

Considerations for a State-of-the-Art Refractive IOL Practice

With the recent approvals of new-technology IOLs, what factors will contribute to the rate of ophthalmologists' acceptance of innovative devices?

INTRODUCTION BY JACK T. HOLLADAY, MD

It is an exciting time for refractive surgery with next-generation diagnostics becoming available to physicians that will have a significant impact on the level of treatment they can offer to their patients. Improvements in anterior segment imaging using high-frequency ultrasound and optical coherence tomography (OCT) are providing ophthalmologists with tools that allow them to evaluate pathologic corneas, eyes with corneal or anterior disease, and the results of anterior segment surgery.

The utilization of several recently developed or evolving tomographers will prove advantageous for ophthalmologists. The instruments offer a higher degree of detail because the wavelength of light is much shorter in the anterior segment. These tomographers can detect minute changes in corneal thickness, thus allowing the successful identification and disqualification of patients who may have early keratoconus or other corneal-thinning disorders that would contraindicate corneal refractive surgery. In addition, the devices permit ophthalmologists (1) to determine the exact position of both phakic and aphakic IOLs in the anterior segment and (2) to evaluate the fixation, centration, and location of these lenses within the eye. The tomographers can also calculate curvatures in the central cornea in a 1.5-mm diameter, a measurement not provided by topographers or keratometers.

Ophthalmologists are able to achieve a higher level of accuracy with IOL power calculations by means of new devices that facilitate precise optical axial length measurements, even in eyes that have fairly transparent media. Combination units now provide topography, wavefront analysis, and refractions. By ensuring that the patient's

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fixation is the same for all three tests, these devices eliminate the problems of alignment and differences between the measurements that would make comparability inadequate. These new technologies have given anterior segment surgeons imaging instruments that enable them to monitor each patient's optical system better.

INDUSTRY ACCEPTANCE

The biggest deterrent to the clinician's adoption of new diagnostic technologies will be their cost. Although the devices represent significant investments, the equation does not simply involve economics. The existence of reimbursement rates and the benefits gained through utilization of the devices (such as physician access to useful information not previously provided) will also be factors that dictate how quickly the different technologies will penetrate the ophthalmic market.

In today's environment, obtaining reimbursement for new diagnostic tests is difficult due to the coding process that must be completed through the Centers for Medicare and Medicaid Services (CMS). The establishment and implementation of CMS codes that reflect the value of certain procedures involves a somewhat lengthy process, and actual reimbursement may be significantly delayed. The expense involved in buying an instrument before a

substantial reimbursement code in place is hard to justify. As a result, it is taking a long time for these products to make an impact on the market.

CONCLUSION

Physicians must balance the quality of care they can provide and that which the CMS regulatory system will enable them to afford. Quality of care always prevails, but it is a slow process, as evidenced by the eventual integration of topographers in the 1980s and tomographers in the 1990s. Nevertheless, I believe that new diagnostic instruments will be commonly available in clinical practices within 1 to 2 years.

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As with any surgical procedure, there are risks associated with the CustomVue treatment. Before treating patients with the CustomVue procedure, you should carefully review the Professional Use Information Manual, complete the Physician CustomVue Certification Course, provide your patients with the Patient Information Booklet for CustomVue LASIK Laser Treatment, and discuss the risks associated with this procedure and questions about the procedure with your patients.

WAVEFRONT-GUIDED LASIK INDICATIONS AND INTENDED USES:

The VISX STAR S4 Excimer Laser System and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of myopic astigmatism up to -6.00 D MRSE, with cylinder between 0.00 and -3.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for correction of myopic astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the myopic astigmatism application is based on a clinical trial of 351 eyes (189 primary and 162 secondary). Of all eyes treated, 318 were evaluated for effectiveness with 98.8% accountability at 3 months, 277 eyes with 96.9% accountability at 6 months, 102 eyes with 95.3% accountability at 9 months, and 86 eyes with 95.6% accountability at 12 months. The studies found that of the 277 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 100% were corrected to 20/40 or better, and 95.8% were corrected to 20/20 or better in 71 spherical myopia eyes; and 99.5% were corrected to 20/40 or better, and 93.2% were corrected to 20/20 or better in 206 astigmatic myopia eyes. The study showed that at the 3 month stability time point: there was a loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in 1 of 239 astigmatic myopia eyes and there was no loss of ≥ 2 lines of best corrected vision in 79 spherical myopia eyes; there was 1 of 239 astigmatic myopia eyes with best spectacle corrected visual acuity (BSCVA) worse than 20/25 and none in 79 spherical myopia eyes with BSCVA worse than 20/25. During the course of study, no eye lost >2 lines of BSCVA and no eye had a BSCVA worse than 20/40.

The VISX STAR S4 Excimer Laser System and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of hyperopic astigmatism up to 3.00 D MRSE, with cylinder between 0.00 and 2.00 D in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 1.00 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for the correction of hyperopic astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the hyperopic astigmatism application is based on a clinical trial of 144 eyes (74 primary and 70 secondary). Of all eyes treated, 134 were evaluated for effectiveness with 98.5% accountability at 3 months, 131 eyes with 97.0% accountability at 6 months, 118 eyes with 90.8% accountability at 9 months, and 27 eyes with 87.1% accountability at 12 months. The studies found that of the 131 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 6 months, 97.3% were corrected to 20/40 or better, and 66.2% were corrected to 20/20 or better in 74 spherical hyperopia eyes; and 93.0% were corrected to 20/40 or better, and 56.1% were corrected to 20/20 or better in 57 astigmatic hyperopia eyes. The study showed that at the 6 month stability time point: there was no loss of ≥ 2 lines of best corrected vision that can be obtained with spectacles in either 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes; none of the 63 astigmatic hyperopia eyes or 74 spherical hyperopia eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/25. During the course of study, one of 63 eyes with astigmatic hyperopia lost >2 lines of BSCVA at 1 month, no eyes with spherical hyperopia lost >2 lines of BSCVA, and no eye had a BSCVA worse than 20/40.

The VISX STAR S4 IR™ Excimer Laser System with VSS™ and WaveScan WaveFront System are approved to perform wavefront-guided laser assisted in-situ keratomileusis (LASIK) treatments for the reduction or elimination of naturally occurring mixed astigmatism when the magnitude of cylinder (from 1.0 to 5.0 D) is greater than the magnitude of sphere and the cylinder and sphere have opposite signs; in patients 21 years of age or older; and in patients with documented evidence of a change in manifest refraction of no more than 0.50 D (in both cylinder and sphere components) for at least one year prior to the date of pre-operative examination.

Wavefront-guided LASIK for the correction of mixed astigmatism is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), conventional LASIK, and other refractive surgeries. Approval of the mixed astigmatism application is based on a clinical trial of 86 eyes.

Of all eyes treated, 86 were evaluated for effectiveness with 100.0% accountability at 3 months, 80 eyes with 95.2% accountability at 6 months, 69 eyes with 86.3% accountability at 9 months, and 63 eyes with 94.0% accountability at 12 months. The studies found that of the 86 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at 3 months, 95.3% were corrected to 20/40 or better, 91.9% were corrected to 20/32 or better, and 61.6% were corrected to 20/20 or better without spectacles or contact lenses. The study showed that of 86 astigmatic eyes, one eye temporarily lost 2 lines of best corrected vision that can be obtained with spectacles at 1 month and at 6 months and none of the eyes had best spectacle corrected visual acuity (BSCVA) worse than 20/40.

CONTRAINDICATIONS:

Wavefront-guided LASIK is contraindicated in patients with collagen vascular, autoimmune or immunodeficiency disease, signs of keratoconus or abnormal corneal topography, patients taking isotretinoin (Accutane™) or amiodarone hydrochloride (Cordarone™) or are pregnant or nursing.

WARNINGS:

Wavefront-guided LASIK is not recommended in patients who have diabetes, a history of Herpes simplex or Herpes zoster keratitis, significant dry eye that is unresponsive to treatment, or severe allergies. Lower uncorrected visual acuity may be anticipated in the treatment of higher degrees of myopia with and without astigmatism (>5.0 D MRSE).

PRECAUTIONS:

The safety and effectiveness of wavefront-guided LASIK surgery has ONLY been established with an optical zone of 6 mm and an ablation zone of 8 mm for myopic astigmatism, and an optical zone of 6 mm and an ablation zone of 9 mm for hyperopic and mixed astigmatism. Long term risks of wavefront-guided LASIK beyond 12 months have not been studied. The safety and effectiveness of the STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of myopic astigmatism in patients: whose WaveScan™-measured pupil size is less than 6 mm, for treatments greater than -6 diopters of MRSE or with greater than 3 diopters of astigmatism and for retreatment with CustomVue LASIK. The safety and effectiveness of the STAR S4 Excimer Laser System have NOT been established for wavefront-guided treatment of hyperopic astigmatism in patients: whose WaveScan-measured pupil size is less than 5 mm; for treatments greater than 3 diopters of MRSE or with greater than 2 diopters of astigmatism and for retreatment with CustomVue LASIK. The safety and effectiveness of the STAR S4 IR Excimer Laser System have NOT been established for wavefront-guided treatment of mixed astigmatism in patients: whose WaveScan wavefront diameter is less than 5 mm, for treatments greater than 5 diopters or less than 1 diopter of astigmatism and for retreatment with CustomVue LASIK.

Although the WaveScan WaveFront System measures the refractive error and wavefront aberrations of the human eyes, including myopia, hyperopia, astigmatism, coma, spherical aberration, trefoil, and other higher order aberrations through sixth order, in the clinical studies, the average higher order aberration did not decrease after CustomVue treatment.

It is possible, after wavefront-guided LASIK treatment, that patients will find it more difficult than usual to see in conditions such as very dim light, rain, snow, fog, or glare from bright lights at night. Visual performance possibly could be worsened by large pupil sizes or decentered pupils. Pupil size should be evaluated under mesopic illumination conditions.

The use of Percentage Nomogram Adjustment should be based upon careful consideration of patient and surgeon information, in addition to environmental conditions surrounding the surgery. The simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment has not been studied in controlled investigations, and should not be attempted until the accuracy of the Nomogram setting has been verified for the same laser, treatment conditions and type of treatment. Therefore, the combined simultaneous use of the Percentage Nomogram Adjustment and the Physician Adjustment is not recommended without careful analysis of postoperative refractive results.

ADVERSE EVENTS AND COMPLICATIONS:

The clinical trial for myopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 351 eyes at any interval up to 6 months post-treatment: inflammation of the cornea under the flap (1.4%); double or ghost images (1.4%); and scratch on the surface of the eye (1.4%). The following subjective symptoms frequency rated "often or always" were increased in the effectiveness cohort at 6 months post-treatment on 258 eyes compared with pre-treatment on 332 eyes: dryness (9% vs. 6%); fluctuation of vision (3% vs. 2%); glare (4% vs. 2%) and halos (7% vs. 5%).

The clinical trial for hyperopic astigmatism showed that the following adverse events or complications occurred in at least 1% of the 144 eyes at any interval up to 6 months post-treatment: cells growing under the flap (2.1%); feeling of something in the eye (1.4%); double or ghost images (11.3%); and scratch on the surface of the eye (2.1%). The following subjective symptoms rated "often or always" were increased in the effectiveness cohort at 6 months post-treatment on 131 eyes compared with pre-treatment on 136 eyes: dryness (17% vs. 6%); blurry vision (10% vs. 7%); fluctuation of vision (14% vs. 6%); halos (10% vs. 5%); double or ghost images (7% vs. 3%).

The clinical trial for mixed astigmatism showed that the following adverse events or complications occurred in at least 1% of the 86 eyes at one or more postoperative examinations up to 3 months post-treatment: miscreated flap (1.2%); cells growing under the flap (4.7%); and double vision (or "ghost images") in the operative eye (6.1%). The following subjective symptoms were reported as present "often or always" by a higher percentage of subjects 3 months after treatment than before treatment: dryness (22% vs. 6%); halos (20% vs. 13%).

*Accutane™ is a trademark of Hoffmann-La Roche Inc.
†Cordarone™ is a trademark of Sanofi-Synthelabo, Inc.

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from the ease of use and quick measurement time that facilitates patient flow. The multifunction platform offers surgeons a high level of confidence in IOL power calculations and resulting outcomes. The IOLMaster reportedly eliminates the technician-dependent results that often limit ultrasound accuracy.

MARCO 3-D WAVE*

Marco, Jacksonville, Florida
(800) 874-5274 or (904) 642-9330
www.marco.com

KEY FEATURES

- Quantifies internal aberrations and astigmatism
- Detects decentered IOLs
- Shows progression of lenticular changes in difference maps and measures angle kappa

The 3-D Wave, a combination autorefractor/keratometer, corneal topographer, and wavefront aberrometer, may be a useful tool for any refractive IOL practice. The product effectively separates the cornea from the entire optical system for evaluation and analysis, with Zernike graphs clearly indicating optical aberrations. Lens vaulting is visible. Refractions are displayed in 2.6-, 3.0-, and 5.0-mm increments to examine how the patient's vision varies throughout the day as pupil size changes.

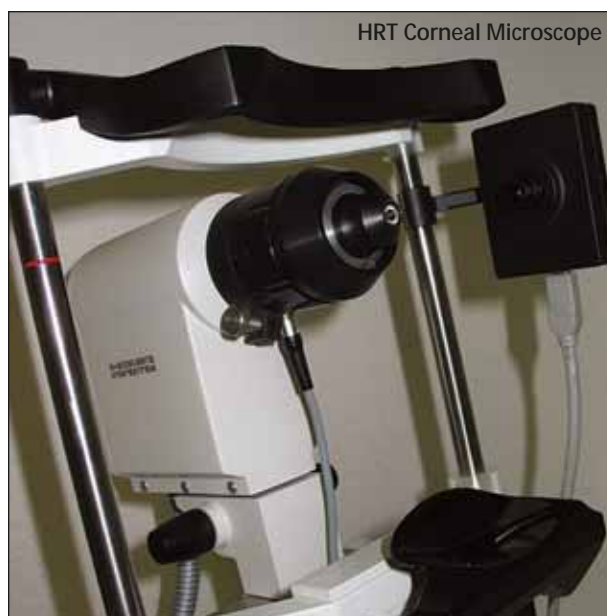
The 3-D Wave aids physicians with IOL selection by providing negative and positive spherical aberrations and displaying mesopic and photopic pupil sizes for each patient prior to implantation. The combination

unit reportedly measures 100% of a patient's optical system in a matter of seconds, thus allowing the clinician to observe and diagnose every aspect of the visual system.

**This product is manufactured for Marco by Nidek, Inc. (Fremont, CA), a company that produces and markets the device as the OPD-Scan.*

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KEY FEATURES

- Allows the monitoring of LASIK flaps and of the regeneration of nerves following surgery
- Performs functions of a powerful histological detection instrument
- Monitors long-term contact lens wear
- Semi-automated cell counting
- Epithelial and intracorneal pachymetry

The HRT Corneal Microscope uses confocal scanning laser technology to image the entire cornea, layer by layer, with a 1- μ m resolution. The properties of the microscope, combined with confocal laser scanning, make in vivo imaging possible and provide the clinician with the capability to see the complete structural histology of the cornea from the superficial epithelium to the endothelium. Diseases such as Fuch's dystrophy, lattice dystrophies, bacterial keratitis, and *Acanthamoeba* may be monitored. In addition, the conjunctiva and sclera may be imaged with the microscope to allow applications such as the examination of glaucoma filtering blebs. The HRT Corneal Microscope features multiple acquisition modes, including movie formats, cell-counting abilities, and image export features.

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Oculus, Inc., Lynnwood, Washington
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www.oculususa.com

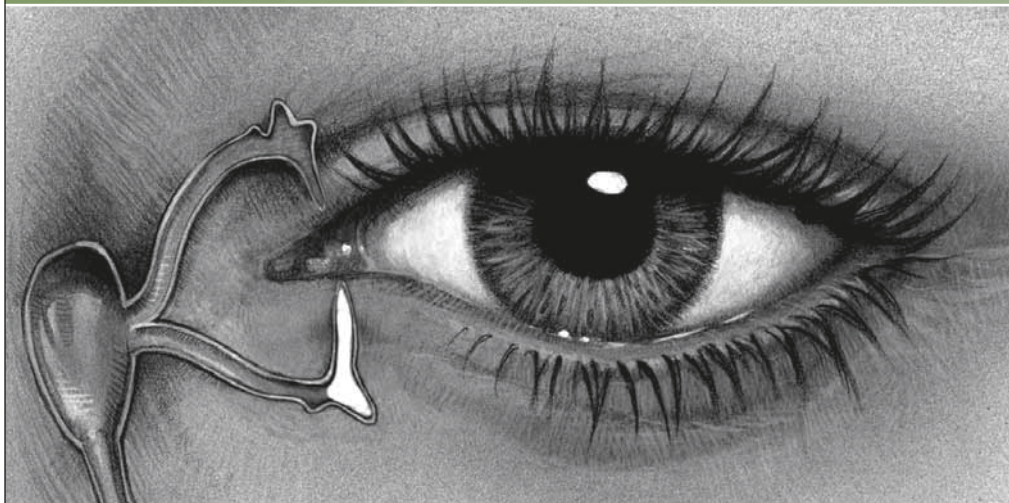
KEY FEATURES

- Displays and quantifies opacification of the crystalline lens
- Achieves keratoconus detection and Zernike analysis of the cornea
- Provides tomographic images of the anterior segment
- Calculates the cornea's true net power for more accurate IOL power calculations in postrefractive surgery patients
- Measures the vault of an IOL from any surface in the eye

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Oculus Pentacam

Oculus, Inc., offers the Pentacam, a rotating Scheimpflug camera that performs topographic measurements (axial, tangential, and height maps) of the entire anterior and posterior surfaces of the cornea from limbus to limbus. The device analyzes the anterior segment with pachymetry readings at any location and calculates its angle, volume, height, and diameter. Chamber height may be measured at any location.

The rotating measurement takes 3-D Scheimpflug pictures in less than 2 seconds. An additional camera detects all eye movement and corrects the Scheimpflug image. In the 3-D mode, the Scheimpflug camera takes up to 50 scans, and each scan has 500 images for a total of 25,000 true measurements and elevation points, thereby providing the most accurate posterior cornea and other measurements available, according to the company.

ULTRALINK ARTEMIS-2

Ultralink LLC, St. Petersburg, Florida

(727) 527-1277

www.arcscan.com

KEY FEATURES

- Provides accurate measurements of corneal layers and anterior segment anatomy
- Performs scanning on multiple meridians
- Produces highly detailed pre- and postoperative imaging with radial, angle-to-angle, and sulcus-to-sulcus measurements



Ultralink Artemis-2

The Artemis-2 is a VHF high-resolution (50MHz) ultrasound system that provides the most accurate measurements of the corneal layers and anterior segment, according to Ultralink. Derived from technology developed at the Weill Medical College of Cornell University in New York, it is an evolving biometric platform technology that can assist the ophthalmologist with refractive surgery and other ocular challenges. The Artemis-2 is the only ultrasound system to provide a visual axis centration beam with a simultaneous optical image of the eye to ensure positional accuracy.

Advanced digital-signal processing exclusive to the Artemis achieves accurate measurements by avoiding problems related to the refractive distortion. The company asserts that only this imaging system can achieve direct quantitative measurements beyond opaque structures. The extension of the Artemis-2 technology to imaging and perfusion analysis of the retina, choroid, and underlying tissues has been demonstrated, which may lead to improved stratification, start- and end-point data for evaluation and treatment of age-related macular degeneration.

This technology can precisely determine the efficacy of microkeratomes in 3-D and facilitates the assessment of complications in LASIK and refractive implant surgery. "We are dealing with a technology that is enabling ophthalmologists to see beyond the surfaces they have been examining in the last few decades with microscopes," stated Dan Z. Reinstein, MD, co-inventor of the Artemis-2. "We are now entering into an era of sub-surface anatomy and microstructure to better plan surgery and treatment modalities." ■