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2020 GLOBAL CONSENSUS ON CORNEAL IRREGULARITY

A continuing medical education activity jointly provided by Evolve Medical Education LLC and The Fundingsland Group.

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2020 Global Consensus on Corneal Irregularity

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CONTENT SOURCE

This continuing medical education (CME) activity captures content from a round table.

ACTIVITY DESCRIPTION

A panel of experts in ophthalmology from around the globe offer recommendations for defining, diagnosing, and treating irregular corneas.

TARGET AUDIENCE

This certified CME activity is designed for general ophthalmologists and specialists who treat irregular corneas.

LEARNING OBJECTIVES

Upon completion of this activity, the participant should be able to:

- **Define** etiology of irregular corneas, including naturally occurring, surgically induced, disease, and/or trauma
- **Describe** the prevalence of these types of irregular corneas' etiology in various geographic regions and patient populations
- **Identify** specific metric levels (surface regularity index and/or higher-order aberrations) for diagnosing various grades of irregular corneas
- **Recommend** diagnostic work-up protocols and describe key conditions to identify as indicators of irregular corneas in conjunction with cataract surgery
- **Design** cataract surgery treatment plans for the various grades of irregular corneas in real-world cases and review conventional and ideal treatment options for these patients

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PRETEST QUESTIONS

PLEASE COMPLETE PRIOR TO ACCESSING THE MATERIAL AND SUBMIT WITH POSTTEST/ACTIVITY EVALUATION/SATISFACTION MEASURES FOR CME CREDIT.

- Please rate your confidence in your ability to identify and treat patients with irregular corneas (based on a scale of 1 to 5, with 1 = "Not at all confident" and 5= "Very confident").**
 - 1
 - 2
 - 3
 - 4
 - 5
- Which of the following is NOT an etiology of irregular astigmatism?**
 - Choroidal neovascularization
 - Pterygium
 - Epithelial basement membrane dystrophy
 - Trabeculectomy
- Which of the following is likely to increase the risk of keratoconus?**
 - UV protection
 - Nordic heritage
 - Middle Eastern heritage
 - Meibomian gland dysfunction
- Thirty-five percent of which population of cataract patients were found to have levels of higher-order aberrations of 0.5 μm or greater?**
 - Australian
 - European
 - Canadian
 - Asian
- Which of the following is a potential cause of transient corneal astigmatism?**
 - Previous radial keratotomy
 - Contact lens-induced corneal warpage
 - Surgical removal of pterygium
 - Trauma
- Which area(s) is (are) more likely to have a higher risk of irregular corneas caused by trauma?**
 - Urban
 - Suburban
 - Rural
 - All are equal
- Which of the following is NOT recommended as a point-of-care test for all cataract examinations?**
 - Slit lamp examination
 - Fluorescein angiography
 - Corneal topography
 - Corneal tomography
- It would be useful to _____ to obtain more accurate measurements for patients with irregular corneas.**
 - Perform and repeat measurements on multiple devices
 - Prescribe topical bromfenac 0.075%
 - Use the ELR formula
 - None of the above
- Which of the following is NOT a quantitative measure of irregular corneas?**
 - Higher-order aberrations
 - Surface regularity index
 - Placido ring assessment
 - All of the above
- Which of the following lenses is the top recommendation from international panelists from this CME supplement for patients with high levels of corneal irregularity?**
 - Small aperture IOL
 - Monofocal IOL
 - Light-adjustable IOL
 - EDOF IOL
- Which of the following lenses is the top recommendation from American panelists from this CME supplement for patients with corneal irregularity?**
 - Monofocal IOLs, and small aperture if available
 - Bifocal IOL
 - Light-adjustable IOL
 - EDOF IOL

2020 Global Consensus on Corneal Irregularity: Expert Panel Offers Recommendations for Defining, Diagnosing, and Treating Irregular Corneas

UNDERSTANDING THE ORIGIN OF IRREGULAR CORNEAS

Corneal irregularities arise from numerous causes.

Irregular corneas present unique challenges to achieving optimal outcomes from cataract and refractive surgery and may be much more common than currently recognized.

TYPES OF IRREGULAR CORNEAS

Corneal irregularities may arise from pre-existing natural causes or induced causes, such as surgical procedures, disease, trauma, and other conditions. Although some cases may be obvious, others may be less understood or remain undetected without thorough diagnosis.

Pre-Existing versus Induced

Irregular corneas have complete asymmetry of the hemi-meridians with respect to the astigmatic axis, said Jodhbir Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS. “Pure primary irregular corneas are not that common compared with secondary irregular corneas, hence primary irregular corneas are normal corneas that happen to be irregular, typically manifest as high higher-order aberrations (HOAs),” he said.

“We know from Ken Hayashi’s work, as well as others that irregular astigmatism increases significantly with age, even in the absence of disease or surgery, so perhaps everyone develops some degree of naturally induced astigmatism,” said Jacqueline Beltz, FRANZCO.¹

“Some naturally occurring corneal irregularities may manifest after cataract surgery. In these cases, even in the setting of a monofocal lens that does not induce any further irregularity and their lower-order astigmatism is fully corrected, they’re still experiencing HOAs,” said Marjan Farid, MD. “There are definite inherent shapes to some corneas—it’s a small percentage—that have a degree of irregularity that’s visually significant.”

A custom Market Scope Survey of US surgeons found that 96% of respondents believed a history of keratoconus may indicate an irregular cornea, followed by irregular astigmatism, corneal trauma, and radial keratotomy (94%); corneal therapeutic surgery (93%); ectasia (91%); and laser vision correction (81%).²

Frank et al performed a review of 200 eyes in 400 patients; approximately one-fourth of patients scheduled for cataract surgery who did not have previous corneal surgery had abnormal corneal topography.³ Ten percent resulted from irregular astigmatism or suggested dry eye; 9% had borderline pellucid marginal degeneration or forme fruste keratoconus, or superior steepening; and the remaining 6% had topographic findings consistent with forme fruste keratoconus, pellucid marginal corneal degeneration, or keratoconus.

Greater ametropia increases the likelihood of irregular astigmatism, said Gerd Auffarth, MD, PhD, FEBO. He explained that irregular corneas are slightly more common in those with myopia or high hyperopia, and patients with myopia always have some degree of astigmatism. “They never have a cornea that is completely even,” he said.

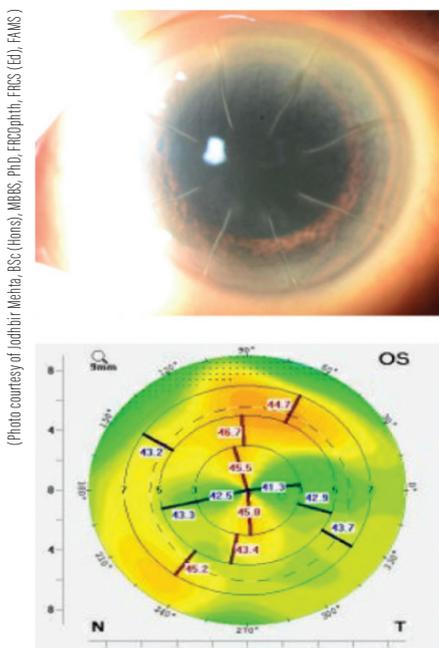


Figure 1. Post-RK cornea.



“Now that we have good topography and tomography analysis, we can diagnose irregular cornea patients a lot easier than in the past.”

— Jodhbir Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS

Surgically Induced

Postsurgical irregular corneas may be seen after laser vision correction, especially if this resulted in ectasia or other abnormalities that change the corneal shape. Other common surgeries that affect the cornea include radial keratotomy (RK), astigmatic keratotomy, cataract surgery, pterygium surgery, corneal transplants, and trabeculectomy (Figure 1).

“I’ve seen some influence on the cornea from scleral buckles as well, especially from segmental buckles,” said Cristos Ifantides, MD, MBA.

Disease Induced

Diseases causing irregular corneas include corneal ectasias, dystrophies, and degenerations, as well as disease. Examples include keratoconus, epithelial basement membrane dystrophy, Terrien’s marginal degeneration, Salzmann nodular degeneration, and pellucid marginal degeneration (Figure 2).

“In my corneal practice, I also see patients with post-infectious corneal scarring that have irregular astigmatism,” said Zaina Al-Mohtaseb, MD.

Some forms of irregular corneal astigmatism may be transient and can resolve if treated. “You always have to rule out other reasons that make it appear irregular,” Dr. Auffarth said. Examples include contact lens warpage or overwear, dry eye, or meibomian gland dysfunction. After treatment, ophthalmologists need to repeat corneal tomography or topography.

In addition, mild limbal stem cell deficiency and irregular epithelium in chronic soft contact lens wearers may induce significant irregular astigmatism, Dr. Farid said. “Sometimes it is transient and can be treated, but sometimes the epitheliopathy and subepithelial fibrosis induce chronic and irreversible irregular astigmatism. It lingers there with remodeling of the epithelial basement membrane.”

“Lid abnormalities, such as chalazion, also can cause temporary irregular astigmatism,” said Richard Lindstrom, MD.

Trauma Induced

Trauma such as a fully or partially penetrating eye injury can cause an irregular cornea, as well as surgery performed to repair the trauma. It can result in scarring, edema, and other abnormalities. ■

(Photo courtesy of William Trattler, MD)

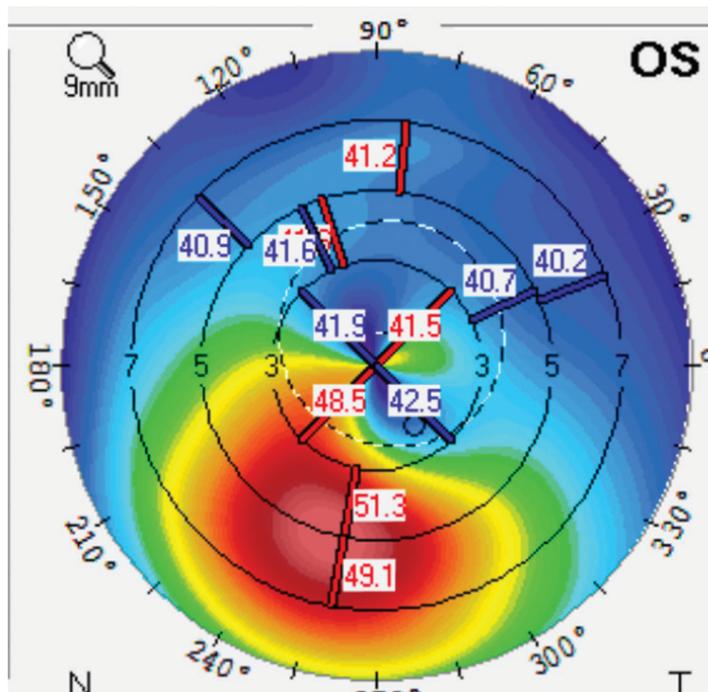


Figure 2. Keratoconus.

1. Hayashi K, Kawahara S, Manabe S, et al. Changes in irregular corneal astigmatism with age in eyes with and without cataract surgery. *Invest Ophthalmol Vis Sci.* 2015; 56:7988-7998.
2. Custom Survey Report of 123 US Cataract Surgeons by Market Scope, September 2020.
3. Frank B, Trattler W, McCabe S, et al. The incidence of topographic abnormalities in patients scheduled for cataract surgery (abstract). *Invest Ophthalmol Vis Sci.* 2014; 55:2477.

DIAGNOSING IRREGULAR CORNEAS

Panelists weigh numerous factors in diagnosing irregular corneas.

Corneal irregularities may be much more common than recognized and can impact the visual results of cataract surgery. Therefore, it is important to aggressively seek out abnormalities.

With increasing expectations in terms of outcomes, surgeons are more likely to measure and discuss naturally occurring irregular astigmatism preoperatively, said Jacqueline Beltz, FRANZCO. “The relevance and importance have increased with greater use of toric IOLs and also bi- and trifocal IOLs,” she said.

Consensus Panel Finding #1 reveals panelists have their own specific diagnostic strategies, but the vast majority agreed that a slit lamp examination and corneal topography or tomography should be performed at the point-of-care during all cataract patient preoperative examinations.

DIAGNOSTIC TOOLS

Slit lamp examination in some cases can help alert the clinician to the presence of irregularity, but diagnosis and quantification may require further investigation (Figures 1 and 2).

Moderate to advanced keratoconus or corneal trauma may be obvious at the slit-lamp. Tests for dry eye, including corneal staining and tear breakup time also can be performed; however, many other abnormalities may not be evident on the slit-lamp exam, so additional diagnostic tools are necessary, said Gerd Auffarth, MD, PhD, FEBO.

In addition, corneal topography or tomography can help the physician focus the slit-lamp examination and detect pathologies that would have been missed, such as epithelial basement membrane dystrophy, said Zaina Al-Mohtaseb, MD.

CONSENSUS PANEL FINDING #1

Slit lamp exams and corneal topography should be performed at the point-of-care for all cataract patient preoperative exams.

“Now that we have good topography and tomography analysis, we can diagnose irregular cornea patients a lot easier than in the past,” said Jodhbir Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS. “Diseased corneas with keratoconus and ectasia are well diagnosed because they have been well studied. Likewise, surgically induced irregular corneas are quite well studied because most refractive surgeons are quite familiar with performing surface analysis or some sort of corneal analysis.”

“The key is to perform corneal topography, whether it’s to rule out keratoconus or if a patient has had previous photorefractive keratectomy, LASIK, or radial keratotomy. Even if the slit lamp exam looks relatively normal, the topography may surprise you with significant irregular astigmatism,” said William Trattler, MD.¹

“There are so many times I’ve picked up previously undiagnosed forme fruste keratoconus with corneal topography,” said Marjan Farid, MD. “You can also get clued in when there’s incongruence between your biometry astigmatism, your topography astigmatism, and your manifest astigmatism.”

During the examination of corneal irregularities, panelists concentrate on whether the abnormality is treatable (ie, dry eye, lower-order astigmatism that can be treated with a toric intraocular lens [IOL]) and consider whether the abnormality is mild, moderate, or severe.

Several panelists emphasized the location of the abnormality in relation to the central visual axis determines the impact on visual acuity. “Any of these can affect it significantly, and the more central the disorder, I think the more effectual on the vision,” Dr. Farid said.

(Photos courtesy of Zaina Al-Mohtaseb, MD)

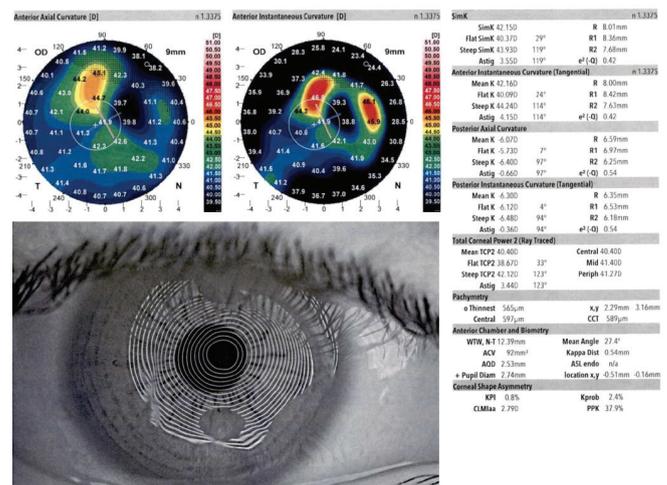
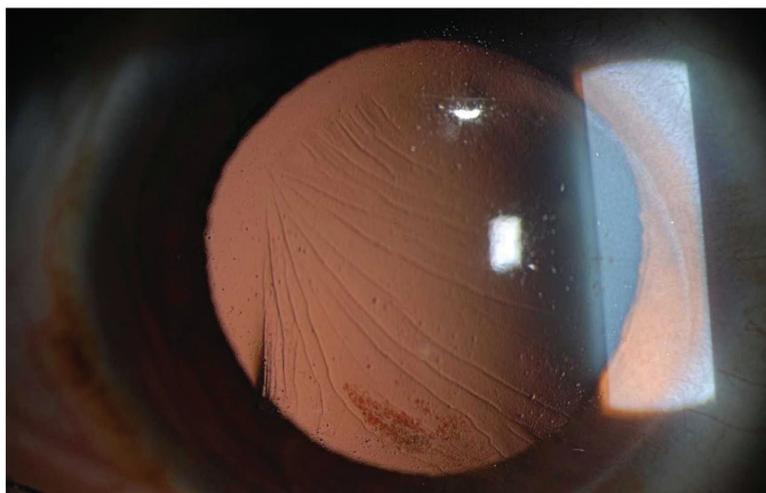


Figure 1. Patient with macrostriae and irregular LASIK flap thickness (h/o microkeratome flap creation) who presented with blurred vision and irregular astigmatism.

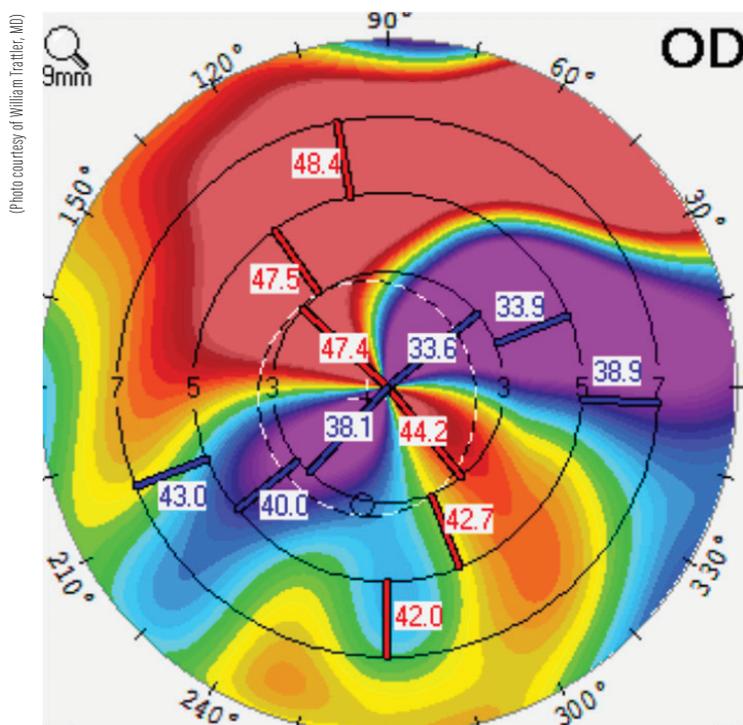


Figure 2. Irregular astigmatism due to Salzmann nodule.

Dr. Al-Mohtaseb agreed. “Location and severity,” she said. “If it’s more irregular, it will have more of an effect on the visual outcome regardless of the etiology.”

“In general, my main priority is to resolve treatable abnormalities, especially here in Denver with low humidity, taking care of the dry eye,” said Cristos Ifantides, MD, MBA. “After that, the centrality of the abnormality is most important and then the severity.”

ASSESSING SRI, HOA, AND IRREGULAR PATTERNS

A 2020 custom Market Scope Survey of US cataract surgeons found that 64% of surgeons use corneal higher-order aberrations (HOAs) to quantify irregular corneas and 62% use surface regularity index (SRI) scores.² A 2020 Clinical Survey by *Cataract & Refractive Surgery Today* showed that 47% use corneal aberrometry and 65% use SRI scores to quantify irregular corneas in cataract patients.³

SRI scores available on some corneal topographers quantify local irregularities in the central part of the anterior corneal surface within the central 3.5 to 4.5-mm (central 10 rings) diameter, Dr. Beltz said. “For preoperative cataract assessment, I prefer to look at total corneal HOAs (RMS) rather than SRI given that total corneal HOAs also take into account the posterior cornea,” she said.

Richard Lindstrom, MD, also measures SRI and corneal HOAs to quantify irregular corneas. However, Dr. Trattler prefers a more qualitative approach. “I use Scheimpflug imaging (tomography) a little more. I’m looking at the regularity or

irregularity of the axial/sagittal view subjectively, and I make a decision based on the regularity or irregularity of the corneal shape,” Dr. Trattler said.

“I use corneal HOAs to quantify irregular corneas prior to cataract surgery,” Dr. Beltz said. She explained that Zernike polynomials allow characterization of aberrations into different components, with first order involving tilt, second order the refractive error correctable with glasses, and higher order including coma, spherical aberration, and others.

Dr. Al-Mohtaseb assesses the quality and quantity of astigmatism using topography and tomography. To diagnose irregular astigmatism, she relies heavily on qualitative assessment of Placido ring imaging in addition to corneal tomography and elevation data.

Dr. Farid performs a slit lamp examination, corneal topography, and a macular OCT. She dives deeper if there is an unexplained reason for visual decline, looking at HOAs with a system combining corneal topography and ray-tracing aberrometry or a device combining corneal topography and wavefront aberrometry to measure specific numbers. “In general, I use Scheimpflug imaging, looking at the shape of the anterior and posterior cornea, and base my decisions on that.” If irregular astigmatism is present, especially in the central 3 to 5 mm, she would think twice about using a presbyopia-correcting or toric IOL.

Sathish Srinivasan, FRCSEd, FRCOphth, FACS, performs corneal topography and tomography on all patients who had previous laser vision correction or visual symptoms without an obvious explanation. He calculates HOAs on patients screened for premium IOLs, particularly multifocal IOLs.

“The incremental benefit of corneal aberrometry is to identify who are the good candidates for premium IOLs and who are not,” Dr. Srinivasan said.

Dr. Auffarth uses a device that includes corneal tomography and wavefront aberrometry, as well as other technologies, to identify corneal HOAs.

“I think tomography provides a bit more detailed analysis of the cornea,” Dr. Mehta said. He explained that tomography does not provide SRI but has numerical values on the ocular surface to show that it is irregular. He remarked that tomography is necessary for diseases that affect the thickness of the cornea and postrefractive surgery patients.

Dr. Mehta noted that total HOAs of the visual pathway can be calculated with a number of wavefront sensors. Corneal HOAs can be measured with both topography and tomography devices. He believes HOA calculations should be performed on all patients. It is useful when considering a lens-based surgical treatment in patients with an irregular cornea. If they have high corneal HOAs, the corneal HOAs will not be corrected by the IOL. “Then you can counsel them with respect to how much visual distortion they may have postoperatively,” he said. ■

1. Frank B, Trattler W, Moccabe S, et al. The incidence of topographic abnormalities in patients scheduled for cataract surgery (abstract). *Invest Ophthalmol Vis Sci*. 2014; 55:2477.

2. Custom Survey Report of 123 US Cataract Surgeons by Market Scope, September 2020.

3. 2020 CRST Clinical Survey of 450 cataract and refractive surgeons by The Fundingsland Group, October 2020.

DEFINING THRESHOLDS OF IRREGULAR CORNEAS

Data and subjective analysis help ophthalmologists identify corneal irregularities.

Data are valuable in determining the percentage of the population with a visually significant level of higher-order aberrations (HOAs) or surface regularity index (SRI) so clinicians can determine how likely they are to see patients with irregular corneas, said Richard Lindstrom, MD.

Consensus Panel Findings #2 and #3 show the panelists' SRI and HOA thresholds that they consider visually significant in addition to similar findings from a recent custom Market Scope Survey¹ and a *Cataract & Refractive Surgery Today* survey.² (However, these values do not indicate the safety level for implanting multifocal IOLs. See articles on surgical decision making beginning on page 13.) Overall, a considerable majority find SRI and HOA levels of 0.5 µm and above as visually significant. "Whether it's SRI or HOAs, the impact it has on vision is about the same as the impact that regular astigmatism has," Dr. Lindstrom said.

ADDITIONAL FACTORS

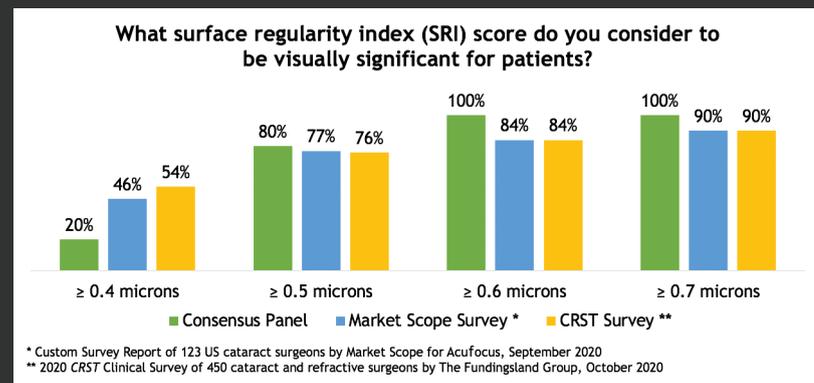
Panelists also emphasized that HOA and SRI values do not tell the entire story when differentiating between lower and higher levels of corneal irregularity.

Sathish Srinivasan, FRCSEd, FRCOphth, FACS, does not use a single number to make this distinction. "I look at their spectacle prescription, levels of astigmatism, and HOAs," he said. "It's a combination of the clinical examination and topography. In my opinion, higher levels of corneal irregularity have a much higher impact than lower levels of irregularity."

Gerd Auffarth, MD, PhD, FEBO, explained that lower levels of corneal irregularity have less of a clinical impact even if other factors such as dry eye are involved. However, patients with higher levels and dry eye are more likely to be dissatisfied. If dry eye is treated, it may be easier to manage the irregularity. ■

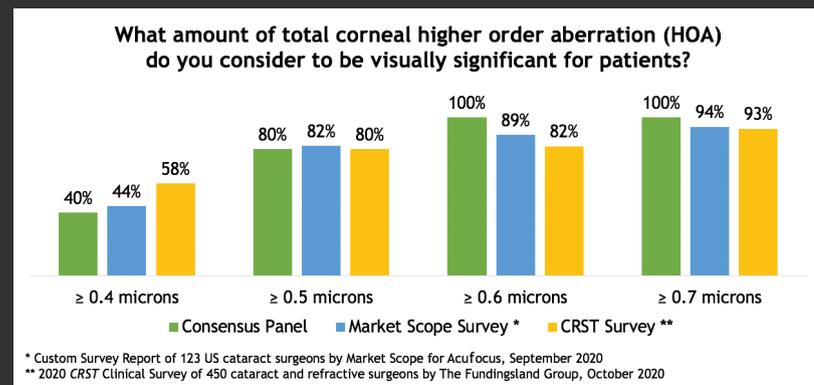
CONSENSUS PANEL FINDING #2

An SRI score of 0.5 µm or greater is visually significant.



CONSENSUS PANEL FINDING #3

HOA of 0.5 µm or greater is visually significant



1. Custom Survey Report of 123 US Cataract Surgeons by Market Scope, September 2020.
2. 2020 CRST Clinical Survey of 450 cataract and refractive surgeons by The Fundingsland Group, October 2020.

IDENTIFYING THE PREVALENCE OF IRREGULAR CORNEAS

Panelists share how often they encounter various types of irregular corneas.

Corneal irregularities, which may be more common than recognized, can significantly affect the visual outcomes of cataract surgery and, ultimately, patient satisfaction. The prevalence of different types of irregular corneas vary throughout the world, based on genetics, ethnicity, environment, economic factors, and other variables.

Consensus Panel Finding #4 identifies the panelists' average prevalence of irregular corneas in the overall population, and in their own cataract and refractive practices. These findings show that approximately 24% of their preoperative cataract patients have irregular corneas, while 15% of their preoperative laser vision correction patients have irregular corneas.

WORLDWIDE AND REGIONAL IMPACT

Genetic factors are believed to be responsible for keratoconus, as well as corneal dystrophies and numerous diseases that impact the cornea, which can result in regional differences in the prevalence of corneal irregular astigmatisms.¹

In Europe, the prevalence of keratoconus may vary by country, said Gerd Auffarth, MD, PhD, FEBO. For example, he said, Mediterranean patients are more likely to have keratoconus, however, Nordic patients are less likely.

William Trattler, MD, also said the prevalence of keratoconus is dramatically higher in the Middle East, although it is unclear if this is related to environmental or genetic factors.^{2,3}

There are many cases of corneal scarring in India from infections, said Marjan Farid, MD. "They are very aberrated corneas and they don't necessarily have access to corneal tissue or transplant technology," she said.

Cristos Ifantides, MD, MBA, who practices in Denver, CO, said surgeons will find significant variation based on humidity levels, UV exposure, and ethnic diversity. "The Denver Metro Area is home to approximately 40,000 Ethiopians, with very different

corneal pathology than we would see in other ethnic groups," he said.

Jacqueline Beltz, FRANZCO, explained that keratoconus has traditionally been said to occur in about one in 2,000 people in Australia, but more recent data suggests that the real prevalence might be much higher—1.2% in a recent Western Australian study.⁴ The reason for the increase in prevalence is likely multifactorial, with improved measurement and diagnostic ability being critical. Geographic location may be becoming less relevant as populations move around more. "Many people presenting for cataract surgery may have subclinical keratoconus that will still result in significant levels of corneal aberrations," she said.

Dr. Beltz believes her colleagues understand the prevalence of diseases such as keratoconus well but may be less aware of the prevalence of naturally occurring irregular corneas.

Jodhbir Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS, noted that Singapore is mainly a Chinese population. "Compared with the Caucasian population, Chinese get less keratoconus," he said. "It's a high-UV exposure area, but most people wear UV protection when they go out. But we do see a lot of people with pterygiums (Figure 1) or diseases of the ocular surface from high levels of UV exposure, which can lead to irregular corneas."

REFRACTIVE SURGERY IMPACT

The prevalence of previous refractive surgery, which varies by country and economic status, is a significant cause of irregular corneas. Radial keratotomy was introduced in 1974, followed by excimer laser refractive surgery in 1995.

Many patients who had these procedures are presenting for cataract surgery. Custom Market Scope Survey data from 2020 showed that 2% of US cataract-age patients (61 to 79 years) had previous laser vision correction, 1% of those from Western Europe, Japan, and other wealthy nations, and less than 1% of those from Latin America.⁵

CONSENSUS PANEL FINDING #4: CATEGORIES OF IRREGULAR CORNEA PATIENTS IN VARIOUS POPULATIONS

	IN THE WORLDWIDE ADULT POPULATION	IN ALL ADULT PATIENTS IN YOUR GEOGRAPHIC REGION	IN YOUR CATARACT PATIENTS	IN YOUR LASER VISION CORRECTION PATIENTS
Naturally Occurring	6%	6%	7%	8%
Surgically Induced	6%	7%	7%	3%
Disease	10%	10%	8%	3%
Trauma	2%	2%	2%	1%
TOTAL	24%	25%	24%	15%

(Photo courtesy of William Trattler, MD)

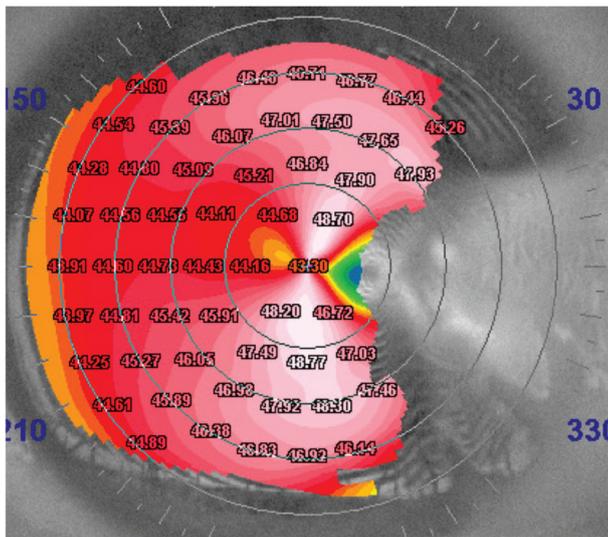


Figure 1. Corneal topography with irregular astigmatism due to a large pterygium.

Practice settings affect percentages. Richard Lindstrom, MD, stated that a survey using higher-order aberrations (HOAs) and surface regularity index showed that cornea specialists had a higher prevalence of patients with irregular corneas (24 to 30%) compared with comprehensive ophthalmologists (average of 12%).⁵

Dr. Trattler reported that 15.8% of his patients scheduled for cataract surgery had irregular corneas from previous corneal refractive surgery.⁶ Furthermore, 9.5% also have transient irregular corneas caused by dry eye or epithelial basement membrane disease.

Dr. Ifantides said 5 to 10% of his patients have irregular corneas from previous refractive surgery. Because he practices in a Level I trauma center, 10% have trauma. He added that trauma is more common in rural areas (Figure 2). Thirty to 50% of his patients have a treatable amount of dry eye.

Dr. Farid, who manages more corneal pathology in an academic setting, stated that at least 25 to 30% of her patients have topographic irregularities. Most cases are treatable, and 5 to 10%

have scars or are post-transplant corneas and about 10% have ectatic disease.

Zaina Al-Mohtaseb, MD, explained that common types of surgically-induced irregular astigmatism that she sees in her academic cornea practice resulted from previous LASIK/photorefractive keratectomy (older versions of the laser), radial keratotomy, and penetrating keratoplasty. Ectatic disease accounts for about 5% of her practice.

Dr. Auffarth believes Germany has half the percentage of refractive surgery cases among the general population compared with the United States. Europe has few post radial keratotomy cases, which have very irregular corneas. He is more likely to see patients who had earlier versions of excimer laser photorefractive keratectomy or LASIK correction.

An increasing amount of refractive correction concerns Dr. Auffarth, particularly if refractive surgery was performed 2 decades ago. "In the 1990s, they treated 10.00, 12.00, and 14.00 D of myopia because they didn't know better, and this created a higher risk of patients having more corneal irregularity," he said.

Dr. Mehta explained that approximately 10% of his preoperative laser vision correction (LVC) patients have irregular corneas, whereas 5% have postoperative irregular corneas. "I do a lot of SMILE for my patients and that induces much less spherical aberration compared with standard LASIK," he said. "You can induce vertical coma from it, but I don't think we will induce more irregularity than LASIK."

IRREGULAR CORNEAS IN CATARACT POPULATIONS

The Table shows results of a meta-analysis of the prevalence of HOAs among cataract patients as reported by 21 peer-reviewed journal papers. This analysis shows on average 28% of the United States, Europe, Canada, and Australian preoperative cataract patients have HOA levels of 0.5 μm or greater, while this number jumps to 35% for Asian cataract patients.

(Photos courtesy of Zaina Al-Mohtaseb, MD)

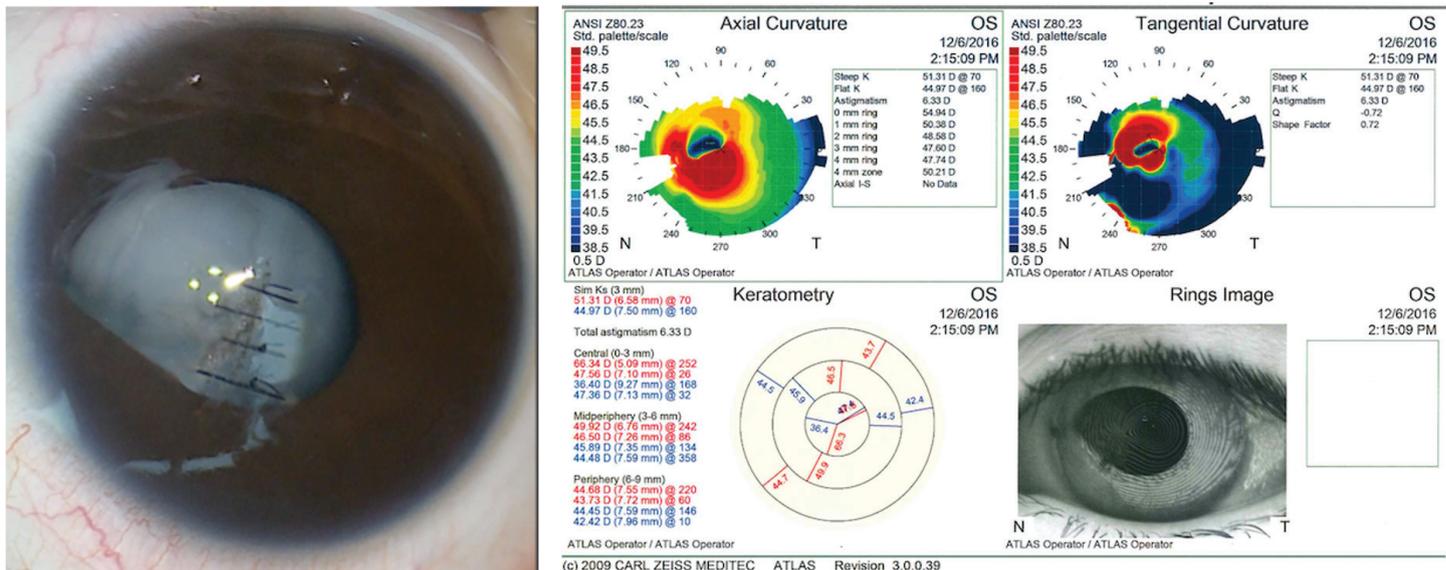


Figure 2. Patient with a history of open globe and resultant corneal scar with irregular astigmatism.

TABLE. PREVALENCE OF IRREGULAR CORNEAS IN CATARACT PATIENTS

	US, Europe, Canada, and Australia ⁸⁻¹⁸	Asia (Japan, China, and South Korea) ¹⁹⁻²⁸
Mean \pm SD HOA RMS in the cataract age group	0.43 $\mu\text{m} \pm$ 0.12 μm	0.55 $\mu\text{m} \pm$ 0.15 μm
Prevalence of HOA \geq 0.6 μm	8%	28%
Prevalence of HOA \geq 0.5 μm	28%	54%
Prevalence of HOA \geq 0.4 μm	50%	75%

Dr. Auffarth said older patients who are having cataract surgery are more likely to have had disease- or surgically induced irregular corneas.

Dr. Al-Mohtaseb sees more surgically induced corneal irregularities among cataract patients, especially postrefractive surgery cases such as radial keratotomy.

Of all Dr. Mehta's cataract patients, 40 to 50% have surgically induced irregular corneas, while 20 to 30% have disease-related irregular corneas because he receives referrals for these cases. Patients who had refractive surgery 15 to 20 years ago are now having cataract surgery. "That is a significant demographic that we see all of the time," he said. In addition, patients with scars and pterygiums are a much older group, he said.

Of all of his cataract patients, Sathish Srinivasan, MD, said 30% have naturally occurring and 10 to 15% have disease-induced corneal irregularities; surgically and trauma-induced irregularities are rare in his cataract patients. He explained that the prevalence of corneal irregularity is not well understood among his colleagues in his geographic region.

Dr. Srinivasan noted that the postrefractive cataract population has been growing for the past 5 years and will continue to grow. He is not as concerned about the level of correction by previous refractive surgery. "The problem is from older-generation laser treatments. This is where we see more of these irregular corneas," Dr. Srinivasan said.

The adoption rate of refractive surgery is fairly high in Australia, Dr. Beltz said. "Incisional refractive surgery such as radial keratotomy/astigmatic keratotomy in the past resulted in highly unpredictable and unstable levels of irregular astigmatism," she said. Dr. Beltz explained that most post-LVC cataract surgery patients had either previous-generation excimer laser photorefractive keratectomy or LASIK with microkeratome flap creation.



"The only intraocular lens category that does not rely on a precise refractive end point is small aperture."

—Jacqueline Beltz, FRANZCO

CHALLENGES AND RISKS OF POST-LVC CATARACT PATIENTS

Patients who had previous refractive surgery have high expectations because they usually had good visual results from their LVC, Dr. Beltz explained. "Given that LVC was performed years ago with older technologies, they often have irregular corneal astigmatism outside the recommended tolerance zone for trifocal intraocular lenses, which might otherwise be their first choice," she said.

Dr. Al-Mohtaseb noted that irregular astigmatism resulted from the older models of lasers due to irregular LASIK flaps, flap folds, decentered ablations, abrupt transitions between the treated and untreated areas of the cornea, and central islands.

In addition, Dr. Farid added that there can be complications after current treatments. "We see epithelial ingrowth into the flap even with more modern LASIK, especially if they've had an enhancement, and that can induce visually significant irregular astigmatism." ■

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IMPACT OF IRREGULAR CORNEAS ON SURGICAL DECISION MAKING: THE INTERNATIONAL EXPERIENCE

Irregular corneas significantly impact surgical planning and lens selection.

Irregular corneas significantly impact cataract and refractive procedures, from preoperative examination to intraocular lens (IOL) implantation.

“It will affect everything from the way I make my corneal incision, how I will do the surgery with respect to whether to use a femtosecond laser or perform a manual technique. It also influences what kind of lens I’ll implant, whether I’ll use intraoperative aberrometry to help me with the lens accuracy, and whether I’ll use anything to help me guide my axis of astigmatism if I’m using a toric lens,” said Jodhbir Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS.

SURGICAL PLANNING

An irregular cornea can significantly impact biometry.

“Irregular corneas can cause irregular corneal topography and irregular astigmatism, and these patients might have tear film problems,” said Sathish Srinivasan, MD. “If the biometry calculations are not accurate, the IOLs will be less accurate as well.” Therefore, he recommended ensuring that the tear film is optimized, and the true shape of the cornea is measured to achieve optimal outcomes from the selected IOL.

To improve the accuracy of IOL calculations, Jacqueline Beltz, FRANZCO, tries to obtain reproducible keratometry, using Ks from Scheimpflug imaging, optical biometry, and manual methods; she performs all three if reproducibility is in question. “The Scheimpflug imaging system is likely the most reproducible of these in the case of significant irregularity because it measures both the front and back of the cornea.”

Gerd Auffarth, MD, PhD, FEBO, also recommended performing calculations with more than one system. “If they

differ significantly, even though they’re already specialized, you have to look into it or redo measurements,” he said.

“I like to consider a small-aperture IOL if the patient has spherical aberration (Z4) of more than 0.5 μm measured with corneal tomography and demands excellent distance and intermediate vision,” Dr. Auffarth said. “The reason for higher values of spherical aberration can be previous refractive laser surgery of the cornea, corneal scars, previous pterygium surgery, or traumatic changes of the cornea. In these cases, I also like to combine the small-aperture IOL with an extended depth of focus (EDOF) or other presbyopia-correcting IOL in the contralateral eye. We have good experiences with the MOSAIC approach (a combination with a refractive asymmetric segmental multifocal IOL).¹

In patients who have had previous refractive surgery, panelists recommended using formulas such as the Haigis-L formula (doctor-hill.com/iol-main/haigis-l.htm), Barrett True K (apascrs.org), or the ASCRS calculator (<https://iolcalc.ascrs.org>).

Dr. Beltz leans toward the higher power lens from the suggested range when using the ASCRS calculator to reduce the chance of hyperopic outcomes for post-RK eyes. For these eyes, she mainly uses the central measurements of corneal power (3-mm zone), leaning toward flatter measurements where possible, because of the tendency toward hyperopic outcomes and hyperopization over time. “A myopic target is important for these patients,” she said.

LENS SELECTION

Premium intraocular lenses can present a challenge in patients with irregular corneas, resulting in postoperative visual side effects.

CONSENSUS PANEL FINDING #5 - INTERNATIONAL PANELISTS CONSENSUS: AVERAGE PREFERRED ORDER OF PREMIUM IOLS FOR CATARACT PATIENTS WITH IRREGULAR CORNEAS

INTERNATIONAL PANELISTS CONSENSUS:

For low levels of corneal irregularity

1. Trifocal
2. Small aperture or monofocal
3. EDOF
4. Light adjustable

For high levels of corneal irregularity

1. Small aperture
2. Monofocal
3. Light adjustable
4. EDOF



“The key is the accuracy of corneal power measurements in these patients.”

— Zaina Al-Mohtaseb, MD

Consensus Panel Finding #5 identifies the average preferred order of premium IOLs that the international panelists would select for patients with low and high levels of irregular corneas.

To avoid perceived complications, many surgeons automatically choose monofocal IOLs for patients with irregular corneas or they may refer patients to specialized surgical centers, especially if they seek presbyopia-correcting IOLs.

Dr. Srinivasan explained that many of his colleagues do not have access to corneal topographers. In addition, there is limited knowledge on the types of IOLs that work well in patients with irregular corneas, so clinicians play it safe by choosing monofocal IOLs. However, he explained that in very irregular corneas (eg, keratoconus), IOL lens power calculations will be less precise.

Dr. Auffarth takes an individual approach for each patient, comparing IOL calculations and repeating measurements if necessary. Then he chooses the lenses he believes are more forgiving. If the patient has a lower level of corneal irregularity, he may be more likely to use a monofocal IOL with more depth of focus or an EDOF that has at least a 1.00- to 2.00-D landing zone. For a higher level of irregular astigmatism, he avoids diffractive trifocal IOLs and is more likely to choose a small-aperture IOL, which can correct up to 1.50 D of astigmatism. If necessary, a postoperative fine tuning with laser or supplementary IOLs is also possible.

“The main advantage of small-aperture IOLs is the ability to reduce the effect of higher-order aberrations (HOAs) with the small aperture, in addition to providing both intermediate and near vision, which is important for current lifestyles,” Dr. Mehta said (Figure). “This is a significant advantage over other available technology.”

In addition, other factors can influence surgeons’ decisions. Dr. Mehta remarked that if a patient with corneal aberrations does not drive and desires good intermediate vision, a trifocal IOL may be acceptable. His decision also may be impacted by whether the patient drives during the day or at night, when irregularities are more apparent.

If Dr. Srinivasan can obtain good measurements and the cornea is stable in patients with irregular corneas, he may consider a presbyopia-correcting or toric IOL. In patients with very irregular or very unstable corneas, the small-aperture lens might come into play. “If patients have a very irregular cornea or dynamic disease, I would be really cautious in using presbyopic IOLs,” he said.

“The only IOL category that does not rely on a precise refractive end point is small aperture,” Dr. Beltz said. “This is because an inbuilt small-aperture will filter the peripheral light rays that are more likely to end up defocused due to corneal aberrations (higher or lower order). This allows an increased and continuous range of focus compared with a regular monofocal IOL. The small-aperture can increase the depth of focus and/or decrease the impact of an irregular cornea.”^{2,3} She most commonly uses the small-aperture IOL to enhance monovision and has found high patient satisfaction; patients with very irregular corneas can sometimes benefit, too. “Post radial keratotomy patients can be so highly satisfied with this IOL that it may be appropriate for bilateral implantation instead of the usual monocular recommendation,” she said.^{4,5}

In most patients with corneal total HOAs (RMS, 4 mm) greater than 0.3 μm , Dr. Beltz avoids multifocal or diffractive EDOFs; she definitely does not use them when it’s greater than 0.4 μm . ■

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(Photo courtesy of Jod Mehta, BSc (Hons), MBBS, PhD, FRCOphth, FRCS (Ed), FAMS)

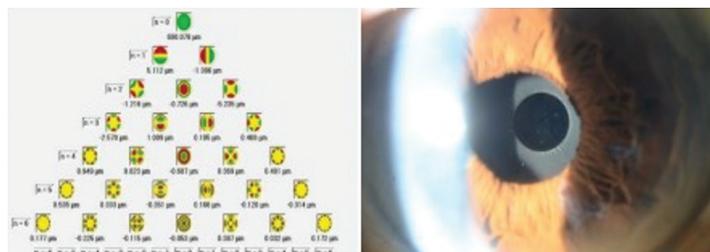


Figure. Irregular cornea from HSV corneal scar undergoing pinhole IOL.

IMPACT OF IRREGULAR CORNEAS ON SURGICAL DECISION MAKING: THE US EXPERIENCE

Irregular corneas significantly impact surgical planning and lens selection.

Irregular corneas significantly impact cataract and refractive procedures, from preoperative examination to intraocular lens (IOL) implantation.

A 2020 custom Market Scope Survey of US cataract surgeons showed 59.5% of US cataract surgeons will only use a monofocal IOL in patients with irregular astigmatism. Fifty-three percent of surgeons believe a better IOL option is needed for cataract patients with reduced vision from significant higher-order aberration (HOA), while 65% believe a better IOL option is needed for patients with reduced vision from significant corneal irregular astigmatism.¹

Consensus Panel Finding #6 identifies that the US panelists typically consider the monofocal IOL the best available option for all levels of corneal irregularity based on IOL options currently available to them. Small-aperture IOLs would be the preferred option of all US panelists if they were available in the United States.^{2,3}

“A small-aperture IOL has completed its clinical trials in the United States. It’s approved in Europe, New Zealand, and Australia and gaining a track record there,” said Richard Lindstrom, MD. “It is helpful in some patients with nontreatable irregular astigmatism.”

Surgeons who have used the small-aperture IOL have been pleased with the results in post-RK patients, Dr. Lindstrom said. “Those patients do remarkably well.”⁴

If the small-aperture lens is approved in the United States, Zaina Al-Mohtaseb, MD, believes it would be useful in patients who have had prior radial keratotomy.

“I’ve been following this lens for a while,” said Cristos Ifantides, MD, MBA. “I’m very excited about it—seeing the high levels of irregular astigmatism and still providing good visual outcomes. I think that it will provide excellent versatility in my clinical setting.”

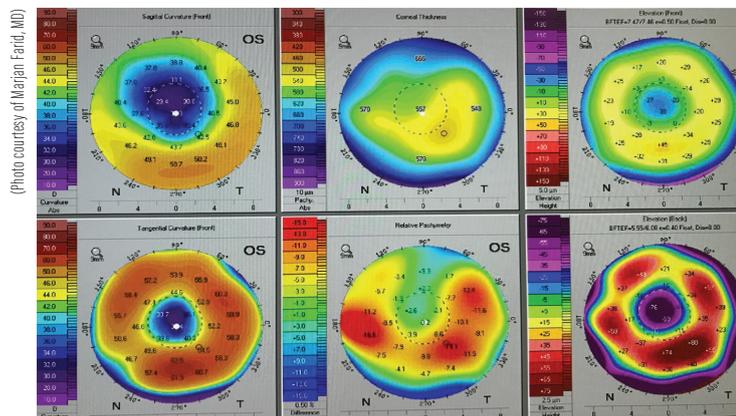


Figure. Corneal topography of post-RK patient with irregular astigmatism.

CONSENSUS PANEL FINDING #6

US Panelists Consensus:

- For all levels of corneal irregularity, monofocal IOLs are the best option available.
- Small-aperture IOLs would be preferred, if they were available in the United States.

SURGICAL PLANNING

If patients with irregular corneas prefer diffractive IOLs, surgeons need to perform a very careful IOL calculation and counseling. Alio et al discussed careful preparation of cataract patients who had previous refractive surgery.⁵

“The key is the accuracy of corneal power measurements in these post-refractive patients,” said Dr. Al-Mohtaseb. “Despite the significant improvement in the formulas we use, IOL calculations following refractive surgery are challenging because of the change in the ratio between anterior and posterior corneal curvature and because of errors in predicting effective lens position. There are also similar difficulties with IOL power prediction with other disease states resulting in irregular astigmatism. Even with a monofocal lens, what do you aim for? I like to aim for a slightly myopic result because, even if you miss, it’s easier to treat a myopic result than a hyperopic result.” She emphasized that it’s also important to set expectations for the surgical intervention.

Dr. Ifantides almost always uses a monofocal IOL in patients with irregular astigmatism. When choosing lenses, he also considers the patient’s personality. Certain personality traits have been shown to impact patient satisfaction with visual outcomes after implantation of multifocal IOLs.⁶

William Trattler, MD, prefers to use neutral aspheric monofocal IOLs in patients with irregular astigmatism. “I tend to target myopia because if they have irregular astigmatism, they tend to tolerate myopia and can actually read, even if they have some irregularity versus distance. They tend to be a little happier if we talk about it ahead of time.”

“We know keratoconus patients’ brains are able to tolerate more HOAs than patients who do not have keratoconic eyes, so in those patients there is the potential for toric IOL placement if you can perform a manifest refraction before surgery and they do well with that,” said Marjan Farid, MD. If they do not improve with manifest refraction of their astigmatism, she prefers to

implant a monofocal IOL and have the patient use a scleral or rigid gas-permeable lens.

“If it’s a cornea that is post-laser vision correction or radial keratotomies and there’s corneal irregularity, Ks that you can’t dependably stabilize or reverse, you’re leaning toward a monofocal lens with a myopic outcome (Figure). Patient expectations should be set appropriately as these eyes may ultimately need a rigid gas-permeable or scleral lens postoperatively,” Dr. Farid said.

If irregular astigmatism is present, even if mild, Dr. Trattler typically does not offer a presbyopic IOL. “We really want a pristine cornea as best as possible to offer patients the best chance they’ll have a good range of vision with presbyopic IOLs.

Dr. Trattler has good experience with irregular astigmatism and the light-adjustable lens. After obtaining a good refraction 3 weeks after surgery, he performs the first light adjustment, which can then be locked in during a subsequent visit once the optimal refraction is achieved. “If someone has reduced best corrected visual acuity due to significant irregular astigmatism, you can’t overcome that loss of best corrected visual acuity with the light-adjustable lens. However, the residual refractive error can be neutralized by adjusting this IOL, leaving patients with the best uncorrected visual acuity possible,” he said.

LASER VISION CORRECTION

Dr. Lindstrom reported that, based on his experience in screening patients for refractive surgery, 10 to 12% of preoperative

laser vision correction patients have irregular corneas that pose a concern.

The prevalence of irregular astigmatism in refractive surgery candidates can be as high as 25% in some ethnicities.⁷ In Dr. Trattler’s practice, approximately 10% of laser vision correction candidates have concerning irregular astigmatism. “Some of these patients with significant irregular astigmatism due to keratoconus and other conditions are not eligible for laser vision correction, and instead would be candidates for crosslinking. Some candidates have only mild irregular astigmatism and can safely undergo photorefractive keratectomy,” Dr. Trattler said.

Dr. Al-Mohtaseb explained that 5 to 10% of her preoperative refractive surgery patients have irregular corneas that would cause her to either lean toward photorefractive keratectomy or not performing laser vision correction at all. “About 10% of patients that I see for laser vision correction will have some irregularity on topography that makes me stop and evaluate for ocular surface disease. I would treat the ocular surface, bring them back, and see if the irregularity has gone away.” ■

1. Custom Survey Report of 123 US Cataract Surgeons by Market Scope, September 2020.

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IRREGULAR CORNEA GLOBAL CONSENSUS EXPERT PANEL MEMBERS

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2020 GLOBAL CONSENSUS ON CORNEAL IRREGULARITY

Release Date: December 2020
Expiration Date: December 2021

INSTRUCTIONS FOR CME CREDIT

To receive credit, you must complete the attached Pretest/Posttest/Activity Evaluation/Satisfaction Measures Form and mail or fax to Evolve Medical Education LLC; 353 West Lancaster Avenue, Second Floor, Wayne, PA 19087; Fax: (215) 933-3950. To answer these questions online and receive real-time results, please go to <http://evolvemed.com/online-courses/2032-supplement>. If you experience problems with the online test, please email us at info@evolvemed.com. Certificates are issued electronically, therefore, please provide your email address below.

Please type or print clearly, or we will be unable to issue your certificate.

Full Name _____ MD/DO participant OD non-MD participant

Phone (required) _____ Email (required) _____

Address/P.O. Box _____

City _____ State/Country _____ Zip/Postal Code _____

License Number _____ OE Tracker Number _____

DEMOGRAPHIC INFORMATION

Profession	Years in Practice	Patients Seen Per Week (with the disease targeted in this activity)	Region	Setting	Models of Care
<input type="checkbox"/> MD/DO	<input type="checkbox"/> >20	<input type="checkbox"/> 0	<input type="checkbox"/> Northeast	<input type="checkbox"/> Solo Practice	<input type="checkbox"/> Fee for Service
<input type="checkbox"/> OD	<input type="checkbox"/> 11-20	<input type="checkbox"/> 1-15	<input type="checkbox"/> Northwest	<input type="checkbox"/> Community Hospital	<input type="checkbox"/> ACO
<input type="checkbox"/> NP	<input type="checkbox"/> 6-10	<input type="checkbox"/> 16-30	<input type="checkbox"/> Midwest	<input type="checkbox"/> Government or VA	<input type="checkbox"/> Patient-Centered Medical Home
<input type="checkbox"/> Nurse/APN	<input type="checkbox"/> 1-5	<input type="checkbox"/> 31-50	<input type="checkbox"/> Southeast	<input type="checkbox"/> Group Practice	<input type="checkbox"/> Capitation
<input type="checkbox"/> PA	<input type="checkbox"/> <1	<input type="checkbox"/> 51+	<input type="checkbox"/> Southwest	<input type="checkbox"/> Other	<input type="checkbox"/> Bundled Payments
<input type="checkbox"/> Other				<input type="checkbox"/> I do not actively practice	<input type="checkbox"/> Other

LEARNING OBJECTIVES

Did the program meet the following educational objectives?

Agree

Neutral

Disagree

Define etiology of irregular corneas, including naturally occurring, surgically induced, disease, and/or trauma

Describe the prevalence of these types of irregular corneas' etiology in various geographic regions and patient populations

Identify specific metric levels (surface regularity index and/or higher order aberrations) for diagnosing various grades of irregular corneas

Recommend diagnostic work-up protocols and describe key conditions to identify as indicators of irregular corneas in conjunction with cataract surgery

Design cataract surgery treatment plans for the various grades of irregular corneas in real-world cases and review conventional and ideal treatment options for these patients

PLEASE COMPLETE AT THE CONCLUSION OF THE PROGRAM.

- Based on this activity, please rate your confidence in your ability to identify and treat patients with irregular corneas (based on a scale of 1 to 5, with 1 = "Not at all confident" and 5 = "Very confident").**
 - 1
 - 2
 - 3
 - 4
 - 5
- Which of the following is NOT an etiology of irregular astigmatism?**
 - Choroidal neovascularization
 - Pterygium
 - Epithelial basement membrane dystrophy
 - Trabeculectomy
- Which of the following is likely to increase the risk of keratoconus?**
 - UV protection
 - Nordic heritage
 - Middle Eastern heritage
 - Meibomian gland dysfunction
- Thirty-five percent of which population of cataract patients were found to have levels of higher-order aberrations of 0.5 μm or greater?**
 - Australian
 - European
 - Canadian
 - Asian
- Which of the following is a potential cause of transient corneal astigmatism?**
 - Previous radial keratotomy
 - Contact lens-induced corneal warpage
 - Surgical removal of pterygium
 - Trauma
- Which area(s) is (are) more likely to have a higher risk of irregular corneas caused by trauma?**
 - Urban
 - Suburban
 - Rural
 - All are equal
- Which of the following is NOT recommended as a point-of-care test for all cataract examinations?**
 - Slit lamp examination
 - Fluorescein angiography
 - Corneal topography
 - Corneal tomography
- It would be useful to _____ to obtain more accurate measurements for patients with irregular corneas.**
 - Perform and repeat measurements on multiple devices
 - Prescribe topical bromfenac 0.075%
 - Use the ELR formula
 - None of the above
- Which of the following is NOT a quantitative measure of irregular corneas?**
 - Higher-order aberrations
 - Surface regularity index
 - Placido ring assessment
 - All of the above
- Which of the following lenses is the top recommendation from international panelists from this CME supplement for patients with high levels of corneal irregularity?**
 - Small aperture IOL
 - Monofocal IOL
 - Light-adjustable IOL
 - EDOF IOL
- Which of the following lenses is the top recommendation from American panelists from this CME supplement for patients with corneal irregularity?**
 - Monofocal IOLs, and small aperture if available
 - Bifocal IOL
 - Light-adjustable IOL
 - EDOF IOL

ACTIVITY EVALUATION/SATISFACTION MEASURES

Your responses to the questions below will help us evaluate this CME activity. They will provide us with evidence that improvements were made in patient care as a result of this activity.

Rate your knowledge/skill level prior to participating in this course: 5 = High, 1 = Low _____

Rate your knowledge/skill level after participating in this course: 5 = High, 1 = Low _____

This activity improved my competence in managing patients with this disease/condition/symptom ___ Yes ___ No

Probability of changing practice behavior based on this activity: ___ Yes ___ No ___ No change needed

If you plan to change your practice behavior, what type of changes do you plan to implement? (check all that apply)

- | | |
|--|---|
| <input type="checkbox"/> Change in pharmaceutical therapy | <input type="checkbox"/> Choice of treatment/management approach |
| <input type="checkbox"/> Change in diagnostic testing | <input type="checkbox"/> Change in differential diagnosis |
| <input type="checkbox"/> Change in current practice for referral | <input type="checkbox"/> I do not plan to implement any new changes in practice |
| <input type="checkbox"/> My practice has been reinforced | |
| <input type="checkbox"/> Change in nonpharmaceutical therapy | |

Please identify any barriers to change (check all that apply):

- | | | |
|---|--|--|
| <input type="checkbox"/> Cost | <input type="checkbox"/> Lack of experience | <input type="checkbox"/> Lack of resources (equipment) |
| <input type="checkbox"/> Lack of consensus or professional guidelines | <input type="checkbox"/> Lack of time to assess/counsel patients | <input type="checkbox"/> Patient compliance issues |
| <input type="checkbox"/> Lack of administrative support | <input type="checkbox"/> Lack of opportunity (patients) | <input type="checkbox"/> No barriers |
| | <input type="checkbox"/> Reimbursement/insurance issues | <input type="checkbox"/> Other. Please specify: _____ |

The design of the program was effective for the content conveyed. ___ Yes ___ No

The faculty was effective. ___ Yes ___ No

The content supported the identified learning objectives. ___ Yes ___ No

You were satisfied overall with the activity. ___ Yes ___ No

The content was free of commercial bias. ___ Yes ___ No

Would you recommend this program to your colleagues? ___ Yes ___ No

The content was relative to your practice. ___ Yes ___ No

Please check the Core Competencies (as defined by the Accreditation Council for Graduate Medical Education) that were enhanced through your participation in this activity:

- | | |
|--|---|
| <input type="checkbox"/> Patient Care | <input type="checkbox"/> Interpersonal and Communication Skills |
| <input type="checkbox"/> Practice-Based Learning and Improvement | <input type="checkbox"/> System-Based Practice |
| <input type="checkbox"/> Professionalism | |
| <input type="checkbox"/> Medical Knowledge | |

Additional comments:

I certify that I have participated in this entire activity.

This information will help evaluate this CME activity; may we contact you by email in 3 months to see if you have made this change? If so, please provide your email address below.
