

Non-surgical wavefront correction

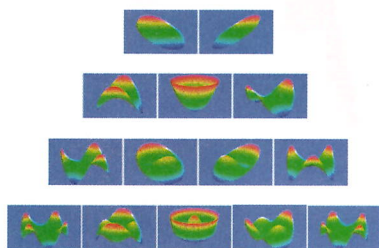
An exciting advancement

Why do stars in the night sky appear to twinkle? The reason is that thermal turbulence deflects the direct path of the star's light. This atmospheric turbulence also poses limitations on how well telescopes can resolve planetary bodies.

During the 1960s, astronomers developed methods to compensate for the atmospheric turbulence, allowing their telescopes to better resolve images. This type of optical optimisation, called adaptive optics, uses computer-controlled deformable mirrors to compensate for wavefront deviations while monitoring with a wavefront sensor. Not only does this technology have military applications in clearing up images taken by spy satellites, it is redefining the eyecare profession's understanding and management of refractive error.

Wavefront comes to eyecare

We are all familiar with how the human eye is an imperfect optical system. Light passing through the ocular media is subjected to 'turbulence' as well. For example, toricity of the anterior corneal surface introduces lower-order astigmatism. Wavefront aberrometry objectively and comprehensively quantifies these optical imperfections (Figure 1). Not only does wavefront aberrometry measure lower-order aberrations (i.e. myopia,



►► **Figure 1**
Wavefront Zernikes
(by courtesy of Alcon Laboratories)



►► **Figure 2**
Ophthonix Z-View

hyperopia, and astigmatism), it also assesses higher-order aberrations which previously were not measurable. These include spherical aberration, coma, secondary astigmatism trefoil, and quadrafoil, among others. Collectively, higher-order aberrations account for about 20% of the visual imperfections for the average individual.

Both lower-order and higher-order aberration measurements are influenced by age-related lenticular changes, the tear film, accommodation, pupil size and the wavelength of light used in measurement. Keeping this in mind, refractive surgeons have already strongly adopted wavefront-guided excimer laser treatment. It is perhaps unusual that wavefront-guided treatment has first come in the form of corneal surgery, since the logical acceptance of new medical treatment evolves from least to most invasive. Only now is non-surgical wavefront-guided treatment of spectacles and contact lenses entering clinical use.

Until recently, the high expense of wavefront aberrometers kept them in academia and refractive surgery centres. Now there are wavefront aberrometers available for less than half the cost of surgical aberrometers despite equivalent quality – namely the Marco 3D Wave and Ophthonix Z-View aberrometers. An increasing number of practitioners are embracing aberrometry, in much the same way that corneal topography was first accepted some 15 years ago.

I have had the privilege of using both the Marco and Ophthonix aberrometers, which are both superb. The majority of my experience, however, is with the Ophthonix Z-View (Figure 2), which my group practice has used for over seven months on more than 2,000 patients at routine examination. In my practice, the Z-View measurement is administered by a technician during the preliminary testing sequence, which includes visual acuities, non-contact tonometry, automated screening visual fields, and Optomap retinal scanning.

How does wavefront fit into routine practice?

At a basic level, I use the Z-View as an autorefractor. In general, the Z-View's wavefront-derived refractions are close to

my manifest refractions. A recent ARVO abstract demonstrated a high correlation between these two measurements, with an R^2 of 0.96 for sphere, 0.85 for cylinder and 0.88 for axis¹. Sometimes the wavefront-derived refraction seems better than my manifest refraction. Yet on other occasions, it is the other way around. I still perform manifest refraction for the majority of patients, as I believe subjective response will always have an important role in refractive eyecare. However, the Z-View measurement reduces my dependency on manifest refraction. The Z-View helps me quickly reach a subjective endpoint by reducing the patient's response burden.

Although the natural instinct of most optometrists is to compare how well the wavefront-derived refractions compare against their manual refractions, doing so distracts attention from what makes these instruments special. The Z-View is unique because, unlike an autorefractor, it quantifies higher-order aberrations. These previously ignored elements of vision are often significant. As an extreme example, consider keratoconus, the prototypical eye disease characterised by higher-order aberrations. The asymmetric corneal surface in keratoconus creates visual distortions, which existing spectacles cannot correct. Over the years, we have referred to these uncorrectable aberrations as 'irregular astigmatism'. But consistent with wavefront aberrometry, 'higher-order aberrations' is perhaps the better term.

With keratoconus, Maeda and co-workers used wavefront aberrometry to show that these patients have a particularly high degree of coma². Of course, most of our regular patients do not have such large degrees of higher-order aberrations. Rather, the average individual has the equivalent of about 0.25 dioptres of higher-order aberrations³. The point here is that there is variation in the amount of higher-order aberrations from one person to another, ranging from a small amount to a large magnitude.

Who has elevated higher-order aberrations?

The information about higher-order aberrations helps in diagnosis. I have found that a disproportionately large number of patients with 'soft' refraction endpoints have above-average amounts of higher-order aberrations. This probably owes to multifocality, creating a range of refraction endpoints. Patients complaining of poor visual quality even with spectacle correction (e.g. certain post-LASIK patients), also often have above-average

amounts of higher-order aberrations. Finally, I have observed that patients with conditions such as anterior stromal corneal scars, Fuchs' endothelial dystrophy, epithelial basement membrane dystrophy, and incipient cataracts, also tend to show greater amounts of higher-order aberrations.

If a new patient to my practice exhibits above-average higher-order aberrations, I now pay special attention to whether an underlying eye disease is responsible. If the primary cause of higher-order aberrations is due to anterior corneal irregularity (e.g. post-RK, keratoconus, pellucid marginal degeneration, post-corneal transplantation), then the ideal treatment is gas permeable (GP) contact lenses.

The GP lens re-establishes an optically clear surface to refract, while the post-lens tear film neutralises most of the higher-order aberrations. Yet if the primary cause of elevated higher-order aberrations is due to other components of the ocular media, further evaluation is required. As an example, if nuclear sclerosis is causing visually significant spherical aberration, the definitive treatment is cataract surgery. In other instances, wavefront-guided treatment may help.

Downsides to wavefront-guided surgery

Wavefront-guided laser vision correction is already regularly performed. While the current excimer treatments try to correct pre-existing higher-order aberrations, the healing response and corneal biomechanical alterations induce new higher-order aberrations. This can undo the benefit of wavefront-guided laser surgery. Surgical wavefront-correction also carries associated risk and cost, and cannot readily parallel small periodic changes in higher-order aberrations due to ageing. Consequently, non-surgical wavefront-correction with spectacles and contact lenses is probably attractive to more patients.

The major challenge of non-surgical wavefront correction is matching the wavefront treatment on a point-to-point basis to the eye, which is termed

'registration'. As an example, translational and rotational position of wavefront-correcting spectacles and contact lenses has to be just right to optimise vision – similar to how an astigmatic spectacle prescription or toric soft lens has to have the right axis to provide good vision.

Wavefront-guided spectacles

Ophthonix recently launched their iZon™ spectacle lens on a limited commercial basis in the United States. The iZon lenses are made using a three-step process, which integrates three proprietary technologies (Figure 3).

First, the Ophthonix Z-View aberrometer captures a patient's unique wavefront measurement. Second, the information is converted into a prescription that corresponds to the patient's unique 'optical fingerprint'. Finally, the prescription is transferred using an ultraviolet laser to an epoxy polymer sandwiched between two optical surfaces. In the last step, the UV laser alters the refractive index of the epoxy polymer on a point-by-point basis, analogous to programming a compact disc, in order to generate the desired refractive profile.

The iZon lens uses 1.6 index cover plates, which cure seamlessly with the epoxy polymer in between. The resulting lenses then receive a premium anti-reflective coating. Currently, the iZon lens is available in single vision only, although there are plans to extend the technology to progressive addition lenses, sunglasses and other spectacle lens types.

In theory, a spectacle lenses that corrects the full amount of higher-order aberrations must move with the eye to maintain perfect registration. This could create a small perceived viewing area. Practically, a spectacle lens with a highly restrictive 'straight-ahead-only' viewing area will not work. However, if a smaller amount of the higher-order aberrations is corrected, the perceived viewing area of the lens is expanded. Stated another way, the perceived viewing area of the iZon lens is inversely proportional to the amount of higher-order correction. This is similar to how the viewing area in a progressive addition lens decreases as the near add increases. However, according to Andreas Dreher, the CEO of Ophthonix, most patients wearing the iZon spectacle lens are not expected to notice a change in visual quality as they view in the usual fields of gaze. Even when patients look peripherally through the iZon lens, their vision should be better than if they were to view through the corresponding area of a conventional spectacle lens.

Preliminary data shows encouraging improvements in vision with wavefront-guided spectacles compared to standard spectacles⁴. In subjects with emmetropia, visual acuity ($p=0.048$), low contrast visual acuity ($p=0.002$), and contrast sensitivity ($p=0.009 @ 6c/d$) were significantly

improved by correcting higher-order aberrations. Even higher significance levels were found for the vision improvement in subjects with myopia (VA: $p=0.0008$, LCVA: $p=0.004$, CS $p=0.007 @ 6c/d$, $p=0.004 @ 12c/d$, $p=0.0009 @ 18 c/d$). The publication of additional data from double-masked studies, sponsored by Ophthonix, comparing iZon versus standard spectacles, is pending.

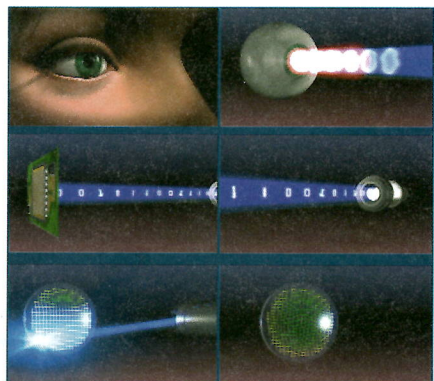
It is too early to predict how the iZon lens will integrate into clinical practice. Just like the controversy on whether laser vision candidates should have wavefront versus conventional laser treatment, it is debatable whether a spectacle lens wearer should have iZon lenses or standard lenses when both are possible. If a patient has a very small amount of higher-order aberrations, it is unlikely that these individuals would notice the visual improvement – even if all of their higher-order aberrations were corrected. Yet if a patient has a very large amount of higher-order aberrations, then correcting even a modest percentage of them with spectacles could create bothersome constraints on the viewing area. Fully correcting a large degree of higher-order aberrations also requires exact vertex distance, pantoscopic tilt, and facial wrap – not something easily maintained if the spectacles lose adjustment.

It makes sense that there is an optimal range of total higher-order aberrations that is not too little or too much, where their correction with iZon lenses would create an appreciable benefit. On the other hand, there is a reasonable argument for putting every spectacle lens wearer into iZon lenses, analogous to refractive surgeons advocating wavefront-guided laser vision correction over conventional treatment whenever possible.

It is also worth considering whether correcting certain patterns of higher-order aberrations more commonly leads to asthenopia. As an example, most clinicians would agree that spectacle prescription changes for oblique astigmatism frequently result in adaptation issues due to asymmetric meridional magnification. I hypothesise that rotationally asymmetric higher-orders, like coma and trefoil, are more prone to adaptation issues than symmetric higher-order aberration, like spherical aberration. Of course, only further study and clinical experience will provide the desired answers.

Meanwhile, Ophthonix continues to garner public and professional interest. This start-up company is venture capital funded by firms including Kleiner Perkins, known for incubating Amazon, Google, Sun Microsystems, among other well recognised companies. Ophthonix has also won acclaim with a 2005 Medical Design Excellence Award (MDEA) and a 2004 UCSD CONNECT Most Innovative Product (MIP) award. Ophthonix recently received CE marking for the Z-View aberrometer.

» Figure 3
Three-step process for iZon lenses



Wavefront contact lenses

There are several commercially available, non-custom soft contact lenses that attempt to correct the higher-order aberration of spherical aberration. These soft contact lenses include the Biomedics® 55 Premier™ and Frequency 55 Aspheric (CooperVision/OSI), Choice AB™ (CIBA Vision), Definition[®] (Optical Connection), and PureVision® (Bausch & Lomb).

Since spherical aberration is rotationally symmetric, prism ballast and other lens stabilisation strategies found with toric contact lenses are not necessary in spherical aberration-correcting soft lens designs. The shortcoming of these spherical aberration 'correcting' lenses is that they correct a fixed pattern of spherical aberration. The manufacturers are assuming that every patient has the same amount of spherical aberration, which unfortunately is not reality. Nevertheless, there is evidence that the Biomedics 55 Premier design is generally effective in reducing spherical aberration⁵.

In actuality, an eye's higher-order aberration pattern is unique like a fingerprint. An earnest attempt at correcting these higher-order aberrations requires a custom-manufactured lens. As mentioned earlier, if all the higher-order aberrations are due only to the anterior corneal surface, a rigid GP contact lens should provide optimal vision. In contrast, a soft contact lens for correcting higher-order aberrations must demonstrate relative translational and rotational stability for proper registration. While a complete lack of lens movement and rotation would provide excellent registration, it would lead to adverse physiologic consequences due to inadequate tear exchange. One study suggested that translational stability should not exceed $\pm 0.5\text{mm}$ decentration, while rotational stability should be within $\pm 10^\circ$. This would suggest that even existing toric soft contact lenses could serve as a platform for higher-order correction.

Optical Connection entered a licensing partnership with Ophthonix to use the Z-View data to manufacture wavefront-guided iZon by Definition soft contact lenses in the US. These contact lenses are

not yet commercially available, although their US launch is anticipated later this year. Their manufacture begins with wavefront data acquisition with the Z-View aberrometer while the patient wears a 'predicate' diagnostic contact lens. Any decentration or rotation of the predicate diagnostic lens on the eye is electronically documented. The wavefront data is then converted into a production code for contact lens manufacture using their proprietary WaveTouch™ process. The custom lenses are then delivered either to the practitioner for dispensing or direct to the patient.

Standard-diameter GP contact lenses are unable to correct higher-order aberrations beyond those caused by the anterior corneal surface because of significant lens movement during blink. An alternative platform for wavefront-guided correction is the SynergEyes™ hybrid lens (SynergEyes) which is awaiting FDA approval. Unlike the older SoftPerm hybrid lens (CIBA Vision), the SynergEyes lens (Figure 4) has a much higher Dk rigid centre (Paragon HDS 100), is not prone to junction separation, and has a specifiable soft skirt radius to accommodate a greater range of eyes.

Unlike traditional GP lenses, the SynergEyes usually exhibits less than 0.2mm of translational movement during blink. A proprietary soft skirt design provides the necessary rotational stability for registration. The 8.4mm diameter rigid centre of the SynergEyes addresses higher-order aberrations caused by the anterior cornea, while the remaining higher-order aberration correction is incorporated in the thickness profile of the rigid centre. Rotationally asymmetric, polish-free lathing is necessary to generate the desired higher-order correction. A theoretical advantage of SynergEyes is that its manufacture does not require compensation of dry to wet expansion, as with hydrogel lenses.

Although the prospect of further improved vision with contact lenses sounds good, there are potential limitations. In a study of 236 lapsed contact lens wearers who had previously tried contact lenses and discontinued, it was found that the majority of subjects (51%) cited discomfort as the principal reason for discontinuation⁷. The reminder here is that even if exceptional vision is possible, factors such as wearing comfort, handling and convenience, may collectively have greater influence on whether patients will routinely wear these contact lenses.

It is also reasonable to wonder if it makes sense to try correcting higher-order aberrations when we have not yet perfected correcting lower-order aberrations. Since the total higher-order aberrations for most eyes amounts to only 0.25 dioptres⁸, perhaps the contact lens manufacturers should first make toric soft

contacts in 0.25 dioptre cylinder steps and in even finer axis gradations. These are important considerations that wavefront-guided contact lens developers should not ignore.

Advancing optometry

The art and science of measuring refractive error has remained unchanged for nearly 100 years – despite the numerous changes in eyecare technology in other areas, from nerve fibre analysers to laser vision correction. Now, wavefront technology holds the potential to advance optometry's traditional core of analysing refractive error and its non-surgical treatment. Indeed, exciting times lie ahead.

About the author

Dr Chou is in private practice in San Diego, California. He is also a consultant for the California Board of Optometry and a clinical investigator and consultant to CooperVision, SynergEyes and Ophthonix.

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» Figure 4

SynergEyes hybrid contact lens

