

# Treatment Strategies and Clinical Outcomes of Aspheric Surgery for Astigmatism Using the SCHWIND Amaris Platform

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## 1. Introduction

An optical system with astigmatism is one where rays that propagate in two perpendicular planes have different foci. If an optical system with astigmatism is used to form an image of a cross, the vertical and horizontal lines will be in sharp focus at two different distances. The term comes from the Greek  $\alpha$ - (a-) meaning "without" and  $\sigma\tau\iota\gamma\mu\alpha$  (stigma), "a mark, spot, puncture".

There are two distinct forms of astigmatism. The first is a third-order aberration, which occurs for objects (or parts of objects) away from the optical axis. This form of aberration occurs even when the optical system is perfectly symmetrical.

The second form of astigmatism occurs when the optical system is not symmetric about the optical axis. This form of astigmatism is extremely important in vision science and eye care, since the human eye often exhibits this aberration due to imperfections in the shape of the cornea or the lens.

If an optical system is not axisymmetric, either due to an error in the shape of the optical surfaces or due to misalignment of the components, astigmatism can occur even for on-axis object points. Ophthalmic astigmatism is a refraction error of the eye in which there is a difference in degree of refraction in different meridians. It is typically characterized by an aspherical, non-figure of revolution cornea in which the corneal profile slope and refractive power in one meridian is less than that of the perpendicular axis.

Astigmatism causes difficulties in seeing fine detail. In some cases vertical lines and objects such as walls may appear to the patient to be leaning over like the Tower of Pisa. Astigmatism can be often corrected by glasses with a lens that has different radii of curvature in different planes (a cylindrical lens), contact lenses, or refractive surgery.

Astigmatism is quite common. Studies have shown that about one in three people suffers from it. The prevalence of astigmatism increases with age. Although a person may not notice mild astigmatism, higher amounts of astigmatism may cause blurry vision, squinting, asthenopia, fatigue, or headaches.

Astigmatism is an optical defect in which vision is blurred due to the inability of the optics of the eye to focus a point object into a sharp focused image on the retina. This may be due to an irregular or toric curvature of the cornea or lens. The most of the astigmatism is corneal. Astigmatism may also be caused by crystalline lens subluxation, coloboma or lenticonus. There are two types of astigmatism: regular and irregular. Irregular astigmatism is often caused by a corneal scar or scattering in the crystalline lens. Regular astigmatism arising from either the cornea or crystalline lens can be easily corrected.

The refractive error of the astigmatic eye stems from a difference in degree of curvature refraction of the two different meridians (i.e., the eye has different focal points in different planes.) For example, the image may be clearly focused on the retina in the horizontal (sagittal) plane, but not in the vertical (tangential) plane. Astigmatism causes difficulties in seeing fine detail, and in some cases vertical lines (e.g., walls) may appear to the patient to be tilted.

In With-the-rule astigmatism, the eye sees vertical lines more sharply than horizontal lines. Against-the-rule astigmatism reverses the situation. Children tend to have With-the-rule astigmatism and elderly people tend to have Against-the-rule astigmatism. The prevalence of astigmatism increases with age.

Astigmatism may be corrected with eyeglasses, contact lenses, or refractive surgery. Various considerations involving ocular health, refractive status, and lifestyle frequently determine whether one option may be better than another. In those with keratoconus, toric contact lenses often enable patients to achieve better visual acuities than eyeglasses. Once only available in a rigid gas-permeable form, toric lenses are now available also as soft lenses.

## **2. Aspheric ablation strategies**

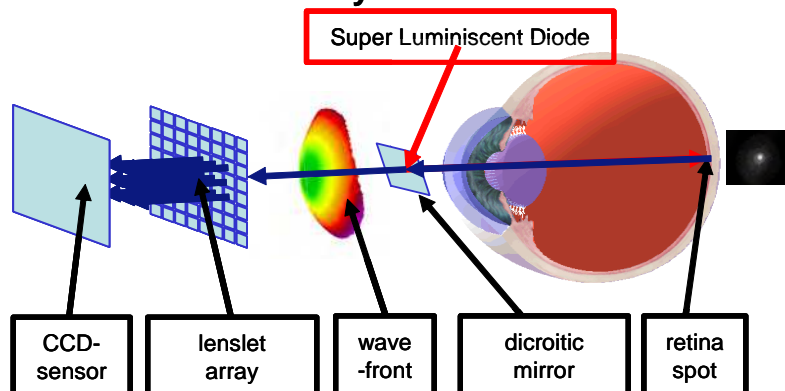
An aspheric lens or asphere is a lens whose surfaces have a profile that is rotationally symmetric, but is not a portion of a sphere. The asphere's more complex surface profile can reduce or eliminate spherical aberration and also reduce other optical aberrations compared to spherical lenses. Aspheric elements are used to reduce aberrations.

In prescriptions for both farsightedness and nearsightedness, the lens curve flattens toward the edge of the asphere. Aspheric ablation strategies for spherical correction are modified by means of spherical aberration compensations, whereas aspheric ablation strategies for astigmatic correction are modified by means of high-order-astigmatism aberration compensations.

## **3. Ocular wavefront (OW) customized ablation strategies**

The treatment plan is developed using OW customised aspheric profiles based on Hartmann-Shack sensing<sup>1</sup>. The high-resolution Hartmann-Shack measurements (>800 points for a 7.0-mm pupil) referred to the entire eye. Optical errors centered on the line-of-sight are described by the Zernike polynomials<sup>2</sup> and the coefficients of the Optical Society of America (OSA) standard<sup>3</sup>.

## Ocular Wavefront Analyzer



- 1452 data points in total
- >800 data points for a 7 mm pupil

Fig. 1. Principle of the OW measurement.

### 3.1 Treatment modality

Preoperative topography and aberrometry measurements are taken, and visual acuity, and mesopic pupil size are measured. To determine the ablation profile of the Custom Ablation Manager (CAM), manifest refraction is measured in each eye and crosschecked with objective refraction from the SCHWIND Ocular Wavefront Analyzer<sup>4</sup>. Each eye is planned according to the manifest refraction using the CAM Wavefront customised treatments.

The CAM aspherical profiles were developed with the aim to compensate for the induction of aberrations (especially but not only spherical aberration) observed with other types of profile definitions<sup>5</sup>, some of these sources of aberrations are those related to the loss of efficiency of the laser ablation for non-normal incidence<sup>6,7</sup>. Optimization is realized by taking into account the loss of efficiency at the periphery of the cornea in relation to the center, as there is a tangential effect of the spot in relation to the corneal curvature (K (Keratometry) -reading). The software provides K-reading compensation, which considers the change in spot geometry and reflection losses of ablation efficiency.

The base-line for correcting refraction (sphere and cylinder) is aspheric, whereas the high order aberrations measured based on Hartmann-Shack sensing of the entire eye are combined with manifest refraction.

Real ablative spot shape (volume) is considered through a self-constructing algorithm. In addition, there are a randomized flying-spot ablation pattern, and controls for the local repetition rates to minimize the thermal load of the treatment<sup>8</sup>.

A central fully corrected ablation zone is used in all eyes with a variable transition size automatically provided by the laser related to the planned refractive correction. Immediately before the ablation, the laser is calibrated per manufacturer's instructions and the calibration settings are recorded.

The CAM software is able to import, visualize, and combine diagnostic data of the eye (manifest refraction and ocular wavefront data in this case) into a customised aspherical ablation profile to optimize the corneal shape. OW based ablations attempt to reduce the wavefront aberration of the entire eye (within Optical Zone, OZ) close to a zero level, compensating, as well, for the aberration induction observed with other types of profiles.

It should be noted that opposing the preoperative wavefront aberration in laser refractive surgery constituted only a first approximation of a perfect refractive correction, as tissue removal occurs. Considerations such as treatment duration or tissue removal make even more difficult to establish a universal optimal profile. Our data suggest that Ocular wavefront customized treatments can only be successful, if the pre-existing aberrations are greater than the repeatability and the biological noise. In particular, the OW customized approach is highly efficient in eyes with greater than 0.25 microns root-mean-square (RMS) ocular HOAb, or where individual components of the OW such as coma, trefoil or spherical aberration are greater than 0.2 microns RMS.

#### 4. Corneal wavefront (CW) customized ablation strategies

The treatment plan is developed using CW customized aspheric profiles based on corneal ray tracing (Salmon 1999<sup>9</sup>). Using the Keratron Scout videokeratoscope (Mattioli & Tripoli 1997<sup>10</sup>) (Optikon 2000 S.p.A, Rome, Italy), the topographical surface and corneal wavefront are analyzed (up to the 7<sup>th</sup> order). Considering a balanced-eye model (Q-Val -0.25) the departure of the measured corneal topography from the theoretically optimal corneal surface is calculated. Optical errors centered on the line of sight are described by the Zernike polynomials (Zernike 1934<sup>11</sup>) and the coefficients of the Optical Society of America (OSA) standard (Thibos et al. 2002<sup>12</sup>).

Ray tracing is a procedure classically performed by applying Snell's law to the corneal surface. However, it is much simpler to understand corneal wavefront in terms of optical path difference and calculate it by Huygens-Fresnel or "least time" Fermat principles (Salmon 1999<sup>9</sup>; Guirao & Artal 2000<sup>13</sup>).

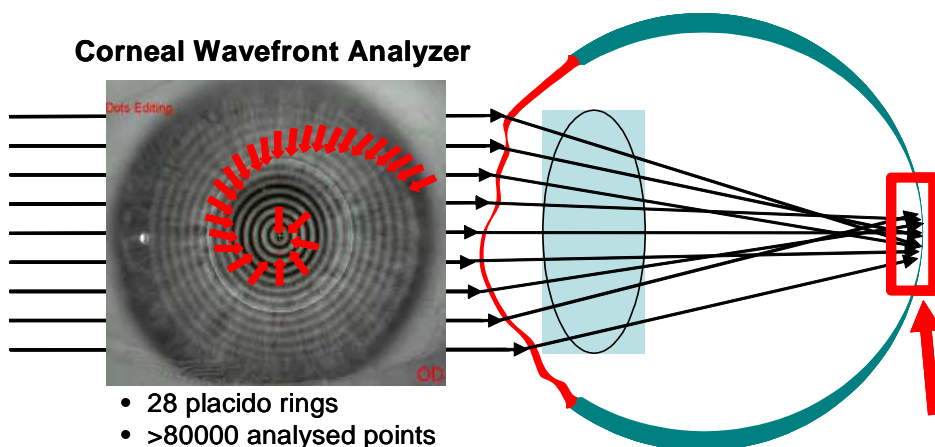


Fig. 2. Principle of the derivation of the CW.

In corneal wavefront analysis, the type and size of any optical error on the anterior corneal surface are registered, thus allowing a very selective correction. The defects are corrected exactly at their origin – the anterior corneal surface. In this context, the precise localization of defects is crucial to successfully achieving optimal results in laser surgery. The corneal wavefront allows for a very precise diagnosis, thus providing an individual ablation of the cornea in order to obtain perfect results.

Applying this treatment strategy, measurement does not require pupil dilation of the eye, so that the treatment zone is not limited by the pupil and accommodation does not influence the measuring results. Mention is made that in this way forcing a fixed asphericity quotient (Q) on the eyes through the treatment is avoided. Instead, this strategy employs a dynamic postoperative expected asphericity quotient (de Ortueta & Arba-Mosquera 2008<sup>14</sup>), being expressed as:

$$Q_{\text{exp}} = \frac{\frac{1}{n^2} - \frac{1}{4}}{\left(1 + \frac{R \cdot SEq_{cp}}{n-1}\right)^3} - \frac{1}{n^2} \quad (1)$$

where  $Q_{\text{exp}}$  is the expected/predicted corneal asphericity quotient; R the apical radius of curvature of the preoperative cornea;  $SEq_{cp}$  the spherical equivalent to be corrected at the corneal plane; and n the refractive index of the cornea.

The expected quotient of asphericity does not incorporate any compensation for the effect of postop corneal biomechanics / healing response, and it is rather derived from a pure optical model of the cornea.

Preoperative topography and corneal aberrometry measurements are taken, and visual acuity, and mesopic pupil size are measured. Each eye is planned according to the manifest refraction using the CAM wavefront customized treatments. Immediately before ablation, the laser is calibrated according to the manufacturer's instructions and the calibration settings are recorded.

When evaluating the outcomes of wavefront customization strategies, wavefront aberration analysis is mandatory to be able to determine whether the customization aims could be achieved. It has been suggested, as well, that the surface ablation procedures are better suited for the wavefront guided ablation as they would avoid the induction of aberrations due to flap and interface (Chun et al. 2006<sup>15</sup>; Buzzonetti et al. 2004<sup>16</sup>). Now with the introduction of thin and ultrathin planar flaps with femtosecond laser and the newer microkeratomes such as the pendular microkeratome, this aspect of the debate will require further research.

Topography is measured under bright light conditions which might cause pupil constriction and also pupil center shift relative to normal photopic levels. Corneal wavefront customized treatments can only be successful, if the pre-existing aberrations are greater than the repeatability and the biological noise. Considerations such as treatment duration or tissue removal make it more difficult to establish a universal optimal profile.

Furthermore, coupling effects between different high order aberration terms, and between HOAs and manifest refraction is still one of the major sources of residual aberrations after refractive surgery. This topic has been discussed from a theoretical perspective by Bará et al. 2006<sup>17</sup> and from a clinical perspective by MacRae 2007<sup>18</sup> or Buehren et al. 2007<sup>19</sup>. They all

found mutually affecting interactions, for example, between defocus and spherical aberration, or between 3 order aberrations and low order terms, between spherical aberration and coma, or between secondary and primary astigmatisms.

The accuracy, predictability, and stability of the refractive power change, together with the minimal external impact of the CAM ablation profiles on the HOAs, leads to very good results in terms of visual quality. In summary, aspheric CW ablation profiles, designed with CAM software for the AMARIS laser platform, yield visual, optical, and refractive results comparable to those of other wavefront-guided customized techniques for correction of myopia and myopic astigmatism. The CW customized approach shows its strength in cases where abnormal optical systems are expected. Apart from the risk of minimal additional ablation of corneal tissue, systematical wavefront-customized corneal ablation can be considered as a safe and beneficial method.

## 5. Decision Assistant Wizard

Our definition of “Customisation” is conceptually different and can be stated as: “The planning of the optimum ablation pattern specifically for each individual eye based on its diagnosis and visual demands.” It is often the case, that the best approach for planning an ablation is a sophisticated pattern, which can still be simply described in terms of sphere, cylinder, and orientation (axis). The Decision Assistant Wizard, which we present here, is based on our experience with the SCHWIND AMARIS laser. While the general principles of this Decision-Tree based planning (Fig. 3) can basically be applied to any other laser platform offering aspheric and wavefront-guided profiles, some specific aspects concerning both diagnosis and treatments may depend on other manufacturers’ specifications.

We begin by acquiring four corneal topographies (Corneal Wavefront Analyzer, SCHWIND eye-tech-solutions GmbH & Co.KG, based on Keratron-Scout, OPTIKON2000, Rome, Italy) and derived CW analyses centred on the line-of-sight for each eye of the patient. We extract the mean, and discard the less representative one (the one with the poorest similarity to the mean). From those remaining three maps, we calculate the mean, and select the most representative one (the one with the highest similarity to the mean).

We continue acquiring, under non pharmacologically dilated pupils, non-cycloplegic conditions, and natural dim light conditions (to avoid pharmacologically induced pupil shifts<sup>20,21</sup>), 3 aberrometries (Ocular Wavefront Analyzer, SCHWIND eye-tech-solutions GmbH & Co.KG, based on irx3, Imagine Eyes, Orsay, France) and objective refractions for each eye of the patient. To minimize the potential accommodative response of the patients, we ask them to “see-through-the-target” instead of “looking at the target.” In this way, patients do not try to get a sharp image from the +1.5 D fogged target, since they were instructed to see-through-the-target. From those aberrometries, we calculate the mean, and select the most representative one (the aberrometry map with the highest similarity to the mean).

We continue assessing subjective refraction based upon non-pharmacologic and non-cycloplegic conditions, under natural photopic illumination. We use the objective refraction analyzed for a sub-pupil of 4 mm diameter, as starting refraction for this step. This is particularly useful for determining the magnitude and orientation of the astigmatism. We measure manifest refraction, uncorrected and best spectacle-corrected Snellen visual acuity<sup>22</sup> (UCVA and BSCVA, respectively). Further rules that we impose for accurately determining

the manifest subjective refractions among equal levels of BSCVA are: taking the measurement with the least negative (the most positive) spherical equivalent (unmasking latent hyperopia), if several of them are equal in terms of spherical equivalent, we choose the measurement with the least amount of astigmatism (reducing the risk of postoperative shifts in the axis of astigmatism). This is particularly useful for determining the magnitude and orientation of the internal astigmatism as a difference between the topographic astigmatism and the astigmatism of the corneal wavefront analyses compared to the subjective astigmatism the astigmatism of the ocular wavefront analyses.

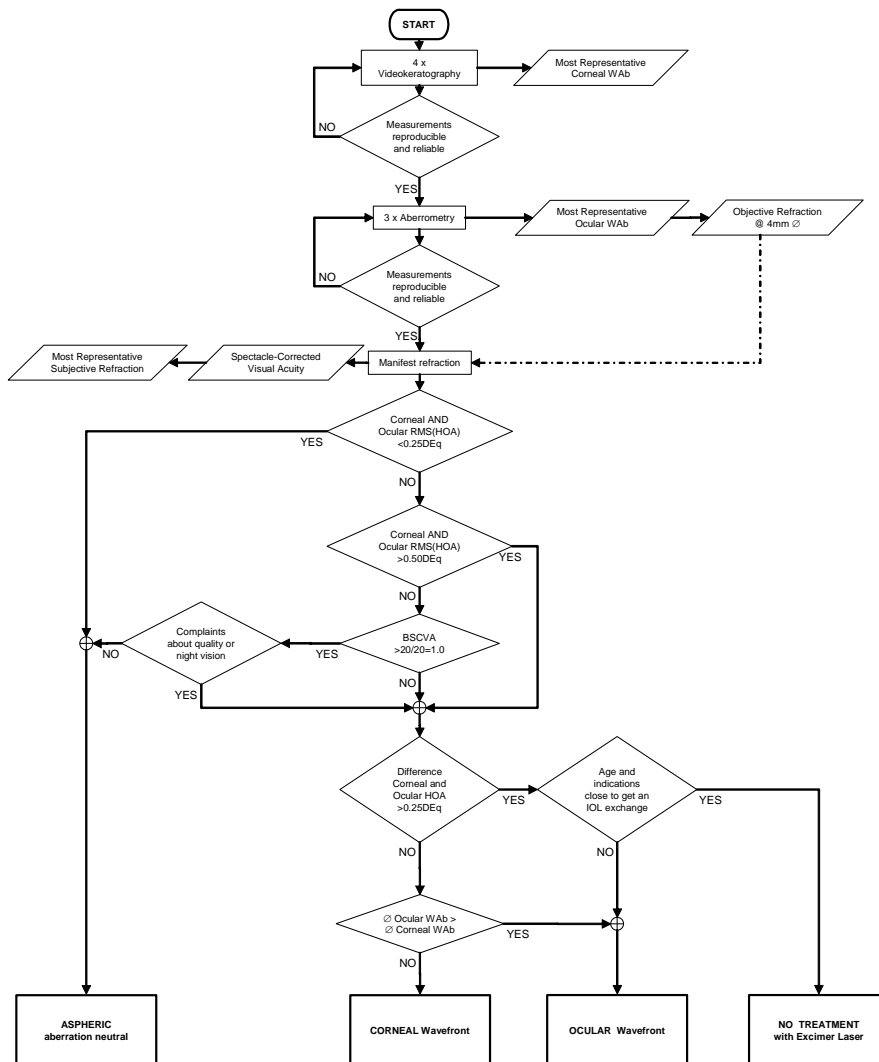


Fig. 3. Decision-Tree applied for selecting the treatment mode (Aspheric aberration neutral, Corneal-Wavefront-Guided, or Ocular-Wavefront-Guided).

The decision process starts by estimating the global optical impairment resulting from the measured wave aberrations. This is done by objectively determining the actual clinical relevance of single terms in a Zernike expansion of the wave aberration. In general, for the same magnitude of aberration, the optical blur produced by high order aberrations increases with increasing radial order and decreases with increasing angular frequencies. Based on this, the dioptric equivalent (DEq) was used.

If the global optical blur for both corneal and ocular wave-aberrations (CWAb and OWAb, respectively) are below 0.25 DEq for both eyes, then the treatment to be applied is Aspheric aberration neutral. If the global optical blur for any corneal or ocular wave-aberrations is between 0.25 DEq and 0.50 DEq for any eye, then we check the BSCVA achieved during the manifest refraction. If the BSCVA is better than 20/20 for both eyes, then we ask the patient about complaints regarding night vision or, in general, quality of vision. If the patient does not report complaints, then the treatment to be applied is Aspheric aberration neutral.

If the patient reports complaints regarding quality of vision, the BSCVA is worse than 20/20 for any eye, or the global optical blur for both corneal and ocular wave-aberrations are above 0.50 DEq for both eyes, then we compare corneal and ocular wave-aberrations. For this, we calculate the differential aberration (CWAb - OWAb, both centred at the line-of-sight) in terms of the Zernike expansion, and estimate the global optical difference. If this global optical difference between corneal and ocular wave-aberrations is below 0.25 DEq for both eyes, we consider both corneal and ocular wave-aberrations as equivalent. In this case, the treatment to be applied depends on the available diameter of the wavefront maps and the scotopic pupil size. If the diameter of the Ocular- or Corneal-WAb map (the one providing the largest diameter) is at least as large as the scotopic pupil size (in natural dark conditions) reduced in 0.25 mm, then Ocular- or Corneal-Wavefront-guided ablation is performed (the one providing the largest diameter), or Aspheric aberration neutral otherwise. Usually the size of the Ocular WAb maps is similar to the size of the scotopic pupils, whereas Corneal WAb maps are wider (up to 10 mm in diameter).

If the global optical difference between corneal and ocular wave-aberrations is above 0.25 DEq for any eye, we consider internal wave-aberration (IWAb) is relevant, then the treatment to be applied is Ocular-Wavefront-guided if the patient is neither in age nor in ophthalmic indications close to get an IOL exchange (due to e.g. lenticular opacities), otherwise no laser corneal refractive treatment is recommended (since IOL exchange is preferred).

Level of aberration	Aspheric aberration neutral	CW-guided	OW-guided
Corneal AND Ocular Wavefronts < 0.25Deq	Always	No	No
Corneal OR Ocular Wavefront between 0.25Deq and 0.50Deq	If BSCVA > 20/20 AND no complaints about quality or night vision	If (BSCVA < 20/20 OR complaints about quality or night vision) AND Internal Wavefront < 0.25Deq	If (BSCVA < 20/20 OR complaints about quality or night vision) AND no lenticular problems
Corneal AND Ocular Wavefronts > 0.50Deq	If wavefront maps smaller than scotopic pupil	If Internal Wavefront < 0.25Deq	If no lenticular problems

Table 1. Indications chart.



There are basically three types of approaches for planning a corneal refractive treatment. The first are those that have as their objective the elimination or reduction of the total aberrations of the eye. The main criticism to this approach argues that the goal "zero aberration" is inconsistent throughout the day due to accommodation, and little lasting, since aberrations change with age<sup>23,24,25</sup>. The second approach is intended to correct all corneal aberrations, since corneal aberrations do not change with age<sup>26,27</sup>. However, this concept might also be wrong considering corneal aberrations interact with internal aberrations, some of them being cancelled, and producing an aberration pattern of the total eye in general different from the aberration pattern of the cornea alone. Therefore, by only removing corneal aberration we might worsen the overall aberrations, since the internal aberration might not find a corneal aberration for compensation. In case that the corneal aberration is of the same sign as the internal aberration, the correction of the corneal aberration would be useful, as it would reduce the total aberration of the eye. A third approach tries not to induce aberrations. This type of treatment is not as ambitious, but much more simple to operate. The goal of the Aberration-Free™ ablation profile is to provide a neutral high-order-aberrations (HOAb) ablation, ie to maintain the same HOAb profile both preoperatively with best spectacle correction and postoperatively without correction.

There is evidence of neural adaptation to the baseline wavefront profile. The interaction between high-order-aberrations can be beneficial to visual quality regardless of the magnitude HOAb. Based on the random nature of the HOAb induction and current research, it may be beneficial to maintain the preoperative wavefront profile for a significant number of refractive surgery candidates.

We are not postulating that customized ablation algorithms in any form (ocular-wavefront-guided, corneal-wavefront-guided, topography-guided) are not be useful. Rather, that specific populations with specific demands deserve specific treatment solutions. Aspheric treatments aimed at preservation of the preoperative HOAb show their strengths in patients with preoperative BSCVA 20/20 or better or in patients where the visual degradation cannot be attributable to the presence of clinically relevant HOAb (e.g. lens opacities).

The corneal wavefront customized approach shows its strength in cases where abnormal corneal surfaces are expected. Apart from the risk of additional ablation of corneal tissue, wavefront customized corneal ablation can be considered a safe and beneficial method. Our experience suggests that wavefront customized treatments can only be successful, if pre-existing aberrations are greater than repeatability (e.g. repeatability of diagnostic<sup>28</sup> and treatment devices) and biological noise (e.g. day-to-day variabilities in visual acuity, refraction, or aberration in the same subject).

Furthermore, coupling effects between different high order aberration terms, and between HOAb and manifest refraction have been found<sup>29,30</sup> for example, between defocus and spherical aberration, or between 3<sup>rd</sup> order aberrations and low order terms, between spherical aberration and coma, or between secondary and primary astigmatisms. These interactions may provide some relative visual benefits<sup>31</sup>, but may as well contribute as sources of uncertainty in the conversion of wavefront aberration maps to refractive prescriptions. Notice that for comparing OWAb and CWAb, the analysis of the IWAb as CWAb - OWAb is mandatory since RMS(IWAb) accounts for any deviation (i.e. inductions and reductions of the wave-aberration both contribute positively to increase the RMS value).

The Decision Assistant Wizard presented here may theoretically be applied to any other laser platform offering aspheric, topography-guided, and wavefront-guided profiles, if appropriate analysis functions for CWAb, OWAb, and IWAb are available. Simplified versions with limited functionalities are also possible, if, for example, neither CW-analyses (i.e. no IWAb) nor topography-guided profiles are available. The desired outcome of non-wavefront-driven refractive surgery is to balance the effects on the wave-aberration, and, to provide normal eyes with perhaps the most natural unaltered quality of vision. While Ocular Wavefront treatments have the advantage of being based on Objective Refraction of the complete human eye system, whereas Corneal Wavefront treatments have the advantage of being independent from accommodation effects or light/pupil conditions; Aspheric treatments have the advantage of saving tissue, time and due to their simplicity offer better predictability.

In highly aberrated eyes, manifest refraction may become an art, a sort of guessing around the least blurred image. In further studies, systematic deviations from the measured manifest refractions, as well as other foreseeable couplings among Zernike coefficients will be evaluated.

## 6. Minimization of depth and time in laser corneal refractive surgery

In laser corneal refractive surgery, one always aims to reduce the ablated tissue thickness (and, to a minor degree, to reduce the intervention time) because an ectasia of the cornea may result from excessive tissue removal. Customized laser corneal refractive surgery on aberrated eyes may yield better results than the standard procedure<sup>18-21</sup> but generally results in higher ablation depth, volume, and time. Therefore, optimizing the customized treatment to reduce the ablated thickness while retaining the positive aspects is pertinent.<sup>22</sup>

The development of new algorithms or ablation strategies for performing laser corneal refractive surgery in a customized form, minimizing the amount of ablated tissue without compromising the visual quality, and potentially maximizing visual performance without increasing risk factors would be of great value for the refractive surgery community and ultimately for the health and safety of patients. The real impact of tissue-saving algorithms in customized treatments is controversial. Minimizing the amount of tissue must be done in a way that does not compromise the refractive correction or visual performance, and it must be safe, reliable, and reproducible.

In general, for the same amount of equivalent defocus, the optical blur produced by HOAs increases with increasing radial order and decreases with increasing angular frequencies. Based on this blur effect of the single Zernike terms, we have defined a dioptric equivalent:

$$DEq_n^m = \frac{8\sqrt{2(n+1)(1+\delta_{m0})}|C_n^m|}{PD^2} \quad (2)$$

where  $DEq_n^m$  is the dioptric equivalent of the optical blur;  $n$ , the radial order of the considered Zernike term;  $m$ , the angular frequency of the considered Zernike term;  $\delta_{m0}$ , the Kronecker delta function of the angular frequency and zero (1 for radially symmetric Zernike terms and 0 otherwise);  $C_n^m$ , the weight coefficient of the considered Zernike term; and PD, the analysis diameter for the optical blur.

In such a way, the dioptric equivalent produced by HOAs increases with increasing radial order and partly decreases with increasing angular frequencies. This dioptric equivalent metric is identical to the power vector notation for the low orders and allows defining a general optical blur as a general expression for the one proposed by Thibos et al<sup>36</sup>:

$$U_G = \sqrt{\sum (DEq_n^m)^2} \quad (3)$$

where  $U_G$  is the general optical blur.

We have expressed each of the Zernike terms as a dioptric equivalent in familiar units to help judge the order of magnitude of the effect. Using common clinical limits, the following classification is proposed:

$$DEq_n^m < 0.50 \text{ D} \Rightarrow \text{might be clinically relevant} \quad (4)$$

$$DEq_n^m \geq 0.50 \text{ D} \Rightarrow \text{clinically relevant} \quad (5)$$

This represents the proposed objective determination of the actual clinical relevance of the single terms in a Zernike expansion of the wavefront aberration.<sup>22</sup>

### 6.1 Objective minimization of the maximum depth of a customized ablation based on the Zernike expansion of the wavefront aberration

One of the minimization approaches consists of simplifying the profile by selecting a subset of Zernike terms that minimizes the necessary ablation depth while respecting the Zernike terms considered clinically relevant. The minimize depth (MD+) function analyzes the Zernike pyramid as described in the previous section and evaluates the ablation depth of all possible free combinations of subsets of Zernike terms while fulfilling several conditions:

- Only terms of third or higher order can be disabled.
- Only terms with optical blur dioptric equivalent less than 0.5 D can be disabled.
- For each subset combination of Zernike terms, the low-order terms are recalculated using the automatic refraction balance method.

From this evaluation, the function selects the subset of Zernike terms that needs the minimum amount of maximum depth.

### 6.2 Objective minimization of the ablation volume of a customized ablation based on the Zernike expansion of the wavefront aberration

The other minimization approach consists of simplifying the profile by selecting a subset of Zernike terms that minimizes the necessary ablation volume while respecting the Zernike terms considered clinically relevant. The minimize volume (MV+) function analyzes the Zernike pyramid as described in the previous section and evaluates the ablation depth of all possible free combinations of subsets of Zernike terms fulfilling several conditions:

- Only terms of third or higher order can be disabled.
- Only terms with optical blur dioptric equivalent less than 0.5 D can be disabled.
- For each subset combination of Zernike terms, the low-order terms are recalculated using the automatic refraction balance method.

From this evaluation, the function selects the subset of Zernike terms that needs the minimum amount of volume for the ablation. Reduced ablation volumes lead to shorter treatment times.

One could use the equivalent defocus applied to each individual Zernike mode to compute its clinical relevance. The basis of the equivalent defocus concept is the notion that the imaging quality of an eye is determined primarily by wavefront variance, and it does not matter which Zernike mode produces that variance. This is only true when the wavefront variance is really small and the image quality is measured by the Strehl ratio. Otherwise, the relationship between wavefront variance and image quality becomes much more complex. It is important to bear in mind that 1 D of ordinary defocus does not necessarily have the same effect as 1 D of equivalent defocus because different types of aberrations affect the retinal image in different ways. Nevertheless, by expressing RMS error in terms of equivalent defocus, the data are put into familiar units that help us judge the order of magnitude of the effect.

Strictly speaking, one cannot consider the clinical relevance of every Zernike term independently without demonstrating whether a single Zernike term is alone responsible for the loss of visual quality. The visual effect of an aberration does not only depend on that specific aberration but also on other possibly present aberrations; for example, the sum of small aberrations, previously considered clinically irrelevant, could lead to a clear loss of overall optical quality. The idea of approximating a distorted wavefront by means of an equivalent dioptric error is much too controversial to be accepted without caution.

Coupling effects between different HOA terms and between HOAs and manifest refraction have been found,<sup>44-46</sup> for example, between defocus and spherical aberration, third-order aberrations and low-order terms, spherical aberration and coma, or secondary and primary astigmatisms. These interactions may provide some relative visual benefits<sup>47</sup> but may also contribute uncertainty in the conversion of wavefront aberration maps to refractive prescriptions.<sup>48,49</sup> One could use more sophisticated equations to model the equivalences between the optical blur produced by the different Zernike terms, but we have used a relatively simple approach driven primarily by the radial order. Different approaches for minimizing tissue ablation in refractive surgery have been proposed and extensively discussed.<sup>22</sup> When to use customized strategies in refractive surgery has been discussed previously as well.<sup>18-21</sup>

Considering that Zernike terms are either planned to be corrected or left uncorrected, visual performance is not compromised because all remaining uncorrected terms are below clinical relevance. The proposed approaches are safe, reliable, and reproducible because of the objective foundation upon which they are based. It is important to note that the selection of the Zernike terms to be included in the correction is not trivial. As mentioned, only Zernike terms considered not clinically relevant or of minor clinical relevance can be excluded from the correction, but they must not necessarily be excluded.

Actually, single Zernike terms considered not clinically relevant will only be disabled when they represent additional tissue for ablation and will be enabled when they help to save tissue. This way, particular cases are represented by the full wavefront correction by disabling all nonclinically relevant terms or by disabling all high-order terms. As per design, the MD group actually optimizes for minimum ablation depth and shows the largest

savings for this aim ( $-8 \pm 4 \mu\text{m}$ , from  $-20$  to  $-1 \mu\text{m}$ ), whereas the MV group actually optimizes for minimum ablation volume (time) and shows the largest savings for this aim ( $-8 \pm 2$  seconds, from  $-26$  to  $-22$  seconds). In this context, and as a rule of thumb, MD minimization could be used in customized myopic treatments when reducing ablation depth is directly related to decreasing the risk of keratectasia, whereas MV minimization could be used in long customized treatments when reducing ablation time is directly related to better maintenance of homogeneous corneal conditions.

## 7. Surgical technique selection

Excimer laser refractive surgery has evolved full circle. Surface ablations in the form of photorefractive keratectomy (PRK) swiftly evolved into intra-stromal procedure of laser in-situ keratomileusis (LASIK) due to its rapid visual recovery and minimal postoperative discomfort. However, with increasing adoption of LASIK grew the concern for post-LASIK keratectasia. The last few years have therefore, witnessed a renewed interest in alcohol assisted surface ablation procedures to avoid complications of LASIK primarily corneal ectasia and flap and interface related problems.

The decision to perform alcohol assisted LASEK or LASIK is based on preoperative central corneal thickness (measured by ultrasonic pachymetry (DGH-550 Pachette 2, DGH Technologies, USA)) and calculated depth of ablation. LASEK is performed on all patients with central pachymetry less than  $500 \mu\text{m}$ . Eyes with central pachymetry above  $500 \mu\text{m}$  are assigned to either LASEK or LASIK techniques, depending on the central pachymetry and the depth of ablation. The decision is based on the target of limiting the ablation to the anterior one third of the cornea (so as to achieve a residual stromal bed thickness of at least  $2/3$ rd of pre-operative pachymetry). Patients were tested for LASIK in case they do not meet the " $2/3$ " condition they were assigned to the LASEK group.

For corneal and conjunctival anesthesia, two drops of proparacaine HCl 0.5% (Aurocaine®, Aurolab, Madurai, India) are instilled three times before shifting the patient to the operation theatre (OT).

**LASIK** - Pachymetry is performed before and after flap creation (stromal bed thickness) with both the integrated online coherence pachymeter (Heidelberg, Germany) and ultrasonic pachymeter. Flap is made using LDV femtosecond laser. Contact lens is applied at the end of surgery (Biomedics 55 evolution, Ocular Sciences, Cooper Vision, Hamble, UK) in eyes with 'achieved' flap thickness less than 110 microns to avoid flap displacements, dislocations or striae.

**LASEK** - 17% alcohol applied for 30 seconds is used for the creation of epithelial flap. Eight or 9 mm diameter epithelial flap is made after incising the corneal epithelium with a trephine. Contact lens is applied at the end of surgery in all LASEK patients.

**Postoperative Treatment** - For LASIK patients, eye drop Tobradex (Alcon Inc, USA) 3 times a day is used for 1 week along with Oasis soft plugs extended duration (6404 Glendora CA) and preservative free artificial tear drops during the first three months. A bandage contact lens is used during the first night in LASIK patients with flap thickness less than  $110 \mu\text{m}$ . For LASEK patients, prior to epithelial healing, eye drops lomefloxacin 0.3 % (Okacin) and pranoprofen (Ofralar, Alcon Inc, USA) are used along with Oasis soft plugs extended

duration. Bandage contact lens is applied in all LASEK patients for 5-7 days until complete healing of the epithelial defect. After epithelial healing, preservative free artificial tear eye drops are given along with efemoline eye drops (Fluoromethalone, Novartis Ophthalmics, Switzerland) 3 times a day for 3 months. The steroids are gradually tapered every month to once a day in the last month.

**Postoperative follow-up** – LASIK patients are followed on first postoperative day, at 1 month, 3 months, and 1 year. LASEK patients are examined on first postoperative day, at 1 week, 1 month, 3 months, and 1 year.

There has been a renewed interest in surface ablation modalities with epithelial repositioning like LASEK to overcome some of the flap and ectasia related complications of LASIK. Though the rate of visual recovery may be slower in surface ablation thus lacking the LASIK 'wow' effect, studies have shown that LASEK is an effective modality for surgical correction of low to moderate myopia.<sup>8-10</sup> However, its utility for correction of high myopia is limited.<sup>11-13</sup> With introduction of thin and ultrathin flaps using femtosecond laser and newer microkeratomes such as the pendular microkeratome, the indications for the 2 surgical modalities are getting indistinct. Introduction of newer ablation profiles such as customized and aspheric ablations has added another aspect to be evaluated.

It has been suggested that surface ablative procedures may be better suited for customized correction though it has not been proven clinically.<sup>1,2,14</sup> It has been suggested that the creation of corneal flap in LASIK patients can induce further higher order aberrations especially coma like aberrations.<sup>15</sup> This may be particularly relevant to thinner flaps which may have a higher incidence of flap striae. The clinical relevance of these flap induced higher order aberrations especially in relation to newer microkeratomes and femtosecond laser and the effect of flap thickness require further investigation.

The aspheric ablation profile is equally successful with both surface ablation as well as intrastromal excimer ablation minimizing the change in higher order aberrations. The latest development in excimer laser refractive is the thin and the ultrathin flap LASIK. It attempts to find the best of both worlds of standard LASIK and surface ablation. Besides pre-existing risk factors, low residual stromal bed thickness is the single most important modifiable factor that increases the risk of iatrogenic post-LASIK ectasia.<sup>38</sup> Thin and ultrathin flap LASIK achieves a thicker residual stromal bed and therefore is believed to decrease the risk of post-LASIK ectasia. Current study indicates that thin and ultrathin LASIK is safe, efficacious, and predictable after short term follow up of 6 months. However, future investigations with long-term follow-up are likely to prove if LASIK utilizing thin and ultrathin flaps translate into the anticipated decreased risk of post-LASIK ectasia.

## 8. 6D Eye-Tracker

Human eyes have six degrees of freedom to move: X/Y lateral shifts, Z levelling, horizontal/vertical rotations, and cyclotorsion (rotations around the optical axis). The analysis of these movements has been made since the middle of the 20<sup>th</sup> century. Schwiegerling and Snyder<sup>32</sup> measured eye motion in patients having laser in situ keratomileusis (LASIK) using a video technique and determine centration and variance of the eye position during surgery. They found a standard deviation in the eye movements in all eyes larger than 100  $\mu\text{m}$ . Taylor et al.<sup>33</sup> determined the accuracy of an eye tracking system

designed for laser refractive surgery. The system demonstrated an accuracy of 60  $\mu\text{m}$  for an intact cornea and 100  $\mu\text{m}$  for a cornea with a thin flap removed.

Bueeler et al.<sup>34</sup> investigated the lateral alignment accuracy needed in wavefront-guided refractive surgery to improve the ocular optics to a desired level in a percentage of normally aberrated eyes. To achieve the diffraction limit in 95% of the normal eyes with a 7.0 mm pupil, a lateral alignment accuracy of 70  $\mu\text{m}$  or better was required. An accuracy of 200  $\mu\text{m}$  was sufficient to reach the same goal with a 3.0 mm pupil. Bueeler and Mrochen<sup>35</sup> quantified the parallax error associated with localizing corneal positions by tracking the subjacent entrance pupil center by means of optical ray-tracing in a schematic model eye. They found tracking error can amount to 30% (or more for eye trackers mounted closer than 500 mm to the eye) of the detected lateral shift. Thus, if the eye tracker registers a lateral shift of the entrance pupil of 200  $\mu\text{m}$  away from the tracking reference axis, the point of interest located on the cornea would essentially be 260  $\mu\text{m}$  away from this reference axis. A laser pulse fired at that moment would be systematically displaced by 60  $\mu\text{m}$ .

Measuring rotation when the patient is upright<sup>36</sup> to when the refractive treatments are performed with the patient supine may lead to ocular cyclotorsion,<sup>37,38</sup> resulting in mismatching of the applied versus the intended profiles<sup>39,40</sup>. Recently, some equipment can facilitate measurement of and potential compensation for static cyclotorsion occurring when the patient moves from upright to the supine position during the procedure<sup>41</sup>, quantifying the cyclorotation occurring between wavefront measurement and laser refractive surgery<sup>42</sup> and compensating for it<sup>43,44,45</sup>. Further measuring and compensating ocular cyclotorsion during refractive treatments with the patient supine may reduce optical "noise" of the applied versus the intended profiles<sup>46,47,48</sup>.

In recent times, many studies have discussed the methodologies and implications of ocular cyclotorsion, but not many papers pay attention to the rolling and axial movements of the eye. The more irregular a cornea is, the more important proper eye-tracking. Astigmatism is the most common aberration with a vector nature, so usually are the astigmatic problems the ones more affected or the ones which benefit the most from advanced eye tracking.

### **8.1 Lateral movements during ablation (1<sup>st</sup> and 2<sup>nd</sup> dimension)**

AMARIS system includes a pupil-registration module for the eye-tracker subsystem, in which, the first pupil image under the AMARIS system obtained with starting the ablation is taken as reference and its location referred to the limbus is used for any further eye-tracker image in order to determine the pupil centre shift compensation (PCSC).

### **8.2 Eye rolling during ablation (3<sup>rd</sup> and 4<sup>th</sup> dimension)**

AMARIS system includes a scleral-registration module for the eye-tracker subsystem, in which, the first few scleral-tracker images under the AMARIS system obtained with starting the ablation are taken as reference (natural rolling) and compared to any further scleral-tracker image in order to determine the eye rolling (ER).

### **8.3 Static cyclotorsion between upright and supine positions (5<sup>th</sup> dimension)**

AMARIS system includes an eye-registration module for the eye-tracker subsystem, in which, the diagnosis image is taken as reference and compared to an eye-tracker image

under the AMARIS system obtained prior to starting the ablation in order to determine the static cyclotorsion component (SCC).

#### 8.4 Dynamic cyclotorsion during ablation (5<sup>th</sup> dimension)

AMARIS system includes an eye-registration module for the eye-tracker subsystem, in which, the first eye-tracker image under the AMARIS system obtained with starting the ablation is taken as reference and compared to any further eye-tracker image in order to determine the dynamic cyclotorsion component (DCC).

#### 8.5 Axial displacements during ablation (6<sup>th</sup> dimension)

AMARIS system includes an scleral-registration module for the eye-tracker subsystem, in which, the first few scleral-tracker images under the AMARIS system obtained with starting the ablation are taken as reference (natural level) and compared to any further scleral-tracker image in order to determine the axial displacements (AD).

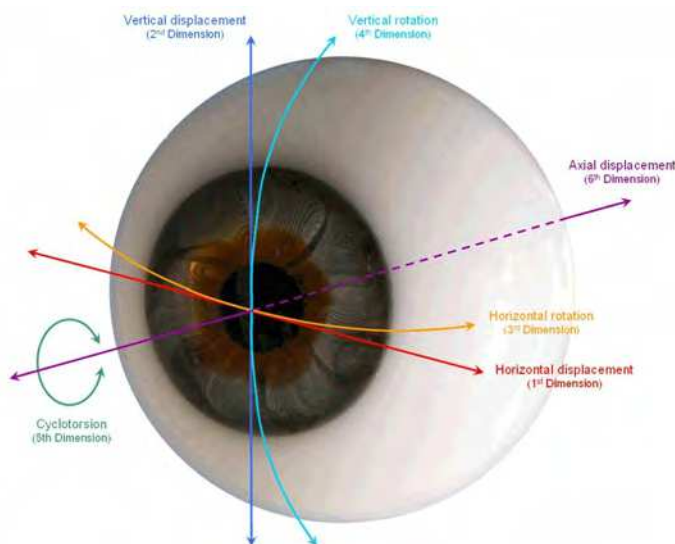


Fig. 4. Lateral movements (vertical and horizontal displacements) 1st and 2nd dimensions, Rolling movements – caused by a tilting of the head or of the eye 3rd and 4th dimensions, Rotations around the visual axis - This happens mostly when changing from upright to supine position, but also during the treatment 5th dimension, cyclotorsion, Movements along the z-axis 6th dimension. All dimensions measured and compensated for static and dynamic movements in an active/passive manner.

The AMARIS TotalTech laser includes compensation for the ocular cyclotorsions occurring from upright to supine position (static cyclotorsion from diagnosis to treatment), as well as the lateral movements, eye rollings, dynamic cyclotorsions, and displacements along the propagation axis occurring during the laser treatment. Further, the differences in pupil size and centre for and during the treatment compared to that during diagnosis<sup>49</sup> are also



compensated for, since the theoretical impact of cyclotorted ablations is smaller than decentred ablations or edge effects<sup>50</sup> (coma and spherical aberration<sup>51</sup>). In this way, additional lateral displacements<sup>52</sup> due to cyclotorsions occurring around any position other than the ablation centre are avoided (induced aberrations emanating from lateral displacements always increase with decentration<sup>53</sup>).

A six dimensional eye-tracker is important since uncompensated pupil movements (lateral movements) induce decentrations<sup>32</sup> which can be visually manifested as comatic aberrations<sup>52</sup>. Uncompensated rolling movements induce decentrations as well<sup>35</sup>, which can be visually manifested as comatic aberrations<sup>52</sup>. Uncompensated cyclotorsional movements induce aberrations<sup>40</sup>, whereas uncompensated axial movements induce undercorrections in an asymmetrical way. Axial movements produce that the laser spots are no longer in focus when they reach the cornea, i.e. ignoring absorption processes in air, for the same energy spot diameter is larger reducing the radiant exposure and the ablation depth of the spot. Axial movements produce as well that off axis pulses hit the cornea more centrally than planned if the eye moves towards the laser system and further peripherally if the eyes moves far from the laser.

### Why is 6D Eye-Tracking so important?

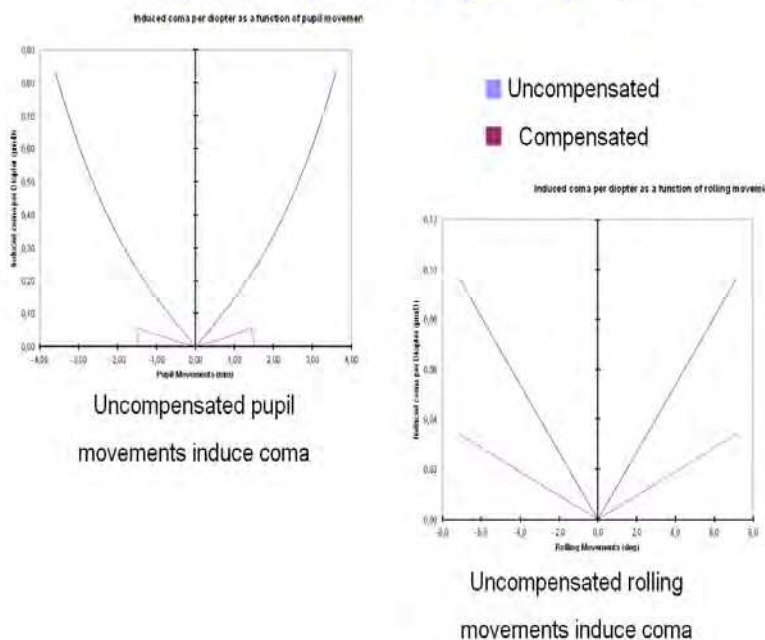


Fig. 5. A six dimensional eye-tracker is important since uncompensated pupil movements (lateral movements) induce decentrations which can be visually manifested as comatic aberrations. Uncompensated rolling movements induce decentrations as well, which can be visually manifested as comatic aberrations.

## Why is 6D Eye-Tracking so important?

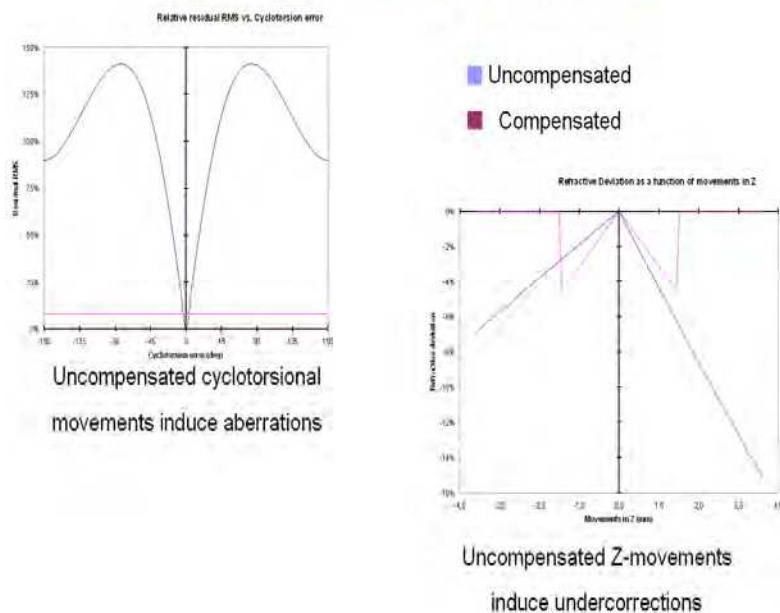


Fig. 6. A six dimensional eye-tracker is important since uncompensated cyclotorsional movements induce aberrations, whereas uncompensated axial movements induce undercorrections in an asymmetrical way. Axial movements produce that the laser spots are no longer in focus when they reach the cornea, i.e. ignoring absorption processes in air, for the same energy spot diameter is larger reducing the radiant exposure and the ablation depth of the spot. Axial movements produce as well that off axis pulses hit the cornea more centrally than planned if the eye moves towards the laser system and further peripherally if the eyes moves far from the laser.

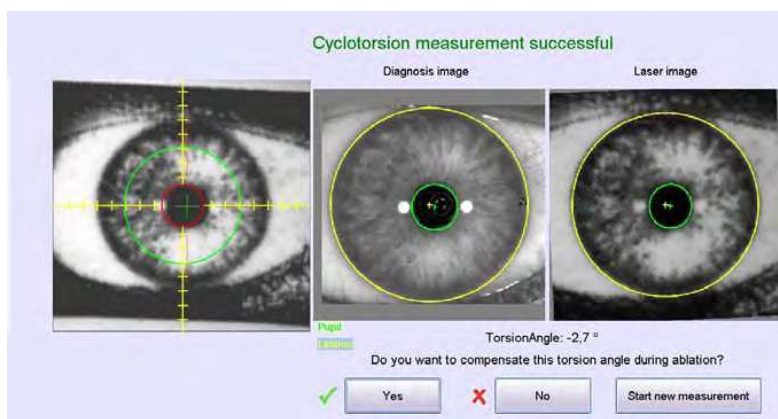


Fig. 7. Static cyclotorsion compensation.

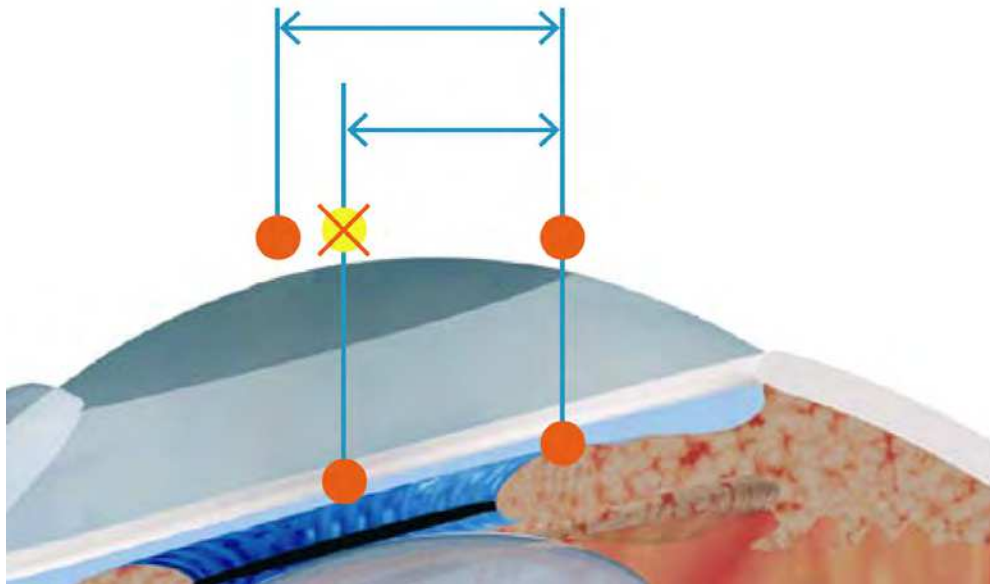


Fig. 8. Rolling compensation.

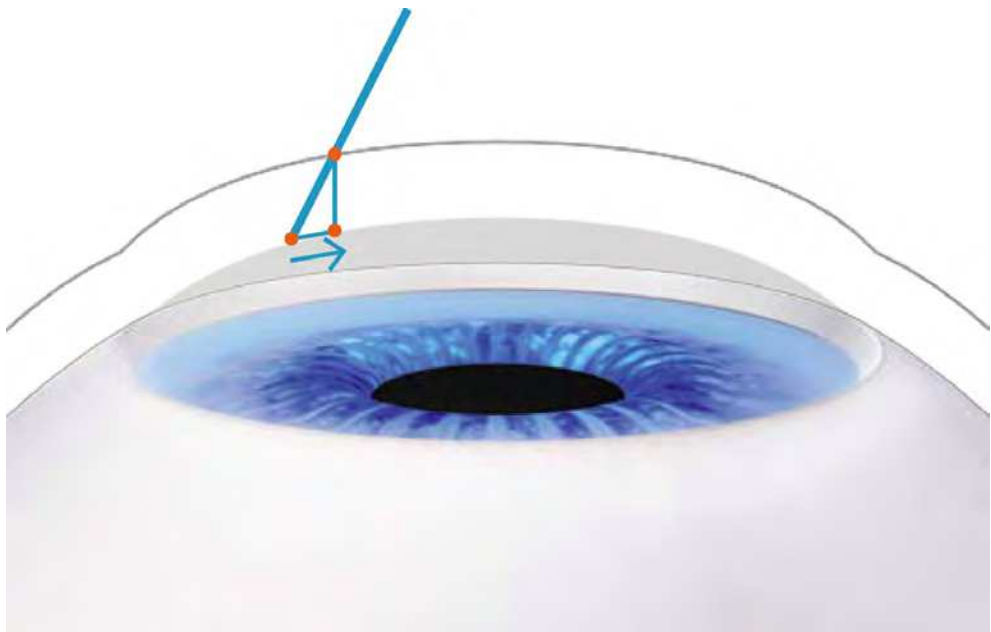


Fig. 9. Axial movements compensation.

In our experience with AMARIS system measuring the pupil displacements, we obtained an average of 150  $\mu\text{m}$ . The distribution of the percentage of eyes vs. pupil displacement showed 3% of eyes had pupil displacements exceeding 1 mm. The ranges for pupil displacements over the treatment are relatively mild, but with peaks of up to about 1.5 mm.

With our system for measuring the rolling movements, we obtained an average value 5°. This value is actually the most commonly accepted value for “natural rolling” measured as angle  $\alpha$ <sup>54</sup>,  $\lambda$ <sup>55</sup>, or  $\kappa$ <sup>56</sup>. The distribution of the percentage of eyes vs. rolling movements shows 3% of eyes had rolling exceeding 8 deg. The ranges for the rolling movements over the treatment are relatively mild, but with peaks of up to about 10 deg.

With our system for measuring the static cyclotorsional error, we obtained an average cyclotorsion of 1°, lower than the observations of Ciccio et al.,<sup>57</sup> who reported 4°. The distribution of the percentage of eyes vs. cyclotorsional error shows 3% of eyes had cyclotorsion exceeding 8 deg. The mean DCC values over the treatment are relatively small, but with peaks of up to about 5 deg. Considering that the average cyclotorsion resulting from the shift from the upright to the supine position is about  $\pm 4$  deg,<sup>57</sup> it is not enough to compensate only for the static cyclotorsion without considering the dynamic cyclotorsion during the laser procedure. Finally, the effects of the DCC can be considered as optical “noise” of the applied versus the intended profiles.<sup>58</sup>

Without eye registration technologies,<sup>59,60</sup> considering that maximum cyclotorsion measured from the shift from the upright to the supine position does not exceed  $\pm 14$  deg,<sup>57</sup> explains why “classical” spherocylindrical corrections in refractive surgery succeed without major cyclotorsional considerations. However, only limited amounts of astigmatism can effectively be corrected for this cyclotorsional error<sup>40</sup>. Currently available eye registration technologies, providing an accuracy of about 1 deg and measuring static and dynamic cyclotorsion components, open a new era in corneal laser refractive surgery, because patients may be treated for a wider range of refractive problems with enhanced success ratios. This requires high-resolution ablation systems as well.<sup>61,62</sup>

With our system for measuring the axial movements, we obtained an average of -300  $\mu\text{m}$ . This negative value is fairly low, but means the patients use to push their head back at the beginning of the treatment and return smoothly closer to level during treatment. The distribution of the percentage of eyes vs. axial movement shows 10% of eyes had axial movements exceeding 1 mm. The ranges for axial movements over the treatment are relatively mild, but with peaks exceeding 1 mm.

In our AMARIS experience of over 8000 treated eyes, 91% of treatments result in a postoperative cylinder within 0.5 D, and 19% of treatments gain lines of BSCVA compared to the preoperative baseline. From the minor induction of aberrations can be inferred that mesopic and low-contrast VA have maintained, at least, the best-corrected preoperative levels. More clinical data are required before we can state how much improvement can be expected from the use of this technology.

6D Eye-Tracker with AMARIS yields excellent outcomes. Refractions are reduced to subclinical values: (mean postoperative defocus  $-0.12 \pm 0.17\text{D}$  and astigmatism  $0.15 \pm 0.25\text{D}$ ) with 70% eyes within  $\pm 0.25\text{D}$  of emmetropia and 19% eyes gain lines of BSCVA. Rate of registration is >90% for Cyclotorsion and >80% for Rolling and Axial movements. Mean

Rolling was within  $\pm 5^\circ$  in 52% of the cases, Dynamic Rolling was within  $\pm 5^\circ$  in 66% of the cases, Static Cyclotorsion was within  $\pm 4^\circ$  in 69% of the cases, Dynamic Cyclotorsion was within  $\pm 2^\circ$  in 72% of the cases, and Z-movement was within  $\pm 0.5\text{mm}$  in 69% of the cases.

6D Eye-Tracker Controls with the SCHWIND AMARIS are safe and very predictable. In summary, using SCHWIND AMARIS, six-dimensional movements of the eye can be effectively measured and compensated for both static and dynamic conditions during laser corneal ablation.

## 9. High speed refractive surgery

The range of repetition rates of the laser systems for refractive surgery currently available in the market runs from about 10 Hz to about 1000 Hz (median 250 Hz), with spot size diameters ranging from 6.5 mm to about 0.3 mm (median 1 mm), corresponding to treatment velocities from about 9 s/D to about 1.7 s/D (mean 5 s/D). If we compare these values to the situation at the beginning of the 21<sup>st</sup> century, a technological quantum leap is observed. In 2001, repetition rates of the laser systems for refractive surgery in the market ranged from about 10 Hz to about 300 Hz (median 50 Hz), with spot size diameters ranging from 6.5 mm to about 0.8 mm (median 2-6 mm), corresponding to treatment velocities from about 19 s/D to about 6 s/D (mean 12 s/D).

To foresee the future trends for these essential values when defining the technological capabilities of a system, four driving forces shall be considered:

- The technological progress of the last 10 years indicating an exponential improvement of the technology
- The non-linear cost-to-benefit ratio for new developments indicating a continued improvement of the technology at a slower rate
- The actual clinical needs for faster or more precise systems indicating a slow-down improvement of the technology achieving maturity and stability
- The limitations imposed by the biological tissue response to the laser interaction (e.g. thermal issues, haze development<sup>63</sup>)

Considering these effects, we can hypothesize a scenario with repetition rates of the laser systems for refractive surgery ranging from about 300 Hz to about 1500 Hz, with spot size diameters ranging from 1.5 mm to about 0.2 mm, corresponding to treatment velocities from about 4 s/D to about 1.3 s/D.

However, due to the presence of local frequency controls, the duration of the treatments is no longer inversely proportional to the repetition rate. The duration of the treatments is inversely proportional to the repetition rate only for slow repetition rates (<180 Hz), and stabilizes asymptotically for high repetition rates (>1500 Hz).

## 10. Bilateral symmetry

Human vision is a binocular process. Having two eyes gives binocular summation in which the ability to detect faint objects is enhanced. It can give stereopsis in which parallax provided by the two eyes' different positions on the head give precise depth perception. Such binocular vision is usually accompanied by binocular fusion, in which a single image is seen despite each eye is having its own image of any object.

Literature suggests that marked anisometropia is uncommon, either in the magnitude of sphere or astigmatism, with few notable exceptions concluding that the axis of astigmatism does not follow any particular rule (mirror or direct symmetry) across right and left eyes.

Porter et al.<sup>64</sup> confirmed in a large population that although the pattern of aberrations varies from subject to subject, aberrations, including irregular ones, are correlated in left and right eyes of the same subject, indicating that they are not random defects. The Indiana Aberration Study by Thibos et al. characterized the aberration structure, and the effects of these aberrations on vision, for a reasonably large population of normal, healthy eyes in young adults, and verified the hypothesis of bilateral symmetry.

Wang et al.<sup>65</sup> found that anterior corneal wave aberrations varied greatly among subjects, but a moderate to high degree of mirror symmetry existed between right and left eyes. To our knowledge, very few studies in the literature have addressed the issue of symmetry of aberrations between eyes after corneal laser refractive surgery<sup>66,67</sup>. Jiménez et al.<sup>66</sup> found that binocular function deteriorates more than monocular function after LASIK, and that this deterioration increases as the interocular differences in aberrations and corneal shape increase. They found that interocular differences above 0.4  $\mu\text{m}$  RMS for 5-mm analysis diameter, lead to a decrease of more than 20% in binocular summation.

If binocular symmetry is manifested on virgin human eyes and it is important for binocular vision, it shall be interesting to assess whether existing symmetry is maintained after treating the cornea for correcting the ametropias using corneal laser refractive surgery. Further analysis of bilateral symmetry according to analysis diameter is also of interest. The analysis of bilateral symmetry should be related to binocular vision status of patients.

Cuesta et al.<sup>68</sup> found that even differences in corneal asphericity might affect the binocular visual function by diminishing the binocular contrast-sensitivity function. Arbelaez et al.<sup>67</sup> found that only four of 25 patients showed preoperatively clinically relevant differences OS vs. OD larger than 0.25 D, whereas 6-month postoperatively only 2 of 25 patients showed clinically relevant differences OS vs. OD larger than 0.25 D. 6-month postoperatively three Zernike terms lost significant correlation symmetry OS vs. OD and 4 Zernike terms gained significant correlation symmetry. However, two of them showed borderline correlations. 6-month postoperatively 6 Zernike terms significantly increased differences in symmetry OS vs. OD and 4 Zernike terms significantly decreased differences in symmetry. However, six of them showed borderline significances of the difference. 6-month postoperatively three patients lost significant correlation symmetry OS vs. OD and one patient gained significant correlation symmetry. However, two of them showed borderline significances of the difference. All these borderline situations actually shall be seen as "almost preserved" bilateral symmetry.

The presented results cannot be extrapolated to patients with symptoms of amblyopia<sup>69</sup>, anisometropia, nystagmus, or aniseikonia<sup>70</sup> without further studies. Bilateral symmetry in corneal aberrations does not mean any "good or bad" point for binocular vision. We cannot evaluate exactly the role of aberrations monocularly (patients with high level of aberrations can have an excellent visual acuity and vice-versa); therefore it is more difficult binocularly.

The important question in binocular vision is “the role of interocular-differences,” and if they can influence significantly binocular performance. Interocular-differences can be minor but significant for visual performance. Further studies shall help to determine the impact of this on binocular visual performance.

The more irregular a cornea is, the more important proper bilateral symmetry for adequate binocular summation. Astigmatism is the most common aberration with a vector nature, so usually are the astigmatic problems the ones more affected or the ones which benefit the most from losing or preserving bilateral symmetry.

## 11. Correction of high astigmatism

Because the corneal ablations for refractive surgery treatments induce aberrations (one of the most significant side-effects in myopic LASIK is the induction of spherical aberration<sup>71</sup>, which causes halos and reduced contrast sensitivity<sup>72</sup>), special ablation patterns were designed to preserve the preoperative level of high order aberrations<sup>73,74,75</sup>. For the correction of astigmatism many different approaches have been tested, with different degrees of success, through the years<sup>76,77,78,79,80,81</sup>.

LASIK has been successfully used for low to moderate myopic astigmatism, whether LASIK is acceptably efficacious, predictable, and safe in correcting higher myopic astigmatism is less documented, specially with regard to the effects of astigmatic corrections in HOA's<sup>82</sup>.

The advantage of the Aberration-Free™ ablation profile is that aims being neutral for HOA, leaving the visual print of the patient as it was preoperatively with the best spectacle correction. The correction of astigmatism has been approached using several techniques and ablation profiles. There are several reports showing good results for compound myopic astigmatism using photorefractive keratectomy (PRK) and LASIK, but ablation profiles usually cause a hyperopic shift because of a coupling effect in the flattest corneal meridian. A likely mechanism of this coupling effect is probably due to epithelial remodeling and other effects such as smoothing by the LASIK flap<sup>83</sup>. In cases of large amounts of preoperative astigmatism, deviations from the target refractive outcome are usually attribute to “coupling factors”. But, the investigation of the coupling factor remains a rather difficult task, because it seems to be dependent on various factors. Individual Excimer laser systems may have different coupling factors, cutting the flap could alter the initial prescription and also different preoperative corneal curvature (K-reading) may have an influence on the coupling factor.

The most dominant correlations of induced HOAb occur for C[4,0], and C[6,0] versus defocus correction, for C[4,+2] versus cardinal astigmatism correction, and C[4,-2] versus oblique astigmatism correction. We evaluated the postoperative clinical outcomes and high order aberrations among eyes with astigmatism higher than 2 D that have underwent refractive surgery using the SCHWIND AMARIS laser system. SCHWIND CAM Aberration-Free Aspheric astigmatic treatments have been performed in all cases.

At six-month follow-up, 50 eyes with preoperative astigmatism higher than 2 D were retrospectively analysed. Ablations performed using the SCHWIND AMARIS flying-spot excimer laser system. LASIK flaps were created using Ziemer LDV Femtosecond laser system in all cases.

Inclusion criteria comprised:

- preoperative astigmatism higher than 2 D targeted for emmetropia
- BSCVA  $\geq$  20/25 (logMAR  $\leq$  +0.1)
- $<0.75 \mu\text{m}$  RMS-HO for 6-mm diameter
- successful completion of 6-month follow-up

We performed following analyses:

- UCVA
- BSCVA
- manifest subjective refraction (SR)
- corneal wavefront up to 7th order at 6-mm diameter without cycloplegia

50 eyes (100%) completed the 6M follow-up, with an average age at the time of the surgery of 28 years (from 17 to 46). 28 eyes were female, and 22 eyes male. 25 patients treated bilaterally. Mean preoperative defocus averaged  $-3.08 \text{ D} \pm 2.32 \text{ D}$  (from  $-7.13$  to  $-1.00$ ), with mean astigmatism  $3.54 \text{ D} \pm 0.85 \text{ D}$  (from 2.00 to 4.75). Mean postoperative defocus averaged  $-0.06 \text{ D} \pm 0.25 \text{ D}$  (from  $-0.75$  to  $+0.75$ ), with mean astigmatism  $0.25 \text{ D} \pm 0.26 \text{ D}$  (from 0.00 to 1.25). 92% of the eyes ended up in UCVA 20/20 or better. 38% of the eyes gained at least one line of BSCVA ( $p < .01^*$ ).  $>75\%$  of the eyes within 0.50 D of astigmatism and U-vector, and  $>90\%$  of the eyes within 1.00 D of astigmatism and U-vector.

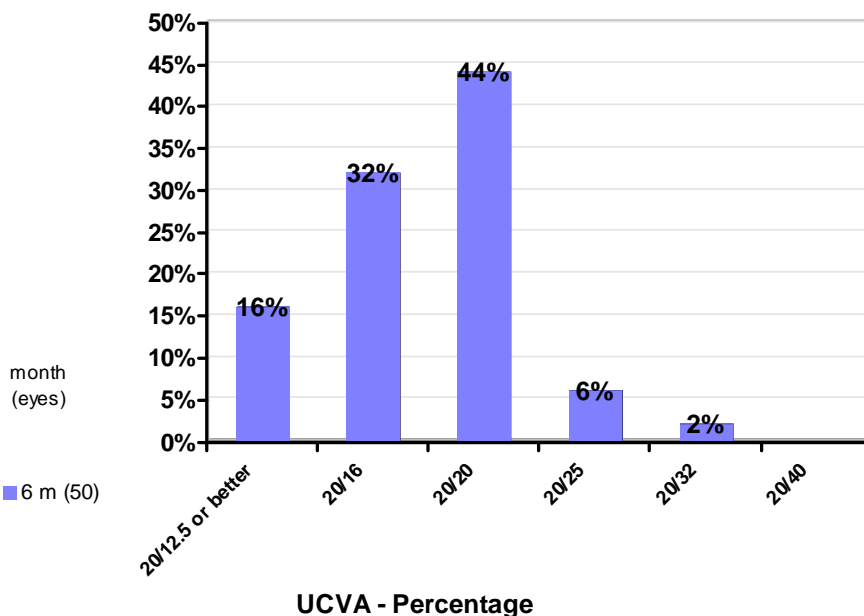


Fig. 10. Efficacy of the correction of moderate to high astigmatism in an aspheric astigmatic setting.



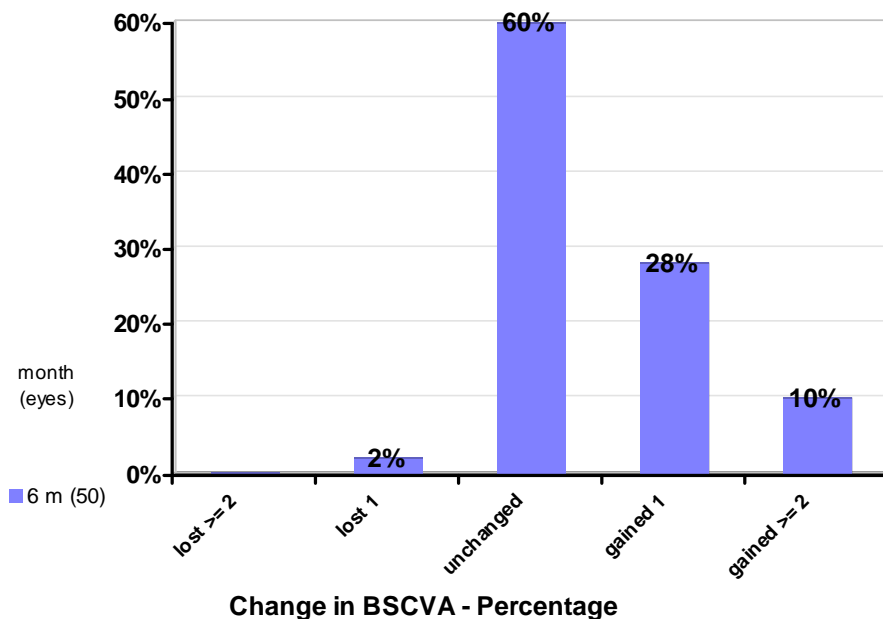


Fig. 11. Safety of the correction of moderate to high astigmatism in an aspheric astigmatic setting.

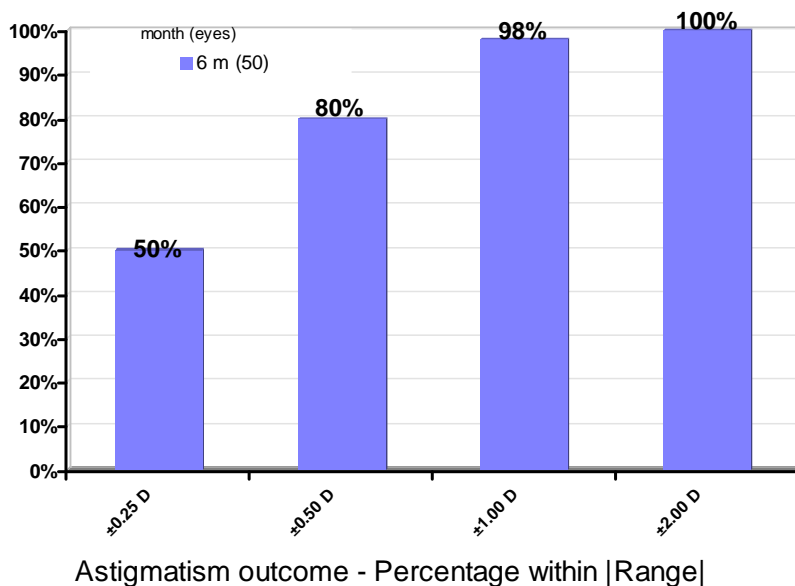


Fig. 12. Refractive astigmatic outcome of the correction of moderate to high astigmatism in an aspheric astigmatic setting.

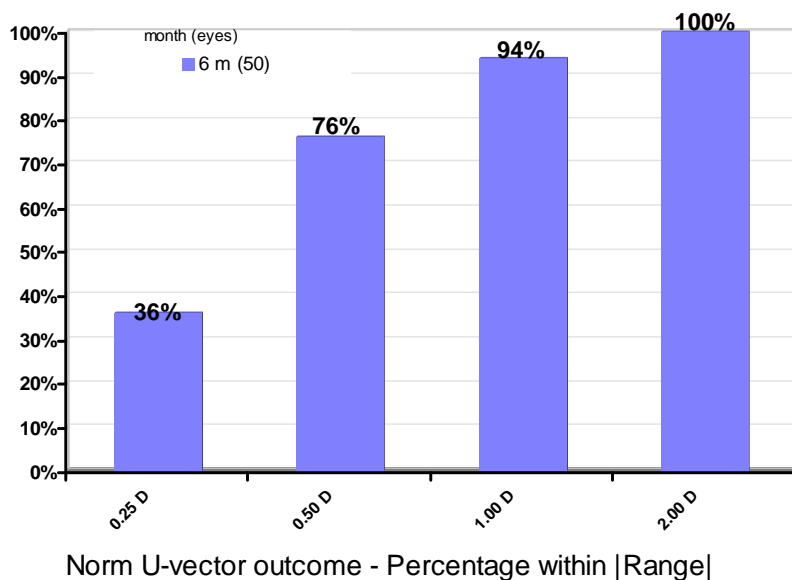


Fig. 13. Residual blur of the correction of moderate to high astigmatism in an aspheric astigmatic setting.

A very slight undercorrection in astigmatism was observed (both cardinal and oblique).

Only 5 HO Zernike terms (out of 30) changed significantly after treatment, whereas 25 HO Zernike terms (out of 30) did not change after treatment.

Zernike term at 6-mm Ø	Preoperative (µm)	Postoperative (µm)	p-value
C[3,-3]	-0.14	-0.02	<.0001
C[4,+2]	-0.08	-0.10	<.05
C[4,+4]	+0.03	+0.01	<.05
C[5,-3]	+0.01	-0.01	<.0001
C[6,0]	0.00	+0.03	<.0001
<b>HO-RMS</b>	<b>+0.47</b>	<b>+0.57</b>	<b>&lt;.0005</b>

Table 2. Statistically induced Zernike terms.

For all of them, the variation was well below the clinical relevance.

50 high-astigmatism treatments were analysed at 6M follow-up. Results were achieved without applying additional nomograms (residual sphere about 0 D, residual cyl about -0.25 D) (>75% within 0.50 D, >90% within 1.0 D). 6-months follow-up time shows the excellent performance of the system (48% eyes 20/16 or better UCVA, 98% eyes 20/25 or better

UCVA). Aberration-Free astigmatic treatments with SCHWIND AMARIS are safe and very predictable (no eye lost >1 line BSCVA, 5 eyes gained >=2 lines BSCVA).

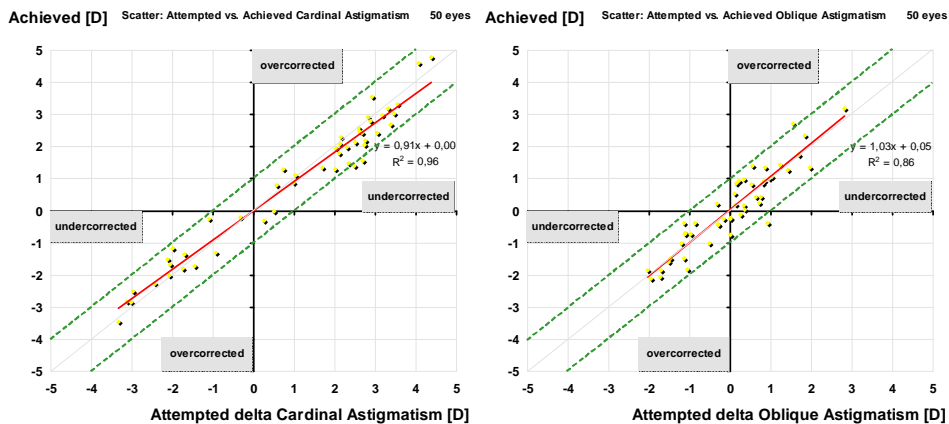
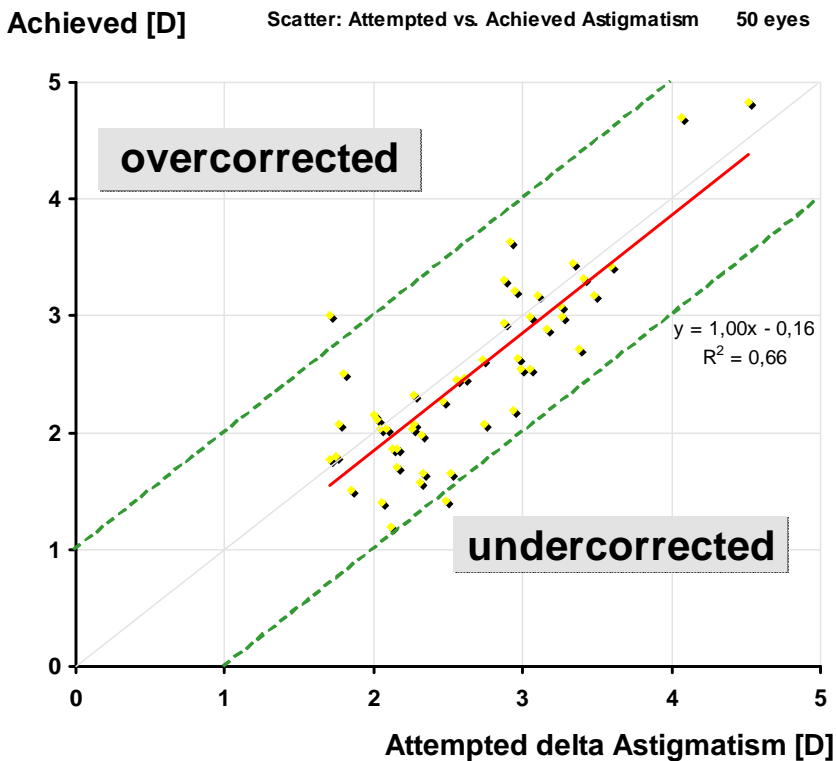


Fig. 14. Scattergram of the correction of moderate to high astigmatism in an aspheric setting.

From VA, 92% eyes UCVA 20/20 or better and 38% eyes improved their pre-op BSCVA, due to the minimum aberrations induction by the AMARIS-CAM profile. Despite large defocus and astigmatism magnitudes, minor significant induction of some aberration terms, well below clinically relevant magnitudes. The most dominant correlations of induced HOAB occurred for: C[4,0] vs. Defocus correction, C[4,+2] vs. Cardinal Astigmatism correction, and C[4,-2] vs. Oblique Astigmatism correction.

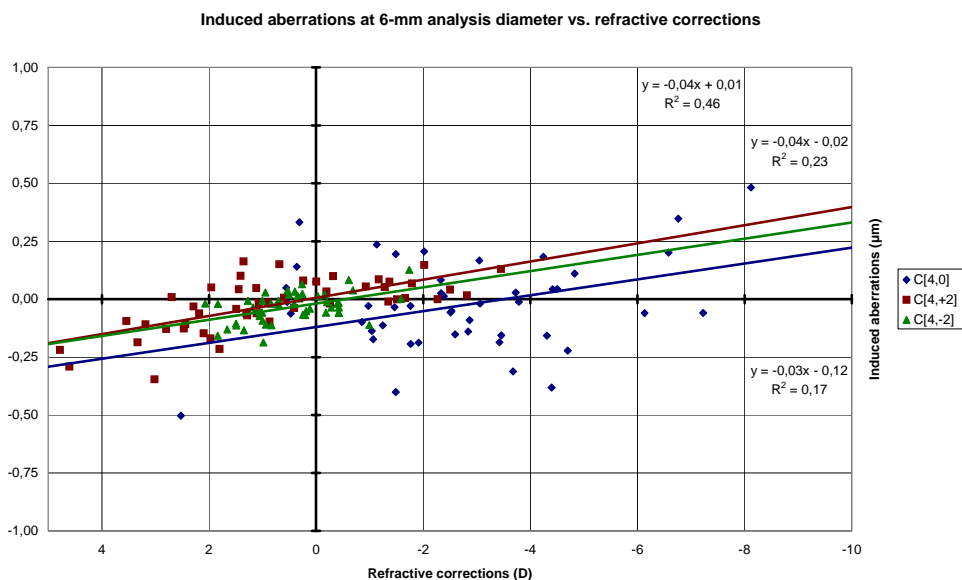


Fig. 15. Induction of aberrations after the correction of moderate to high astigmatism in an aspheric astigmatic setting.

All ablations were non-wavefront-guided treatments. Despite low aberrations, some astigmatisms were not regular. Treatments were centred at the corneal vertex. Despite myopic corrections, 40% of the treatments needed an offset >150 µm.

Laser settings were planned with the manifest astigmatism (magnitude and axis). Topographic astigmatism was not considered for the calculations. No nomogram compensations were applied. With a slight nomogram, further refinements could have been achieved.

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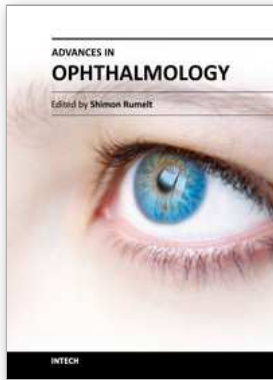
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## **Advances in Ophthalmology**

Edited by Dr Shimon Rumelt

ISBN 978-953-51-0248-9

Hard cover, 568 pages

**Publisher** InTech

**Published online** 07, March, 2012

**Published in print edition** March, 2012

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In order to correctly reference this scholarly work, feel free to copy and paste the following:

Maria C. Arbelaez and Samuel Arba-Mosquera (2012). Treatment Strategies and Clinical Outcomes of Aspheric Surgery for Astigmatism Using the SCHWIND Amaris Platform, *Advances in Ophthalmology*, Dr Shimon Rumelt (Ed.), ISBN: 978-953-51-0248-9, InTech, Available from:

<http://www.intechopen.com/books/advances-in-ophthalmology/clinical-outcomes-of-aspheric-refractive-surgery-for-astigmatism>

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