Therapeutic Refractive Surgery

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In this issue of the Journal of Refractive Surgery, we introduce a new section on Therapeutic Refractive Surgery, which will focus on surgical procedures that are directed at restoring corrected distance visual acuity (CDVA) and quality of vision. We highlight techniques and technology for helping patients who have suffered complications after refractive surgery, methods for treating eyes with previous medical corneal surgery (eg, penetrating keratoplasty), and addressing corneal irregularities from corneal dystrophies, scarring, and other trauma.

Although most patients undergoing modern corneal refractive surgery achieve extraordinary visual outcomes and serious complications are rare, I believe it is critical to focus more attention on developing methods and technologies to help those patients who have suffered complications and currently may be thought to have “no options.” Of course, we have at our disposal repair tools that work well in certain circumstances, but there are still particular types of complication that fall into the category of “irreparable.” We hope that by providing a rigorous scientific forum for developing technology and reporting such cases, we can foster increased development speed of new techniques, expand the group of surgeons interested in treating patients with corneal irregularities, and realize the final goal, which is to be able to fix anything.

Since the early 1990s when the concepts of keratomileusis, the microkeratome, and the excimer laser were combined to create LASIK, more than 51 million laser procedures have been performed globally.1 Huge advances have been made in technology and our understanding of the procedure that have resulted in a quantum leap in safety and efficacy, to the point where the most up-to-date reports demonstrate our ability to leave nearly all patients with visual acuity of 20/20 or better, and virtually every patient 20/40 or better, particularly if one semantically includes “enhancements” under the rubric of treatment. However, no surgical procedure can completely eliminate complications; overall safety in terms of loss of two lines of CDVA has decreased from between 2%,2,3 and 11%4 in the early to mid 1990s to 0.56% in the early 2000s.5 Analysis of the last 10,000 consecutive myopic LASIK procedures performed at the London Vision Clinic shows that patients are undertaking only a 0.04% probability of losing two lines of CDVA (personal communication, Dan Z. Reinstein). Despite this low visual complication rate, as a result of the large numbers of patients undergoing refractive surgery there will always be a significant number of patients needing therapeutic intervention. And remember that all patients who had refractive surgery chose to undergo the elective procedure for life-enhancing reasons, but certain (albeit rare) individuals have ended up with a devastatingly reduced quality of life because technology or techniques to fix the complication are not commercially available.

Although most of us will probably never use the airbags in our cars, few today would consider buying a car without them—I believe we should be able to offer refractive surgery “with airbags.” We should be able to say to prospective patients, “Yes, if you have a complication, we can fix it.” But I believe we also need to be able to get back and help patients who are waiting with what seem to be hopeless situations having had treatment during the learning and development curve that happened through the 1990s where the safety was probably not high enough given the rapid growth and rise of the surgical volume treated. For example, it was not until 1995 that optical zone sizes were expanded to modern parameters,6 and aspheric ablation profiles were not commercially implemented until the early 2000s (despite having been first described for corneal refractive surgery in 19937), meaning that a proportion of the 3.8 million procedures1 performed treated during the 1990s were much more likely to suffer significant induced aberrations with increased glare, halos, starbursts, ghosting, and reduced contrast sensitivity, for which there was no treatment. In the 1990s, the only treatment for patients with significant irregular astig-
matism was a rigid contact lens or, if they could not be comfortably fitted with this, a corneal transplant.8

The primary elements necessary to advance the efficacy of therapeutic refractive surgery include optimal diagnostic equipment, ablation profiles, and perhaps out-of-the-box thinking to stimulate novel reparative strategies. The development of each of these areas is critical and is covered in more depth in Appendix A (available in the online version of this article).

With the currently available techniques of custom ablation profiles based on wavefront aberrometry9 and corneal topography,10,11 combined with the understanding of epithelial masking and the therapeutic use of transepithelial phototherapeutic keratectomy (PTK),12-15 we are able to repair the majority of highly irregular corneas. For example, Figure 1 shows the topography of a patient presenting with +6.00 -8.50 × 110 and a CDVA of 20/50, 26 years after radial keratotomy that included trapezoidal crossing incisions superiorly and inferiorly, in whom we achieved an outcome of plano, 20/20, following a multi-stage repair treatment program consisting of transepithelial PTK and topography-guided ablation.13 This case demonstrates how we can now take an eye with severe irregularities that had been previously offered a corneal transplant as the only option and restore preoperative CDVA with a normal topography centered on the visual axis (as opposed to the entrance pupil). The great challenge ahead is in perfecting these techniques to enable the correction of irregularly irregular astigmatism in a single procedure including accurate refractive control.

The major limiting factor with current therapeutic procedures is the compensatory epithelial response, which must be considered when developing any therapeutic surgical plan, otherwise a false diagnosis and treatment plan can be made (described in more detail in Appendix A, Figure A [available in the online version of this article]). Fortunately, the benefit of epithelial remodeling from a surgeon’s point of view is that we can use it as a natural masking agent in a transepithelial PTK procedure to isolate the ablation onto the peaks of the stromal surface and thereby reduce the irregularities.12-15 One downside to this technique is that refractive shifts due to epithelial compensation go unaccounted for, which is demonstrated in the case described above where the first-stage procedure, consisting only of a transepithelial PTK, achieved a refractive change of 3.50 diopters cylinder.

Therefore, as demonstrated above, the logical next step was to combine transepithelial PTK with topography-guided ablation to theoretically fully correct the stromal irregularities based on the assumption that the stromal irregularity consists of the sum of the corneal surface irregularity and the epithelial remodelling.14-16 An excellent example of this technique is included in this issue, where Abdulaal et al.16 describe successful treatment of patients following buttonhole LASIK flap. However, care needs to be taken because corneal tissue is often at a premium in these repair cases, and there is also the possibility of rendering the eye significantly off target refractively due to the optical power of epithelial compensation.13,17

Our study included in this issue takes this approach one step further to the source of the irregularity itself, the stromal surface; we report the first case where the custom ablation was preoperatively derived from the stromal surface topography, calculated by subtracting the epithelial thickness profile from the anterior surface elevation.17 This method is therefore treating the irregularity directly at its source. Another innovative approach, the custom phototherapeutic keratectomy procedure,18 involves removing the epithelium and intraoperatively obtaining bare stromal topography measurements that are then used to produce a topography-guided ablation profile.

When all else fails, the option of corneal transplantation is still available and has also developed
significantly, allowing deep anterior lamellar grafts to provide visual acuities comparable to penetrating keratoplasty while greatly reducing recovery time and the probability of rejection and graft failure. However, we should always endeavor to use a corneal transplant as the last resort, exemplified by the third article in this issue in which Weissman and Randleman\(^\text{19}\) attempted flap amputation as a therapeutic treatment for flap opacities, irregular astigmatism, and patients with chronic pain in whom other more conservative measures had been ineffective.

We have already made great strides in reducing and treating complications. A major achievement has been in the prevention or management of ectasia (see Appendix A). We have begun to see the importance of layered anatomical diagnosis taking center stage, in particular the relevance of epithelial thickness remodeling, as more devices become able to map it.\(^\text{20-22}\) We have developed repair tools that can cope well with regularly irregular astigmatism and the majority of cases with irregularly irregular astigmatism can also be treated, although usually over the course of multiple treatments. We hope that complex therapeutic refractive surgery will move from being the esoteric interest of a select group of researchers to being a mainstream option for any practicing refractive surgeon. We have the technological components of the puzzle at our fingertips, we just need to figure out how to piece it all together. We hope that this new section of the Journal will provide the environment to achieve this goal and advance the practice of therapeutic refractive surgery.

**REFERENCES**


APPENDIX A

DIAGNOSTIC DEVELOPMENTS IN THERAPEUTIC REFRACTIVE SURGERY

When considering the treatment of complications, it is vital to first make an accurate diagnosis. During the 1990s, in parallel to advances in excimer laser technology, a range of diagnostic instruments were being developed, including corneal topography, tomography, and whole-eye wavefront, which were improving our understanding of the changes being made to the cornea. However, topography, tomography, and wavefront sensors cannot diagnose subsurface irregularities, so to truly understand significant corneal irregularities it is critical to have intracorneal layered imaging and biometry; this has been provided by optical coherence tomography or my main research focus since 1991, very high-frequency (VHF) digital ultrasound.1-9

With advanced imaging capabilities, we have been able to unravel the true underlying cause and anatomy of any corneal complication and have demonstrated in many cases how this would have never been possible with corneal surface mapping or wavefront-sensing techniques due to the sometimes dramatic epithelial remodeling that occurs to compensate for irregularities on the stromal surface.3-9

THERAPEUTIC DEVELOPMENTS IN THERAPEUTIC REFRACTIVE SURGERY

The introduction of wavefront-guided ablation profiles brought the promise of fully controlling higher-order aberrations,10 but these proved less effective than was hoped for when applied to corneas previously operated on, achieving only approximately a 25% to 30% reduction in higher-order aberrations (although all studies report a subjective improvement in quality of vision).11-23 Topography-guided ablations first became commercially available in 1998 with the MEL 70 (Carl Zeiss Meditec, Jena, Germany),24 and were also developed for other laser platforms, including the Corneal Interactive Programmed Topographic Ablation (CIPTA LIGI, Taranto, Italy),25 the Keracor 117C and Technolas 217C (Bausch & Lomb Surgical Technolas, Munich, Germany), and the EC-5000 (Nidek, Gamagori, Japan).28 Topography-guided ablations have further matured, with innovations such as calculating the ablation profile based on the corneal morphological axis.29

Topography-guided ablations are currently commercially available on the Nidek Advanced Vision Excimer (NAVEX; Nidek, Gamagori, Japan),30 the ESIRIS and AMARIS (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany),31 the ALLEGRETTO WAVE Eye-Q (Alcon Laboratories Inc., Fort Worth, TX),32,33 the MEL 80/MEL 90 (Carl Zeiss Meditec, Jena, Germany),34 and the iVis (CIPTAmax; iVis Technology, Taranto, Italy).35

Topography-guided ablations now offer an effective treatment for small and decentered optical zones, as well as for use in correcting topographic asymmetries after corneal transplantation. However, as with wavefront-guided profiles, the hope that topography-guided profiles would be the final solution was short-lived because they were found to be ineffective in cases of irregularly irregular astigmatism.34 Figure A shows an example of a topography-guided ablation and a map of the stromal ablation predicted for a transepithelial phototherapeutic keratectomy (PTK) derived from Artemis VHF digital ultrasound (ArcScan Inc., Morrison, CO) epithelial and stromal mapping. The difference is obvious. This demonstrates that epithelial masking can mean a topography- or wavefront-guided treatment may actually make matters worse and highlights the importance of accurate, layered corneal diagnostic imaging and biometry in all cases of corneal irregularities to decide on the most appropriate treatment.

Figure A. (Left) Transepithelial phototherapeutic keratectomy (PTK) versus (right) topography-guided ablation of the same eye. In this case, the areas of maximum stromal ablation predicted for a transepithelial PTK ablation (outlined in pink) are seen to not correspond to the areas of maximum ablation for a CRS-Master topography wavefront-guided ablation profile. This demonstrates that epithelial remodeling had masked a large proportion of the stromal surface irregularities such that they were no longer detectable by front corneal surface topography and resulted in a topography-guided ablation profile that would not have addressed the stromal surface irregularities.
As discussed earlier in the main article, the benefit of epithelial remodeling from a surgeon’s point of view is that we can use it as a natural masking agent in a transepithelial PTK procedure to isolate the ablation onto the peaks of the stromal surface and thereby reduce the irregularities. The downside to this approach is that we are limited to treat only the proportion of the irregularity that has been masked by the epithelium. Other groups are working on using synthetic masking agents, with an ablation rate similar to that for stroma, so that further smoothing can be performed after removal of the epithelium. Transepithelial PTK treatments are also used in the treatment of corneal conditions such as recurrent erosion, corneal dystrophies, and scarring, as well as for reducing the cone in keratoconus combined with cross-linking.

**Specific Developments: Postoperative Corneal Ectasia**

We have already made great strides in treating complications—one of the major achievements being the management of ectasia, which during the past decade has seen a focus on prevention by improving keratoconus screening, and the introduction of thin-flap LASIK with femtosecond lasers, and on treatment with the advent and development of corneal cross-linking.

**REFERENCES**


