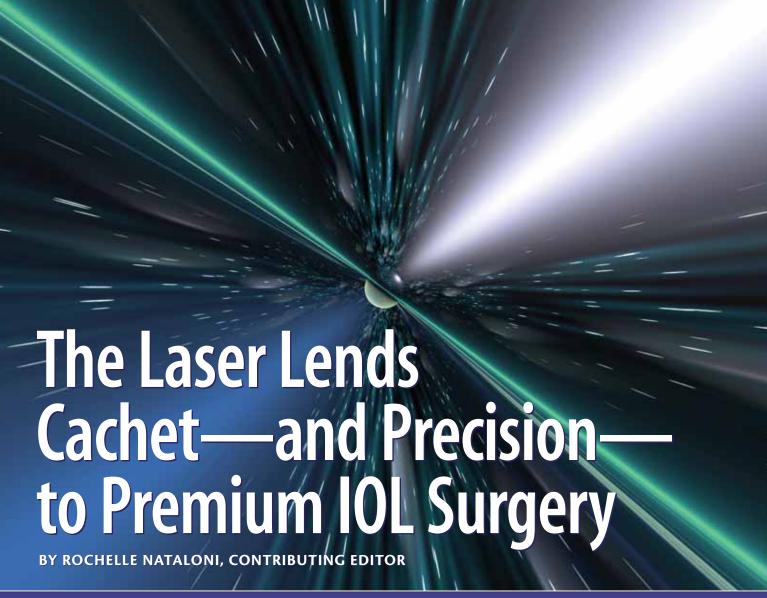
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The Laser Lends Cachet—and Precision—to Premium IOL Surgery

Prospective patients believe laser anything is better.

BY ROCHELLE NATALONI, CONTRIBUTING EDITOR

With the advent of the femtosecond laser for cataract surgery, we are rapidly approaching a tipping point first described 20 years ago by Richard Lindstrom, MD: All cataract surgery is a form of refractive surgery.

The comments included from interviews with several surgeons and administrators at leading practices make the case that premium practices will want to adopt the femtosecond laser. This month's Premium Practice Today article mirrors the cover stories in this issue of Cataract & Refractive Surgery Today; together they demonstrate how these once separate fields in ophthalmology are converging.

Of particular interest are the results from the consumer focus groups conducted by associate editor James Dawes at Sarasota's Center For Sight. The strong response from consumers regarding their willingness to pay for laser cataract surgery is in line with earlier data published by SM2 Strategic, Inc. (Pleasanton, CA), in 2009 on consumers' interest in premium IOLs. Conclusion: the demand is there. Implication: surgeons and their staff have a lot of work to do in order to realize this demand within their practices.

—Section Editor Shareef Mahdavi

ecent regulatory developments have paved the way for laser cataract surgery's debut on the US market—possibly as soon as early summer. Initial findings suggest that this new modality offers increased precision and improved outcomes. The trickle-down effects with respect to refractive lens surgery and the premium IOL's placement are clear. Surgeons who are already gung ho about providing multifocal, accommodating, and toric correction via IOL surgery can soon offer their patients precise laser capsulotomies and limbal relaxing incisions, with the added benefit of decreased ultrasonic power in the eye. Surgeons who, so far, have refrained from offering premium IOLs to presbyopic and cataract patients may soon reconsider their stance when more data on laser cataract surgery are available.

POISED TO INCREASE VOLUME

Practice administrators who plan to incorporate femtosecond lasers into their practices are poised to ride this exciting evolutionary wave to a new peak. James Dawes, the administrator of Center For Sight in Sarasota, Florida, says as laser cataract surgery becomes available, sophisticated patients will demand

the best technology.

"We have learned through our consumer research (see *Center For Sight's Focus Group Findings*) that when given the option, patients overwhelmingly prefer the thought of a laser procedure over traditional methods," Mr. Dawes says. "Our sugeons feel that the precision and predictability offered through laser cataract surgery will enhance patients' outcomes and improve their quality of life. Patients' subsequent satisfaction will continue to drive business growth in both standard and advanced-technology IOLs."

Center For Sight is one of the highest-volume cataract surgery facilities in Florida, which boasts the most cataract surgery in the country. Since the FDA's approval of presbyopia-correcting IOLs, the surgeons in the practice have embraced these lifestyle-enhancing, premium-channel products, and to date have implanted nearly 10,000 advanced-technology IOLs. Delivering on the promise of improved vision has been the fundation of Center For Sight's success, Mr. Dawes says.

"We have witnessed in our practice that positive word of mouth from satisfied patients will drive increased volume, and we continually survey our

patients to ensure that we are meeting their expectations," Mr Dawes says. "We learned through our discussions with focus group participants that there is a general lack of understanding about modern cataract surgical techniques and what level of vision one might expect after cataract surgery. When we educated the participants about the difference between laser cataract surgery and nonlaser cataract surgery, overwhelmingly, the participants desired the precision and predictability delivered through laser technology. More than 80% of the participants said that they were willing to pay some portion of the fee out of pocket for a laser cataract procedure.

"Our surgeons feel strongly that the femtosecond laser technology will not only improve the results for our advanced-technology lens patients, but [it] will allow us to more effectively treat astigmatism and refractive error," Mr. Dawes says. "Our desire is for more patients to achieve their personal best vision without glasses after cataract surgery. By achieving this goal, surgeons can expect to see their premium channel grow through positive word-of-mouth referrals."

PATIENTS WILL DEMAND IT

Brad Houser, the administrator of St. Luke's Cataract & Laser Institute, another of Florida's leading cataract facilities, says his practice also expects to adopt femtosecond technology sometime this year, depending on its availability (see *The Future is Now*).

"We believe patients—particularly those who are purchasing premium lenses—will demand the latest technology, and laser-assisted cataract surgery has a definite cachet attached to it," says Mr. Houser. St. Luke's surgeons have implanted several thousand presbyopia-correcting and toric IOLs in the past 3 years. "St. Luke's has historically been a market leader in cataract surgery. To maintain and enhance our position, and to continue to offer our patients the latest and most advanced technology, we will definitely be early adopters," he says.

CLINICAL IMPERATIVE, FINANCIAL CHALLENGE

Two femtosecond lasers for cataract surgery have cleared the necessary regulatory hurdles. Now, the biggest challenge standing between the technology's adoption and its withering on the vine is the ability of ophthalmic surgeons to add these lasers to their prac-

Tips: Return-on-Investment Considerations With Laser Cataract Surgery

- Cataract surgery is a Medicare-covered procedure, so balance billing patients is not currently an option.
- In the case of refractive laser cataract surgery, practices can charge patients for diagnostic services not covered, such as those that determine astigmatism, refractive error, and the potential efficacy of a refractive treatment.
- With refractive laser cataract surgery and premium IOLs, shared billing for astigmatic correction for optimum results is allowed under the Centers for Medicare & Medicaid Services' regulations.

tices cost effectively.

The key, say those interviewed for this article, is implementing an effective business model. "It will be very important that the early adopters put in place a business model that allows all patients to have access to laser cataract surgery and a mechanism that allows patients to pay an additional fee for a refractive procedure," explains Mr. Dawes.

The simplest scenario exists for patients who opt for a refractive lens exchange with laser lens replacement surgery at a non-Medicare participating facility, Mr. Dawes says. "[In that case,] the entire procedure is noncovered and therefore elective. However, when dealing with insured patients with qualifying cataracts, things become a little more complicated."

Mr. Dawes describes a business model in which a surgeon charges a reasonable fee for diagnostics in order to determine refractive error—such as astigmatism, hyperopia, and myopia—and the likelihood that a patient would benefit from a refractive procedure. In this model, the information needed by the surgeon is gathered and reviewed with the patient so a determination can be made if refractive laser cataract surgery and/or an advanced-technology lens is appropriate for him or her. According to Mr. Dawes, patients' education is everything. Having the necessary diagnostic information is fundamental to allowing the patient to determine if he or she wants to go forward with a refractive procedure. Moreover, if the patient chooses to receive an astigmatic treatment or an advanced-technology IOL,

"There is no upgrade or premium charge that insurance companies or CMS will provide for the use of technology that supercedes earlier iterations."

—John A. Vukich, MD

an appropriate fee would be charged to him or her for the portion of the procedure not covered.

UNIT PRICING, PER-CLICK FEES, AND REIMBURSEMENT

Although the exact price of femtosecond lasers for cataract surgery has yet to be disclosed, prospective early adopters say they are sure the up-front cost will be substantial, and a "per-click" fee like those associated with refractive lasers is all but a given. Absorbing these costs to establish a healthy return on investment is the challenge. Based on the past, the likelihood is slim that the Centers for Medicaid & Medicare Services (CMS) will increase cataract surgery reim-

bursement for femtosecond laser procedures despite anticipated improvements in outcomes.

John A. Vukich, MD, is a partner at the Davis Duehr Dean Center for Refractive Surgery in Madison, Wisconsin, and a consultant to and investigator for femtosecond laser manufacturer OptiMedica Corp. (Santa Clara, CA). He says, "There is no upgrade or premium charge that insurance companies or [CMS] will provide for the use of technology that supercedes earlier iterations."

He recalls that this was the case back when diamond blades came into vogue, and he expects that history will repeat itself. "When we first started to understand that the quality of the corneal incision and size could influence astigmatic control, there was a move to use diamond blades as an improved method of creating the corneal incision. [CMS] determined that it would not increase reimbursement—even if outcomes were better—and even though diamond blades cost more to procure, use, and maintain for that purpose," explains Dr. Vukich. "[CMS] essentially decided that surgeons were free to use whatever instruments they wanted to but that it was not going to get into the business of deciding what the best technology was

Center For Sight's Focus Group Findings

James Dawes, administrator of Florida's Center For Sight, facilitated unscientific focus groups of non-Center For Sight patients to evaluate what they think about cataract surgery and lasers and the combination of the two.

"Since we know that femtosecond lasers for cataract surgery are coming, and we will be early adopters, we conducted focus groups to see how to position the technology in the marketplace," Mr. Dawes explains. "There is no doubt that these lasers will increase the precision of premium lenses, and I feel confident, based on our focus groups' findings, that patients will be willing to pay [more] to have a better visual outcome."

Center For Sight held three focus groups that included a diverse selection of 45 participants, 45% of whom were men and 55% women; all had phakic eyes.

1. After an educational presentation, participants were asked, "in addition to out-of-pocket costs for cataract sur-

gery, what would you pay for laser cataract surgery for both eyes?"

- Of the respondents, 81% said \$2,500 or more.
- 2. After an educational briefing related to IOLs, participants were asked, "knowing the out-of-pocket costs of laser cataract surgery with a presbyopia-correcting IOL, which option would you choose?"
- None of the respondents said they would choose nonlaser surgery with a standard IOL.
- A total of 45% said they would choose laser surgery with a standard IOL.
- A total of 55% said they would choose laser surgery with an advanced-technology IOL.

The Future Is Now

As of press time, there appear to be four viable laser cataract surgery systems. They are manufactured by LensAR, Inc. (Winter Park, FL); LenSx Lasers Inc. (Alcon Laboratories, Inc., Forth Worth, TX); Optimedica Corp. (Santa Clara, CA); and Technolas Perfect Vision (St. Louis, MO).

The laser from LenSx has cleared the necessary regulatory hurdles in the United States to be marketed, first being approved for capsulotomy, then corneal incisions, and finally lenticular segmentation. The laser from LensAR has 510(k) approval for the creation of the anterior capsulotomy, and the company has submitted an application for lens fragmentation.

LensAR positions itself as having the laser that brings the accuracy and precision of lasers to cataract surgery by replacing blades and greatly reducing the need for ultrasonic power. LenSx touts its integrated proprietary optical coherence tomography technology, which enables surgeons to view the eye's three-dimensional anatomy. The system can also be programmed to perform a comprehensive, computer-controlled surgical procedure (including anterior capsulotomy, corneal incisions, and lens fragmentation) in a single step.

OptiMedica is performing ongoing clinical trials at Centro Laser in Santa Domingo, while gathering the necessary data to gain FDA clearance for the system's distribution in the United States. OptiMedica reports that its platform allows

surgeons to optimize the primary cataract incision as well as the paracentesis so that they are reproducible with predictable results. Technolas Perfect Vision, which debuted its platform at ESCRS and AAO in 2010, has incorporated its cataract surgery module into its femtosecond platform, which is already being used for LASIK flap creation. Technolas Perfect Vision positions its platform as having unique advantages for all surgeons—purely cataract and refractive cataract surgeons—with its "one laser does all" approach that is backed by service and support already in place worldwide.

The Center For Sight's administrator James Dawes and his counterpart at St. Luke's Cataract & Laser Institute, Brad Houser, expect that the lasers from LensAR and LenSx will ship mid- to late 2011. Mr. Dawes says, in the meantime, he is focusing on developing a sound business model and developing the details of his practice's marketing campaign by facilitating additional focus groups.

"We don't know at this point if we will have a femtosecond laser for cataract surgery by summer or early next winter," says Mr. Dawes. Mr. Houser adds that the timeline at St. Luke's is in the hands of the vendors. A late summer arrival would be ideal, he says, so that the kinks can get ironed out before Florida's influx of "snowbirds" next fall. "It will be important to be ready for prime time by Thanksgiving," Mr. Houser says.

and paying more for better technology. [CMS] decided that technology will evolve and surgeons could decide clinically what makes sense."

Based in Great Neck, New York, Kenneth Rosenthal, MD, recalls a similar scenario when the CMS refused to upgrade reimbursement for the use of capsular tension rings despite evidence that they contributed to improved outcomes in select cataract cases.

"I think that, from a marketing point of view, being able to say you have the laser will definitely provide a certain marketing cachet, so those of us who choose to use it will have a marketing advantage," says Dr. Rosenthal. "From a clinical perspective, using a femtosecond laser for cataract surgery will make it eas-

ier for us to do some things and may even make it better and more consistent. Ultimately, I think it will result overall in better outcomes, because the outliers will come within bounds." Dr. Rosenthal says he would like to add the technology to his armamentarium this year.

PREMIUM IOLS PLUS LASERS EOUALS SUCCESS

Dr. Vukich says that the complementary nature of premium IOLs and femtosecond lasers may be the winning ticket to an effective business model.

"We believe this instrument will facilitate the more accurate use of the premium implant, so the two are

"We are working with the equipment vendors to develop an economic model that will work for us, the patients, and the vendor."

—Brad Houser

really synergistic. There has been some pretty convincing evidence that, with femtosecond lasers, we can be more accurate with our capsulotomy and that we can decrease phaco time," says Dr. Vukich. "The benefit of those things may very well be in allowing us to more accurately use premium lenses," he continues. "So, now when we talk about a refractive outcome as one of our standard goals with femtosecond lasers—as opposed to just clearing the visual axis to get rid of the cataract—it becomes clearly a refractive procedure When the primary goal is restoration of functional vision whether via multifocality or with astigmatic control ... there is an up-charge that is available and allowed by [the CMS]."

Roger F. Steinert, MD, is the director of The Gavin Herbert Eye Institute School of Medicine at the University of California, Irvine. He says, "In a study with Zoltan Nagy, MD, from Semmelweis University in Budapest, Hungary, we developed preliminary data suggesting that the precise size and location of the femtosecond laser capsulotomy results in a more predictable IOL location compared to manual capsulorhexis. The antero-posterior location of the IOL is a major factor in the variability of effective IOL power. If further studies prove improved outcomes in IOL power predictability, the femtosecond laser will have added a refractive component to the cataract procedure that is substantially beneficial to premium IOL patients. This refractive component would represent an uncovered service and be eligible for patient self-payment under the laws governing Medicare."

Dr. Vukich says he does not know of any premium IOL surgeons who are not eager to incorporate the new technology into their practice. "It's just a matter of figuring out how to work it into the practice in a way that makes the patient's care more uniform and provides better quality vision and still makes sense economically," he says

Mr. Houser says that, for the economics to work, there needs to be a cooperative approach. "We are working with the equipment vendors to develop an economic model that will work for us, the patients, and the vendor," he explains. "From the vendor's standpoint, there is a capital component and then a per-use component. From our standpoint, we are getting paid on a per-use basis, but we are not getting any big payment up front. So, one of the things we have talked to the vendors about is amortizing that capital component over some number of procedures—in a sense increasing the per-click fee—as opposed to doing a big payment on the front end." Mr Houser says, of course, they would rather have no per-use fee, "but the vendors are driving the technology right now."

CONCLUSION

Mr. Dawes says that it is easier for patients to make the leap to paying out of pocket, whether for premium IOLs or laser cataract surgery, once they understand that even standard cataract surgery may not be completely covered by insurance or Medicare.

"There's an assumption that, if you have Medicare or good insurance, you are not going to have any out-ofpocket expense for standard cataract surgery, but that is not necessarily so," he points out. "There are deductibles and copays or in some cases a 20% coinsurance fee. So, we try to educate patients about what their out-of-pocket fees will be with standard cataract surgery and about what their out-of-pocket fees will be if they opt for premium IOLs." Mr. Dawes suggests that, once patients realize neither option is free, they are better able to make an informed choice. In the meantime, he is focusing on developing the refractive laser cataract business model and finalizing the details of the practice's educational materials for patients by facilitating additional focus groups.











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