

LaserSight Alternatives in Topography-Based Custom Ablation

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The concept of customized ablation (CA) developed in the mid-nineties was corneal topography-based. Treatment of irregular astigmatism (IA) was its primary aim,¹⁻⁴ but due to the complexity of the task, as well as the underdeveloped diagnostics and treatment equipment, the initial results were below expectations.^{5,6} Introduction of wavefront technology around the year 2000, backed by an enormous marketing effort, led to a paradigm shift in CA, turning its focus to virgin eyes.⁷⁻¹⁰ Such historical background and obvious commercial advantage of an immensely larger virgin eye market seems to have influenced research and development policy within the LaserSight company as well. It led to the development of their own “Custom Eyes” solution, based on the AstraMax diagnostic workstation and AstraPro ablation planning software (primarily designed for vision correction in virgin eyes) and turning away from an already mature third party CA system based on Orbscan diagnostics and CIPTA (Ligi, Taranto, Italy) software, despite the latter systems’ unique and unsurpassed results in treatment of IA.^{11,12}

ASTRAMAX WORKSTATION

The two widely available corneal topography technologies (“Placido disk” and “scanning slit”) were not originally designed for use in CA. It requires higher precision and accuracy of corneal elevation mapping than the current instruments can provide. Monocular Placido disk-based topographers that register cornea curvature information were developed primarily for contact lens fitting. The Orbscan scanning slit topographer, although registering the corneal height information, was not designed with CA in mind and lacks the necessary precision for such a task.

Monocular Placido-based systems rely on information from one camera, one angle, and “one shot”. Under such circumstances, direct measurement of height information for a single independent point on the corneal surface is not possible. The mathematically calculated height of each point using the arc step method depends on neighboring points, and an artifact can easily lead to a cumulative error, significantly affecting the accuracy of the system.

Height measurements of the Orbscan’s scanning slit system are more accurate due to the use of the triangulation method. However, they lack the necessary precision due to a relatively long data acquisition time that requires eye movement compensation and causes errors due to abnormal light scattering on dry corneal surface, as well as any other type of blocking of light transmission including corneal scarring, irregular epithelium, edema, irregular corneal collagen, or interface fluid.

AstraMax is a “checkerboard disk”, three-camera-based topographer. It is the only topography system designed from inception to provide triangulation-based corneal elevation information for use in CA. It generates anterior and posterior corneal height maps and spatial pachymetry, as well as scotopic and photopic pupillometry including the registration of pupillary center with respect to the anterior surface intercept of the visual axis (which is the center of its topography map by default). The projection of the pupil on the anterior surface of the cornea is measured under different lighting conditions with an infrared instrument, providing both the surgical registration data used for automatic centration of the ablation (achieved by the laser’s eye-tracker) as well as the scotopic pupil diameter used for the ablation size planning. Reflected corneal surface image of the checkerboard “polar grid” target (Figure 14-1) is acquired by use of a three-camera system (Figure 14-2). This system employs

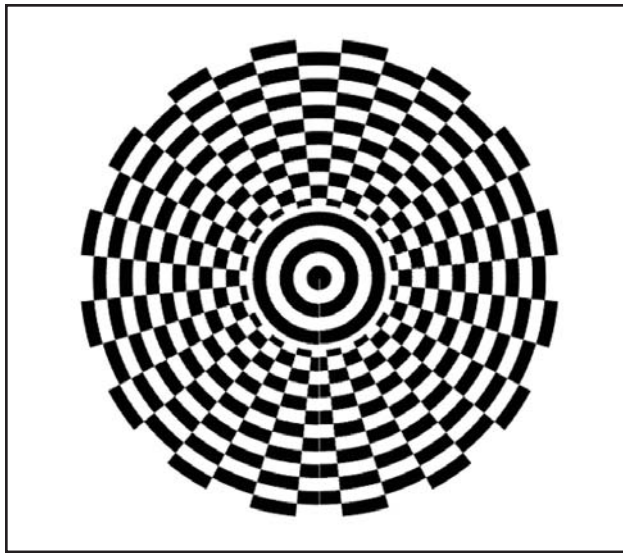


Figure 14-1. Checkerboard, polar grid target of the AstraMax.

an advanced surface reconstruction algorithm designed to provide accurate and precise height maps, as well as accurate sensing of corneal asphericity. This is possible even in cases of irregular corneas with significant discontinuities of shape. A laser cross can be projected for measurement of the posterior corneal surface and optical pachymetry. All measurements are taken simultaneously with respect to a single axis in only a fraction of a second, providing robust data without having to attempt to compensate for eye movements. This instrument is still under development, and its hardware capabilities are only partially exploited by this time.

In its original incarnation, the AstraMax/AstraPro system has been primarily designed for CA treatment of virgin eyes and it seems to provide its users with outcomes comparable to any current wavefront-based system. AstraMax data, including the first surface higher-order aberrations (HOAs), pupillometry, and the ablation registration information, is fed to the AstraPro ablation planning software combined with the surgical information concerning the desired spherocylindrical correction and targeted asphericity. The registration of the ablation center is achieved by registration of the pupillary center with respect to the center of the topography map which, in the AstraMax, represents the first corneal surface intercept with the visual axis. The amount of light used for the acquisition of registration can be set to the level approximating the amount of light during the surgery, in order to prevent error caused by drift of the pupillary center if different lighting conditions are used during the surgery. Finally, the surgeon provides the patient's refractive data, nomogram adjustment, as well as the desired postoperative asphericity

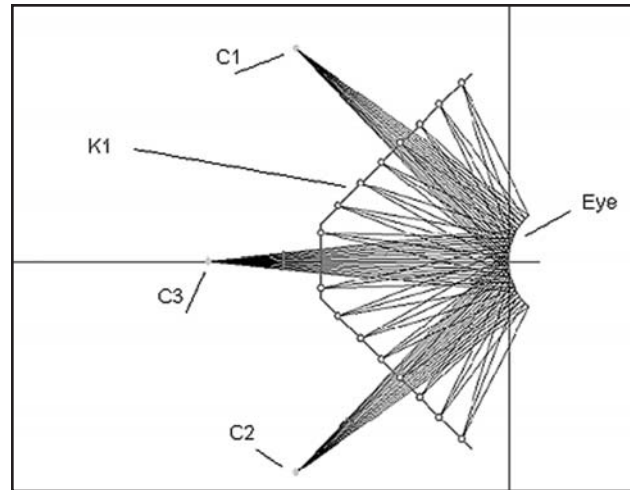


Figure 14-2. Use of three-camera system for data acquisition.

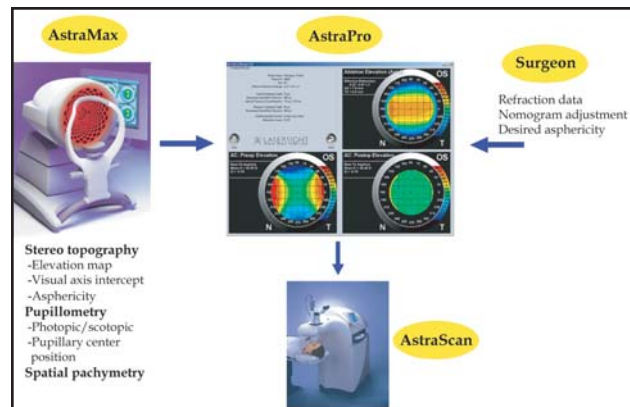


Figure 14-3. AstraMax/AstraPro CA system.

ty value. This is illustrated in Figure 14-3. Cyclotorsional registration is achieved by manual marking.

ASTRAMAX/ASTRAPRO SYSTEM IN TREATMENT OF MYOPIA AND ASTIGMATISM IN VIRGIN EYES

The author performed a prospective, randomized, double-masked study comparing the outcomes from the AstraMax/AstraPro CA with standard LaserSight treatments. One hundred and twenty eyes of 60 patients were treated for myopia with or without astigmatism with bilateral LASIK. One eye was treated with CA and the fellow eye with standard treatment. Virgin eyes with best spectacle-corrected visual acuity (BSCVA) of 20/25 or better, with myopic astigmatism, with sphere up to -10 D and cylinder up to -3 D were included in the study. Baseline

TABLE 14-1
PREOPERATIVE REFRACTION:
STANDARD VS. ASTRA GROUP

Mean MRSE (D)		Mean cyl. (D)	
Standard	Astra	Standard	Astra
-3.57 ± 2.11	-3.48 ± 1.94	0.67 ± 0.45	0.65 ± 0.48
(-1.0 to -9.50)	(-1.12 to -8.13)	(0.25 to 2.25)	(0.25 to 2.50)

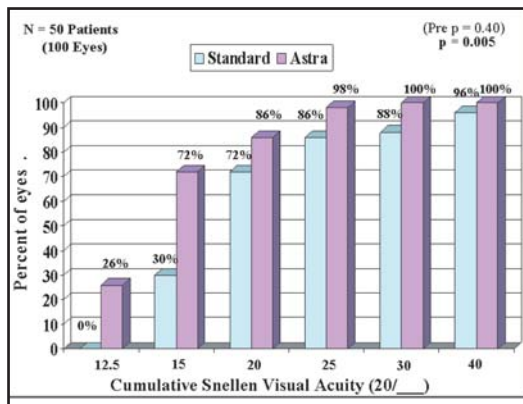


Figure 14-5. Efficacy of Astra vs. standard treatments 6 months after surgery.

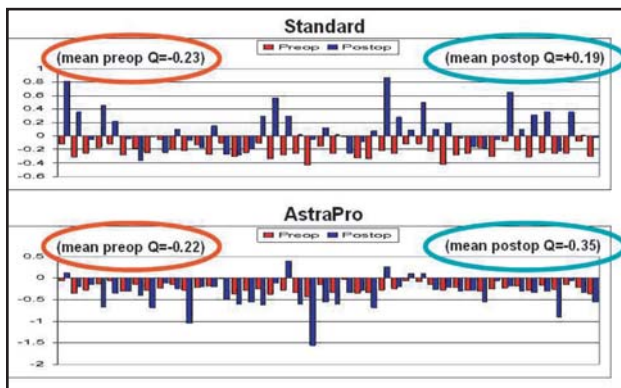


Figure 14-7. Asphericity change in Astra and standard treatments from preoperative to 6 months after surgery.

refraction is shown in Table 14-1. One year after the surgery, 50 out of 60 patients were available for evaluation. Two standard eyes and one Astra eye lost one line of BSCVA, 46% of the standard eyes gained lines of BSCVA, while 80% of Astra eyes gained lines and almost half of those gained 2 lines or more. The difference between the standard and AstraPro eyes was statistically significant (Figure 14-4). The difference between the two groups was also statistically significant concerning the achieved UCVA (Figure 14-5). Ninety percent of the Astra eyes vs.

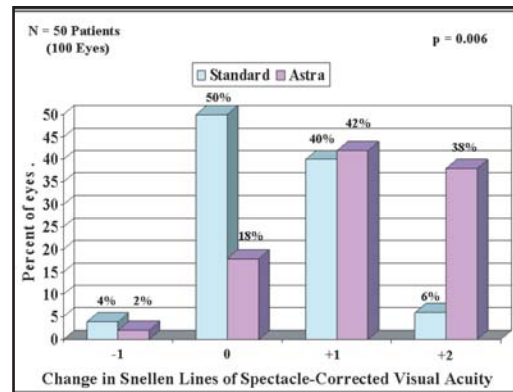


Figure 14-4. Safety of Astra vs. standard treatments 6 months after surgery.

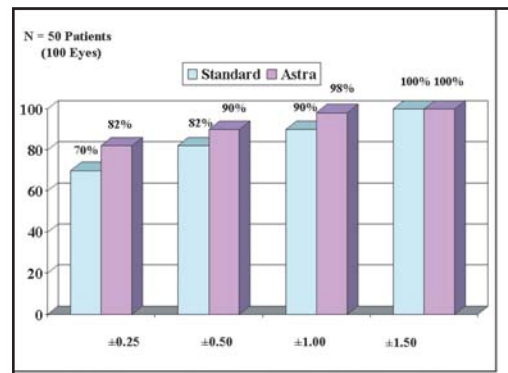


Figure 14-6. Predictability of Astra vs. standard treatments 6 months after surgery.

82% of the standard eyes were within 0.5 D of emetropia. Predictability was stronger as well, with more eyes within 0.25 D of emetropia achieved in the Astra group (Figure 14-6). Asphericity index for the two groups went the opposite directions. Standard eyes changed from prolate to oblate asphericity while Astra eyes maintained their prolate shape, shown in Figure 14-7. The patients graded the quality of their postoperative vision on a scale from 1 to 10. The difference in favor of Astra eyes was statistically significant, and is shown in Figure 14-8.

This double masked comparative study showed statistically significantly better outcomes with Astra treatments compared to the standard. When we looked for the possible reasons for the inferior outcomes of standard treatments, the most apparent was the induction of spherical aberration and coma, both of which could be traced to changes in corneal topography. Induction of spherical aberration was attributed to the new oblate shape. This may result from the laser energy reduction towards the periphery (cosine effect), as well as by the corneal biomechanical response to creation of LASIK flap.¹³ The induction of coma-like HOAs could be attributed to asymmetric

corneal optics due to displacement of the ablation with respect to the optical center of the cornea, as well as the cyclotorsional registration errors. Thus, the reasons for superior results with Astra treatments was most likely the correction of these shortcomings of standard treatments, and not the treatment of preoperative HOAs. Most of all, preoperative prolate asphericity was maintained, resulting in less induced spherical aberration and better quality of vision in low light. The correct centration and registration with respect to cyclotorsion resulted in less-induced asymmetric coma-type HOAs. The question remains how much, if at all, the correction of the HOAs in virgin eyes contributes to the superior outcomes in eyes treated with AstraPro, or any type of current CA. The author is especially concerned that an attempt to correct HOAs in virgin eyes actually introduces an unnecessary risk of induction of iatrogenic HOAs due to the artifacts produced by limited precision and accuracy of current diagnostic devices.

If we define the aim for treatment of virgin eyes as elimination of a need for spectacles and/or contact lenses, as well as preservation of the preoperative quality of vision, then correction of low-order aberrations without induction of new HOAs should be our goal. That implies that neither the first surface HOAs nor wavefront data are required to achieve our goals. Asphericity optimized ablation, based on precise measurements of preoperative sphere and cylinder and perfectly centered on the corneal optical center with a perfectly registered treatment axis, should not induce iatrogenic HOAs.

ORBSCAN AND CIPTA IN CUSTOM ABLATION FOR IRREGULAR ASTIGMATISM

The LaserSight platform currently provides its mainstream users with its own AstraMax/AstraPro CA technology while systems sold in Italy, as well as the selected few systems in the rest of the world, were modified to enable the use of CIPTA CA software. CIPTA uses Orbscan-generated information for compiling its CA.

An issue in CA treatment of IA that has not been discussed much is evaluation of different ablation planning strategies, something that the CIPTA system provides. It seems that the CA plans based on data confined to the eye's visual optics (commonly used in CA treatments of virgin eyes), and the plans based on the eye's geometrical optics can be very different for eyes with IA. The principal elements of the optical system of the eye (cornea, pupil, and the crystalline lens) are not centered with respect to each other. Additionally, the eye's neural axes (visual axis and the line of sight) and optical (geometrical) axis do not coincide because of the eccentric placement of

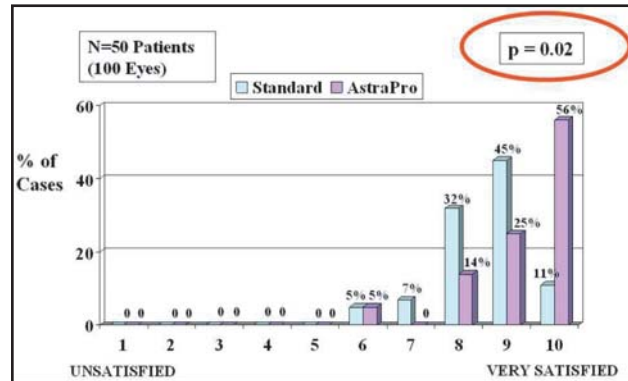


Figure 14-8. Subjective quality of vision score, Astra vs. standard treatments 6 months after surgery.

the fovea. Consequently, the target object can be placed on fovea only by rotation of the eye. Hence the corneal optics can be considered and analyzed from both geometrical (morphological) and neural (visual) aspect.

Ablation planning in excimer laser corneal refractive surgery has traditionally been based on measurements that in one way or another reflect the eye's visual function. Wavefront aberrometry, autorefractometry, Placido-based corneal topography, and even manifest refraction are all dependent on patient's fixation during the examination. Consequently, the data or maps acquired under such circumstances are referenced to the rotational position of the fixating eye. The concept of using the measurements that reflect the eye's visual function seems logical in refractive surgical ablation planning, since the goal of the refractive surgery is improvement of the existing visual function. Such a concept has also proved to be very successful in standard and customized excimer laser treatments of virgin eyes. Unfortunately, the same reasoning cannot be applied to treatment of cases with visual disturbances secondary to induced asymmetric corneal irregularities after refractive surgery, other eye surgery, corneal injuries, etc. Decentered corneal optics radically change the eye's visual optics, forcing the visual axis "to move" from its original (physiologic) position to a new one. The eye then adapts to the changed optical circumstances by assuming a new rotational position in an attempt to place the targeted image on the fovea. Hence an ablation plan that uses topography or aberrometry information referenced to the visual axis (or line of sight) would attempt to optimize the corneal optics on the basis of a pathological rotational position.

The author investigated the influence of centration and orientation of the ablation profile using simulated outcomes of customized treatments. Cases of irregular astigmatism due to decentered ablations were treated with respect to the amount of tissue removal and the smooth-

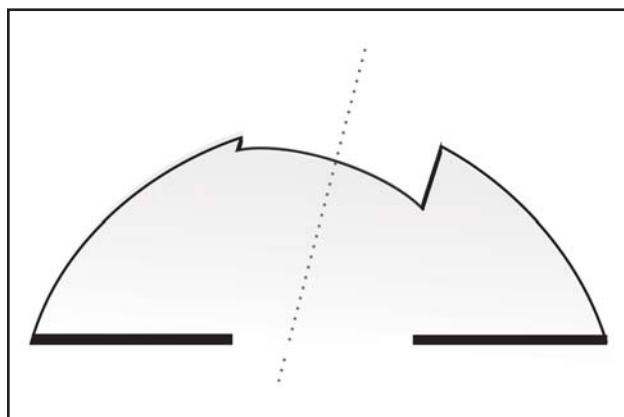


Figure 14-9. Schematic presentation of visual axis strategy.

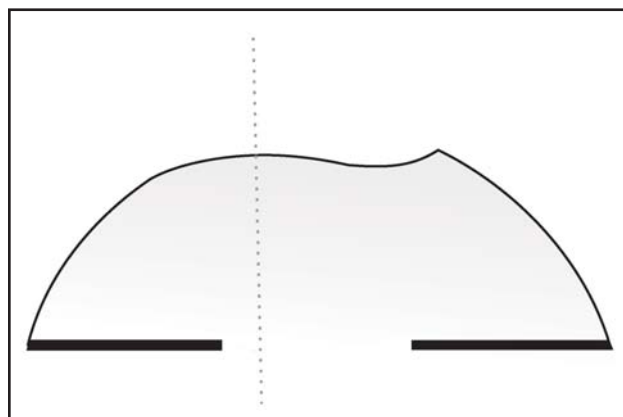


Figure 14-10. Schematic presentation of morphological axis strategy.

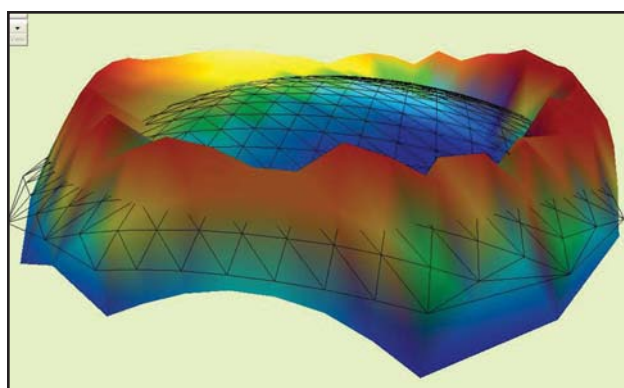


Figure 14-11. Three-dimensional map of a decentered LASIK case.

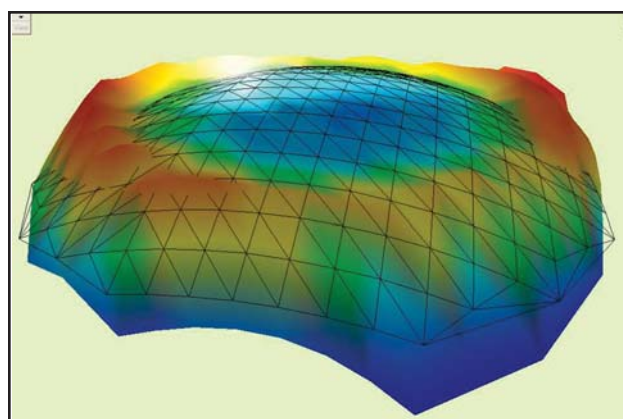


Figure 14-12. Three-dimensional map of a simulated outcome with visual axis strategy.

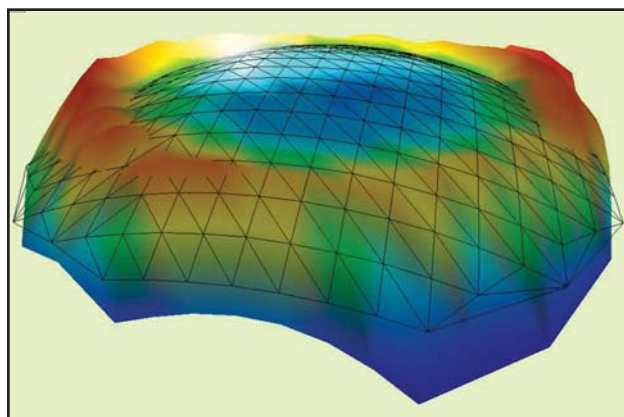


Figure 14-13. Three-dimensional map of a simulated outcome with morphological axis strategy.

ness of transition zone. The ablations based on the corneal morphological axis resulted in significantly shallower ablations, and smoother transitions compared to the ablations based on visual axis.¹⁴ Figures 14-9 and 14-10 show schematics of the two customized ablation strategies. The

same targeted surface was fitted perpendicularly to the visual axis, which is defined as a line drawn between the topography camera and the patient's macula (Figure 14-9), and to the CIPTA proprietary corneal "morphological" axis that approximates the best match between the axis of symmetry of the ideal shape and that of the current shape of the cornea (Figure 14-10). The visual axis strategy uses local corneal morphology around the visual axis as a foundation for computation of its ablation, without considering the cornea beyond the ablation area, while the corneal morphological axis strategy is based on a global three-dimensional assessment. It uses the morphology of the entire corneal surface as a foundation for its ablation in attempt to restore the damaged corneal symmetry. Figure 14-11 shows preoperative topography for the simulation, while Figures 14-12 and 14-13 show postoperative simulations based on visual and corneal morphological axis for a case of irregular astigmatism after a decentered LASIK. These figures show that the treatment simulations based on the visual axis attempt to optimize the primary decen-

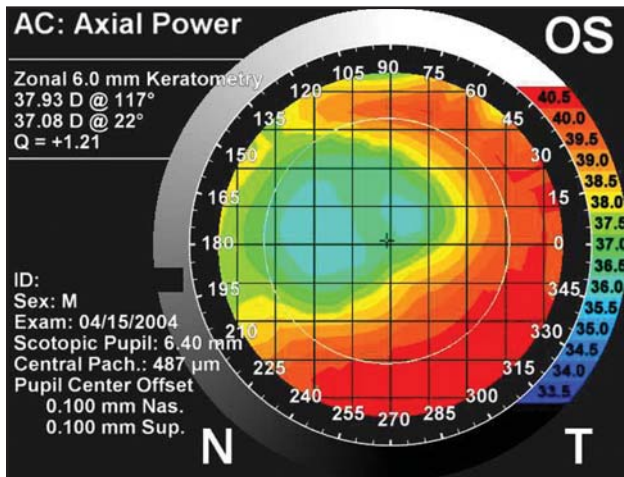


Figure 14-14. Axial curvature map of a decentered LASIK case.

tered treatment area: increasing the corneal asymmetry and creating an abrupt transition towards the untreated area (Figure 14-12), while the treatment simulations based on the corneal morphological axis attempt to “recenter” the primary treatment by placing the ablation on the previously untreated area which should have been treated during the primary surgery (Figure 14-13).

To our knowledge, only the CIPTA CA software “freely” explores the ablation possibilities because it is able to “uncouple itself” from the visual axis perspective. It can globally evaluate the raw elevation data and consider the corneal shape from a purely morphological aspect. This opens a possibility for a free, three-dimensional simulation of the desired targeted surface; providing infinitely more ablation alternatives than the systems referenced to visual axis. The AstraPro customized ablation system bases its ablation planning on the corneal elevation data referenced to the visual axis and places its targeted surface perpendicular to that axis. Such an approach results in deep ablations in cases with irregular astigmatism, and the AstraPro provides a solution to that problem by employing so called “advanced” ablation planning alternatives. The software automatically adjusts the ablation center (but keeps the ablation axis orientation unchanged) until the targeted surface is fitted to a position that requires the least amount of tissue removal. T-cat customized ablation system (WaveLight Laser Technologies, Erlangen, Germany) uses Placido disk-based topography information. Curvature data referenced to the visual axis is converted to ele-

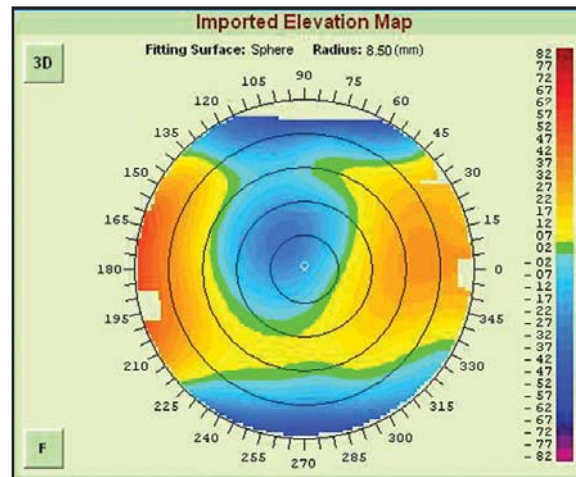


Figure 14-15. Floating elevation map of a decentered LASIK case.

vation data and decomposed into orthogonal Zernike polynomials. Since this approach, like AstraPro and the visual axis strategy of CIPTA, results in deep ablations in treatments of irregular astigmatism, T-cat provides an ablation planning alternative where the tilt component can be removed from the ablation plan. This way the orientation of the fitting axis is changed to a new position that results in reduced tissue removal, but the centering of the ablation axis is kept intact (ie, still attached to the intercept of the “pathological” visual axis).

In their default constellation, both the AstraPro and T-cat systems base their ablation on the visual axis. They obviously recognize the problem of that approach in treatment of irregular astigmatism and they allow for modifications of either centration or orientation of the visual axis. Neither of the two systems leaves the visual axis completely, something that CIPTA system does. Ablation simulations on the three aforementioned systems were performed for an eye with a decentered ablation causing irregular astigmatism. Targets included a 6.5-mm optical zone, 7.5-mm total ablation diameter, a curvature corresponding to the curvature of the flattest preoperative meridian, and asphericity with a Q-index value of -0.30. The preoperative floating elevation is shown in Figure 14-14. The axial curvature map is shown in Figure 14-15. Two ablation maps (one using the visual axis, the other using the system specific solution for treatment of IA) were generated for each of the three systems and are shown on Figures 14-16 through 14-21.

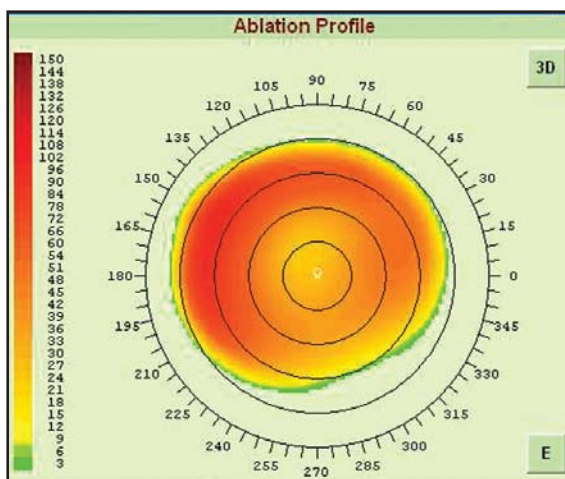


Figure 14-16. CIPTA ablation map using visual axis strategy.

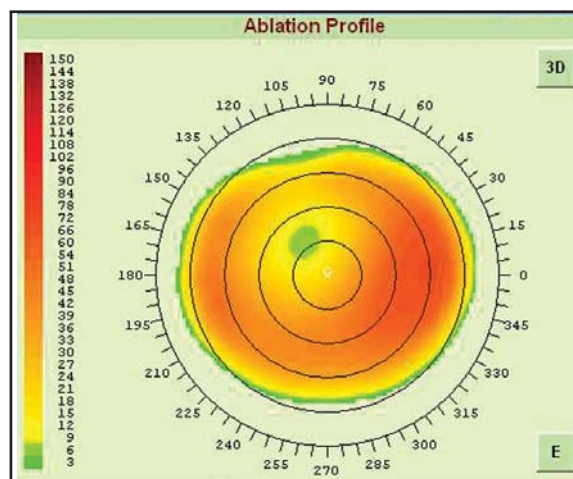


Figure 14-17. CIPTA ablation map using morphological axis strategy.

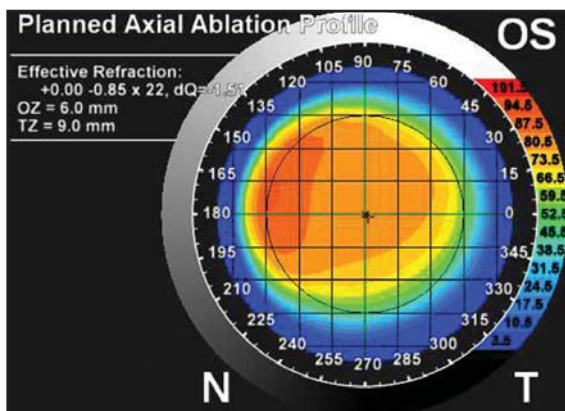


Figure 14-18. AstraPro ablation map using standard (visual axis) mode.

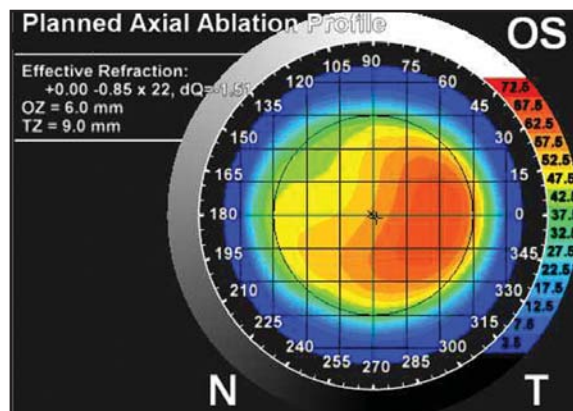


Figure 14-19. AstraPro ablation map using "advanced mode".

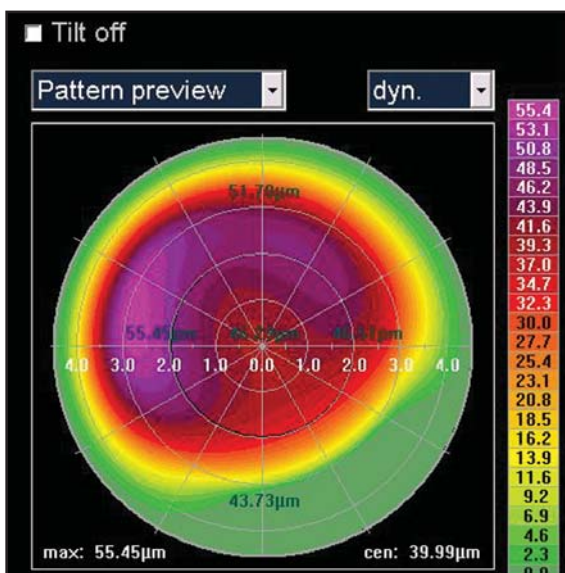


Figure 14-20. T-cat ablation map using "tilt on" mode.

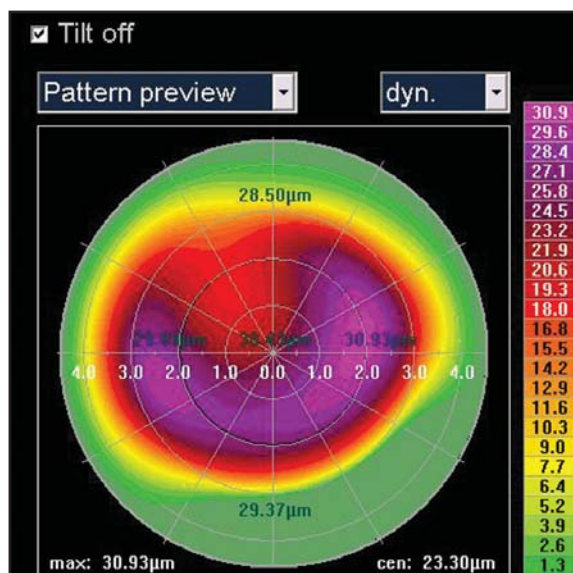


Figure 14-21. T-cat ablation map using "tilt off" mode.

TABLE 14-2

PREOPERATIVE REFRACTION AND VISUAL ACUITY OF CIPTA TREATMENTS

Mean MRSE (D)	Mean cyl. (D)	Mean BSCVA	Mean UCVA
-0.95±1.65	1.37±1.46	20/25	20/60
(-2.88 to +2.25)	(0.25 to 6.50)	(20/60 to 20/20)	(20/400 to 20/25)

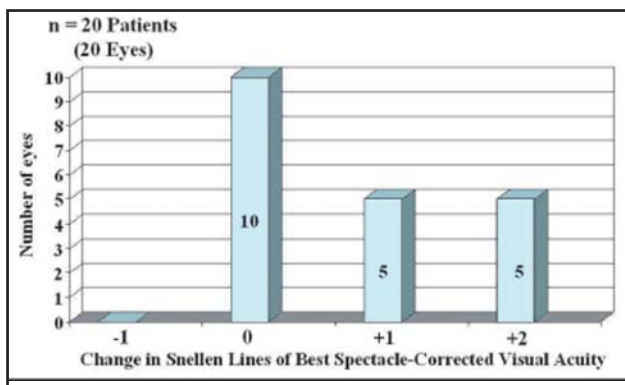


Figure 14-22. Safety of CIPTA treatments of irregular astigmatism 6 months after surgery.

CIPTA TREATMENT OF IRREGULAR ASTIGMATISM

An ongoing prospective study for the evaluation of customized treatments for irregular astigmatism causing visual disturbances after previous LASIK or PRK is being performed by the author using the CIPTA morphological axis strategy. The study has been conducted at the eye department of the University of Tromsø in Norway since March 2002. The primary aim of the treatment was to alleviate the patient’s visual disturbances, such as multiple images, halos, glare and night vision problems, and improvement of visual acuity using spectacles or soft contact lenses. The secondary aim was correction of any existing spherocylindrical refractive error. These goals were addressed by regularizing the corneal surface, optimizing the corneal asphericity, and changing the corneal base curve in order to eliminate the spherocylindrical error. Regularizing the corneal surface would address the first surface HOAs responsible for multiplopia, halos, and similar visual disturbances. Optimizing the corneal asphericity would address the spherical aberration of the whole eye responsible for low-light visual disturbances and low contrast sensitivity. Aiming for a certain corneal curvature would address the correction of the manifest sphere and cylinder.

TABLE 14-3

PREOPERATIVE VISUAL DISTURBANCES RELATED TO TOPOGRAPHIC FEATURES

Visual disturbancy	Topographic feature		
	Decentered (n=12)	Insuff. abl. diameter (n=4)	Irregular surface (n=4)
Multiple images/ contours (n=13)	12	0	1
Night driving problems (n=17)	10	4	3
Decreased BSCVA (n= 11)	8	1	2

TABLE 14-4

POSTOPERATIVE VISUAL DISTURBANCES

Preoperative visual disturbancy	N	Postoperative 6 Months			
		Worse	Unchanged	Improved	Cured
Multiple images	13	0	0	6	7
Night driving problems	17	0	0	8	9
Decreased BSCVA	11	0	1**	5	5*

*if postoperative BSCVA ≥ primary preoperative BSCVA, than the “decreased BSCVA” was considered cured.
 ** BSCVA < 20/25 before surgery

Forty eyes of 40 patients with visual disturbances and corneal irregularities after previous LASIK or PRK were enrolled. Twenty patients to date were available for evaluation 6 months after surgery. Preoperative spherical equivalent was relatively low, while the cylinder ranged up to 6.5 D and the mean BSCVA was reduced to 20/25 (Table 14-2). If one correlates the topographic changes to the visual complaints, patients with decentered ablations mainly complained of multiplopia and most of them had night driving problems with reduced BSCVA. The patients with insufficient ablation diameter mainly complained of night driving problems (Table 14-3). At 6 months after surgery, no eyes lost lines of BSCVA while 50% gained lines. Twenty-five percent gained 2 lines or more. Safety index, the ratio between postoperative and preoperative BSCVA, was 1.21. This is shown in Figure 14-22. The measure of

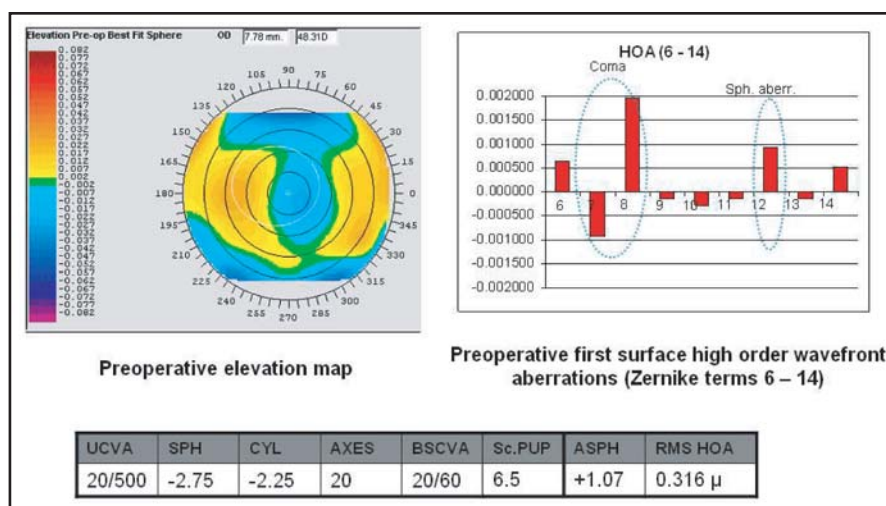


Figure 14-23. Floating elevation topography, HOAs, and clinical data in a decentered LASIK case.

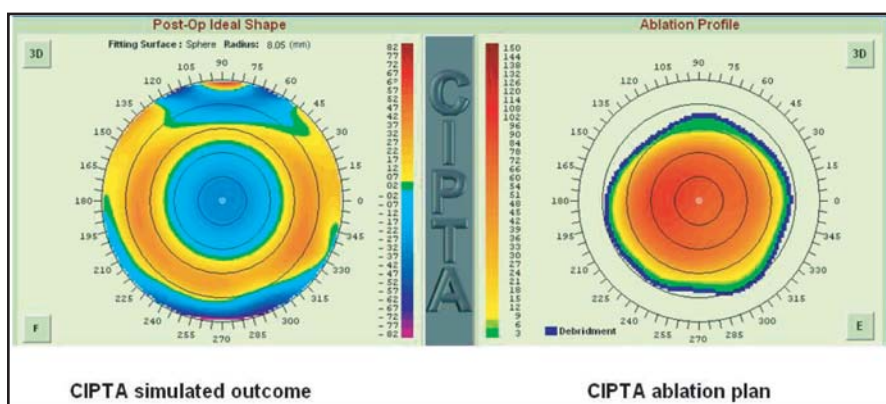


Figure 14-24. Ablation map and simulated topographic outcome.

efficacy of the treatment for this group of patients is the amount of visual disturbances after the surgery. Table 14-4 shows that the preoperative visual disturbances were either reduced or eliminated at 6 months after surgery.

CASE STUDIES

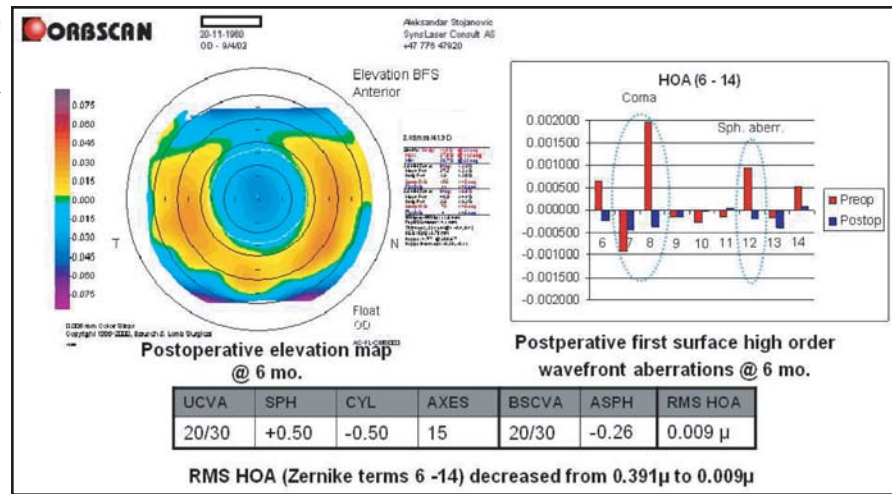
A 40-year-old female with a preoperative refractive error of -11.00 D, BSCVA 20/30, and 6.5-mm scotopic pupils, was treated using LASIK OD in 1996. After surgery, BSCVA fell to 20/60 and the patient was disturbed by multiplopia, halos, glare, and night driving problems. Corneal topography showed a nasally and inferiorly decentered and very narrow ablation. The asphericity was oblate with a Q-value of +1.07. First surface Zernike analysis showed a significantly increased coma (8th and 7th terms) and, as expected, an increased positive spherical aberration. This is shown in Figure 14-23. The patient’s elevation data as well as the patient’s refractive data were input into the CIPTA ablation planning software. Transepithelial PRK was performed on top of the

flap due to the limited amount of stromal tissue available for the ablation.. Mitomycin C was used prophylactically. Figure 14-24 shows the ablation map and the simulated outcome.

Six months after surgery, most of the visual disturbances improved, with a significant improvement in visual acuity and minimal residual refractive error. Postoperative topography showed a well-centered and widened ablation. Asphericity went from oblate to prolate. First surface Zernike analysis showed a significant decrease of terms from 6 to 14, and especially the coma. A significant decrease in spherical aberration occurred as well. This can be seen in Figure 14-25.

The CIPTA approach showed a high level of safety and efficacy. Most importantly, the preoperative visual disturbances were decreased or eliminated. Topographies were vastly improved and the first surface HOAs were significantly reduced. The author has used CIPTA software for treatment of other types of corneal irregularities as well. It seems that with use of its “morphological axis” strategy ,the challenging cases (like those with high-grade irregular astigmatism after cornea transplantation and significant

Figure 14-25. Floating elevation topography, HOAs, and clinical data after CIPTA retreatment of a decentered LASIK case.



irregularities due to corneal scarring after injuries or keratitis) are no longer beyond the reach of laser refractive surgery.

GENERAL CONCLUSIONS

A topography based CA that uses corneal surface information independent of the visual axis seems to be the best treatment modality for IA, while an ideal treatment of virgin eyes might be achieved by correction of low-order aberrations (sphere and cylinder) and by the optimization of corneal asphericity and ablation registration. A CA plan that includes correction of higher-order aberrations in virgin eyes (with no preoperative visual disturbances) might be counterproductive because of the possibility of introduction of new, iatrogenic aberrations using currently available preoperative diagnostics. Between the CIPTA system (admittedly used only within a limited number of clinics) for treatment of IA and the AstraPro for treatment of virgin eyes (especially with a newly added option of removal of correction of the first surface HOAs from the ablation plan—while keeping the asphericity and registration customization information from the AstraMax), the LaserSight platform can at this moment provide a more complete CA solution than most of the competing systems.

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