# Trends-in-Medicine

**May 2007**

*by Lynne Peterson*


## SUMMARY

LASIK procedure volume is flat and likely to remain that way this year, and surgeons are dubious about presbyLASIK. ♦ Multifocal IOL use is flat and unlikely to pick up without new and better technology. Cost, physician issues, lack of consumer awareness, and lack of a "wow" factor are limiting use. ♦ *Acanthamoeba* keratitis appears due to changes in water treatment, not corneal staining, silicone hydrogel lenses, or differences in contact lens solutions, none of which kill it. ♦ Some experts are excited about new corneal inlays, especially those from AcuFocus, but the data are very limited and early. ♦ Increasingly, a femtosecond laser is a must-have, for marketing purposes if nothing else, and AMO/IntraLase remains the 900-pound gorilla, but there is still a market for other femtosecond lasers, and Ziemer has started making U.S. sales. 20/10 Perfect Vision and Zeiss are not yet selling their femtosecond lasers in the U.S. ♦ China is a growing but challenging market, and companies are having varying degrees of success there.





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## AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY (ASCRS)

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Thirty cataract and refractive surgeons were interviewed at ASCRS, and they painted a picture of a fairly stable but unexciting market. Both the premium IOL market and LASIK procedure volume are holding fairly steady. While there are small share shifts going on among the vendors, there was no new technology that captured everyone's attention or is poised to be a game-changer, at least in the near term.

### CORNEAL STAINING

Optometrists have been reporting a growing incidence of corneal staining, and different brands of contact lens solution have different rates of corneal staining, with many believing B&L's ReNu has the highest rate. The ***potential*** negative side effects from corneal staining are primarily blurred vision, discomfort, irritation, infection, and keratitis. But corneal staining can also compromise corneas, mildly decrease vision, and cause dry eye, edema, and even corneal ulcers. It can also lower contact lens wearing time. Optometrists have been divided on what is ***mostly*** to blame for corneal staining: a particular contact lens, a particular contact lens solution, silicone hydrogel lenses, a combination of lens and solution, dehydration, dry eye, lack of patient compliance, patients wearing contact lenses too long (over wear), and/or poor patient hygiene.

Cornea specialists and general ophthalmologists at the ASCRS meeting were asked about this problem, and most of them said they hadn't even heard about the issue. They were unaware of the debate raging in the optometric community and said they are not seeing these patients, that they are not being referred to them. There simply was no buzz about this issue at all at ASCRS. A New York doctor said, "A lot of corneal staining is due to the iron content of tears, not contact lens solutions." Another specialist said, "Corneal staining has a lot to do with patient compliance, over-wearing lenses, and using old eyeliner…It could be the solution or the lenses, but don't leave out patient factors or fitting – and patients with dry eye are being inappropriately fitted (with contact lenses)." A Virginia doctor said, "I don't see a significant issue with corneal staining. It is not a big level of concern." A Midwest doctor said, "We all have corneal staining patients, but you can't relate that to contact lens solutions." Dr. Elmer Tu of the University of Illinois at Chicago warned, "*Acanthamoeba* can look like corneal staining. If the staining doesn't resolve, *Acanthamoeba* should be considered."

## KERATITIS

Bausch & Lomb recalled its ReNu with MoistureLoc contact lens solution from the market in 2006 after an outbreak of *Fusarium* keratitis, but cases of *Fusarium* still occur, though the levels have dropped back to normal or near-normal. Then, in November 2006 Advanced Medical Optics (AMO) recalled 18 lots (nearly 200,000 packages) of 12-ounce Complete MoisturePlus multipurpose contact lens solution and Complete MoisturePlus Active Packs due to possible bacterial contamination. AMO blamed production-line problems at a manufacturing plant in China that supplied both Japan and the U.S. for the problem.

Dr. Eduardo Alfonso of Bascom Palmer Eye Institute said the risk factors for *Fusarium* keratitis are:

- 45% trauma
- 12% previous eye surgery
- 10% topical medications (especially corticosteroids)
- 33% Medical problems (e.g., diabetes, HIV)

Dr. Alfonso described the results of a test of the ability of various contact lens solutions to kill *Fusarium solani* when Johnson & Johnson's Acuvue lenses were soaked in the solutions from 1 hour to 7 days. He concluded, "I think the multipurpose solutions all have a problem…The way they led patients to stop doing some of the common things they were doing before, like rubbing the contact lens to dislodge organisms that were attached, not cleaning the contact lens cases, topping off the contact lens cases…I think those things are all common with contact lens users…I'm not seeing an epidemic proportion of cases, but I am still seeing *Fusarium* and other organisms, including *Acanthamoeba*."

- Alcon's Opti-Free Express and Opti-Free Replenish – maintained fungicidal activity.
- Bausch & Lomb's ReNu – significant uptake of preservative into lenses resulting in a decrease in the fungicidal activity.
- AMO's Complete – significant uptake of preservative into lenses resulting in a decrease in the fungicidal activity.

*Acanthamoeba* is the organism that is drawing attention now. It is a free-living protozoa found in most sources of water and soil. It was first recognized as an eye pathogen in 1973 in south Texas, but it is uncommon, occurring in about 1 in 500,000 contact lens users per year (which translates to an expected rate of ~60 cases per year).

On March 7, 2007, the Centers for Disease Control and Prevention (CDC) started an investigation into the increased incidence of *Acanthamoeba* keratitis. They are currently in the case-finding stage.

Dr. Tu reported that there has been a "dramatically increasing incidence" of *Acanthamoeba* keratitis, with the prognosis heavily dependent on early diagnosis (within two months of the start). He reported that his eye center alone has seen 65 cases since 2003, and the vast majority (95%) were contact lens wearers, with 89% soft contact lens wearers (11% gas permeable lenses). The patients had a varied history of poor hygiene, sleeping in lenses, etc.

Dr. Tu suggested the problem is city water treatment methods, not contact lenses or contact lens solutions. He explained that the EPA in 1998 mandated that water treatment facilities reduce the amount of carcinogenic byproducts. The new rule was implemented in 2002 for large water systems and in 2004 for smaller systems. Dr. Tu said the *Acanthamoeba* problem is multifactorial, but the water treatment changes account for the vast majority of the increase in *Acanthamoeba* infections, "Our hypothesis is that this has resulted in microbial overgrowth, which is the food for *Acanthamoeba*." Since the water treatment changes are probably here to stay, Dr. Tu said that doctors and patients have to be more conscious of hygiene.

Comments on keratitis and contact lenses and lens solutions included:

- *New York:* "The increase in these infections is due to bad hygiene. It doesn't matter what the contact lens is. We're seeing it with all contact lenses. People are sleeping in their lenses and not caring for them. If optometrists spent a little more time with patients, then ophthalmologists wouldn't be dealing with (corneal) scarring and transplants (so much)…Too many people are told they can wear their contact lenses for a month."
- *Florida:* "The water supply is the problem, not contact lenses or solutions."

*Are any of the contact lens solutions better at killing these dangerous organisms?* Dr. Tu doesn't believe there is any significant difference in the ability of any of the leading solutions – ReNu, Opti-Free, Complete, or Novartis/Ciba Vision's Clear Care – to kill *Acanthamoeba*. He said, "Testing of the solutions is largely company-sponsored. They all have different efficacy vs. *Acanthamoeba* in those studies, but there are few independent studies…The differences in the testing methods are not necessarily related to the real world…There is nothing in the published literature to support use of one solution over another…None are completely protective against these atypical organisms…Hydrogen peroxide systems are broadly protective but not widely used because more handling is required…ReNu's (preservative) alexidine was the broadest killer; it was superior to the others on *Acanthamoeba*."

One of the problems in diagnosing *Acanthamoeba* is that there appears to be wide variation among labs in their ability to identify it.

## LASIK

As in past years, LASIK procedure volume in the first quarter of 2007 was fairly strong, but experts have learned that the first quarter numbers cannot be annualized to predict how the year will go. With April finished and May booked, surgeons estimated that second quarter procedure volume will be flat compared to 1Q07 and compared to the same period last year. For all of 2007, sources also predicted that procedure volume will be flat to down an average of 2%. Yet, surgeons did not sound or appear depressed, and they are still investing in new lasers and other equipment. A Florida doctor said, "Doctors who are up or down are all market share shifts. There isn't any market growth." A North Carolina surgeon said, "2007 depends on the housing market." A Midwest doctor said, "Our LASIK volume is up considerably, but we are pushing it and advertising more."

The recent contact lens solution problems and recalls have had no noticeable impact on LASIK procedures. A few doctors said that they have talked with patients about these issues but that they are not pushing patients over the edge into surgery.

### Demographics

Dr. Karl Stonecipher, medical director of TLC Laser Eye Centers of Greensboro NC presented a demographic analysis that he and Dr. Guy Kezirian of Refractive Consulting Group in Scottsdale AZ did of why refractive procedures are flat. They examined 40,231 eyes operated on between 2004 and ASCRS. They found:

- **Overall.** Females accounted for 55.4% of refractive surgery patients overall. They suggested, therefore, that marketing in women's media might be more effective.
- **Myopia.** Procedures are decreasing as baby boomers age. The mean procedure age has remained fairly constant between 37 and 40, with baby boomers "aging out of this range" and Generation Xers aging into the range. They forecast: higher LASIK volumes as Gen Xers enter the LASIK age range and a continued trend for young patients to have LASIK as physicians market to them.
- **Hyperopia.** Hyperopia as a proportion of eyes treated increased from 10% in 2004 to 16% in 2006 – a 60% increase. Hyperopic LASIK age increased by 7 years to 50.1 years. Aging baby boomers are making up more of the hyperopic market. They forecast: higher hyperopic LASIK volumes as boomers dominate this age.

### Pricing

Pricing, on the other hand, is increasing slightly. Several surgeons said they just recently raised prices or plan to do so between now and July, some boosting fees as much as $500 per eye. A surgeon said, "Even though our area has gotten more competitive with a TLC center there already and a LasikPlus (LCA-Vision) opening soon, we are holding our price steady. The TLC center has been open about six months; it is high end and doing mostly newspaper ads, but it is absolutely dead because it is perceived as too new a player. LasikPlus will have to carve out a niche based on low cost." Another said he is holding price steady but is offering fewer discounts.

A surgeon said he tried switching to tiered pricing, charging a $695 base price with a mechanical microkeratome, $1,695 for custom ablation with a mechanical microkeratome, and $2,195 for custom ablation with an IntraLase flap. It was a disaster. He changed to a flat price of $2,495 for all patients, with custom ablation and an IntraLase flap included. Business picked back up.

### Excimer lasers

In this environment, excimer laser sales appear to be holding up. AMO's Visx remains the dominant excimer laser, but WaveLight is in recovery mode, with a renewed energy level and a pick up in Allegretto sales. Alcon's laser business was described as "getting killed" but not because of market softness – because of the central islands with its LadarVision 6000. Alcon recently disclosed that it has instructed doctors with a 6000 not to use it for custom ablation, and some doctors who upgraded to the 6000 have asked (and gotten) their old 4000 back. Alcon reportedly submitted a software fix to the FDA for the 6000 in February 2007, but the FDA has not yet approved it, and the "fix" reverses the direction and slows the machine down. Doctors who bought a 6000 can't be very happy, and this is helping both Visx and WaveLight.

### LCA-Vision's LasikPlus

LasikPlus centers account for about 14% of LASIK volume in the U.S. A LasikPlus doctor said 1Q07 was pretty comparable to 1Q06, with volume down a little but the price per procedure up a little, causing revenue to be a little higher year-to-year.

At LasikPlus centers, the cost of enhancements have been built into the LASIK price for the first 90 days, but patients can purchase a package that extends the enhancement coverage (guarantee) for one year or for lifetime. However, the Securities and Exchange Commission (SEC) recently told LCA-Vision that the enhancements have to be bundled into the LASIK price. A LasikPlus surgeon said LCA-Vision hasn't decided yet whether lifetime plans will be continued. He predicted that (1) their prices will be raised, regardless of the decision on enhancement duration, and (2) going forward there will be a set price with an enhancement for a set period (yet to be determined)."

### Ophthalmology residents

A survey of 117 ophthalmology residents in the U.S. found that these doctors were more likely to get certified in refractive surgery if they trained where there were more faculty members and more lecture hours. Certification was not affected by access to a laser or the faculty's laser procedure volume.

ASCRS has a new initiative aimed at residents. 2007 ASCRS President Dr. Richard Lindstrom of Minnesota Eye Consultants said, "The future of our profession is the young ophthalmologist. We want them to become more engaged in our meeting and our society. In the fall of this year (2007), we will offer our first-ever resident's day at an ophthalmic meeting in New York. In addition, we will reach out to the academic community to encourage them to send their Residents and Fellows in training to the ASCRS Symposium in addition to the Academy and ARVO meetings."

### PresbyLASIK

Two-thirds of surgeons questioned said they are skeptical or dubious about presbyLASIK, which uses a multifocal ablation pattern with the central zone steepened for near and the peripheral zone targeted for distance. The other doctors called it interesting but unproven. AMO/Visx is doing studies in this area, and sources said Alcon also is quietly investigating presbyLASIK.

Comments on presbyLASIK included:

- "The medical-legal ramifications are enormous. It isn't easy to reverse, and fixing it is a lawsuit waiting to happen."
- *California #1:* "I'm interested, and I would try it."
- *Colorado:* "It will be very popular when and if it gets FDA approval."
- *Florida:* "I think the irregular sculpting is concerning, and when the patient has a cataract removed later, that may be an issue."
- *Michigan:* "With presbyLASIK, you may have to remove the ablation, which is worse than taking out a lens."
- *Missouri:* "I'd be very interested if it works."
- *Oregon:* "It is not a good procedure."
- *Tennessee #1:* "I wouldn't have it done on my dog."
- *California #2:* "I'm dubious based on my knowledge of anatomy and physiology, but if it were perfected, it would be a phenomenal procedure that would have a demand that would be difficult to meet."
- *Virginia:* "The jury is still out. A lot of presbyopia technology is a trade-off."
- *Tennessee #2:* "It makes no rational sense."

## MULTIFOCAL AND ACCOMMODATING LENSES

### Cataract surgery

Of cataract surgeons questioned, only a few (~25%) are not using one or more of the FDA-approved multifocal or accommodating IOLs – Alcon's multifocal ReStor, AMO's multifocal ReZoom, or eyeonics' accommodating Crystalens. With two exceptions, these doctors use P-IOLs (premium or prebyopia IOLs) for an average of 9% of their cataract patients. A West Coast doctor said 40% of her cataract patients get a multifocal or accommodating IOL, but she has a large referral practice "because people know I do them and because I do ***all*** the lenses" (including many still in development). Another surgeon uses multifocal or accommodating IOLs in 95% of his cataract patients, but he noted that he is unusual and doesn't accept any insurance.

### Refractive lens exchange

Multifocal and accommodating IOLs are being used for refractive lens exchange (RLE) by only a third of these doctors, and then for only an average of 6% of their patients. While some surgeons see these lenses as a good option for even early cataract patients, they are reluctant to put them in younger patients (as a clear lens exchange) just to correct presbyopia.

### The outlook

The outlook is for the use of these lenses to remain flat over the next 6-12 months. There are several possible explanations for why these lenses aren't catching on faster:

- **Cost.** The price of the lenses and the procedure cost is holding fairly steady. The typical price a doctor pays for a multifocal lens is $895, but one said he pays $760 and another quoted $800. Medicare patients are being charged an additional, uncovered $500-$3,100 per eye for the procedure, with most doctors charging ~$1,600; so the typical out-of-pocket total cost to a Medicare patient is about $2,500 per eye. Non-Medicare patients are paying $250-$1,400 more per eye than this in some practices, for a typical total out-of-pocket cost of $2,750-$4,900 per eye. An Alabama ophthalmologist said, "The companies are trying to put patients on a credit plan, but that is not taking care of the patient's financial well-being."
- **Physician issues** – technique, chair time, etc. A surgeon said, "The vast majority of ophthalmologists are slow to motivate. If they don't even believe in LASIK, it is harder to convince them to use premium lenses. As younger surgeons come out of school, interest will increase."
- **Lack of consumer awareness.** However, a Florida doctor said, "Patients are starting to come in asking about multifocals. A year ago that didn't happen."
- **Technology.** While the current lenses are very good, experts generally agreed that they still "aren't quite there." A surgeon said, "The lenses will improve, but we are still in the infancy. We need a truly accommodative IOL, then there will be a large degree of satisfaction." Another surgeon said, "We are not there yet with any of the presby-IOLs. Patients want to wake up the next morning with 20/20 distance, intermediate, and near vision, and they want to do both eyes the same day. They want it easy, yesterday, and free. We are not there yet, but we are further down the road."

- **Lack of immediate "wow" factor.** When soft contact lenses were introduced, they were easy to use, and patients saw a dramatic difference immediately. The same thing happens when patients get LASIK. So, they go home and rave to their friends, and word-of-mouth brings in new patients. With multifocals, the time needed for neuro-accommodation and the frequent need for touch-ups or enhancements often doesn't give patients that same immediate before/after comparison. An expert said, "We are in competition with ourselves. LASIK has great results, so the bar is enormous, and IOLs are competing with that." Another expert said, "I think the 'wow' factor is there for cataract patients. I think where it is an issue is with RLE patients."

Other surgeon comments on multifocal and accommodating lenses included:

- *Florida #1:* "There are too many unhappy patients. They don't understand the lenses aren't perfect. Your brain has to adjust. It is not instantaneous. I'll do it if a patient asks, but I don't push it."
- *Florida #2:* "I'm waiting on multifocals to see if they match up to their promise, but I'm hearing about some ***very*** unhappy patients, and unhappy patients are the bane of my existence. And they cost extra, so they can create a negative impression (about me or my practice) with patients. Do I believe we are going in that direction? Yes. Do I put them in yet? No. But they will take over – eventually, after the lenses improve."
- *Colorado:* "Only 20% of our cataract patients get multi-focals, which is not very good, especially since we market them. We obviously don't effectively convey the message that it is affordable – $2,500 (per eye with lens)."
- *Michigan:* "There hasn't been enough education by manufacturers about the lenses. We surgeons spend time to educate patients and sell them on the lens, but the manufacturer reaps the benefit. These patients take a lot of chair time."
- *Midwest:* "Education is good, but ophthalmologists have to change. What most ophthalmologists are still seeing is 'not visually significant' cataracts by insurance standards, but I can see changes that are significant earlier. We need to do more RLE and use presbyopia-correcting lenses, etc."

## New lenses

There is a fair amount of excitement about AMO's Tecnis lens. The FDA requested additional data on the lens before approving it, and the company indicated that this could delay its U.S. entry by up to 18 months. However, the FDA reportedly is allowing AMO to submit its European data, which is supposed to be very good, and this may allow the company to get it approved much quicker than most people expect (perhaps by the end of 2007). An Alabama doctor said, "Tecnis will replace both ReStor and ReZoom. If it truly does what the company says, it may be the better lens."

Alcon also has two new ReStor versions in development, including a 3+ ReStor that reportedly has better intermediate vision. Sources predicted this will help Alcon by allowing doctors who are mixing-and-matching ReStor and ReZoom to use two different ReStor lenses instead.

The new Crystalens Five-O (5.0) has rejuvenated interest in that lens, and a few doctors who stopped using Crystalens said they have either started again or plan to start again, but use is still expected to be very small (<5%) compared to either ReStor or ReZoom, which share the multifocal lens market (**~67% and ~33%, respectively**). Comments included:

- *Florida #1:* "I send all my multifocal patients to someone else. He stopped using Crystalens, but he has restarted with the new Five-O."
- *North Carolina:* "Crystalens Five-O is a winner. They are finally turning the corner."
- *Missouri:* "I'm using the Five-O, and I'm pretty happy with it. It is certainly worth trying Crystalens again, and it is pretty good."
- *Oregon:* "Lack of predictability is the problem with Crystalens. We've had a 15% enhance rate. They are saying the Five-O is more predictable, but the Five-O is stiffer than the 4.5.
- *Texas:* "This is easier for surgeons to implant, more stable."
- *Florida #2:* "We are getting more and more comfortable that the near vision will stand up over time with this lens…In my practice I try to move the majority of patients to Crystalens mostly because of the lower chance of dissatisfied patients after surgery…They are the happiest group of patients, with the least complaints – excellent visual outcome, no disturbing visual side effects, decreased chair time, no explantations to date."

Dr. James Loden from Nashville TN discussed a surprising ultrasound study that shed new light on how Crystalens works. He showed a video that showed the haptic actually moves posterior and the lens bulges at near. The assumption, he said, was that the haptic would move anteriorally, and the ultrasound pictures contradict that.

And new accommodating lenses are on the horizon. Doctors are paying particular attention to **Visugen's Synchrony**. A surgeon said, "Synchrony will grow the market because that is what doctors ultimately want. It will hurt both ReStor and ReZoom." Another surgeon said, "It will replace Crystalens, and it will be good for the halo-phobes."

### Market share shifts

While some doctors are moving from ReStor to ReZoom, an equal number appeared to be moving the other way, so the ReStor/ReZoom battle appears to have stalemated. However, sources predicted any up tick in Crystalens use will hurt ReZoom the most, particularly since Crystalens is being mix-matched more often with ReStor.

### Mix-match

Mixing-and-matching of multifocal and accommodating lenses is still a hot topic. Some doctors still aren't doing it; others do mix-match for as much as 90% of their patients. Now that the early adopters are doing it, uptake of this approach has slowed, but it is continuing. Most commonly, mix-match surgeons are implanting a ReStor first in the non-dominant eye (for reading) and then a ReZoom in the dominant eye; others do the dominant eye first. There really is no agreement on this.

### Presbyopia awareness

With grants from AMO and Alcon, the ASCRS Foundation has undertaken a 3-pronged campaign to educate doctors and the public about presbyopia and its treatments.

1. A Harris Interactive **survey** to assess the level of public knowledge of presbyopia and the need for public information about presbyopia. Harris polled 500 adults age 45-65 and 250 ASCRS patients who had undergone surgical treatment options to correct their presbyopia. The poll found that only 61% of patients who had a presbyopic-IOL (multifocal or accommodating lens) were spectacle-independent after the surgery results, which is below the 80% satisfaction rate Alcon's ReStor showed in clinical trials submitted to the FDA for approval. 2006 ASCRS President Dr. Samuel Masket of UCLA said, "We'd like to see 80% or more, but to achieve that, you need the right patients and doctors have to perform the surgery the right way."
2. A **website** – **www.readclearlyagain.org** – has been created that talks about varying options for treating presbyopia. Dr. Masket said it will be "as non-commercial as it can possibly be…Unfortunately, of the three products (multifocal lenses) on the (U.S.) market, only two (Alcon's ReStor and eyeonics' Crystalens) were subject to FDA trials. The other (AMO's ReZoom) was grandfathered."
3. Establish **branding** that will be easily understood, "easily recognizable as erectile dysfunction, for example." ASCRS wants to find a term acceptable to all the industry players so they can use it. ASCRS held a contest among its membership looking for a name or slogan but didn't find anything they wanted to use, so now ASCRS may hire a professional firm to come up with a term and test it in focus groups.

**Harris Interactive Poll Results - 1**

| Question | General population | ASCRS patients treated for presbyopia |
|---|---|---|
| Experienced presbyopia | 62% | 70% |
| Not at all knowledgeable about presbyopia | 79% | 56% |
| Described presbyopia as "beginning at middle age, the need to use reading glasses to read or focus at distances" | 9% | 10% |
| Not sure of the correct definition of presbyopia | 50% | 48% |
| Believe age alone causes presbyopia | 22% | 23% |
| Have, at some point, discussed with the eye doctor how vision changes with age | 61% | 60% |
| Know a great deal or something about cataract surgery | 48% | 74% |
| Do not know much about P-IOLs – "bifocal lenses permanently implanted onto the eye" | 58% | --- |
| Believe prescription glasses or bifocal lenses would be very effective or effective in managing presbyopia | 70% | --- |
| Believe a P-IOL would be very effective or effective in managing presbyopia | 33% | --- |
| Unsure of the effectiveness of a P-IOL | 31% | --- |
| Focusing on objects close has/would have some impact on their lives | 81% | 81% |
| Focusing on objects close has/would have ***major*** impact on their lives | 38% | 42% |
| Willing to get an artificial lens if the procedure is FDA-approved | 66% | --- |
| Discussed vision correction surgery with eye doctor at some point | 25% | 63% |
| Wear glasses now or in the past | 77% | --- |

**Harris Interactive Poll Results - 2**

| Question | General population | ASCRS patients treated for presbyopia | |
|---|---|---|---|
| | No surgery | Prior to surgery | After surgery |
| Difficulty reading ordinary newspaper or magazine print without glasses | 43% great deal | 70% great deal | 49% no difficulty |
| Difficulty reading a restaurant menu without glasses | 39% great deal | 57% great deal | 51% no difficulty |
| Difficulty driving | --- | 55% great deal | 71% no difficulty |
| Difficulty with work or hobbies | 34% great deal | 50% great deal | 51% no difficulty |

**Harris Interactive Poll Results - 3**

| Question | Answer |
|---|---|
| **Obstacles to surgery among non-surgery patients** | |
| Lack of knowledge about the procedure | 55% |
| Comfortable wearing reading glasses | 54% |
| Cost | 51% |
| Worried about complications | 51% |
| **Reasons ASCRS patients underwent surgery** | |
| It became hard to see things well | 74% |
| Thought it would give more freedom | 59% |

**Harris Interactive Poll Results - 4**

| Question | ASCRS surgery patients |
|---|---|
| Vision correction surgery/cataract surgery had a major positive impact on life | 64% |
| Surgery "gave you the freedom to live your life the way that you want" | 72% |
| Would recommend it to others | 84% |
| Changed their life | 59% |
| Strongly disagree that recovery was difficult | 82% |
| **Benefits of surgery** | |
| More comfort driving | 72% |
| More active | 62% |
| More self-confidence | 65% |
| More active social life | 42% |
| More fulfilling career or work life | 46% |

*Why is ASCRS getting involved in this presbyopia campaign?* Dr. Masket said P-IOLs may be "underappreciated" and "underutilized," but education is the key reason, "Our most important task is to educate our physicians, and we think we need unbiased information...that can be used industry-wide. We would like to eliminate the competition among manufacturers on presenting the information…We also think we have an important role in public education…We think we can present the least-biased view and the most information." John Ciccione, ASCRS's communications director, added, "One of the concerns we have with presbyopia lenses is expectations are not raised too high too soon. By providing accurate information we can temper that, and we can get realistic, reliable data out there to head that off."

*Asked if he is concerned that presbyopic lenses are not getting off on the right foot*, Dr. Masket said, "It is my sense that the manufacturers may have had in mind that once they released these lenses, the doctors would put them in, and everyone would be happy. But there is more to it than that…My concern is that they are not necessarily appropriately applied. Market projections are below what the companies anticipated, and the question is whether (that's due to the) reluctance of physicians because they don't want to take the added steps or because they are skeptical of the performance, but when new technology comes on the market, if it is not appropriately applied, there is very little chance of it becoming successfully incorporated into the armamentarium of what we do."

Dr. Masket said his own personal experience has been good with multifocal IOLs, "I'm disappointed if patients who are candidates for these devices choose not to have them because I think I've let them down, because I see the happiness patients experience when they are spectacle-independent and the discontent of those who otherwise have perfect vision with monofocal lenses but can't function without putting glasses on and off…The lens I use matches my expectations…but I can easily understand why the problem exists because I understand how fastidiously the surgeon has to approach these patients, and the margins for success are very narrow, but if you stay within those margins, the success is there."

*What will it take to get the P-IOL market growing?* Dr. Masket predicted that it will be at least two years, minimum, before there are any new multifocal IOL products, but he doesn't think that's what's needed, "We think patients and physicians can be successful with the current technology if it is done properly." What it will take, he said, is education – of both physicians and patients – about these lenses. Dr. Masket explained, "Expectations have to be real, patient selection has to be very specific, surgical technique is demanding, and the ability to enhance, guide, and counsel the patient are all important parts of the formula for success with presbyopic lenses. I think we are providing a service to patients and physicians…If physicians without careful thinking, education, what have you, start incorporating these lenses in their practice, the new technology will get a bad name."

Dr. Masket emphasized that ophthalmologists need to recognize that multifocal lenses are not as simple to use as monofocal lenses, "Amytropia following refractive or multifocal lens implants is much more important in the function of the lens or the visual results than with monofocal lenses. For example, a patient with a monofocal lens can tolerate 0.75 or 1.0 diopter of astigmatism and have good uncorrected vision. That isn't necessarily the case with multifocal lenses. So amytropia is a limiting factor. We find that multifocal patients require a higher percentage of enhancements for alteration of optical outcomes than monofocal lens patients…More than half the enhancements are for astigmatism."

*Asked if multifocal lenses are having any impact on LASIK procedure volume*, he said no, explaining, "LASIK and refractive lens exchange are partners. One doesn't affect the other. (But) the indications for LASIK have changed. Patients probably shouldn't have LASIK with high myopia or high hyperopia, and now we can offer other tools…My LASIK volume is unaffected by the use of 'premium or lifestyle lenses,' but they may have increased LASIK enhancements…Multifocal lenses expand the number of patients eligible for surgery that want to reduce or limit the use of glasses…If patients are good LASIK candidates, they should have LASIK, but if they need a lens exchange because of cataracts or refractive error not correctable by LASIK, then this is an option…So they are cooperating technologies and expand the number of patients who could benefit."

The survey had several limitations:

- It didn't have a control group, so there is no way to tell how the results/opinions with the multifocal lenses compare to monofocal lenses.
- There was no identification of which lens patients got – ReStor, ReZoom, or Crystalens.
- Cost was not an item, thought patients were told there was a premium price for multifocal lenses.

- It did not look at use of mix-and-match of different multifocal lenses, and Dr. Masket said this is an area that the society does ***not*** intend to pursue but which does require further study.
- The study did not include any monovision patients.

*When is it better for a patient to have a monofocal lens than a multifocal lens?* Dr. Masket suggested patients would do better with monofocal lenses if they had:

- Any significant disease of the optic nerve (e.g., glaucoma).
- Certain degrees of macular degeneration.
- Macular pucker.
- Negative personalities.
- Certain occupations (e.g., truck driver, work-related night driving, airline pilots).
- Spectacles with prism.

## CORNEAL INLAYS

New corneal inlays are in development that may solve some of the problems earlier versions had, and some experts are very excited about them, but most sources are taking a very cautious approach, reserving judgment until they see more data. Bausch & Lomb has invested in **ACUFOCUS**, which is developing the ACI-7000 corneal inlay.

Dr. Jason Stahl of Durrie Vision in Overland Park KS, an AcuFocus investigator, is a believer in this technology. He said, "Presbyopia is a difficult beast to tame. Multifocal lenses are popular and growing in popularity, but they are intraocular, so there is a little higher risk…Accommodating lenses are probably (better), but we are many years away from a truly accommodating lens. AcuFocus has the same risk profile as LASIK, but may be easier for patients to adapt to vs. (LASIK) monovision...It has a long FDA process, but all the investigators are excited to be involved."

The AcuFocus corneal inlays procedure is relatively simple. First, topical anesthetic eye drops are put in the patient's eye, then a femtosecond flap created. The lens is inserted and centered over the pupil and dried, then the flap is closed. Dr. Stahl said the AcuFocus ACI-7000 corneal inlays "essentially gives you a 1.6 mm pupil…1.6 is the optimal aperture to increase depth of focus."

While thinner flaps are the trend with LASIK, Dr. Stahl said that, at least for now, they are avoiding thin flaps with ACI-7000. He said, "We are not going too thick or too thin, usually a ~140 micron flap or thicker." Another investigator, Dr. Michael Knorz of Germany, said, "We are afraid to use thin flaps for this."

Features of the AcuFocus ACI-7000 include:

- Removable.
- Overall diameter of 3.8 mm, with a central aperture (sort of a donut-hole opening) of 1.6 mm.
- Thin. It is 10 microns thick (1/10 the thickness of a standard sheet of paper).
- Opaque inlay with thousands of little holes drilled into it to allow some light through and, more importantly, to let nutrients come through from the posterior to the anterior cornea. Dr. Stahl said that with other inlays there have been issues with getting nutrients to the posterior cornea, and that isn't a problem with this lens.
- Ease of implantation. Dr. Stahl said the procedure takes <30 minutes, start-to-finish. The lens stays in position once it is placed (and dried), and when you look at a patient, you can't see that it is in the eye.
- Minimal effect on distance vision.
- Few side effects – mostly a little glare and halos.

So far, more than 100 patients have had an ACI-7000 implanted in Phase I studies in Turkey, Europe, Singapore, and the U.S. All of the patients have been age 45-60 plano presbyopes who needed correction for near vision between 20/40 and 20/100. Dr. Knorz reported on the:

- **12-month experience with 39 patients in Turkey:** No loss of uncorrected visual acuity, no effect on distance vision, but an improvement on near visual acuity that was maintained out to 12 months.
- **44 patients in Europe,** with 17 of these at 3-month follow-up: A one line loss of distance vision, and a slight delay in the increase in near vision. He said, "It takes a couple of weeks and stabilizes at about one month."

Reading acuity takes time to get to J1 – 1-3 months – though it varies from patient to patient. Dr. Stahl said, "The patient might come in and test better initially, but to use that vision is a different story…That is where neuro-adaptation takes place ...but there is significant improvement at a month, and it can continue to improve past that point."

In the future, the AcuFocus lens potentially could be used for:

- Post-LASIK patients in lieu of monovision LASIK.
- Cataract patients with a multifocal IOL. Sources said this has been tried and works.
- Cataract patients with a monofocal lens.
- Correcting distance vision, possibly, but this has not been proven yet. So far, AcuFocus is not putting the lens in patients with refractive error, but it is conceivable that a lens with power could be put in the middle of the inlay in the future.

In fact, cataract surgery has been done in patients with this lens implanted to see if they could do it, and Dr. Stahl said, "It can be done. The principle is the same. As long as you don't have refractive error to affect vision."

Among the comments on the AcuFocus corneal inlays were:

- "It is very exciting technology. I hope they become available during my career. If they are reversible, why not use them?"
- "They show promise. They are easy to put in, and you can remove them if there is a visual problem. At least it is reversible."
- "AcuFocus is exciting. It looks good for plano presbyopes, for LASIK patients with congenital aberrations, and pseudophakics."
- "I'm skeptical."
- "You put something in the cornea, and it's a problem. The surgery is easy, but the problem is in patient satisfaction and side effects."
- "It shows promise. There is a bit of trade-off in terms of halo and some decreased night vision, but it goes in the non-dominant eye, there are no problems with the cornea, and the material is proven…It is a pin-hole approach."

## Implantable Contact Lenses (ICLs)

Both Staar's Visian ICL and AMO's Verisyse P-IOL are approved by the FDA to correct myopia (nearsightedness). Both correct vision by aiding the eye's natural lens instead of replacing it, and both are removable. The Verisyse clips onto the iris, and Visian is placed in the posterior chamber. Doctors at ASCRS generally agreed that these lenses are niche products and will remain niche products, but the more experienced refractive surgeons said they do have a role.

Among the comments were:

- *Florida:* "I offer them, but I'm not a proponent. I wouldn't have it done to me or anyone in my family. They have a very limited indication."
- *Oregon:* "They have a niche. They're starting to catch on a little, but the average ophthalmologist will not do ICLs."
- *Big ICL user:* "They are one of the best procedures, and use will pick up, but it is a limited market. People think they are dangerous because they are intraocular, but there have been no cases of endophthalmitis. ICLs may catch on with refractive surgeons but not general ophthalmologists…The induction of cataracts with ICLs is surgeon-dependent, not due to the lens. It is the surgeon touching the anterior lens capsule during the procedure…But ICLs are a niche product."
- *California:* "I use Staar's Visian. It has a niche, and it will stay that way."

## Femtosecond Lasers

Increasingly, a femtosecond laser is becoming a must-have, for marketing purposes if nothing else. Laser company executives said that the next generation of femtosecond lasers will not only make flaps but also will expand into therapeutic applications. Eventually, experts predicted, femtosecond lasers will become standard-of-care for LASIK and an important technology for corneal transplants.

Initially, some doctors were calling LASIK using AMO's IntraLase femtosecond laser "Intra-LASIK," but a new term that is more generic has started to gain popularity – SBK (sub-Bowman's keratomileusis). A surgeon said, "We are seeing faster visual recovery with SBK, approaching PRK, and less dry eye. There is better quality of vision early, and long-term vision is the same…SBK is still controversial because there are not enough data, but it is something new that could get the (patient) population excited about having surgery now."

Comments on femtosecond lasers included:

- *Midwest #1:* "We have an IntraLase at one of our five centers, and we are doing close to 100% of patients with it. Now we are transitioning to an IntraLase at all five centers…We decided to go with standard U.S. technology…But results are still good with a (mechanical) microkeratome, so I wouldn't say doctors have to go with a femtosecond. Or, doctors who don't have a femtosecond could get a mobile femtosecond or use an open-access center…LasikPlus probably doesn't need to do femtosecond yet, but eventually they probably will have to go that way. While they are doing so well, they don't feel the need to change."
- *Midwest #2:* "Other femtoseconds will be players. They are good technology. Femtos are the only way to do SBK. I think they all can do SBK. The key isn't which femtosecond laser you have, but you have to have a femto to do SBK."
- *Ohio:* "I want a femtosecond so I can advertise and because it is giving you a very controlled, uniform thickness flap. It will increase predictability and control negative mechanical changes. There is a mechanical microkeratome that can make a 90 micron flap, but it is only 90 microns in the middle, not necessarily in the periphery."
- *Asked if IntraLase will make it impossible for competing femtosecond lasers to be successful in the U.S., a West Coast surgeon said:* "The guy who is first gets to pick the cherries. Visx still dominates the excimer laser market. There is room for other excimer laser companies and other femtosecond laser companies, but it will be really, really hard to penetrate the IntraLase market. I just can't see IntraLase not keeping up with technology."

**AMO'S IntraLase** has a well-established base, and it is continuing to grow, even with competitors proliferating. Sources all agreed that IntraLase will remain the gorilla in this space, but they also believe the competitors can be successful.

The integration of IntraLase into AMO appears to be going well. Sources in the U.S. and Europe – inside and outside AMO – as well as customers reported no problems. A speaker joked, "These lasers (Visx and IntraLase) were really made for each other…It is a love affair...These lasers have been sleeping together, keeping company, and now it is a marriage made in heaven."

**ZIEMER OPHTHALMIC SYSTEMS** has renamed its Da Vinci laser the Ziemer LDV to avoid name confusion and conflicts with Intuitive's Da Vinci robot, and the company has made some sales and has started shipping lasers. Their booth was busy, and a number of deals were being finalized. Ziemer officials wouldn't say how many Ziemer LDVs have been sold yet or where they have been placed, but an official said, "We've sold a few systems so far, and when we have 50 in the U.S., we'll discuss where they are going (geographically)."

It appears that the greatest interest is coming from lower volume refractive surgeons (≤75 procedures a month) who want a mobile laser they can share with another office or colleague. A Ziemer official said the price is comparable to IntraLase, but the consumable costs are lower. Asked what the biggest challenge is, he said, "We are at least two years behind IntraLase. They claim to have done one million procedures, which gives customers confidence, but people also are sensitive to the way the company is dealing with them. IntraLase has made it clear to customers that they are the only source."

One advantage that IntraLase has over the LDV is a z-axis, but a Ziemer official said that is in development and will be available in less than 12 months.

Ziemer claims the LDV is stable enough for roll-on/roll-off (Ro/Ro), so it can be moved from office to office or from the operating room to the refractive surgery suite without requiring recalibration, and the IntraLase doesn't have this same Ro/Ro capability. A doctor contemplating the purchase of an LDV said, "I already have an IntraLase, but I'm considering a new venture where I can't justify an IntraLase… IntraLase has a tremendous head start, z-control, and greater pulse width. The Ziemer is faster and lower energy, and that may have benefits."

**20/10 PERFECT VISION** also introduced its new femtosecond system at the American Academy of Ophthalmology (AAO) meeting in November 2006. The Femtec has both FDA approval and a C.E. Mark, but it is not being sold in the U.S. yet. CEO Reinhard Mueller-Spaeth would only say that the number of installed systems is in the "double digits" in 10 countries, but he wouldn't say when they will be offered in the U.S.

Although the LASIK market is flat, 20/10 officials said that femtosecond procedures are increasing, not only in flap making but in therapeutic areas. Mueller-Spaeth said, "We are introducing a new procedure at this meeting, FLEK (femto-laser-assisted endothelial keratoplasty), which is basically a posterior keratoplasty, similar to manual DSEK. That is a trend we are seeing…It is basically replacing a posterior lamellar graft in the patient, which is cut with a femtosecond in patients at a pre-determined depth, with a perfectly matching donor that is cut the same way, so the endothelium is not being touched mechanically in either the donor graft or the recipient. The advantage of doing micron-precision control of the geometry in the recipient as well as the donor will show significant clinical advantage for posterior corneal transplant."

Although the FLEK procedure was first done in Europe, Dr. Frieder Loesel, 20/10 general manager/founder/chief technology officer, said Singapore has been active in this and coined the term. Asked how FLEK compares to SBK, Dr. Loesel said, "This (FLEK) is very exciting, and clearly we are keeping a close eye on SBK, but SBK is just a new term for the same thing they did before…The question is whether the (SBK) trend will persist because there have been approaches of cutting very thin flaps around for some time…We will have to see if everyone can handle those thin planes." Mueller-Spaeth added, "We also have some additional features. The flap is the standard procedure for us, but we want to be the most versatile system on the market, so (we're) expanding beyond flaps to more and more therapeutic areas. We just released a software update where you can cut geometrical shapes like hexagons or pentagons, with corners, for keratoplasty. You don't have to stay round any longer. That will make the life of the corneal surgeon easier."

*Asked who is buying femtosecond lasers*, Mueller-Spaeth said, "Corneal surgeons are certainly a target group, but there are also corneal surgeons doing refractive work." Dr. Loesel said, "Femtosecond is coming out of just being a flap maker to being the universal tool for the corneal surgeon or long-term for the ophthalmic surgeon. At every trade show, there is a new procedure to use the femto…Clearly, flap-making today is still the volume application, but the technology is not limited by any means, and it has great potential." Mueller-Spaeth added, "We have a special interface, and we feel this is especially necessary in doing therapeutic indications."

**CARL ZEISS MEDITEC AG** unveiled its femtosecond laser, VisuMax, at the AAO 2006, and since then the company received FDA 510(k) approval for it, but Zeiss isn't taking orders yet in the U.S. President/CEO Jim Taylor said, "We were unveiling a technology platform we believe to have significant innovations and advantage from a potential standpoint, but we also recognize that we have to clinically validate the applications…in order to develop its full potential. So, since that time, we continued to do clinical work with…the applications and to tweak a few things…We are doing research on the full refractive potentials. Those studies are ongoing…We want to make sure we can deliver what we

promise, and we have been building production and supply capabilities."

**SCHWIND EYE-TECH-SOLUTIONS'** CEO Rolf Schwind said that his company is still working on its own femtosecond project, but it will not be unveiled any time soon. He said, "As only a flap maker, it might be too late, so we are looking at medical applications as well."

**WAVELIGHT** has new momentum with its excimer lasers, and CEO Wolfgang Tolle said, "I no longer get questions about what is happening with WaveLight…The interest has totally shifted. We have a 'wow' factor as a company." And WaveLight is keeping an eye on femtosecond lasers. Tolle said his company is "interested in working with anyone" on a new femtosecond laser, adding, "Five FDA approvals in nine months show that we are continuing to invest in innovation." Luca Sergio, vice president of marketing, said, "What makes us special is our attention to product development and applications, so for us to ignore (femtosecond) development wouldn't make sense…And behind the 'wow' factor is a framework on which to build future growth."

## THE CHINA MARKET

Laser officials agreed that China is a growing market, and they are trying to gain footholds into the country's potentially lucrative market, with various degrees of success. But it is also a challenging market. Most sources agreed that business there has slowed somewhat, but it remains a good market, and most of the major ophthalmic laser companies have a presence there.

- **WaveLight**'s Tolle claimed to be doing very well in China, with more than 200 Allegretto lasers placed there, "We have a strong presence in China."

- **Zeiss**'s Taylor said, "It is a dynamic market. I think it was a rapidly growing business for a while. There are still opportunities there. As part of the overall government change in focus – the focus on containment – we are seeing real pressure from the government side, both in business practices and on trying to control costs, and that has put some brakes on what was a growing market for some time." Zeiss doesn't use distributors in China: "The people who have figured out how to work China generally need a third party. HP Medical did a good job with a third party and also with a direct organization." Another Zeiss official said, "The market is down in China. We did 150 (lasers) annually three years ago, and this year is not close to that."

- An **Iridex** official said, "China has been an interesting market because of reform in the ophthalmic realm – the changing practice of how to purchase and who is involved." In the short term, he believes that China is a challenging market, "but there will be great opportunity there." Iridex uses distributors in China, and an official explained, "We have had a strong relationship with distributors. There have been changes in the market that have affected sales, but I'm not saying that going direct is the right approach." He said the whole sales process is changing in China, and that has impacted the market more than the distributors.

- **20/10 Perfect Vision**'s Mueller-Spaeth called China "a difficult market altogether." He added, "We are just getting registration there. We have not yet commercially promoted there, but we are working with a distributor there, a Singapore company that also covers China." Dr. Loesel said, "You need good partners…(China) is a very significant global market, so that is why we are dedicated to being there." They added, however, that 20/10 continues to concentrate on areas in which they know they will succeed.

- **Ellex** CEO Peter Falzon disagreed with the characterization of China as a difficult market. He said, "It is a market where ophthalmology is on the cutting edge of what happens around the world. They don't want anything but the best technology, and their centers are interested in world-class treatments, not in locally modified or copied technology and treatments. So, for premier device companies, it is a terrific market because they really appreciate the real thing. They also are investing in the infrastructure, so that every year access to the global standard of ophthalmologic care is available to more and more people. As they expand that infrastructure, they are taking a very high level approach to it. They want the best." Falzon said GT Medical, a division of Guotong Holdings Company Ltd., is Ellex's exclusive distributor in China, "We are their flagship brand. We are direct in Japan, with 21 employees supporting about a $15 million per year business, and you have to take the same approach in China. You have to have marketing and technical support. We've had staff in China the last three months training the distributor. If you are willing to treat it with the respect you would the U.S. or Japanese market or any country with high expectations, then it is a great market."

## ASCRS 2006 PRACTICE STYLE AND PREFERENCES SURVEY

For the 2006 survey, 628 doctors answered, and they offered some interesting insights into their practices. Among the findings were:

- LASIK volume has been relatively flat since 2001.
- Non-flap procedures almost doubled compared to the previous year.
- 48% believe acrylic lenses hold the most promise for small incision cataract surgery.

**ASCRS Survey: Excimer Laser Preferences**

| Laser | Currently use | Would like to use/acquire |
|---|---|---|
| Visx | 74% | 31% |
| B&L | 4.3% | 2% |
| Alcon | 11% | 31% |
| Lasersight | 1% | 0 |
| Nidek | 2% | 5% |
| WaveLight | 6% | 31% |

**ASCRS 2006 Survey Results**

| Question | 2005 | 2006 |
|---|---|---|
| Preferred phaco machine | --- | Alcon 61% |
| Phaco market share | Alcon 65.3%<br>B&L 15%<br>AMO 16.2% | Alcon 64.7%<br>B&L 16%<br>AMO 16.2% |
| Non-flap procedures (PRK and LASEK) as a percentage of total procedures | 15% | 29% |
| **Multifocal IOL (presbyopic IOL) use** | | |
| ReStor | 52% | 62% |
| ReZoom | 21% | 28% |
| Tecnis | 2% | 0.3% |
| Crystalens | 15% | 10% |
| **Preferred prostaglandin analog** | | |
| Allergan's Lumigan (bimatoprost) | --- | 13% |
| Pfizer's Xalatan (latanoprost) | --- | 60% |
| Alcon's Travatan (travoprost) | --- | 10% |
| No preference | --- | 17% |
| Perform no LASIK | --- | 58% |
| Do CK | --- | 12% |
| Use corneal inlays | --- | 2% |
| Do refractive surgery on both eyes at the same time | --- | 89% |
| Co-manage refractive patients | 34% | 35% |
| Plan to stop doing LASIK | --- | 3% |
| **Procedures doctors themselves have had** | | |
| LASIK | --- | 14% |
| PRK | --- | 4% |
| Cataract and IOL | --- | 3% |
| **Procedure** | **Starting** | **Stopping** |
| Corneal inlays | 14% | 0.2% |
| CK for bilateral hyperopia | 11% | 1% |
| CK for unilateral presbyopia | 14.3% | 0.2% |
| Presby-IOLs | 56%<br>already doing | 42% |

## MISCELLANEOUS INFORMATION ON SPECIFIC COMPANIES

### ADVANCED MEDICAL OPTICS (AMO)

- A new multipurpose contact lens solution will be launched in 2008. The company suggested it will have "more robust" disinfection and will work well with all lenses, including silicone hydrogel lenses.
- Approval of presbyLASIK is expected in 2009.
- AMO has an accommodating lens or lenses in the "feasibility" stage.
- AMO acquired Wavefront Sciences, which was spun off in 1995 from Sandia National Labs. It currently has 54 people and did about $7 million in sales last year. It is growing and cash flow is positive. Wavefront Sciences does micro optics and wavefront sensors. The claim is that their wavefront has four-times the number of spots as the nearest competitor, yielding better resolution.
- The next generation Tecnis IOL will be introduced at ESCRS in Amsterdam in September 2007, and Tecnis multifocal IOL is expected to be approved in the U.S. in 2009.

### BAUSCH & LOMB

Stellaris Vision Enhancement, the company's new phaco-emulsification system, was introduced at the American Academy of Ophthalmology in November and was featured at ASCRS. John Guckes, vice president of global strategy for cataract surgery, said, "(It) is completely new from bottom up. It's the next generation phaco system." Stellaris gives surgeons the choice of fluidics and provides modes for both bimanual and coaxial microincisional surgery.

The FDA approved the system earlier this year; B&L is now taking orders and will start shipping later in the summer. So far, the orders have come mostly (~70%) from B&L's installed base of phaco customers. Guckes said, "They're excited about the technology. Our older machine is out a number of years, and we are rotating that base. And we have a lot of competitors' customers taking a look at it."

Guckes described the system's four key points:

- It is designed to take doctors to sub 2 mm microincision cataract surgery. It will support standard coaxial cataract surgery, but it will take doctors down the path to sub 2 mm.
- It has a brand new and redesigned fluidics management system, with two different fluidics management options: vacuum- or flow-based.
- A new, ergonomically-designed handpiece operates at a very cool 28.5 kHz, resulting in cooler, more efficient removal of the cataract. There is also modulation software that allows doctors to choose from a wide range of modulation frequencies.
- It is versatile and user-friendly with wireless foot control, a big wide screen, and easy user interface.

Guckes said, "We have enhanced the performance of the fluidics. It is more responsive and with an added feature – stable chamber tubing. We are able to readily control the whole fluid dynamics of vacuum and flow, and there are advanced flow fluidics for doctors who like flow-based fluidics. We have the ability with this system for the doctors to toggle between flow and vacuum intraoperatively within a procedure. So, if they want to sculpt in flow, they can. And if they want vacuum-based response, we can do that. We have really tightened up the specs around this flow module. It has extremely good surgeon control. It's all about control and safety."

*Asked why a surgeon would choose Stellaris over AMO's WhiteStar Signature*, Guckes said, "I would say, 'Doctor, we are the company that takes you to sub 2 mm…We have the fluidics option…We have phaco technology with our modulation software. And we have phaco needles and sleeves that are specifically designed to go to sub 2 mm.'" He added that the phaco category is important to B&L, with the phaco machine the anchor product: "All of our IOLs, viscoelastics, etc., are related to that."

B&L is introducing several new technologies outside the U.S., and it plans to bring some to the U.S. In particular, Guckes pointed to the Akreos AO, an aberration-free acrylic lens, that is expected to be launched in the U.S. later this year. Akreos AO has been submitted to the FDA, and B&L is waiting for an answer. B&L has had an acrylic lens on the market in Europe since 1998. Asked why it's being introduced so late in the U.S., he said, "We had an acrylic lens that launched a couple of years ago, and this is the next generation. This is the first acrylic with this particular material, a new, improved material. The unique things about it are that it has an AO platform and is designed to be aberration-free, which improves the quality of vision, even in low light. The one available in the U.S. can go through standard 2.8 mm incisions, the same as in Europe, but the second generation Akreos AO micro-incision lens is designed to go through sub 2 mm incisions… The key to this (Akreos AO) is that it's aberration-free and aspheric design, with Violet Shield technology, so it's not only aberration-free, but we are shielding out harmful ultraviolet rays, which is ideal for retinal health."

Sub 2 mm is a theme at B&L. Guckes predicted that, over time, devices will all move to sub 2 mm, which he called leading edge, "Most doctors are doing the standard 2.8 mm incision, but research says this (sub 2 mm) is where they want to go." He said, "We introduced SofPort AO with BIOshield – a silicone based lens – last year." *Asked if this new technology will pull B&L back into the market forefront*, he said, "I think this will really accelerate it. We think we're already back. We're there right now. This is a great leading edge technology. All our market research tells us this is where doctors want to be, and we are excited about it."

*Asked about the cataract surgery market in general*, he said, "Market growth in procedures is 5%-6% per year, but we are right on the cusp of the baby boomers moving into their 60s, so what we will see over the next few years is a huge increase (in cataract procedures)…We are on the cusp of some new products in our cataract business…This is an exciting time for us, but there are market dynamics that I think everyone has to struggle with."

### IRIDEX

Iridex was talking about its laser modality for treating glaucoma, a micropulse technology called the IQ810 Laser System, which "activates the same healing response we see with SLT." The device has 510(k) approval from the FDA. Greg Halstead, global marketing manager for ophthalmology, said the advantage of the IQ810 over an SLT is that the IQ810 is designed to be multifunctional, "(It has all the) standard indications for photocoagulation, can be used with slit lamps, a laser ophthalmoscope, etc. And it is a third less expensive… I haven't seen one downside yet."

Iridex believes the IQ810 will have appeal among general ophthalmologists as well as glaucoma specialists. Halstead said, "We've really taken the approach to introduce it with an air of caution. Our goal is to show that there are choices in treating glaucoma. It is not simply ALT or SLT. MLT is another therapy."

*Asked if there is any coagulative damage with the IQ810*, Halstead said, "At the settings used for micropulse laser trabeculoplasty (MLT), it doesn't have the coagulative destructive damage associated with ALT, but the amount of damage is selectable by the physician. The physician can determine how much coagulative damage he'll create…Our system is indicated for photocoagulation in retinopathy of prematurity. That is the classic indication for this laser. But these micropulse settings are specifically designed to mitigate the spread of thermal energy. It is not selective. Lumenis says SLT is selective, causes cellular disruption…With micropulsing we can create a temperature rise below coagulation that causes the same healing response. The trick is to injure a cell so it calls for help and gets macrophage recruitment. We found there are multiple ways to trigger that response."

*Asked how the integration of Laserscope's aesthetic business is going*, Halstead said, "(The integration) is going very well. The first phase was the process of ordering and selling the equipment. We brought on their services and sales and integrated the marketing. We are not scheduled to integrate manufacturing until the summer." He said that the decision was a good one, "We wanted to grow the business…The right deal came along at the right time. It helps bolster our presence in the aesthetic market and adds a lot of new technology."

*Asked why Iridex would be able to effectively sell what Laserscope couldn't*, he said, "We have a presence already in the cosmetic market…When Laserscope was purchased by AMS, they announced they were immediately divesting their aesthetic division, so there was a six-month period with little-to-no emphasis on that segment, and that played a big part of the slowdown in sales." He said that the technology Iridex acquired from Laserscope "is complementary to what we have and broadens the portfolio of offerings."

Looking ahead, he said, "We are in a strong growth strategy…In the ophthalmic arena, we are looking at a new treatment modality for MLT, introducing new probes to bolster our revenue stream in the retinal community, and that helps us substantially in the OR (operating room) setting, and we are also introducing new laser technologies. We have a new laser coming out in 2H07 that is a 577 nm (a true yellow), and that will be a strong draw from retina physicians who used

very old dye lasers. That laser will have micropulse technology as well, so we're taking infrared technology, creating laser technologies that retina specialists have gravitated to – yellow – and taking the best of both worlds. We found interest in yellow and micropulse technology and combined them. This was demonstrated at AAO in 2006 and will be for sale by AAO 2007."

### LUMENIS

Lumenis did not have anything new at ASCRS, according to Alym Dowell, product manager of ophthalmology. He said that the company is still positioning its SLT laser as the best solution for glaucoma management. He claimed the Lumenis' SLT is better than Iridex's laser, "They do micropulsing technology, and there's a big difference between my SLT and their laser. Their laser creates some coagulative damage, and ours doesn't, so we're not creating any damage within the meshwork. Another differentiator is that we have five to six years of data on SLT, and they don't have that data."

*Asked if there is more focus on glaucoma today than in the past*, Dowell said, "It seems to be pretty steady. I think there is a little more focus, more solutions now, so I think there is an increase (in patients being treated). We now have new diagnostic tools like the Heidelberg HLT which enables us to do HRT a little faster and more effectively, and consumers are becoming more educated about the disease. Three million people in the U.S. have glaucoma and only half of them know it. More are asking about it, and more are getting treated." He said the most growth is in the comprehensive and general ophthalmology market than among glaucoma specialists.

Lumenis also has a multicolor retinal laser, the Varia, which was not shown at ASCRS. Dowell said that Lumenis is launching some new products later this year, including the Selecta platform, a single laser with three different modalities – laser photocoagulation, laser photodisruption, and SLT.

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