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Accommodating IOL: ASCRS Comeback Player of the Year

One year ago, at the ASCRS meeting in San Francisco, presbyopia-correcting IOLs were the hot product category, and prospects for continued market growth looked promising. The ReSTOR and ReZoom multifocal IOLs attracted nearly all of the attention, supported by huge marketing efforts from Alcon and Advanced Medical Optics (AMO), respectively. (See EyeQ Report No. 5, at www.EyeQReport.com.) The big controversy at the meeting was whether or not physicians should consider "mixing and matching" these two multifocal IOLs in a single patient, in order to mitigate some of the drawbacks of each lens. Lost amidst this well funded marketing battle was the crystalens accommodating IOL. One year ago, eyeonics was focused on explaining the mechanism of action of this lens to doubting surgeons.

One year later, in the spring of 2007, market growth in the presby-IOL category has stalled at about 4-5% penetration in the US, and crystalens has begun to reclaim share from the multifocals. Market segment growth actually began to hit the brakes during the second half of last year. As an illustration of this decelerating growth, Alcon ReSTOR worldwide sales of $102 million for 2006 were double the full year sales in 2005, but by the fourth quarter of 2006 the year-over-year growth rate had slowed to only 5%. Alcon did not break out ReSTOR sales for Q1-2007, but it is safe to assume that ReSTOR sales were flat at best versus Q1-2006.

We highlighted some of the key reasons for slowing presby-IOL market segment growth six months ago in our AAO recap report: the need for surgeons to spend significantly more chair time with patients, higher patient expectations due to out-of-pocket payment, lack of consumer awareness, and presby-IOLs that have not lived up to expectations.

Even the New and Improved Multifocals are Still… Multifocals

At this year's ASCRS, the most notable development was a renewed appreciation for the fundamental drawbacks and limitations of multifocal IOLs: glare and halos, "waxy" or "Vaseline" vision, loss of contrast sensitivity, time required for neuroadaptation (and the inability of a small percentage of patients to adapt at all), and in the case of ReSTOR, compromised intermediate vision. A longer term concern regarding multifocal IOLs is the impact on vision if a patient eventually develops macular degeneration. At the same time, a number of product changes have improved the performance of the accommodating crystalens, which does not suffer from the fundamental drawbacks that are associated with multifocal IOLs.

Over the past year, the "ideal" presby-IOL treatment has shifted from the mix/match combination of ReSTOR/ReZoom to bi-lateral crystalens, often with a small amount of monovision dialed in. In terms of actual implant volumes, bilateral

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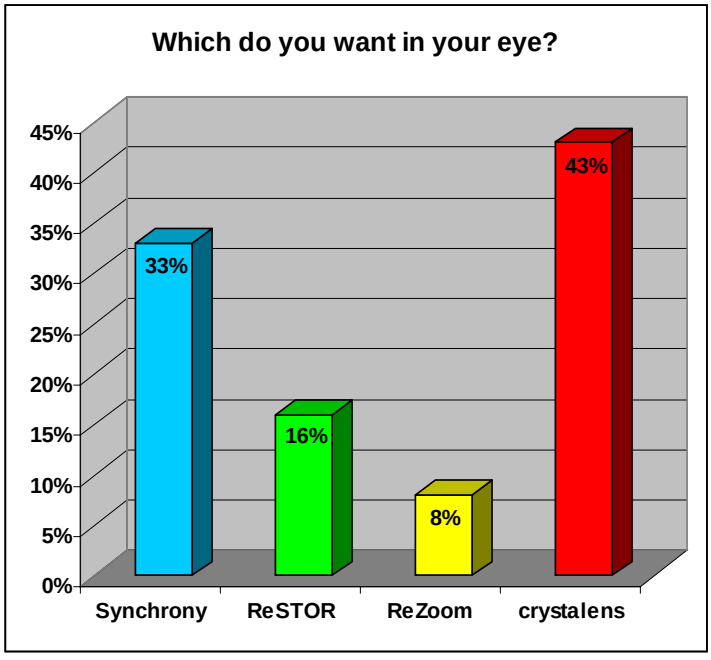
ReSTOR has remained the market leading lens combination during this entire time period, driven by Alcon's strong position in the cataract market. Although the mix/match combination of ReSTOR/ReZoom has never been used in a high percentage of patients, clinical experience presented at last year's ASCRS provided evidence that, for many people, outcomes were better with this combination of multifocals than with either one implanted bilaterally.

Exiting this year's ASCRS, our impression is that the current "state-of-the-art" in presby-IOL treatment is bi-lateral crystalens Five-O, with about -0.75D of monovision in the non-dominant eye to enhance reading vision. While crystalens is still far from being the market share leader, it is clearly taking share from the multifocal competition. In the first quarter of 2007, while multifocal IOL sales were flat at best, crystalens sales grew 36% versus Q1-2006 to $5.5 million, and implants were up 45%.

An audience poll taken at the end of this year's ASCRS meeting illustrates how much attitudes have shifted away from multifocals and in favor of accommodating IOLs. At the Clinical Carryout Session, surgeons in attendance were asked which of four lenses they would want in their own eye. At 4:15pm on the final day of the conference, those still in attendance were probably not a representative sample of cataract and refractive surgeons, or even of ASCRS attendees. But the number of voters was large (about 180) and this was not a company sponsored session, making the results even more remarkable:



Source: ASCRS Clinical Carryout Session, May 1, 2007

Accommodating IOLs received 76% of the votes, with only 24% of votes going to multifocal IOLs. crystalens placed first with 43% of the votes, and even the Visiogen Synchrony dual-optic accommodating IOL, which is still in a pivotal US clinical trial, attracted twice as many votes as the market-leading ReSTOR.

The mix & match furor has died down, and has transformed from a passionate debate to a more pragmatic one. Mixing and matching of presby-IOLs has been employed by only a minority of surgeons, but it has become generally accepted that it is an attractive option for some patients that are less than fully satisfied with the visual outcome from their first treated eye. David F. Chang, MD suggested during an EyeWorld symposium that mix/match may also be a good choice for younger patients that have researched all of the lenses extensively and just cannot decide on one of them. Within the mix & match debate, it would seem that the "odd man out" is the ReZoom multifocal IOL, which provides neither the visual quality of crystalens nor the extreme near/reading vision of ReSTOR.

crystalens Product Improvement Continues

In the 3 ½ years since crystalens received FDA approval, a number of product improvements have enhanced performance of the product and addressed physician concerns. First, a square-edge design eliminated PCO and "Z syndrome." At last year's AAO in November, eyeonics introduced the crystalens Five-O, which features a larger 5.0mm diameter optic, and rectangular plate haptics that allow for greater movement of the lens. The Five-O lens is easier to implant and more stable within the capsule.

The next product enhancement for the crystalens is the "HD-100," which incorporates a small aspheric surface in the center of the optic. This approach aims to create a small amount of additional near-add, to potentially improve reading vision by about one line. This lens could be implanted bi-laterally or just in the non-dominant eye. Anecdotally, results so far are very encouraging. A clinical trial of the HD-100 is ongoing, and the product could be available next year.

ASCRS Promotes Presbyopia-IOL Surgery

Outgoing ASCRS president Samuel Masket, MD hosted a press conference at which he detailed efforts that the Society is undertaking to encourage adoption of presbyopia correction technology. Key elements include: (1) assessing public awareness and knowledge of presbyopia through a

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Harris Interactive survey; (2) providing information through a new web site, www.readclearlyagain.org; and (3) development of a presbyopia "branding" program akin to the "E.D." branding that supported the marketing of such products as Viagra.

ASCRS worked with Harris Interactive to conduct a poll of 500 adults in the general population (aged 45-64) and 250 patients who have undergone surgical treatment to correct presbyopia with either a multifocal or accommodating IOL. Topics included awareness of presbyopia and the impact of presbyopia correction surgery on quality of life. Results of the survey are available on the new ASCRS web site at www.readclearlyagain.org/results.html.

The first takeaway from the survey is that there is a low level of awareness and understanding of presbyopia: 79% of the general population, and even 56% of those treated with presbyopia-correcting IOLs, are not at all knowledgeable about presbyopia.

Quality of life survey results for presby-IOL patients are encouraging, but the lack of monovision or monofocal control groups makes the results difficult to interpret:

	Great difficulty before surgery	No difficulty after surgery
Reading print in newspapers or magazines without glasses	70%	49%
Reading a menu at a reataurant	57%	51%
Driving without glasses	55%	71%
Doing work or hobbies	50%	51%

Source: ASCRS Harris Interactive Survey of 250 Presby-IOL Patients

Note that in the table above a relatively high percentage (55%) of presby-IOL patients reported great difficulty driving without glasses prior to surgery. Driving is a distance task, not a near task, suggesting that much of the pre-op visual impairment, even for near tasks, may have been the result of a cataract, and not necessarily due to presbyopia.

IOL-based presbyopia correction received high marks on a number of other quality of life metrics: 64% of respondents said that the procedure had a major positive impact on their lives, and 84% strongly agree that they would recommend it to others. However, standard monofocal cataract surgery also has a major positive impact on patients' quality of life, so any incremental benefit of presbyopia-correcting technology is impossible to quantify without a monofocal control group. Also, cost was not addressed in the survey, so no conclusions can be drawn from the data regarding cost/benefit perceptions of premium IOL surgery.

Dell Provides Inside Intel on Presby-IOL Patient Selection and Counseling

At an EyeWorld educational symposium, Steven J. Dell, MD provided useful insights into Presby-IOL patient selection and counseling. The Dell Survey (www.crstoday.com/Pages/DellIndex.doc) is a widely used questionnaire that helps surgeons assess which patients might or might not be suited to presbyopia-correction surgery, and to determine which lens is the most appropriate. The survey itself has value in communicating to patients upfront that there are trade-offs and compromises. Some of Dr. Dell's observations and conclusions:

- Presby-IOL patients are generally happy, regardless of the IOL used, when refractive targets are hit precisely.
- Surgeons should tell patients that there will be some spectacle use post-op; the goal is to reduce dependence on them.
- It has been assumed that perfectionists are tougher to please than "easy-going" patients. But in a study of Dell's own patients, the perfectionists scored slightly higher on overall happiness, perhaps because they received more intensive counseling. This suggests that even "easy-going" patients require attentive consultations. Interestingly, the least happy patients were the ones that rated themselves right in the middle of the perfectionist scale - perhaps these are indicative of passive/aggressive people "not cooperating with the form." **Q**

The Case for Pseudophakic Monovision for Cataract Patients

William F. Maloney, MD presented a compelling case for IOL-based monovision as the current gold standard in presbyopia correction for cataract patients. He characterizes pseudophakic monovision as the best choice for the vast majority of patients, and the only choice for many patients. According to Maloney, none of the three currently approved presby-IOLs is an off-the-shelf solution for every patient, capable of delivering the full range of near-to-far accommodation. Once such a solution becomes available (likely at least ten years away), the surgeon's role will simply be to safely implant this lens. In the meantime, pseudophakic monovision provides the ability to tailor focus zones to the individual needs of the patient.

According to Maloney, probably the greatest lesson learned about multifocal IOLs over the past year is the extent to which neuroadaptation represents a challenge for patients. The process takes about nine months, and given the lack of physiologic precedent, it's a testament to the adaptability of the visual cortex that this is ever accomplished at all. Maloney has treated close to 3,000 patients over the past 20 years with pseudophakic monovision, and says that adaptation typically takes 1-2 days because it relies on "binocular rivalry," which the brain is hard-wired to handle.

Maloney draws a clear distinction between optometric (contact lens-based) monovision and surgical (pseudophakic/LASIK/CK) monovision. The difference mostly comes down to the trial-and-error approach usually employed for contact lens wearers, versus the methodical pre-op evaluation ("presbyometry") that is appropriate for surgical patients. As an example, optometric monovision generally relies on sighting dominance alone, while a full surgical monovision work-up also incorporates sensory and oculomotor dominance. This difference is driven mostly by economics and the "time value of testing." While doctors fitting contact lenses generally cannot charge for all of this extra work, the CMS decision to allow up-charging of Medicare cataract patients for presbyopia correction makes the additional testing financially feasible for the surgeon. One of the paradigm shifts at work here is that Dr. Maloney charges patients an out-of-pocket fee to cover these extra refractive-based services (less than the typical up-charge associated with the premium IOLs), despite the use of standard monofocal IOLs.

At the Cornea Day program, Robert J. Cionni, MD suggested that monovision with monofocal IOLs is probably the best choice for patients that have had success with monovision before.

While Maloney's talk was focused on the use of standard monofocal IOLs in pseudophakic monovision, it seems to follow that "modified monovision" using crystalens would represent an attractive alternative. The use of premium IOLs would lead to a higher overall procedure cost, but the accommodative function of the lens allows the surgeon to target a myopic defocus of about 0.75D, versus the need for 1.5D or more myopic defocus using standard IOLs. **Q**

Update: CustomVue, Multifocal LASIK, and CK for Presbyopia

AMO expects to receive FDA approval for monovision CustomVue treatment this year. At ASCRS, favorable results were presented from the US clinical trial for correction of myopic presbyopia using wavefront-guided monovision LASIK. In the study of 160 patients, up to -2.0D of myopia was targeted in the non-dominant eye to provide near vision. Patients with intolerance to monovision, determined using a contact lens trial, were excluded. At 12 months, 20/20 or better visual acuity was achieved in 93% of patients at distance, 87% of patients at intermediate, and 92% of patients at near. Binocularly at 12 months, simultaneous distance and near vision of 20/20 or better was achieved in 86% of patients; 97% achieved 20/25 or better. Patient satisfaction was very high: 98% of patients said that they would have the procedure again, and at six months 99% said that they were either satisfied or very satisfied with depth perception.

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LASIK & CK for Presbyopia from Page 4

W. Bruce Jackson, MD provided an update of the AMO/ VISX clinical trial of aspheric/multifocal LASIK for hyperopic presbyopes. AMO expects FDA approval of this procedure in 2009. Visual acuity outcomes remain encouraging, while patient satisfaction results and surgeon attitudes toward the procedure continue to leave us cautious regarding eventual adoption. In patients receiving aspheric LASIK treatment bilaterally, at 12 months, 100% of patients achieved both 20/25 distance and J3 near or better; 87% achieved 20/25 and J1 or better. At 12 months, among patients with bilateral aspheric LASIK, 56% reported spectacle use for reading (near task) and 42% were using spectacles for the computer (intermediate task). 16% reported being somewhat/ very dissatisfied with night vision, versus only 9% pre-op with correction. Rates of dissatisfaction were notably higher post-op versus pre-op for both near and distance vision in dim light. Iris registration technology, which was introduced during the course of the study, does improve results. Investigators have noted that patient satisfaction is higher with bilateral aspheric treatment, and that many patients have said that they would be happier with a greater amount of near-add.

Also at ASCRS, we got an early look at the Bausch & Lomb Zyoptix approach to multifocal LASIK for hyperopic presbyopia. The approach is similar to the one employed by VISX, with the peripheral cornea corrected for distance and the center corrected for near vision. In a 32 patient feasibility trial, 80% of patients achieved distance VA of 20/25 or better along with near visual acuity of J1.

At ASCRS, Refractec introduced the OptiPoint Corneal Template, which should be available by this summer. This product is designed to make it easier for surgeons to perform NearVision CK by providing more accurate centration and more consistent spot placement and depth control. The device also minimizes variations in hand position, and helps standardize tip pressure using the LightTouch technique. All of this will likely shorten the learning curve for new surgeons adopting NearVision CK, and should lead to more consistent outcomes. **Q**

Competitive Developments in the Femtosecond Laser Market

IntraLase is now part of AMO/VISX, and the company continues to penetrate the worldwide LASIK flap market with its 60kHz femtosecond laser. AMO is already working to leverage the full product bundle: we heard from multiple sources that, in select markets, the company is offering attractive discounts to customers that acquire both a VISX STAR S4 excimer laser system and an IntraLase system.

Carl Zeiss Meditec is planning a worldwide launch of its VisuMax system at the AAO meeting this fall. Initial marketing efforts will focus on the US and Europe, with Asia to follow. The initial focus outside the US will probably be customers that already own a Zeiss MEL-80 excimer laser. The key point of differentiation of the VisuMax system will likely be precision: anecdotally, flap thickness precision is on the order of 3µ, versus about 15µ for other FS lasers. At ASCRS, three scientific papers were presented that reported excellent outcomes in about 60 LASIK eyes.

Ziemer Ophthalmic Systems has launched its FEMTO LDV (previously called DA VINCI) femtosecond laser system in both the US and Europe. The company has re-acquired marketing rights to the Amadeus II microkeratome from AMO, and has opened a sales and service office in St. Louis. The key points of differentiation of the FEMTO LDV system are portability (for multi-room and multi-site users) and small footprint (which improves patient flow by allowing the femtosecond laser to be placed alongside the excimer laser). At ASCRS, two scientific papers were presented that reported satisfactory outcomes in 142 LASIK eyes.

20/10 Perfect Vision is still planning an eventual launch of its FEMTEC system in the US, likely with a marketing partner, with a focus on LASIK flaps. However, commercial efforts are still limited to Europe and Asia today, with a focus on therapeutic applications such as corneal transplant and creating channels for Intacs. The key point of differentiation of the FEMTEC system will likely be the spherical, non-applanating patient interface. The company is currently awaiting FDA clearance for upgrades that will make the system faster, and thus more competitive for LASIK. At ASCRS, three scientific papers and one poster were presented that reported experience with therapeutic applications. **Q**

Alcon and AMO Analyst Meeting Highlights

Alcon Analyst Meeting Highlights

The launch of Alcon's toric IOL is progressing very well, aided by the recent dual aspect reimbursement decision by CMS. Alcon presented survey results showing about 90% intended usage for Alcon's product, versus only about 10% for the Staar Surgical toric IOL offering. Prospects for continued growth are strong: 30% of surveyed surgeons currently implant toric IOLs, and 76% expect to utilize them over the next 3-6 months.

Alcon is developing a 3.0 diopter-add version of its ReSTOR multifocal IOL, which should be available in Europe by early 2008 and in the US by mid-2008. The current ReSTOR features a near-add of +4.0D, which provides the best near vision of any premium IOL but lags the competition at intermediate distance. The new +3.0D version pushes out the near-vision focal point by about 2.5 inches; some surgeons will likely implant some patients with the +3.0D version in one eye and the +4.0D in the other eye, which Alcon will position as "harmonization" rather than "mix and match." Alcon also acknowledges the need for a toric version of ReSTOR, given the importance of astigmatism correction in multifocal IOL patients.

Alcon's anterior chamber angle-supported phakic IOL should be available by the middle of this year in Europe. US approval will take much longer, due to the likely need for three year follow-up in the clinical trial.

Alcon management believes that resolution of the LADAR6000 situation could come very soon. On February 21, Alcon issued a safety alert directing customers to discontinue using the machine for myopic CustomCornea procedures. Alcon feels that it was acting "with an abundance of caution" when it issued the alert based on a small number of cases, and the FDA is proceeding with more caution than the company had expected. Alcon has submitted a PMA supplement to the FDA with data and proposed corrective actions, and is in the process of changing the speed and ablation pattern of the system.

AMO Analyst Meeting Highlights

AMO's analyst meeting began with a presentation of the advanced aberrometer technology that came to the company via the January 2007 acquisition of WaveFront Sciences, the world's leading manufacturer of wavefront sensor products. Prior to the AMO acquisition, WaveFront Sciences' revenue run rate was about $7 million, and growing. This acquisition, however, has less to do with direct product sales than it has to do with technology synergies with the rest of AMO. These synergies include IOL metrology for both R&D and manufacturing applications, and vision diagnostics (such as accommodation measurement and refraction accuracy) to help evaluate a wide range of AMO products.

David F. Chang, MD presented the new WhiteStar Signature phacoemulsification system with "Fusion Fluidics." The most notable feature of this new system is the incorporation of dual pump technology: surgeons can switch "on the fly" between a slower, safer peristaltic pump and a faster, more efficient Venturi pump. The new system will also incorporate a number of features that will significantly improve the set-up process: a one-step, auto-loading tubing pack, a faster prime cycle, and one-step surgeon programming. The system retains the core WhiteStar safety benefit of reduced energy delivery and heat generation. AMO will begin shipping the new WhiteStar Signature System during the second half of 2007. **Q**

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