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Zyoptix: the Bausch & Lomb wavefront platform

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With supervision a virtual reality, the desire to deliver is only underscored by the need to understand the potentials of the human eye, yet unexplored. Based on the Nyquist theorem, the maximum spatial frequency that can be detected is equal to half of the sampling frequency of the detecting device (Fig. 1). In the human eye, this sampling frequency means the photoreceptor spacing on the fovea. Given the foveal cone spacing of about 120 samples per degree, the maximum detectable spatial frequency, and the ultimate visual acuity, equals 60 samples per degree. This translates into a maximum visual acuity of about 20/10 in the absence of diffraction, chromatic, and wavefront aberrations.

The basis of this estimation is an average value of the human foveal cone spacing; therefore, the resulting maximum visual acuity of about 20/10 is an average value as well, meaning that some patients will be able to achieve slightly better than 20/10 acuity, whereas others may fall slightly short of this goal. In reality, the gains in visual performance provided by correcting the monochromatic higher-order wavefront aberrations of the eye will most readily be appreciated as increases in retinal image contrast, and hence contrast sensitivity, rather than purely resolution enhancement as measured by Snellen acuity. As such, correction of the wavefront aberrations of the human eye is a worthwhile endeavor, because improvements in contrast sensitivity of up to two to three times have been predicted in limited laboratory measurements.

The Zyoptix system

The Bausch & Lomb Zyoptix (Rochester, New York) system includes the Zyoptix Diagnostic Workstation (combining the slit-scanning technology of the Orbscan system for true elevation measurement with the Zywave wavefront detector based on the Hartmann-Shack principle), the Hansatome microkeratome, and the Technolas 217Z excimer laser.

Data in the Zyoptix system are measured at the newly integrated Dual Head Workstation composed of the Zywave aberrometer and the Orbscan. These data are then assimilated into a customized ablation using Zylink software and stored as a treatment file on a disk that is kept with the patient's records. The treatment data are then uploaded into the Technolas 217Z laser, and Zyoptix laser in situ keratomileusis (LASIK) surgery is performed.

Zywave aberrometer

There are two common ways of measuring wavefront aberrations. The first method is to measure the actual aberration of the wavefront itself from an ideal reference wavefront. This method is typically performed using interferometric techniques when measuring optical surfaces or lens elements, or in high-energy laser technologies.

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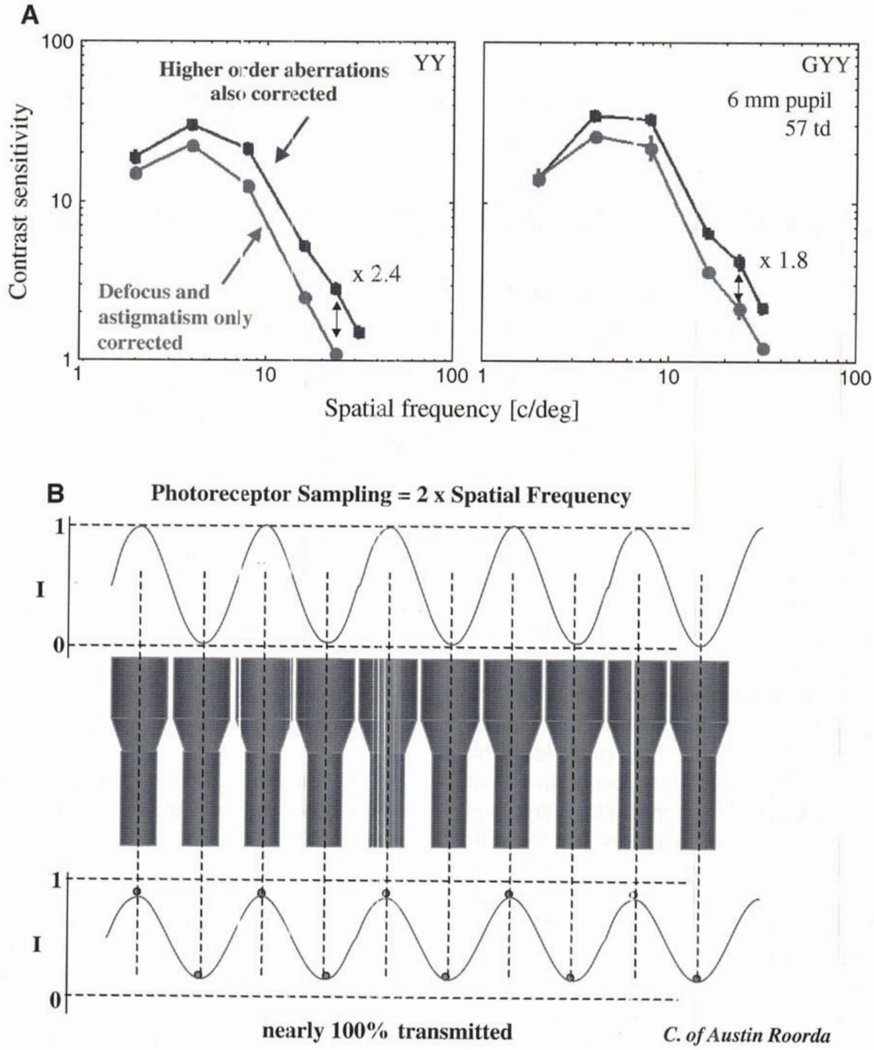

Fig. 1. (*A*) Spatial frequency and contrast sensitivity relation. (*B*) Nyquist's theorem elicited by showing that the maximum spatial frequency is detected at half the sampling frequency.

The second method involves reconstruction of the wavefront by measuring the localized slope at many positions across the wavefront. The most common technique used for ophthalmic applications to reconstruct the wavefront is borrowed from the world of astronomy and is called the Shack-Hartmann technique after its inventors. This method uses an array of microlenses to capture information about the local slope of the wavefront exiting the eye at dozens of locations across the pupil. An extremely small-diameter infrared laser beam is focused onto the retina. The small size of the beam ensures that the aberrations of the eye do not affect the light coming into the eye. The small spot on the retina acts as a point source emitting light rays out of the eye. These rays are affected by each of the optical elements in the ocular system and contain the entire aberrations of the eye. The lenslet array is conjugate to the pupil plane of the eye in these systems; each lenslet defines the same area in the pupil that it does in the array. A lenslet array with a resolution of 720 μm per lenslet would gather information about the wavefront exiting the eye every 720 μm across the pupil in the vertical and horizontal directions. The system is calibrated with a plano perfect wavefront, providing the focus positions on a CCD camera placed in the focal plane of the lenslet array. When a real eye is measured, any deviation in the horizontal or vertical meridians of each lenslet's measured focal point from the theoretical position can be attributed to the tilt of the light entering the system relative to the optical axis of that lens. By measuring this displacement of the focal point, the tilt of the wavefront for that bundle of rays can be calculated. Combining the information from all of the single lenslets (whose typical dimension is less than 1 mm) of the entire array allows the full wavefront to be reconstructed across the pupil of the optical system.

Fig. 2 shows the Hartmann-Shack image from a human eye. The grid represents the optimal positions of the focal points of the laser beam, whereas the white points are the actual images from each of the lenslets. Based on the deviation of the actual images from their optimal positions, the software algorithm calculates the shape of the wavefront. The Zywave aberrometer in the Zyoptix system uses the Hartman-Shack method of analysis of the outgoing wavefront that measures up to fifth-order Zernike aberrations, including coma, trefoil, and spherical aberrations.

Use of the Zyoptix system involves multiple steps and calculations. The new Zywave software (version 4.4 of the Zyoptix Evolution Package) for Zyoptix produces a composite aberration map from the best three of five aberration maps. The two outlier maps are discarded. To obtain the wavefront map with the Zywave system, the pupil must first be dilated to at least 6.0 mm. Studies performed at Bausch & Lomb Surgical (Rochester, New York) have found that using a small amount of cycloplegic agent does not adversely affect the wavefront map.

The Orbscan presents an ideal method of obtaining corneal thickness in this setting, because the measurements are obtained optically without any corneal touch, which could otherwise affect the wavefront analysis. The wavefront map is produced and presented in a manner similar to topography maps. This presentation includes a wavefront map on the top left side of the screen, which demonstrates all of the wavefront errors including the second-level Zernike errors of sphere and cylinder. The red color indicates higher-level aberrations, whereas the blue color indicates lower-level aberrations.

The wavefront map on the right side of the screen shows the higher-order root mean square (HORMS) aberrations, which include third-, fourth-, and fifth-order aberrations. This map does not include the spherical and astigmatic components of the wavefront error. The bottom right portion of the screen demonstrates the point-spread function (PSF), or the effect of the aberrations of the visual system on a point source of light. The PSF is helpful as a demonstration tool for patients to illustrate the effect of aberrations on their vision and the potential benefits of custom LASIK surgery. On the Zywave system, the PSF has

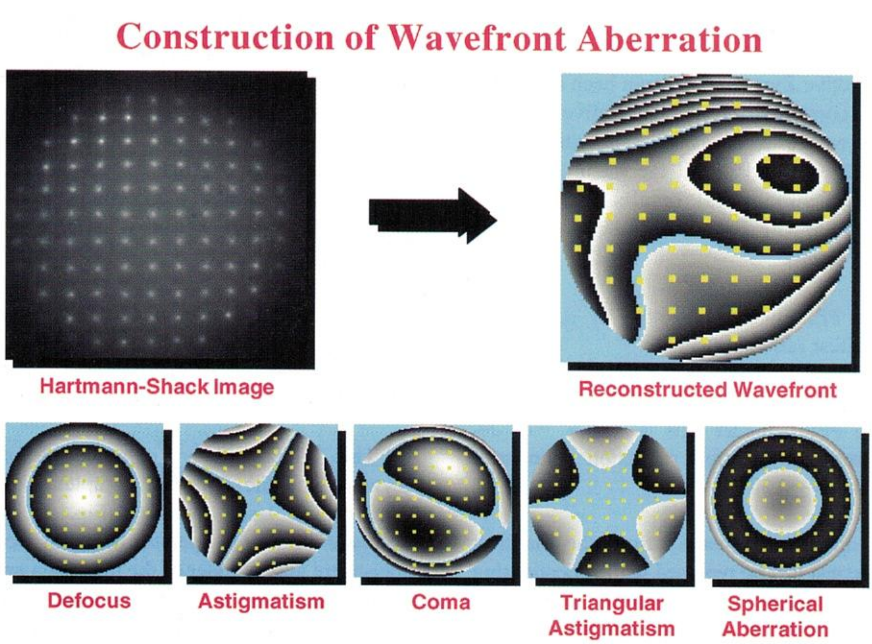

Fig. 2. The Hartmann-Shack image and its derivative wavefront forms.

a standardized scale so it can be used by experienced operators as a qualitative method of evaluating the wavefront error. The PSF at a pupil size of 3 mm is optimized, because the effect of diffraction is balanced by the effect of the wavefront aberration, emphasizing the importance of pupil size in the final analysis. The Optical Society of America has proposed that all wavefront aberrations be reported over 6-mm pupil sizes.

The bottom left side of the screen contains some of the key data points of the wavefront analysis. The total aberrations are recorded as root mean square (RMS). The RMS unit is used to get a sum of the HORMS by adding all of the positive and negative Zernike aberrations to avoid the canceling effect of the negative HORMS on the positive ones. The HORMS are recorded below the RMS value. The RMS is the most important value on the aberration screen, because it represents the sum of the HORMS that the Zyoptix LASIK aims to correct. A preoperative HORMS value of 0.25 to 0.4 μm has been suggested as an indication for Zyoptix LASIK surgery.

The Zywave aberrometer also calculates the PPR, which allows a comparison of the manifest refraction with the refraction generated by the Zywave aberrometer. The PPR is the mean of the sphere and cylinder measurements over a specific pupil size. The PPR values vary according to the pupil size, with the degree of myopia increasing as the pupil dilates. The PPR values are presented with the pupil sizes in one of the Zywave presentation screens. Once the objective Zywave data have been collected, they must be compared with the subjective manifest refraction to ensure consistency. Large differences between the Zywave PPR and the manifest refraction will give suboptimal results for Zyoptix LASIK. The following criteria have been suggested by Bausch & Lomb:

- Zywave PPR sphere is within $\pm$ 0.75 D of the manifest refraction sphere.
- Zywave PPR cylinder is within $\pm$ 0.50 D of the manifest refraction cylinder.
- Zywave PPR cylinder axis is within $\pm$15 degrees from the manifest refraction cylinder if the cylinder $\geq$0.50 D.

If the PPR differs significantly from the manifest refraction, the test can be repeated while encouraging the patient to relax his or her eyes and look in the direction of the distance target during the testing. If repeated tests yield different results, Zyoptix treatment should not be performed.

The Zywave is first measured on the undilated pupil. If the patient accepts the Zywave refraction in the Phoropter, dilated Zywave examinations are performed, and the acceptance of the measurement is checked. If the patient does not accept the Zywave refraction, Zyoptix LASIK is not performed.

Orbscan

The Orbscan is a multidirectional slit-scanning system that collects 9000 data points in 1.5 seconds. The New Orbscan IIz has an upgraded microprocessor that speeds up the calculation time. The Zyoptix mode of the Orbscan IIz must be selected for a minimum level of repeatability and irregularity to be met for the acquisition. A single examination result or an average of multiple examinations can be used. The Orbscan must be performed with an undilated pupil; therefore, it is usually performed before the dilated Zywave map.

The Orbscan Quad map of the cornea provides three-dimensional information about the cornea. The anterior float map demonstrates the anterior elevation of the cornea. The posterior float map demonstrates the posterior elevation of the cornea and becomes important in diagnosing patients with preoperative posterior keratoconus or post-LASIK corneal ectasia, who are not qualified as candidates for LASIK. Generally, greater than 50 μm of deviation from the normal posterior elevation of the cornea is indicated by a red color on the map and should be considered a contraindication for surgery. The refractive map is similar to the keratometric map created with most topography units. The pachymetry map demonstrates the corneal thickness through the entire cornea as well as the thinnest point of the cornea. This data map offers advantages over central corneal ultrasound, because the central portion of the cornea may not be the thinnest point. By reviewing the four color maps together, the clinician can create a mental three-dimensional reconstruction of the cornea.

Zylink software

The Zylink software combines the data of the Zywave and the Orbscan, completing the Zyoptix platform for laser treatment (Fig. 3.). The Zylink software allows the operator to adjust the amount of the sphere and cylinder of the refraction and to set the optical zones of the ablation program. The ablation zone is usually at least the size of the pupil diameter in dim light as measured by Colvard pupillometry. The most commonly desired optical zone is 6.5 mm.

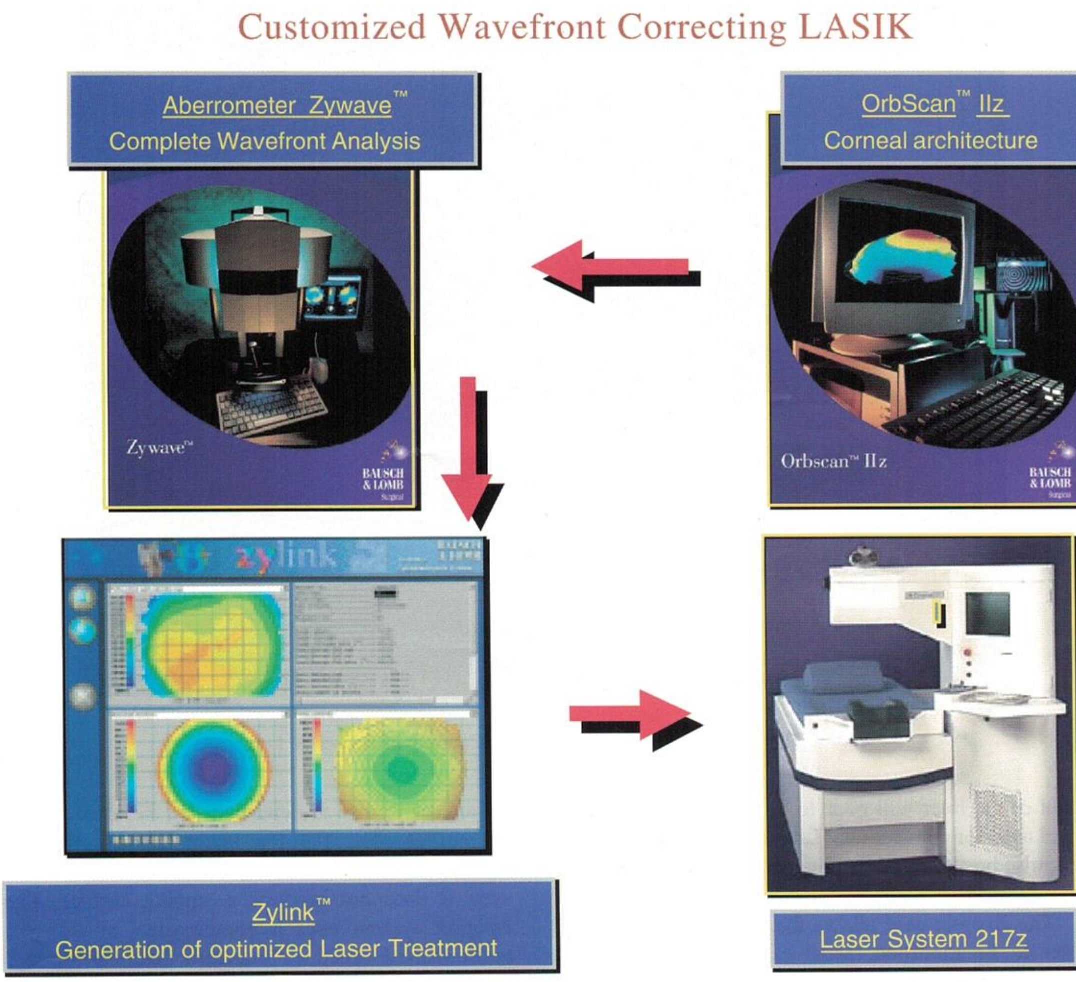

Fig. 3. The tetrad of the Orbscan, Zywave, Zylink, and T217Z forming the interactive Zyoptix platform. (Courtesy of Baush & Lomb.)

Bausch & Lomb suggests an optical zone of at least 0.2 to 0.5 mm more than the scotopic pupil size. The principles of lamellar refractive surgery apply wherein the residual stromal bed should maintain a thickness of at least 250 μm.

In standard LASIK surgery, ablation times range from 30 to 40 seconds for a −6.0 D correction with a 6.0-mm optical zone. With the Zyoptix system, which performs four steps at a 2-mm spot size and then goes into a 1-mm spot size for another four to eight steps, this prescription and zone would take about a minute and a half. If an even larger optical zone is used, such as 7.0 mm, the ablation times increases substantially. The Zylink software produces a custom ablation profile window that includes the pachymetry map, the anterior keratometric map, and the customized ablation map, along with the treatment data.

Technolas 217Z laser

The custom treatment file is saved onto a 3.5-in floppy disk, which is fed into the drive of the Technolas 217Z laser. The Zyoptix option is selected from the treatment menu and the special card inserted (Fig. 4). A centration check is performed to ensure that the 1-mm and the 2-mm spots are centered. If the spots are not aligned, the device indicates incorrect card alignment in the laser, and a new card should be used. A fluence test is then performed. Because the laser beam is now passed through the card, the energy

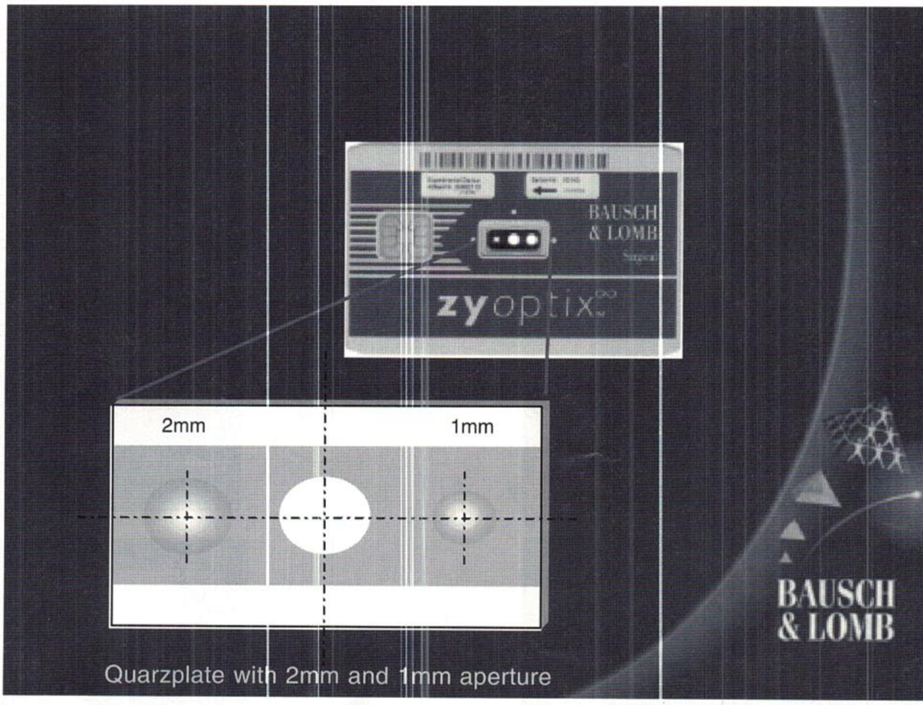

Fig. 4. The special Zyoptix treatment card. (Courtesy of Bausch & Lomb.)

level of the laser will need to be increased from the level used for conventional LASIK surgery. Once the 65-pulse breakthrough is obtained, the procedure can be performed.

The Zyoptix card allows the beam profile of the laser to be modified. Most excimer lasers use a Gaussian beam profile, which provides a smooth ablation surface; however, the effective beam diameter for each pulse is dependant on the hydration of the cornea. The flat top beam has a consistent diameter with different degrees of hydration; however, it does not produce a smooth surface. The Zyoptix system uses a combination of the two beam shapes, called a "truncated Gaussian beam," to achieve the benefits of both beam types (Fig. 5). The 2-mm beam allows most of the refractive error

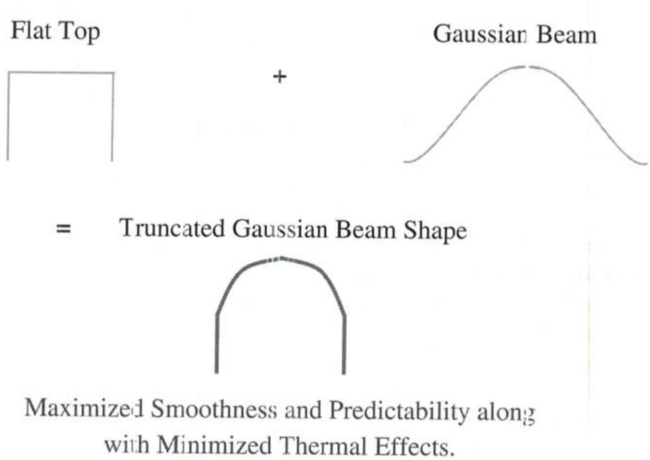

Fig. 5. The truncated Gaussian beam combines the advantages of the flat top and Gaussian beams.

to be corrected in an efficient manner. The 1-mm beam is then used for the more specific ablation patterns and transition zones.

The Technolas 217Z laser has a video-based infrared eyetracker with a frequency of tracking from 60 to 120 Hz. This eyetracker is advantageous, because it does not require pupillary dilation for tracking, which helps pupillary centration and offers greater patient convenience. The eyetracker marks the tracked center of the pupil, which allows adjustment during the procedure. Similarly, the z-axis (height) is also marked on the cornea and can be monitored during the procedure. Instruments can be used during the tracking mode without damaging or disengaging the tracker, which can occur with other systems.

The dynamic eye-tracking module has been added to the 217Z laser. This module recognizes whether the eye movements are too fast for the tracker, and interrupts the laser pulse sequence. The frequency of the tracker is 120 Hz, resulting in an 8.3-ms interval between each capture. The dynamic eye-tracking software will allow 200 μm of movement over the 8.3 ms, which equals 24 μm/ms. Because an ocular saccade occurs at about 25 μm/ms, all fast eye movements are detected. If more than 200 μm of movement occurs, the next laser pulse is interrupted. By applying this technology, the degree of error in the eye tracker is reduced. Using a scanning and flying spot technology, the Technolas 217Z (Table 1) allows surgeons to treat up to −12.00 D of nearsightedness, up to +6.00 D of farsightedness, and up to 5.00 D of astigmatism.

Having been fortunate to use most of the excimer laser systems, the author (ACG) agrees with Slade [1] that the T 217Z platform is ergonomically friendly for the LASIK surgeon. The system has a perfect working distance and offers superior magnification along with an excellent depth of field. The bed is also stable and well designed. There is no distortion of the z-axis, and, above all, the Zyoptix system is a truly excellent workstation.

Table 1
Technolas 217Z specifications

Parameter	Value
Homogenization	Optical integrator
Pulse rate	50 Hz
Beam shaping	Quartz for 2 mm +1 mm truncated Gaussian
Beam size	2 mm = 1 mm truncated Gaussian
Zyoptix	Combine wavefront and multi-3D mapping
Energy/pulse	200–400 mJ
Energy/pulse at laser head output	3.7 mJ
Acoustic shock	Moderate
Ablation zone	15 mm × 15 mm
Transition zone	2.6–7.2 mm
Fluence	120 mJ/cm^2
Adjustable transition zone	Optimized
Tracking system	Active and passive
Eye fixation	Constant
Hyperopic and cylinder treatment	Yes
Limits to tracker	120 Hz
Card	Card-positioning robot
Gases required	3-cylinder ArF premix
Gas fill quantity	2–3 days/20 L
Cooling system	Internal H_2O cooled

Results

Conventional LASIK surgery has traditionally achieved excellent results [2] on the appropriate patients using contemporary techniques and lasers [3–5]. An improvement in the best-corrected visual acuity (BCVA) and contrast sensitivity is a more appropriate measure of the benefits of the Zyoptix system. The best way to quantify the improvements in vision after Zyoptix treatment is to measure the improvements in individual aberrations such as coma, trefoil, and spherical aberration.

In a study of 91eyes, wavefront analysis was performed on 46 standard LASIK-treated eyes and 45 Zyoptix-treated eyes at six sites in the United States, Singapore, and Australia (Bausch & Lomb, unpublished data, 2003). The investigators performed wavefront analysis before LASIK surgery and again at the 1-week, 1-month, and 3-month visits. The range of myopia in Zyoptix patients ranged from −0.58 to −7.90 D, indicating that the subjects were not a preselected group of patients who would respond best to Zyoptix.

The preoperative HORMS present in the 91 eyes demonstrated that the contribution of aberrations to the total HORMS decreased as the Zernike level increased. The analysis revealed that, in eyes with significant preoperative HORMS, the Zyoptix system successfully reduced the higher-order aberrations, particularly when the preoperative HORMS were greater than 0.4 μm. Standard LASIK surgery increased the presence of HORMS. In particular, the results indicated that the Zyoptix system substantially

Table 2
FDA phase III Zyoptix results

Outcome	Percentage
20/16 or better	70.3
20/20 or better	91.5
20/40 or better	99
Gained between 1–3 lines of BCVA	60
Improved UCVA compared with BSCVA	78
Reported improved night vision	40.3
Satisfied or very satisfied	91
Would choose refractive surgery again	98

Abbreviations: BCVA, best-corrected visual acuity; BSCVA, best spectacle-corrected visual acuity; UCVA, uncorrected visual acuity.

reduced coma (third-order aberration) and spherical aberrations (fourth-order) when compared with conventional treatment. Optic zones greater than 6.0 mm were found to be more effective in reducing HORMS.

In another study of study of 193 eyes (Bausch & Lomb, unpublished data, 2003) the distribution of HORMS was found to be in the shape of a bell curve with the median at 0.4 μm. Interestingly, the level of HORMS was not related to the degree of myopia but was related to the pupil size. These results suggest that the level of HORMS cannot be predicted without wavefront testing, and explain why patients with large pupils have greater night glare even preoperatively.

The US Food and Drug Administration (FDA) phase III Zyoptix results in 340 eyes with myopia up to 7.0 D with 6-month follow-up have recently been reported by Slade and coworkers in the Bausch & Lomb outcome report (Table 2). Most impressive was the improved BCVA in 60.4% of eyes and the finding that, in 78.3% of eyes, the postoperative uncorrected visual acuity (UCVA) at 6-month follow-up was better than the preoperative BCVA. Mesopic contrast sensitivity was worse in 4.1% of the eyes, the same in 75.9%, and better than preoperative values in 22.1%. Subjectively, 20.9% of the patients reported improved night glare, and 40.3% reported improved night driving at 6 months.

Summary

Not every patient is ideally suited for custom LASIK surgery. Wavefront aberrations often cancel each other and maintain good vision [6–8]. When such wavefronts are corrected, they can, in fact, expose an aberration that affects the visual result and quality. Surgeons should remember this point so that the excitement of FDA approvals and industry hype does not result in overzealous propulsion of this technology.

Standard conventional LASIK surgery can achieve good vision in most cases, and there is also a subset of the population that will surely need custom LASIK surgery [9]. It is essential to determine which patients will benefit from custom LASIK. The following criteria for Zyoptix treatment have been suggested:

Significant preoperative higher-order RMS aberrations should be present. The studies by Bausch & Lomb suggest that this value is approximately 0.4 μm HORMS. Some surgeons use a lower value of 0.3 μm HORMS, which will result in many more candidates.

Scotopic pupil size should be at least 5.5 mm. Bausch & Lomb studies suggest that smaller pupil sizes benefit less from Zyoptix treatment.

The tissue-sparing aspects of the Zyoptix software are helpful for the treatment of higher myopia when tissue preservation is important. This usually occurs with myopia greater than 5.0 D or astigmatism greater than 2.0 D.

The PPR Zywave refraction does not differ significantly from the manifest subjective refraction.

The PPR Zywave refraction is tolerated well by the patient.

The quest for supervision has increased patient expectations and outcome medians. In the author's (ACG) practice, which has a large referral base of complex cases and patients with complications from previous refractive surgeries, the use of wavefront technology has allowed additional finesse in the surgical approach and diagnostic abilities, raising the bar. Presbyopia is another frontier that deserves the application of a customized approach to corneal sculpting [10].

Unresolved questions remain regarding the role of time and age in the ongoing optical changes in the eye, the role of corneal epithelium and its impact in wavefront modulation, the best refractive surgery to address wavefront aberrations, and, of course, the potential capability of supervision in all patients. Based on the authors' experience with four different types of phakic implants in the complete spectrum of refractive surgical procedures, it is hoped that this technology can be applied to all aspects of eye care as we have, indeed, reached a higher dimension of intervention and expectations.

References

[1] Slade S. Point/counterpoint on customized ablation. Cataract and Refractive Surgery Today 2003;Feb: 53–5.
[2] Gulani AC. Wavefront technology: simplified & applied. San Francisco, CA: ASCRS Instruction Course; May 2003.
[3] Nuijts RM, Nabar VA, Hament WJ, Eggink FA. Wavefront-guided versus standard laser in situ keratomileusis to correct low to moderate myopia. J Cataract Refract Surg 2002;28(11):1907–13.
[4] Vongthongsri A, Phusitphoykai N, Naripthapan P. Comparison of wavefront-guided customized ablation vs. conventional ablation in laser in situ keratomileusis. J Refract Surg 2002;18(3 Suppl):S332–5.
[5] US Food and Drug Administration, Center for Devices and Radiological Health. LASIK eye surgery: FDA-approved lasers for LASIK. Available at: http://www.fda.gov/cdrh/LASIK/lasers.htm.
[6] Gulani AC. Wavefront guided-assisted LASIK surgery. Ocular Surgery News 2003;21(7):1,6–12.
[7] Gulani AC. Wavefront aberrometry helps in figuring out best treatment options. Eyeworld 2003;8(2):16–7.
[8] Gulani AC. Wavefront technology becomes important preop, postop tool. Ophthalmology Times 2003;28(7): 14–5.
[9] Knorz MC. Wavefront guided ablations: the Zyoptix system. In: Buratto L, Brint S, editors. Custom LASIK: surgical techniques and complications. Thorofare (NJ): Slack; 2002. p. 24–30.
[10] Gulani AC, Probst L. Cons of presbyopic LASIK. In: Probst L, editor. LASIK: advances, controversies & custom. Thorofare (NJ): Slack Incorporated; 2004. p. 367–9.