FEMTOSECOND LASERS: Expanding The Premium Cataract Surgery Market

by Michael Lachman

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Femtosecond (FS) lasers represent the first truly disruptive technology in cataract surgery since the introduction of ultrasonic phacoemulsification in the late 1960s and foldable intraocular lenses (IOLs) in the 1980s. Developments in this arena have come at a rapid pace: laser cataract technology was formally introduced to the ophthalmic community only three years ago, in late 2009, and the first lasers became commercially available in the beginning of 2011. (*See "Laser Cataract Surgery: Sorting Out The Business Case,"* Medtech Insight*, November/December 2011.*)

Because it became apparent very early on that FS lasers would bring unprecedented precision to cataract surgery, the key questions surrounding this emerging field quickly shifted from clinical and technical issues to questions about commercial viability and business models. Specifically, it was not clear how US cataract surgeons and facilities would be able to pay for this expensive new laser technology in a procedure that is reimbursed almost entirely by Medicare, and therefore subject to strict billing limitations. A survey of early laser adopters in the US, detailed below, suggests that surgeons are successfully navigating these regulatory hurdles and incorporating the new lasers into their practices.

Paying For Expensive Technology While Navigating The Medicare Minefield

FS lasers have been used in ophthalmic surgery for the past decade to create corneal flaps for laser-assisted in situ keratomileusis (LASIK), the most commonly performed refractive surgery procedure. These ultrafast lasers work by delivering closely spaced spots of energy beneath the tissue surface; by aligning hundreds of thousands of these pulses, cleavage planes are created within tissues without burning or ablating. The new generation of FS lasers are designed to bring improved precision and safety to the fundamental steps in cataract surgery: (1) corneal incisions, which are traditionally created using metal or diamond blades; (2) anterior capsulotomies, traditionally created by tearing tissue using forceps; and (3) lens fragmentation, typically performed using ultrasonic phacoemulsification. In addition, the laser may be used to create arcuate incisions in the cornea, which are sometimes used to correct astigmatism during or after cataract surgery.

However, the costs associated with laser cataract systems are significant. The lasers sell for about $500,000, and single-use disposable components cost about $400 per case. In addition, there are laser 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. These costs, however, may not be simply passed on directly to Medicare beneficiaries. Although Medicare has not yet issued a formal policy regarding the new FS lasers, the "golden scalpel" rule would seem to apply. That is, the use of a more expensive surgical tool to perform a covered step of a covered procedure does not increase the amount reimbursed by Medicare, and the additional cost may not be passed on to the patient or to a secondary insurer.

Given the fact that Medicare cataract surgery reimbursement levels are insufficient to cover the additional cost of laser technology, and that beneficiaries may not be "balance billed" for any costs related to covered steps of the procedure, the ability of providers to generate sufficient revenues to cover the costs of laser technology rests upon their ability to balance bill patients for noncovered refractive services associated with cataract surgery, a door that was opened when premium IOLs entered the scene. According to guidelines issued jointly by the American Academy of Ophthalmology (AAO) and American Society of Cataract and Refractive Surgery (ASCRS) in January 2012, Medicare Part B permits patients to be billed for incremental professional services used to implant premium refractive IOLs (presbyopia-correcting or PC-IOLs, and toric IOLs) for medically necessary cataract surgery, including the cost of the IOLs themselves.

This patient-shared billing policy covering premium IOLs was the result of a landmark 2005 decision by the Centers for Medicare and Medicaid Services.

In reality, there is enough flexibility in the setting of professional fees for premium IOL implantation that a portion of the cost of the FS laser may be recovered. However, the joint AAO/ASCRS guidelines advise against explicitly recovering such laser-related costs in this way. Even more specifically, the guidelines state that premium IOL patients should not be offered tiered pricing (ie, one price without the laser and a higher price with the laser), as this would amount to charging the patient directly for covered steps of the procedure, which would be a clear violation of Medicare policy.

The more direct avenue available for billing patients for use of the FS laser involves use of the laser to correct astigmatism during medically necessary cataract surgery. This represents a substantial opportunity for providers, given that over one-third of cataract patients have at least 1.0 diopter (D) of astigmatism and roughly two-thirds have at least 0.50 D. Medicare does not cover concurrent correction of astigmatism during cataract surgery, and patients may therefore be charged a fee for creating astigmatism-correcting corneal incisions. Because this is a noncovered service, patients may be charged a higher fee for creating such incisions with the laser instead of with a blade. Again, the AAO/ASCRS guidelines state that such charges should not be associated with use of the laser for covered steps in the procedure, such as capsulotomy and lens fragmentation.

Competitive Environment: Crowded Highway With Few Remaining M&A Exit Ramps

There are at least six FS laser systems that are either on the market or under development for cataract surgery. The early market leader is **Alcon Inc./Novartis AG** with its *LenSx* Laser, which it acquired in 2010 for $361.5 million in cash, plus possible milestone-based contingent payments of up to $382.5 million. This was the first system to receive 510(k) marketing clearance from the US Food and Drug Administration (FDA), and US commercialization began in early 2011. To date, Alcon has shipped 200 LenSx laser systems, about half of those in the US and the rest to 41 other countries. Over 500,000 procedures have been performed and about 1,000 surgeons have been trained with the system.

Others currently competing in this market include **OptiMedica Corp.**, **LensAR Inc.**, and **Technolas Perfect Vision GMBH** (TPV) in collaboration with **Bausch & Lomb Inc.** (B&L).

OptiMedica received 510(k) marketing clearance for its *Catalys* Precision Laser System in December 2011. This clearance covered capsulotomy and lens fragmentation, and the company received its clearance for corneal incisions in September 2012. OptiMedica launched its product in the US in February 2012. The Catalys System received CE Mark approval in Europe for capsulotomy and lens fragmentation in September 2011, was launched in Europe in December 2011, and added European approval for corneal incisions in April 2012. To date, OptiMedica has shipped over 20 Catalys lasers, about 40% of those in the US, and about 4,000 procedures have been performed globally with the system. 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.

LensAR initially received 510(k) clearances for its *LensAR* Laser System in May 2010 for anterior capsulotomy, and in March 2011 for lens fragmentation. But the 510(k) clearance for these two laser applications that the company announced in June 2012 will allow it to market its latest-generation system, designed for commercial use. LensAR still awaits FDA clearance for corneal incisions. In September 2011, LensAR announced a strategic partnership with **Topcon Europe Medical BV/Topcon Corp.** for European distribution and marketing, which also involved an equity investment in LensAR. The LensAR 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

LensAR has product launches underway in the US and Europe and expects to have 10-12 systems installed globally by the end of

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September. By the end of 2012, the company anticipates market clearance in both the US and Europe for corneal incisions.

TPV and B&L are jointly marketing the *VICTUS* Femtosecond Laser Platform globally. The VICTUS platform is differentiated from competing systems by its ability to perform incisions for cataract surgery as well as create corneal flaps for LASIK surgery, an "all-in-one" package that should appeal to surgeons that perform both procedures. In August 2012, the companies announced 510(k) marketing clearance in the US for a system that addresses both applications, although the initial cataract surgery clearance is limited to anterior capsulotomy and does not include lens fragmentation or corneal incisions. TPV had previously received 510(k) clearances for each of these two laser applications performed on separate systems: in November 2011 for anterior capsulotomy, and in February 2004 for LASIK flaps. Although TPV has had FDA marketing clearance for LASIK flap creation for over eight years, the company has not previously commercialized its laser systems in the US. Following the most recent 510(k) clearance, TPV and B&L were planning an immediate US launch. In Europe, the VICTUS platform received CE Mark approval in November 2011 for LASIK flaps and all cataract incisions. TPV has installed over 30 of its systems to date, most of them in Europe. About 5,000 procedures have been performed on VICTUS lasers so far, about 75% cataract procedures and the remainder LASIK flaps.

TPV was formed in 2009 through a joint venture between B&L and **20/10 Perfect Vision Optishe Gerate GMBH**, and in September 2011, the companies announced that they had entered into a definitive agreement providing B&L with an option to purchase all outstanding shares of TPV that it did not already own as part of its joint venture. 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 the time). B&L has not yet exercised its option to acquire TPV.

With Alcon having acquired LenSx Lasers and B&L having acquired an option to purchase TPV, the only major global cataract surgery player that has not yet made a strategic move in this area is **Abbott Medical Optics Inc.** (AMO)/**Abbott Laboratories Inc.** It is not yet clear how AMO plans to approach this market over the long term, and whether it will rely solely upon internal product development or acquire one of the external technologies. AMO is the global market leader in FS lasers for LASIK surgery as a result of its $808 million acquisition of IntraLase Corp. in 2007. AMO appears to be crafting a near-term strategy that would involve adapting its large installed base of *IntraLase* FS Lasers to make clear corneal incisions and astigmatism-correcting incisions during cataract surgery. Longer term, AMO will have to upgrade its IntraLase platform or acquire new technology in order to reach beyond the cornea and perform anterior capsulotomy and lens fragmentation as well. Either way, with AMO the only major strategic player that has not yet made an acquisition in this field, it is unlikely that successful M&A exits will be achieved by all of the competing privately held companies that are developing laser cataract systems. Alternatively, some emerging players may ultimately tap the IPO market to achieve an exit for current investors.

In addition to AMO, there are two other companies that market FS lasers for LASIK surgery that have the potential to adapt their systems for cataract surgery. **Ziemer Ophthalmic Systems AG** has announced that it is developing an OCT-guided cataract surgery module for its *FEMTO LDV Z6* Laser System and plans to launch the system commercially in 2013. **Carl Zeiss Meditec AG** (a division of **Carl Zeiss AG**), which manufactures and markets the *VisuMax* Femtosecond Laser System, has not formally announced plans to address cataract surgery.

FS Laser User Survey Shows Encouraging Commercial Trends

Earlier this year, SM2 Strategic Inc. and Lachman Consulting LLC conducted the first-ever survey of users of the new laser cataract technology in the US in order to assess usage patterns during the first year of product availability. The survey participation rate was very high: responses were received from 63 surgeons operating in 30 centers that had acquired lasers, representing 65% of the 46 total lasers that had been installed in the US by the end of 2011. Centers had, on average, six months of experience with their lasers, with a range of 1-15 months. Because the

survey predated the US launches of competing systems, only Alcon/LenSx Lasers were represented.

Findings from the survey, summarized below, are encouraging with respect to patients' willingness to pay for laser cataract technology and initial success with incorporation into cataract surgery practices.

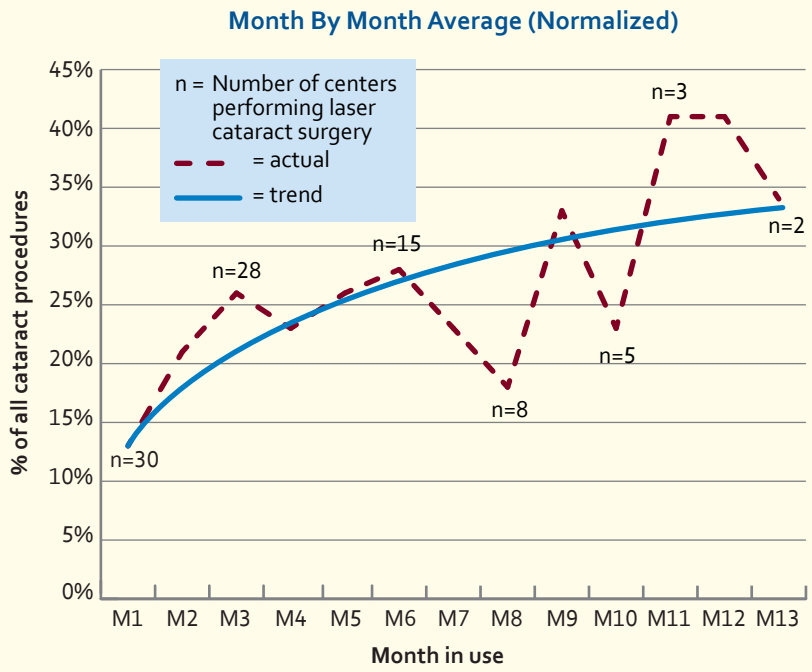
1. Procedure penetration has been rapid in centers with lasers. In the 28 of 30 centers that reported at least three months of laser usage, overall penetration of the laser into cataract procedures had reached 26% by the third month. (*See Exhibit 1.*) In the 15 centers that had reached the six-month milestone, laser penetration had reached 28% by that time point, and the penetration rate appears to approach approximately 33% at one year, although this is based on data from a small number of centers.

2. Premium IOL procedures are generating high laser penetration rates, but conventional IOL procedures are generating high laser volumes. When laser penetration rates are broken out for conventional, toric, and PC-IOLs, the highest laser penetration rate, 70%, is seen in the PC-IOL segment. (*See Exhibit 2.*) This was expected, given that the laser represents an incremental upgrade to a procedure in which the patient is already paying a premium price for a refractive outcome (ie, near vision as well as distance vision). Within the toric IOL segment, which also involves patient-shared payment, the laser penetration rate is also significant at 42%. It is not surprising that this penetration rate is lower than the 70% rate for PC-IOLs, because the laser itself can be used to correct astigmatism, making it somewhat redundant with toric IOLs.

Most notable in Exhibit 2, however, is the significant contribution of the conventional IOL segment (based on use of the laser for astigmatism correction) to the overall volume of laser procedures. This is a classic example of a "small slice of a large pie." Although laser penetration into the conventional IOL segment was only 13%, conventional IOLs represent 77% of total cataract procedures among surgeons surveyed, versus 12% for PC-IOLs and 11% for toric IOLs. As a result, the conventional IOL segment generated a higher volume of laser cataract procedures than did either the PC-IOL or toric IOL segment during the first quarter of 2012. This is an impor-

Exhibit 1

Laser Cataract Procedure Penetration

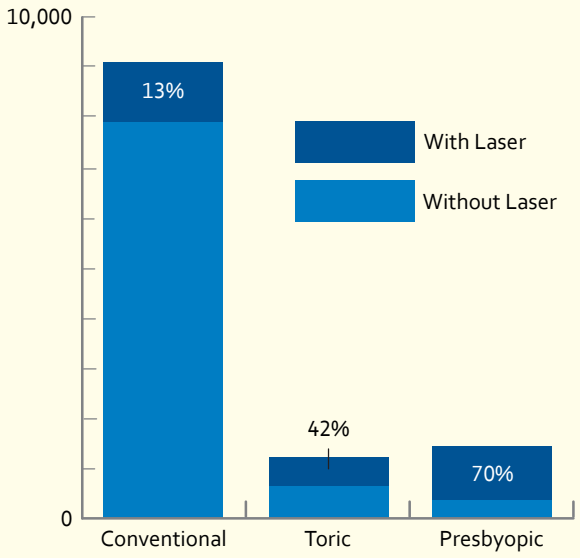


Note: All data have been normalized so that each center's start date begins at Month 1 for comparative analysis.

SOURCE: 2012 Laser Cataract Survey, SM2 Strategic and Lachman Consulting LLC

Exhibit 2

Percent Of All Cataract Procedures Using Laser; Q1 2012, By IOL Type



Laser Cataract Procedures	1,210	524	1,030
Total Cataract Procedures	9,069	1,252	1,477

SOURCE: 2012 Laser Cataract Survey—SM2 Strategic and Lachman Consulting LLC

tant trend from a commercial standpoint, since there was uncertainty prior to the US launch of the new lasers regarding their ability to penetrate the large conventional IOL market segment based upon astigmatism correction.

3. Laser cataract surgery is driving significant incremental patient-paid procedure fees. In order for laser cataract surgery to represent a favorable financial proposition for surgeons and surgery centers, these procedures must generate enough incremental revenues to cover the $425 cost per case for laser disposables, plus allow centers to recoup the cost of acquiring and servicing the laser, which can total $700,000 over a five-year period. In the survey, the overall weighted average fee to patients for laser procedures, incremental to other premium fees paid for refractive IOLs, was $945. (*See Exhibit 3.*) This suggests an average per-case variable margin of $520.

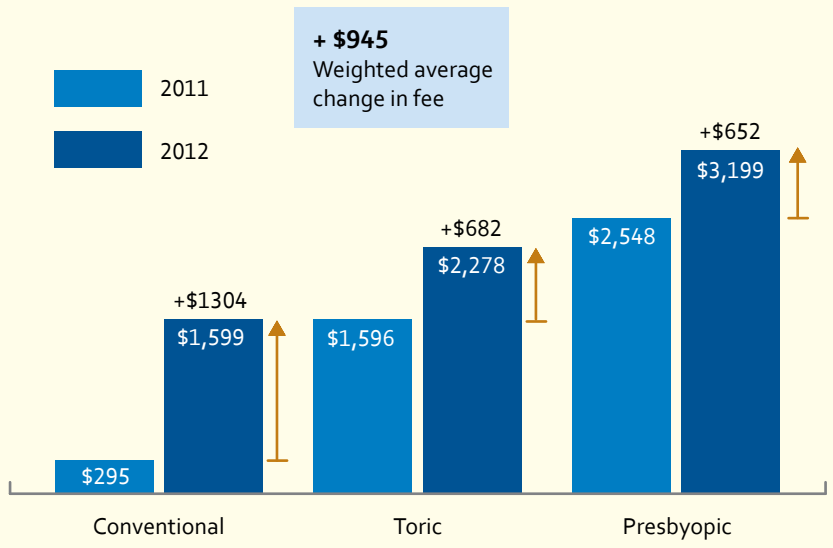
In order to break even and pay back the $700,000 capital and service cost over a five-year period, approximately 1,350 total laser procedures would be required. Assuming a 30% long-term laser cataract penetration rate in centers with this technology, which should be a conservative assumption given the early user data outlined above, a surgery center would have to perform a total of 900 cataract procedures per year in order to be able to afford this technology. In the surveyed population, the surgeons averaged 850 total cataract procedures per year, and facilities averaged nearly 1,600 per year, suggesting that this initial group of early adopters should have sufficient overall volume to make the business model work from a financial standpoint. If three or four surgeons were to share each laser, instead of the two-surgeon average per laser in the survey, the payback period would be even shorter.

Interestingly, as shown in Exhibit 3, the largest incremental procedure fees were derived from procedures involving conventional IOLs. The average incremental fee for conventional IOL cases was $1,304, versus $682 and $652 for toric and PC-IOL procedures, respectively. It is likely that surgeons are able to charge higher incremental fees for conventional IOL procedures because patients are paying little or nothing out-of-pocket for such procedures without the laser, allowing for greater upside. It is interesting to note that the average fee for conventional IOL cases in which the laser is used to achieve correction of astigmatism was $1,599, which is nearly identical to the $1,596 average fee charged for procedures in which a toric IOL was used without the laser to correct astigmatism.

The higher incremental fees for laser cataract cases involving conventional IOLs make this segment even more impactful to the overall business model from a commercial standpoint. (*See Exhibit 4.*) While the conventional

Exhibit 3

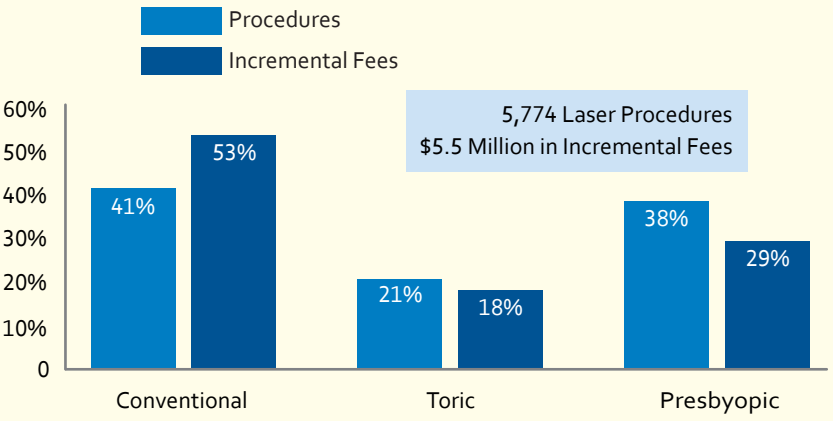
Refractive Package Fee Schedules



SOURCE: 2012 Laser Cataract Survey—SM2 Strategic and Lachman Consulting LLC

Exhibit 4

Laser Cataract Procedures And Incremental Fees, Relative Contribution By IOL Type



Note: Incremental fees are defined as current fee schedule minus the pre-laser fee schedule for each tier.

SOURCE: 2012 Laser Cataract Survey—SM2 Strategic and Lachman Consulting LLC

IOL segment accounted for 41% of procedures in the survey data, this segment accounted for 53% of total incremental procedure fee dollars. In contrast, PC-IOLs accounted for 38% of laser procedures, but only 29% of incremental fees.

4. Importantly, the survey results suggest that FS laser technology is expanding the definition of premium cataract surgery. Prior to the US launch of the new FS lasers, some surgeons and others in the industry believed that laser use would be mostly limited to penetration within the toric and PC-IOL segments, which together represent only about 15% of all US cataract procedures today. As detailed above, the laser has successfully penetrated premium IOL procedures in practices where it has been adopted. In addition, it was hoped that use of the laser would help boost the penetration of premium IOLs beyond today's 15%, but findings from the survey show that this is not yet happening – overall usage of toric and PC-IOLs has remained relatively constant among survey respondents. However, the fact that a majority of laser-based fees are being generated from astigmatism correction in procedures involving conventional IOLs demonstrates that the laser has expanded the definition of premium cataract surgery, along with the market opportunity that it represents.

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