As a surgeon I define success through my patients’ satisfaction. With newer, advanced technologies targeting decreased higher order aberrations, we now have the opportunity to provide even better outcomes for a wider range of cataract and refractive patients.

Eric D. Donnenfeld, M.D.

Innovations in Corneal and Cataract Refractive Surgery

Patient Visual Quality and Acuity Outcomes Redefined with Fully Customized Procedures

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Results from our recent study of naval aviation patients show that wavefront-guided/femtosecond LASIK represents the best refractive procedure performed today. Patients experience rapid visual recovery by two weeks post-op. The refractive results are stable in the majority of patients at one week. In addition, patients have improved quality of vision, and they have no complications or subjective complaints. One hundred percent of patients strongly recommend the procedure for fellow aviators.

**Navy study**

For our Phase I Return to Flight Study, 30 Class II aviators (USN / USMC) were enrolled and treated (six female, 24 male). These aviators (51 myopic/myopic astigmatism eyes, four hyperopic eyes, and five mixed astigmatism eyes) received wavefront-guided LASIK with 60 kHz Intralase and the Visx S4 IR (Advanced Medical Optics); there were no nomogram adjustments. The surgical regimen included Pred Forte (prednisolone acetate, Allergan, Irvine, Calif.) and Vigamox (moxifloxacin HCI ophthalmic solution, Alcon, Fort Worth, Texas) qid for one week and Restasis (cyclosporine ophthalmic emulsion, Allergan, Irvine, Calif.) bid for three months. There were weekly exams for four weeks, then monthly through three month post-op. Aviators were eligible to return to flight by one month. Treatment was completed December 2007.

For uncorrected visual acuity, at one week a little over 90% were 20/20 uncorrected. At two weeks, 100% were 20/20 uncorrected and 94% were 20/15 uncorrected. In addition, at two weeks, over half the patients were 20/12 uncorrected and 25% were 20/10. At four weeks, 87% were 20/12 following wavefront-guided LASIK. For best spectacle corrected visual acuity, there was significant improvement at four weeks, with 93% of eyes at 20/12 or better with wavefront-guided LASIK (Figure 1). A significant number of eyes gained BSCVA vision; 43% gained one line and 18% gained two lines of best corrected vision. No eye lost more than two lines of BSCVA. The study also showed that LASIK patients have a greater percentage of eyes with better low contrast visual acuity than PRK.

**Return to flight**

There are clear advantages of performing wavefront-guided LASIK, including faster return to visual function, and in the aviator patient population this means a faster return to duty. It appears based on our study data that myopes (who comprised well over 90% of our population) are stable at two weeks following wavefront-guided femtosecond LASIK.

More studies are underway including those in the designated aviator population (pilots), as well as studies in the accessioning population, which will allow student aviators who have had successful LASIK to enter flight training.

**Navy preferred**

Wavefront-guided ablations with femtosecond flap creation represents the preferred refractive procedure performed in the U.S. Navy today. The excellent data and findings of this study will likely result in waverebility approval of WFG LASIK for naval aviation.

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Fewer high order aberrations yields better visual performance

The goal of customized LASIK is to reduce all higher order aberrations

by Jack T. Holladay, M.D.

A recent study demonstrates that the wavefront-guided LASIK procedure induces significantly less higher order aberrations, spherical aberration, trefoil, and coma than the wavefront-optimized LASIK procedure. In some cases, wavefront-optimized LASIK induced aberrations. Thus, wavefront-guided ablations provide the best results for the vast majority of patients with the lowest rate of retreatment over conventional LASIK and wavefront-optimized LASIK.

Reducing aberrations

Studies show that less higher order aberrations in the eye result in better quality of vision. In the laboratory, Pablo Artal, Ph.D., showed eliminating all higher order aberrations produces the best visual performance. In addition, studies from Steve Schallhorn, M.D., with 140 pilots and 228 clinic patients showed that the best visual performance occurred with the lowest amount of higher order aberrations. Similarly, pilots who had never had surgery naturally had lower higher order aberrations.

With wavefront-optimized LASIK, the goal is not to reduce the spherical aberration, but simply not increase it. The treatment basis is sphere and cylinder. Optimized simply means “not intended to induce spherical aberration,” and therefore does not address pre-op spherical aberration or any higher order aberrations. Numerous studies have shown that by the time most patients reach their 40s, they have positive ocular spherical aberrations. With wavefront-guided LASIK, the goal is to reduce all higher order aberrations. The spherical aberration target is zero.

Study and results

The purpose of our study is to compare wavefront-optimized and wavefront-guided procedures to determine which is more effective. The retrospective chart review study of 200 IntralASIK procedures included 100+ Intralase (Advanced Medical Optics, AMO, Santa Ana, Calif.) Waveight (wavefront-optimized) eyes and 100+ Intralase CustomVue (AMO) (wavefront-guided) eyes. Pre-op and post-op wavefront scans were done on all eyes at a 6-mm pupil size. Primary spherical aberrations, primary coma, primary trefoil, and total higher order aberrations were measured.

One hundred and nine CustomVue eyes and 102 Waveight eyes were reviewed in 2006 and early 2007. These study results show that wavefront-guided ablation with femtosecond technology is optimal for the majority of patients.

Overall, the wavefront-guided treatment induces significantly less higher order aberrations, spherical aberration, trefoil, and coma than the wavefront-optimized procedure (Figure 1 and 2). There was significantly more variation with the wavefront-optimized eyes. This study indicates that for all higher order aberration in the wavefront-guided group, about 12% of patients were better, 76% were the same, and 12% were worse post-op. With wavefront-optimized, about 8% were better, 51% were the same, and 41% were worse. There was significantly greater safety for the patients with the guided procedure. The wavefront-guided procedure had the greater efficacy for total higher order aberrations, and the better safety with the lowest induced aberrations.

We have found that wavefront-guided LASIK has the best chance of maintaining or improving higher order aberrations, and therefore has the best chance of providing optimal visual quality.

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Figure 1: Wavefront-guided ablations were shown to improve or have no change on higher order aberrations (HOA) in 88% of all patients in the study

Figure 2: Wavefront-optimized ablations worsened higher order aberrations (HOA) in 41% of all patients treated in the study, compared to 12% with wavefront-guided ablations
ASIK retreatment rates have been steadily declining. In my own practice, the rate of enhancements has declined from about 5% to 6% in 2004 to less than 2% in 2007. New technology has been the major driver in this trend.

I recently analyzed retreatment rates for more than 15,000 procedures over a three-year period, from August 2004 to August 2007. All the procedures were performed by me at TLC centers in Chicago, Illinois, Madison, Wisconsin, and Greenville, South Carolina.

The resulting graph (Figure 1) shows how the different technologies have influenced the rate of retreatments. One caveat in understanding this graph is that during the period tracked, the number of custom procedures I performed was increasing and the number of conventional procedures was declining (Figure 2). By the end of 2005, very few of my patients opted for a conventional ablation. Most of those who did were people for whom a custom procedure was not possible for some reason. They may have had unusually high prescriptions or perhaps were difficult to capture with the WaveScan (Advanced Medical Optics, AMO, Santa Ana, Calif.) and therefore probably skewed toward a higher retreatment rate anyway.

Today, I no longer perform conventional procedures at all. If the cornea is not thick enough for the planned custom ablation, I prefer to decrease the ablation depth by adjusting the ablation zone rather than move to a conventional procedure. With this approach, the patient still benefits from higher-order aberration correction, iris registration, and other custom technology.

At the same time that conventional procedures were declining, the number of microkeratome procedures was also rapidly declining. In fact, beginning in January of 2007 when TLC changed its pricing model to bundle IntraLase (AMO) flaps with custom ablation, virtually everyone who got one technology upgrade got them both (this is represented on the graph by the Custom IntraLase line). By default, every conventional case also had a microkeratome flap.

Custom and femtosecond technologies seem to have a symbiotic effect in reducing the enhancement rate. By mid-2007, I had personally stopped using a microkeratome at all, and the Advanced CustomVue (AMO) and IntraLase group has the lowest enhancement rate on the graph. Conversely, the number of patients who receive conventional and microkeratome procedures is so small that the enhancement rate for those lines looks disproportionately high.

The combination of Advanced CustomVue and IntraLase takes us that much closer to the ultimate goal that every patient sees 20/20 or better uncorrected the day after surgery. The best part about reducing enhancements is not some theoretical cost savings for the practice; it is that we end up with more happy patients who reach their visual goals the first time around. Those patients will be great spokespeople for LASIK and for our practices in the future.

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High-definition wavefront: 5X resolution

Therapeutic treatments will be the first application, but high-definition scans and new-technology topography may eventually be incorporated into routine cases

by Stephen C. Coleman, M.D.

The current generation WaveScan (Advanced Medical Optics, AMO, Santa Ana, Calif.), which is already very good, captures an average of 240 data points from a 7.0-mm pupil and analyzes all available data using Fourier reconstruction. AMO’s new high-definition technology, however, will offer five times greater resolution, encompassing over 1,250 data points from a 7.0-mm pupil. Even with a much smaller pupil of only 5.0 mm, the system will capture over 600 data points.

The device, called the iDesign Advanced WaveScan Studio, will also have a broader dynamic range, able to image wavefronts from –16 D to +12 D of sphere, up to 8 D of cylinder, and up to 8 microns of RMS higher-order aberration. By comparison, the current system measures up to 1.3 microns of RMS error. This advanced system will incorporate five measurements in one: wavefront aberrometry, new-technology topography, autorefractometry, pupillometry, and keratometry.

In addition to obtaining more information, the higher resolution aberrometer will provide much better spot quality, resulting in a far more accurate representation of the true wavefront.

Stephen C. Coleman, M.D.

As a first step, for example, we will be able to import true topographic data from many spots on the cornea to more fully compensate for the cosine effect.

In the future, state-of-the-art laser refractive surgery will involve centralized diagnostic planning in a single device, and topography-assisted, wavefront-guided ablation with iris registration.

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“In addition to obtaining more information, the higher resolution aberrometer will provide much better spot quality, resulting in a far more accurate representation of the true wavefront.”

Stephen C. Coleman, M.D.
Femtosecond technology now provides surgeons with the ability to biomechanically design the LASIK flap by controlling its shape (diameter, hinge size, side cut architecture, elliptical or round) and thickness, while also increasing safety and speed.

The technology has evolved tremendously since its commercial introduction in 2001. Now, a 5th generation femtosecond laser (iFS Advanced Femtosecond laser, Advanced Medical Optics, AMO, Santa Ana, Calif.) allows the flap to be created in less than 10 seconds.

**Speed**

The increased speed allows surgeons to use less energy per spot and to place the spots and lines closer together. Less pulse energy has the potential to decrease the incidence of the opaque bubble layer (OBL). In addition, faster flap creation means less suction time on the eye which contributes to patient comfort.

*Arturo Chayet, M.D., Tijuana, Mexico, conducted the first two clinical studies using the iFS laser. The first series determined the optimal settings for the laser while the second series looked at the clinical advantages of customizing flap dimensions for a given patient.*

With the iFS laser, the spot line separation can be decreased from the current 8 to 9 microns spot and line separation to as low as 5 x 5 microns (although the software permits even tighter placement). Thus flap lifts are virtually effortless and the beds potentially smoother than even those with the current IntraLase FS system.

**Mechanical stability**

The iFS uses new software that allows surgeons to customize the shape of the flap based on the patient’s corneal diameter, shape, and the excimer laser ablation profile. The surgeon may choose the elliptical flap option which creates a larger stromal bed area. While maintaining the vertical diameter, the horizontal diameter is enlarged, pushing the hinge away from the ablation zone. This prevents the risk of hinge ablation or allows the creation of a wider hinge, enhancing flap stability (Figure 1).

Perhaps the most interesting and unique feature of the new iFS laser is the ability to create an inverted “bevel-in” side cut. The new iFS laser side cut can be programmed from 30 to 150 degrees (similar to a mechanical microkeratome).

The purpose for making a more vertical flap edge was initially based on a pig eye study that measured how much force it took to dislocate a flap. When the walls are more perpendicular it is more difficult to move that flap. Studies conducted independently and most recently by Prof. John Marshall and Prof. Michael Knorz prove that the 140 to 150 degree bevel-in side cut is an essential component to a biomechanically stable cornea (Figure 2). Prof. Knorz’s comparative study concluded that flaps created with the iFS laser, utilizing a 140-degree side cut, required three times as much force to dislodge than those created with a modern microkeratome.

Side cut architecture with the iFS femtosecond laser may also decrease the incidence of epithelial ingrowth, which is common after enhancing a microkeratome flap, but it’s much less common after enhancing a femtosecond flap.

Femtosecond lasers have many clinical applications. In addition to flap-making capabilities, surgeons also have the ability to create channels for the implantation of intracorneal ring segments, wedge resections, corneal tattooing, limbal stem cell transplantation, lamellar and full thickness corneal transplants, retinal keratoplasty, corneal biopsies, and IntraLase Enabled Keratoplasty (IEK) patterns. This state-of-the-art technology truly represents a significant advance in the field of refractive surgery.

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**Elliptical vs Round Excimer Ablation**

*Figure 1: An elliptical flap enlarges the stromal bed area, moving the hinge away from the ablation zone.*

*Figure 2: Studies have shown that side cut angles have a large impact on the stability of the cornea; bevel-in angles produce the least strain change on the cornea; the iFS has the ability to customize the side cut angle from 30 to 150 degrees.*
Studies conducted at the Naval Medical Center in San Diego have demonstrated that we can achieve significantly better uncorrected visual acuity with femtosecond laser flaps (300 eyes) (IntraLase 15 Khz, Advanced Medical Optics, AMO, Santa Ana, Calif.) than with microkeratome flaps (436 eyes) (Hansatome, Bausch & Lomb, Rochester, N.Y., and Amadeus, AMO) three months post-op.

One week post-op, 76% of femtosecond eyes were 20/16 or better, compared to 58% of the microkeratome eyes, and twice as many femtosecond eyes were 20/12.5 or better (Figure 1). By three months, there were still more femtosecond patients with better than 20/20 vision, but the microkeratome group was catching up.

The femtosecond eyes also had better low-contrast acuity under both photopic and mesopic conditions.

The advantages of the femtosecond laser may be due to flap architecture. When a mechanically created flap is repositioned on the eye it may be difficult to surgically discern the perfect position, while the side cut of the femtosecond flap makes correct repositioning more obvious.

We only followed these patients for three months. It is possible that both groups would have attained the same levels of visual acuity and low-contrast acuity by six or 12 months post-op, but if the main advantage of LASIK is rapid visual recovery, sooner is better.

The femtosecond flap group in our study did experience more photophobia and foreign body sensation on the first post-op day, a phenomenon that seems to have disappeared with the faster iterations of the laser.

Future improvements

Future generations of femtosecond technology such as the iFS Advanced Femtosecond Laser (AMO), will offer a number of advantages over the current IntraLase system:

Speed. We have already moved from 15 to 60 Khz and future femtosecond lasers will be faster still. In addition to faster throughput with flap creation in under 10 seconds, there are a number of clinical advantages, including a smoother bed, a flap that is easier to lift, and increased patient comfort.

Flap stability. An angled bevel in the femtosecond laser side cut might improve the strength of the LASIK flap, according to two recent studies. Michael Knorz, M.D., compared flaps created with the Amadeus microkeratome and the IntraLase laser, with either a 70- or 140-degree side cut angle. Three months later, the 140-degree IntraLase flaps were more than three times as strong as the microkeratome flap (Figure 2).

Arturo Chayet, M.D., showed that beveled-angle flaps are much more difficult to re-lift 10 weeks later, again indicating that we may be able to increase flap stability with modifications to the side-cut architecture.

Customization. With the next generation iFS, we will be able to customize the shape of the flap itself, to make a more elliptical flap. Instead of the one-size-fits-all approach, we are entering an era when the flap will be tailored to the individual eye.

I believe transitioning to laser flap creation is worth the costs associated with new technology. There is tremendous potential to continue improving and more fully customize surgery with the femtosecond laser.

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Dry eye syndrome is particularly prevalent in post-menopausal women, people over 65, and younger people who have become contact lens-intolerant.

The first defense against dry eye will almost always be artificial tears. I am certainly an advocate of topical cyclosporine therapy and mild steroid treatment as needed, but I think it is important to start with a high-quality tear that can provide symptomatic relief on its own or as an adjunct to prescription therapies.

One new entrant in the market is Blink Tears (Advanced Medical Optics, AMO, Santa Ana, Calif.). In addition to the active ingredient, polyethylene glycol 400 (PEG-400), this tear also has unique properties that make it quite similar to the natural mucin found in human tears.

Our group recently conducted a randomized, double-masked, parallel-group study in which 110 dry-eye patients, ranging in age from 19 to 78, were given either Blink Tears or Systane (Alcon, Fort Worth, Texas), an HP guar-based artificial tear. Patients were instructed to use the drops four times a day for 30 days and were examined on days 7, 14, 21, and 30.

There was significantly less blur (P = .046) and better comfort on instillation (P = .017) with Blink Tears compared to Systane. End-of-day vision quality was comparable between the two groups. Objective testing, including corneal/conjunctival staining and tear film break-up time (TBUT) analysis, also showed that the two drops were comparable in efficacy.

Thirty-six percent of the Blink Tears group preferred the new drop to their previous artificial tear, while only 12% preferred Systane over the products they had previously used.

Both drops were similar in terms of retention. My colleague Kerry Solomon, M.D., has demonstrated in optical tear film interferometry studies that the mean retention time for Blink Tears is longer than 31 minutes and that more of these patients are likely to achieve a retention time greater than 30 minutes than those using Systane (Figure 1).

Pilot study

AMO also undertook an internal pilot study to evaluate subjective comfort and vision quality with Blink Tears. In this double-masked trial, 24 subjects were randomized to either Blink Tears or Systane, with 12 in each group.

There were important differences in visual quality. Subjects in the Blink Tears group had an improvement in quality of vision of 0.33 ± 2.2 points, compared to a decrease in quality of −2.05 ± 2.5 in the Systane group. Moreover, subjects in the Blink Tears group reported significantly less blur on instillation (Figure 2) and were more than twice as likely (90% vs. 42%) to say that the tear had no effect on their quality of vision immediately after instillation.

This is quite striking. Blurring on instillation is a tradeoff that patients don’t like.

Based on my own clinical experience thus far, I consider Blink Tears to be a truly refractive tear. Not only does it smooth out and regularize the tear film...but it also appears to have no short-term negative effect on the quality of vision, as other long-lasting drops typically do."

Eric D. Donnenfeld, M.D.
Dry eye is a pervasive condition in many of our patient populations; appropriate diagnosis and treatment can have a positive impact on patient satisfaction

by Edward J. Holland, M.D.

Dry eye is such a common condition that in our practice it has become the default diagnosis for external disease symptoms until something in the exam indicates otherwise. One is most likely to see dry eye in post-menopausal women, the elderly, post-surgical patients, and those suffering from contact lens intolerance.

For patients who experience dry eye symptoms only under certain environmental conditions, artificial tears alone may be sufficient. For most chronic dry eye patients, however, I quickly move to add topical cyclosporine (Restasis, Allergan, Irvine, Calif.) as maintenance therapy and a course of loteprednol (Lotemax, Bausch & Lomb, Rochester, N.Y.) for induction therapy as well as for breakthrough inflammation.

Restasis has dramatically changed our ability to manage these patients, but it certainly does not eliminate the need for tears for symptomatic relief. The problem with tears is that patients rapidly become symptomatic again and then get frustrated with the inconvenience of having to frequently instill tears throughout the day. Gels last longer and make the patient feel more comfortable, but those benefits have generally come at the expense of reduced quality of vision.

Recently, we’ve seen a major breakthrough with a new tear product, blink Tears (Advanced Medical Optics, AMO, Santa Ana, Calif.). The unique properties of this tear help it adhere to the corneal surface so that it reduces symptoms for a longer duration. In fact, for its viscosity, blink Tears is one of the longest-lasting tear products available. Optical tear-film interferometry studies have shown that the mean retention time after just one instillation of blink Tears is longer than 31 minutes, and in some cases, the tear film maintains its thickness for an hour or longer.

But in addition to the long duration of effect, what really distinguishes blink Tears are its superb optical qualities. Patients experience very little blurring or other problems with visual clarity when using this tear. In fact, they report improved quality of vision over time (Figure 1) and significant improvement in comfort after using the drops for a few weeks (Figure 2).
Recently, I had an opportunity to try the latest phacoemulsification modality, transversal ultrasound, using the Ellips Transversal Ultrasound handpiece for the WhiteStar Signature system (Advanced Medical Optics, AMO, Santa Ana, Calif.).

Ellips adds a horizontal component to the traditional longitudinal movement of the phaco needle, creating an elliptical cutting pattern (Figure 1). By incorporating two directions of movement (lateral and longitudinal), we would theoretically expect to achieve more efficient cutting of nuclear material. Moreover, it also has the potential to reduce the repulsion of material away from the phaco tip, hopefully improving followability of fragments and reducing the jackhammer effect.

During a field observation study, I performed 20 cases in my own surgery center, all with bimanual phaco and transversal ultrasound. There was no learning curve of any significance for a surgeon who is familiar with the Sovereign (AMO) or WhiteStar Signature system. In order to best assess the potential advantages of the new ultrasound mode, I deliberately made no changes to my customary technique, settings, or instrumentation. I was able to use the same irrigating chopper that I normally use, and the same tip—a 19-gauge, straight 30-degree bevel phaco needle.

I chose routine cases for the initial experience. I began each case with longitudinal phaco for nuclear sculpting. Once the nucleus was cracked, I advanced to the transversal setting for quadrant removal at higher vacuum settings (Figure 2).

The purchase, followability, and efficiency of nuclear removal was excellent. Very little phaco power was needed to remove the nuclear particles. The transversal setting seemed to perform slightly better on soft to moderate nuclei rather than very dense nuclei. However, it is too soon for me to say with any authority how this technology can best be used until I and others have had an opportunity to adjust settings and fully customize the system to my surgical technique and nuclear density.

What was most impressive about my initial experience was the post-op day one results. The corneas were beautifully clear—in fact, noticeably clearer than I am accustomed to with my current phaco machines and settings. This was quite surprising, as one would expect to see more corneal edema, not less, after the first surgical day with a new technology.

Based on the clarity of the corneas post-op, I believe that transversal ultrasound may be less traumatic for the eye, delivering less energy with less irrigation fluid and less damage to the endothelium compared to conventional longitudinal phaco.

While clear corneas are certainly gratifying for the surgeon to see on the first day post-op, they are also indicative of a great experience for the patient. That patient is going to have faster visual recovery, increased comfort, and the ability to proceed with surgery on the second eye in a more timely fashion. The more atraumatic we can make cataract surgery, the better the overall experience for the patient, and the more likely he or she is to recommend us or refer friends.

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Figure 1: Ellips adds a horizontal component to the traditional longitudinal movement of the phaco needle, creating an elliptical cutting pattern

Figure 2: Nuclear quadrant removal with Ellips Transversal Ultrasound
Central to modern, state-of-the-art phacoemulsification surgery is the ability to use fluidics to maintain a stable chamber. We know that newer phaco devices have significantly reduced surge.

In a recent study, my colleagues and I devised a way to objectively compare the fluidics of the three latest-generation phaco machines: Infiniti (Alcon, Fort Worth, Texas), Stellaris (Bausch & Lomb, Rochester, N.Y.), and WhiteStar Signature (Advanced Medical Optics, AMO, Santa Ana, Calif.). Each device was first properly primed and tuned. The phaco tips of all three devices were inserted into a single fresh, 81-year-old human eye bank eye. The tips were inserted about 3.0 mm into the sclera, through watertight corneoscleral tunnel incisions placed 90 degrees apart. We used similar, non-ABS, 19-gauge tips for each one.

To mimic post-occlusion surge, we set the vacuum pressure at 400 mm Hg and the aspiration rate at 40 mL/min. The irrigation bottle height was 70 cm. The surge test was performed with peristaltic pumps, using no surge-control modes, and was repeated 20 times.

The anterior chamber depth of this eye was 4.1 mm. Average chamber shallowing was 1.51 mm for the Infiniti system, 0.83 mm for the Stellaris, and 0.67 mm for the WhiteStar Signature (Figure 1), with tight standard deviations across the board (p<0.00001 between the three machines).

At the high end of that spectrum, chamber shallowing of 1.5 mm, or nearly one-third of the total chamber depth, is certainly problematic. The WhiteStar Signature system was the most stable platform, even without the fluidics adjustments that surgeons would use in the real world.

We also tested unoccluded flow by setting the bottle height at 60 cm, aspiration rate at 60 mL/min, and maximum vacuum of 550 mm Hg. The lower the unoccluded flow, the safer it should be for the tip to approach the capsule or iris.

The machine-indicated unoccluded vacuum at the tip ranged from 203.2 mm Hg for the INFINITI to 132.6 mm Hg for the WhiteStar Signature (Figure 2). Actual flow was closest to the machine-indicated levels for WhiteStar Signature (58.5 mL/min), least for Stellaris (53.5 mL/min), and intermediate for Infiniti (55.8 mL/min; p<0.00001 between the three machines).

As cataract surgeons, we are lucky to have three outstanding phacoemulsification machines available to us, and for many routine cases, any one of these devices should perform well. However, in tough situations, there are statistically and clinically significant differences among them. In our head-to-head, objective comparison, the WhiteStar Signature system provided the best fluidics, both in terms of the lowest post-occlusion surge and the lowest unoccluded flow vacuum.

Randall Olson, M.D., is the John A. Moran Presidential Professor and Chair of the Department of Ophthalmology and Visual Sciences at the University of Utah Health Sciences Center. He is a consultant for AMO. Contact him at 801-581-2352 or Randall.Olson@hsc.utah.edu.
We have recently begun enrolling patients in an online patient registry to track the outcomes of presbyopia-correction IOL (PCIOL) implantations. This registry is being conducted both nationally and internationally at this time for the CustomMatch process which involves implantation of either a ReZoom or Tecnis Multifocal PCIOL (Advanced Medical Optics, AMO, Santa Ana, Calif.) in the first eye. After the first eye is implanted, the same or a different lens is placed in the second eye based on patient feedback.

The online patient registry will include pre- and post-op patient questionnaires on spectacle use at different distances and also have the patient evaluate glare and halo. There will be pre- and post-op surgeon questionnaires measuring uncorrected visual acuity (far, near, and intermediate). Follow-up will be six months after the last patient procedure.

For this trial, data is collected in a prospective fashion. In general, active patients who desire spectacle independence and who have a frequent demand for intermediate vision (such as computer use) but who do not want to sacrifice distance vision do quite well with the ReZoom IOL in both eyes.

**Staged implantation**

Staged implantation is a strategy for effectively matching available PCIOLs to each patient's specific needs. With CustomMatch, the patient receives a ReZoom refractive presbyopic IOL in the first eye and then the surgeon makes a decision on lens selection for the second eye based on whichever technology matches the patient's needs. This customized approach to lens selection allows patient participation in the process and provides a safety net because decisions are made in a step-wise approach, allowing the flexibility to change course if necessary.

In my experience in the U.S., about 90 to 95% of patients will be satisfied with a bilateral “match” (the same IOL in each eye). About 5 to 10% may do better with a mixed lens approach that employs a different IOL product in each eye. Staged implantation involves three steps: Implant the primary IOL in the initial eye; assess the patient at one to two weeks (acuity and satisfaction); and then choose the fellow-eye IOL based on patient feedback.

The registry results will provide a validated roadmap for applying multifocal IOL technology to best fit your patient needs. I look forward to sharing the results as they become available in the coming months.

David R. Hardten, M.D., is a founding partner of Minnesota Eye Consultants, Minneapolis, Minn. Contact him at drhardt@mneye.com.

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**Tecnis Multifocal Update**

by Eric Donnenfeld, M.D.

In the recent U.S. clinical study, the Tecnis Multifocal intraocular lens (Advanced Medical Optics, AMO, Santa Ana, Calif.) demonstrated excellent visual acuity, reading acuity and speed, and patient satisfaction. The investigational Tecnis Multifocal lens is a three-piece intraocular lens that is available on two different platforms, a silicone platform as well as an acrylic platform. The optical surface of the lens has a full diffractive posterior surface which makes the diffractive optics pupil-independent. One of the major advantages of this lens is the addition of the wavefront-designed aspheric anterior surface. This is unique among all of the currently available lenses. As such, this lens targets zero spherical aberrations, which multiple studies have shown provides peak visual performance (similar to what occurs at age 19, when the average spherical aberration is 0.0 microns).

**The trial**

The multicenter, evaluator-masked comparative clinical evaluation included 121 bilateral multifocal and 122 bilateral monofocal subjects, and was conducted at 13 investigational sites. Results are available at one year for 114 multifocal subjects. Subject assignment was based on patient’s choice for a multifocal or monofocal IOL.

In the study, 94.6% of subjects indicated they would choose the lens again. Eighty-seven percent of subjects were 20/20 or better BCDVA, while 94% of subjects were 20/32 or better with distance correction at near. Ninety-three percent of subjects achieved simultaneous vision at age 19, when the average spherical aberration is 0.0 microns.

The registry results will provide a validated roadmap for applying multifocal IOL technology to best fit your patient needs. I look forward to sharing the results as they become available in the coming months.

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**Ability to Function Comfortably without Glasses**

The vast majority of subjects reported being able to function comfortably without glasses at all distances.
Canadian long-term follow-up on refractive IOLs

The Canadian ReZoom registry outcomes show high satisfaction at six months

by George Beiko, BM, BCh, FRCS(C)

Patients implanted with the ReZoom presbyopia correcting intraocular lens (PCIOL) (Advanced Medical Optics, AMO, Santa Ana, Calif.) report high satisfaction in 88% of cases, and 91% of patients have overall spectacle independence at six months post-op, according to the Canadian On-line Patient Registry (Figure 1).

Twenty Canadian surgeons were recruited and a goal to complete 100 to 150 bilateral patients, with six-week and six-month follow-ups, was set. Pre-op and post-op patient questionnaires on freedom from glasses at different distances, and pre-op and post-op surgeon questionnaires measuring uncorrected visual acuity (far, near, and intermediate) were completed. In addition, pre- and post-op patient questionnaires to evaluate halos and glare, and potential neuroadaptation between six-week and six-month follow-up visits were given.

As of November 2006, 18 surgeons had recruited patients for implantation of bilateral ReZoom intraocular lenses. The ReZoom Advisory Trial included hyperopic, presbyopic, and cataract patients. The target was emmetropia and the goal was precise outcomes to achieve the benefits of multifunctional vision. One hundred and sixty-one patients were enrolled; 106 patients had completed the six-week post-op follow-up, and 98 patients had completed the six-month post-op follow-up. The aim was for the patient to be plano to slightly myopic to provide good distance vision for driving and functional near vision. Patients with significant dry eye, corneal scarring, mild-to-moderate myopia, pupil size less than 2.5 mm, monofocal implant in the first eye, uncorrected post-op astigmatism greater than 0.5 D, or unstable capsular support were excluded.

Study findings

Patients had excellent far and intermediate vision and good near vision. Patients demonstrated improved performance after bilateral implantation. Younger patients were found to have greater spectacle independence. At the six-month mark, a higher percentage of patients were able to attain 20/20 vision.

We have found that patient neuroadaptation occurs between the six-week and six-month follow-up visits. According to the registry, surgeons indicated that important factors in selecting a multifocal lens included distance quality vision, minimal amount of halos, near vision quality, minimal amount of glare, and intermediate quality vision. On average, around 66% of patients saw an improvement over time in halos and glare. Post-op visual quality issues, such as glare and halo, resolve in the majority of cases and should not inhibit surgeons or patients from selecting this lens (Figure 2).

George Beiko, BM, BCh, FRCS(C), is in practice in Ontario, Canada. He can be contacted at georgebeiko@hotmail.com.
The new Tecnis one-piece acrylic lens (Advanced Medical Optics, AMO, Santa Ana, Calif.) combines the many benefits of the Tecnis three-piece acrylic lens with the ease of implantation of a one-piece platform.

**Stable design**

The Tecnis has a one-piece acrylic construction with multiple points of fixation. This unique fixation design allows the optic to stay positioned very tightly and closely to the posterior capsule, away from the haptic plane. Therefore, when it is placed in the bag it remains centered. This provides additional stability over traditional single-piece lenses. The result is a quick and long-term stabilization of the optic and refraction.

The Tecnis one-piece also has a coplanar fixation so that the haptics are slightly offset from the optic. This ensures the optic is positioned very tightly and closely to the posterior capsule, which minimizes posterior capsule opacification (PCO) and aids in centration.

Another benefit of this lens design is the 360-degree posterior square edge. The barrier edge continues through the optic-haptic junction, which may minimize that risk of PCO. Other available single-piece lenses allow for lens epithelial cells to migrate along the haptic-optic junction and create posterior capsular opacification.

Additionally, the edges of the Tecnis one-piece are frosted to minimize edge glare. The haptic loops are also highly polished, which allows the lens to unfold gently and easily into the eye after implantation, even through an unenlarged, micro-coaxial phaco incision.

**Acrylic material**

Studies have shown that the acrylic material used in the Tecnis IOL is vacuole-free and has fewer glistenings. Other lenses with glistening formations have been shown to affect visual acuity. For example, patients come in and these little vacuoles or glistenings can be seen at the slit lamp. If it gets to a moderate stage, objective measurements in clinical trials have shown with glistenings there can be a loss of contrast and decreased Snellen acuity.

In addition, with the Tecnis design there is no “cat-eye” reflex because of the curvature of the lens design, as well as the index of refraction of the material. With this lens there is minimal spherical aberration and also minimal chromatic aberration. When we were doing the trials with this lens, we saw some of the highest percentages of 20/20 visual acuities post-op out of many of the studies because of this material.

**Superior optics**

The anterior surface of the one-piece has the same optics as the Tecnis three-piece lens, allowing patients implanted with the new lens design to experience the same benefits. Studies have demonstrated that youthful vision is better achieved when patients have either zero to slightly negative total ocular spherical aberration post-op. The new one-piece IOL is designed to reduce spherical aberrations to essentially zero, thus improving quality of vision, night driving and safety in the vast majority of patients (Figures 1 and 2). Overall, the combination of premium optics, material, and design make the Tecnis one-piece a leap forward in one-piece IOL design. The benefits include sharper vision, ease of implantation, persistent centration, and longer-term clarity.

Y. Ralph Chu, M.D., is the founder of the Chu Vision Institute in Edina, Minn. He is also adjunct assistant professor of ophthalmology, University of Minnesota and clinical professor of ophthalmology, University of Utah. Contact him at 952-835-1235 or at yrchu@chuvision.com.
Intraocular lenses (IOLs) with negative asphericity should play a larger role in ophthalmology practices than they currently do, according to our theoretical calculations. Our studies have shown that for normal eyes, the mean asphericity of an IOL should actually be around –0.35 microns to maximize visual quality.

Optimal quality

Although prior studies have suggested that decentration of IOLs with negative asphericity would negatively impact quality of vision, our studies demonstrated that even with decentration of as much as 0.5 mm, these lenses outperform IOLs with either zero asphericity or standard IOLs with positive asphericity.

We also concluded that in eyes that have undergone myopic excimer laser procedures, the optimal mean asphericity of the IOL should be ~0.45 microns. On the other hand, for eyes that have undergone hyperopic procedures, the optimal asphericity is zero. There is greater individual variability in these groups compared to virgin eyes.

Accommodation

Another advantage of an aspheric IOL relates to pseudoaccommodation. In lenses with positive asphericity, there is a hyperopic shift as pupil size decreases (remembering that the refractive power of the IOL increases from center to periphery). For a reduction in pupil size from 6 to 3 mm, the magnitude of this shift could be around 0.5 D. This will impair depth of focus with accommodative miosis.

On the other hand, the refractive power of lenses with negative asphericity does not change as pupil size increases or decreases. Thus we would expect that IOLs with negative asphericity should provide greater depth of focus than standard IOLs.

Although these studies are based on sound theoretical calculations, they are not clinical studies. They also do not take into account the very important, but not yet well understood factor, of the role of neuroadaptation. There may be some neuroadaptive processes that may alter these results slightly.

Overall, we are confident that optically this information represents what will prove to be true clinically.

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