Of 142,575 cataract extractions an absolute biometry prediction error can occur in 2% of cases

Refractive Surprise: The Big Taboo
INTRODUCTION

Unexpected poor refractive outcomes after cataract surgery – also known as “refractive surprise” – remain a vexing challenge, even as overall visual outcomes steadily improve. The incidence of refractive surprise, technical reasons why it occurs despite improving biometric technology, and what can be done to correct it were topics of a EuroTimes educational symposium, sponsored by Rayner and held at the XXXIII Congress of the ESCRS in Barcelona.

THE BIG TABOO

Thanks to advances in biometry, lens power calculation formulae, and precision surgical equipment and technique, cataract surgery refractive outcomes have steadily improved in recent years. Yet “refractive surprise” remains a challenge.

Indeed, in 2014 nearly one in 50 cataract extraction cases ended up two or more dioptres off target, according to European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) records. “The numbers don’t lie,” said EUREQUO Clinical Director Mats Lundström MD, PhD, who is also Adj Professor Emeritus of Ophthalmology at Lund University, Lund, Sweden.

Absolute biometry prediction errors of 2.0D or more spherical equivalent were reported in 2,510, or 1.8 per cent, of the 142,572 EUREQUO cases that included complete pre- and post-op refractive values operated in 2014, Dr Lundström said. Of these, about one-fifth of errors were much larger, with 4.0D or more seen in 433 cases, or 0.4 per cent of the total – and an astonishing 10.0D or more in 40 cases, or 0.03 per cent.

Overall, about 90 per cent of cases were within 1.0D of the refractive target and 72 per cent within 0.5D, Dr Lundström said. About 40 per cent achieved refractions within 0.5D sphere of plano with less than 1.0D astigmatism. “Around 40 per cent of cases we operate and aim at emmetropia actually get emmetropia.”

COMPLICATIONS AND COMORBIDITIES

Dr Lundström’s purpose was to identify clinical factors that might be useful for assessing risk for “refractive surprise”. The first task was defining the term. A literature search revealed no standard definition, so Dr Lundström defined it as a refractive outcome 2.0D or more above or below the refractive target. This is roughly two standard deviations greater than the mean refractive outcome error reported in several recent large series.

Analysis of the 2014 EUREQUO data found that nearly half of refractive surprises were caused by complications. These included surgical complications, most often capsule-related, and post-op complications, mostly corneal oedema. Since these complications cannot be prospectively identified, Dr Lundström excluded these cases from the risk factor analysis.

Of the remaining 1,412 cases of refractive surprise, 190 had errors of 4.0D or more and 19 had 10.0D or more. Looking closer at cases with very high errors, Dr Lundström found most involved rare and complex circumstances, such as pre-op visual acuity of light perception only or patients requiring general anaesthesia. Based on these findings, he excluded cases above 6.0D error, leaving 1,287 cases of refractive surprise between 2.0D and 6.0D, or 0.9 per cent of all cases.

Logistic regression analysis found several factors significantly related to refractive surprise. These include poor pre-op visual acuity, younger age, myopic target refraction, ocular comorbidities, and surgical difficulties such as previous corneal refractive surgery or corneal opacities.

Focus on “Refractive Surprise”

- Analyzing EUREQUO data from 2014 (Year of surgery)
- Refractive outcome available for 142,575 cataract extractions
- An absolute biometry prediction error of:
  - ≥ 2D exists in 2,510 cases (1.8%)  
  - ≥ 4D exists in 433 cases (0.4%)  
  - ≥ 10D exists in 40 cases (0.03%)  
- Half of the cases with refractive error are caused by surgical (capsule compaction) or postoperative complications (corneal edema)
- If complications are excluded:
  - ≥ 2D exists in 1,412 cases  
  - ≥ 4D exists in 190 cases  
  - ≥ 10D exists in 39 cases = mostly special cases

Around 40 per cent of cases we operate and aim at emmetropia actually get emmetropia.

Mats Lundström MD, PhD
MULTIPLE FACTORS MULTIPLY RISK

Combining these risk factors greatly increased the chance of a large refractive error, Dr Lundström said. For example, 9.5 per cent of patients with the three risk factors of pre-op visual acuity of 20/200 or worse, age below 70, and target refraction of -2.0D or less ended up with a refractive miss of +/-2.0D or more.

Adding glaucoma to those three upper poor refractive outcomes to 13.3 per cent of cases. Adding amblyopia to the three raised it to 17.9 per cent. Corneal opacities raised risk to 28.6 per cent.

The results suggest very poor vision due to dense cataracts and corneal defects may impede accurate biomeetry, and interfere with fixation for accurately assessing corneal curvature and astigmatism. Dr Lundström plans further analysis of EUREQUO data to identify other clues as to the causes of refractive surprise – and what might be done to further reduce the risk of poor refractive outcome after cataract surgery.

ABOUT EUREQUO

The European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO) is intended to help improve treatment and standards of care, and develop evidence-based guidelines for cataract and refractive surgery across Europe. EUREQUO currently includes records of more than 1.8 million cataract extractions and 35,000 refractive procedures gathered from thousands of European ophthalmic surgeons through national registries, electronic medical records systems and a manual Web portal. Financed entirely by the ESCRS since 2011, EUREQUO was launched in 2008 with support from the European Union, the ESCRS, and 11 national societies for cataract and refractive surgery. Patient-reported outcomes are also now included in the database.

THE DATA-REALITY GAP

VA predictions still complicated by lens position, subjective refraction

In 2010 the UK Royal College of Ophthalmologists adopted as cataract surgery outcome benchmarks that 85 per cent of post-op refractions end up within 1.0D of target and 55 per cent within 0.5D. Through the use of careful biomeetry, and selection of appropriate lens power formulae and optimised A-constants, these marks had already been surpassed by 2006 in a large UK series (Gale RP et al. Eye (Lond) 2009 Jan;23(1):149-52. Epub 2007 Aug 24).

Indeed, these benchmarks have been well exceed in several subsequent series around the world, leading some to recommend raising them to 90 per cent within 1.0D and 60 per cent within 0.5D (Sheard R. Eye (Lond) 2014 Feb; 28(2): 118–125). In theory, 95 to 97 per cent within 1.0D is achievable, with one USA academic centre reporting 94 per cent in a 2010 retrospective study (Simon S et al. Ophthalmology. Published online November 27, 2013).

Outstanding as these results may be – and they are superb compared with early cataract refractive outcomes – they aren’t likely to impress the next generation of cataract patients, said James Wolffsohn PhD, of the Ophthalmic Research Group, Aston University, Birmingham, UK.

Younger patients are used to refractions within one-quarter dioptre and have many options for visual correction, including contact lenses and corneal refractive surgery, explained Prof Wolffsohn, who is also Professor and Deputy Executive Dean at Aston’s School of Life and Health Sciences. “When it comes to IOL implantation they expect a similar level of refractive outcome,” he said.

And while ophthalmologists can do much to improve cataract refractive outcomes, some aspects of predicting post-op refraction remain challenging, Prof Wolffsohn explained. Chief among these are accurately predicting postoperative lens position and patients’ subjective refractive preferences. Accurately predicting toric lens outcomes is also challenging, particularly with lower cylinder corrections.

When it comes to IOL implantation they expect a similar level of refractive outcome

James Wolffsohn PhD

SOURCEs OF PREDICTION ERROR

Improving cataract refractive outcomes requires addressing the sources of prediction error, Prof Wolffsohn pointed out. These sources have been extensively modelled, with one study suggesting 35.5 per cent of post-op refractive error derives from errors predicting lens position, while 17 per cent is due to axial length measurement errors and another 10 per cent due to keratometry
Fixing even a small refractive surprise can greatly improve patients’ lives.

**THE SULCOFLEX® SOLUTION**

What bothered this lady most was the loss of her intermediate vision and any ability to read unaided, Dr Barsam said. Surgery

---


Axial length measurement improved dramatically with introduction of partial coherence interferometry, which is accurate to within about 0.01 mm compared with 0.1 mm for ultrasound, Prof Wolffsohn noted. “We are far more accurate than we used to be.

However, ultrasound may still be indicated in some cases where optical biometry fails, typically eyes with dense posterior subcapsular cataracts as a measure of axial length is critical to IOL calculation.

Corneal power measurement also have improved, from subjective keratometers that measured curvature in the central 2.0 mm of the cornea to objective keratometers that include a second set of spots further out, to devices that image the entire anterior and posterior surface using technologies including video topography and raster scanning. These help provide a better understanding of corneal shape, which is not a sphere but a prolate ellipse, Prof Wolffsohn clarified. “The cornea provides two-thirds of the refractive power of the eye and is therefore very important,” he said.

Understanding corneal topography is especially important with toric lenses, Prof Wolffsohn added. Studies show that manual, automated and simulated measurements made by various devices are similar in magnitude, but may vary more in astigmatic meridians (Visser N et al. J Cataract Refract Surg. 2012 Oct;38(10):1764-70). However, differences in the toric lens power indicated by different devices can also be significant.

Predicting effective lens position is more complicated, but may also benefit from improved measuring technology, Prof Wolffsohn said. Optical biometers such as the IOL Master can measure anterior chamber depth through imaging, while optical coherence reflectometry can locate both the front and the back surface of the crystalline lens due to the improved signal to noise ratio. However, the location of the crystalline lens does not necessarily translate into the position of the implanted IOL.

Some lens power formulae incorporate information related to the crystalline lens position while others rely purely on prediction from other biometrics, and different formulae are more accurate for different axial lengths. Constants for particular IOLs may also change with axial length and are specific to individual surgeons, requiring record-keeping and effort to adjust. “This will always be a challenging part of biometry,” Prof Wolffsohn said.

Post-op subjective refraction is also hard to predict because it is, by definition, subjective. “There will always be people who don’t quite tolerate an objective measure,” Prof Wolffsohn said. Studies show the standard deviation of subjective refractions is about 0.4 dioptres, suggesting a considerable range for variation.

Other factors that can affect corneal measurement are head tilt and tear film, Prof Wolffsohn noted. The impact of poor tear film stability leading to break-up can easily be seen watching Placido ring reflections, and will result in unreliable measurements of corneal power and astigmatism. Assuming that all components of the ocular system have the same refractive index also can result in errors, with appropriate adjustments improving biometry accuracy (Camps et al. Optom Vis Sci. 2013 Jul;90(7):639-49).

Prof Wolffsohn commended a “traffic light” approach to biometry measures, in which the measure is taken and the quality of the measure considered as well before making a treatment decision. This is a particular issue with measuring axis for toric lenses, where the best approach may be using several instruments to assess corneal shape and looking for a degree of agreement among them.

Perfect vision requires good axial length measure, lens position prediction and corneal power measure. Prof Wolffsohn concluded. “These are significant challenges, but challenges we are beginning to tackle.”

---

The case seemed simple enough. A mildly myopic 88-year-old lady presented with bilateral cataracts. Her best corrected distance vision had dropped to 20/80 in her right eye with plano sphere and -1.25 x 125° cylinder prescription, and to 20/32 in her left with -1.0D sphere and -1.75D x 65° cylinder.

“I targeted emmetropia for distance and she understood she would need reading glasses thereafter. This is the kind of patient with dense cataracts where you think ‘I really can’t go wrong here’. But how wrong I was,” said Allon Barsam MA, FRCOphth, of Luton & Dunstable University Hospital, University College London Partners, UK.

Preoperative keratometry revealed two dioptres of against-the-rule corneal astigmatism bilaterally. So Dr Barsam implanted a Rayner Toric T-flex® IOL in each eye in uncomplicated phacoemulsification procedures.

Objectively, the results were superb. Uncorrected distance vision was 20/16 in the right eye and 20/20 in the left. Refractions were +0.25D sphere and +0.5D sphere respectively, with negligible astigmatism in either eye.

Subjectively, however, the patient was miserable, Dr Barsam recalled. “She actually thought that her life had been ruined on account of the +0.5D in her left eye.”

At this point, a surgeon unused to thinking of cataract surgery as a refractive procedure might dismiss such complaints in light of the objective results, Dr Barsam said. “You are probably seeing these patients and may just think they are just being fussy.”

---

A better strategy is to listen to the patient and try to figure out why they are unhappy – and think about what you can do to help them, Dr Barsam said. Often, that involves refractive surgery to correct small errors that that patient may not be comfortable with for whatever reason.

“Providing your patient is of sound mind and says they are not happy, that means they are unhappy. And today there are a myriad of options to move them from unhappy to happy. If you have yet to explore those options I strongly encourage you to think about using them,” Dr Barsam said.

---
had transformed her into a slight hyperope from a mild myope. She missed seeing the rich intermediate distance world, with faces of family and friends, and flowers and books and interior spaces that meant so much to her.

This kind of subjective outcome is not unusual, said Dr Lundström. His research using Swedish National Cataract Register data suggests that about six to seven per cent of patients with excellent post-cataract surgery distance vision are unhappy with the outcome. “It is almost always elderly people who had poor distance vision but reasonably good reading vision before surgery,” he said.

Given this patient’s expressed preference for intermediate vision, Dr Barsam thought she might be a candidate for mini-monovision. Working with an optometrist, he arranged a one-day trial with a soft contact lens over the left eye targeting a -1.50D refraction. “I was more inclined to treat the left eye because it had more refractive error,” he said.

The patient tolerated monovision well, but had some difficulty with the contact lens itself, Dr Barsam reported. Nonetheless, he considered the trial a success. “The real question is not whether they can tolerate the contact lens, but whether we can be successful with a surgical solution.”

Like many patients in her age cohort, this lady was at high risk for ocular surface disease. Her tear film break-up time was about four seconds, and she had significant Meibomian gland dysfunction. This made her a poor candidate for laser refractive surgery, Dr Barsam said. “She would almost certainly end up with chronic dry eye.”

So Dr Barsam proposed a Rayner Sulcoflex® IOL. Specifically designed as an add-on for pseudophakic patients, Sulcoflex® is implanted in the sulcus, between the in-the-bag lens and iris. This makes it possible to correct refractive surprise, or even add toric or multifocal function, to an existing IOL without the risk of expalnting the in-the-bag lens.

STABLE AND PREDICTABLE

In Dr Barsam’s experience, Sulcoflex’s 14.00mm haptic length centres well in the ciliary sulcus, while their 10° posterior angulation reduces risk of iris chafe and pupillary block. He noted the 6.5mm optic with rounded edge reduces the risk of unwanted photic effects. “It is also aberration-neutral, which I quite like in monovision because it increases depth of focus, providing more associated reading vision,” he said.

Dr Barsam uses Rayner’s online Raytrace® software to calculate lens power for the Sulcoflex®. The programme requires axial length and anterior chamber depth; in this case 22.05mm and 5.16mm respectively as measured by optical interferometry. The lens requires a minimum anterior chamber depth of 3.0mm, which most pseudophakic patients have, he added.

Corneal K values, pre-op refraction, surgically induced astigmatism and target refraction are also considered. In this case, the target refraction was -1.50D from pre-op +0.5D for a total of 2.0D. Since astigmatism had been successfully corrected at the first surgery with Rayner Toric lenses, Dr Barsam selected a standard aspheric Sulcoflex® with a power of 3.0D.

“The three-dioptre lens was equivalent to inducing two dioptres add in the spectacle plane, reducing the refraction to -1.5D,” Dr Barsam explained.

At surgery, Dr Barsam made a 2.5mm primary incision, enlarged to 2.7mm to admit the tip of the Rayner lens injector. Before inserting the lens he also injected cohesive viscoelastic to open up the space between the anterior capsule and iris. “What I like about all Rayner injectors is the one-handed injection system, so you can control the eye with your non-dominant hand during insertion, and tuck the haptics under the iris as you inject.”

The Sulcoflex® is a little larger than an in-the-bag lens so it takes a little more time to load, and Dr Barsam tucks the leading haptic first followed by the trailing haptic as it emerges from the injector. Dr Barsam placed the haptics of the Sulcoflex® at 90° to the existing in-the-bag IOL haptics. This avoids stacking the haptics of the two lenses, which risks crowding the angle, he said.

Preoperatively, Dr Barsam also noted a few wrinkles in the capsule and some PCO. But he held off on a posterior capsulotomy until after surgery, preferring to keep the capsule intact to avoid any danger of vitreous loss during the sulcus-fixed implantation.

Surgery was uneventful and the final refraction was -1.25D. “The patient is enjoying mini-monovision with restoration of intermediate vision and some reading vision – and restoration of her positive outlook. Sulcoflex® is a really nice option, potentially the only viable option, for someone with ocular surface disease who has a small refractive surprise,” Dr Barsam concluded.

ABOUT SULCOFLEX®

The Rayner Sulcoflex® is a one-piece, hydrophilic acrylic, sulcus-fixed pseudophakic supplementary lens that can be implanted with an in-the-bag IOL, including multifocal lenses. Sulcoflex® is available in aspheric monofocal and multifocal, as well as toric and toric multifocal varieties.

All models feature a 14.00mm undulating haptic ensuring stability in the sulcus. Haptics are angulated 10° to the rear to prevent iris chafe. The optic is 6.5mm in diameter to ensure complete coverage of an in-the-bag IOL optics, and features a rounded edge to reduce unwanted photic phenomena. The posterior optic is concave to prevent contact with an in-the-bag lens, reducing the risk of epithelial cell ingrowth between the two lenses, or hyperopic shift due to distortion of the anterior surface of the in-the-bag lens.

DEMONSTRATED SAFETY

Sulcoflex® can be implanted in eyes with a minimum anterior chamber depth of 3.0mm. It has also been shown quite safe. In a five-year study of 178 patients receiving Sulcoflex® lenses conducted by Michael Amon MD, Professor and Head of the Department of Ophthalmology at the Academic Teaching Hospital of St John, Vienna, Austria, no instances of pigment dispersion, interlenticular opacification or iris trauma were observed.

Intraocular pressure (IOP) remained within normal limits and flare cells were less than those associated with phacoemulsification, Dr Amon said. Clearance was maintained between optic and iris and supplementary optic and in-the-bag optic in all cases. No cases of optic capture or pupil ovalisation were observed.

In general, Dr Amon does not perform an iridotomy except when implanting Sulcoflex® in children or eyes with axial length of 20mm or less. Dr Barsam also reports that he never performs and iridotomy, and has had no issues with elevated pressure or glaucoma following Sulcoflex® implantation.
Dr Amon described the case as “straightforward”. But it was complex enough that another surgeon had given up, leaving Dr Amon to rescue an attempted refractive cataract case.

The 64-year-old female patient had undergone uneventful phacoemulsification surgery at another centre in February 2014. Diffractive multifocal IOLs were implanted in both eyes.

By general cataract surgery standards, the refractive outcome wasn’t terrible. Uncorrected distance vision in the right eye was about 20/30 and in the left about 20/25. Refractions were +0.75D sphere with +0.25D x 16° cylinder right, and +0.5D sphere with +0.5D x 178° cylinder left, with correcting to 20/20 in each eye.

But the patient was unhappy – not surprising given the premium lenses implanted, Dr Amon said. “In cases where we use multifocals it is absolutely important that we reach emmetropic status.”

AVOIDING AN EXPLANT

The original surgeon attempted to fix the problem with a YAG posterior capsulotomy. That didn’t work. By the time the patient got to Dr Amon, she was complaining of difficulties with reading and depth perception, and constant headaches.

Worse, the capsulotomy made an in-the-bag lens exchange very risky, Dr Amon said. “If you have to step in for the next surgery you have a chance of having to deal with vitreous. In that situation, in my eyes it was best to implant a supplementary lens to correct the refraction.”

With a pseudophakic lens in place, calculating the power of a Rayner Sulcoflex® sulcus-fixated add-on lens is simple, Dr Amon said. “You just need the spherical equivalent of the refraction, and multiply the spherical equivalent by 1.5 for hyperopia and 1.2 for myopia.”

Using these calculations, the patient required +1.5D lenses in both eyes, Dr Amon said. He implanted the lenses in April 2014 using a temporal clear corneal incision.

At the last visit in June 2015, the patient was 20/20 uncorrected in each eye. All complaints of visual difficulties and headaches had vanished.

REVERSIBLE PROCEDURE

Dr Amon believes the supplementary lens is superior to laser corneal surgery because, in his view, laser surgery is not reversible while the Sulcoflex® is. Following the same logic, for cataract patients wanting a multifocal lens, he usually implants a monofocal lens first, and then adds a multifocal Sulcoflex®.

This not only allows dialling in the refraction with the supplementary lens, it also makes it much easier to remove the multifocal optic if the patient doesn’t tolerate it, Dr Amon said. “We aim for zero and put the multifocal on top. My patients are very happy with this.”

Dr Amon’s only concern with the supplementary lens is rotational stability. He has observed 10° or more of rotation in about 10 per cent of cases where he has implanted toric lenses. Therefore, when treating patients with astigmatism who want a multifocal lens, he prefers to place a toric lens in the bag with a multifocal add-on in the sulcus. However, he will place a toric lens in the sulcus of a patient with an in-the-bag lens, sometimes suturing the lens in place in cases of rotation.

In a refractive surprise case with a perforated capsule, inserting the Sulcoflex® is much less complicated than explanting the in-the-bag lens, which would almost certainly involve vitreous loss and require an anterior vitrectomy. “I think the Sulcoflex® is a very elegant solution for these indications,” Dr Amon concluded.
hree months after cataract surgery in both eyes, the 61-year-old woman arrived in the office of Dr Ferreira, unhappy with the vision in her left eye.

With uncorrected distance acuity of 20/400 improving to just 20/50 with a +3.50D sphere -2.75D x 30° cylinder prescription, it’s not hard to see why — particularly since the right eye was 20/20 uncorrected with about three-quarters dioptre residual astigmatism. She also had a history of amblyopia in the left eye, Dr Ferreira said.

Slit lamp biomicroscopy showed a paracentral localised depression of the posterior cornea with guttae on the zone of depression in the left eye, Dr Ferreira said. In other words, posterior keratoconus.

Corneal tomography using the Pentacam (Oculus, Wetzlar, Germany) confirmed the diagnosis, showing inferior steepening and reduced corneal thickness in the left eye. The posterior showed localised elevation with an inferonasal island, with a maximum elevation of 263 microns above the best-fit sphere. An anterior area of flattening corresponded with the zone of posterior elevation. Mean K value was 43.1D and thinnest pachymetry 196 microns, Dr Ferreira said. The posterior elevation was also clearly visible on spectral-domain OCT images.

Corneal tomography also indicated possible anterior keratoconus in the right eye, Dr Ferreira added. He noted inferior steepening, with K1 of 44.9D, K2 46.8D, and K max 51.0D with 1.9 D corneal astigmatism.

“It was the first time I saw the patient, so I said ‘let’s wait a few months to see if the refraction and topography remain stable.’ We waited six months, and they were stable,” Dr Ferreira said.

Satisfied that the cornea was stable, Dr Ferreira implanted a Rayner Sulcoflex® Toric 635T in the patient’s left eye. Using Rayner’s Raytrace® software, he selected a lens with +1.5D sphere and 3.0D x 119° cylinder. This improved her uncorrected visual acuity from 20/400 to 20/50. With a +0.5D sphere -0.5D x 35° cylinder correction, that improved to 20/40, with less difficulty binocularly than with the 3.50D difference in spectacle lens power required before surgery.

The Sulcoflex® Toric is a viable option for stable keratoconus in some cases, but may not work in others, noted Dr Nuijts. You have to be realistic; there should be some data that you will get good visual acuity. If you have a bad outcome you have to take the lens out.” He suggests an expected visual acuity outcome threshold of 20/40 or better.

Generally, the supplementary lens is an option in cases showing topography K values up to about 51D, Dr Nuijts added. “We don’t implant in K values of 52 or 53 or higher, but they work for lower.”

In Dr Ferreira’s case, the Sulcoflex® worked just fine. “She was a very happy patient in the end,” he said.

Sulcoflex® Toric 635T 1.5 +3.0x119°

Postoperatively

UDVA 20/50

CDVA 20/40 (+0.50 -0.50x35°)

Happy patient!