# CONTOURA TOPOGRAPHY-GUIDED LASIK PLANNEN WITH PHORCIDES



#### **BY MARK LOBANOFF, MD**

n the United States, topography-guided treatment planning is not a controversial topic. Using only manifest refraction data to calculate treatment with the Contoura Vision System (Alcon) is improper and not the practice of most US surgeons. My contribution to this article provides evidence that Contoura topography-guided LASIK planned with the Phorcides Analytic Engine (Phorcides) achieves better results than manifest refraction.

#### SURGERY CHANGES THE MANIFEST REFRACTION

A patient has a refraction of plano sphere. Wavefront-optimized treatment of plano +2.75 x 180° results in a tissue ablation pattern of 43.9 µm at the 12 and 6 clock positions (Figure 1). The refraction does not remain plano sphere after treatment. The cornea has been altered. The original manifest refraction is no longer valid or accurate.

Imagine the same patient has a refraction of plano sphere and undergoes

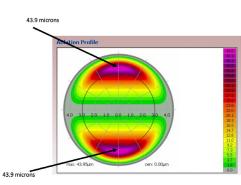
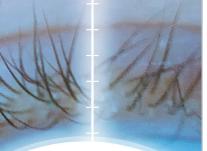
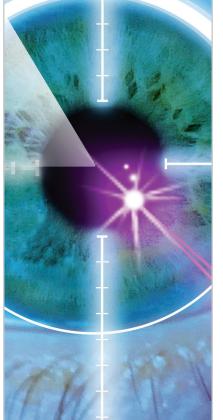


Figure 1. For a wavefront-optimized LASIK treatment of plano +2.75 x 180°. 43.95 um of tissue is removed. The patient's manifest refraction changes after surgery.

### What Is the **Optimal Target Input for Primary** Topography-Guided Treatment of Astigmatism?





## **BIG DATA ANALYTICS** PROVIDE AN ANSW

### **BY AVI WALLERSTEIN, MD,** FRCSC. AND MATHIEU **GAUVIN, BENG, PHD**



oon after the Contoura Vision System (Alcon) became available, surgeons noticed that the magnitude and axis of manifest refractive astigmatism (RA) usually differed significantly from that measured topographically. Many refractive surgeons have therefore struggled to choose an astigmatic treatment target. As part of the investigative team at the McGill Refractive Surgery Research Unit, we have employed big data analytics to provide an answer.

#### THE IMPACT OF HIGHER-ORDER ABERRATIONS

Topography-guided technology was initially developed for treating eyes with significant corneal irregularity induced by conditions such as keratoconus, post-refractive surgery corneal ectasia, irregular and decentered LASIK flaps, radial keratotomy irregularities, trauma-induced irregular astigmatism with higher-order aberrations (HOAs), and scars. The FDA trial for the Contoura Vision System specifically assessed only symmetrical healthy virgin corneas and excluded eyes with mild irregularity (Figure 1). When topographyguided treatment targets manifest RA, the astigmatic component from significant anterior coma may cause treatment inaccuracies and refractive surprises in these extreme cases. In such abnormal corneas, the prevailing recommendation is to overlook the manifest refraction and instead treat anterior corneal astigmatism (ACA) and HOAs. The question arises, can this approach be uniformly applied to eyes that are otherwise normal and healthy?

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Arguments for and against the use of manifest refraction data.

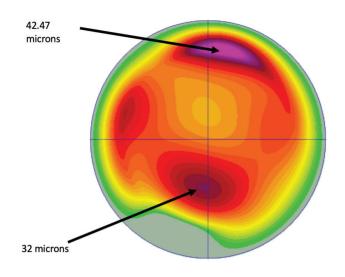


Figure 2. A Contoura LASIK treatment of plano sphere addressing the topographic irregularities only in the same eye described in Figure 1. The tissue ablation pattern is on the right, and 42.47 µm of tissue is removed.

excimer laser treatment of only the topographic irregularities (Figure 2). After the ablation of 42.5 and 32 µm of tissue at the 12 and 6 clock positions, respectively, the manifest refraction does not remain plano sphere. The cornea has been altered, and the preoperative manifest refraction is invalid.

#### EARLY EXPERIENCE

When Contoura entered the US market in 2016, Alcon recommended planning topography-guided LASIK using the manifest refraction. Surgeons quickly found that many patients experienced a flipped astigmatic axis, residual astigmatism, and poor postoperative uncorrected distance visual acuity (UDVA). A. John Kanellopoulos, MD,<sup>1</sup> and I separately compared our clinical outcomes with

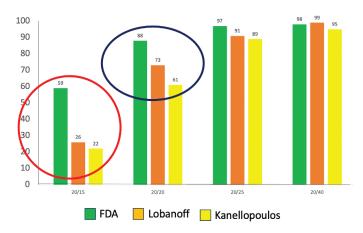
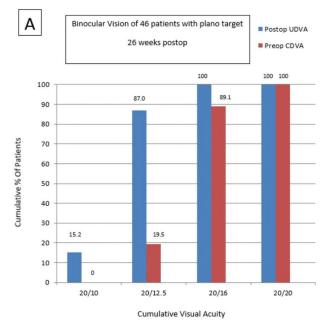


Figure 3. Contoura treatment planned with manifest refraction: FDA study results (green) versus unpublished data from Dr. Lobanoff (orange) and published results from Dr. Kanellopoulos (yellow). topography-guided treatment performed with Contoura based on the manifest refraction against the FDA trial data (Figure 3). Far fewer patients achieved 20/20 and 20/15 UDVA in our studies.<sup>2</sup>

I spoke with R. Doyle Stulting, MD, who ran the FDA trial. He said only corneas with minimal to no topographic irregularities were used. Three corneal specialists confirmed an eye's topography was perfect before it was allowed into the study. In a real clinic, only 15% to 20% of patients arrive with perfect corneas. In everyone else, topographic irregularities contribute to the manifest refraction. If topography changes, the manifest refraction to be treated changes.

#### **A DIFFERENT APPROACH**

A different method of treatment calculation was required, one that accounted for the refractive effects of topographic irregularities as well as corneal and lenticular astigmatism. The Phorcides Analytic Engine was created to meet that need. In a prospective study of Contoura topography-guided LASIK treatments planned with the software, 100% of eyes achieved a UDVA of 20/20, 89% achieved a UDVA of 20/15 or better, and 99% had residual astigmatism of 0.25 D or less.<sup>3</sup> These were the best refractive surgery results ever published until a 2023 study reported that 100% of patients achieved 20/15 or better UDVA with Phorcides-planned Contoura treatment (Figure 4).<sup>4</sup>



### Figure 4. Binocular visual acuity after Phorcides-planned Contoura. All patients achieved 20/15 or better UDVA.

Adapted from Rush SW, Pickett CJ, Wilson BJ, Rush RB. Topography-guided LASIK: a prospective study evaluating patient-reported outcomes. Clin Ophthalmol. 2023;17:2815-2824. Phorcides considers all refractive information, including anterior corneal, posterior corneal, topographic, and lenticular astigmatism.

#### CONCLUSION

Most US surgeons no longer use manifest refraction for the calculation of Contoura. For those who do, it is time to consider switching to treatment planning with Phorcides. Theoretical,<sup>5</sup> retrospective,<sup>6</sup> and prospective<sup>3</sup> studies found that Contoura topography-guided LASIK planned with Phorcides versus the manifest refraction achieved better results. Studies by multiple independent groups across the United States have confirmed the results.<sup>47,8</sup>

 Kanellopoulos AJ. Topography-modified refraction (TMR): adjustment of treated cylinder amount and axis to the topography versus standard clinical refraction in myopic topography-guided LASIK. *Clin Ophtholmol.* 2016;10:2213-2221.

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#### (**Big Data Analytics Provide an Answer**, continued from page 57)

Primary topography-guided LASIK for healthy, normal eyes can be approached in multiple ways, including the following:

- Utilizing manifest RA with nomogram adjustments, the established standard for excimer laser platforms;
- Employing ACA as the treatment input, such as with the topographymodified refraction<sup>1</sup> and layer yolked reduction of astigmatism protocols;<sup>2</sup>
- Choosing a treatment midpoint between manifest RA and ACA; and
- Implementing analytic software, which aims to account for the refractive effects of anterior corneal HOAs.

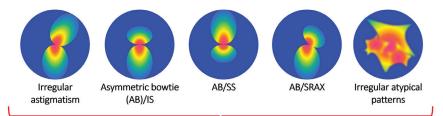
The final trio of methodologies employing ACA as the treatment input, selecting a midpoint treatment target, and using commercial analytic software—overlook the manifest RA. This is based on the presumption that anterior corneal HOAs contribute to subjective RA, even in healthy, unoperated eyes with minimal HOAs. If this assumption is valid and the presence of anterior corneal HOAs explains the discrepancy between RA and ACA, there should be a direct relationship between the amount of anterior corneal HOAs and the amount of discrepancy between the RA and ACA. This hypothesis was the focus of our research unit's investigation, which included a comprehensive study of nearly 40,000 eyes from a general patient population.

When calculated vectorially, the discrepancy between RA and ACA is

termed *ocular residual astigmatism* (ORA). This is the best parameter to quantify the difference (in diopters) between manifest and topographic ACA because it considers both the magnitude and axis discrepancies.

Of the various types of anterior corneal HOAs, anterior corneal coma is believed to be the greatest contributor to ORA. We found no meaningful relationship, however, between the anterior corneal coma magnitude and ORA magnitude or the anterior corneal coma axis and ORA axis (Figure 2). Anterior corneal coma therefore cannot be a significant cause of the observed discrepancy between RA and ACA in healthy primary eyes. The main contributors to the difference must instead derive from posterior corneal astigmatism (PCA), other internal ocular factors, and cortical perception. This conclusion has been corroborated by a similar study conducted by independent researchers.3,4

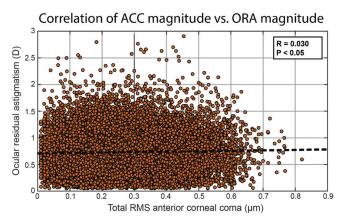
Our findings prompted the hypothesis that targeting the manifest refraction in untreated eyes, even those with higher-than-average amounts of anterior corneal HOAs, does not result in clinically significant adverse outcomes. Our study of 9,722 consecutive eyes treated with manifest refraction as the target compared the standard refractive outcomes. The comparison was between 3,246 eyes with the shallowest ablation depth for anterior corneal HOAs (5.4  $\pm$ 0.9  $\mu$ m) and 3,362 eyes with the deepest preoperative ablation depth

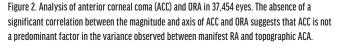


#### EXCLUDED FROM FDA TRIAL

Figure 1. The topographic patterns excluded from the FDA trial for the Contoura Vision System. Only symmetrical healthy virgin corneas were assessed.

Abbreviations: AB, asymmetric bowtie; IS, inferior steepening; SS, superior steepening; SRAX, skewed radial axis.





(11.0  $\pm$ 1.7 µm). Overall, no clinically meaningful correlation was found between the preoperative anterior corneal HOAs and the amount of postoperative sphere, RA, and spherical equivalent. Both groups, with low and high amounts of anterior corneal HOAs, showed excellent efficacy, accuracy, and safety. Consequently, the influence of anterior corneal HOAs on topography-guided outcomes appeared to be minimal. This lack of significant effect can be attributed to the fact that the average HOA ablation depth within the central optical zone of healthy normal eyes is only 6.6  $\pm$ 2.2 µm. Furthermore, 94% of eyes had less than 10 µm of HOA ablated, and only 0.4% had more than 15 µm. These depths were insufficient to induce a predictable refractive effect in 99.6% of healthy eyes.

Eyes with the largest amount of preoperative anterior corneal HOAs trended toward lesser outcomes because they also had a much higher amount of preoperative cylinder. The outcomes in these rare cases of extreme HOA were on par with or surpassed those seen in eyes with moderate to high levels of cylinder. Based on these results, eyes with large amounts of anterior corneal HOAs should not be excluded from topography-guided surgery and can be treated safely on the manifest refraction.

#### **NO BASIS FOR EXCLUSION**

Some surgeons consider a disparity between ACA and RA magnitude greater than 0.75 D or an axis discrepancy greater than 10° to be contraindications for topography-guided LASIK. Based on the results of our previous studies,<sup>5,6</sup> we hypothesized that there would be no clinically meaningful detrimental effects from targeting the manifest refraction in untreated eyes with high amounts of ORA. We studied 21,581 consecutive eyes treated using the manifest refraction as the target and compared the standard refractive outcomes of the 7,180 eyes with the lowest ORA (0.35  $\pm$ 0.13 D) and the 7,208 eyes with the highest ORA (1.13  $\pm$ 0.25 D).<sup>7</sup> The efficacy index of eyes with low versus high ORA was identical. Additionally, a similar percentage

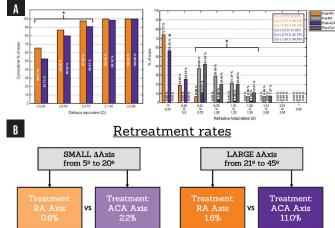


Figure 3. Comparative analysis of defocus equivalents and retreatment rates for LASIK-treated eyes with large axis discrepancies. Orange bars and boxes represent eyes treated based on the manifest RA; purple bars and boxes indicate ACA-treated eyes. The defocus equivalent was significantly higher in the latter (A). Inaccurate astigmatism treatment led to higher retreatment rates in ACA-treated eyes (B).

had a spherical equivalent within  $\pm 0.50$  D of the intended target. The safety and astigmatism correction indices and average preoperative total, horizontal, and vertical anterior corneal coma were also similar. These findings provide evidence that the magnitude of preoperative anterior corneal HOAs does not correlate with ORA, unlike with eyes that have highly aberrated irregular corneas after LASIK and ectatic eyes with high coma.

We also analyzed data on more than 25,000 eyes to determine whether the amount of preoperative axis discrepancy negatively affected refractive and visual outcomes after primary topography-guided LASIK targeting the manifest RA.<sup>8</sup> It did not. Consequently, we concluded that these eyes may be treated based on the manifest RA.

The discrepancy between RA and ACA did not meaningfully influence postoperative outcomes in primary eyes and should not be used as an exclusion criterion.

#### THE SCIENCE BEHIND ALTERNATIVE TREATMENT APPROACHES

Targeting ACA in primary eyes. Manifest RA and ACA rarely coincide in magnitude or axis preoperatively. Surgeons debate whether to treat manifest or corneal astigmatism to optimize outcomes and reduce refractive surprises.

Preliminary research suggested that treating topography-measured ACA is beneficial, but subsequent studies have not supported the idea.<sup>9,10</sup> Our analysis of 1,274 consecutive LASIK eyes demonstrated inferior defocus equivalent outcomes, particularly in cases with large axis discrepancies (Figure 3A).<sup>11</sup> Notably, 15% more ACA-treated eyes had lower uncorrected distance visual acuity compared to their corrected distance visual acuity. Additionally, this group exhibited a 2.5-fold increase in residual astigmatism of 0.75 D or greater postoperatively, which consequently led to a substantially higher retreatment rate (Figure 3B). These outcomes necessitated the early discontinuation of our ACA treatment protocol. Subsequent studies by other investigators have directly or indirectly replicated our findings, demonstrating more accurate refractive outcomes when topography-guided LASIK used the subjective manifest RA versus the topographymeasured ACA, particularly if the difference between the manifest RA and ACA was great.<sup>12-17</sup>

Aiming for the midpoint. Current treatment guidelines for the Contoura recommend reducing the ACA-targeted correction to the midpoint between the ACA and RA in eyes where the former is greater than the latter. This and other approaches do not appear to achieve greater RA accuracy compared to treating the manifest RA. Comparative studies are required.

**Using analytic software**. Commercial topography-guided treatment planning software is designed to refine astigmatism treatment by incorporating objective measurements of anterior corneal HOAs, ACA, and PCA. This method presupposes a significant influence of anterior corneal HOAs on subjective refractive measurements and seeks to adjust for this impact accordingly. As indicated by our previously published research, however, this assumption does not hold true. To date, the sole prospective, randomized, observer-masked contralateral eye study comparing Contoura with Phorcides with Contoura with manifest refraction input showed no benefits from using the analytic software.<sup>18</sup> Further studies are required to establish an advantage of using commercial treatment planning software such as the Phorcides Analytic Engine (Phorcides).<sup>19-21</sup>

A question raised by such analytic software is whether PCA influences topography-guided LASIK outcomes. Our study of 4,541 consecutive eyes found that PCA did not negatively affect the outcomes of topography-guided LASIK targeting the manifest refraction.<sup>22</sup> Considering PCA when planning treatment is unnecessary because ACA, PCA, and internal astigmatism are already included in the manifest refraction.

#### CONCLUSION

The dogma that the discrepancy between manifest RA and ACA influences refractive and visual outcomes has led surgeons to seek alternatives to entering the manifest RA value into primary topography-guided treatment plans. Our research, which includes data from more than 200,000 primary, healthy eyes and has been independently verified, has shown the fallacy of the assumptions underlying these approaches.

Topography-guided treatment targeting the manifest refraction works well because manifest RA includes all perceived sources of astigmatism—ACA, PCA, and lenticular astigmatism. It also reflects the subjective cortical perception of astigmatism, something no alternative method does.

Although the influence of anterior corneal HOAs on RA may be relevant in cases of irregular corneas caused by disease, injury, or surgical complications, this assumption is not applicable to healthy, untreated corneas. Moreover, even in eyes where HOA-dominant optics are present, the exact impact of HOAs on manifest refraction remains unknown.

Scientifically, there is no clinical evidence supporting a change in methodology away from the manifest protocol in healthy primary eyes. Accurate manifest refractions and the use of modern, calibrated nomograms are essential to achieving successful outcomes with any form of laser vision correction.

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