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Quick Pulse

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LASIK and Multifocal IOL Update

Five cataract surgeons, five refractive surgeons, and eight ophthalmologists who do both cataract and refractive surgery were interviewed about the latest trends in refractive surgery volumes and the outlook for multifocal IOLs. Refractive volume continued to slow in the fourth quarter of 2005, and sources predicted that trend would continue in the first quarter of 2006. Multifocal lenses are gaining popularity with cataract surgeons, but refractive use is limited to surgeons who are familiar with the lenses from their cataract surgery.

LASIK trends

In November 2005, refractive surgeons reported that LASIK procedure volume had picked up slightly from the summer/early fall slump but was tracking down a little from the same period in 2004. Sources are now saying that procedure volume for the last three months of 2005 was down an average of 8% year-to-year. The CEO for a large eye care center said, "(Volume is) down 15%. Private practices coast-to-coast are reporting volumes off by 10% to 20%. Any other reports that vary from that percentage are suspect."

For all of 2005, surgeons had predicted that year-to-year LASIK procedure volume would be down an average of 3% from 2004. Dave Harmon of Market Scope had estimated that this would translate into 1,418,000 procedures for 2005. His final figures are not yet ready, but he said the early reports coming in suggest that volume is down slightly, with the "downs" outnumbering the "flats" 2:1.

2006 is getting off to a slower start than surgeons expected. In November sources had expected procedure volume to pick up in the first quarter of 2006, but they are now saying 1Q06 volume is likely to be down an average of 4% compared to the first quarter of 2005. A high volume center is predicting a decline in 1Q06, but an official there said, "The only unknown in this equation is that Section 125 plans (a/k/a flex spending accounts) didn't expire on December 31st as in previous years. The IRS now allows a 2.5 month extension. This could have a positive impact in March, and it certainly had a negative impact in December."

LCA Vision is expected to report another increase in procedure volume this quarter, but sources believe it is taking market share from other local centers, not growing the overall LASIK market.

Sources estimated that an average of 73% of their LASIK procedures are custom LASIK (custom cornea or wavefront), which is higher than the average (which is <55%). Harmon cautioned that several factors account for this difference: "Alcon

and Advanced Medical Optics/Visx custom mix continues to climb, but I don't count Wavelight procedures, which have ~10%-15% market share, as custom. So, an increased market share for Wavelight reduces the overall custom penetration. In addition, LCA Vision, which has ~13% market share, is still not doing much custom, and as it gains market share, it also reduces overall custom penetration." If the 73% reported by sources is discounted by 25% for Wavelight and LCA Vision, then the results are in the same ballpark as Harmon has found (~55%).

Sources predicted that their custom cornea/wavefront would increase slightly – to 78% of their LASIK procedures by the end of 2006. A source said, "The low hanging fruit has already been grabbed. It has gotten more difficult to notice the benefits unless you are really monitoring patients. There is only a very marginal improvement. In a certain group of patients, custom LASIK probably helps a lot, but that isn't a big group of patients. From here on, the steps in improvement in wavefront will be pretty small."

Visx users were mixed as to the importance of Iris Registration Technology, with only one doctor considering it very important. The technology is a hardware product upgrade to the Visx Star laser. It adjusts the laser ablation to compensate for cyclotorsional movement or pupil migration when the patient lies down. A source explained, "Originally, the whole focus was on tracking cyclotorsion movement, but what they found out is they had a pupil centroid problem, and they didn't realize it. The center of the pupil was different sitting up than lying down; you can't just line the laser up with the center of the pupil because the pupil is not necessarily centroid because the iris doesn't always open and close symmetrically. Iris Registration allows you to identify if a pupil is centroid based on the iris, so it doesn't change when the patient moves." A Minnesota doctor said, "Iris Registration is very helpful for getting wavefront ablation aligned correctly." Dave Harmon added, "I'm hearing anecdotally that surgeons are very positive on this new feature, and it is improving results."

However, some other surgeons dismissed the Iris Registration Technology. A Tennessee ophthalmologist said, "It's not very important; there are no clear clinical benefits."

LASIK prices remain stable. One physician said prices are down, and another said his prices have increased, but all other sources reported no change in their pricing. A source said, "Prices appear to be firm." An Illinois surgeon said, "We lowered the price by $200 an eye." A Midwest doctor said, "We haven't lowered our prices; we've actually increased them. We do periodically offer $100 per eye coupons to members of our medical group."

Competitors' prices also appear to be stable, with only one physician saying that his competitors have lowered prices (by 20%-30%). A Minnesota doctor said, "I'm not aware of our competitors lowering prices…Marketing is not based on pricing at this time." Another Midwest doctor said, "It seems that there have been no recent changes in price. Some are still pretty low." A Florida surgeon said, "Nobody has lowered prices. If anything, there have been increases because some places have started to do IntraLase."

Multifocal IOLs

None of the doctors questioned who do ***only*** refractive surgery uses multifocal IOLs, but every cataract surgeon uses them, and refractive surgeons who also do cataract surgery use them as well, generally for mostly cataract but also some refractive patients. Overall, multifocal IOL use among these sources breaks down as follows:

- **Cataract surgeons** plan to use them for an average of 15% of their cataract patients in 2006. At peak usage, sources estimated that an average of 39% of cataract patients will get a multifocal IOL, but the range was broad (from 20% to >80%). An Iowa surgeon said, "The peak will probably be 30% until we have a true accommodative IOL." A Utah ophthalmologist said, "The present generation will peak at <10%, but newer IOLs will push this higher." A Minnesota doctor said, "I think we will see slow growth from 10% over the next several years." A North Carolina ophthalmologist said, "It will probably take five to seven years, but it will reach 80% – assuming a price reduction." An Ohio doctor added, "Eventually, it (a multifocal) will be the standard."

- **Refractive/cataract surgeons** are using multifocals for a few of their refractive surgery patients, but only a few. Sources estimated that very few of their refractive patients are getting one of these lenses, but they predicted use would grow.

Cataract surgeons estimated that their use of the three currently available multifocal lenses breaks down as follows:

- **Alcon's ReStor** – 55%, which is clearly less than its reported market share. Half the doctors questioned said they use ReStor exclusively.

- **Advanced Medical Optics' (AMO's) ReZoom** – 31%, which is clearly higher than its reported market share. Only one surgeon uses ReZoom exclusively. A ReStor user said, "I'm considering trying ReZoom for intermediate distance users."

- **Eyeonics' Crystalens** – 14%. Fewer than a third of sources use this lens at all, and no one uses it exclusively. A non-user said, "I don't believe in the fundamental principles of this lens."

Use of both ReStor and ReZoom are likely to increase slightly during 2006, but ReZoom may take a little market share from Alcon. A doctor said, "I won't change my use unless the IOLs announced an improved design/function." Another surgeon said, "Use (of both) will slowly increase as more positive feedback from patients and from media advertising raises patient awareness." Harmon added, "Alcon's ReStor is clearly the market leader, but use of ReZoom is starting to pick up.

ReZoom's focus on intermediate vision is gaining some attention, and we may see this product gain share. Use of Crystalens is also growing. Doctors are open to trying all three lenses, and many are doing this. Plus, many doctors are listening to Dr. Richard Lindstrom (of Minnesota Eye Consultants) and others when they suggest mixing lenses (using a different lens in each eye for the same patient)."

Several surgeons who currently use ReStor exclusively plan to try ReZoom. One of these explained, "The interest I have in ReZoom is because it tries to address intermediate vision more than ReStor."

Market Scope's Harmon offered an explanation of why he believes doctors are starting to give ReZoom a look: "AMO's acquisition of Visx is key to what is going on in the marketplace. Historically, there is little company loyalty to excimer lasers, and Visx had the lion's share of that market… Previously, IOL products were by Alcon, and refractive products were from Visx (now AMO)…The merger is giving AMO an 'in' to the Alcon accounts. It's too soon to say what effect this re-ordering of the market will have. However, AMO has organized its marketing efforts for refractive IOLs with the refractive marketing effort to capitalize on the strength of the Visx brand and on its team of business development staff. Alcon is not organized in the same way. Ultimately, selling presbyopic IOLs is much like selling custom LASIK or IntraLase. Doctors and their staff need to sell their patients on the technology by telling patients, 'You may qualify for one of the new lenses. It is much better than anything we had. The old style lens only gives vision in one range, and you will have to wear reading glasses. Medicare will pay half the cost (of the multifocal lens).'"

How do ReStor and ReZoom compare? Price does not appear to be a differentiator for ReStor and ReZoom. Sources insisted they are priced the same, at about $895.00 per eye. Doctors agreed that each lens has its advantages, but they didn't agree on which is best for what type of patient.

- "It comes down to patient selection."
- *Midwest:* "Many things about them (ReStor and ReZoom) are similar. The main difference is there is a little more very near vision with ReStor and a little more intermediate (computer distance) vision with ReZoom."
- *North Carolina:* "The two lenses approach multifocality in different ways."
- *Texas:* "ReStor is a refractive/diffractive optic. Light rays are split into near and distance focal points. That is better for close vision. Intermediate vision is poor. ReZoom is a refractive optic. There are two sets of light rays, some for near, and some for distance. That is better for intermediate vision."
- "ReZoom gives better quality distance and intermediate vision. ReStor gives better quality near vision. Some patients are more distance- and intermediate-motivated. Some are more near-motivated. The two (lenses) are quite complementary, and some surgeons are using ReZoom in one eye and ReStor in the other with good outcomes. They are both also pupil size-dependent. A small pupil does better with ReStor and a large pupil with ReZoom."
- "ReStor gives better reading vision but less intermediate vision. On average, adding the pluses and minuses, satisfaction has been about the same. More computer time would favor ReZoom and more reading time favors ReStor."
- "People who've been putting in ReStor are starting to put in ReZoom. I think they got tired of the complaints from patients with ReStor, and they get fewer complaints with ReZoom…Cataract patients have been presbyopic for years, but in the middle area, where they used to see well, they don't see as well with ReStor, and so they complain. With ReZoom, patients have a little problem with near vision, but their intermediate vision is more what they were used to, so they tend to be happier."

AMO's Tecnis lens, the first multifocal IOL with a modified prolate optic, is approved in Europe for the treatment of presbyopia, and it is expected to be approved in the U.S. in 2007. Cataract surgeons are already aware of Tecnis and fairly excited about it. A source said, "I don't think one (lens) is dramatically better than the other. I don't think the Tecnis aspheric optics add that much, but it has different optical zones, a different number of zones, different powers, and a different arrangement. I think for intermediate vision, ReZoom and Tecnis are pretty close; both target intermediate vision more than near vision."

Interestingly, ReStor users offered fairly positive comments on Tecnis:

- *ReZoom user:* "I think it will be better than both ReStor and ReZoom, and it will reduce some use of all three of the other lenses (ReStor, ReZoom, and Crystalens)."
- *ReStor user #1:* "It is probably similar to ReStor."

Surgeon Comparison of Multifocal IOLs

Lens	Near vision	Intermediate vision	Distance vision	Glare	Ideal patient
ReStor	Best	Poor	Good	Present	Small pupil size. Patient who reads and watches TV all day.
ReZoom	Poor	Best	Good	Present	Large pupil size. Patient who works on computer all day.
Crystalens	Average	Best	Best	None or minimal	Patient who drives at night. Patient who works on computer all day.

- *ReStor user #2:* "It is possibly better than ReZoom."
- *ReStor user #3:* "It will have a minority following."
- *ReStor user #4:* "It may compare favorably with ReStor and ReZoom. As it is less pupil-dependent, it may be better for near vision but worse for driving."

Other cataract surgeons also generally were optimistic about the outlook for Tecnis:

- "Tecnis will do very well. In all the comparative studies, it came out on top."
- "It is similar to ReStor with no pupil size dependence."
- "I just know it is coming. I don't know what advantages it may have."

Some experts believe that multifocal IOLs are simply a "placeholder" for accommodating IOLs. And there are some promising accommodating IOLs in the pipeline. A source said, "Ultimately, accommodating IOLs will beat out multifocal IOLs, assuming they get enough accommodation to work. I don't think Crystalens delivers enough accommodation. You need 4-5 diopters, and Crystalens gives 1.5-2.0 diopters. The next generation accommodating IOLs will have 3.5 diopters, and then the third generation should give 4-5 diopters. Once we get there, then multifocal IOLs will go away."

Phakic IOLs

AMO's Verisyse, a phakic IOL which is implanted in the anterior chamber and attached to the iris, was approved in 2004 for the treatment of moderate-to-severe myopia. None of the cataract-only surgeons questioned are currently using AMO's Verisyse lens, but about a quarter of the refractive/cataract surgeons are using it, and they all said they like it. A cataract surgeon said, "I won't start using this. The incision is too large, it's rigid, and it is bad for eye rubbing, etc." A non-user cataract surgeon commented, "I'm not using it. I'm waiting for a foldable, injectable lens." A North Carolina refractive surgeon said, "I'm not using it, mostly due to inertia, but I'll start." Another non-user said, "I'm certified, but I have not implanted any yet. The market for this type of phakic IOL is too small to get excited about."

Interest is much higher in Staar Surgical's Visian, an implantable collamer lens (ICL), which the FDA approved in December 2005. Visian, which is implanted behind the iris through a small incision, is the only minimally-invasive foldable lens of its kind approved in the U.S. Almost half the surgeons have patients interested in or on a waiting list for Visian, but few of the other sources plan to try the lens. A Midwest surgeon said, "I already have a few scheduled for February." A Texas refractive surgeon said, "I have 10 patients waiting for it." Another surgeon said, "I had a list compiled three years ago. I will have to call them back to gauge their interest." Another refractive surgeon said, "I have hundreds of patients!" A cataract surgeon commented, "Possibly I'll try it, though I am waiting for something better." Another cataract surgeon said, "I have no plans to try it at this time. I'm worried about the cataract induction issue."

Harmon is very bearish on phakic IOLs. "I think there will be stronger demand for Visian than for Verisyse…There is a large group of surgeons waiting for Visian before considering phakic IOLs, but the market is not that big…In the past 85% of doctors told us they planned to use phakic IOLs, but now only 18% are saying they will put in a phakic IOL…Many of these viewed phakic IOLs as a way for cataract surgeons to get into the refractive business, but once they understood what was going on, they changed their mind…The question is whether the smaller incision and more familiarity with a posterior chamber IOL (Visian) than an anterior chamber IOL (Verisyse) will interest these doctors…But the custom high myopia results with Visx (LASIK) are fantastic, and it will be difficult to match that with a phakic IOL, particularly without a toric component to address astigmatism. So, ultimately, phakic IOL use may be limited to really high myopes, and it turns out there are very few of those in the population…There may be people who didn't want to put in a Verisyse who will put in a Visian. Right now 12,000-15,000 Verisyse are sold annually in the U.S., and I think that could go to 30,000-50,000 a year, so the market may double, but it may take several years to reach that level. When a toric IOL is available, that may change. The results are much better with a toric Visian than a sphere-only Visian, and most high myopes have some astigmatism."

Doctors must go through a training and certification process, which includes proctoring of the first five surgeries, before they can implant Visian on their own. Doctors not planning to use Visian did not cite the proctoring as a reason, but most of the surgeons who plan to use Visian view the proctoring as an impediment, perhaps more an irritation than a barrier. A Tennessee ophthalmologist said, "It's frustrating, but hopefully it's not a big obstacle." Another doctor said, "It's frustrating to have to have five proctored."

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