LASER CATARACT SURGERY: Sorting Out The Business Case

by Michael Lachman

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A trio of conferences this fall provided updates on the latest developments in ophthalmic surgery: the *XXIX Congress of the European Society of Cataract and Refractive Surgeons* (ESCRS), held in Vienna in September, the *2011 Annual Meeting of the American Academy of Ophthalmology* (AAO), held in Orlando in October, and the third annual *Ophthalmology Innovation Summit*, held just prior to the start of AAO. The latter provided a look at recent regulatory and venture investment trends in the ophthalmology arena. With the first femtosecond (FS) laser for cataract surgery now commercially available and several other systems slated for launch in the coming months, this emerging technology remains the most prominent topic of discussion within the ophthalmic device field.

Laser Cataract: Five Competitors In Competitive Race

The once staid US cataract surgery market has evolved considerably over the past several years, beginning with the 2004 introduction of premium presbyopia-correcting intraocular lenses (IOLs) and the landmark 2005 ruling by the Centers for Medicare & Medicaid Services (CMS) that allowed patient-shared billing for these lenses. The premium IOL market continued to see slow but steady growth in 2011, reaching about 15% penetration of US cataract surgery procedures, split roughly equally between toric and presbyopia-correcting IOLs, according to Market Scope LLC. However, this market has been a disappointment for many in this arena, who had predicted a much steeper adoption curve for these devices. As a result, all eyes are now on the FS laser market as the next big opportunity.

As previously reported, the new FS lasers are designed to bring improved precision and safety to several of the fundamental steps in cataract surgery, including corneal incisions, anterior capsulotomies, and lens fragmentation. In addition, the lasers may also be used to create arcuate incisions in the cornea to correct astigmatism. (*See "Ophthalmology Community Focuses on Laser Cataract Technology"* — Medtech Insight, *December 2010.*)

There are now five companies that have entered the race to introduce FS laser technology to cataract surgery. The *LenSx* Laser, marketed by **Alcon Inc./Novartis AG** following a 2010 acquisition, has a clear first-to-market advantage. It is the only system that has received 510(k) marketing clearances from the US Food and Drug Administration (FDA) for all key laser functions and the only cataract laser that has been commercialized in the US. By the time of AAO in October, there were over 150 trained surgeons in 16 countries that had performed about 6,000 procedures, and there were about 20 LenSx Lasers installed in the US. The list price of the LenSx Laser is $550,000, and the per-procedure cost for the patient interface kit is $425.

The only other company with a 510(k) clearance at this time is **LensAR Inc.** The company currently has 510(k) clearances in the US for anterior capsulotomy and lens fragmentation and anticipates clearance for corneal incisions by Q3 2012. LensAR expects to initiate US commercialization in Q2 2012. At ESCRS, LensAR announced a strategic partnership with **Topcon Europe Medical BV/Topcon Corp.** for European distribution and marketing. The companies expect CE mark approval and a European market launch in the first quarter of 2012. In early October, the companies announced that Topcon would also be making an equity investment in LensAR. The *LensAR* Laser System features a proprietary 3-D CSI (confocal structured illumination) imaging and measurement technology and a docking device featuring a fluid interface with the cornea. The company hopes to demonstrate superior ability to fragment even hard cataracts. More than 550 eyes have been treated to date with the LensAR Laser outside the US.

Just prior to the start of ESCRS, **OptiMedica Corp.** announced that it had received CE mark

approval in Europe for capsulotomy and lens fragmentation using its *Catalys* Precision Laser System. The company anticipates CE mark approval for corneal incisions and European commercialization in the near future. OptiMedica is still awaiting its initial 510(k) marketing clearances in the US. The Catalys System features integrated optical coherence tomography (OCT) imaging and a *Liquid Optics* Interface. The company hopes to differentiate itself with the overall precision and accuracy of its laser system, along with superior ergonomics and workflow.

In early September, prior to the start of ESCRS, **Bausch & Lomb Inc.** announced that it had entered into a definitive agreement with **Technolas Perfect Vision GMBH** (TPV), acquiring an option to purchase all outstanding shares of TPV that Bausch does not already own as part of its joint venture with **20/10 Perfect Vision**. Based on the achievement of certain milestones and earn outs, the deal placed a total company valuation for TPV at €450 million (about $635 million). At ESCRS, Bausch and TPV introduced the *VICTUS* Femtosecond Laser Platform. The key feature that will distinguish this system from its laser-cataract competitors is versatility: the new system will incorporate the capabilities of TPV's *FEMTEC* Laser, which will allow it to create corneal flaps for LASIK procedures, perform therapeutic procedures such as keratoplasty (corneal transplantation), and outside the US, deliver the *INTRACOR* Presbyopia-Correcting Procedure. The ability to use the laser for a broader range of procedures beyond cataract surgery could improve the overall return on investment for laser purchasers. Over two-thirds of surgeons polled at the AAO meeting said that a dual-purpose FS laser would be highly or moderately valuable. (*See Exhibit 1.*) TPV filed for its first 510(k) clearance for cataract surgery applications in early 2011, and expects to receive initial clearances by early 2012. The company announced CE mark approval of the VICTUS platform in December 2011. At the time of ESCRS, over 400 cataract cases had been performed with VICTUS in India.

While two of the "big three" ophthalmic surgery companies, Alcon and Bausch, have made major strategic moves to acquire cataract laser technology, it is not yet clear how **Abbott Medical Optics Inc.** (AMO)/**Abbott Laboratories Inc.** plans to approach this market over the long term. However, the company appears to be crafting a near-term strategy that would leverage its large installed base of *IntraLase* FS Lasers that primarily address flap-making for LASIK. Surgeons that have access to the latest versions of the IntraLase Laser (FS60 and iFS) and the *IEK* (*IntraLase Enabled Keratoplasty*) software could be able to use these lasers to make clear corneal incisions and astigmatism-correcting incisions during cataract surgery, thereby allowing them to market some of the benefits of "laser-assisted cataract surgery" to their patients without a significant up-front investment. Longer term, AMO will have to upgrade its *IntraLase* Platform or acquire new technology in order to reach beyond the cornea and operate on the lens of the eye as well.

Focus On Reimbursement And Financial Considerations

Much of the discussion surrounding laser cataract surgery at the fall conferences centered on reimbursement and business model issues and specifically on how surgeons will be able to profitably introduce lasers into their cataract practices without running afoul of Medicare regulations. The costs are significant: the lasers are expected to cost between $400,000 and $550,000, and single use items are expected to cost $350-$450 per case. In addition, there will be maintenance costs in the range of $30,000-$50,000 per year after the first year, along with additional surgical time to perform the laser portion of the procedure and additional chair time to explain this option to patients.

At the same time, Medicare regulations will place limitations on surgeons' ability to recover these substantial costs via patients out-of-pocket fees. Patients may be billed for noncovered refractive testing and surgery, such as presbyopia-correcting IOLs and astigmatism correction using either incisions or toric IOLs, but surgeons cannot up-charge patients for steps of the cataract procedure that are covered by Medicare. Medicare regulations also prohibit surgeons from charging a premium to patients for "safer" surgery, even if patients would be willing to pay for it. Because the basic corneal incisions, anterior capsulotomy, and lens fragmentation are all covered steps of the procedure, the ability to charge patients for astigmatism correction using laser incisions will be the key to generating laser-based revenues. This represents a substantial opportunity, given that over one-third of cataract patients have

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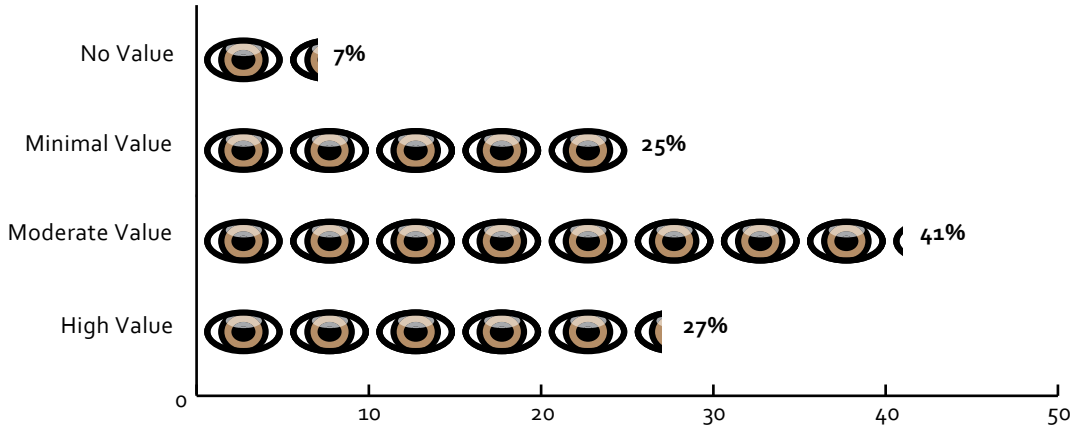
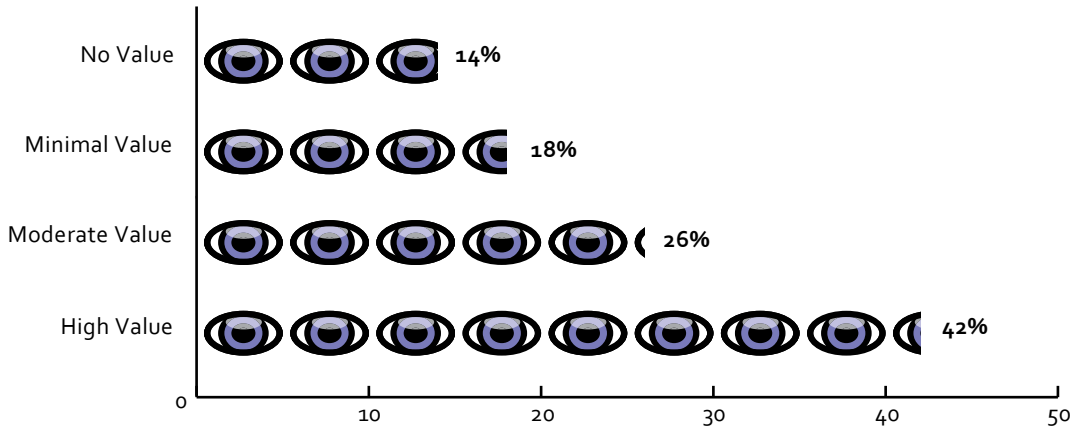
Exhibit 1

FS-Assisted Cataract Surgery: The Tough Questions

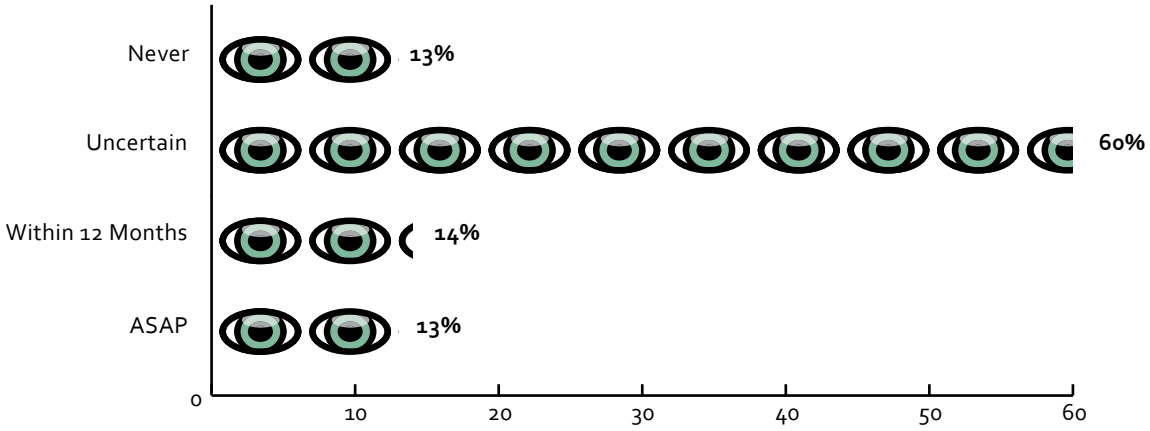
Value Of FS Laser Treatment Of Lens And Cornea Prior To Cataract Surgery



Value Of A Dual Purpose FS Laser: LASIK Flaps And Cataract Surgery



When Do You Plan To Acquire A FS Laser For Cataract Surgery?



SOURCE: Audience Poll at 2011 AAO Meeting

at least 1.0 diopter (D) of astigmatism and roughly two-thirds have at least 0.50 D.

Surgeons will still be able to charge patients for premium IOL procedures, but will probably not be able to charge different fees for premium IOL procedures performed with and without the laser, because such a tiered fee structure would assign an explicit value to use of the laser for the Medicare-covered steps of the procedure, which is not allowed. According to Kevin J. Corcoran of the Corcoran Consulting Group, any out-of-pocket charges for noncovered services must be reasonable and defensible within the context of a physician's overall practice and fee structure.

According to John A. Vukich, MD, assistant clinical professor of ophthalmology at the **University of Wisconsin, Madison**, "How the cost is recovered remains a central question to the success of this technology." At AAO, Dr. Vukich presented a financial analysis that, assuming a patient up-charge of $1,000 per eye, resulted in an average annual break-even volume of just under 300 procedures for each of the first five years following laser acquisition. This represents 15% penetration for a center that is performing 2,000 cataract cases per year. Of course, volumes would have to exceed the break-even level in order for surgeons and centers to generate a positive return on investment.

With regard to the premium patient fees that the market will bear for the new laser technology, attendees at an *EyeWorld* "Town Hall" meeting held during AAO were asked to estimate what additional up-charge patients would be willing to pay before the added cost seriously drives down volume. The most common response among seven choices was $500 (chosen by 39% of respondents), and the average of all responses was $760. Less than one-third of surgeons said that the market would bear $1,000 or more per eye without a significant impact on premium cataract volume. These results were consistent with a demand elasticity curve that was presented by Kevin Corcoran, indicating a roughly one-third drop in premium cataract demand at a laser price point of $500 and about a 60% reduction in demand at a $1,000 price point.

Cataract surgeons are still sorting out the real benefits of this new technology and how they will pay for it. At AAO, cataract surgeon David F. Chang, MD, presented results of a 2011 *EyeWorld* survey of over 1,000 physicians in which 72% of respondents ranked financial factors over five other choices as their single greatest concern regarding the technology. In the same survey, only 8% said that they were "sold" and ready to acquire the technology, 47% said that they were either skeptical or not sure the technology is needed, and 45% said that they like or want the technology, but only if clinical data confirms the advantages or if reimbursement is sufficient. Audience polls taken at the AAO meeting support the view that most surgeons plan to take a "wait and see" approach while the benefits of laser cataract technology are validated.

At the fall conferences, surgeons presented some of the first clinical data indicating that FS lasers not only bring high precision to cataract surgery, but also improve refractive outcomes. At ESCRS, clinical data from a series of cataract patients treated using the LenSx Laser showed fewer higher order aberrations, improved quality of vision, and a higher percentage of eyes achieving target refraction for LenSx procedures versus standard cataract surgery. (*See Exhibit 2.*) Similarly, a study using the LensAR Laser showed faster visual recovery following cataract surgery.

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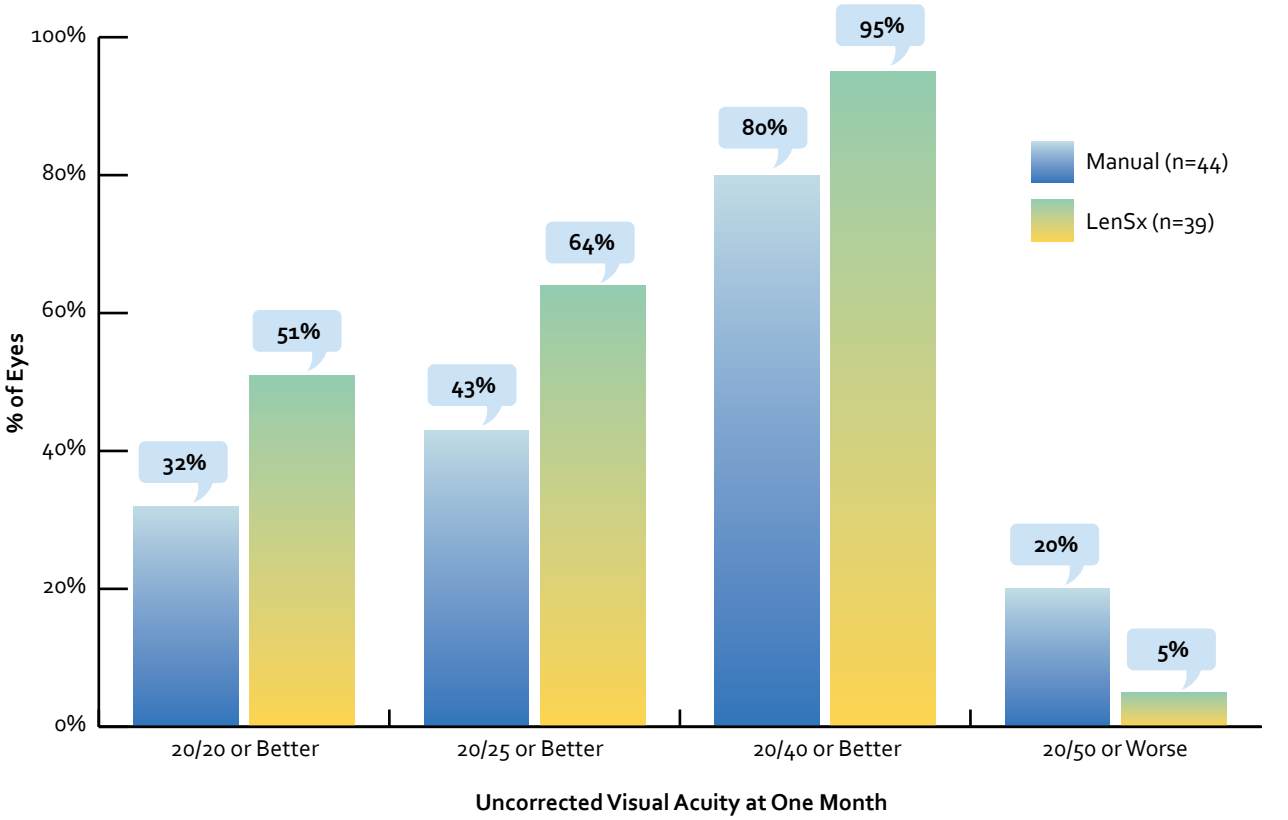
Lasers Spark Renewed Interest In Intraoperative Wavefront Aberrometry

Only about 50% of cataract surgery cases result in highly accurate refractive outcomes, defined as within ±0.50 D of the intended refraction. Determining the correct IOL power using preop measurements is even more challenging in eyes that have had previous LASIK. As patients and surgeons begin to pay premium fees for FS laser technology, expectations will become even more demanding with respect to refractive outcomes. This is leading to renewed interest in intraoperative wavefront aberrometry, a technology that can have a significant favorable impact on visual outcomes following cataract surgery.

The leader in this field is **Wavetec Vision Systems Inc.**, which introduced the *ORange* Wavefront Aberrometer in 2009. This diagnostic tool is attached to the operating microscope and measures the eye's refractive status during cataract surgery, both before and after implantation of the IOL. This information is used by surgeons to confirm the choice of IOL power and to fine-tune the correction of astigmatism by assisting with the alignment of either toric IOLs or astigmatism-correcting incisions.

Exhibit 2

Postoperative Uncorrected Visual Acuity-Prospective Multisite Study: LenSx Laser Versus Manual Capsulotomy



SOURCE: Zoltan Nagy, MD; Alcon/LenSx Lasers

In the first half of 2011, WaveTec provided an *ORange* System upgrade, which delivers refractive accuracy within ±0.50 D about 75% of the time. The company also introduced a new business model based on a monthly flat-rate subscription instead of a per-use fee, which is generating more frequent use of the system. At AAO, WaveTec introduced its next generation *ORA* (*Optiwave Refractive Analysis*) System, which has the potential to deliver precise refractive outcomes in 85% or more of cataract procedures.

The next entry in the intraoperative wavefront aberrometry market is likely to be the *Holos IntraOp* System from **Clarity Medical Systems Inc.** Because the Holos System displays the refractive error continuously in real-time, rather than collecting wavefront data over several seconds and then displaying a "snapshot" of refractive data, it has the potential to offer a time savings versus the ORA System. Clarity also expects Holos to be a more compact device than ORA.

Several companies are developing systems that will allow cataract surgeons to transfer surgical planning and preop diagnostic information into the operating room (OR), visible either on a monitor or directly in the microscope field of view. Although these systems do not perform real-time intraoperative diagnostics, they project overlays and gridlines that track with eye movements and help surgeons place corneal incisions, achieve capsulotomies with the desired size and shape, and align toric IOLs. The *SMI Surgery Guidance* System from **Senso-Motoric Instruments GMBH** was introduced about one year ago and is currently available in Europe and Japan. The *CALLISTO eye 3.0* assistance system from **Carl Zeiss AG**'s **Carl Zeiss Meditec AG**, which integrates with the company's *OPMI LUMERA 700* Surgical Microscope, is also available outside the US. **TrueVision 3D Surgical** markets a stereoscopic high definition video system in the US that displays the surgical field of view in real-time on a flat panel display in the OR. The company's *Refractive Cataract Toolset* displays the types of diagnostic and surgical guidance information described above.

Presbyopia-Correcting IOLs Continue Slow, Steady Growth

Over the past year, penetration of presbyopia-correcting IOLs (PC IOLs) has grown marginally, from about 7% to about 7.5% of US cataract procedures, according to Market Scope LLC. Including approximately 7.5% penetration of toric IOLs for astigmatism correction brings total US premium IOL market penetration to 15%. Without any major new product approvals in the US in recent months, Alcon's *AcrySof IQ ReSTOR* Multifocal IOL continues to lead the market with roughly 50% share of PC IOLs in the US, followed by the AMO *TECNIS* Multifocal IOL and the Bausch & Lomb *Crystalens* Accommodating IOL. Alcon plans to file in early 2012 for FDA approval of a toric version of ReSTOR. Although FDA approval had been expected about one year ago for AMO's *Synchrony* second-generation dual-optic accommodating IOL, an FDA panel review has still not been scheduled. **Lenstec Inc.** is also awaiting FDA approval for its *Tetraflex* Premium IOL.

With respect to new PC IOL technology, **PowerVision Inc.** continues to make progress with its *FluidVision* Accommodating IOL, which has the potential to deliver a greater degree of accommodation than either Crystalens or Synchrony. FluidVision utilizes the eye's natural muscular accommodating forces to move fluids within the lens, resulting in a shape change in the lens optic that is designed to provide at least 4 D of accommodation. The initial patient cohort of six eyes has demonstrated stable refraction and accommodation after one year of follow-up. The company is preparing to begin a clinical trial in 2012 involving 30-40 patients that could lead to CE mark approval by 2013.

Presbyopia Correction: Corneal Inlays Stealing The Spotlight From Laser-Based Treatments

Surgical approaches to the treatment of presbyopia in precataract patients, addressing the 40-to 65-year-old age group, mostly involve modification of the cornea, as opposed to more invasive surgery to replace the crystalline lens. These treatments aim to increase the eye's depth-of-focus or introduce multifocal optics into the cornea, in order to boost near vision and reduce the need for reading glasses without significantly sacrificing distance vision. This represents a potential improvement over standard monovision, in which the nondominant eye is simply made nearsighted to improve near vision, with the eye losing as many lines of distance vision as it gains in near vision.

A number of techniques have been studied clinically that use excimer lasers to ablate multifocal profiles into the cornea. The most recent of these "presby-LASIK" approaches is the *SUPRACOR* procedure from TPV, which aims to boost depth-of-focus by introducing an aspheric optical profile. TPV has also introduced and obtained CE mark approval for the INTRACOR procedure, which utilizes a FS laser to introduce a similar aspheric profile to the cornea. While many of these laser-based approaches have shown some success in achieving the desired near/far range of focus, the issue that has prevented widespread adoption is that a meaningful percentage of patients are not satisfied with the results, and reversibility of the effect has not been reliably demonstrated.

In the face of these concerns, there has been a resurgence of interest in intracorneal inlays as a promising treatment for presbyopia. Three different types of inlays, described below, have demonstrated the capability to boost near vision (gain of 3-4 lines) with minimal loss of distance vision (1-2 lines). All three inlays are intended for implantation in the patient's nondominant eye. Because inlays are removable, their optical effects can be reversed if patients are not satisfied with their vision or have changing visual needs over time. Improvements in materials, product design, and implantation technique have helped address the key challenges associated with inlays: biocompatibility and corneal health associated with a long-term implant. Within the US Investigational Device Exemption (IDE) studies, inlays have been implanted in eyes with only minimal levels of refractive error (myopia, hyperopia, or astigmatism). However, the vast majority of commercial cases have been performed in conjunction with an LVC procedure to also correct a refractive error. Patients with prior LASIK or cataract surgery are being treated as well.

Because of their CE mark approvals and commercial availability in Europe, inlays were a significant focus at the ESCRS meeting. At ESCRS, Jorge Alió, MD, PhD, of VISSUM Instituto Oftalmológico in Spain, likened inlays to a "tsunami," with ease of implantation and reversibility making them "very attractive for surgeons and patients." Dr. Alió noted that

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intraocular surgery, compared to corneal surgery, has ten-fold more complications and more severe complications. At AAO, inlays were the subject of the opening keynote at the Refractive Surgery Subspecialty Day, delivered by Richard Lindstrom, MD, of Minnesota Eye Consultants, PA. Dr. Lindstrom noted that corneal inlays are now being commercialized after 30 years of development. "More long-term clinical trials are required, and risk/benefit is still being determined," he noted. "But this is now becoming an attractive option for patients with presbyopia, either alone or in combination with myopia, hyperopia, and astigmatism."

The inlay that is closest to FDA approval in the US and has been most widely used outside the US is the *KAMRA* Inlay from **AcuFocus Inc.** The KAMRA Inlay is a flat (5 microns thick), ring-shaped device measuring 3.8 mm in overall diameter with a 1.6 mm diameter central aperture, which creates a "pinhole effect" that increases depth of field. The black/opaque polymer material contains 8,400 tiny holes to allow for flow of oxygen and nutrients within the cornea. It is typically implanted at a depth of about 180-200 microns within a corneal pocket created using a FS laser. In the past, the KAMRA Inlay was implanted at a more shallow depth of about 120 microns, which is a typical depth for LASIK flaps, but some patients experienced problems with corneal health. Compared to the two competing hydrogel inlays described below, KAMRA delivers slightly better distance vision (loss of one line or less), but blocks incoming light, which can reduce contrast sensitivity and low-light performance.

To date, more than 5,000 KAMRA Inlays have been implanted commercially worldwide and this number could reach 7,000 by the end of 2011. In addition, over 1,000 KAMRA Inlays have been implanted in clinical studies. About 80% of commercial implants have been performed at a single site, the Shinagawa LASIK Center in Tokyo, Japan, where the current rate of implants stands at about 600 per month, and the vast majority of cases involve concurrent LASIK. The product is currently available in 15 countries in Europe, Asia-Pacific, the Middle East, and South America. AcuFocus projects sales in excess of $4 million in 2011 and over $14 million in 2012. In the US IDE study, 507 patients were enrolled at 24 sites in the US, Europe, and Asia. This cohort has now been followed out to 24 months, and the company plans to submit a Premarket Approval (PMA) application to the FDA in the first quarter of 2012.

Next in line in the US clinical trial process is the *PresbyLens/Vue+* Inlay from **ReVision Optics Inc.** PresbyLens/Vue+ is a 2-mm diameter, 30-micron thick clear hydrogel implant that has the same refractive index and water content as the surrounding corneal tissue and is placed under a FS laser corneal flap at a depth of about 150-160 microns. The draping of the corneal flap over the implant creates a central steepening of the cornea that improves near and intermediate vision with minimal loss of distance vision. The company has completed enrollment in its US Phase II IDE study and is preparing to begin Phase III.

The *Flexivue Microlens* from **Presbia Coöperatief UA** is a 3-mm diameter, 20-micron thick, clear donut-shaped hydrogel bifocal lens that is implanted in a laser-created pocket 280-300 microns deep in the cornea, deeper than either the KAMRA or Vue+ inlays. Flexivue has a refractive index that is higher than that of the surrounding cornea and provides near refractive power not at the center of the cornea but within the peripheral zone of the lens. It is available in a range of add-powers from +1.25 D up to +3.00 D. Presbia is marketing Flexivue in Spain, France, and Italy, as well as other countries in South America, Africa, Asia, and the Middle East. The company has initiated the regulatory approval process in the US but has not yet begun to enroll a US IDE study.

Notwithstanding the single high volume center for AcuFocus in Japan, all three companies are taking a careful, staged approach to their international product rollouts rather than going forward with full commercialization programs. They are choosing sites and surgeons carefully, providing hands-on training, and closely monitoring patient selection, surgical technique, and clinical outcomes data in order to improve the likelihood of long-term success.

Industry Overview: VC Investment In Ophthalmology Remains Strong

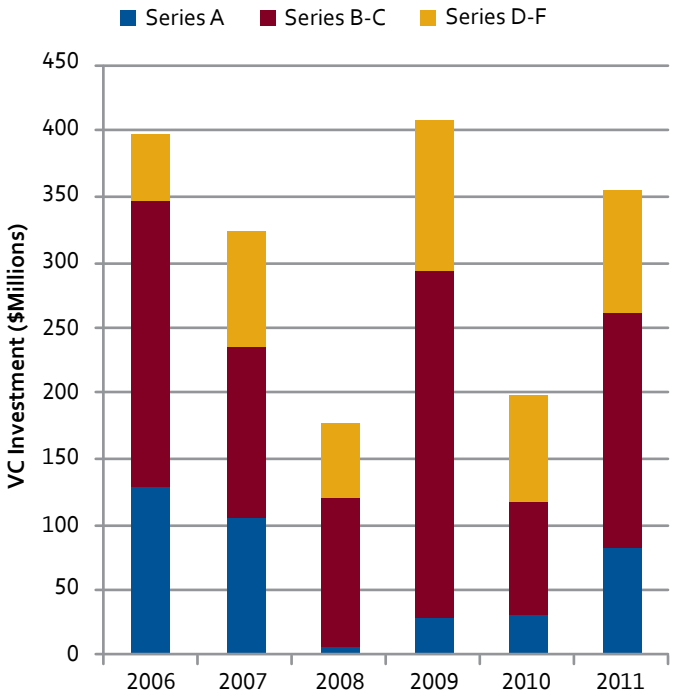
At the *Ophthalmology Innovation Summit* (OIS), Emmett T. Cunningham, Jr., MD, PhD, of Clarus Ventures LLC provided an overview of recent regulatory developments in the ophthalmic device field. Over the past year 104 PMAs were issued by the US FDA for ophthalmic devices, representing about 5% of all PMA approvals over that period. However, all of these ophthalmic approvals were for PMA supplements and not for new devices.

Dr. Cunningham noted that first new device in the emerging field of minimally invasive glaucoma surgery, the *iStent* Trabecular Micro-Bypass implant from **Glaukos Corp.**, received a favorable FDA panel recommendation in mid-2010 and is awaiting FDA approval.

Also at OIS, Ellen Foster Licking of *Medtech Insight*'s parent company, Elsevier Business Intelligence, reported that the venture investing environment in ophthalmology continues to be favorable. In fact, 2011 was one of the strongest years on record for private placements in ophthalmic companies, with ten pharmaceutical and nine device companies raising over $350 million in capital from an increasingly diverse group of VC investors. Through the first nine months of 2011, ophthalmology attracted 8% of total venture investment in health care technology, versus 2-3% in the 2007-2010 time period. Of note, there has been a significant rebound over the past year in Series A investing in ophthalmology, with the largest amount of capital committed to early-stage deals since 2007. (*See Exhibit 3.*) Against this favorable backdrop, the first ophthalmology focused venture capital

Exhibit 3

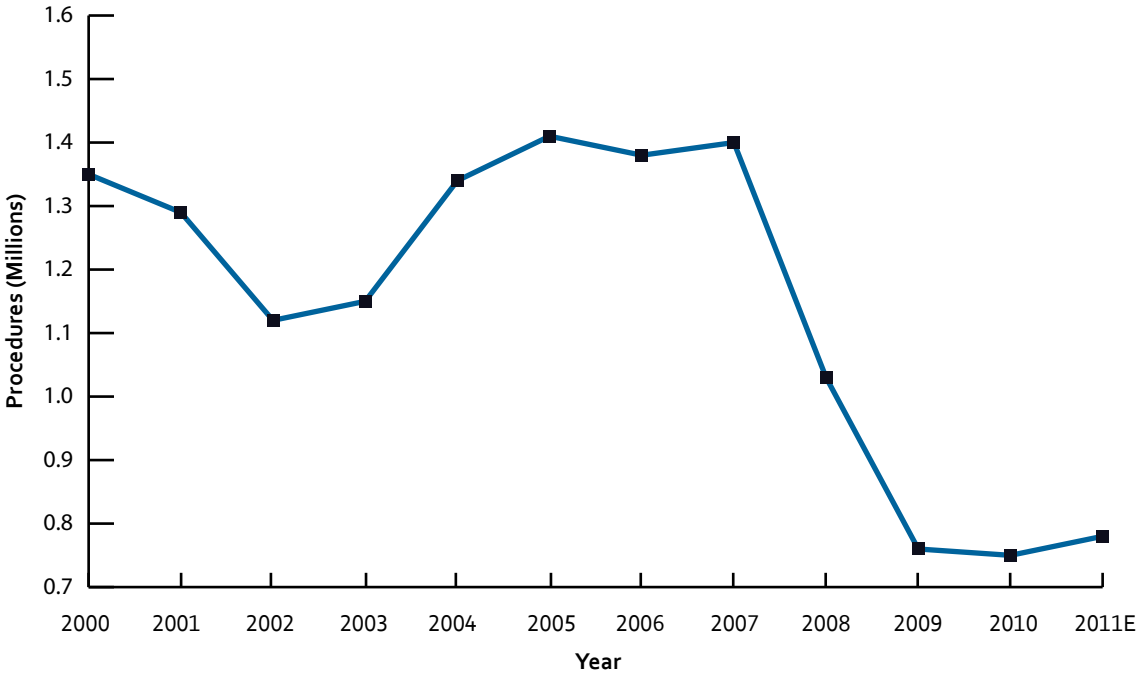
Where Are VCs Placing Their Bets In Ophthalmology?



SOURCE: Elsevier's Strategic Transactions

Exhibit 4

US Laser Vision Correction Procedures: 2000-2010 Actual, 2011 Estimated



SOURCES: 2003-2011 data from Market Scope LLC; 2000-2002 data from Lachman Consulting LLC

fund, OneFocus Ventures, an affiliate of Versant Ventures and ForSight Labs LLC, was recently launched and will invest exclusively in eye care-related companies and technologies.

Meanwhile, the two bellwether surgical procedures in the ophthalmic field, cataract surgery and laser vision correction (LVC), which includes laser in-situ keratomileusis (LASIK), each grew at low single-digit rates in the US in 2011. Cataract surgery continued to grow at its historic 3% annual rate, driven by aging demographics. LASIK encountered less of a negative publicity headwind than it had faced in 2010 and witnessed the first year of growth (albeit a modest 4%) since the economic downturn of 2008. According to Market Scope, US LVC procedure volume reached approximately 780,000 in 2011, demonstrating relative stability during the 2009-2011 period, at an annual volume of just over half of the 1.4 million annual procedures reported in 2005-2007. (*See Exhibit 4.*)

[A#2011700008]

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