In response to the paper by Brunson et al. (2020).

Wallerstein & Gauvin. 2021

Study bias leads to artificially superior Phorcides outcomes in a recent Contoura LASIK article.

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Abstract

We read “Clinical Outcomes After Topography-Guided Refractive Surgery in Eyes with Myopia and Astigmatism – Comparing Results with New Planning Software to Those Obtained Using the Manifest Refraction” by Brunson and colleagues. The authors report superior outcomes in Phorcides-treated topography-guided LASIK, compared to using manifest cylinder as input, but this seems unfounded considering the inaccurate nomogram and selection bias of higher preoperative cylinder in Manifest eyes. In this commentary, we engage and stimulate the discussion about this important topic of primary topography-guided LASIK surgery, and we point out to several weaknesses of Brunson’s study, which likely resulted in a flawed study conclusion.

We read "*Clinical Outcomes After Topography-Guided Refractive Surgery in Eyes with Myopia and Astigmatism – Comparing Results with New Planning Software to Those Obtained Using the Manifest Refraction*".[1] The authors report superior outcomes in Phorcides-treated topography-guided LASIK, compared to using manifest cylinder as input.[1]

They state, "*Manifest group had slightly higher preoperative refractive astigmatism"* but minimize this study weakness by saying "*mean difference was less than 0.30 D.*" Preoperative cylinder was 34% higher in Manifest eyes and introduced a selection bias. Studies report how higher preoperative cylinder leads to lower astigmatism accuracy postoperatively.[2, 3] This study, where cylinder was not matched preoperatively, advantaged Phorcides eyes. The Phorcides group sample size was also 15% smaller, reducing the likelihood of detecting outliers.

Average preoperative cylinder in the Manifest group was 1.15 D, yet their nomogram treated 1.04 D, undercorrecting by 10%. Since Manifest eyes had higher preoperative cylinder, this inaccurate nomogram expectedly had a greater impact on outcomes. The histogram of preoperative astigmatism, and cylinder vector analysis would have revealed to what extent refractive cylinder was inaccurately corrected in Manifest eyes. The authors did not conduct these fundamental investigations, without which concluding on outcomes is not possible.

Postoperative outcomes are also contradictory. There was only 0.06 D refractive cylinder difference between groups postoperatively with identical SEQ (P = 0.650). However, a larger number of Phorcides eyes achieved 20/15 and 20/20. This clinical finding of having superior acuity yet identical SEQ accuracy is hard to rationalize and contrary to current understanding and

literature on LASIK outcomes. Similar inconsistencies were present in another comparative study by the same authors (Potvin), with statistically inferior refractive accuracy in Phorcides eyes matched to the FDA criteria.[4]

The authors inaccurately state, "*residual refractive cylinder data using Phorcides are better than those reported for topography-guided ablations in some previous large studies". using the manifest refraction*" and cite references that don't back this claim. The Ozulken et al. reference did not use the Manifest as treatment input and Wallerstein et al. studied preoperative cylinder above 0.75 D. The current Phorcides study used eyes with lower preoperative cylinder, making both cited comparisons invalid.

The authors also state "*This then allows the expected optical effect (on both sphere and cylinder) of 'smoothing' these irregularities to be determined*." They assume preoperative HOA has a clinically meaningful refractive effect in virgin eyes. However, publications report no correlation between preoperative HOAs and preoperative manifest vs. topographical cylinder difference, validating that preoperative HOAs do not contribute to refraction in normal eyes.[5]

In summary, the authors' conclusion "*Phorcides Analytical Engine yielded improved postoperative uncorrected visual acuity and lower variability in residual astigmatism than … manifest refraction"* is unfounded considering: cited references do not back their claims, both an inaccurate nomogram and selection bias of higher preoperative cylinder in Manifest eyes, and a same author (Potvin) clinical study showing opposite findings with superior refractive accuracy in *Manifest eyes*.

Disclosure

Dr Wallerstein has indirect ownership in LASIK MD clinics and has no financial or commercial interests in the subject matter or materials presented in the current Commentary. Dr Gauvin has no conflict to disclose and no financial interest in the subject matter or materials presented in this Commentary.

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Author Contribution

A.W. and M.G. wrote the main manuscript text and did critical revision of the manuscript.