# Trends-in-Medicine

**September 2007**

*by Lynne Peterson*


## SUMMARY

Multifocal IOL (mIOL) use for the next year is expected to be relatively flat in the U.S. but to grow slightly in Europe. ♦ **Acri.Tec's** Acri.Lisa mIOL is generating a lot of interest and has the potential to challenge Alcon's ReStor and Advanced Medical Optic's ReZoom and Tecnis, especially since Acri.Tec's purchase by Carl Zeiss Meditec. ♦ Interest in mix-and-match mIOLs lenses appears to have stalled. ♦ Refractive surgery procedure volume in this year in the U.S. is expected to be flat to slightly down, with Europe flat to slightly up. ♦ PRK is taking a growing share of the refractive surgery procedures in the U.S. and in Europe, and that trend is expected to continue. ♦ **WaveLight's** Allegretto excimer laser is gaining popularity in Europe, and that's what most buyers said they plan to get. ♦ **Ziemer's** LDV femto-second laser has gotten off the ground and interest is growing, though it is still being fine-tuned.




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## EUROPEAN SOCIETY FOR CATARACT AND REFRACTIVE SURGERY (ESCRS)

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Most of the presentations at ESCRS were short five- or six-minute talks in which various surgeons commented on relatively limited experience – often 10 to 100 patients – with a particular technology, and then there were the corporate symposiums which presented their mostly one-sided view. Few large, solid, prospective, randomized clinical trials and virtually no head-to-head comparisons were presented. Yet, trends did emerge, and shifts in sentiment or opinions about different products and technology were apparent.

The key takeaways were:

- Multifocal IOL use is relatively flat at about 16%-17% of cataract lenses in the U.S. In Europe, multifocal IOLs have a much smaller market share (3%-4%). European use is expected to increase but still remain in the mid-single digits (5%-6%) over the next year.
- **Acri.Tec's Acri.Lisa** multifocal intraocular lens (mIOL) has become a competitor for Alcon's ReStor and Advanced Medical Optic's ReZoom and Tecnis, and Acri.Tec's purchase by Carl Zeiss Meditec may give this lens the marketing clout to impact those lens giants.
- Interest in mix-and-match lenses appears to have flattened out and is not growing.
- The outlook for refractive surgery volume in the U.S. is for a flat to slightly down 2007 vs. 2006, with possible deterioration later this year and in 2008 if the housing/credit situations do not improve. In Europe, the outlook is slightly better – for flat to slightly up volume.
- PRK is accounting for a growing share of the refractive surgery market both in the U.S. and in Europe, and that trend is expected to continue.
- **WaveLight's Allegretto** excimer laser is gaining popularity. All of the surgeons questioned who plan to buy an excimer laser are getting or plan to get an Allegretto.
- **Ziemer's LDV** femtosecond laser has gotten off the ground. It is still being fine-tuned, but early clinical reports indicate it has some advantages besides mobility that will help it compete with Intralase.

### MULTIFOCAL IOLS

Few European cataract patients get multifocal lenses, mostly because of the cost, but European ophthalmologists are optimistic that use over the next year will increase significantly. While there are numerous multifocal lenses on the European market, the leaders are Alcon's ReStor, AMO's ReZoom and Tecnis,

and, surprisingly, Acri.Tec's Acri.Lisa. Alcon's new AcrySof ReStor aspheric (SN6AD3) IOL (which has been referred to as the ReStor-IQ but which is not being sold by that name) was introduced at ESCRS.

Of the 20 European physicians interviewed about the outlook for mIOLs, a third are not using any mIOLs. Eleven of those currently using mIOLs estimated that an average of 9% of their cataract patients currently get multifocal IOLs (mIOLs), with two using mIOLs for ≥65% of their patients (both practices with a high number of private-pay patients). Almost half of the surgeons currently using mIOLs expect their use to increase over the next 12 months to an average of 11%. One surgeon not using mIOLs plans to start, but a Greek surgeon predicted his use will go down. A few surgeons also are using mIOLs for most or all of their clear lens exchange (CLE) patients, but they said that doesn't represent many patients annually, and most said CLE use of mIOLs will only grow as the whole CLE category grows.

Cost is not the only issue hindering use of mIOLs among European surgeons. Comments by physicians who are not using mIOLs and have no plans to start included:

- *Switzerland:* "I don't do any multifocal IOLs because they don't work, though they've been pushed heavily by industry."
- *France:* "I want to see longer term data before I start using these lenses."
- *Greece:* "I'm not convinced they are an improvement."
- *U.K.:* "Cost is the barrier. Insurance doesn't cover them."
- *Belgium:* "There is not enough experience with those lenses, and there is no patient demand. I won't start unless there is patient demand."

AMO and Alcon have ***not*** let up on their commitment to multifocal marketing. Both companies have been putting strong emphasis on mIOLs, and the sales reps for each are enthusiastic about their products. Lectures on both companies' products were well attended, and doctors appeared eager to learn more about them.

ReStor is the 100 pound (not 500 pound) gorilla in Europe, and many users said that is their primary mIOL because of their long and/or extensive relationship with Alcon and its other products. But Tecnis is a strong #2 and appears to have eclipsed ReZoom among AMO users. There was a buzz about Tecnis and ReStor, but not much about ReZoom.

- *Switzerland:* "Tecnis is good for driving and distance and has better night vision. ReStor is good for near but not so good for high illumination distance. ReStor is good for the computer but driving in high light is a problem. The Acri.Lisa is pretty good. But there is not one lens that makes everyone happy."
- *Sweden:* "We use ReStor mostly because we are a big Alcon user. ReStor is okay but not perfect."
- *South America:* "I'm just starting multifocals with ReStor because of the cost problem…but I will do some mix-match with ReStor and ReZoom."
- *Spain #1:* "I use both ReStor and Acri.Lisa. Both are very good. I'm trying to decide which is best right now, but I need to keep both available. I may try a few ReZoom and Tecnis in the next few months."
- *Germany #1:* "Only about 1% of my cataract patients get a multifocal IOL because of the cost and lack of long-term results. But use is growing, and next year it might be ~2% because there are increasing data and experience with these lenses."
- *Italy:* "I don't currently use mIOLs, but I will probably start, and I'll use ReStor because the data look good."

**Multifocal vs. Monofocal IOLs**

| Measurement | Multifocal IOLs | Monofocal IOLs |
|---|---|---|
| Unaided near VA | Better | --- |
| Best corrected VA | Same | Same |
| Contrast sensitivity | --- | Better |
| Glare/halo | --- | Better |
| Dependence on spectacles | Less | --- |
| Visual satisfaction | Same | Same |

**Comparison of Different Multifocal and Accommodative IOLs**

| Measurement | Alcon ReStor | AMO Tecnis ZM9000 | AMO ReZoom | Acri.Tec Acri.Lisa | Eyeonics Crystalens |
|---|---|---|---|---|---|
| Material | Hydrophobic acrylic | Hydrophobic silicone | Hydrophobic acrylic | Hydrophilic acrylic with hydrophobic surface | silicone |
| Optics | Refractive/ diffractive | Refractive/ diffractive | Refractive | Refractive/ diffractive | Accommodative |
| Reading acuity | ReStor and Tecnis similar | | --- | --- | --- |
| Reading acuity under low light | Tecnis better than ReStor | | --- | --- | --- |
| Reading speed | Tecnis better than ReStor, especially in low light | | --- | --- | --- |
| Distance VA | Good | --- | Excellent | --- | Excellent |
| Distance VA | All similar | | | --- | --- |
| Intermediate VA | Better with Tecnis, ReZoom, and Lisa | | | | --- |
| Intermediate VA | Fair | --- | Functional | --- | Excellent |
| Near VA | Tecnis and ReStor better than ReZoom | | | --- | --- |
| Near VA | Excellent | --- | Very good | --- | Fair/excellent |
| Contrast sensitivity | Tecnis and ReZoom better than ReStor | | | Best | --- |

- *Germany #2:* "I use bilateral Tecnis because that has better near vision."
- *Portugal:* "I use mostly ReStor, but I use some ReZoom for mix-and-match. Use is growing slowly."
- *Spain #2:* "A monofocal IOL is still a good surgical option, and we should keep that in mind, especially when we can't use a multifocal lens."
- *Ireland:* "I use Tecnis. I think it is better than ReZoom because it is one piece, but the drawback is that the haptic is all one color, and you can't see it when you are loading it as you can with the two-color ReZoom."
- *Venezuela:* "I put mIOLs in 65% of my cataract patients, often with mix-and-match ReStor/ReZoom lenses, but I'm waiting for Lisa."

One thing that may be helping mIOL sales in the U.S. is IOL Counselor, a software-based educational tool produced by Patient Education Concepts. The program can be used to educate patients about life with a multifocal lens. It includes an eight-minute video and daytime and nighttime simulations (of a baseball game, a city street, and night driving) to show patients how vision is likely to be altered after an mIOL. ***Eye World*** magazine reported that, as of August 2007, IOL Counselor had 1,200 physician customers. IOL Counselor is supported by an educational grant from Alcon, AMO, and CareCredit (a division of GE Money).

## Mix-and-match

AMO is still pushing mix-and-match with mIOLs – with Tecnis and ReZoom in Europe – and Alcon continues to insist bilateral ReStor is best, but one of the biggest proponents of mix-and-match, Dr. Richard Lindstrom, president of the American Society for Cataract and Refractive Surgery (ASCRS), has pulled back a little, suggesting that surgeons take a staged approach to mIOL implantation. His advice: Put the first ReZoom lens in, wait a month, then decide what to use in the other eye. He explained, "If the patient is ecstatic with the first eye, then put a ReZoom in the other eye. If the patient says, 'My near vision is great but night vision drives me crazy,' then in the second eye use a Crystalens or Tecnis aspheric lens. If the patient says, 'Near is not as good as I want,' then you can use a Tecnis (either as a first choice) or a ReZoom with -0.75 myopia – or use a ReStor."

Dr. Lindstrom said using a staging approach:

- Provides a safety net for the surgeon.
- Eliminates possible patient dissatisfaction.
- Allows the patient to participate in decisions.
- Has the potential to increase overall patient satisfaction.

## Acri.Tec's Acri.Lisa

There is a new and ***potentially*** serious threat to both Alcon and AMO: Acri.Tec's Acri.Lisa refractive/diffractive, aberration-correcting bifocal IOL. A lot of European doctors have successfully tried this lens, and many others are very interested in it. And the data are building. There were numerous presentations at ESCRS on Lisa, and most of them were head-to-head with ReStor, ReZoom, or Tecnis – and Lisa looked as good or better. Acri.Tec sales reps claim 96% of patients become glasses-free with Lisa. Perhaps Lisa wouldn't be a serious threat if Zeiss weren't acquiring Acri.Tec, but it is, and Zeiss is.

**Czech Comparison of Acri.Lisa and ReStor at 3 Months**

| Measurement | ReStor n=60 eyes | Lisa n=60 eyes |
|---|---|---|
| Intermediate J1 vision | 35% | 32% |
| BCVA (mean) | 0.90 | 0.98 |
| Best J1 near vision | 95% | 94% |
| Never wear spectacles | N/A | 95% |
| Glare and halo | Similar | |

Dr. Pascal Rozot of France compared ReStor, Tecnis, and Lisa in 290 eyes. He found:

- All were effective in providing satisfying near vision.
- Intermediate vision was slightly better for Tecnis.
- Distance UCVA was better for Lisa.
- Lisa had better contrast sensitivity than Tecnis.

A Swiss doctor compared Lisa to an Acri.Tec monofocal lens, Acri.Sil. He found both were "good performing" lenses. Post-op spherical equivalent was good for both, and there was no posterior capsule opacification (PCO) with either lens. He found no statistically significant difference in visual acuity.

Dave Harmon of Market Scope said, "I'm impressed with the number of sessions and scientific data covering Acri.Tec's Acri.Lisa. The fact that surgeons are comparing the IOL in heads up studies to ReStor and ReZoom, and Tecnis MF in multiple presentations (at ESCRS) tells me the doctors and the company are very confident of that IOL. Many of the studies had better Acri.Lisa results, though none of the data that I saw was dramatically better."

Currently, the only sales of Lisa for use in humans are in Europe, but a company source said they sell "all we can produce." The lenses also are sold in the U.S. for veterinary use – dogs, cats, and fish (yes, fish!).

Carl Zeiss Meditec is in the process of buying Acri.Tec, and Zeiss appears committed to bringing Lisa and other Acri.Tec lenses to the U.S. This is one lens that has the potential to be a threat to Alcon and AMO – not today but not in the distant future either – in the U.S., and it may already be starting to affect AMO and Alcon in Europe. An Acri.Tec official said, "Lisa is close to Tecnis, but it has better contrast sensitivity."

A Swiss doctor said, "My high volume friends are doing a lot of Acri.Lisa. It seems to work well, and patients are happy, and I plan to start using it."

Acri.Lisa is priced comparable to, or less than, Tecnis, depending on the country.

### AMO's Tecnis

An Indian doctor who said he has "always been skeptical of multifocal lenses" has been convinced of the value of mIOLs by Tecnis. He said, "I would (now) recommend this (Tecnis) lens." He put Tecnis in 63 eyes and reported that at 1 month:

- Tecnis proved good unaided distance and near vision.
- The main problem was reading at an intermediate distance.
- Glares and halos were minimal and "probably due to the prolate anterior surface design."
- Overall satisfaction was high – 72% of patients were highly satisfied, 16% fairly satisfied.

### ALCON'S ReStor and ReStor aspheric

ReStor aspheric reportedly has a clearer image and contrast sensitivity than the original ReStor, and it is 4% thinner. A Norwegian doctor, who gave a talk about the lens at the Alcon booth, said, "There are fewer dropouts and complications with the aspheric lens, slightly better distance vision, and similar patient satisfaction." He said that his experience has shown that nurses and dental assistants have more complaints about mIOLs than office workers or manual laborers. He urged surgeons initially to try to find "super candidates" and only later go to "normal candidates." He added, "I'm more enthusiastic about ReStor today than two years ago, but patient selection is still very important. (ReStor aspheric) is an improvement, but it is still a challenging product."

Dr. Francesco Carones of Italy said that in low light the aspheric ReStor "sends light energy to the distant focal point for enhanced distance vision…It has minimal visual disturbances compared to other multifocal designs…and gives patients the greatest opportunity to be free from glasses."

Alcon sales reps said the new ReStor aspheric mIOL is intended as a replacement for the old ReStor, that the original ReStor will be phased out soon, though they said the company is recommending that doctors not mix original ReStor and aspheric ReStor in the same patient. Thus, they anticipate both ReStor lenses will initially be available. However, Alcon's Chief Marketing Officer, Kevin Buehler, said a decision on when to retire the original ReStor has not yet been made. He indicated the company is waiting to see how the new ReStor is accepted, "No decisions have been made about it…This is a relatively early-on roll-out of ReStor aspheric. We are very encouraged by the results we are getting (with ReStor aspheric) on improved visual acuity and improved contrast sensitivity…but we are relatively short in terms of clinical experience in the open market, the commercial setting …The first step is to really demonstrate the clinical performance…The second step is to figure out how it fits into patient management by a doctor…If one eye is ReStor non-aspheric, we probably have to be sensitive to a doctor's desire to have a similar product in the other eye. But we expect the market to move to an aspheric market…but it is a temporary timing thing."

A Dutch study on the long-term (3-year) safety and efficacy of ReStor found a decrease in symptoms between six months and three years and an improvement in binocular vision:

- ≥75% of patients never wore glasses.
- Vision was stable.
- <5% of patients complained of glare/halo in the long-run.
- ~90% of patients had no trouble with intermediate vision tasks.
- Young patients preferred wearing glasses when using a computer, but when they do, they are able to do computer tasks with no problem.

Another speaker compared Tecnis to ReStor in his practice, and ReStor was the winner. He said the big advantages of ReStor are the smaller incision size, the ease of use, and centration.

**Comparison of Tecnis vs. ReStor**

| Measurement | ReStor aspheric | Tecnis |
|---|---|---|
| Spherical aberration | 0.20 | 0.27 |
| Haptic unfolding | Easier | --- |
| Incision size | 2.2-2.6 mm ☺☺☺ | 3.2-3.5 mm ☺ |
| Distance VA in daylight | ☺☺☺ | ☺☺☺ |
| Distance VA in dim light | ☺☺☺ | ☺ |
| Near VA in daylight | ☺ | ☺☺ |
| Near VA in dim light | ☺ | ☺ |
| Ease of use | ☺☺☺ | ☺☺ |
| Centration | ☺☺☺ | ☺☺ |
| Night halos | ☺ | ☺☺ |

### Pupil size

Data presented at ESCRS suggested that pupil size could determine success with multifocal IOLs. The smaller the patient's pupil, the better Alcon's ReStor performed in terms of both near and distance vision. Dr. Kjell Gunnar Gundersen of Sweden compared ReStor and Alcon's monofocal AcrySof-IQ in a prospective, randomized, 98-patient study. He found that patients with a small pupil size who got a ReStor had significantly less spectacle dependency at near and intermediate distance. Post-operative monofocal patients were not significantly more satisfied than ReStor patients, but monofocal patients had significantly better uncorrected and best corrected distance visual acuity. His recommendation: "All potential candidates for ReStor lenses should have pupil measurements on pre-operative examination."

## PRESBYOPIA

The options for presbyopic patients are: mIOLs, monovision LASIK or IOLs, corneal inlays, and presbyLASIK. Dr. Ivan Ossma of Colombia summed up well the dilemma with presbyopic patients: "Presbyopic patients expect an unaided functional range of vision at all three distances with no detrimental optical quality…They want good contrast and no unwanted visual phenomenon."

**Multifocal IOLs.** Experts debated the advantages of monovision vs. multifocal IOLs for presbyopia.

- **PRO monovision:** Dr. J. E. (Jay) McDonald II of Arkansas contended, "Monovision is more compatible with the human visual situation…The retina is sensitive to contrast orientation, and the human visual system is designed to see edges. But in the multifocal format, we split the image in the same eye…so on the same receptor it is either diffractive or refractive. We are seeing conflicting information, and something has to give…The problem is we really are over-taxing our visual situation with an mIOL…Another problem with mIOLs is poor, waxy vision…You can always give spectacles to cataract monofocal patients…but you can never get a multifocal IOL patient back to binocularity."

- **PRO mIOLs:** Dr. Oliver Findl of Austria argued, "The basic principle of mIOLs is simultaneous vision…Two images are formed on the retina simultaneously, superimposed, causing retinal rivalry, and the brain chooses the best image…Even professional golfers use these lenses, so they must work well…There are four negatives to monovision: (1) compromised binocular visual function, (2) imbalance of sensory dominance (dominant eye has to be the distance eye), and identifying the dominant eye is not an easy task, (3) timing (you have to do the dominant eye first, even if that is not the worst cataract), and (4) fear factor (patients like the concept, but the thought of monovision scares patients). The one advantage is that monovision is cheap."

### REVISION OPTICS' PresbyLens

This removable (exchangeable) lens is made from a transparent bio-compatible material. It is put under a LASIK flap or perhaps minimally invasively in a pocket created by a femtosecond laser. The effect is obtained by steepening the central cornea. Dr. Jack Holladay of Texas noted that pupil size is the limiting factor, with the "sweet spot" 2-3 mm. He added, "PresbyLens has potential as an add-on for LASIK in presbyopic patients…This is a monocular implant. Patients will give up some distance for near vision, and patients have to decide if they want to do that."

There were promising results in early clinical trials. The company indicated it would get an IDE in 3Q07.

### PresbyLASIK

There appears to be little interest in this so far in Europe. There were several talks on it, and they were well-attended, but none of the doctors questioned are doing it yet. A speaker said presbyLASIK "works pretty well in low hyperopes. The difficulty is the myope. That is the real challenge."

Dr. Efekan Coskunseven of Turkey, speaking at an AMO-sponsored satellite session, reported on the initial international experience with treating presbyLASIK with the Visx/Intralase femtosecond laser, saying the results have been positive, and patients have a "high degree" of satisfaction with their vision. There is some decline in distance vision, but it is often not recognized by the patient. He said the ideal patients for presbyLASIK are:

- ≥40 years old.
- ≤+4 diopters of hyperopia and up to 1.5 diopters cylinder.
- Minimal near add of +1.25 diopters at 4 cm.
- A WaveScan and manifest refraction that match.
- Pupil size of 5-7 mm on WaveScan without pharmacological dilation or modification of ambient lighting.

### ACUFOCUS'S ACI-7000

The company did not have a booth, and there was very limited discussion of these lenses at ESCRS. Many ophthalmologists remain highly skeptical of these lenses, which use a random pinhole effect to increase depth of field and improve presbyopia. The AcuFocus corneal inlay procedure is relatively simple. First, topical anesthetic eye drops are put in the patient's eye, then a femtosecond flap is created. The lens is inserted and centered over the pupil and dried, then the flap is closed.

In data presented from the experience with this lens in Turkey, all patients were near 20/20 or better, with the worst at 20/32. In the European experience so far (66 patients reported with 3-month follow-up), most had 20/20 at 9 months, and the worst was 20/30.

A Spanish surgeon said, "This is a very promising device." An American surgeon agreed. An investigator said, "I'm a believer, but the device needs and is getting two changes: It is being made thinner, and there will be a smaller annulus (fewer pinholes)." A German surgeon said, "We were supposed to participate in their trial. They contacted us, and then we never heard from them again."

## ACCOMMODATING LENSES

### EYEONICS' Crystalens

Crystalens was noticeably absent from the exhibit floor, and there was very little about this lens in the lectures. Competitors said this was because the company is focusing on the U.S. market. European refractive surgeons are aware of the Crystalens, but none of those questioned have plans to use it

yet. A Swedish doctor said, "I heard people are not happy with Crystalens." However, other sources insisted that the new Five-0 (5.0) lens is a significant improvement. An industry source said, "The Crystalens Five-0 improvement is real, which we can see from imaging, and their sales appear to be increasing."

One talk that did discuss Crystalens was by an Italian surgeon who presented his study of 120 eyes in 60 patients with 12-month follow-up, comparing Crystalens to ReStor and ReZoom. He concluded that distance vision was similar, near vision had the best results with ReStor, patient satisfaction was high with all the lenses, and better accommodation and better contrast sensitivity was obtained with Crystalens.

### POWERVISION'S FluidVision

A speaker said this lens has an accommodative range up to 5-10 diopters and near natural accommodation. It reportedly has been tested in animals and cadavers but not yet in live humans.

### VISUGEN'S Synchrony

Dr. Ivan Ossma of Colombia discussed the binocular performance of Synchrony vs. monofocal and multifocal IOLs in cataract patients. He said, "It is a very promising technology with the optical quality of a monofocal and a good range of vision…Synchrony is, in essence, a monofocal lens."

Dr. George Beiko of Canada said he has implanted 18 Synchrony lenses in older patients (>age 75). He pointed out that Synchrony can be implanted through a suture-less 3.6-3.8 mm incision, using a pre-loaded injector system. With the first 10 patients, he reported:

- No severe complications out to two years, though there were three cases of mild PCO, two of which required a YAG capsulotomy, and two cases of rebound iritis (one of which developed cystoid macular edema).
- 75% of patients could read without difficulty.
- Patients were very satisfied.
- At intermediate distance, 87.5% of patients could read.

**Dr. Ossma's Comparison of Synchrony to mIOLs**

| Measurement | Synchrony | ReZoom | ReStor | Tecnis |
|---|---|---|---|---|
| Intermediate vision | Best | Second best | --- | -- |
| Near vision | Not as good as ReStor | --- | Best | --- |
| Reading speed | Tied for second | --- | Tied for second | Best |
| Reading in mesopic conditions | No loss | --- | Huge drop | No loss |
| Halos at 6 months | 6.4% | 14.8% | 21% | 17.6% |
| Severe halos | 0 | 0 | 3.5% | 0 |
| Need for YAG capsulotomy | No | Yes | Yes | --- |
| Functional range of vision | Best | --- | --- | --- |

- Both static (VA) and dynamic (reading speed) visual outcomes were good.

## PHAKIC IOLS

In June 2007 the French government ordered a recall of Ioltech's NewLife angle-supported, anterior chamber phakic IOLs, both presbyopic and myopic lens, citing concerns about excessive endothelial cell loss. The lenses removed from the market were: Corneal's Icare and Ioltech/Zeiss Vivarte and NewLife phakic IOLs. Studies showed significant endothelial cell loss in patients who had received angle-supported phakic IOLs 2-3 years post-operatively. Corneal (which is now owned by ChromaPharma) called the recall "temporary," pending the results of a retrospective study. The recall cast a cloud over all hinged, anterior chamber phakic IOLs in development.

### ALCON'S AcrySof phakic IOL

Alcon has a foldable, hinged, one-piece, acrylic, anterior chamber phakic IOL with a 6.0 mm optic in development (AcrySof AC phakic IOL), using the Monarch II delivery system. From presentations at ESCRS, it looks as if it could succeed where these other anterior chamber, hinged phakic IOLs have failed. Dr. Thomas Kohnen of Germany concluded, "Seven (anterior hinged phakic) lenses are not implantable any more because the outcome is not good. I still think the AcrySof lens has potential."

In Phase I studies, the Alcon lens did not show excessive acute endothelial cell loss at 6 months: 1.0% centrally and 4.5% in the corneal periphery. This difference from the other recalled lenses was explained as due to a low compression force and good rotational stability resulting from its unique haptics. However, at least two- or three-year data may be needed before this lens is really proven safe.

An ongoing Phase III non-randomized trial in stable high myopes found:

- At one year, 57.8% of patients had ≥20/20 vision, 84.5% were ≥20/25, and 93.8% were ≥20/30. Also at one year, 44.7% of patients had no change in BCVA, 31.1% gained 1 line, and 18.0% gained 2 lines.
- At 2 years, best corrected visual acuity of ≥20/25 was achieved by 98.4% of patients. Refraction was reported to be within ±0.5 D of target in 78% of the patients and more than half of the patients gained 1-2 lines of VA.
- No concerning late adverse events. The most common complication was increased IOP, which was blamed on incomplete viscoelastic removal.
- Endothelial cell loss was 1.7% from 6 months to 2 years.

**STAAR'S Visian ICL** (implantable collamer lens) phakic IOL appears to have survived this bad news unscathed. Sources said there has been no effect on their opinion of or interest in Visian from the recall. However, interest in Visian is picking up. A Spanish surgeon said, "I use the Visian ICL a lot, and my use is going up. The French recall was for anterior chamber devices, a totally different design. If anything, the recall has had a positive impact on Visian because it means the ICL passed the time test."

There have been rumors that B&L intends to buy Staar, but sources at ESCRS were dubious about this.

## CONTACT LENSES AND CONTACT LENS SOLUTIONS

This was the wrong meeting to ask about these products. Surgeons all said contact lenses and solutions are handled by optometrists and opticians.

However, a knowledgeable AMO source said the European market is segmented into two extremes: single-use daily wear contact lenses on one side and silicone hydrogel long extended wear lenses (monthly and two-week lenses) on the other side. He estimated that ~50% of the contact lens market in Sweden and 25% of the U.K. market is now once-daily lenses. He does not believe that the lens solution recalls – of Bausch & Lomb's Renu with MoistureLoc and AMO's Complete MoisturePlus – have had any effect on contact lens preferences. He and surgeons questioned agree that solutions recalls are not driving patients out of contact lenses and into refractive surgery. The AMO rep said contact lens volume in Europe is generally flat, with "churning" going on in terms of patients switching from one type of lens to another (e.g., away from traditional lens to either once-daily or long-term silicone hydrogels).

A U.S. source said there is an ***"undercurrent" of concern*** that silicone hydrogel lenses are "a major factor in *Acanthamoeba* keratitis infections with contact lens solutions – but only one of the factors."

## REFRACTIVE SURGERY

As of September 2007, an expert estimated that 11.5 million eyes have had refractive surgery in the U.S., accounting for 7.7% of all spectacle/contact lens wearers. By 2010, he estimated that 10% of all American spectacle and contact lens wearers will have undergone refractive surgery. Worldwide, 30 million procedures have been performed, with 5,000 laser systems installed. Refractive surgery is done mostly by lower volume surgeons; reportedly, 40% of all U.S. refractive surgeons perform <16.6 procedures a month.

### Procedure volume

The current outlook for the U.S., according to Dave Harmon of Market Scope, is for a total of 1,414,000 refractive procedures this year, down from his earlier estimate of 1,440,000, making 2007 relatively flat compared to 2006. He said, "Generally, the market is still pretty solid. None of our survey data or anecdotal reports are indicating that demand is falling at the moment; however, I am concerned that the tight credit market in the U.S. may have some effect in the longer term."

U.S. refractive surgeons as well as industry sources suggest 2007 will be flat to slightly down, perhaps off 2%-3%. Sources agreed that if the housing situation worsens, procedure volume could contract slightly more than that. At this point, no one is predicting 2008 volume, and most surgeons questioned are very nervous about the housing and credit markets and their effect on consumer confidence, consumer liquidity, and consumer ability to finance the procedure. They quite simply have their fingers crossed that the market holds steady and doesn't worsen; none are predicting an up tick in 2008.

The outlook in Europe is slightly more positive. Some European surgeons said they have been seeing a small up tick in the last six months, but most expect flat to a small increase in procedure volume over the next 12 months. A Slovakian surgeon said, "As our economy grows and people have more money, LASIK volume goes up. The best times of year for us are summer and Christmas." A Swedish surgeon said, "Volume is up marginally, but there is more competition." A Swiss surgeon said, "Refractive volume is up and down. The last six months it seems up."

If there is any bright spot, it is Asia/Pacific, and that is where industry appears to be focusing. Ziemer President/CEO Frank Ziemer said, "There is no reason to think things will pick up. The future looks flat in the U.S. We all know that in Asia there is a clear trend to an increase. Overall, we are not really depending on an increase in LASIK procedures because…our market is, first, the installed base. Because that isn't saturated, it is not an issue for us."

Alcon chief marketing officer Kevin Buehler said that the market is indeed slow but he predicted that Alcon can still do better by gaining market share, "What we're seeing is low single digit growth in the U.S., and obviously what we see in refractive laser correction is under-indexed in terms of the potential audience, but the first place to start is in the clinical management of the patient…In refractive surgery today you still have to manage the astigmatism, either with limbal relaxation or a laser, so we are looking to manage the entire clinical need, and at the same time manage the product offering today to that cataract/refractive surgeon. We have a lot of room to grow in terms of category growth even if the market share isn't growing. Even if the category is relatively slow in growth, there is room for market share growth."

Lamar Chandler, director of Nidek's global marketing, agreed the LASIK market is flat to slightly down, explaining, "Disposable income is not out there, and it's getting worse

with the (failing) housing market. And consumers are more aware of complications with LASIK…Intralase has helped the LASIK market because patients see it as an all-laser procedure, but a lot of doctors look at the cost of Intralase. Intralase is doing great marketing, but it hasn't boosted procedure volume."

### Pricing

European doctors indicated pricing is holding fairly steady, though a few doctors are planning to raise prices with the addition of a femtosecond laser. A Slovakian surgeon said, "Pricing has been very low, and now is the time to raise prices, and I think we can do it. We got a new WaveLight (excimer) laser – the only one in our country – so we have a marketing advantage…At $400 per eye there is also a push for medical tourism that we may be able to take advantage of."

### PRK (photorefractive keratectomy)

European refractive surgeons may not agree on many things, but they generally agreed that PRK is increasing as a share of their refractive procedures. The reasons cited included:

- *Sweden:* "PRK is up because of problems with LASIK. Personally, I'd rather have LASEK than LASIK if I were a -3.0 (myope)…I would do PRK on everyone if it didn't have a haze issue."
- *South America:* "My PRK use is up because, with mitomycin, I'm not afraid of haze and because the cornea in some patients isn't wide enough to do LASIK."
- *Switzerland:* "PRK is safer, the pain is better controlled than in the past, and there are excellent visual results which are equivalent to LASIK."
- *Dr. Richard Lindstrom, Minnesota:* "When my patients say they want the very safest procedure, I always do surface ablation."

**Comparison of PRK and LASIK**

| Measurement | PRK vs. LASIK |
|---|---|
| Ectasia | PRK less, making it safer for thinner corneas |
| Buttonholes | None with PRK, making it safer for steeper corneas |
| Free flaps | None with PRK, making it safer for flatter corneas |
| Correction range | Wide range with PRK, somewhat less with LASIK |
| Surgeon expertise required | PRK safer for low volume surgeon |
| WaveFront results | Better with PRK |
| Medicolegal situation | Fewer malpractice lawsuits with PRK |
| Pain | More pain with PRK but less than in past |
| Speed of return of vision | PRK slower but improving |
| Haze | Can occur with PRK but may be close to elimination |
| Dry eye | Possibly less with PRK |
| Ease of procedure | Easier with PRK |
| Chance of infection | Possibly less with PRK |
| Enhancements | Possibly fewer with PRK |
| Higher order aberrations | Same |

- *Dr. Marguerite McDonald, U.S.:* "Will PRK replace LASIK? No. Will it always exist as a viable alternative to LASIK and have significant (market) share? Yes… Surface ablation in 2007 provides excellent clinical results and is still the best in the laser vision correction industry. Pain and the slow return of vision are mostly conquered."
- *Nidek's Chandler:* "It comes down to surgeons realizing that PRK is a much more stable procedure. It is more painful for the patient, and healing time is longer, but with a conventional microkeratome, you see a wide range of flap thickness. Even if the number of procedures hasn't gone up, PRK is increasing."

### Excimer laser sales

***All*** of the European and South American refractive surgeons questioned at ESCRS with plans to buy an excimer laser over the next year said they have already chosen a WaveLight Allegretto or they expect an Allegretto to be their choice. One of the key reasons – but not the only reason – is the lack of a per-procedure fee. A European surgeon said, "We chose WaveLight because it is the best laser."

A physician who was critical of the WaveLight laser said, "It has an 18% enhancement rate, there is no 3-D eye tracking, and you can't do wavefront-guided LASIK. Well, they have that, but it doesn't work 40% of the time."

## FEMTOSECOND LASERS

Does every refractive surgeon need a femtosecond laser? Many experts were predicting that eventually, femtos will be standard-of-care, but worldwide penetration is low, so a lot of doctors still believe mechanical microkeratomes do the job just fine. A speaker cited several issues with femtos, including: uneven raster lines, undissected islands leading to flap tears, gas bubbles that can dissect into the anterior chamber causing micro-buttonholes, decentered flaps, and transient light sensitivity. A U.S. surgeon said, "I switched from a microkeratome to a femtosecond laser, but I prefer a microkeratome. The economics of a femtosecond are not favorable, and microkeratomes are more patient-friendly and faster."

There is no question that Intralase continues to dominate the femtosecond laser market, even with the entry of several competitors and others on the horizon. Surgeons are very impressed with the wealth of data that Intralase has collected. However, Ziemer claims to have sold and delivered 25 LDV lasers (12 in the U.S.), and an official said these are currently in use. One South American surgeon said he is purchasing a 20/10 Perfect Vision Femtec laser "because of their longer experience with the cornea than Intralase."

**Comparison of Femtosecond Laser vs. Microkeratome**

| Measurement | Advantages | Disadvantages |
|---|---|---|
| Microkeratome | Time tested, good reproducibility, fast, low cost, edge is clean, larger flaps | Slight-to-large loss of accuracy from bed hydration, flap complications, visual problems, ectasia, striae, epi ingrowth, increased dry eye syndromes |
| Femtosecond laser | Improved accuracy, uniform thickness of flap, thin and reproducible flaps without buttonholes | Inflammation (related to energy level), bubble blocking the tracker and potentially interfering with the ablation rate, difficult or decentered flaps |

Other comments on femtosecond lasers included:

- *Sweden:* "I don't have a femtosecond laser, and I have no plans for one. There are problems with that, too. And volume would have to increase first."
- *South America:* "We are getting a WaveLight laser, but no femtosecond laser, though in the future I plan to get an Intralase."

Dr. Michael Knorz of Germany told an AMO-sponsored seminar that the ideal flap is about 80 µm, but clinically a 100 µm is probably best, he said, adding, "(100 µm) weakens the cornea only by ~15% and expands the range of treatments." Asked how thin femtosecond flaps should go, Dr. John Marshall of the U.K. said, "80-90 µm is thin enough...That is about the limit."

## Femtosecond LASIK

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). Dr. Marshall said a study he did of SBK vs. PRK and LASEK found LASEK, without enhancement, became less stable after 3.5-4 years, "just like the presbyopic shift in RK (radial keratotomy)." He commented, "PRK is mechanically stable but is associated with haze and pain. LASIK has no haze or pain but an unstable cornea…My proposal…is sub-Bowman's ablation – SBK."

Dr. Holladay of Texas compared wavefront-guided LASIK using a Visx excimer laser and an Intralase femtosecond laser

**Visx Wavefront-Guided LASIK vs. WaveLight Optimized LASIK**

| Measurement | WF-Guided n=35 | WF-Optimized n=39 |
|---|---|---|
| **Higher order aberrations (HOAs)** | | |
| Pre-op | 0.36 µ | 0.36 µ |
| Pre-op standard deviation (SD) | 0.14 | 0.14 |
| Post-op (mean) | 0.38 µ | 0.50 µ |
| Post-op SD | 0.17 | 0.29 |
| % HOA same post-op | ~ 33% | ~ 25% |
| % HOA worse post-op | ~ 33% | ~ 60% |
| % HOA better post-op | ~ 33% | ~ 15% |
| **Primary spherical aberration (SA)** | | |
| Pre-op | 0.12 µ | 0.1 µ |
| Pre-op SD | 0.13 | 0.15 |
| Post-op (mean) | 0.10 µ | 0.09 µ |
| Post-op SD | 0.15 | 0.24 |

to optimized LASIK with a WaveLight laser and an Intralase femtosecond laser. He has done 450 eyes with each and is in the process of a retrospective analysis of them, using two wavefront analyzers on each patient. So far, he has analyzed 74 eyes and reported better results with the Visx wavefront-guided system, which is what he now uses exclusively. He said, "Very few patients have zero spherical aberration, and most of those who do are in their early 20s or younger. Wavefront-guided ablation is better for the vast majority of patients who do not have zero spherical aberration."

At a session sponsored by the International Society of Refractive Surgery (ISRS) and the American Academy of Ophthalmology (AAO), a speaker said, "If you are using a Visx laser, there is no question you should use wavefront-guided ablation…But that does not mean this is the best option for everyone…We learned that wavefront corrections are only needed in about 19%-20% of eyes, and definitely in ~4% of eyes. Most eyes do not have enough pre-operative wavefront error to need wavefront-guided surgery. And the only eyes that got worse were the eyes with a significant amount of lens aberrations, and that is about up to one-third of eyes. I think we need to be careful about doing wavefront-guided surgery on every eye." Dr. Steve Schallhorn of California, former director of cornea and refractive surgery for the Naval Medical Center in San Diego, said, "The modeling I've done predicted that wavefront-guided would induce fewer HOAs (higher order aberrations) in those patients who had very little to begin with…You take someone with little (HOAs) to begin with, and those you induce may be more troubled by aberrations if you induce more of them." A Swiss surgeon said, "Eventually, I think wavefront-guided surgery will be used for everyone." Dr. Guy Kezirian of Arizona added, "I submit there isn't and never will be an ideal profile (for wavefront-guided surgery)…I think in five years we will see an increasing movement to inside of eye, with better and better phakic IOLs to limit the amount of ablation of the cornea to the point where the aberrations we induce are so small that patients don't notice them." Dr. Holladay added, "The future is going to be combined topo- and wavefront-guided ablation."

## INTRALASE: Therapeutic applications

Dr. Roger Steinert of the University of California, Irvine, speaking at an AMO-sponsored satellite session, called IEK (Intralase-enabled keratoplasty) "the first major advance in corneal transplantation since the operating microscope and 10-0 nylon were introduced in 1970…In less than four years this has gone from a lab dream to reality."

**Penetrating Keratoplasty (PKP) vs. IEK**

| Measurement | PKP | IEK |
|---|---|---|
| Sutures | Relatively tight | Not as tight |
| Healing time | At least 1 year in adults | Faster |
| Astigmatism | High | Less |
| Wound dehiscence | ~ 4% | No |

Dr. Steinert prefers the zig-zag shape for IEK over a top-hat or mushroom cut. He said, "Top-hat and zig-zag both promote even and stable alignment…Mushroom does not. The problem with top-hat is that you may not get the watertight benefit you are looking for and which you get with zig-zag."

He reported on his results on 30 eyes done with a zig-zag cut as of September 2007: "What's really exciting is that, in 13 of the 30 eyes with normal macular function pre-op, by three months 100% were 20/30 or better, and by six months 100% had 20/30 and three had 20/20." He has now started a controlled study, and the preliminary results of that study are showing that IEK patients have less astigmatism, faster recovery, and higher levels of BCVA."

### ZEISS VisuMax

An expert said the VisuMax is "more like the 20/10 Perfect Vision Femtec laser." But Dr. Dan Reinstein of the U.K. praised the VisuMax, saying that with this femtosecond laser a surgeon doesn't have to change the post-op regimen at all; it's the same as with a microkeratome – no steroids. The advantages of VisuMax include:

- The different f stop of the optics.
- Very small spot size.
- Energy a fraction of other devices.
- High repetition (rep) rate.
- Spiral patterns.
- Negligible bubble formation.
- No waiting time before excimer treatment.

### ZIEMER LDV

President/CEO Frank Ziemer said there is no real trend yet to say who the LDV buyers are, but about 25% of the U.S. machines are being used as mobile (roll on/roll off) units. Mobility is an "important feature" with the LDV, Ziemer said, adding, "It is important for people who want to use it as mobile, but it is also convenient for (our) sales people. Making a demonstration is so much easier; we can put it in a van and very easily drive it to those people."

This laser appears to have a lot of potential, but, even though it is being sold, it is still somewhat in the development stage, with some fine-tuning continuing to be done. The key features of this laser are:

- Compact and mobile.
- Articulated arm, which rotates to treat right and left eyes.
- Single-stage, solid-state 1040-1060 nm laser.
- High pulse rep rate >1000 kHz, which compares to 60 kHz for the Intralase.
- Low energy per pulse (100 nJ), so minimal bubbles are created and those that are created disappear quickly, so there is no waiting time before starting a procedure. An official said, "Because of the low pulse energy, we can go closer to the Descartes membrane."
- No "tissue bridges" are formed.
- The flap lifts easily. Dr. Richard Foulkes of the University of Illinois said the LDV flap lifts easily with forceps. Other investigators don't always find the flap as easy to lift, but Dr. Foulkes said increasing the threshold resolves that issue. A Swiss doctor said, "Initially, lift was an issue, but in the last three months with 'expert mode,' there has been no issue."
- Less photosensitivity. There is a small optical aperture with LDV because the spots are <2 µm, and the focal length is shorter, so there is less shock-wave effect.
- Room temperature. The room where the femto is kept/ used does not need to be kept cool as with the Intralase femto.

One of the limitations of the LDV is that it doesn't have a z-axis – yet. Ziemer said, "We are working on that. It may be available in about 12 months…From a sales point of view, it is not critical. We have a backlog at the moment, and our clients are happy with the features we offer. We can't offer everything right now, that's true, but we haven't lost a lot of sales. We have lost a few sales, but not very important (ones) for us."

An AMO official said the LDV uses "set depths and optical zones" to avoid infringing on Intralase's "Michigan" patent. In contrast, he explained, with the Intralase femto, the surgeon can set the depth ≥90 µm and the optical zone size.

Dr. Jerome Vryghem of Belgium said >1,400 procedures have been done so far with LDV. He said, "The technology is still improving, with better suction and higher reproducibility in flap thickness. There was a learning curve for both the manufacturer (Ziemer) and the surgeon, but now I am quite satisfied with the results…Now, two months after I purchased an LDV, I do femto-LASIK in 85% of patients."

**Dr. Vryghem's Comparison of LDV and Intralase**

| Measurement | LDV | Intralase |
|---|---|---|
| Pulse rate | Fast | Slow |
| Spot size | Smaller | Big |
| Tissue bridges | No | Yes |

Dr. Vryghem also presented the preliminary results with LDV using an Allegretto excimer laser in 214 consecutive eyes. During this period the laser continued to be improved, so he put the procedures into three groups, and each got progressively better. After doing more than 100 eyes, he bought an LDV in June 2007, and he has done 79 eyes since then. He said microbubbles never delayed a procedure, bed quality was excellent "in most cases," the flaps lifted very easily, and no or very small hinges were the biggest complication. He added, "The geometry of the flap is similar to a microkeratome with smooth edges. There is equal thickness of the flap over the full cornea…Since I purchased the laser, mean flap thickness has been 101 µm, with a standard deviation (SD) of 8.75 µm, and I was targeting 110 µm…Hinge size average 4.64 mm. Visual recovery is similar to classic LASIK on Day 1, with no increased photosensitivity and comparable dryness." Visual results were also good.

Dr. Vryghem offered some tips and tricks for using an LDV, including:

- Before each treatment, check the vacuum, do a slow scan test, and pay attention to the message that asks, "Have you removed the previous foil?"
- Treatment time comes down as you get used to the laser. He said he started at 45-50 seconds and is now at 25 seconds.
- Total treatment time is only slightly longer than with a microkeratome (7.5 minutes vs. 6 minutes).
- Apply markings after the flap cut because the ink absorbs laser rays and causes adhesions.
- Apply suction only when the applanation covers two-thirds of the surface of the window.
- Once suction is established, don't lift the eye. Maintain continuous pressure. "Trust the machine, and you will be lucky and have no suction loss," he said.
- Avoid decentered flaps with the margin of the flap through limbal tissue.
- When making the cut, use minimal magnification.
- In the beginning, avoid femto-LASIK flaps in corneas with scars or radial or arcate incisions (post-RK or AK) because adhesion can be an issue in these patients.
- Use the 140 µm foil.

Dr. Jorge Alio of Spain discussed flap configuration with an LDV "because after safety, it is what matters most to us for outcomes." He concluded that the LDV creates flaps with planar configuration, with a smooth transition to the edges, "It seems a very valuable tool for refractory surgery, generating predictable flaps."

Dr. Bojan Pajic of Switzerland reported 36 eyes in the first prospective clinical study with the LDV vs. an Amadeus microkeratome (made by Ziemer and sold by AMO), using a B&L Tecnolas excimer laser. He said, "Visual acuity improved significantly faster and significantly more with LDV than Amadeus ($p<0.001$). You could see a difference at Day 1, and the visual acuity continues to improve out to 6 months with LDV but stylizes at three months with the Amadeus…There is also significant corneal tissue saving with LDV ($p\leq0.05$), and there was less edema with LDV." He concluded that the LDV has high pricing, is tissue-saving, and increases visual acuity, with cutting time of 20-25 seconds.

Dr. Foulkes said he was an early Intralase adopter and has done ~8,000 Intralase procedures, but he has now switched over completely to LDV, which he has had for a month. He said, "This is a 21st century laser, not a 20th century laser. The benefits will move femto forward." He said the LDV offers "orders of magnitude faster, smaller, and more stable flaps" than a microkeratome. He emphasized the reduction or near elimination of tissue bridges with the LDV vs. Intralase, "My results have been very easy flap lifts with forceps. And we found we could increase the energy significantly and get a better lift…I'm not having to manipulate the eye as much, so there is less inflammation and no problems with OBL (opacified bubble layer). A smooth lift means a quiet eye. An easy lift is less traumatic, causing less inflammation and less edema and results in better early vision…LDV is the best marriage of a microkeratome and the femtosecond laser."

One area where LDV is getting some attention is from eye banks. A U.S. eye bank source said, "Intralase can do penetrating keratoplasty but not DSEK reliably. LDV can only make planar cuts now, but the company is working on 3-D cutting possibilities."

### Next generation custom ablations

Dr. Schallhorn predicted the future will see:

- **Higher quality wavefront units.**
- **More precise ablation alignment.** He said, "Already we have iris registration, but I think soon we will have cyclotorsional alignment during a procedure. I think that will incrementally improve results."
- **Custom flap creation.** He said the advantages of custom flaps include improved visual outcomes, smallest flap created for the treatment area, greater corneal stability, and less dry eye, adding, "One area that is low flying fruit is the mismatch between flap and ablation area."
- **Topography-guided custom ablation.** He said, "There are some patients better served with topo-guided ablation ...I think we will do that in the future…That will come along." Dr. Holladay added, "The only way you can be sure whether the aberrations you are treating are lenticular or topographical is to do both (topo-guided and wave-front-guided in combination)."

## SPECIFIC COMPANIES

### ADVANCED MEDICAL OPTICS (AMO)

A speaker at an Alcon-sponsored session said centration may be an issue with the Tecnis mIOL.

### ALCON

At an Alcon-sponsored seminar, the advantages of Alcon's blue-light filtering AcrySof-IQ (SN60WF) were discussed. Dr. Samuel Masket of California said there are several advantages to this lens besides its blue-light filtering, including:

- Thin profile.
- Excellent long-term centration.
- Can be implanted through a 2.2 mm incision.
- Less surgically-induced astigmatism.

Dr. Miguel Burnier Jr., an ocular oncologist from McGill University in Canada, urged ophthalmologists to use this lens to help reduce the incidence of uveal melanoma. He said, "Bright light exposure is a risk factor for human uveal melanoma…Blue-light filtering lenses may reduce or prevent the incidence of uveal melanoma, which is the most common primary intraocular tumor in adults. Uveal melanoma has a mortality of 50% at 7-10 years, especially if there are liver metastases…For adult patients we should use blue-filtering IOLs. If you use blue-filtering lenses, you can reduce this disease…and I hope you do that."

### ALCON acquisition of WAVELIGHT

Alcon and WaveLight officials were very upbeat about Alcon's proposed acquisition of WaveLight. WaveLight CEO Wolfgang Tolle emphasized what each company brings to the deal, "WaveLight is a medium-sized company, and Alcon is much larger. We have great technology, and…it is the combination of the best technology in the world with a very large company with tremendous resources." Tolle wouldn't comment on any plans post-merger, saying, "Nothing is defined…It's business as usual." Kevin Buehler, senior vice president for global markets and chief marketing officer, said that the WaveLight acquisition is a "strategic fit" for Alcon, "When we think of the refractive laser business, we think of it as broader than the laser business, including the entire channel of cataract and refractive surgeons. When you look at the (WaveLight) technology, it is a proven technology with a relatively large installed base around the world and the fastest laser approved in the U.S. today…For us, it's a strategic fit to our products in that channel."

WaveLight has a femtosecond laser in development, though an Alcon official indicated Alcon has not decided yet whether that will be continued or whether Alcon buys some other femto (hmmm, Ziemer?). Alcon's Buehler said, "Clearly it would be in our interest to continue to expand that product, either to improve clinical results, whether with theirs (WaveLight's) or someone else's. If the strategy is to broaden that area, then we are interested in any of the clinical areas, including femtosecond lasers, additional diagnostics, topography, etc."

### A.R.C. LASER

This private company currently has no ophthalmic products in the U.S., but it presented its new FOX-G photocoagulator at ESCRS. FOX-G is a small, portable, battery-driven unit similar to other devices, with the same power output, but it is less expensive. A company official said, "It is a price sensitive market, and right now we are a European company producing in Germany. With the low dollar at the moment, compared to the euro, we have some problems selling in the U.S. The exchange rate makes us 35%-37% more expensive than U.S. companies. However, with this unit, I think we are still lower, price-wise." A.R.C. is looking for a distributor in the U.S.

Other ophthalmic devices made by A.R.C. include:

- SLT laser.
- Combo YAG/SLT.
- Photodisruption.
- $CO_2$ laser for blepharoplasty applications.
- Phaco laser system consisting of a phaco machine and laser. "We are the only company worldwide building and selling phaco lasers. We have placed a lot of instruments around the world except the U.S. We do have one at Manhattan Eye & Ear."

A.R.C. has a new laser in development for posterior capsule opacification (PCO) prevention. Dr. Rudolph Walker, head of the application department, said, "There is a new design/method for using the technology for doing PCO prevention. A second cataract can be prevented…Cleaning the capsule during phaco and afterwards, there is no PCO, and the patient won't need a YAG treatment. This technology will influence lens technology because right now all the lens technology is focused on PCO prevention, with sharp edge technology to prevent cell growth, and lenses are placed preferably in a stable capsular bag. But to do a YAG laser capsulotomy, you have to rupture the bag, and accommodative and toric lenses rely on an intact capsular bag. So technology to prevent PCO and preserve the capsular bag is a revolution in ophthalmology. Then you can implant lenses that preserve accommodation. So, the first way to get an injectable lens to preserve accommodation is to preserve the PCO."

Dr. Walker said that research on this new technique is being done at the University of Utah and at some European centers, including one in Spain, "We are in *in vitro*, animal, and human cadaver eyes now, and then we'll start doing human eyes at the beginning of next year." This is a stand-alone device which can be added to A.R.C.'s existing laser.

### BAUSCH & LOMB

"Is Bausch & Lomb even in the game?" That was the question an expert posed, predicting, "We will see an inflection point with B&L in the next year, and then we'll find out if they are in the game...If there are no changes, they won't be; they will slowly fade away and be replaced by Zeiss. But with the acquisition by a private equity firm (Warburg Pincus) and changes in their structure and thinking, I could see them coming back in (the game)."

At ESCRS, B&L's focus – at least for the cataract division – was on minimally-invasive cataract surgery (MICS), surgery through a 1.8 mm incision. B&L's new phacoemulsification system for cataract surgery, Stellaris, was displayed at ASCRS in April 2007, but sales did not begin until just before ESCRS, with the first commercial (non-beta) machine recently delivered in the U.K. and due to start operating right after ESCRS. There are 8 U.S. sites and >20 sites worldwide that had tested Stellaris and now will start using it outside of trials. Stellaris is priced comparable to other phaco machines. An official said, "We see Stellaris as a solution for MICS…It can do bilateral and axial phaco…so we see it as a very versatile system which will enable all surgeons to transition to MICS." Another B&L official described Stellaris as "elegance, defined as sophistication without complications."

Prof. Burkhard Dick of Germany described the first European experience with the Stellaris phaco system, commenting, "This is a breakthrough moment for the company." He said he has done 50 cases with Stellaris, "My technicians loved it even before I did…because it is so easy for them to get ready for surgery. It is wireless (bluetooth) with direct internet connection to the company…I've had no complications. For me, it is the logical step ahead."

The key Stellaris features he highlighted were:

- 1.8 mm biaxial (or axial) approach for nuclear removal through a very small incision.
- Best irrigation rate.
- 19- and 20-gauge needles.
- Ergonomic.
- 6-crystal hand piece.
- Custom control software.

B&L doesn't have a femtosecond laser in development, but it has other refractive and lens technology that was being featured at its booth, including new:

- Monofocal lens, Akreos.
  - B&L is waiting for FDA approval for the Akreos AO, which is expected "soon."
  - The MICS version of Akreos (the Akreos MI60) isn't expected in the U.S. until at least 2009.
  - An official would not provide any information on a possible multifocal Akreos in the future. Dr. Dick said surgeons in his hospital have found the Akreos MI60 to have good folding and very good centration. A surgeon who has implanted this lens said there is a very short learning curve, and the lens offers "the same results as standard aspheric lenses designed for 3 mm incisions. It opens the era of aberration-free cataract surgery."
- Eye tracking technology, ACE. It is not available yet, but it was demonstrated at ESCRS, and an official said it should be available in 4Q07.

However, Akreos AO and MI60 are not the only micro-incision lenses available. Others include:

- ChromaPharma/Corneal's Quatrix.
- Physiol's Microslim.
- Human Optics' Microcryl (a 1.8 mm acrylic lens).
- Alcon's AcrySof-IQ (which Alcon officials said would go through a 1.8 mm incision if a "D-tip" is used). This lens is expected to be on the European market soon, and it was used in a live case at ESCRS.

Dr. Anders Behndig of Sweden said, "There is substantial evidence that reducing incision size and lower mean phaco time means less surgically-induced astigmatism and less induced HOA, better optical quality, more rapid improvement in BCVA – without inducing additional inflammation or endothelial cell count…I used to believe 2.8 mm incisions were pretty good. We don't have much induced astigmatism …but half of the patients have induced astigmatism of 1 diopter or more…and there doesn't seem to be any of that with MICS…Aspheric IOLs were 24.5% of all IOLs in 2006 in Sweden. For 2007 I think it will be >50%. It is rapidly increasing."

Dr. Behndig said a head-to-head comparison of Akreos AO and the Tecnis Z9000 found lower spherical aberration with Tecnis, but a larger depth of field with Akreos AO, and, he added, "There were significantly more subjective visual disturbances with Tecnis eyes."

### ELLEX

CEO Peter Falzon said Ellex's focus is still on developing its sales and service operations in the U.S., "We announced in June 2007 the appointment of Christin Harris as vice president of U.S. sales…She started September 1, and she comes with >20 years of sales and sales management experience in the industry, most recently with Coherent and Lumenis for 11 years. Her charter is to expand our sales presence in the U.S. with direct sales people and really build the U.S. sales team.

The new items shown at ESCRS – which were also on display at ASCRS – included Eye Cubed, an ultrasound imaging device. Falzon said, "At ASCRS, it was still new, but now it is fully integrated into the product line, and we are starting to introduce it to markets outside the U.S. through distributors

and to subsidiaries in Japan and Australia…Because Eye Cubed imaging has such good resolution, we are doing a lot of work and seeing a lot of interest in anterior segment imaging, particularly presbyopic and multifocal IOLs…With Eye Cubed you can see the movement of the Crystalens inside the capsule, which validates it is doing what it is supposed to be doing."

*Asked what is hot right now in ophthalmology*, what doctors are willing to spend money on now, Falzon said, "Changes in anterior segment surgery, especially going from stand-alone cataract lenses to accommodating and mIOLs, is driving a demand for more precise imaging. Implanting these lenses (mIOLs) are more complicated, going into patients of a younger age who want to see as well or better than before, and the lenses themselves are a different material – more complex shapes – sometimes need to be placed more accurately or differently. So, it is important to measure the space, including from sulcus to sulcus very accurately to implant the correct lens in the correct way."

*Asked where Ellex is in its transition phase*, Falzon said, "Our focus at ASCRS was sales and technical support investments. We just announced our fiscal year 2007 full year results on August 23…Our revenue grew 28%, Ellex-brand product sales grew 55%, and our OEM sales were only 4% of revenue, meaning 96% of revenue for the year came from Ellex-branded sales…That means we have completed the transition away from reliance on an OEM to relying on our own distribution channel…Our guidance for the coming year is another 15% top line growth and improved profitability gains…Japan is now 25% of our revenue, and we started a Japan direct-sales operation five years ago…And that turned out to be a very good investment. Now that that's up and running and profitable, turning our attention to accelerating the development of the U.S. sales team…My strategy for Europe is to treat each country as an individual market and not think of Europe as one market, because our customers think of themselves as a very nationalistic environment."

## LUMENIS

Lumenis will officially launch its new Nd:YAG laser, the Aura-II, in the next few weeks, but the company had it on hand at ESCRS. The new machine has an interior and posterior offset of 500 µm, with improved optics and better ergonomics compared to the company's earlier lasers.

Asked if the company still plans to position its SLT laser as the best solution for glaucoma management, Kfir Azoulay, marketing manager for ophthalmology in Europe, the Middle East, and Africa, said, "Yes. SLT needs to be seen not as first-line therapy but as first adjunct foundation therapy, in lieu of ALT, to augment medication. Right now, we are positioning SLT as ideal therapy for open angle glaucoma, but it doesn't have to be at the expense of something else. It can be stand-alone therapy and help patients on multiple medications to drop to only one medication."

*How does the Aura-II compare to Iridex's laser?* Azoulay said, "Ours is quite simple. Iridex is a thermal laser. If you want a thermal laser, why buy Iridex? Why not use the thermal lasers that hospitals and doctors already have? What is revolutionary about ours is that it has the same clinical results as ALT, but it isn't thermal. We are the only one with a non-thermal glaucoma laser."

He believes the emphasis on glaucoma is increasing, "I think it is a growing market. The population is aging, so the number of patients with glaucoma is increasing. Pathology in glaucoma is growing. The refractive business is more private, glaucoma is pathology, and the incidence is growing."

Lumenis also has a multicolor retinal laser, the Varia, which was not shown at the ASCRS meeting in April 2007. Azoulay said, "Retinal pathology also is growing because of increasing global diabetes. We have several different lasers for retina. The yellow wavelength of Varia gets the same results but is much more gentle for patients. Patients come for treatment because it is significantly less painful than the green or Argon (blue-green) lasers."

Lumenis planned to launch the Selecta platform this year, but apparently that launch has been delayed. The Selecta platform will work with three types of lasers: YAG, SLT, and photo-coagulator.

Asked about Lumenis' future, Azoulay said, "We got $160 million last year from an investment company, and that was an important cash infusion, which we are using to improve service, invest more in R&D, and provide added value for customers. We are always on the lookout for acquisitions and strategic alliances."

## NIDEK

Nidek claims to have 45% of the excimer laser market in Japan and 52% of the microkeratome market there, but Nidek has <10% of the excimer market in Europe, and it is hoping to increasing its 9% share of the U.S. market. Outside of the U.S., the EC-5000 excimer laser is approved with all of its features, including torsion error correction (TEC), which is not approved in the U.S.

Lamar Chandler, director of Nidek's global marketing, said that the FDA is reviewing Nidek's EC-5000 CXIII excimer laser for custom aspheric treatment, and Nidek expects a decision by the end of this year. The FDA approved the EC-5000 for hyperopia and hyperopic astigmatism in October 2006.

Nidek is committed to making inroads in the U.S. market, according to Chandler, who said, "We are looking at ways to improve the U.S. market for our excimer laser. We've had a sales increase, but I don't know if that is because of (Alcon's) LADARVision 6000 coming off the market or the heads-up display on our arm...The pricing is comparable to other

excimer lasers, but we are different, in that we don't have a per-procedure fee. It lists for $350,000, but there is no additional per-procedure fee. For example, WaveLight has a per-procedure fee for custom."

As for what's new and interesting, Chandler mentioned a new excimer laser ablation algorithm, called optimized prolate ablation, which uses both topography and ocular aberrometry and maintains or improves the natural corneal shape post-operatively. He said, "That will be a big deal."

Dr. George Waring of Emory University in Atlanta, who is a Nidek consultant, spoke about topo-guided ablation using the EC-5000. He said 135 eyes were treated in an FDA clinical trial. Many were under-corrected because investigators were not allowed to do any nomograph adjustments or individual adjustments – just the out-of-the-box software. Despite this, he said, the results were good, with good stability over time, less spherical aberration than would normally be expected, a reduction in induced-higher order aberrations, and a decrease in moderate/severe symptoms. He commented, "This is remarkable. Before surgery, 23% had trouble with night driving. Six months post-surgery, none had a problem."

## OCCULOGIX/SOLX

The company completed enrollment of more than 160 eyes in a titanium laser trabeculoplasty (TLT) clinical trial for 510(k) approval for its Solx 790 titanium-sapphire laser. Preliminary review of the data showed consistent, equivalent intraocular pressure (IOP) reduction for both Argon Laser Trabeculoplasty (ALT) and TLT in patients followed for up to one year. The trial is a multi-center, outpatient study looking at the equivalency of TLT to ALT in reducing IOP in patients with primary open angle glaucoma in eyes with poorly controlled IOP on maximally tolerated medications and/or prior failed glaucoma surgery.

Solx president, OccuLogix glaucoma division, Doug Adams said, "This laser is the first of its kind to use the 790 wavelength, which has been shown to penetrate the tissue deeper than other laser trabeculoplasty procedures while preserving the integrity of the trabecular meshwork." Kim Tietz, general manager of OccuLogix' glaucoma division, said, "The preliminary review was a quick look at the data, and only about half the patients have been in the study for one year, but it looks perfect, which means that we will be equivalent to the Argon laser. We have to follow patients for a year, so we need the second half (data)…The 790 nm has much deeper penetration without any thermal damage, so we think it may lead to longer efficacy."

The company plans to submit the six-month data to the FDA by the end of 2007 or early 2008 and is hopeful that it could get conditional approval with that data. If the full one-year data are required, Tietz estimated that the company would be able to submit that by the second half of 2008.

Tietz described several ongoing projects:

- **RHEO rheopheresis for dry age-related macular degeneration (AMD).** The ongoing RHEO-AMD study, a multi-center, prospective, randomized trial is designed to evaluate the safety and efficacy of the Rheo procedure in patients with intermediate-to-late stage dry AMD. The study started recruiting patients at nearly 20 sites in March 2007. Asked why the MIRA-1 trial of Rheo failed, Tietz emphasized the differences in the RHEO-AMD trial and the MIRA-1 trial: "This has top clinical trial sites, very experienced physician investigators, and the inclusion criteria are stricter."

- **Glaucoma, particularly the gold shunt.** Solx already has C.E.-approved products available and selling in Europe, including the laser and a gold microshunt. Dr. Gernot Richter of Germany said, "We are very excited about this new surgical approach…The surgery actually is fast and simple, with a low complication rate, and, compared to other glaucoma surgeries, it is done in a way that you can use the surgery for patients who need early stage glaucoma treatment. It can be used as an alternative to drug treatment, which is important in Europe because usually glaucoma patients in the early stage are treated with drugs, which are extremely expensive. We also have the problem that health insurance (payors) are paying less for glaucoma treatment, and patients have to pay part of the cost. And doctors are budgeted and can't go over budget for drug treatment, so we have a very strong need for surgeries which are good enough to be an alternative for drugs. Surgeries commonly used are complicated, take a long time to do, have lots of complications, and five-year follow-up is not very successful. With the gold shunt, we see the possibility of overcoming these problems."

Tietz added, "It is a new surgical technique, so there are some new skills that have to be learned. The learning curve is 3-4 shunts, not 20-30. Because there is no bleb, psychologically it is a big change for glaucoma physicians."

Universities reportedly are the fastest growing users of the gold shunt, but reimbursement is an issue. An official said that while the number of users is growing, there is a reimbursement problem because the gold shunt is considered an implant in Europe. Some countries and parts of countries pay for implants, others don't. Tietz said, "For example, you may get $1,000 for glaucoma surgery, irrespective of whether they use a $500 implant, and in some places doctors are penalized for using a better implant. In other places that is not true."

- **Tear Lab.** In November 2006 OccuLogix acquired controlling interest in OcuSense, which is developing technologies to test for highly sensitive and specific biomarkers in tears at point-of-care. The project is still in development and in the prototype stage. Tietz said the product is expected to launch in Europe in 2Q08 with a C.E. Mark and in the U.S. with 510(k) approval and a CLIA waiver in 2009. The first test available will be for the measurement of tear osmolarity.

### SCHWIND

Schwind launched its Amaris "TotalTech" excimer laser, which has a "true" repetition rate of 500 Hz, at ESCRS. It is now on sale in Europe and everywhere else in the world except the U.S., Canada, and Japan. A Schwind official said, "We have developed an all-around laser with unmatched performance, thereby offering an extraordinarily high level of accuracy and safety. It is the first and only laser to combine all available state-of-the-art technologies in one system."

Will Amaris come to the U.S.? An official said, "The barriers to enter the American market are high. And it's not the quality of the product but the minimum investment to get FDA approval, which is $6 million. On the one hand, this exceeds the capabilities of a medium-sized company. On the other hand, our first priority is to invest our funds in the continuous development of our technology in favor of the surgeon and, finally, of the patient. Moreover, we at Schwind eye-tech-solutions consider the FDA more an obstacle than an advantage. Any change to the technology (new or further development) means a new FDA approval, and, thus, considerable time delays between research, production, and launch."

Other features of the Amaris laser include:

- The first laser to work with two different energy levels – 80% of high fluence for speed and 20% low fluence for precision.
- 0.54 mm small beam diameter for maximum precision and extremely smooth treatment surfaces (compared to other excimer lasers).
- Thermal control.
- Significantly shortened treatment time (<2.5 seconds per diopter).
- High speed eye tracking (1050 Hz), with a response time <3 ms.
- Rotation balance, which compensates for eye rolling.
- Both static and dynamic cyclotorsion control, compared to other systems which have one or the other.
- Unique plume and particle aspiration system.
- Integrated online pachymetry. During the procedure, changes in corneal thickness are displayed in real time.
- Treatment-assisted management software
- Ergonomic design with a 90 degree swiveling arm.
- A new microscope developed specifically for Amaris.

The Amaris costs more than Schwind's Esiris excimer laser, according to an official, and pricing varies depending on the features. The company has received orders from Scandinavia. Even in the current relatively flat LASIK market, Schwind officials are optimistic about sales. One said, "New people are entering the market, and we think there is a demand."

Schwind is still developing its femtosecond laser but is uncertain where it will launch the device. As for the market, she said, "Microkeratome is a very competitive market, but I think that we have a good opportunity in this market with our microkeratome. Our Carriazo-Pendular microkeratome has been on the market since 2004, and FDA approval for a 90 µm flap is expected soon. We already have FDA approval for 110, 130, and 150 µm flaps."

### STAAR SURGICAL

This is the 10th anniversary in Europe of Staar's Visian ICL (Implantable Collamer Lens), a phakic IOL for the treatment of myopia and other refractive errors. Hans Blickensdoerfer, Staar's Vice President, International, said, "Today's version is the same one that has been on the market since 2000, and it is the FDA-approved version. It is starting to take off big time now…It seems like internationally we are reaching the critical mass point...We are now seeing surgeons who are not participating (in Visian) are feeling left out…We have just passed the 120,000-Visian implants point, and our toric ICL is accelerating, too, internationally and will help when it is approved in the U.S. – (which he expects in mid-2008)."

Blickensdoerfer gave three reasons for the increased interest in Visian:

1. "The technical and surgical procedure has been fine-tuned and is now almost easy to master, where in the past it was limited to specialists.
2. The whole market is developing – clear lens exchange as well as cataract patients. Now, with mIOLs, the paradigm is shifting. ReStor and ReZoom are helping us ***a lot***.
3. Patient perspectives are changing. Implants are no longer just for grandparents."

*Asked about any impact from the French recall of anterior chamber, hinged phakic IOLs*, Blickensdoerfer said, "That was clearly anterior chamber lenses. It had an impact, but our ICL is the only option, so there is an up tick in sales in France as well."

*Asked about an old rumor that B&L is buying Staar*, Blickensdoerfer would say only, "We have a lot of intellectual property and a global reach, including Japan, so I wouldn't be surprised if a bigger player is interested in our company."

### WAVELIGHT

In the time since U.S. CEO Wolfgang Tolle joined WaveLight, in August 2006, he has helped energize and reorganize the company. He said, "I turn things around and grow them, and I have a passion for growth." He said the past year has been "all about getting (WaveLight) to the next level. The company had three FDA approvals in November 2006 and six approvals total in the fiscal year that just ended. The newest FDA approval was the Oculyzer for diagnostic use."

Tolle also said that the company has been changing its operations, hiring "a lot of experienced executives with gray

hair." There is a new CFO, a new vice president of business development, and a new vice president of customer service. Tolle said, "We changed how we approach and serve our customers. I truly believe that is an important part of the recipe – to be a lot more American in how we approach the market, service the customer, how we sell and market – while not foregoing our German roots, but doing it the American way."

Looking ahead, Tolle predicted that the trends for WaveLight will be the same as the past nine months, claiming that the company is well-positioned for additional growth. As for the market in general, he said, "The market itself is difficult, but we, as a company, can do very well in that market. The market will continue to be difficult for the industry…Clearly (the challenges include) what is going on in the financial markets, and I can't predict what will happen there. I do think that influences consumer confidence and behavior. Consolidation will also influence the industry."

**Rondo microkeratome.** WaveLight's most important product is obviously its laser, but Tolle and other officials were excited about other products as well, particularly the new microkeratome (Rondo). It is priced at €39,000 plus €50 for each blade, which is comparable to other microkeratomes. The key advantages of this microkeratome, according to WaveLight officials are: constant flap thickness, very smooth stromal bed, sharp flap cutting edges, and ease of handling. Maximilian Reindl, President/CEO of WaveLight AG, noted that everyone is talking about using femtosecond lasers to cut the cornea, but many surgeons will still continue to use microkeratomes. He said, "A lot of surgeons are not very satisfied with (Bausch & Lomb's) Hansatome, Moria, and other microkeratomes, and they want to switch. They are always looking for new microkeratomes because of new developments."

Mario Klafke, director of product management for ophthalmology for WaveLight, said, "There was a lot of work and effort into this new microkeratome…especially patient safety and user-friendliness. The microkeratome cut is the most dangerous thing of the whole surgery…The results with a femtosecond laser are no better than a good mechanical microkeratome. I think perhaps in the U.S. a femtosecond laser will be the only solution for the next five years, but there are other markets like India, China, and Brazil, where a femto doesn't have a huge chance. And if you look at the pricing for microkeratomes and femtos, in the next 10 years, there is no possibility of reducing the price to where they can compete with microkeratomes…The second disadvantage of a femto is you have to give steroids for a period of time, and this is not really a very good solution…Maybe with the next generation of femtos, it won't be necessary, but today it is…So, I think both can live in parallel in the worldwide market."

Among the Rondo features WaveLight officials were highlighting are:

- **Uninterruptible power supply.**
- **Integrated computer** with a hand piece with a motor, 3 different cutting heads (100, 130, and 150), and a suction ring.
- The console has a **closed-loop control** from the computer to the motor. This means the computer always knows where the motor is on the eye.
- **Light, titanium construction.**
- **2 integrated vacuum pumps** for suction to make sure no suction gets lost. One is an aspiration pump that, with a lid speculum, allows aspiration of all the fluid put on the eye during the treatment.
- **Blade:**
  - **Loading.** Blades are pre-loaded into an injector, and every blade is 100% under quality control management. Klafke said, "We check the sharpness of every blade. The blades are covered in plastic. Handling of this blade is unique because no one needs to touch it. There is a blade injector where you can put the blade on, and like a syringe you put the blade directly into the head. That is a safety concept. No one touches the blade with their fingers. And the tech can't be hurt."
  - **Control.** Klafke said, "The computer always knows the position of the blade…If the motor is going harder because of a particular eye, the computer increases the power so the cut is smooth at all times …Flap thickness is very reproducible…Inside the cutting head is a special wave-shaped contour to keep the blade in an exact position, and both the blade and the construction of the head account for the very low variation in flap thickness…With other microkeratomes, the flap thickness may vary a little, and we have worked hard to keep the standard deviation as small as possible (<10 μm)."
- **Documentation.** All the specs from the blade are automatically entered into the computer. Klafke explained, "You will have a patient document later on, so you can put all the specs and what you did into the patient documentation…Later, if the patient comes back, you always know what you did and with what equipment you worked. No one else has documentation like this." This documentation currently is paper-based, but the company expects to make it able to be integrated into an electronic medical record (EMR) in the future.
- **Ease of use.** Klafke said, "The system is pre-assembled by an assistant, calibrated by an assistant, and the surgeon takes the hand piece completely mounted and has nothing to assemble on the patient's eye…He can start immediately with LASIK; there is no assembling on the patient."

### CARL ZEISS MEDITEC

An industry source said, "What Zeiss is doing with this, its excimer laser, and its femtosecond laser tell me that they will be a long-term player, and that is a threat to Alcon, AMO, and B&L."

A Zeiss official said, "We are focused on becoming a predominant player in ophthalmology…by focusing on organic growth…We continue to spend ~10% of annual revenue on R&D. We have also looked to acquisitions…and we've made a number of acquisitions to complement our product portfolio with new technologies or to enter into fields like IOLs or consumables that we previously didn't have access to…(With the acquisition of Acri.Tec) we accelerated business development in IOLs…But ophthalmic surgery is an area where we expect to grow our business and to have a big focus going forward…but cataract, refractive, and retina will be a focus as well. We have new systems and devices for retinal diagnosis (coming) and new surgical microscopes (coming)."

Products and product areas that were highlighted at ESCRS include:

➢ **OCT.** Gerard Kunath-Fandre PhD, product manager for OCT, said Zeiss will now have multiple OCT retinal platforms on the market:

- **Stratus**, which "is the gold standard time domain system with a wealth of clinical experience." He said this would continue to be choice for the everyday retina office.
- **Cirrus HD-OCT** (High Definition Optical Coherence Tomography), a new spectral domain OCT with high resolution was unveiled at ESCRS. It performs high-resolution B-scans and sampled macular scans, allowing precise localization of retinal structures in 3-D. The system uses three parallel acquisition channels: the Iris Viewer, the Line Scanning Ophthalmoscope, and the OCT live scan. Dr. Kunath-Fandre said, "We strongly believe this OCT will revolutionize the market again…At this time it is pure OCT for ophthalmology…(but) we may develop glaucoma applications in the next release." He said this OCT is likely to appeal to research-minded centers.
- **Visante OCT**, a high-resolution, non-contact OCT, customized for the anterior segment. It was being previewed at ESCRS and was to be officially released soon. An official said, "At ESCRS we are presenting the new software version. With Visante OCT 2.0 there is even better image quality, higher definition, and a zooming function. It allows customizing the system by adding application-specific software modules: refractive (LASIK, phakic IOLS – especially iris fixated) and glaucoma." Existing Visante customers can order a software upgrade for their equipment.

➢ **IOLMaster**, an all-in-one IOL surgical planning work-station. This was shown for the first time in Europe at ESCRS. The IOLMaster Version 5's software is faster and allows more comfortable measurement compared to earlier versions. The company said, "The software automatically calculates a highly accurate axial length value, even with clouded ocular media…Previously, it was often not possible to calculate the power of the lens at an advanced cataract stage." The system has a new algorithm for signal preparation so that even patients with extremely clouded lenses can be measured, according to the company.

An official said, "Premium IOLs are becoming more and more popular. Cataract surgery is turning into refractive surgery, and patient expectations are rising. This induces a high demand on prices, biometry, and high performance IOL power calculations…We believe the mIOL market in the U.S. is increasing…AMO's array has been on the market six years, and it has not been a success because they didn't do their calculations well…but I am convinced this will be a growing market in the future…It definitely is a growing business… 60% of all offices answering a survey at ASCRS this year said they have an IOLMaster."

➢ **OPMI Lumera and OPMI Lumera T**, the latest surgical microscopes. Both are equipped with Stereo Coaxial Illumination (SCI) technology, resulting in a new quality of red reflex: high contrast, stable, and first-class detail recognition. An official said, "The compact Lumera is more for ACS and cataract clinics…The Lumera T is designed for teaching institutions and university clinics…This will replace for the most part our current microscopes that we have on the market…The Visa 160 we will leave on the market for some time, but for all practical purposes, this is a replacement." The first units are being delivered now, and an official predicted that several hundred systems will be in use by the AAO meeting in November 2007.

Features of these microscopes include:

- DeepView, the depth-of-field management system, enabling surgeons to optimize the system for depth-of-field or light transmission.
- Apochromatic optics for quality high-contrast imaging.
- Retinal protection device to protect against phototoxic injuries.
- Fully automatic halogen bulb.
- The Lumera T also has an optionally integrated video monitor and assistant's microscope.

➢ **Aspheric monofocal IOLs.**

### INDUSTRY CONSOLIDATION

The ophthalmic industry has seen a number of mergers and acquisitions in the last year, and sources expect more consolidation in the future. Ziemer President/CEO Frank Ziemer said his company plans to remain independent "for the moment," but he believes the current consolidations are a

positive for the industry, "Alcon will put a lot of strength behind WaveLight technology, and I think WaveLight has very good technology. Alcon, in a short time, will offer WaveLight technology in all of its markets, and the Wave-Light technology will drive the market. From a surgeon's point of view, it will be good for the industry, in a way."

Alcon's Buehler predicted more consolidation in the industry, "There are two scenarios: There are a couple of very large players – Bausch & Lomb, AMO, Alcon – and then a collection of a number of companies that are specialists in a single product area or don't have a broad product line. So, the opportunity for additional product consolidation to broaden product offerings and commercial capability (is there), and I think you will continue to see consolidation and broadening product portfolios."

Lumenis's Azoulay also predicted that consolidation in the industry will continue, "It's not over in my opinion. I think the consolidation has a lot of positive sides because it brings together companies with complementary technology and market presence and helps also to create larger R&D budgets. The consumer also benefits from larger, stable, and healthier companies that can invest more in R&D…Consolidation comes in waves. Right now we're in a big wave." He said that usually when big companies like AMO, B&L, and Alcon are involved it "generates a lot of ripples, and you hear about it much more. But one tier down, you see smaller companies bought, acquired, merging, and you don't hear as much about that."

## MISCELLANEOUS

The June 2008 World Ophthalmology Congress in Hong Kong, which is being held jointly with the Chinese Ophthalmological Society and the Asian-Pacific Academy of Ophthalmology, was described by several sources at ESCRS as "the most important ophthalmology meeting in 2007 or 2008."

Interestingly, there are some very good optical coherence tomography (OCT) machines in ophthalmology, but those OCT companies do not appear to be investigating applications in other medical fields, where opportunities are developing (e.g., cardiology).

### Companies and products to watch:

- **Optovue**, a privately held company which has a time-domain optical coherence tomography (OCT) machine, RT Vue-100, that it claims is 60-times faster and twice as reproducible as Zeiss's Stratus OCT, which is a spectral-domain device. The Optovue device has been on the U.S. market since October 2006, and it is attracting attention. The company has a new cornea module which allows it to be used for cornea as well as retina applications.
- **Mediphacos**, a privately-held Brazilian company that is a distributor for Intralase in that country. What's interesting about Mediphacos is its Keraring, implantable intra-stromal corneal rings for keratoconus.
- **Pixilateral optics.** This is a silicone capsular tension ring with a battery that will give a degree of auto focus. That ring fits over the eye and is recharged once a year. It was not shown at ESCRS, but it is being developed by Innovation Factory.

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