explain why."

Patient-centric discussions are critical when the benefits and drawbacks of each IOL are quite different, and how these characteristics are viewed by the patient is completely individual. A recent meta-analysis summarised the differences between available IOLs as: trifocal IOLs provide better near vision compared with

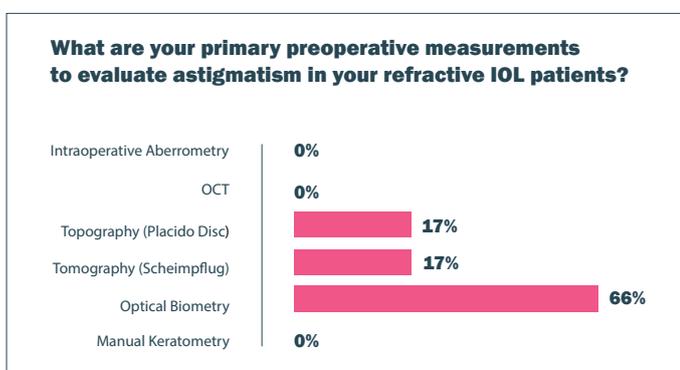


Figure 3. ESCRS Consensus Roundtable survey: A majority of faculty use optical biometry to measure astigmatism in their preoperative assessments

extended depth of field (EDOF) IOLs, while EDOF IOLs offer better contrast sensitivity.¹

Dr Kohnen advocated a simple approach to this discussion, asking the question of what the patient wants to achieve after cataract surgery. The faculty advised that understanding of desired visual acuity, expectations of night vision, expectations of reading vision and the level of independence from spectacles are key to informing selection of a monofocal, multifocal, trifocal or EDOF IOL.

Dr Ribeiro summarised the IOL selection process with patients: "I think the point is not only independence of glasses, but to think a little bit further to providing the patients with functional vision for their daily life." Dr Srinivasan agreed, concluding: "I think the clinical characteristics have to match with the person's personality to meet the functional need of the patient."

Preoperative processes to improve outcomes with toric intraocular lens implantation

In treating astigmatism during cataract procedures, the 2019 ESCRS Clinical Survey data showed that for patients with less than 1D of cylinder, on-axis incision is preferred by around half of responding physicians. In patients with 1.25D of cylinder or greater, toric IOLs are used most commonly (46%) by surgeons. The success of toric implantation owes a great deal to preoperative measurement and alignment with the axis during implantation. The ESCRS Consensus Roundtable survey reported that most of the faculty use optical biometry to measure astigmatism in their preoperative assessments, with some use of corneal topography and tomography assessment (Figure 3).

A shift towards digital support for toric IOL surgery was also observed in the ESCRS Clinical Survey, with digital image axis alignment becoming more common in the period 2016 (13% of

How do you align the intended axis of placement for a toric IOL?

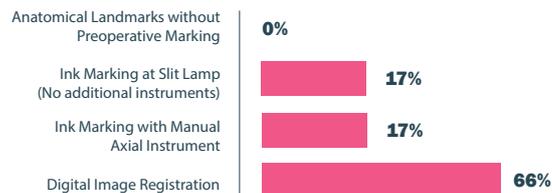


Figure 4. ESCRS Consensus Roundtable survey: For preoperative axis alignment in patients receiving toric IOLs, 66% of faculty use digital image registration

responding surgeons) to 2019 (22%), although around half of physicians rely on ink marking with the aid of manual tools, and just under a third use ink marking with a slit lamp alone. The ESCRS Consensus Roundtable survey showed that the majority use digital image registration for axis alignment (66%; Figure 4).

Dr Carones noted that, while using digital alignment primarily, he also applies ink marks as a backup to allow continuation with surgery in case of failure of the digital system. Dr Carones also explained that his system of digital astigmatism assessment and axis alignment combines with his femtosecond laser-assisted surgery: "This gives me a consistency of measurement, marking and incision throughout the journey of the patient's surgery."

In contrast to the integrated, automated digital systems, Dr Cummings explained a process that is achievable in any environment and ensures accuracy without advanced tools. A mark is made at

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Dr Filomena Ribeiro, MD, PhD, FEBO

the limbus as close as possible to the perceived 180° axis while the patient is laying down prior to surgery. Once the patient is in a seated position, just prior to surgery, Dr Cummings uses an axis assistance application on a smartphone that shows how many degrees out from 180° the initial mark is. This margin of error is then noted and corrected for during implantation.

In addition to being a readily available approach to axis alignment, Dr Cummings feels that this can make alignment more accurate than ink marking with handheld tools: "It's hard with a handheld tool to display the 180° axis and simultaneously mark it accurately; with this approach if the mark is off by a few degrees I can detect that, mark the necessary adjustment on the eye and align my lens precisely in surgery." Although not widely used, there appears to be great merit to this approach, and it may well be suited to clinics without the budget for digital alignment systems, but who are focused on accurate outcomes.

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Intraoperative Keys for Success

Optimising implantation of an intraocular lens

There are numerous types of IOLs available, and each has their own characteristics. IOLs are available in different materials, including hydrophobic or hydrophilic acrylate, rigid polymethylmethacrylate lenses and more flexible silicone lenses. Each IOL requires a different optimal incision size and aperture for the haptic anchors, as well as a specific rotation. Complications of IOL implantation can include inflammation, infection, bleeding and raised intraocular pressure. In order to reduce patient dissatisfaction with IOL surgery, several aspects of surgery can be optimised.

Dr Cummings explained that with a toric lens implantation, he aims to maximise contact between the IOL and the capsule. With the lens in the correct orientation, excess viscoelastic is removed so that the lens sits in aqueous in the capsule; at this point the lens is gently pushed down onto the posterior capsule.

Dr Carones noted that all IOLs are different and require specific approaches to optimise their implantation. When implanting monofocal IOLs, emphasis is placed on aligning the haptics along the axis as accurately as possible, and with multifocal IOL surgery, alignment with the preoperative imaging is key. Sufficient time should be allowed for full extension of the haptics, and this will be specific to a particular IOL.

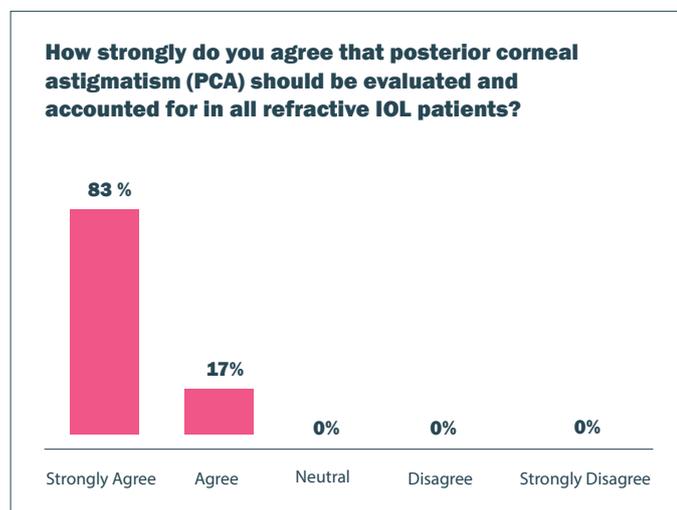


Figure 5. ESCRS Consensus Roundtable survey: All faculty agree or strongly agree that PCA should be assessed and accounted for in all patients undergoing IOL surgery

Dr Carones also reiterated the importance of removing excess viscoelastic from behind the IOL. Any retained viscoelastic may raise intraocular pressure (IOP) and contribute to capsular bag distension; in addition, it will impact lens performance through introducing inaccuracy in effective lens position calculations and allowing postoperative IOL rotation.

Evaluation of posterior corneal astigmatism

Posterior corneal astigmatism (PCA) is an important consideration in the determination of total corneal power and IOL power. A toric IOL lens selected using anterior corneal measurements, without accounting for PCA, may overcorrect eyes with “with-the-rule” astigmatism and under-correct eyes with “against-the-rule” astigmatism.^{1,2}

There was unanimous agreement among the ESCRS Consensus Roundtable faculty that PCA should be assessed and accounted for in all patients undergoing IOL surgery (Figure 5). Dr Carones felt that while the number of patients with PCA that might affect their outcome is relatively small, it is impossible to predict which patients these will be, and therefore assessment of posterior corneal curvature in all patients ensures that no case is missed. PCA should be evaluated in the preoperative measurements.

Dr Cummings strongly supported PCA evaluation, stating: “We measure PCA in absolutely all of our patients, including those receiving monofocal lenses, with the aim of avoiding any surprises.” Incorporation of PCA into calculations yields improved postoperative refractive outcomes,² and consequently PCA should be accounted for, following measurement, with the calculator the physician is using for the surgery.

The Barrett toric calculator and Abulafia-Koch formula have both been shown as providing low astigmatic prediction errors for corneal power calculations.³ A recent study, conducted by Dr Ribeiro’s team at the Hospital da Luz, Lisbon, found no significant benefit in direct measurement of total corneal power compared with estimating it using formulae.³ Dr Reus said that incorporating PCA in the selection of IOLs in his practice has led to an increase in the correction of lower amounts of astigmatism. Dr Reus also noted: “By aiming for 0.5D or less of remaining astigmatism after surgery, we have seen an increase in spectacle independency in our patients.”

Understanding surgically induced astigmatism

Surgically induced astigmatism (SIA) is related to the length, width, type, location and structure of the incision for implanting an IOL and

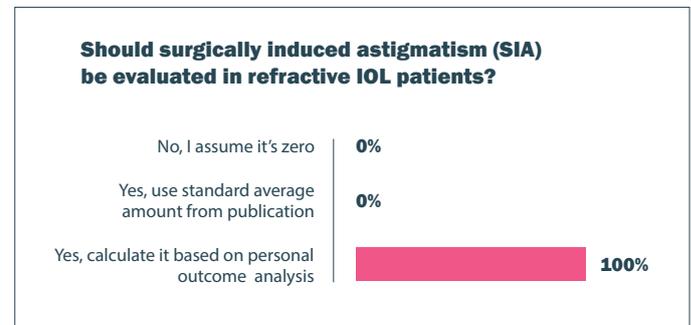


Figure 6. ESCRS Consensus Roundtable survey: Faculty are in unanimous agreement that SIA should be evaluated in all patients

plays a key role in visual outcomes. The ESCRS Consensus Roundtable faculty were united in agreeing that SIA should be evaluated in all patients, and furthermore that calculations should be based on the surgeon’s personal experience rather than standardised values or assumptions (Figure 6).

As a surgeon becomes practiced and familiar with a particular lens and standard procedure, data collected can be used to inform future prediction of SIA and calculations to compensate for this. This makes it relatively easy to account for SIA in routine practice with repeated procedures; however, Dr Cummings advised that, even with no changes to a protocol, checks should be made periodically to ensure that a surgeon’s predicted SIA is still accurate.

It is of critical importance to re-evaluate SIA any time there is a change to a standardised procedure. Dr Carones also recommended routine measurements and calculations to ensure the highest degree of accuracy. There was agreement that a prediction of SIA based on a physician’s own experiences and data was always preferable to using values published in the literature or and assumption of no SIA with procedures.

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Postoperative Refractive & Rotational Error

Managing postoperative refractive error with intraocular lenses

The goal of modern cataract surgery with premium IOLs is to achieve emmetropia, within 0.5D, with less than 1D of astigmatism. In some cases, suboptimal refractive outcomes or refractive surprise may occur, and this is a leading cause of dissatisfaction with the procedure.¹ There are contrasting views in the literature on which tools to use to correct residual refractive error; however, LASIK, photorefractive keratectomy (PRK) and lens modification (additional piggyback lenses or lens exchange) are considered the most effective.^{1,2} Laser vision correction with LASIK or PRK is often preferred for correction of small spherical and cylindrical error because it allows precise and predictable adjustment, whereas piggyback IOLs and IOL exchange may be more suited to correcting large spherical errors.²

The ESCRS Consensus Roundtable survey revealed that half of the faculty prefer PRK for correction of residual refractive error, with LASIK also being used (Figure 7). Dr Cummings expanded on this, explaining that the time period in which correction is made may help select the most appropriate mode of adjustment. Where a correction is made in the six-to-12 weeks that follow surgery, Dr Cummings said: "I will use PRK preferentially, because I don't want to use LASIK on top of the recent corneal incisions. If the adjustment is made several years after the initial surgery, LASIK

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Dr Francesco Carones, MD

may be used.” Where a patient wants multifocal or trifocal utility and currently have a monofocal lens implanted, piggyback lenses may be most appropriate. The process of selecting a lens to add is done in close consultation with the patient to understand their needs and discuss visual compromises. The process may be aided by trial use of multifocal contact lenses before implantation of an IOL.

Dr Cummings did note that before an adjustment is made, a discussion is held with the patient to determine if they are happy to wear glasses to provide any necessary correction. If a patient is satisfied using spectacles, this is the approach taken; if not, then a corrective modality is selected.

Understanding rotational error with toric intraocular lenses

Many patients presenting for cataract surgery have some degree of astigmatism, which contributes to blurry vision, visual fatigue and diplopia.

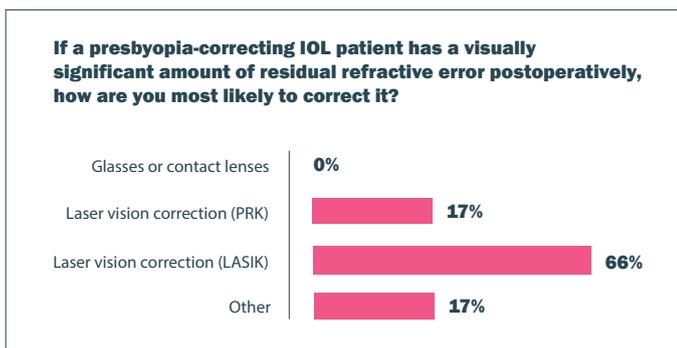


Figure 7. ESCRS Consensus Roundtable survey: Faculty prefer the use of PRK and LASIK for correction of residual refractive error, post IOL implantation

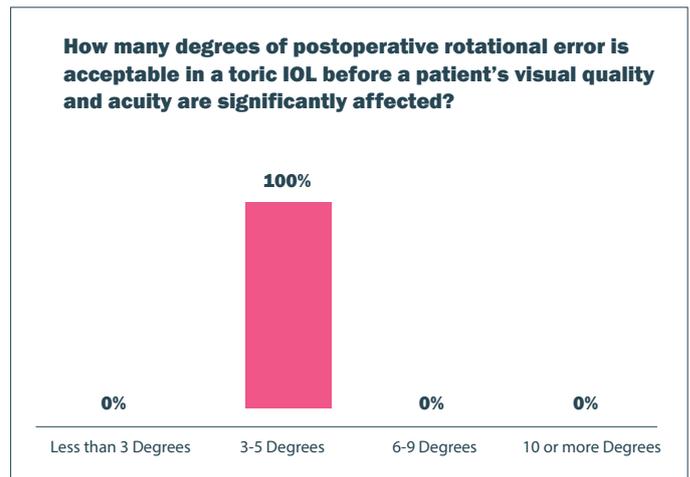


Figure 8. ESCRS Consensus Roundtable survey faculty are in unanimous agreement that 3-5° of post-implant rotation are acceptable with a toric IOL, before the patient's visual quality and acuity will be noticeably affected

An estimated 22% of patients with cataract have 1D to 1.5D of corneal astigmatism, with 10-12% of patients having 1.5D to 2D and 8-13% of patients having 2D or more.³ Implantation of toric IOLs is an effective method of reducing astigmatism, particularly in patients with more than 1D of cylinder. However, the literature suggests that up to 70% of eyes treated with toric IOLs will have some residual refractive astigmatism, on the order of $\leq 0.5D$.⁴ The leading causes of residual astigmatism are orientation error at implantation and postoperative rotation.

For every degree that the orientation of a toric lens differs from the ideal, there is an approximate 3.3% decrease in its effectiveness at reducing astigmatism; thus if a toric lens is 30° away from its ideal orientation, the magnitude of the pre-existing astigmatism is unchanged and a new axis of astigmatism is created. In practice, rotational stability takes around one month to establish, with the toric lens most likely to rotate in the 14 days following implantation. The rate of significant misorientation requiring surgical reorientation is relatively low, around 1%.⁴ Overall, toric IOL rotation is often less than 5° by the time the lens stabilises.⁴

The ESCRS Consensus Roundtable faculty consider that 3-5° of post-implant rotation are acceptable with a toric IOL, before the patient will experience noticeable effect on visual acuity (Figure 8). Dr Carones expanded on this overview: "While 3-5° is the most that the eye should tolerate in many cases, of greater importance is the amount of astigmatism that was corrected by the toric IOL. If you are correcting a high degree of astigmatism, you must be extremely precise, because even a small rotation would lead to a significant amount of uncorrected astigmatism. On the other hand, if you are correcting a relatively small degree of astigmatism, a larger margin of error can be tolerated without significant fault in the patient's vision." Ideally, a rotational error of less than 3° may be needed for high degrees of pre-existing astigmatism; 3-5° of rotation should be tolerable in the correction of 2-5D of astigmatism; and in cases of correcting less than 2D, a rotation of more than 5° might go unnoticed by the patient.

Dr Cummings explained that where the refractive outcome is suboptimal because of a misaligned toric lens, and measurements suggest that lens rotation will provide a better refractive result, then the lens should be rotated.

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Patient Satisfaction

Drivers of satisfaction and dissatisfaction in patients receiving premium intraocular lenses

Overall, patient satisfaction following cataract surgery and premium IOL implantation is reported as being relatively high. A recent analysis of peer-reviewed literature reported spectacle independence as 80% or more patients for distance vision, 100% for intermediate vision and 70% for near vision in the different groups studied, with good visual acuity results across various distances with multifocal IOLs.¹ The main reasons for patient dissatisfaction following a multifocal IOL implantation include residual refractive error, photic phenomenon, posterior capsule opacification and dry eye, and it is notable that these reasons for dissatisfaction are all manageable and rarely require lens exchange.^{1,2}

Other studies agree with these findings, observing that dissatisfaction with presbyopia-correcting lenses was due to blurry or foggy vision both for distance and near (68% of patients in the study), attributed to residual refractive error (57%) and dry eye (35%). Laser correction was only performed in 8% of these eyes, with the common interventions being prescription of glasses or contact lenses (46%) and treatment for dry eye (24%); this study commented that with this approach, a significant number of patients remained dissatisfied.³

“Some visual phenomena, for example glare and halos, are a consequence of choosing a particular IOL, and not a complication associated with a poor result

Dr Francesco Carones, MD

Planning for a satisfied patient

Extensive consultation, preoperative measurement, intraoperative discipline and postoperative correction all play a role in improving patient satisfaction. The ESCRS Consensus Roundtable faculty consider that management of patient expectations is crucial in the lens selection dialogue. Drs Ribeiro, Carones and Cummings all stated that they remove the concept of independence from glasses as a pivotal measure of success in routine discussion. In many cases, a lessened reliance on spectacles, or more choice in the activities for which spectacles are beneficial could be a more appropriate treatment goal.

In order for a patient to understand there is no single IOL that is “best”, they need to be educated on the types of lens and surgeries, so they can manage their expectations and consequently their markers of success following treatment. Dr Cummings advocated using the ocular scatter index (OSI) to help determine how eyes will respond to different IOL options, particularly with a view to determining compatibility with multifocal lenses that will increase the experience of glare and halos.

Dr Ribeiro summarised: “It’s important to make the patient the center of the decision-making process and, for that, we have to explain to the patients everything, the pros, the cons, even though that takes a lot of time.” Dr Carones commented that, “With better understanding of the characteristic of each IOL: patients can understand that some visual phenomena, for example glare and halos, are a consequence of choosing a particular IOL, and not a complication associated with a poor result.”

“It’s important to make the patient the center of the decision-making process and, for that, we have to explain to the patients everything, the pros, the cons, even though that takes a lot of time

Dr Filomena Ribeiro, MD, PhD, FEBO

Assessment of satisfaction following treatment and management of dissatisfied patients

The ESCRS Consensus Roundtable faculty felt that the best assessment of satisfaction comes direct from discussion with the patient. Dr Carones supplements the discussion with a pair of questionnaires that are completed a month after surgery. One set of questions aims to capture feedback on the patient’s vision during daily tasks and household activities. The validated Catquest-9SF questionnaire is also used to assess overall quality of life following cataract surgery and IOL implantation.

Improving the experience for patients who are unhappy with their procedure requires understanding the source of dissatisfaction. If a patient is unhappy with the refractive results of surgery, postoperative adjustments can be made to rectify the issue. If the patient is in a period of ocular surface discomfort and poor tear film production, then this needs to be treated with appropriate eyedrops. For patients who feel they have made the wrong choice of IOL – an occurrence that can hopefully be minimised in the preoperative discussions – then an IOL exchange might be appropriate.

Advancing technology to increase patient satisfaction

Dr Srinivasan and Dr Kohnen discussed how technology allowing patients to simulate the experience with their IOL prior to implantation could help in IOL selection. Simulation of halo, glare and IOL-associated dysphotopsia would be of particular value, considering this is a frequent concern for patients. Dr Srinivasan felt this could increase patient confidence in their treatment selection: “I think that will be very useful to have a device on the market where we can simulate, different IOLs with different rings, to the patients. Then they can make an informed decision on whether they can live with the associated phenomena or not.”

Dr Cummings and Dr Carones are currently using technology to help patients understand how they use their vision during the average day, with the aim of pairing the patient’s needs to an appropriate IOL. A sensor attached to spectacles captures data throughout the day to create an accurate picture of the balance of near-, mid- and longer-distance vision requirement the patient has, along with orientation data and light levels in which the patient relies on their sight. Objective data, rather than subjective interpretation of the patient’s needs may help more patients feel they select the “right” IOL, increasing confidence and post-surgery satisfaction.

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