

Femtosecond Laser: Buy Now or Later?

When should the average cataract surgeon consider a femtosecond laser?

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There is tremendous excitement in the ophthalmic community about the introduction of femtosecond laser technology for cataract surgery. Several manufacturers (eg, Abbott Medical Optics Inc., Santa Ana, CA; LensAR Inc., Winter Park, FL; OptiMedica Corporation, Santa Clara, CA; and Technolas Perfect Vision GmbH, Munich, Germany) have products entering the marketplace in the United States and/or abroad. The LenSx Laser (Alcon Laboratories, Inc., Fort Worth, TX) is the first to be cleared by the FDA in the United States.

Should you buy a femtosecond laser or take a wait-and-see approach? The answer to this question is not obvious and depends on how you assess the capabilities of the current products and your business model. This article analyzes everything you should take into consideration when making a decision.

THE PRODUCT

To obtain clearance to market a femtosecond laser in the United States, the manufacturer must demonstrate to the FDA that the product is both safe and effective for the intended application. Does meeting this basic requirement warrant a purchase? No, you also have to know if the femtosecond laser performs better than your current technology. At this time, it is widely agreed that the femtosecond laser might be better than manual techniques for making a capsulorhexis or fragmenting a nucleus, but there are no long-term data to prove it. There is little question that a femtosecond laser makes more precise incisions in the cornea than can be fashioned by hand, but there is no clinical study that has demonstrated better clinical outcomes with corneal relaxing incisions. The femtosecond laser has been in use for a little more than 1 year, and fewer than a dozen surgeons as of mid-2011 have performed 2,500 cases in the world. The technology is brand new! Even if femtosecond lasers do a better job than traditional instruments and techniques, are they so much better that it justifies the purchase price (about \$400,000), the click fee (about \$400 per

case), and the maintenance contract (about \$40,000 per year)?

THE BUSINESS MODEL

In economic terms, the affordability of a femtosecond laser depends on its cost, the expected revenue, and the minimum return on investment. The big limiting factor is Medicare. Because cataract surgery is most often performed on the elderly, who are commonly enrolled in Medicare, this exciting new technology poses some serious challenges for billing and reimbursement. In particular, you must determine which services are reimbursed by Medicare and which are not. Other third-party payers usually emulate Medicare in ways that make similar distinctions in coverage. Because the vast majority of ophthalmic surgeons accept assignment on claims for reimbursement, participating providers may only bill beneficiaries for noncovered services that are refractive, cosmetic, or prophylactic (Table). Medicare and other third-party payers would assert that a laser capsulorhexis and laser lens fragmentation are elements of cataract surgery and not separately chargeable to beneficiaries.

While Medicare beneficiaries are entitled to "one pair of conventional eyeglasses or contact lenses furnished subse-



Figure. Economic function.

TABLE. COVERED AND NONCOVERED SERVICES

	Facility	Surgeon
Eye examination	----	Covered
Biometry ^a	----	Covered
Refractive testing ^b	----	Not covered
Corneal topography ^c	----	Rarely covered
Specular microscopy ^d	----	Covered
Screening ^e	----	Not covered
Laser capsulorhexis ^f	Covered	Covered
Laser lens fragmentation ^f	Covered	Covered
Phacoemulsification	Covered	Covered
Postoperative care ^g	----	Covered
Refractive surgery ^h	Not covered	Not covered

^aOne A-scan or optical coherence biometry scan.¹

^bTesting for refractive errors, including refraction (sphere, cylinder, add, and prism), corneal topography (cylinder), or wavefront aberrometry (higher order aberrations) are not covered services under Medicare.² Beneficiaries with supplemental insurance that includes a vision benefit may have separate coverage.

^cRegular astigmatism is not a covered indication for Medicare. Corneal pathology may be covered.³

^dThe *National Coverage Determination (NCD) for Endothelial Cell Photography* states that, "when a presurgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it."⁴

^eProphylactic testing (eg, scanning computerized ophthalmic diagnostic imaging) is not a Medicare benefit unless specifically authorized by Congress.

^fLaser capsulorhexis and lens fragmentation are an integral part of cataract surgery, so there is no merit for a separate professional charge.

^gThe *National Coverage Determination for Refractive Keratoplasty* states that "the use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eyeglasses or contact lenses, which are specifically excluded by §1862(a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by section §1862(a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered."⁵

quent to each cataract surgery with insertion of an intraocular lens;^{6,7} they may choose cosmetic corneal refractive surgery in order to reduce their dependency on eyeglasses. Medicare and other third-party payers treat the surgical correction of corneal astigmatism as a noncovered service when it is not treating a surgically induced complication, whether the surgeon uses a femtosecond laser or another surgical instrument.⁸ Only then is a charge to the beneficiary for the noncovered refractive service permitted. Only 34.8% of patients desiring cataract surgery have clinically significant astigmatism of 1.00 D or more,⁹ so it would be imprudent to rely only on these patients to pay for all of the costs associated with a femtosecond laser.

In the annals of Medicare payments for cataract surgery, the Centers for Medicare & Medicaid Services' 2005 ruling on presbyopia-correcting IOLs¹⁰ and the 2007 ruling on astigmatism-correcting IOLs¹¹ provide a useful point of ref-

erence. The rulings make a clear distinction between covered and noncovered items and services. There is no change in Medicare coverage of medically necessary cataract surgery and the corresponding payments. The surgeon's and the facility's charges for additional items and services to correct presbyopia or astigmatism are not covered and are the patient's financial responsibility. In the context of refractive cataract surgery with femtosecond lasers, the same distinctions apply. It is important to note that the type of IOL does not affect the charges associated with the use of the femtosecond laser and vice versa.

PRICING

Because a limited number of noncovered items afford additional revenue, a successful business model depends heavily on the volume of patients and the level of total charges for additional procedures. Based on surveys of

clients from my consulting practice, I have estimated the economic function for the price elasticity of demand, which relates volume to price (Figure). This classic function states that higher charges result in few takers. The “sweet spot” on this curve is around \$1,000, where about 40% of eligible patients will pay for additional noncovered services.

DISCUSSION

To answer the question of whether you should buy a femtosecond laser now or later, I have built a financial model that incorporates the relevant variables. It postulates that all additional revenue will be divided equally between paying for the femtosecond laser and the professional surcharges for noncovered services; there is no residual profit. Where the annual volume of cataract cases at the surgical facility was small (fewer than 5,000) and the beneficiaries were reluctant to spend money on refractive surgery, the model recommends waiting. Conversely, where the volume of cases is great and beneficiaries embrace new surgical technologies, even when accepting the added expense, the model recommends buying now. Of course, that leaves unanswered the question regarding the utility of the femtosecond laser compared with your current technique. In the end, there are simply too many variables for me to provide a universal response, but there is no doubt that the topic will continue to generate interest. ■

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