Topography-driven Photorefractive Keratectomy

Results of Corneal Interactive Programmed Topographic Ablation Software

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Objective: This study evaluated the efficacy, predictability, stability, and safety of a software program (Corneal Interactive Programmed Topographic Ablation (CIPTA) LIGI, Taranto, Italy) which, by transferring programmed ablation from the corneal topography to a flying-spot excimer laser, provides customized laser ablation.

Design: Noncomparative consecutive case series.

Participants: Forty-two eyes of 34 subjects with a mean age of 33.9 (range, 20–54) had CIPTA at the Cattedra di Ottica Fisiopatologica of Bari (Italy). Twenty-eight eyes were treated for hyperopic astigmatism and 14 for myopic astigmatism. All the subjects had irregular astigmatism.

Operation: Topography was acquired by a corneal topography mapping system (Orbscan, Orbtek, Inc., Salt Lake City, UT). These data were processed to obtain a customized altimetric ablation profile, which was transferred to a flying-spot laser (Laserscan 2000, Lasersight, Orlando, FL).

Main Outcome Measures: Data on uncorrected (UCVA) and best-corrected visual acuity (BCVA), predictability, and stability of refraction and any complications were analyzed.

Results: Mean follow-up was 13.2 months. At the last postoperative examination, 26 eyes (92.8%) in the hyperopic group and 12 eyes (85.7%) in the myopic group had an UCVA superior to 20/40. Twelve hyperopic eyes (42.8%) and five myopic eyes (35.7%) had a UCVA of 20/20. All patients fell between 1 diopter of attempted correction in the spherical equivalent. Only 1 (2.4%) of the 42 eyes, belonging to the hyperopic group, lost 1 Snellen line of BCVA. We did not observe any decentration and/or haze after photorefractive keratectomy treatment or any irregularity in the flap-stroma interface in the three laser in situ keratomileusis operations performed in this study.


Excimer lasers have worked well in patients with spherical error or with regular astigmatism. However, the results have not been so satisfactory in subjects with irregular or asymmetric astigmatism. The reason for this is that all excimer lasers, although using different algorithms, carry out identical ablations in all patients with the same refractive error and optical zone. Some of the theoretical advantages of topography-driven photorefractive keratectomy (PRK) are a better astigmatic correction, the possibility of correcting irregular astigmatism, and a smaller ablation volume compared with standard treatments, resulting in better visual performance.

Various authors have studied the possibility of performing topography-assisted excimer laser treatments. Seitz et al presented their data for topography-based flying-spot correction of irregular corneal astigmatism based on the Zernike decomposition of topography height data. Wiesinger-Jendritza et al published their results with laser in situ keratomileusis (LASIK) assisted by corneal topography on 23 eyes of 22 patients for the treatment of irregular astigmatism, and reported a high percentage of undercorrection and regression because of underestimation of the corneal irregularity.

In January 1996 we developed a software program (Corneal Interactive Programmed Topographic Ablation [CIPTA] LIGI, Taranto, Italy) that couples a corneal alti-
metric topography mapping system (Orbscan, Orbtek, Inc., Salt Lake City, UT) with a flying-spot laser (Laserscan 2000, Lasersight, Orlando, FL).

The software is based on the following principles:

1. The ablation takes into account the true corneal shape of the patient, acquired with the elevation map, not only a mathematical model of it.
2. The volume of the ablation is defined by the intersection of the three-dimensional shape of the cornea and the best aspheric surface for refraction. Among all the possible ablation patterns, the one that minimizes the ablation volume, while at the same time respecting the optical zone, is chosen. This is determined by choosing the smallest perimeter that fully circumscribes the entrance pupil in scotopic conditions.
3. The transition zone of the intersection between the two surfaces described has a constant slope in all directions, thus minimizing the risk of regression. For this reason, the transition zone is larger in the meridian with the highest refractive change.

Patients and Methods

Patients

After having tested the program on polymethyl methacrylate and eye bank eyes, we started the clinical trials in October 1997. We treated 42 eyes of 34 subjects (22 men, 12 women) ranging in age from 20 to 54 (mean, 33.9; standard deviation [SD], 9) at the Cattedra di Ottica Fisiopatologica, Department of Otorhinolaryngology and Ophthalmology of the University of Bari (Italy). Mean follow-up was 13.2 months (range, 6–18; SD, 5.5). In this study we have not considered the first 20 eyes treated by means of CIPTA because these were considered part of the learning curve, which was required both for the software and the surgeons. The conversion factor between ablation on polymethyl methacrylate and living human cornea had to be assessed. Because the software is interactive, we had to learn how to weight the relative importance of centering the width of the optic and of the transition zone.

All the patients had irregular or asymmetric corneal astigmatism. This was defined as such an irregular corneal surface that it could not be refracted with any optical corrective device and required surface smoothing.2 Twenty-eight subjects were treated for hyperopic astigmatism; 13 subjects had a spherical equivalent (SE) between 0 and +3 diopters (D) and 15 between +3.12 and +6 D. Fourteen subjects needed treatment for myopic astigmatism; 5 subjects had an SE between 0 and −3 D, 3 between −3.12 and −6 D, 6 between −6.12 and −10 D. The hyperopic group included 28 eyes of 20 patients (11 men and 9 women). Nineteen eyes had native irregular astigmatism. Nine eyes had postsurgical astigmatism. Nine eyes had postsurgical astigmatism: one postcataract surgery and eight post-PRK (five posthyperopic and three postmyopic PRK). The myopic group included 14 eyes of 14 patients (11 men and 3 women). Two eyes had native irregular astigmatism. Twelve eyes had postsurgical astigmatism: seven postmyopic PRK (one central island and six decentered treatments), two post-LASIK (one button-hole and one decentered treatment), and two surgical leukomas.

Subjects with clinical or topographic signs of keratoconus or evidence of corneal infection were excluded.

Patients gave informed consent to the experimental nature of the treatment.

Clinical Examination

All eyes had a comprehensive preoperative ophthalmic examination including slit-lamp biomicroscopy, applanation tonometry, indirect ophthalmoscopy, and optic pachymetry by means of the Orbscan. In the two eyes with corneal leukomas, we performed acoustic pachymetry because the Orbscan lacks accuracy for this measurement when corneal scattering is high.

Uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BCVA) were tested preoperatively and monthly during follow-up. Refraction was measured preoperatively under cycloplegia and postoperatively using the fogging (high plus) technique. We evaluated subjective refraction because of the difficulty in assessing this objectively in irregular astigmatisms. In our series the difference between refractive and corneal astigmatism never exceeded 1 D.

Vector analysis of astigmatism, according to Alpins’ method,4 was based on the refractive data. The following parameters used in the “Results” section are briefly explained. Target-induced astigmatism (TIA) corresponds to the amount and direction of the dioptric force required to achieve the astigmatic goal from the preoperative astigmatic state. Surgical-induced astigmatism (SIA) corresponds to the amount and direction of corneal steepening needed to achieve the operative result from the preoperative astigmatic state. Ideally, the TIA and SIA are the same in magnitude and axis and are perpendicular to the axis of preoperative astigmatism, so as to correct the latter. The magnitude of error is a direct parameter for measuring how close in magnitude the SIA is to the TIA and is calculated by subtracting the vectorial TIA from the vectorial SIA. The angle of error is the angle between the vectors of the SIA and the TIA on a 180° vector diagram. Success can be determined by assessing how close the magnitude and mean angle of error are to zero.

Subjective evaluation of quality of vision was assessed by asking the patients whether halos, glare, and monocular diplopia were less, the same, or worse than before surgery with glasses or contact lenses.

Corneal topography was acquired before surgery and monthly after the treatment.

Surgical Technique

Preliminary steps of the procedure included acquisition of the corneal shape by means of the Orbscan and a knowledge of the patient’s subjective refraction. To increase the accuracy of the topography, three acquisitions are required differing <3 μm in height in the central 5 mm. The pupil diameter was measured under scotopic conditions with the infrared camera of the laser eye tracker.

These data were processed by CIPTA to obtain a customized altimetric ablation profile, which was transferred, by means of an interface, to the Laserscan 2000.

Laserscan uses a calibrated video and scanning slit-beam system to measure three-dimensional locations of several thousand points on the corneal surfaces, which are used to construct the true topographic surface.

Laserscan 2000 works with a microspot of 800 μm, a frequency of 100 Hz, and an energy at the cornea of 0.7 to 1.2 mJ per pulse. CIPTA features six interactive steps:

1. Centering of the refractive treatment. The treatment could be centered on the fixation, the corneal reflex of the fixation target of the Orbscan, when the original visual axis of the patient was to be preserved (in hyperopic and/or native asymmetric astigmatism); on the pupil centrally, in decentered treatments; on the corneal apex, in extremely irregular corneas to enable maximal sparing of tissue ablation; on the
pachymetric thinnest point, on the cursor; or on the mathematical coordinates. These options are available for future applications of the software to prepare the bed for lamellar keratoplasty for example. In this study we used the first two options.

2. Definition of the minimal useful refractive diameter (inner limit) and selection of the outer limit of the treatment.

3. Choice of treatment axis: this could be the visual axis or the axis of the best aspheric surface for the patient.

4. Input of the desired refractive correction and/or the keratometric values.

5. The level of ablation could be superficial (PRK) or intrastromal (LASIK). At this stage, the software constructs the new ideal aspheric corneal surface.

6. The slope and minimum width of the transition zone may be changed by the surgeon.

At the end of the interactive process, the ablation statistics and scheme appear. At this stage it is possible to measure the difference in height, for each point, between the two surfaces: real (preoperative) and ideal (postoperative aspheric surface).

Finally, the software processes the ablation map, which is transferred to the flying-spot excimer laser by means of a grid of Cartesian coordinates.

The spot’s energy was calibrated on the SE of each treatment. In PRK, 18% ethanol epithelial debridement (Ethanol 95°, CarloErba Reagenti, Milano, Italy) was performed in primary treatments, whereas in retreatments, excimer laser epithelial debridement to a depth of 50 μm was carried out. In post-LASIK retreatment, the flap was elevated by a spatula.

After surgery, a contact lens was applied, and topical 0.1% metholone drops (0.2%) were used four times a day for the first month, three times a day for the second month, twice a day for the third month, and once a day for the fourth month. Acetylcysteine (preoperative) and ideal (postoperative aspheric surface).

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Efficacy

Results

Efficacy

In the hyperopic group, mean UCVA improved from 0.54 logarithm of the minimum angle of resolution (LogMAR)° (20/80) preoperatively (range, 1–0.1 LogMAR; SD, 0.2) to 0.09 LogMAR (20/22) (range, 0.5–0 LogMAR; SD, 0.12) at the last examination; in the myopic group, mean UCVA improved from 0.9 LogMAR (20/200) preoperatively (range, 1.3–0.3 LogMAR; SD, 0.4) to 0.13 LogMAR (20/27) (range, 0.4–0 LogMAR; SD, 0.14) at the last examination (Figs 2 and 3).

Predictability—Spherical Equivalent

In the hyperopic group, mean preoperative SE was +3.12 D (range, 0–+5 D; SD, 1.4); at the last postoperative examination, mean SE was +0.2 D (range, −1–+1 D; SD, 0.5). In the myopic group, mean preoperative SE was −4.58 D (range, −0.375–−8.375 D; SD, 2.8); at the last postoperative examination, mean SE was −0.27 D (range, −1–0.5; SD, 0.46). Table 2 shows preoperative and postoperative refractive data (mean ±SD), up to 18 months.

At the last postoperative visit, in the hyperopic group 64.2% (n = 18) of the eyes were within ±0.50 D and 100% (n = 28 eyes) were within ±1D of attempted refractive change. Of the eyes in the myopic group 78.5% (n = 11) were within ±0.50 D of the desired postoperative refractive error; 100% (n = 14) of eyes in the same group were within ±1D of the intended correction (Figs 2 and 3).

Predictability—Astigmatic Correction

Mean TIA was 2.08 (SD, 1.7) in the hyperopic group and 1.73 (SD, 2.44) in the myopic group; mean SIA was 1.9 (SD, 1.6) in the hyperopic group and 1.28 (SD, 2.1) in the myopic group. The magnitude of error had a negative value, indicating undercorrection for both the hyperopic group, −0.18 (SD, 0.5), and the myopic group, −0.5 (SD, 0.7). The angle of error was 2.4 (SD, 8) for the hyperopic group and 2 (SD, 12.8) for the myopic group. The percentage of eyes with an angle of error less than 10° was 82.1% in the hyperopic group and 85.7% in the myopic group.

Mean preoperative SIA was 2 (SD, 1.4) in the hyperopic group and 2 (SD, 1.28) in the myopic group. The mean postoperative SIA was 0.75 (SD, 1.1) in the hyperopic group and 0 (SD, 12.8) in the myopic group. The percentage of eyes with a SIA less than 10° was 82.1% in the hyperopic group and 85.7% in the myopic group.
Achieved versus attempted spherical equivalent correction at the last postoperative examination (□ myopic, n = 14; △ hyperopic, n = 28).

Stability

The stability of postoperative refraction was quantified by comparing changes at different time points after PRK. Stability being defined as a 1-D difference in manifest refraction SE between follow-up visits. From the 1-month to the 3-month examination, 6 (42.8%) of the myopic eyes (n = 14) were stable within 1 D and 8 (57.1%) showed a myopic shift of more than 1 D. In the hyperopic group (n = 28), 18 (64.3%) eyes were stable within 1 D, whereas 6 (21.4%) eyes showed a shift toward myopia and 4 (14.4%) toward hyperopia. From the 3-month to the 6-month examination, 12 (85.7%) myopic eyes (n = 14) and 24 (85.7%) hyperopic eyes (n = 28) were stable within 1 D. Two eyes (14.3%) in the myopic group and 5 eyes (19.6%) in the hyperopic group had a change in SE of manifest refraction of >1 D toward myopia; 1 eye (3.5%) in the hyperopic group had a change >1 D toward hyperopia. From the 6-month to the 18-month follow-up visit, all the eyes in both groups were stable within 1 D of the manifest refraction. Mean SE ± SD change over time is depicted in Figure 5.

Stability of UCVA was analyzed by comparing changes at different time points after PRK. Stability being defined as a 1 Snellen line difference in UCVA between follow-up visits. From the 1-month to the 3-month examination, in the myopic group (n = 14) 4 (28.6%) eyes gained more than 1 Snellen line of UCVA, 2 (14.3%) lost more than 1 Snellen line of UCVA, and 8 (57.1%) eyes remained stable. Over the same interval, in the hyperopic group (n = 28) 16 (57.1%) eyes gained more than 1 Snellen line of UCVA, 2 (7.1%) lost more than 1 Snellen line, and 10 (35.7%) were unchanged. From the 3-month to the 6-month examination, in the myopic group (n = 14) 3 (21.4%) eyes gained more than 1 Snellen line of UCVA and 11 (78.6%) remained stable. Over the same interval, in the hyperopic group (n = 28) 5 (17.8%) eyes gained more than 1 line, and 23 (82.1%) remained stable. No eye lost more than 1 Snellen line of UCVA in either group. From the 6-month to the 12-month examination, in the myopic group (n = 10) all the eyes (100%) remained stable; in the hyperopic group

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Safety

In the hyperopic group, mean BCVA passed from 0.1 LogMAR (20/25) (range, 0–0.2 LogMAR; SD, 0.08) preoperatively to 0.025 LogMAR (20/21) (range, 0–0.2 LogMAR; SD, 0.05); in the myopic group, mean BCVA passed from 0.16 LogMAR (20/28) (range, 0–0.7 LogMAR; SD, 0.18) preoperatively to 0.04 LogMAR (20/22) (range, 0–0.2 LogMAR; SD, 0.08). Only 1 (2.4%) of the 42 eyes in this study, belonging to the hyperopic group, lost 1 Snellen line of BCVA, passing from 20/25 to 20/32. The treatment therefore achieved a positive safety index5 (mean postoperative BCVA/mean preoperative BCVA = 1.10) (Fig 4).
(n = 14), 1 (7.1%) eye gained more than 1 Snellen line of UCVA, 13 (92.8%) remained stable. From the 12-month to the 18-month examination, in the myopic group (n = 9) all eyes (100%) were unchanged; in the hyperopic group (n = 13) 1 eye (7.1%) gained more than 1 Snellen line, and 12 (92.3%) remained unchanged.

**Subjective Evaluation of Quality of Vision**

Halos and glare, present preoperatively in 41 (97.6%) and 7 (16.6%) patients, respectively, disappeared postoperatively in all patients but 1 (2.4%). The monocular diplopia present preoperatively in 8 (19%) patients reduced in all.

### Table 3. Analysis of Refractive (D) Astigmatic Vectors (Mean ± SD)

<table>
<thead>
<tr>
<th></th>
<th>Hyperopia</th>
<th>Myopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Targeted-induced astigmatism (TIA)</td>
<td>2.08 ± 1.7</td>
<td>1.73 ± 2.44</td>
</tr>
<tr>
<td>Surgically-induced astigmatism (SIA)</td>
<td>1.9 ± 1.66</td>
<td>1.28 ± 2.1</td>
</tr>
<tr>
<td>Difference vector</td>
<td>-0.31 ± 0.8</td>
<td>-0.5 ± 0.8</td>
</tr>
<tr>
<td>Angle of error</td>
<td>2.36 ± 8</td>
<td>2 ± 12.8</td>
</tr>
<tr>
<td>Magnitude of error</td>
<td>-0.18 ± 0.55</td>
<td>-0.47 ± 0.7</td>
</tr>
<tr>
<td>Index of success</td>
<td>0.15</td>
<td>0.26</td>
</tr>
</tbody>
</table>

We did not observe any complications, either sight-threatening or non-sight-threatening, in our series.

**Case Reports**

**Case 1.** One patient had myopic PRK (Sph −6.50) in December 1997, resulting in with-the-rule myopic astigmatism (UCVA was 20/40 and BCVA was 20/25 with Cyl −0.75 × 180°) because of an inferior and nasal decentered treatment of 1.4 mm × 295°; the temporal border of treatment was near the pupil border in photopic condition (Fig 6A). In September 1998, customized ablation, centered on the pupil axis, aimed at emmetropia was performed to center treatment and enlarge the optical zone (Fig 7). One month postoperatively, refraction revealed hyperopic shift (Sph +1.75); 6 months postoperatively UCVA was 20/20, refraction was plano, with the treated area centered and encompassing the entrance pupil (Fig 6B).

**Case 2.** Two years after myopic PRK (Sph −8.75), a patient presented with glare and halos with an UCVA of 20/200, and a BCVA of 20/25 with Sph −1.25, Cyl −1.75 × 175°. The keratometric-axial map revealed a central island associated with regression (Fig 8B). Customized ablation, centered on the pupil, was carried out (Fig 9). One month postoperatively, refraction was Sph +1; 6 months postoperatively UCVA was 20/20 with no visually disturbing symptoms (Fig 8A).

**Case 3.** A 24-year-old patient with monolateral primitive asymmetric with-the-rule hyperopic astigmatism (Fig 10B) had a UCVA of 20/40 and BCVA of 20/25 with Sph +1.75 Cyl +1.25 × 80°. CIPTA hyperopic treatment centered on the line of sight was performed in November 1997 on the left eye (Fig 11). One month postoperatively, UCVA improved to 20/20 and refraction was plano (Fig 10A). One year postoperatively, UCVA remained 20/20 and BCVA was 20/20 with a refraction of Cyl +0.50 × 90 (Fig 12).

**Discussion**

Customization of treatment is based largely on the acquisition of an accurate elevation map. Projection-based topographic systems measure elevation above a reference surface. Thus, they can measure corneal height, irregular and
nonreflective surfaces, and the entire corneal surface with uniformly high accuracy in the center and periphery. Placido ring systems, on the contrary, derive height by integrals: this can cause error; moreover, they do not provide reliable elevation data for shapes that have nonlinear changes in curvature, as occur after refractive surgery. In addition, the slit-beam videokeratograph acquires the real corneal shape regardless of the cornea’s orientation relative to the instrument, whereas Placido-based systems require the rings to be coaxial with the cornea. Also, the latter assumes the surface to be continuous and differential: if there is a break on the corneal surface, there will be a break in the display produced and localized areas of irregular astigmatism may be ignored.

A limitation of the Orbscan topography is the long acquisition time (1.4 sec) that decreases the accuracy of the elevation map. To increase its precision, at least three measurements are carried out. These are assumed to be accurate when the difference in height in the central 5 mm among them is <3μm.

A flying-spot laser with a narrow beam with a Gaussian profile is necessary to perform topography-assisted treatments. Thanks to its small spot size (800 μm), Laserscan 2000 can provide flexible, high-accuracy treatments of any
shape and depth in a single-pass; furthermore, it can reach corneal zones as peripheral as the limbus.

The possibility of choosing the center and axis of the treatment is fundamental to improve visual quality, not only in patients with decentered treatments but also in patients with a significant angle $k$. In fact, especially in hyperopic treatments when centering of the treatment is more important, symmetric treatment of the pupil center could result in refractive decentration. Instead, we centered the customized treatments on the corneal light reflex because of its relative accuracy in approximating the visual axis. In this way, we achieved a symmetric and regular corneal shape around the visual axis.

Impaired quality of vision can result from not considering the pupil size and anterior chamber depth when performing refractive surgery. CIPTA takes these parameters into account by means of Orbscan and allows planning of large optical zones. Ablation zones as large as 10 mm can be carried out with this software.

By creating a best-fit aspheric surface for the eye, this software solves the conflict between treatments that use only topography or only refraction to determine surgical treatment. Moreover, the interactive process allows optimization of the treatment according to the parameters the surgeon considers most important. Our goal was to obtain the most regular shape for each eye, like a rigid contact lens.

Figure 8. Axial-keratometric maps of case 2. Pretreatment map (A) shows a central island. Posttreatment map (B) shows an enlarged treatment, without the central island. Differential map (A and B) of the same case.

Figure 9. Elevation map of planned topographic ablation of case 2. In green-yellow are depicted the ablated zones. Darker areas correspond to deeper ablations.
does, minimizing the risk of regression caused by the correction of noncorneal astigmatism. In the latter case, in fact, a differential regression in the axis of steeper ablation is possible.

UCVA and BCVA improved in both groups of patients. These results are especially positive if we consider that, preoperatively, 30 of the 42 eyes included in the study did not reach 20/20 of BCVA because of irregularities in corneal topography or amblyopia.

Predictability was extremely good in terms of both refractive and topographic results. All the patients fell between 1 D of attempted correction in SE; three myopic and eight hyperopic eyes were undercorrected by more than 0.5 D, two hyperopic eyes were overcorrected by more than 0.5 D. As already observed in photoastigmatic refractive keratotomy (PARK)9,10 our results also showed a tendency toward an undercorrection of the cylinder (Fig 13). Nevertheless, in all our patients except the one that lost a Snellen line of visual acuity, we regularized the corneal surface and visual symptoms disappeared. The possible reasons for the suboptimal accuracy of the astigmatic correction might be due to causes not accounted for with this software, namely, the possible cyclotorsion of the eye under the microscope, the noncorneal sources of astigmatism, the topographic ac-
quisition of the elevation maps, the eye-tracking system of the laser, and the surgeon’s experience in programming the customized ablation.

Although the follow-up is too short to draw definitive conclusions, so far we have not observed any significant regression. This could be related to the large and homogeneous ablation and transition zone diameters and to the constant slope of the transition zone realized by CIPTA.

Our approach differs substantially from Seitz et al’s experimental data, being based on a directly acquired elevation map as opposed to the Zernike decomposition of topography height data.

Wiesinger-Jendritza et al’s data featured a high percentage of undercorrection and regression caused by underestimation of corneal irregularity. A possible explanation is that their algorithms were based on corneal height values integrated by the axial radii of curvature and not on altimetric data. Furthermore, the scanning slit laser used cannot provide such flexible ablations as those generated by the flying-spot laser.

In contrast to the preceding methods, CIPTA can provide preoperative statistical information about the ablation volume, area, and depth; also, because Orbscan can acquire pachymetric data, it can calculate the residual apex thickness.

Regularizing the corneal shape has the theoretical advantage of improving the quality of vision. Although in this study we did not measure contrast sensitivity, all patients but one reported a subjective improvement in vision, with a reduction of halos, glare, and monocular diplopia.

Although the use of customized ablation appears to have been effective in this population, there was no attempt to compare this treatment with a control group having standard spherocylindrical treatment, which might have been effective in some cases.

The ultimate goal of CIPTA is to create a better-than-normal corneal refractive surface. Another possible approach to customized ablation aims to achieve an aberration-free visual system. Although this presents theoretical advantages compared with CIPTA, the real influence of the other dioptric surfaces still has to be ascertained.

References