EFFICACY AND SAFETY OF PERSONALIZED TOPOGRAPHY-GUIDED-LASIK LASER REFRACTIVE CORRECTION: A TARGETED LITERATURE REVIEW

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Background & Objective

- Topography-guided Laser-Assisted In Situ Keratomileusis (TG-LASIK) provides patients with corrected visual acuity and quality within a short period of time after surgery.
- Personalized diagnostic tools can help to achieve the enhanced vision that patients now expect from refractive error correction.
- This targeted literature review (TLR) assessed the clinical efficacy and safety of personalized TG-LASIK, including comparative data with non-personalized SMILE, and when clinical decision support software was used.

Methods

- The following search strategy and criteria were used for this TLR:

Databases:	MEDLINE
Date range:	January 1st, 2015 - September 1st, 2022
Search Terms:	• “myopia”, “astigmatism”, “LASIK”, “topography”, “analytics software”, and “topolyzer”,”Phorcides”
Inclusion criteria:	• Observational studies and RCTs. • Outcomes available for 3-months post-op • English language.
Outcomes of interest:	• Visual outcomes: UDVA, CDVA lines gained, HOA, OSI • Safety outcome: Loss of ≥2 CDVA Snellen Lines • Refractive outcomes

Results

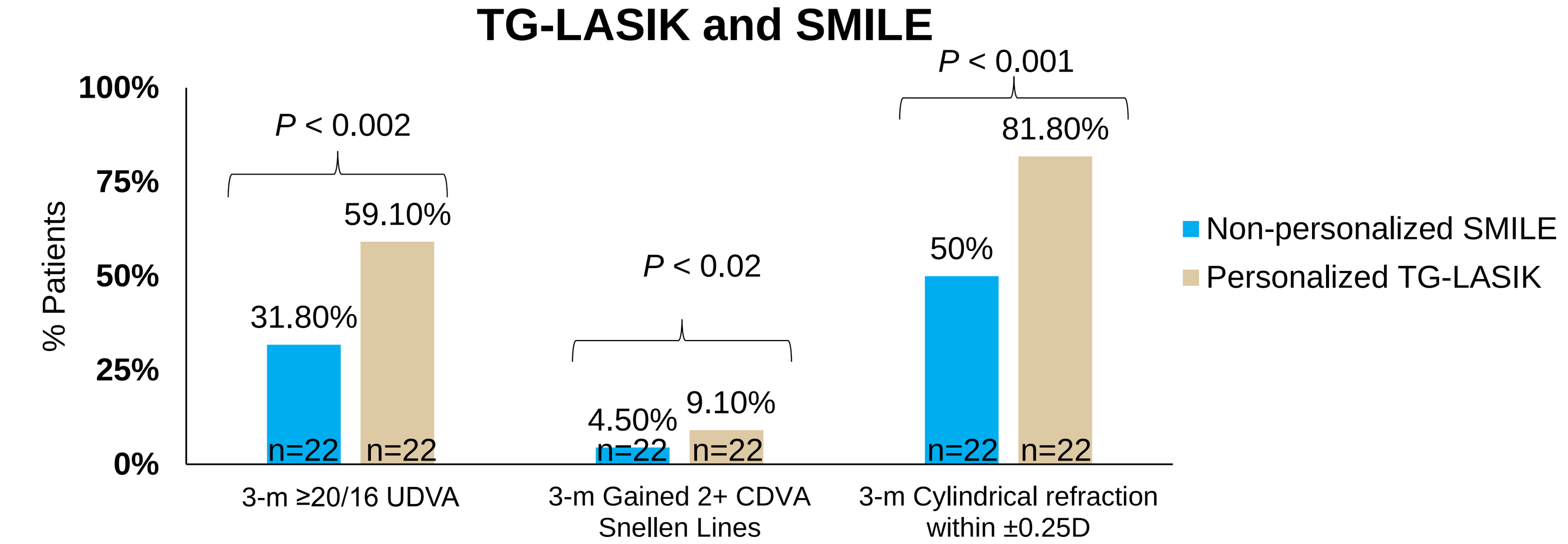
- Five studies compared personalized TG-LASIK with non-personalized SMILE.
- Seven non-comparative articles reported on outcomes with personalized TG-LASIK (4 prospective, 3 retrospective).
- Four studies compared TG-LASIK based on clinical decision support software (Phorcides Analytical Engine) with TG-LASIK based on manifest refraction.

Personalized TG-LASIK Versus Non-Personalized SMILE Studies

- At 3 months post-op, across two studies, a **significantly greater proportion** of TG-LASIK patients had **≥20/16 UDVA** (n=1)[1], **gained 2+ CDVA Snellen Lines** (n=1)[1] and obtained **cylindrical refraction within ±0.25 D** (n=1)[1] than SMILE patients ***(Figure 1)***.

Results

Figure 1. Significantly Different Visual Acuity and Refractive Outcomes between TG-LASIK and SMILE



- Other visual acuity differences were non-significant but a numerically higher proportion of patients with personalized TG-LASIK obtained **≥20/13 UDVA** (n=1; 30% vs. 11%)[2], **≥20/12.5 UDVA** (n=1; 4.5% vs. 0%)[1] **and gained 1 CDVA Snellen line** (n=1; 63.60% vs. 36.40%)[1] than with non-personalized SMILE across two studies.
- Personalized TG-LASIK had **significantly lower mean total HOA** [2] and numerically lower **OSI**[1] than non-personalized SMILE ***(Figures 2 and 3)***.

Figure 2. Difference in HOA between personalized TG-LASIK and non-personalized SMILE

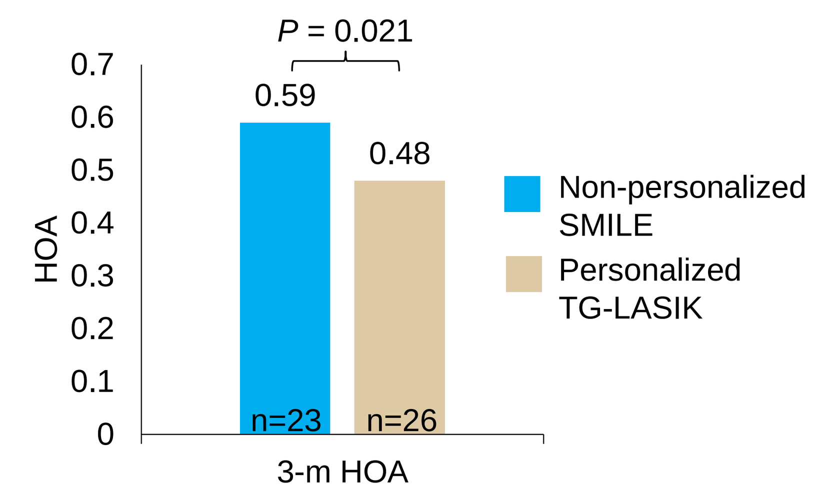
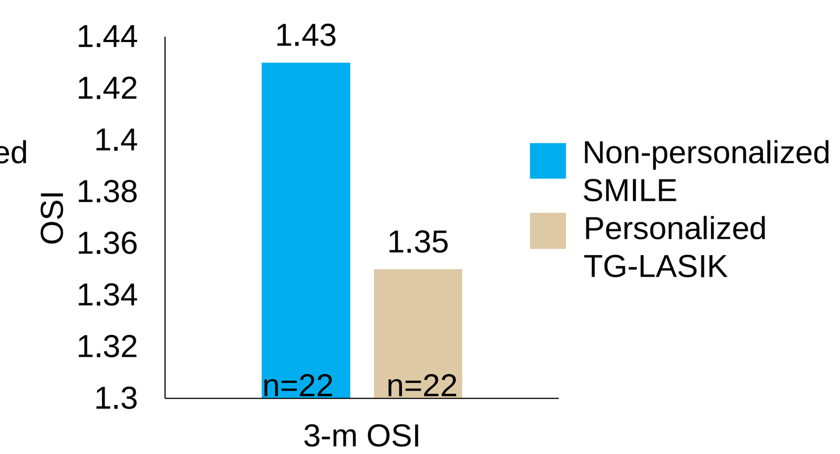


Figure 3. Difference in OSI between personalized TG-LASIK and non-personalized SMILE



- **No ≥2 CDVA line loss** was observed for either group in one study.[1]

Non-Comparative Personalized TG-LASIK Studies

- Three-month outcomes across 7 non-comparative personalized TG-LASIK studies found % patients achieving **UDVA ≥20/16** and **≥20/12.5** to range from 9-76% (n=6)[3-8] and 6-28% (n=4),[3,5,8-9] respectively ***(Table 1)***.
- Two studies reported **UDVA ≥20/15** achievement by 89%[9] and 54%[6]; two studies reported **UDVA ≥20/12** and **≥20/10** achievement by 26%[7] and 6%[6] of patients, respectively.

Table 1. UDVA outcomes across non-comparative TG-LASIK studies

≥20/16 UDVA	[9% (n=32)[3] to **76%** (n=50)[4]][3-8]
≥20/12.5 UDVA	[6% (n=48)[5] to **28%** (n=130)[9]][3,5,8-9]

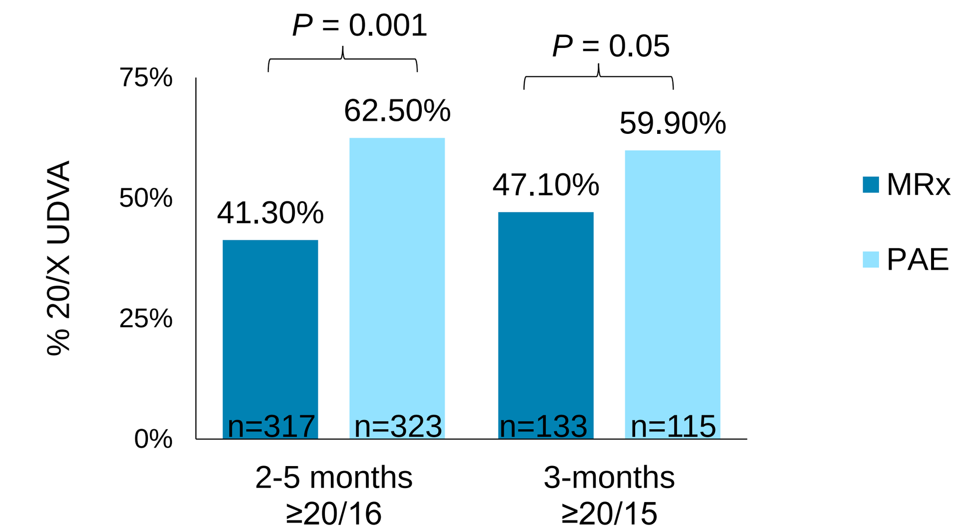
- Across four studies, **no ≥2 CDVA line loss** was observed.[3,5-6,9]

Results

TG-LASIK with Decision Support Software Studies

- At 3 months post-op, across two studies, a significantly higher proportion of patients achieved **≥20/16**[10] and **≥20/15**[11] **UDVA** with personalized TG-LASIK based on a clinical decision support software compared with manifest refraction ***(Figure 4)***.

Figure 4. UDVA outcomes with TG-LASIK based on PAE or MRx



- In another study, PAE predicted the **most accurate refractive outcomes**, followed by topographic measurements and manifest refraction. (Mean calculated error vector (D): 0.39±0.28 vs. 0.47±0.33 vs.0.56±0.42).[6]
- In the “High” groups (>0.75D vector difference between Manifest and Topo), the mean error magnitude in the Phorcides High group was nearly 0.25 D lower than for the Manifest High group[6] ***(Table 2)***.

Table 2. Mean error with TG-LASIK based on high or low vector difference

	Mean Error Vector Magnitude		
	Manifest	**Phorcides**	**Topo**
High	0.70 [0.46]	0.48 [0.28]	0.47 [0.35]
P-value	**<0.01**		NS
Low	0.33 [0.23]	0.26 [0.20]	0.48 [0.31]
P-value	**<0.01**		**<0.01**

High = Vector difference between Manifest and Topo cylinder >0.75D

Low = Vector difference between Manifest and Topo cylinder <0.75D

- Across three studies, **no ≥2 CDVA line loss** was observed for either group.[6,10-11]

Conclusions

- Refractive error correction using personalized TG≥-LASIK offers patients substantial advantages in visual, refractive and safety outcomes compared with non-personalized SMILE.
- Use of TG-LASIK with clinical support software is expected to provide superior VA compared with manifest or topographic measurements.

References

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Abbreviations: CDVA = corrected distance visual acuity; HOA = high order aberration; MRx = manifest refraction; OSI = objective scatter index; PAE = Phorcides analytical engine; RCT = randomized clinical trial; SMILE = small incision lenticular extraction; TG-LASIK = topography-guided LASIK; UDVA = uncorrected distance visual acuity; VA = visual acuity.