CHAPTER 22

Irregular Astigmatism

Regularizing the Cornea and iVIS Suite Approach to Treatment

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Treatment of visually disturbing irregular astigmatism remains one of the most difficult challenges in refractive surgery. The introduction of custom ablation technologies raised hopes of overcoming this serious challenge because of its capability of delivering asymmetric ablation patterns complementary to the corneal or wavefront irregularities. Nevertheless, the results of custom ablation in treatments of irregular astigmatism have so far been of variable quality at best[1-10] and the reasons for lesser success can probably be grouped into 3 main categories: (1) Use of preoperative measurements that do not include the relevant details of irregular astigmatism; (2) use of ablation-planning software that fits the desired postoperative surface based on an ideal wavefront, without considering the actual shape of the irregular cornea and not considering the cornea outside the optical zone; and lastly, (3) use of surgical techniques and lasers that have been optimized for treatment of optically symmetrical virgin corneas.

Combining its Scheimpflug-based topographer/tomographer (Precisio), dynamic pupilometer (pMetrics), topography-based ablation planning software (CIPTA), and high-resolution 1-KHz flying spot laser (iRES) in its transepithelial mode (cTEN), the iVIS Suite custom ablation system (LIGI, Taranto, Italy) attempts to circumvent the above described shortcomings to address the specific requirements for treatment of complex cases with irregular astigmatism (Figure 22-1).

Unlike other custom ablation systems that rely on third party–supplied topographers that are actually not constructed for surgical treatment purposes, but rather for diagnostic purposes, the Precisio topographer/tomographer (Figure 22-2), used as part of the iVIS Suite, is specifically designed as a custom surgical data acquisition device. It is fine tuned for registering precise 3-dimensional (3-D) morphology of the cornea with resolution, sensitivity, and specificity suited for detecting the details relevant for treatment of irregular astigmatism. Additionally, whereas the other current systems use wavefront aberrometry or monocular Placido-based topography that both provide only "single shots" of the eye or corneal optics, and are bound to the line of sight or to the fixation axis, respectively, the iVIS Suite uses high-definition elevation maps calculated by triangulation (Figure 22-3). Uniquely, the elevation data are statistically evaluated over 2 or more serial examinations to assure that the data have repeatability appropriate for use as surgical data rather than requiring the operator to average multiple maps or subjectively determine if any one single map is appropriate.

To optimize/customize the ablation's optical zone size, iVIS Suite uses a pupilometer, pMetrics (Figure 22-4), which is specially designed for that purpose. It makes 2 camera measurements of the pupil's dynamic responses to specific visual environments and lighting conditions, weighted according to the lifestyle of the patient. A detailed statistical analysis of this data suggests an "Ideal Pupil" dimension, which encompasses 2 standard deviations of all pupil dimensions normally encountered for the specific patient. This dimension is typically determines the optical zone. Figure 22-5 shows a data output sheet from pMetrics.

Rather than using refractive or wavefront data measured only through the pupil, the iVIS Suite incorporates a synthesis of refractive, elevation (Precisio), and pupillometry (pMetrics) data that are imported into Corneal Interactive Programmed Topographic Ablation (CIPTA)

Figure 22-1. The concept of the iVIS-suite for correction of irregular astigmatism.

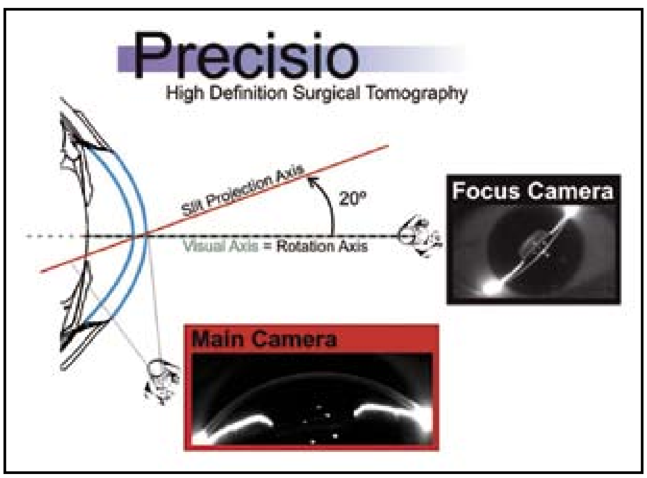

Figure 22-3. Triangulation technique. (Courtesy of Dr. Alesandro Mularoni.)

software. CIPTA compiles an ablation that transforms the actual corneal shape into a regularized aspheric shape of desired curvature, within a customized treatment zone. CIPTA software fully customizes the ablation inclusive of parameters such as tilt, centration, and asphericity of the targeted corneal surface. Additionally, the size and the shape of the optical and transition zones are customized, allowing the surgeon to chose and fit the desired corneal shape in a variety of ways. For treatment of severely irregular corneas CIPTA designs a "restored morphological" axis, a computer-generated axis of restored primary optical symmetry of the cornea. In addition to representing the most logical approach to restoring the damaged corneal optics in irregular astigmatism, the "restored

Figure 22-2. The Precisio topographer/tomographer uses Scheimpflug imaging technology.

Figure 22-4. pMetrics pupilometer.

morphological axis" is also the least invasive approach by consuming the least amount of corneal tissue with the smoothest transition towards the periphery.[11] Unlike any other current ablation planning strategies, CIPTA also takes into account the corneal shape outside the ablation area, thoroughly customizing the transition area by calculating a constant gradient of curvature change over 360 degrees. This achieves a smooth transition between the ablation area and the untreated cornea, essential in avoiding regression.

The CIPTA-generated ablation plan is transferred to a high-resolution 0.6-mm dual-flying-spot iRES excimer laser, which delivers an effective frequency of up to 1 KHz (2 × 500 Hz) (Figure 22-6). The laser features a high-speed, dynamic threshold eyetracking system with cyclotorsional compensation based on scleral vessel registration, as well as constant frequency per area (CF/A) delivery. The latter ensures a constant, effective ablation rate, which is unique to this system (Figure 22-7). Traditional lasers maintain the same delivery frequency regardless of layer area, which results in increasing frequency per area as the

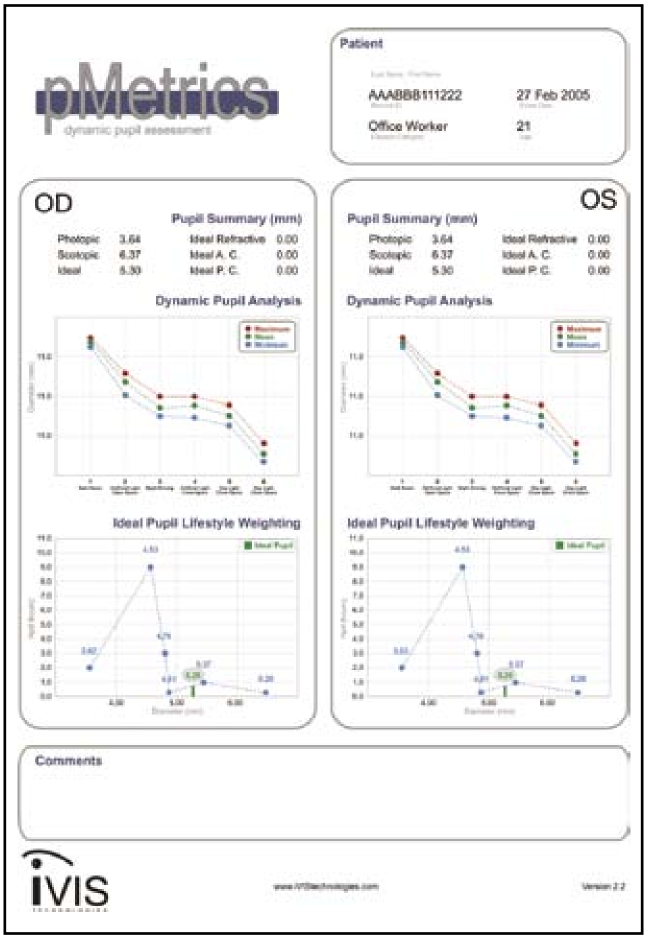

Figure 22-5. pMetrics data output sheet.

Figure 22-6. The 1-kHz iRES laser.

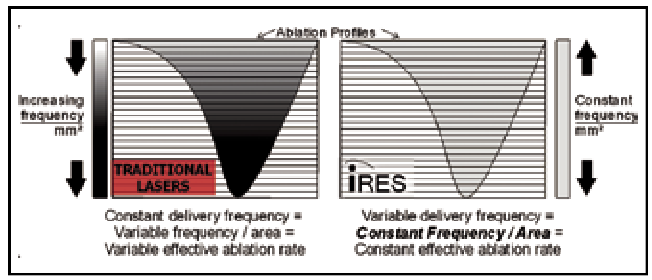

Figure 22-7. Constant frequency per area (CF/A) ensures a constant effective ablation rate. By varying the delivered pulse rate such that it remains constant per area (at 5 Hz /mm2), the entire ablation retains consistent delivery of energy. This results in an increase of the ablation predictability, especially in complex custom shapes and contributes to increased ablation smoothness.

ablation layer decreases in diameter, yielding an increase in plume absorption effect. Other systems compensate for this effect by empirically generated nomograms, which do not usually represent a problem in treatment of virgin eyes with symmetric shape. However, nomograms represent more of a problem in the treatment of cases with major corneal irregularities where highly irregular patterns must be delivered, and where nomograms cannot be applied with any specificity. By varying the delivered pulse rate to remain constant per area (at 5 Hz/mm^2), the entire ablation retains consistent delivery of energy. This results in an increase of the ablation predictability, especially in complex custom shapes and contributes to increased ablation smoothness.

An exceptionally smooth ablation surface from the constant frequency per area and the laser's high speed allows a predictable transepithelial surface ablation, cTEN (custom transepithelial no-touch), which seems to be a surgical technique of choice for treatment of irregular astigmatism. It is superior to surface ablation, where the epithelium of an irregular cornea, which as a rule is of an uneven thickens (Figure 22-8) due to remodeling, is mechanically or chemically removed. In such cases, a surface of an unknown morphology would be treated according to custom data plan, which is based upon a topography (or aberrometry) examination that had been taken while the epithelium was still covering the cornea. It is also superior to laser in situ keratomileusis (LASIK), because it does not compromise tectonic stability of the cornea by ablating deeper corneal layers or add additional unmeasured aberrations from flap generation. With cTEN, the epithelial removal with excimer laser is a fully integrated part of the ablation plan. This technique is achieved by adding a constant ablation depth of 60 to 80 µm analogous to a phototherapeutic keratectomy (PTK) component, which does not induce change in curvature or asphericity, to the CIPTA custom ablation plan (Figure 22-9). The entire custom treatment is executed in a single step and is typically delivered in less time that the treatment without epithelial removal performed by other laser systems.

Clinical Outcomes

Although the iVIS Suite was released in the middle of 2006, early CIPTA software has existed since the mid-1990s and has been used on over 500,000 keratorefractive treat-

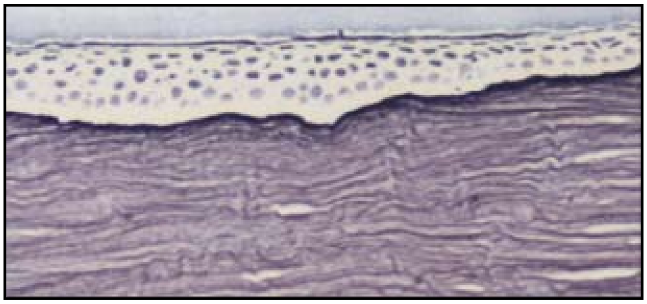

Figure 22-8. Variable epithelial thickness after remodeling in case with irregular astigmatism. (Courtesy of Dr. Giovanni Alessio.)

ments (information provided by the manufacturer) using third-party hardware, mostly Orbscan II (Bausch & Lomb, Rochester, NY) topographer and the LSX (LaserSight Technologies, Winter Park, FL) laser. The vast majority of those treatments were for virgin eyes. Nevertheless, several studies have been published, reporting clinical results with CIPTA treatments of irregular astigmatism.[6-8,10] The author of this chapter has performed treatments of visually disturbing irregular astigmatism using the new iVIS Suite with the cTEN ablation technique. The surgeries were performed at the Eye Department of the University Hospital of North Norway in Tromsø, Norway. Irregular astigmatism was secondary to previous refractive or other eye surgery, injury, or keratitis. The primary treatment goals were (a) elimination or reduction of visual disturbances that could not be corrected with spectacles or soft contact lenses and (b) improvement of the best spectacle-corrected visual acuity (BSCVA). Emmetropia and improvement of uncorrected visual acuity (UCVA) was only a secondary treatment goal, pursued only in cases where ample corneal tissue was available. The first treatments were performed in August 2006 and 26 eyes of 26 patients have passed the 6-month postoperative evaluation point at the time this chapter was written. Preoperative dominant patient's complaints were categorized into the following 3 groups: (1) multiplopia and halos, (2) night vision disturbances including glare and starburst, and (3) decreased visual acuity uncorrectable by spectacles or soft contact lenses. Demographic and baseline refractive data, as well as the correlation between the symptoms and the dominant preoperative topography features, are summarized in Tables 22-1 and 22-2.

Six months after surgery, none of the 26 eyes lost lines of BSCVA, 46% (n = 12) were unchanged whereas 27% (n = 7) gained 1 and 27% (n = 7) gained 2 or more lines (Figure 22-10). Safety index (ie, ratio between postoperative and preoperative BSCVA) was 1.31. The measured efficacy of our treatment was the amount of visual disturbances after the surgery. Table 22-3 shows the subjective change in visual disturbances compared with the preoperative level. Scatter diagram (Figure 22-11) illustrates the predictability of spherocylindrical correction.

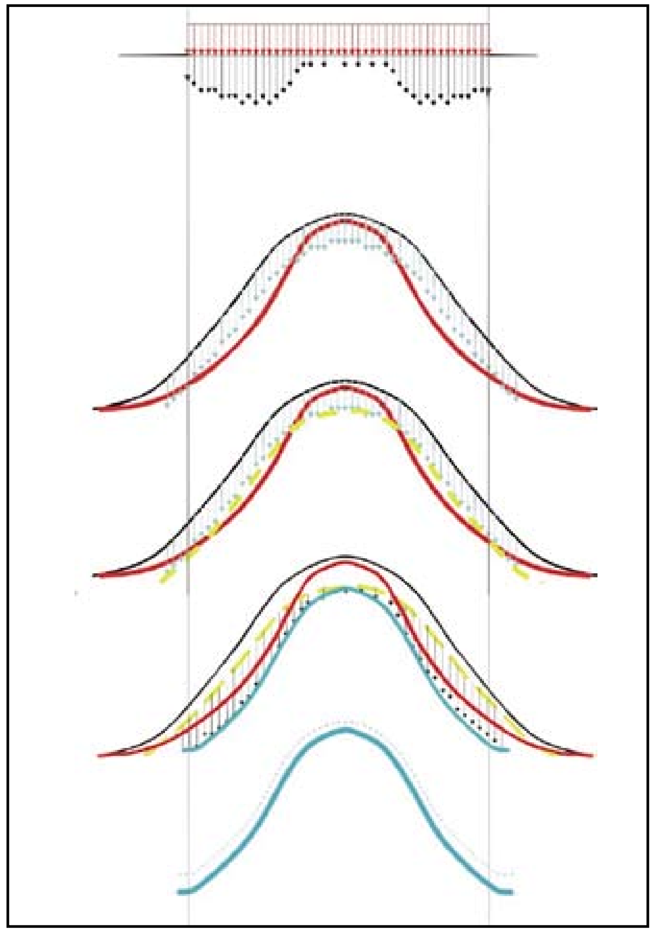

Figure 22-9. cTEN comprises a constant thickness treatment and a refractive treatment, based on comparable ablation rates between stroma and epithelium. The yellow line represents the profile resultant from the removal of a constant thickness of tissue. The green line, now entirely positioned in the stroma represents the final profile inclusive of the refractive treatment. The resultant stromal surface will introduce regularity that minimizes regression phenomena. Upon reepithelialization, the new epithelial surface has a strong tendency to remain a constant thickness along the regularized stromal surface.

Case Study

A 42-year-old male with moderate myopic astigmatism and a 6.2-mm scotopic pupil, was first treated with bilateral LASIK 14 months before referral to our clinic. The original surgery was uneventful, except for the fixation loss of the left eye quite early during the laser ablation. Postoperative UCVA in his left eye was 20/30, without any measurable improvement with spherocylindrical correction, whereas the right eye was correctable to 20/20. The patient was seriously disturbed by multiple images, but he also complained of haloes and night vision problems mostly in his left eye.

Corneal topography (Figure 22-12) of his left eye showed a major decentration (asymmetry within the central 3 mm was measured to 4.1 D) and his corneal

TABLE 22-1

Demographics and Baseline Visual Acuity and Refraction (n = 26)

Age	*Sex*	*Mean MRSE* (D)*	*Mean Cylinder (D)*	*Mean BSCVA*	*Mean UCVA*
34.1 ± 9.7 (24 to 57)	14 (54%) males; 12 (46%) females	−1.85 ± 1.75 (−6.50 to +2.75)	2.37 ± 1.96 (0.75 to 11.50)	0.66 (0.10 to 1.00)	0.28 (0.01 to 0.80

*MRSE = manifest refraction spherical equivalent.

TABLE 22-2

Dominant Preoperative Topographic Feature Versus Type of Visual Disturbances

Dominant Topography Feature (n = 26)

Type of visual disturbances	**Decentred corneal optics (n = 19)**	**Insufficient optical zone diameter (n = 5)**	**Irregular astigmatism (n = 2)**
Multiplopia/haloes	19	1	1
Night vision problems	12	5	2
Decreased BSCVA	10	1	2

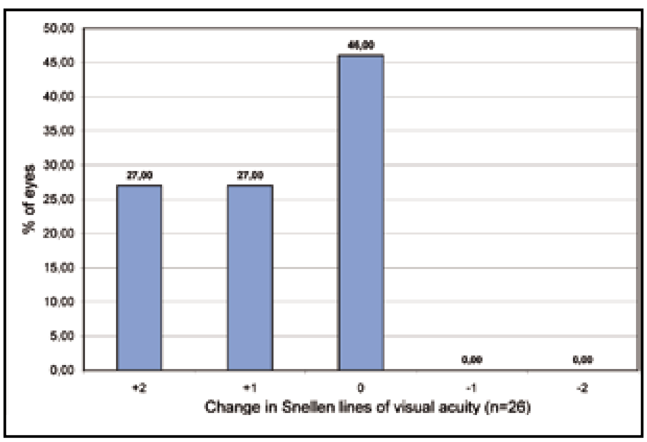

Figure 22-10. Treatment safety; lines of BSCVA gained/lost.

asphericity was oblate with a Q index of +0.56 within the central 4.5 mm. Both first-surface Zernike analysis of elevation topography and wavefront aberrometry showed a significant increase in higher-order aberrations, especially the odd order, as well as increased positive spherical aberration.

An iVIS, cTEN ablation on top of the LASIK flap was performed, aiming for a re-centered optical surface. Restored morphological axis mode of the CIPTA software was used in ablation planning. The ablation map is shown on Figures 22-13.

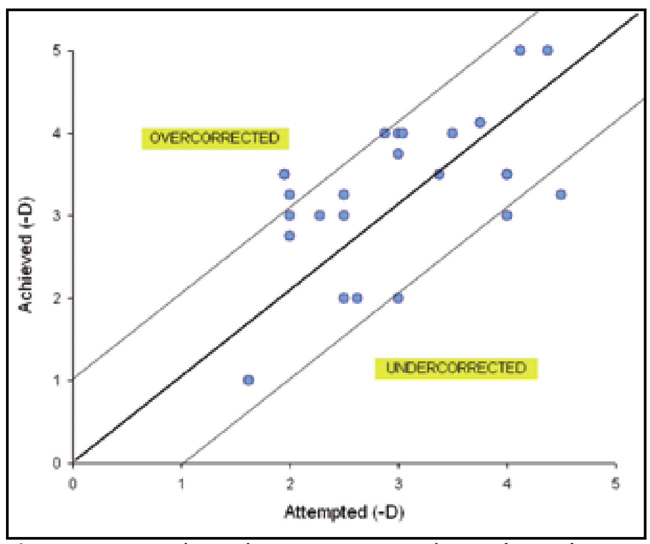

Figure 22-11. Achieved versus attempted manifest refraction spherical equivalent (n = 26).

Six months after surgery, most of the patient's visual disturbances were eliminated, and Q index changed from oblate (0.56) to prolate (−0.22). Precisio elevation map, taken 6 months after the surgery, is shown on Figure 22-14.

TABLE 22-3

Change in Visual Disturbances Compared With the Preoperative

Preoperative Visual Disturbances (Pnstances of Patients' Complaint)	*6 months After Surgery*			
	Worse	**Unchanged**	**Better**	**Cured for symptoms**
Multiplopia/haloes (n = 21)	0	2	7	12
Night vision problems (n = 19)	0	1	9	9
Decreased BSCVA (n = 13)	0	2	5	6*

*BSCVA reached the level of before the event that caused irregular astigmatism.

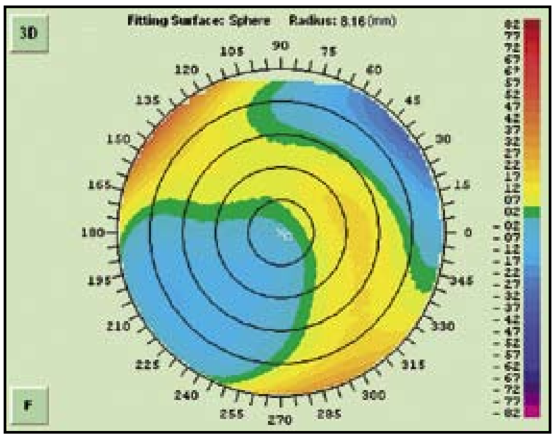

Figure 22-12. Precisio anterior elevation map showing the decentered ablation.

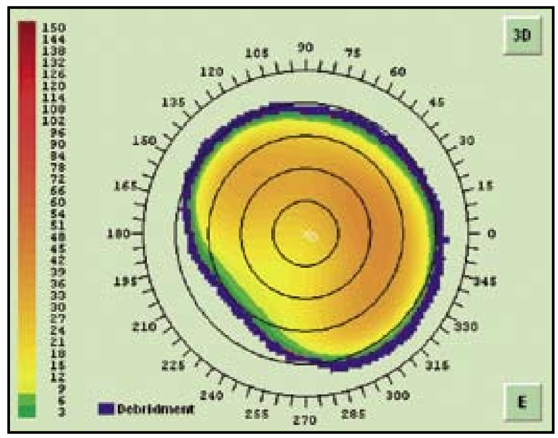

Figure 22-13. CIPTA simulated ablation plan to correct the decentration shown in Figure 22-12.

Discussion

Wavefront technology has provided excellent results in treatment of refractive errors in virgin eyes, but it has unfortunately fallen somewhat short of expectations concerning the treatment of cases with severe visual disturbances. Recent evidence shows that Zernike representation of local irregularities, used in most of the current wavefront-guided technology, might be inadequate in describing complex wavefront distortions and that visual symptoms in certain cases do not correlate well with wavefront data. Besides, aberrometry maps do not cover the area beyond the pupil, which can be a problem when treating the visual disturbances traceable to aberrations caused by corneal irregularities located outside the aberrometry-measurements. Additionally, because it was keratorefractive changes resulting in irregular astigmatism causing the visual disturbances in the first place, the elevation map of the corneal surface should, in the authors' opinion, be the most appropriate source of information, rather than the wavefront aberrometry of the whole optical system. Yet the early custom ablation systems utilizing corneal topography, introduced in the mid-1990s, reported only limited success.[1-4] The combination of low-precision diagnostics from monocular Placido disk–based topographers and low-resolution lasers were some of the probable reasons for the failure

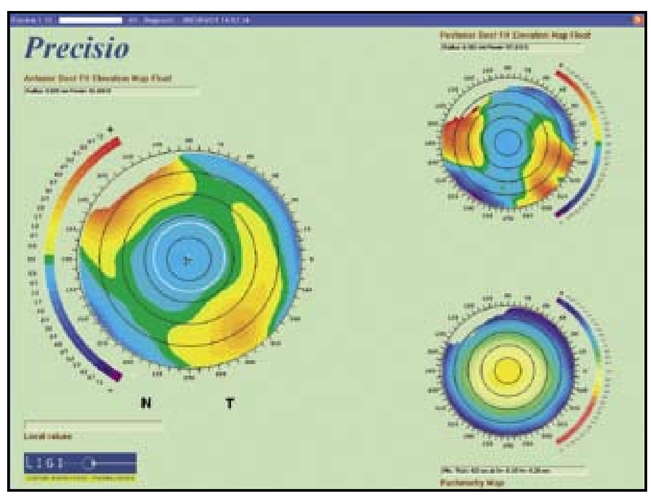

Figure 22-14. Precisio map 6 months after surgery showing improved centration.

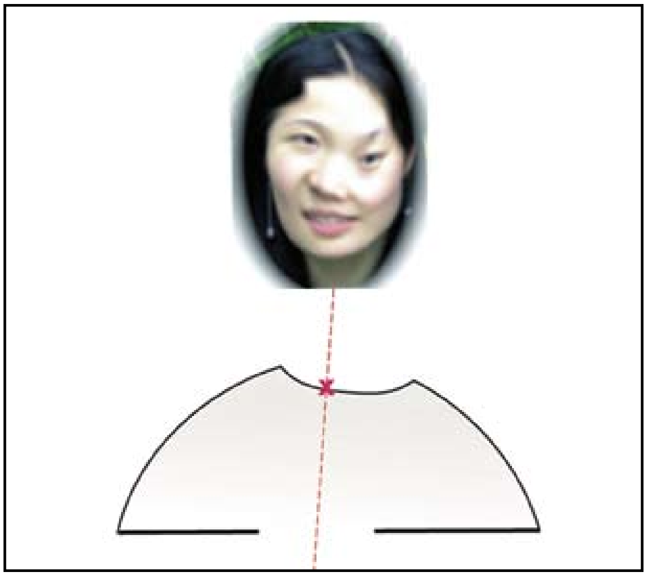

Figure 22-15. Asymmetric corneal optics along the eye's original fixation axis results in highly distorted images.

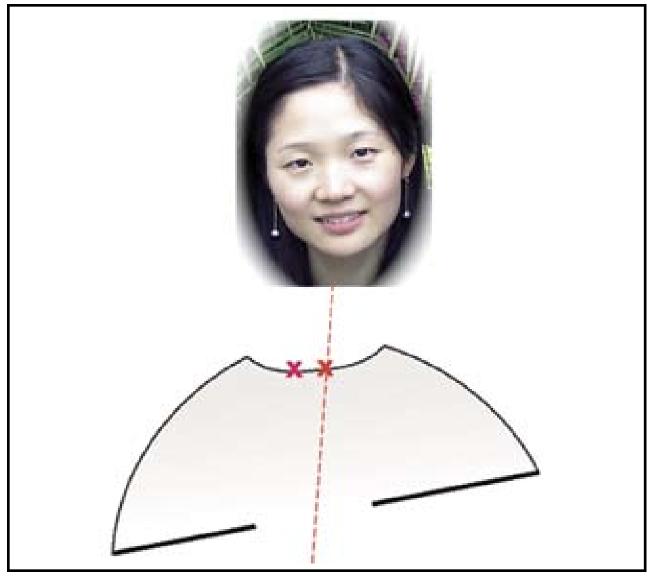

Figure 22-16. Eye with asymmetric corneal optics rotates into a new, adapted position in "search" of a nondistorted image.

of those pioneer systems. Placido topographers calculate corneal elevation data from curvature data using an arc step method, which causes an inherent cumulative error. These data were further combined with underdeveloped ablation planning software for less satisfying outcomes.

Concerning the ablation planning, laser refractive surgery has traditionally attempted to mimic the effect of a contact lens when treating refractive errors. When performing a keratorefractive procedure, the laser ablated tissue to remove a concave, convex, or toric lenticule from the cornea to establish the desired refractive result independent of the preoperative corneal shape. Even current custom ablation profiles continue this approach by modifying the mentioned lenticule by refining its shape with wavefront refractive information. Even the few existing topography-guided custom ablation systems, other than those based on CIPTA software, construct their ablation algorithms by converting their corneal surface information into Zerinicke polynomials and then subtracting those from an imaginary ideal wavefront in order to construct a lenticule, ie, they fail to consider the real corneal shape in treatment planning. CIPTA is the only system that incorporates a 3-D model of the cornea into the laser treatment plan. It creates an ideal corneal model based upon the refractive requirements of the eye and compares this ideal surface to the existing corneal surface. Unlike other systems, CIPTA directly determines the ablation shape and volume as defined by an intersection of those 2 surfaces. Additionally unique to CIPTA is the ability to disconnect the adaptive fixation axis along which the measurements must be taken, and reassess the cornea's structure and shape to determine the "morphological" corneal axis. These capabilities are especially important in eyes with complex corneal irregularities, where the manifest refraction as well as wavefront aberrometry measurements may be difficult to obtain. Any ablation plan in such cases that fails to consider the true elevation map of the corneal surface independent on the fixation axis may actually worsen the situation rather than correct it and it might require significant additional removal of corneal tissue.[11] The iVIS Suite is not vulnerable to the fact that in irregular astigmatism, the position of the corneal intercept of the fixation axis, as well as the fixation axis inclination is changed compared to the primary situation, before the eyes optics were damaged. A patient with distorted corneal optics compensates for his/her visual disturbances (Figure 22-15), by rotating the eye and finding a new fixation axis in order to "find" the least distorted image (Figure 22-16) under the current circumstances. Figure 22-16 shows that a single image of an eye with decentered corneal optics in a fixating position would reflect the information referenced to an adapted (pathological) eye position, with pathologic tilt and the position of the corneal intercept of the fixating axis. An ablation plan based on such information would obviously be wrong.[11]

Surface ablation, contrary to LASIK, preserves the deeper corneal tissue, which usually is a rare commodity in secondary cases. Transepithelial surface ablation featured in the iVIS Suite is not only the least traumatic way of epithelial removal in surface ablation, but it customizes the de-epithelialization area to a necessary minimum with sloped uniform edges, a condition that significantly reduces reepithelialization time and patient's discomfort. Most importantly, it is the only reliable way to perform custom surface ablation on secondary cases where significant epithelial remodeling is expected to have occurred. In such cases topography (or wavefront) data would differ significantly if measured with and without epithelium.

If traditional de-epithelialization techniques were used, we would be treating a quite different topography or wavefront compared to the one that we measured and based our custom ablation plan on. This would necessarily result in reduced predictability of outcomes, probably significantly exceeding the error that might be caused due to ablation rate differences between epithelium and stroma.[12] The transepithelial ablation technique requires not only the software that would add a stipulated maximal epithelial depth to the custom ablation plan (see Figure 22-9), but it also requires a fast laser with a spot and energy distribution that results in a very smooth ablation surface. The latter feature might even turn out to be the most important because of its impact on minimizing the chances of postoperative haze. The iVIS Suite is engineered to perform custom transepithelial surface ablations, by creating a smoother surface in a fraction of time compared to other existing systems. That is achieved thanks to the laser's optimized beam profile, spot pattern design, constant frequency per area, and very high speed.

One remaining problem with topography-guided approach is that the spherocylindrical portion of the treatment necessary to achieve the aimed refractive end point relies on measurements of subjective refraction in the midst of higher-order aberrations, omnipresent in cases with irregular astigmatism. Unfortunately, wavefront aberrometry measurements, which should ideally provide objective information on low-order aberrations, seem to lack reliability in highly aberrated cases, if they can be acquired at all, so that the problem remains currently unsolved.

In conclusion, the iVIS Suite, with its specially designed diagnostic and laser treatment hardware, seems to have come a long way in complementing its CIPTA software that had been introduced almost a decade before. CIPTA also has developed and matured in tandem to offer new tools and customizing features for the refractive surgeon. CIPTA moves the concept of an ideal corneal surface closer to reality representing a promising and unique improvement of our options to successfully meet the challenges in treatment of irregular astigmatism.

References

1. Seitz B, Langenbucher A, Kus MED MER, Harrer M. Experimental correction of irregular corneal astigmatism using topography-based flying-spot-mode excimer laser photoablation. *Am J Ophtalmol*. 1998;125:252-256.
2. Weisinger-Jendritza B, Knorz MC, Hugger P, Liermann A. Laser in situ keratomileusis assisted by corneal topography. *J Cataract Refract Surg.* 1998;24:166-174.
3. Dausch D, Schroder E, Dausch S. Topography-controlled excimer laser photorefractive keratectomy. *J Refract Surg.* 2000;16:13-22.
4. Alio JL, Belda JI, Osman AA, Shalaby AMM. Topography-guided laser in situ keratomileusis (TOPOLINK) to correct irregular astigmatism after previous refractive surgery. *J Refract Surg.* 2003;19:516-527.
5. Hjortdal JØ, Ehlers N. Treatment of post-keratoplasty astigmatism by topography supprted customized laser ablation. *Acta Ophtalmol Scand.* 2001;79:376-380.
6. Alessio G, Boscia F, La Tegola MG, Sborgia C. Topography-driven excimer laser for the retreatment of decentralized myopic photorefractive keratectomy. *Opthalmology.* 2001;108:1695-1703.
7. Alessio G, Boscia F, La Tegola MG, Sborgia C. Corneal interactive programmed topographic ablation customized keratectomy for correction of postkeratoplasty astigmatism. *Opthalmology.* 2001; 108:2029-2037.
8. Mularoni A, Laffi GL, Bassein L, Tassinari G. Two-step LASIK with topography-guided ablation to correct astigmatism after penetrating keratoplasty. *J Refract Surg*. 2006;22:67-74.
9. Jankov MR 2nd, Panagopoulou SI, Tsiklis NS, Hajitanasis GC, Aslanides M, Pallikaris G. Topography-guided treatment of irregular astigmatism with the wavelight excimer laser. *J Refract Surg.* 2006;22:335-344.
10. Pedrotti E, Sbabo A, Marchini G. Customized transepithelial photorefractive keratectomy for iatrogenic ametropia after penetrating or deep lamellar keratoplasty. *J Cataract Refract Surg.* 2006; 32:1288-1291.
11. Stojanovic A, Suput D. Strategic planning in topography-guided ablation of irregular astigmatism after laser refractive surgery. *J Refract Surg.* 2005;21:369-376.
12. Seiler T, Kriegerowski M, Schnoy N, Bende T. Ablation rate of human corneal epithelium and Bowman's layer with the excimer laser (193 nm). *Refract Corneal Surg*. 1990;6:99-102.