

THE LITERATURE



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RESULTS OF TOPOGRAPHY-GUIDED LASER IN SITU KERATOMILEUSIS CUSTOM ABLATION TREATMENT WITH A REFRACTIVE EXCIMER LASER

Stulting RD, Fant BS, and the T-CAT Study Group¹

ABSTRACT SUMMARY

This multicenter, prospective, nonrandomized trial evaluated the safety and efficacy of a topography-guided customized ablation treatment (T-CAT) using the Allegretto Wave Eye-Q excimer laser and the Allegro Topolyzer (both from Alcon) to correct myopia and astigmatism—up to -9.00 D of manifest refraction spherical equivalent (MRSE) myopia and up to 6.00 D of astigmatism. The investigators studied 249 eyes of 212 patients aged 18 to 65 years. Patients with a history of refractive surgery or other ocular pathology were excluded. Visual outcomes, including uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), were measured up to 1 year after surgery.

The study was performed at nine centers. The investigators used treatments based on manifest refractions to address lower-order aberrations and topographic data obtained from two to eight images from the Topolyzer, selected for consistency, adequate coverage, and mire detection. The LASIK flaps were created by either a mechanical microkeratome or a femtosecond laser.

Outcome measures included UDVA, CDVA, visual symptoms, responses on Refractive Status and Vision Profile questionnaires, adverse events, corneal aberrations, and eye examinations. The investigators evaluated aberrations by comparing preoperative root mean square (RMS) measurements from the Topolyzer with 3-month postoperative RMS measurements.

Results from this study showed a significant decrease in MRSE and cylinder, with stabilization 3 months postoperatively. At 1 year, the UDVA was 20/16 or better in 149 (64.8%) of 230 eyes and 20/20 or better in 213 (92.6%) of 230 eyes. At least 90% of eyes achieved a UDVA equal to or better than preoperative CDVA.

At 1 year, 71 eyes (30.9%) had gained 1 or more lines of UDVA compared with the preoperative CDVA.

The safety of the procedure was excellent, with five reports of a transient loss of 2 or more lines of CDVA after 1 month, including three eyes with tear film deficiency, one eye with interface inflammation, and one eye with keratitis secondary to medicamentosa. All eyes had recovered by



ATA GLANCE

- Three recently published studies demonstrated a variety of clinical scenarios in which topography-guided ablations may be used.
- The first study showing the accuracy of topography-guided LASIK in normal corneas with myopia and astigmatism also found a surprising improvement in postoperative visual acuity and quality of vision.
- In the second study, investigators reported excellent refractive results using topography-guided PRK with mitomycin C for the treatment of irregular astigmatism after corneal transplantation.
- The third study showed the usefulness of combining topography-guided treatment that limits tissue ablation depth with corneal collagen cross-linking to stabilize progressive keratoconus and improve visual outcomes.

the next postoperative visit. One patient suffered bilateral retinal detachments unrelated to the procedure 6 months postoperatively. The most common visual symptoms were difficulty driving at night and dryness, both of which were mild to severe in approximately 50% of eyes. Most visual symptoms, including light sensitivity, difficulty with night driving, dryness, reading difficulty, fluctuation in vision, and night vision disturbances, improved by 3 months postoperatively compared to preoperative levels. Only double vision and foreign body sensation increased at 3 months but resolved by 1 year. Dry eye symptoms were reported in three (1.3%) of 230 eyes at 1 year. Quality-of-life responses to Refractive Status and Vision Profile questionnaires showed an improvement in all scores compared to preoperative visits at 1 year, and 98.4% of patients said they were satisfied and would have the procedure again. In the paired RMS analysis comparing aberrations at 3 months with preoperative data, total RMS values decreased 8.9%, and corneal astigmatism decreased 24.4%. Higher-order aberrations (HOAs; third- through fifth-order Zernike polynomials) increased by 8.8%, although all changes were less than 1 nm and were judged by the investigators to be visually insignificant.

DISCUSSION

Wavefront-guided customized corneal ablations have been the standard treatment to correct refractive errors for many years. Topography-guided ablation differs from wavefront-guided ablation by using topographic data to determine corneal HOAs. Because topography-guided systems do not measure lower-order aberrations (sphere and cylinder), surgeons must use refractive data in treatment planning as well. Unlike wavefront-guided ablations, topography-guided treatment does not depend on the size of the pupil, is not subject to errors from a pupil centroid shift, and is able to treat peripheral aberrations. In addition, T-CAT does not treat aberrations in the lens or the vitreous and is not affected by accommodation.

Topography-guided ablations have been used successfully to treat highly aberrated corneas² such as those with irregular astigmatism secondary to corneal transplantation² or previous laser vision correction,²⁻⁴ keratoconus,⁵ or trauma.² This is the first report of T-CAT performed on healthy eyes without significant aberration. Two of the significant findings in this study are that (1) visual acuity appeared to improve to levels greater than preoperative corrected levels and (2) visual symptoms and quality-of-life measures appeared to improve as well. Given that there were no significant improvements in HOAs, the mechanism for the improved visual outcomes is not entirely clear. The investigators postulate that there are subtle topographic changes that were not measurable or that subjective advantages in a visual system that is free of glasses or contact lenses could perhaps account for these improvements. In this study, no control group had wavefront-guided treatment. The authors refer to another study in which wavefront-optimized LASIK was compared to topography-guided LASIK.⁶ Although both techniques produced good visual outcomes, the topography-guided procedure induced fewer HOAs.

IRREGULAR ASTIGMATISM AFTER CORNEAL TRANSPLANTATION—EFFICACY AND SAFETY OF TOPOGRAPHY-GUIDED TREATMENT

*Lains I, Rosa AM, Guerra M, et al*⁷

ABSTRACT SUMMARY

This is a retrospective observational case series of 31 eyes of 30 patients who underwent topography-guided PRK (TG-PRK; off-label use of the laser system) to treat irregular astigmatism after penetrating keratoplasty (PKP). The eyes underwent PKP at least 1 year prior to TG-PRK, and all sutures were removed at least 6 months before laser treatment. Refractive stability (< 0.50 D change) was necessary for 6 months prior to TG-PRK. Twenty-three (74.2%) of 30 patients had an underlying diagnosis of keratoconus, two had corneal scarring secondary to herpetic keratitis, and six had corneal scarring from other causes.

Treatment plans were based on the corneal topographic data obtained by the Allegro Topolyzer, followed by

compensation for the induced refractive change and then input of the manifest refraction. During surgery, a spatula was used to remove the corneal epithelium manually. PRK was performed using the Allegretto Wave Eye-Q 400-Hz excimer laser. Mitomycin C (MMC) 0.02% was applied to the cornea after ablation for 40 seconds, followed by copious saline irrigation. A bandage contact lens was placed and worn for 4 days. Patients used topical antibiotics for 2 weeks, and topical steroids were tapered over 3 months. Acyclovir was used at a maintenance dose of 400 mg twice daily in patients with a history of herpetic keratitis.

In this study, the patients were observed for at least 6 months (range, 6-33 months; average duration, 9.2 months). Outcome measures were UDVA, CDVA, MRSE and cylinder, pachymetry, endothelial cell count, and corneal topographic irregularity indices at the central 3 and 5 mm.

There was a significant improvement in UDVA and CDVA in this study, with a reduction in MRSE and cylinder. All but one eye gained lines of UDVA; 42% gained at least 5 lines of UDVA. Twenty-three eyes (74.2%) gained CDVA; four eyes gained 5 or more lines of CDVA. One eye lost 1 line of CDVA, and one eye lost 3 lines of CDVA due to the development of grade 3 haze and a recurrence of herpetic keratitis with corneal scarring, respectively. Among eyes with less than 6.50 D of preoperative manifest cylinder (18 eyes), 36.8% had less than 1.00 D of postoperative refractive astigmatism. Topographic irregularities showed a significant improvement in the central 3-mm zone but not in the central 5 mm of the cornea. Six eyes (19.4%) developed haze. As mentioned, the haze was classified as grade 3 in one eye; all others had grade 1 haze that resolved with topical steroid treatment.

DISCUSSION

The authors have presented the largest published series of TG-PRK for irregular astigmatism after PKP. The positive refractive results contrast with those in a previously published series in which the researchers did not use MMC and the postoperative incidence of corneal haze was higher.⁸ After surface ablation on healthy eyes without scarring or previous surgery, the increased risk of corneal haze is low, but after LASIK⁹ as well as after PKP,¹⁰ surface ablation increases the incidence of postoperative haze. The safety and efficacy of adjunctive MMC use in these patients¹¹ as well as in those who have had other previous corneal refractive surgery has been well documented in the literature. In this study, MMC was applied for 40 seconds, but the optimal dosage and timing are not known. It is possible that the one case of grade 3 haze could have been prevented or ameliorated with a longer application of MMC.

Because topography-guided ablations can induce refractive change, it has been thought that they are inherently more unpredictable in terms of a refractive endpoint. In this study,

however, using the TG-PRK treatment planning protocol, refractive results were satisfactory, particularly because the preoperative astigmatism values were as high as 11.00 D and TG-PRK only allows treatment of up to 6.00 D of astigmatism. Most important in patients with irregular astigmatism from PKP, correction by TG-PRK can help them regain acceptable vision with standard soft contact lenses or glasses.

LONG-TERM COMPARISON OF SIMULTANEOUS TOPOGRAPHY-GUIDED PHOTOREFRACTIVE KERATECTOMY FOLLOWED BY CORNEAL CROSS-LINKING VERSUS CORNEAL CROSS-LINKING ALONE

Kontadakis GA, Kankariya VP, Tsoulnaras K, et al¹²

ABSTRACT SUMMARY

This prospective interventional case series of 60 eyes of 48 patients with progressive keratoconus compared the results of simultaneous TG-PRK followed by corneal collagen cross-linking (CXL) versus CXL alone over 3 years. Thirty eyes were treated in each group. The groups were matched for age and keratoconus stage. Progression was defined as an increase of 0.75 D in keratometry of the cone apex or a myopic shift of 0.75 D in the cycloplegic refraction spherical equivalent. Patients were excluded if central corneal thickness was less than 400 μm . Patients in the TG-PRK group with CXL were required to have more than 400 μm of residual corneal thickness after excimer laser ablation prior to CXL; if corneal thickness was expected to be less than 400 μm , they were only eligible for CXL alone.

The epithelium was debrided in both groups. The CustomVis Pulzar Z1 solid-state laser (CustomVis; not available in the United States) was used to create the ablation; it was modified to partially correct sphere and cylinder and adjust customization so as to minimize the depth of excimer laser ablation to be no more than 50 μm . CXL was then performed after riboflavin drop instillation every 3 minutes for 30 minutes, using the UV-X system (Peschke Meditrade; not available in the United States) to apply ultraviolet-A treatment for 30 minutes. Patients wore a bandage contact lens until corneal re-epithelialization occurred. Topical fluorometholone 0.1% was then applied for 1 month, with weekly tapering.

Outcome measures included UDVA, CDVA, keratometry, and corneal confocal microscopy to examine endothelial cell density and depth of the CXL ablation. Mean follow-up was 39 months.

Mean UDVA improved by 9.1 letters of logMAR visual acuity in the CXL group and by 26.9 letters of logMAR visual acuity in the TG-PRK with CXL group. Mean CDVA improved by 4.7 letters of logMAR visual acuity in the CXL group and by 8.6 letters in the TG-PRK with CXL group at last follow-up. The differences in mean UDVA and CDVA between the two groups at last follow-up were statistically

significantly better in the TG-PRK with CXL group. The percentage of eyes that had improved by 2 or more Snellen lines of vision was higher in the TG-PRK with CXL group (63% vs 27%). No eye lost more than 2 lines of Snellen visual acuity in either group. Spherical equivalent and defocus equivalent improved significantly after TG-PRK with CXL but not after CXL alone. In the combined treatment group, the average attempted spherical equivalent refractive correction was -1.23 D, but the average achieved spherical equivalent refractive correction was -2.32 D. After surgery, both steep and flat keratometry values were significantly flatter in the combined treatment group compared to the CXL group. There was no difference in the stability of keratometry postoperatively between the two groups. Depth of CXL treatment was significantly greater in the combined treatment group. Endothelial cell density was unchanged in both groups.

DISCUSSION

This study confirmed the combined effectiveness of CXL to stabilize the progression of keratoconus and TG-PRK to improve the visual quality of these corneas. Previous studies have shown improvement over years with PRK alone for the treatment of stable or forme fruste keratoconus.^{5,13} Subsequent studies have demonstrated the successful treatment of keratoconus with TG-PRK and CXL.¹⁴⁻¹⁶ One report showed superior results with simultaneous treatment (Athens protocol) compared to CXL followed by TG-PRK sequentially 6 months later.¹⁷ The current study, which used the Dresden protocol for CXL, is the first to report the greater ablation depth of the CXL treatment in the group pretreated with TG-PRK. The anterior stromal keratocyte nuclei were diminished in both groups, but this depopulation was more long lasting and pronounced in the combined group. The authors postulate that the absence of Bowman layer leads to greater penetration of riboflavin and higher absorbance of ultraviolet irradiation into the stroma. The safety of the procedure, when following the standard safety considerations for CXL, was confirmed by the stable endothelial cell density and sustained refractive results reported in this study.

CONCLUSION

The FDA approved topography-guided LASIK in September 2013, but the technologies are not yet widely available in the United States. Two laser systems have gained approval, the Allegretto Wave Eye-Q and the Navex Quest EC-5000 (Nidek). The three recently published studies summarized herein demonstrate a variety of clinical scenarios in which topography-guided ablations may be used. Until recently, the technology was limited to the treatment of irregular corneas. The first study shows the accuracy of topography-guided LASIK in normal corneas with myopia and astigmatism and demonstrated a surprising improvement in visual acuity and quality of vision postoperatively.¹

The second study reported excellent refractive results using TG-PRK with MMC for the treatment of irregular astigmatism after corneal transplantation, especially impressive given the high preexisting astigmatism in some of these corneas.⁷ The third study shows the usefulness of combining a restricted topography-guided treatment that limits tissue ablation depth with CXL to stabilize progressive keratoconus and improve visual outcomes.¹² As these technologies develop and become more widely available, they should provide a valuable tool in the refractive armamentarium to treat patients in an increasingly customized fashion. ■

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