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American Society of Cataract and Refractive Surgery
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newsletter highlighting
information and events of
importance to eye care
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March Madness at Moscone: More Multifocal Mixing and Matching

As expected, much of the attention at this year's American Society of Cataract and Refractive Surgery (ASCRS) meeting was centered on the emerging field of presbyopia surgical correction. Podium presentations and CME events were filled with data comparing the three approved presbyopia-correcting IOLs and their various mix/match combinations, as well as lenses still under development.

The three approved IOLs that are vying for the attention of cataract and refractive surgeons are the ReSTOR multifocal IOL from Alcon, the ReZoom multifocal from

AMO, and the accommodating crystalens from eyeonics. Because each of these three lenses has distinct strengths and weaknesses, they are proving to be complementary, and the case for mixing and matching these lenses in a single patient is building momentum. In our view, ReSTOR/ReZoom stood out as the current favorite combination, followed by ReSTOR/crystalens. To some extent, eyeonics' message got lost amidst the well-funded battle between Alcon and AMO.

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LASIK Update from ASCRS: IntraLase 60kHz Looks Like the Real Deal

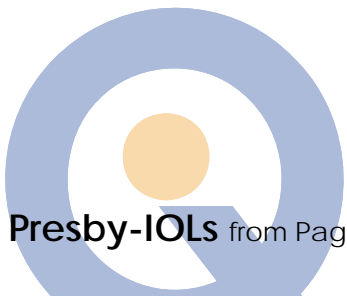
On the laser side of the refractive surgery world, ASCRS belonged to IntraLase and its new 60kHz femtosecond laser for flap creation. There continues to be noise on the competitive front, but nothing yet has risen to the level of a direct threat to IntraLase. On the excimer side, AMO/VISX has the most positive momentum, driven by building evidence that wavefront-guided ablations and iris registration are improving visual outcomes, and an improving market presence in Europe. With regard to overall US LASIK procedure growth, feedback from surgeons at ASCRS was very consistent: procedure volumes are running flat versus 2005 levels.

With its latest upgrade, which comes less than one year following the introduction of the FS30 30kHz system,

IntraLase has addressed the single most important issue that has been raised by current and potential customers: the need to bring flap-making speed up to a level that is competitive with bladed microkeratomes. The new system can create LASIK flaps in 15-20 seconds.

Early clinical experience with the 60kHz system suggests benefits beyond just speed. Other advantages seem to include faster visual recovery, improved early contrast sensitivity, reduced enhancement rates, less energy delivered into the cornea, and smoother and easier-to-lift flaps. The transition from 15kHz to 30kHz and now 60kHz has reduced post-operative inflammation as well as the incidence of transient light sensitivity syndrome (TLSS, or photophobia), a

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Presby-IOLs from Page 1

With regard to products in the pipeline, clinical data for the Tecnis Multifocal suggest that it will be a strong rival to the ReSTOR following its expected FDA approval in late 2007 or early 2008. Expectations are also building for the next two accommodating lenses in the pipeline: the Kellan Tetraflex single-optic IOL from Lenstec, and the Synchrony dual-optic IOL from Visiogen.

The relative merits of the three approved presbyopia-correcting IOLs are already well understood, consistent with data presented at ASCRS. ReSTOR provides the best near vision (particularly in bright light) and good distance vision, but is lacking at intermediate and can cause glare and halos. ReZoom is not as strong as ReSTOR at near, and unlike ReSTOR, it provides its best near vision in dim light. ReZoom is slightly better than ReSTOR at distance and notably better at intermediate; as a multifocal, it can cause glare and halos. Outcomes with the ReSTOR/ReZoom

combination are helped by the fact that for near tasks, ReSTOR performs best in bright light and ReZoom performs best in dim light, and for distance vision the opposite is true. crystalens avoids the compromises associated with multifocals and thus provides the best visual quality, but provides the least add-power of the three lenses and is thus the weakest at near.

Strategies for mixing and matching these IOLs are based on the relative strengths and weaknesses of these three lenses, and the particular needs of each patient (i.e., importance of close-up reading versus computer use, and sensitivity to glare and halos).

At an AMO-sponsored CME event, Frank Bucci, MD presented his findings from two cohorts of patients: 55 with

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How They Fared at ASCRS

Tracking the "Conventional Wisdom" in Refractive Surgery



Presbyopia Treatments

Presby-IOLs and RLE

The category is hot

ReSTOR

Better with ReZoom or crystalens

Multifocal/Presby-LASIK

The wrong tool for the job?

ReZoom + ReSTOR

The preferred mix/match combo

ReZoom

Better with ReSTOR

Tecnis Multifocal

Better than ReSTOR?

crystalens

Better with ReSTOR

Tetraflex and Synchrony

Promising products for 2008-09

NearVision CK

Still finding its niche

LASIK

IntraLase 60kHz

Now as fast as a blade, and better

LASIK Procedure Volumes

Flat versus 2005

Bladed Microkeratomes

OK, but yesterday's technology

Custom with Iris Registration

The technology keeps progressing

Wavefront Optimized

Better than standard LASIK

Standard LASIK

OK, but yesterday's technology

Ziemer DA VINCI FS Laser

FDA-cleared, but still untested

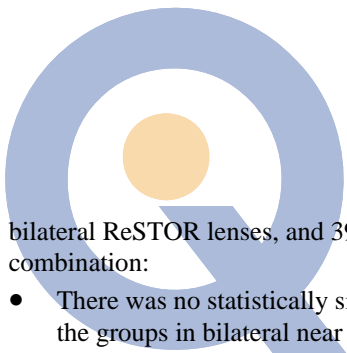
Phakic IOLs

Visian ICL

Preferred implantation approach

Verisyse

Anterior chamber, large incision



bilateral ReSTOR lenses, and 39 with a ReZoom/ReSTOR combination:

- There was no statistically significant difference between the groups in bilateral near vision: J1.00 for the ReSTOR group vs. J1.07 for the mixed group. Unilaterally, ReSTOR delivered mean near vision of J1.25, versus J1.56 for ReZoom.
- There was, however, a statistically significant difference in bilateral intermediate vision, with the ReSTOR group achieving an average of J3.81, versus J2.39 for the mixed group. Unilaterally, ReSTOR delivered mean near vision of J4.42, versus J3.03 for ReZoom.
- These findings are consistent with data presented in February at the World Cornea Congress in Brazil.
- The combination is leading to higher levels of spectacle independence and patient satisfaction.

ReSTOR: A Reality Check for the Market Leading Presby-IOL

We would not characterize this ASCRS as a positive event for Alcon's ReSTOR multifocal IOL, despite the fact that sales are growing rapidly and the likelihood that it will remain the market leading presby-IOL for the foreseeable future. ReSTOR was launched in the US one year ago, with a marketing message that characterized the lens as the all-in-one, single best, bilateral solution for cataract or RLE patients seeking accommodation or multifocality. After one year of real-world clinical experience, the reality has not lived up to the initial hype. Alcon is still expressing strong opposition to mix/match strategies involving the ReSTOR, arguments which surgeons are increasingly viewing as commercial rather than clinical.

Because it delivers the strongest near vision of the three approved presby-IOLs, ReSTOR has a secure place in the current product mix. In fact, many surgeons that are employing mix/match strategies start with a ReSTOR lens to assure that good close-up/reading vision is achieved. However, ReSTOR is not without compromise, the key drawbacks being inadequate intermediate (computer) vision, and the complications inherent to multifocals (glare/halos and loss of contrast sensitivity). Some bilateral ReSTOR patients use +1D or +1.25D reading glasses to adjust their distance vision to computer distance, while some others use -1D spectacle correction to extend their near vision to reach a computer screen.

Alcon plans to expand the ReSTOR product line with new products. Over the next twelve months or so, the company will likely introduce an "IQ" (aspheric) version of the lens that will make it more competitive with AMO's Tecnis multifocal. A toric version, which will take longer to bring to market, is also in the works.

crystalens: Focus on Mechanism of Action

It is generally known that most crystalens patients achieve greater accommodation than can be accounted for by the measurable forward/backward movement of the IOL within the eye. eyeonics came to ASCRS with the goal of shedding additional light on the mechanisms of action of the crystalens.

Measured forward movement of crystalens is in the range of 0.6-1.4mm, versus only 0.1mm for standard IOLs. In addition to forward translation of the optic, the following additional mechanisms were suggested in presentations by Drs. Steven Dell and Kevin Waltz:

- Accommodative arching: Increased depth of focus due to an accommodation-induced myopic astigmatism that results from bending of the flexible optic. Tracey wavefront analysis shows that the eye's natural lens generates a similar effect, with increased asymmetry and higher order aberrations during near accommodation.
- Tilt: Asymmetric forward translation of the optic that may also increase depth of field.

As with most matters related to the crystalens, surgeon reaction to the additional mechanism of action information was mixed. Some surgeons expressed appreciation for the new information and the scientific approach taken, while others expressed skepticism regarding the real impact of accommodative arching, as well as concern that the original mechanism of action communicated by the company does not seem to fully explain the accommodative effect.

Separately, data was presented showing that the 10-20% LASIK enhancement rate for crystalens patients is due to heightened patient expectations rather than unpredictable refractive outcomes. This rate of LASIK enhancement has been seen not only with crystalens, but with ReZoom and ReSTOR as well. According to Michael Colvard, MD, using the Zeiss IOL Master, the average difference between target and achieved refraction for the crystalens is only 0.12D, which is in line with the difference seen with standard IOLs.

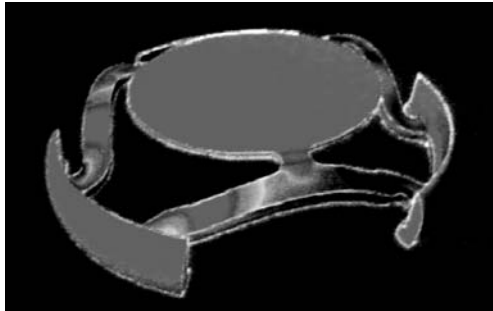
No look into the pipeline. When we saw crystalens surgical champion Steven Dell, MD on the ASCRS program, speaking on "The Pipeline of Accommodating IOLs," we were hoping to get a glimpse into the eyeonics product pipeline. However, the presentation described products under development by other companies, and eyeonics remains mum on future products.

Continued on next page

A First Look at the Bausch & Lomb OPAL Single-Optic Accommodating IOL

In EyeQ Report No. 3 on January 23, we updated Bausch & Lomb's stated plans to enter the accommodating IOL field through a staged approach involving both single-optic and dual-optic lenses. Bausch's primary entry in the accommodating IOL field is its Sarfarazi dual-optic lens, which is targeting 3D of accommodative amplitude like the Visiogen Synchrony, but appears to be at least a year behind Synchrony. The Sarfarazi lens has been implanted in humans, but the design has not yet been finalized, so the pivotal trial has not yet begun. Bausch hopes to reach this step by later in 2006. A European launch is targeted for the end of 2007, with a US launch possible 12-18 months thereafter (2009).

At ASCRS, we learned more about the single-optic accommodating IOL that Bausch has in-licensed. With targeted accommodative amplitude of about 1D, this product would be a direct competitor to the eyeonics crystalens and Lenstec Tetraflex. Bausch plans to launch this lens in Europe and Asia by the end of 2006 or early 2007. We have heard from some sources that Bausch has licensed technology from HumanOptics AG of Germany, maker of the Akkommodative 1CU lens, and is making its own modifications to the lens prior to OUS launch. However, the source of Bausch's single-optic technology has not been confirmed.



Bausch & Lomb OPAL Accommodating IOL

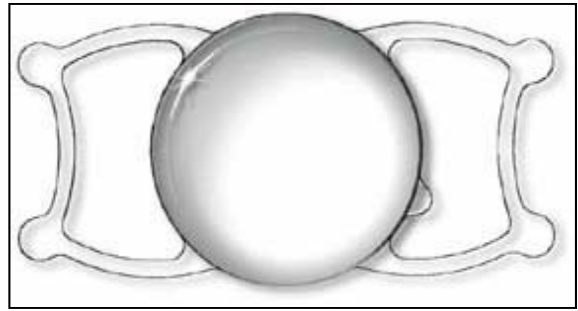
Bausch & Lomb's new lens, called OPAL, was discussed during a scientific presentation at ASCRS by Louis D. "Skip" Nichamin, M.D. The B&L OPAL more closely resembles the C-Well IOL from Acuity Ltd. of Israel than it does the Human Optics 1CU, but it is identical to neither lens. B&L's OPAL is a one-piece acrylic lens with a 5.5mm optic and a 9.7mm overall diameter, designed to vault anteriorly with a decrease in capsular bag diameter. The single-optic is supported by three "outrigger" haptics that are designed to aid centration within the capsular bag.

Data was presented from 55 patients enrolled unilaterally with the OPAL lens at three sites in the UK and Germany. Best distance-corrected near visual acuity (DCNVA) ranged from 20/25 (J2) to 20/159 (J14), with a median of 20/50 (J6). A subset of 20 patients from the UK achieved mean subjective accommodative amplitude of 2.3D (range of 0.6-5.8D) and mean objective accommodation of

only 0.50D (range of 0.2-1.6D). These initial outcomes fall short of the results achieved with crystalens, which delivers about 1D of objective accommodation and monocular distance-corrected near visual acuity of 20/40 or better in nearly 90% of eyes (median of 20/32).

Pivotal Trial Enrollment has Begun for the Kellan Tetraflex IOL

At ASCRS, we learned more about the Kellan Tetraflex single-optic accommodating IOL from Lenstec, which will likely be one of the next two accommodating IOLs that will become available in the US. The Tetraflex is an acrylic IOL with a 5.75mm optic and contoured haptics that incorporate a 5° forward angulation. The other accommodating IOL with a visible path toward US approval is the Synchrony dual-optic lens from Visiogen, which has shown monocular objective accommodative amplitude of nearly 3D in clinical studies, and has delivered monocular DCNVA of 20/40 in over 90% of eyes. Both the Tetraflex



Lenstec Kellan Tetraflex Accommodating IOL

and Synchrony lenses started enrolling pivotal US trials late last year, and both are targeted for approval in the US in the 2008-2009 timeframe.

Clinical data from the UK for about 100 eyes with Tetraflex lenses shows median DCNVA of about 20/40 (62% of eyes achieved DCNVA of 20/40 or better at 6 months or later). This is about one line better than the early data for the B&L OPAL lens but about one line worse than results achieved with the crystalens. Subjective accommodative amplitude averaged between 2D and 3D, similar to results seen with both crystalens and OPAL. We have not seen any objective amplitude data for the Tetraflex.

At a Lenstec-sponsored symposium, Paul Dougherty, MD described his comparative experience with crystalens (70 implants) and Tetraflex (10 cases). So far, Dr. Dougherty has observed potential benefits for the Tetraflex IOL in the areas of refractive accuracy, amplitude of accommodation and percentage of patients with meaningful accommodation, stability in the capsular bag, surgical technique, lens material, and optic size. Q



LASIK Update from Page 1

treatable complication that occurred in a small percentage of patients treated with earlier versions of the IntraLase system.

Winning over the skeptics. We have been following the IntraLase story for a long time, and have definitely encountered some skeptics within the refractive surgery community along the way. Sources of concern have included slow flap-cutting speeds and the effect on patient flow, high up-front cost with questionable economic payback, and uncertain clinical superiority versus bladed microkeratomes. With IntraLase's two product upgrades over the past year, the company is clearly winning over many of its critics.

We also sense that IntraLase has reached something of an inflection point in the US. Up until now, many LASIK surgeons acquired IntraLase lasers in order to differentiate their practices by offering the latest technology, with the goal of increasing their procedure volumes and market share, and generating higher profit per procedure. Now that IntraLase has further distanced its technology from bladed microkeratomes and has captured 25% of US LASIK procedures, many LASIK surgeons are acquiring IntraLase systems in order to defend their market shares against earlier acquirers, and to "sleep better at night" because they know it's best for their patients. Also contributing to interest in IntraLase is heightened awareness of the risk of corneal ectasia after LASIK, and the resulting desire to keep flaps as thin and consistent as possible to maintain the biomechanical stability of the cornea. We don't get the sense that many IntraLase users today believe that the technology is increasing either their procedure volumes or profit margins.

60k for 60k. The new 60kHz system lists for \$425,000. Owners of 15kHz systems can upgrade to 60kHz for \$60,000, and those that have obtained the 30kHz upgrade over the past year for \$50,000 can go the rest of the way for an additional \$10,000.

Therapeutic applications complement LASIK flap-making. IntraLase management says that about half of its users express interest in therapeutic procedures, with interest weighted toward international customers that tend to have more diverse corneal and refractive practices. The company is developing a number of therapeutic applications, including the cutting and shaping of grooved corneal transplants that fit precisely into a recipient's eye, potentially allowing removal of sutures within 2-3 months, versus the 12 months required today. Femtosecond laser technology will also find use in the creation of flaps and pockets for corneal inlays that are under development for the treatment of presbyopia and hyperopia. At a company-sponsored event, William Culbertson, MD, of Miami's Bascom Palmer Eye Institute, predicted that eventually 75% of therapeutic corneal surgery will be facilitated by the femtosecond laser.

Ziemer's DA VINCI Laser Receives FDA Clearance, but...

In the days leading up to ASCRS, Ziemer Ophthalmic Systems of Switzerland announced FDA 510(k) clearance of its DA VINCI Femtosecond Surgical Laser. The company was in order-taking mode at the convention, but we expect that Ziemer will pose little competitive threat to IntraLase over the near term. Although the system has been cleared by the FDA and the company is gearing up for a US commercial launch in June, the system is untested on sighted human eyes. Human eye treatment is just beginning, and no clinical data are yet available.

Key advantages that might appeal to some LASIK surgeons will be the smaller footprint of the laser and mobile capability. The swing-arm design will likely be of greatest benefit for Alcon, Bausch & Lomb, and WaveLight laser users (VISX users can swivel the chair between the IntraLase and VISX lasers). The current DA VINCI handpiece can only create a LASIK flaps; a different handpiece would be required for therapeutic applications.

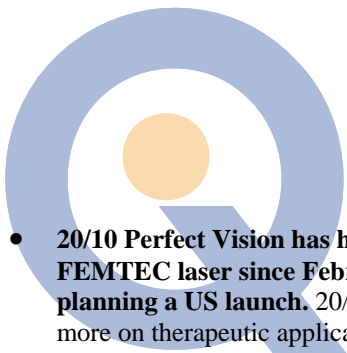
Much faster than IntraLase, but only half as fast? The company claims an extremely high pulse rate, in the megahertz range, implying a speed advantage over IntraLase. However, due to the ablation pattern delivered by the laser, actual flap creation time is about 40 seconds, versus 15-20 seconds for the new 60kHz IntraLase system. Ziemer claims that the faster pulse rate delivers less energy to the cornea and creates smoother flaps, but we have no data by which to compare flap quality at this time.

Ziemer plans to charge about \$400,000 for its laser and about \$260 per patient for disposables, which is comparable to IntraLase pricing. At these prices, it will likely be difficult for the company to place a significant number of lasers until favorable clinical experience on sighted human eyes is documented.

Other FS Laser Competitors in the Wings

- **We learned at ASCRS that Carl Zeiss plans to enter this market,** but the company is saying very little about its product at this time. Early indications are that the system will be more similar to IntraLase than to Ziemer. The company claims to have performed some early clinical trials, with more planned. No launch date or pricing has been announced. Carl Zeiss is a technology leader in several ophthalmic market segments, and has to be taken seriously as a potential competitor.

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- **20/10 Perfect Vision has had 510k clearance for its FEMTEC laser since February 2004, and is now planning a US launch.** 20/10 seems to be focusing more on therapeutic applications, viewing LASIK as a “commercial necessity.” The key differentiating feature versus other femtosecond lasers is the spherical patient interface that avoids flattening (applanation) of the cornea. Although a US launch did not seem to be in the cards last fall at AAO, the company now says it is planning a US launch for late 2006, and claims to be putting together US distribution at this time. The laser is selling for about €400,000 in Europe; plans call for a \$400-500,000 price tag in the US, including the patient bed. The laser creates a flap using a spiral cut, requiring 30-60 seconds for flap creation. Again, without a more attractive price point than IntraLase, the selling proposition to US refractive practices appears to be less than compelling.
- **Last fall at AAO, WaveLight announced plans to introduce a femtosecond laser in 2006,** but provided no updated information at ASCRS and is not committing to showing a product at this year’s AAO.

More Cautious View of Presby-LASIK

It is our sense that refractive surgeons are not yet convinced that presby-LASIK, involving the ablation of a multifocal pattern into the cornea, is the best way to achieve multifocality for the presbyopic patient. This is beginning to feel like one of those procedures that surgeons might be hesitant to have performed on themselves or their family members.

The timeline for expected FDA approval of the AMO/VISX multifocal treatment pattern for hyperopic presbyopia may be slipping. As recently as the AAO meeting last fall, approval was slated for 2007-2008. AMO is now positioning this as a 2008 product in the US. There was some initial data presented at ASCRS from a European study of a VISX-designed multifocal treatment for myopic presbyopes, but AMO management considers the myopic treatment a much longer-term development project.

A number of presentations at ASCRS highlighted the long visual recovery time that is being observed in presby-LASIK patients. Refractive stability is occurring at 6-12 months or more post-op, which is a departure from the rapid visual recovery that has contributed to the LASIK “wow factor.”

The number of re-treatments in many presby-LASIK studies has been high. In an Italian study of the VISX multifocal treatment for myopic presbyopia, there was a 15% re-treatment rate. In a French study of a multifocal treatment

using the Nidek laser, 17% of patients required one re-treatment, and 2% required two or more. An Indian study of the Nidek multifocal treatment reported a 34% enhancement rate.

Excimer Laser Competitive Updates

- **AMO/VISX appears to have the most momentum among the excimer laser manufacturers at present.** This is particularly true in Europe, a part of the world where VISX historically underperformed and where the AMO sales and marketing infrastructure is making a big difference. In the US, where change is more incremental, the steady stream of clinical evidence supporting the value of custom treatments and iris registration are working in the company’s favor.
- **Alcon is still awaiting FDA approval for its LADAR 6000 system,** and will probably remain in something of a “holding pattern” until approval is received. We highlighted this new system in EyeQ Report No. 3 in January. Alcon was already awaiting final approval of this system at that time, having received an approvable letter in November. The LADAR 6000 is a completely new system, with advantages in the areas of speed, ergonomics, and service, and with 80% new components that are not part of the LADARVision 4000. However, surgeons may still view the new system as more incremental than revolutionary. Rather than conceding defeat to AMO/VISX in the excimer laser market, we have heard that Alcon is hiring and investing in its Orlando Technology Center, and is developing an entirely new system that will replace the LADAR 6000 within a few years.
- **WaveLight has been placing ALLEGRETTO WAVE lasers into the crowded US market at a healthy pace** of about 50 per year in the 2 ½ years since the product received FDA approval. The laser is premium priced at over \$400,000, and users seem happy with it, particularly for the treatment of hyperopia. AMO/VISX has placed a high priority on differentiating its “wavefront-guided” technology from WaveLight’s “wavefront-optimized” approach, although WaveLight has developed a wavefront-guided system that has not yet been approved in the US. It will likely be difficult for WaveLight grow its rate of US laser placements in the face of continued product improvements and label expansions by its US-based competitors.
- **Just prior to ASCRS, Bausch & Lomb announced FDA approval of its 100 Hz Zyoptix excimer laser.** The new system, which can be installed as an upgrade to current Zyoptix lasers, cuts LASIK treatment time in half. The system will be commercially available in the US in July. Q



Visian ICL Receives Favorable Reception at ASCRS

After a lengthy regulatory review process that culminated in an FDA approval in December 2005, STAAR Surgical was finally able to launch its Visian ICL at a major cataract and refractive meeting. Although the Visian ICL went before an FDA advisory panel 2 ½ years ago, in October 2003, four months prior to AMO's Verisyse panel meeting, Verisyse received FDA approval in September 2004, more than a year earlier than the Visian ICL approval.

We've long believed, and still believe, that (1) phakic IOLs (PIOLs) will be a niche market, reserved mostly for the small population of high myopes, -8D and beyond, and (2) the Visian ICL will be preferred over the Verisyse, mostly due to familiar surgical technique.

With regard to the potential market for the Visian ICL, a lot has happened in the 2 ½ years since the FDA panel meeting. On the positive side, the presby-IOL wave has raised awareness regarding lens-based refractive surgery, and has set a precedent for the Visian ICL's \$800 price tag. Also, heightened awareness regarding conreal ectasia following LASIK might tip the scales away from LASIK and toward phakic IOLs in high myopes and patients with thin corneas. Although AMO had more than a one-year head start in the US phakic IOL market, the company has downplayed Verisyse results, suggesting only modest uptake of the

anterior chamber lens. Feedback from surgeons at ASCRS suggests a greater comfort level with the Visian ICL's cataract-like surgical technique, posterior lens placement, and smaller sutureless incision.

On the negative side, LASIK outcomes for high myopia have continued to improve, particularly with wavefront-guided technology. Also, the high-hyperopia niche will likely be dominated not by phakic IOLs but by refractive lens exchange using presbyopia-correcting IOLs, since this is an older patient population.

The Visian ICL US rollout is underway. Prior to ASCRS, 57 surgeons in the US had been fully proctored and had implanted lenses; about 1,000 have been through the first phase of didactic and lab training. Proctoring for the Visian ICL involves a hands-on training process in the OR during a surgeons' first several lens implants. STAAR Surgical hopes to have about 500 surgeons proctored by the end of 2006. Surgeons are pricing the surgery to patients in the range of \$3,500-4,000 per eye. Although most PIOLs will likely be used in high myopes (at least -8D), some procedures will migrate down to as low as -3D due to quality-of-vision advantages over LASIK and corneas that are too thin for LASIK. Some procedures are already being performed down in this "LASIK sweet spot" range, although STAAR Surgical is not breaking out the percentages. Q





Highlights from the 2005 ASCRS Refractive Surgery Survey

The annual “US Trends in Refractive Surgery” survey, conducted by Drs. David Leaming and Richard Duffey, incorporated responses from 723 ASCRS members (16% response rate). The survey was distributed in August 2005, and represents an early-fall 2005 snapshot of opinions.

More detail can be found at www.leadingsurveys.com and at www.duffeylaser.com/physicians_resources.php.

Some highlights:

1. Preferred Surgery for a 30 y/o -10D Myope (2005)

LASIK	25%	Refractive Lens	
Surface Laser	8%	Exchange (RLE)	5%
Phakic IOL	24%	Wait	36%

2. Preferred Surgery for a 45 y/o Hyperope

	+3.0D			+5.0D		
	2003	2004	2005	2003	2004	2005
LASIK	69%	62%	47%	14%	12%	8%
Surface Laser	4%	5%	6%	1%	1%	0%
Phakic IOL	4%	4%	2%	8%	8%	6%
RLE	9%	11%	22%	45%	42%	49%
CK	2%	3%	0%	---	---	---
Wait	12%	17%	24%	33%	37%	36%

Our comments on #1 and #2 above: LASIK remains the overwhelming choice for low to moderate myopia and the first choice for low to moderate hyperopia. For high myopia (-10D), waiting (doing nothing) is the first choice and surgeons are evenly split between LASIK and PIOLs. For moderate hyperopia (+3D), refractive lens exchange is gaining ground and LASIK is losing ground; the percentage of surgeons that would recommend waiting has doubled, possibly indicating some confusion over the increasing number of available options. For high hyperopia, LASIK is becoming a less popular choice, and RLE and waiting remain #1 and #2, respectively. From these responses, it is clear that surgeons view PIOLs as a solution for high myopes, and RLE as a solution for moderate-to-high hyperopes.

3. Excimer Laser Used Most

Results have been relatively steady over the past three years. In 2005, VISX was up slightly to 73%, Alcon down slightly to 16%, Bausch & Lomb up slightly to 7%, WaveLight up slightly to 3%, and Nidek down slightly to 1%.

4. Present or Future Refractive Plans

	2003	2004	2005
LASIK	85%	78%	59%
Epi-LASIK	---	---	35%
Corneal Inlays	---	---	12%
CK for Hyperopia	43%	43%	26%
CK for Presby.	---	---	33%
Phakic IOLs	79%	76%	61%
RLE	86%	85%	71%

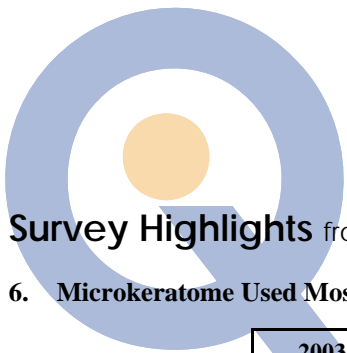
Our comments: These results are promising for both PIOLs and RLE, although it is unclear why the percentages were lower in 2005 versus 2003-2004. Results are also encouraging for CK presbyopia and for corneal inlays. The drop in the percentage of surgeons that plan to perform LASIK is surprising, and either represents a shift in focus toward intraocular approaches, or is an artifact of the inclusion of Epi-LASIK in the 2005 survey.

5. Preferred Surgery for Presbyopia

	2004	2005
Array	7%	2%
ReSTOR	5%	18%
Accommodating (crystalens)	17%	4%
CK	7%	4%
ReZoom	0%	1%

Our comments: ReSTOR was the big winner in the 2005 survey, at the expense of all other options. Note, however, that the survey was conducted in the fall of 2005, when Alcon was heavily promoting ReSTOR as the one-size-fits-all solution for presbyopia, and AMO had barely begun to market the ReZoom lens (which barely registers at all). We would expect to see ReZoom and crystalens close the gap with ReSTOR in the 2006 survey this fall.

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Survey Highlights from Page 8

6. Microkeratome Used Most

	2003	2004	2005
Hansatome	53%	47%	43%
Amadeus	13%	13%	14%
IntraLase	3%	8%	13%
Moria	26%	24%	23%

Our comments: IntraLase is clearly taking share from the Bausch & Lomb Hansatome, although the survey result understates IntraLase’s share of US procedures as of mid-late 2005. Moria seems to be losing some ground, and the AMO Amadeus is holding steady.

7. Wavefront-Guided Custom Ablations in Your Practice

	2003	2004	2005
0%	48%	25%	26%
1-10%	14%	8%	8%
11-25%	12%	13%	8%
26-50%	13%	12%	8%
51-75%	8%	14%	12%
76-100%	4%	29%	38%
Blended Average	17%	42%	49%

Our comments: Custom LASIK made more headway in 2005. While the percentage of surgeons performing wavefront-guided LASIK remained steady at about 75%, overall penetration increased. The “blended averages” in the table were approximated using the midpoints of each of the ranges listed in the left-hand column. Q

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