Resources

# Achieving Greater Predictability in Corneal and Lenticular Refractive Surgery

## Refractive Surgery Outlook | April 2015 By Tony Hampton

While there is much talk about the convergence of refractive and cataract surgery, these procedures differ significantly in terms of predictability. A recent report noted that in a best-case scenario perhaps 60% of cataract surgeries could achieve outcomes within 0.5 D of target.<sup>1</sup> In contrast, LASIK and PRK surgeons come that close to target in nearly 90% of eyes. However, new diagnostic technology may take corneal and lenticular refractive surgery to the next level, increasing their predictability.

#### Limitations of cataract surgery

To find and eliminate the sources of variability in cataract surgery, Michael Mrochen, PhD, founder and CEO of IROC Science AG in Zurich, Switzerland, notes that one has to look at the entire cataract surgery process, from preoperative biometry through lens selection, surgical placement and changes in IOL position following surgery. Approaching the problem like an engineer, Dr. Mrochen suggests creating an "error budget" and working systematically to eliminate or minimize each source of variability.

A useful place to start is by attacking the steps that have the greatest potential to impact outcomes. Studies have found that inaccurate prediction of where the IOL will position in the postoperative optical system—the effective lens position (ELP)—is a key source of postoperative refractive error.<sup>2</sup> Within the same capsular bag, different lenses may position in different places.

According to Damien Gatinel, MD, PhD, associate professor and the head of the department of anterior segment and refractive surgery at the Rothschild Foundation in Paris, "The current IOL power calculation process can only predict the behavior of the IOL in a given eye from the average response of a large eye population with the same characteristics."

The process is good but far from perfect, and it can lead to refractive surprises, especially in eyes that are very large, very small or have unusual refractive parameters, such as post-refractive surgery eyes.

#### **Corneal power**

Dr. Gatinel continues, "As the aphakic eye's optical power results solely from the anterior and posterior surfaces of the cornea, an accurate estimate of the corneal power as a 'thick lens' would improve the results of IOL power

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calculation. But in most of our current devices, posterior corneal power is 'predicted' from the anterior corneal power, rather than measured directly."

He notes that recent studies have drawn attention toward the posterior surface of the cornea and its effects on the estimation of the corneal cylinder power, which is critical to achieve proper astigmatism control with toric IOLs.<sup>3</sup> Lenticular surgery, he says, would benefit from a device that accurately measures the optical power of both corneal surfaces.

Dr. Mrochen notes that assumptions made about the refractive index of the crystalline lens and cornea in the IOL calculation process may not be accurate.

"To calculate the power of different refractive elements, three basic parameters are required: the curvature of a surface, the distance between refractive surfaces and refractive index of each of the media," he explains. "Today's optical biometry devices lack the ability to measure refractive index and so must assume it based on population averages. Unfortunately, these assumptions may not accurately reflect the individual situation."

The crystalline lens, in particular, is subject to changes in refractive index with aging and disease. If we could measure the refractive index, Dr. Mrochen states, we could get more precise eye length data from our optical measurements.

#### **IOL** formulas

Drs. Mrochen and Gatinel note that IOL formulas predict IOL power quite well in normal eyes. But faced with very long eyes, very short eyes or eyes with unusual geometry (like post-refractive surgery eyes), the assumptions on which these formulas are based no longer hold. Dr. Mrochen notes that different formulas have been recommended for patient groups with specific differences from normal. But, he adds, this has led to a situation where, if a surgeon has to select an IOL for a very high myope or other unusual eye, choosing a formula can be quite confusing. The criteria for choosing one formula over another are, he states, poorly defined, and surgeons can make inappropriate choices.

Dr. Mrochen is looking forward to devices that will make these choices for the surgeon—devices that perform biometry *and* calculate the IOL power using a formula appropriate to the specific measurements it has made. Ideally such a device would measure thickness, distance, curvature and index of refraction and apply them to ray tracing algorithms to improve accuracy and predictability.

#### Intraoperative aberrometry

It would seem that intraoperative measurement of power with the new IOL in place would obviate the need for perfect IOL calculations. However, while intraoperative aberrometry has been helpful, it has significant limitations. As Dr. Gatinel explains, intraoperative aberrometry can significantly improve the alignment of a toric IOL, but it offers less help in spherical power prediction

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because the eye during surgery is far from its natural state.

During surgery, the shape of the cornea is affected by hydration, the anterior segment may be partly filled with viscoelastic, the scleral shell may have a different shape due to the fluidics pressure and even the eyelid speculum exerts a slight distorting effect. The result is axial length and refractive indices that are not the same as they will be after surgery. The ideal IOL power under those conditions may not be the same as IOL power required for good vision after surgery.

#### Limiting factors in corneal refractive surgery

The key to better predictability in refractive surgery lies in the refraction, says Dr. Mrochen.

"Corneal surgery is purely driven by the accuracy of the refraction," he says. "If you do error budgeting and look at the sources of error that affect outcomes in laser refractive surgery, the number one factor is the refraction."

To improve refraction, he urges surgeons to calculate their refraction in a standardized way and to be aware of the limits of subjective refraction, especially in patients with significant higher order aberrations (HOAs) or cornea irregularities.

Wound healing and the biomechanical response of the cornea to ablation also significantly influence outcomes in refractive corneal surgery. Wound healing, states Dr. Gatinel, is responsible for most of the long-term refractive changes after surgery, changes that can erase some of the effects of surgery, particularly in large hyperopic and astigmatic corrections. He notes that "10 microns of relative central or peripheral epithelial hyperplasia is sufficient to create a meaningful dioptric power shift over a 5-mm optical zone." As a result, ablating to achieve an accurate and stable asphericity of the corneal contour can be a difficult task.

"Locating the visual axis intercept at the corneal plane would likely improve treatment outcomes in eyes with large angle kappas, provided that the position can be registered in such a way that its location is properly transferred to the laser unit," Dr. Gatinel adds.

### Can refraction be made objective?

If variability in refraction is a limiting factor, why not ablate based on an objective refraction? Dr. Gatinel notes that vision "involves much more than the bleaching of retinal photoreceptors. Vision is the end result of a process that includes cortical processing, so refracting a human eye can never be as predictable as measuring the focusing power of a telescope." Subjective refraction is attractive to surgeons because it is based on what patients actually perceive.

Dr. Mrochen notes that there is only one large comparative study of objective versus subjective refraction: the clinical trial for the WaveLight wavefront-guided

ablation platform. In that study, there was a control group of eyes for which ablation was based on subjective refraction. The differences in outcomes between the wavefront refraction and the manifest refraction groups were unnoticeable until the data was stratified by the degree of HOA.

Although at lower levels of HOA there was little difference in outcome, in patients with visually significant levels of HOA (i.e., aberration with root mean square values greater than about 0.4 microns), refractive outcomes were better when ablations were based on the objective refraction. However, Dr. Mrochen notes that the proportion of the population with this level of wavefront error is fairly small—perhaps 10% to 20%.

## **Topographic ablation**

Short of surgery, few things improve vision like a rigid contact lens. So why not use topographic ablation to create a similarly perfect anterior refracting surface? According to Dr. Mrochen, while this idea is attractive, there are limiting factors. First, he notes the accuracy of the measurement. If there are issues with the tear film or if there is light scattering within the cornea, the topographic measurement could be affected. A second limitation is the epithelium, which has a tendency to smooth out stromal irregularities. Dr. Mrochen says that when we do topography today, we don't know the degree to which the epithelium is masking underlying stromal irregularity.

"You are planning a treatment based on an epithelium map, rather than on a stroma map, but we are ablating and trying to regularize stroma," he says.

This, he adds, is not important in regular corneas but can be critical in irregular corneas. Finally, he adds, we cannot predict the biomechanical response to such a refractive procedure.

## Conclusion

As good as our current cataract and refractive procedures are, they can be better. Work is ongoing at centers around the globe to make these important surgeries more predictable.

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# DISCLOSURES

Damien Gatinel, MD, is an associate professor and the head of the Anterior Segment and Refractive Surgery Department at the Rothschild Foundation in

Paris. He has recently been a consultant for Physiol, Nidek, Alcon Wavelight, Bausch & Lomb, AcuFocus, Hoya, and Reichert.

Michael Mrochen, PhD, is the owner of IROC Science, AG, and co-founder of ClearSight Innovations and IROC Innocross. He has recently been a consultant for Alcon, Wavelight, Avedro, and IOptics.

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