

What Will the Next Big Thing Be in Ophthalmology?

New Procedures Performed Simultaneously With Cataract Surgery



By Gil Kliman, MD, MBA

One cannot go near an ophthalmology conference these days without hearing the loud buzz around laser cataract surgery. The excitement about the new procedure, being pioneered globally by companies such as Alcon Laboratories, Inc. (LenSx), and others is the laser shot heard around the world. There is much more to this revolution, however, than simply replacing manual parts of the traditional phaco procedure with the laser. The elegance of the femtosecond laser approach represents a complete rethinking of how we surgeons perform cataract surgery, including what else we might do while the patient's eye is in focus in the OR (Figure).

During the past century, there has been a trend toward doing more during cataract surgery, starting with removing the crystalline lens from the eye and then adding the step of replacing it with an IOL for distance vision correction, as pioneered by Sir Harold Ridley after World War II. The advent of the laser approach for cataract surgery opens up the possibility of performing more procedures simultaneously with cataract surgery, directly with the laser or not. Because

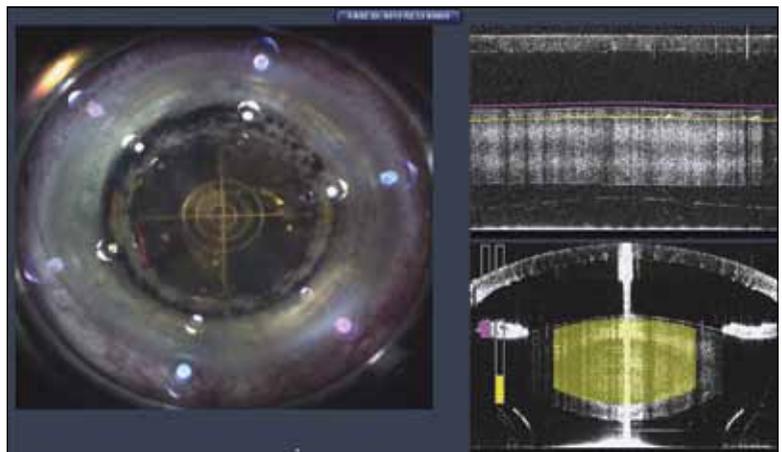


Figure. The elegance of the femtosecond laser approach represents a complete rethinking of how surgeons perform cataract surgery.

of the broad appeal of laser cataract surgery to patients and the wave of baby boomers reaching cataract age, I anticipate huge growth in procedural volume during the next decade. Laser technology increases the possibility for millions of patients to derive benefits beyond cataract treatment alone, including relief from other conditions such as astigmatism, presbyopia, glaucoma, and even retinal diseases such as age-related macular degeneration.

REFRACTIVE PROCEDURES

Ancillary refractive procedures are already being performed at the time of cataract surgery, most notably the placement of limbal relaxing incisions for the treatment of astigmatism. It is widely accepted that femtosecond lasers can increase the accuracy of these inci-

sions. More refractive procedures could evolve rapidly. A LASIK flap can easily be placed (but not lifted) at the time of cataract surgery to allow easy access for future excimer laser enhancement. New lasers may be able to “do it all,” although currently, this would likely be performed with a separate corneal femtosecond laser. Taking that a step further, a surgeon could create a flap or pocket and place a corneal inlay to correct presbyopia at the time of cataract surgery while implanting a standard monofocal IOL for distance correction. This approach could also allow upgrading or refocusing the presbyopic correction over time as indicated by replacing or adjusting the inlay.

GLAUCOMA PROCEDURES

It is known that approximately 20% of patients undergoing cataract surgery have glaucoma. With the advent of microinvasive glaucoma surgery, surgeons will soon be able to place tiny ab interno stents at the time of cataract surgery, lowering IOP and allowing patients to decrease or eliminate their need for glaucoma medication. Additionally, microdevices are under development for the sustained-release delivery of glaucoma medication. If this technology is approved, at the time of cataract surgery, implanted drug therapy could be instituted, reducing the patient’s need for topical medication. In the future, femtosecond laser pulses may create customized incisions for these devices, allowing precise placement that is unattainable with manual techniques.

RETINAL DRUG DELIVERY

It may become possible to treat the retina during cataract surgery, due to the evolution of minimally invasive drug-delivery devices that treat age-related macular degeneration. These devices may be integrated with an IOL, or they may stand alone. The technology may even be effective when placed in the anterior chamber or cornea, depending on the drug’s kinetics. They could spare patients from unpleasant monthly intravitreal injections, improving their vision both pharmacologically and optically and dramatically increasing their quality of life.

CONCLUSION

The best is yet to come in cataract surgery, as these simultaneous approaches reach fruition. To paraphrase a once-popular song, the future’s so bright, we gotta implant shades (during cataract surgery).

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Technologies Driving Enhanced Outcomes in Cataract Surgery



By William J. Link, PhD

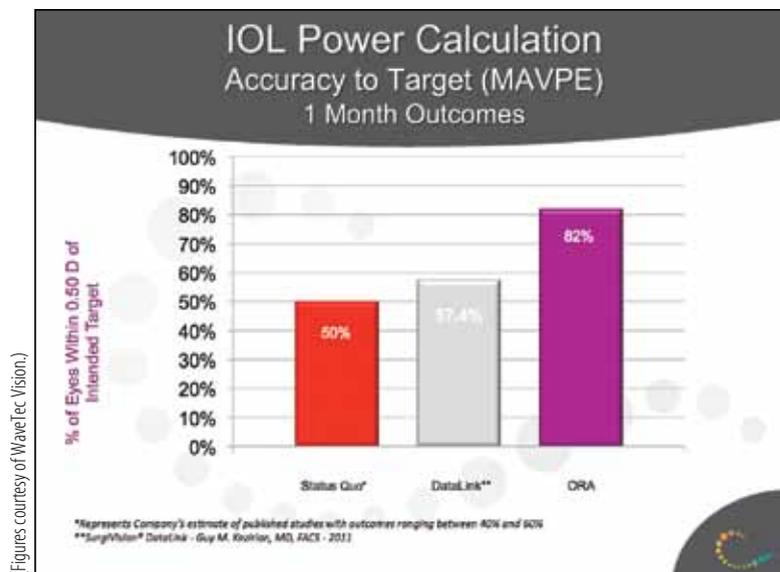
Those who know me have heard my opinion that innovation is directed toward areas where it is rewarded. There was a surge of innovation in cataract surgery from the mid-1970s to the late 1980s with the development of phacoemulsification, IOLs, viscoelastics, and the like. Millions of patients, thousands of surgeons, and many companies have benefitted. When reimbursement for these procedures and products collapsed in the late 1980s, innovation in cataract surgery stalled. Interestingly, some of these resources were redirected toward refractive surgery, with LASIK’s emerging as the preferred surgical procedure of most surgeons and patients. Although few of us were directly comparing refractive outcomes and patients’ satisfaction with LASIK against refractive outcomes and patient’ satisfaction with cataract surgery, a select group of innovative surgeons and entrepreneurs were. Thanks to Andy Corley and the Eyeonics team, on May 10, 2005, there was a breakthrough in reimbursement for cataract surgery: the Centers for Medicare & Medicaid Services ruled that treating presbyopia was not a covered service, allowing the patient to pay for this premium treatment. The combination of greater reimbursement and the view that cataract surgery could be improved has led to the “next big thing(s)”: technologies focused on enhancing cataract surgical outcomes. This article will address three technologies improving outcomes: femtosecond lasers, premium IOLs, and intraoperative aberrometers.

TECHNOLOGIES AND RESOURCES FOCUSED ON ENHANCED OUTCOMES IN CATARACT SURGERY

A lot of resources are dedicated to improving outcomes in cataract surgery. I estimate that industry leaders and venture capitalists have invested more than \$2 billion in the combined technologies of femtosecond lasers, premium IOLs, and intraoperative aberrometry in the past 10 years. I project that another \$1 billion will be invested in the coming 5 years or so. Thus, innovation has and will continue to occur in cataract surgery.

FEMTOSECOND LASERS

Anyone close to the field of ophthalmic surgery is keenly aware of the disruptive innovation being driven by the development and commercialization of advanced



(Figures courtesy of WaveTec Vision.)

Figure 1. A comparison of accuracy to target (mean absolute value of the prediction error) at 1 month postoperatively in 187 eyes with the ORA System compared with data in DataLink and published literature.

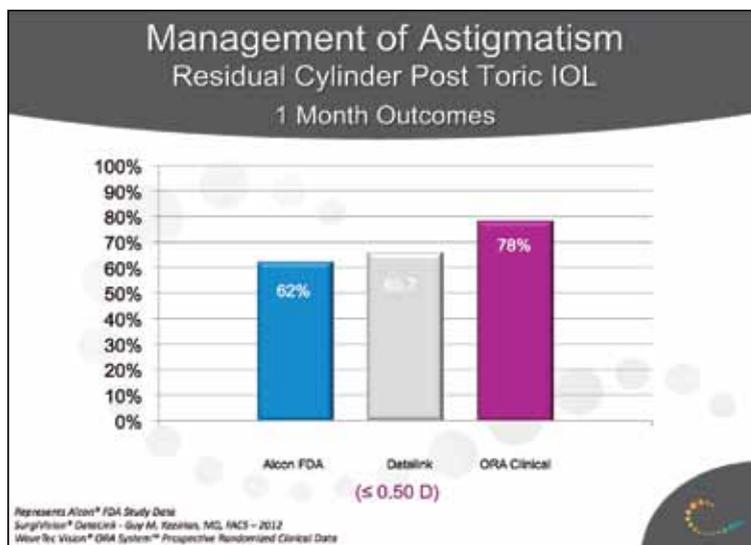


Figure 2. A comparison of residual cylinder with toric IOLs 1 month postoperatively in 63 cases using the ORA System compared to cases in DataLink and the Alcon FDA trials of AcrySof IQ and Restor IOLs.

femtosecond lasers for use in conjunction with cataract surgery. This technology should dramatically improve outcomes and likely safety in cataract surgery.

PREMIUM IOLs

With the approval of accommodating, multifocal, and toric IOLs in the past decade, surgeons around the world are routinely treating presbyopia and astigma-

tism. Numerous novel premium IOLs are in development, so ophthalmologists and their patients can anticipate further advances in the coming years.

INTRAOPERATIVE ABERROMETRY

A more recent area of innovation in cataract surgery is intraoperative aberrometry. The concept is to provide the surgeon with real-time, intraoperative, phakic, aphakic, and pseudophakic refractive measurements. Done well, this practice will improve outcomes. Two companies are seriously pursuing intraoperative aberrometry with promising results, WaveTec Vision and Clarity Medical Systems, Inc. Surgeons using WaveTec Vision's ORA System achieved postoperative refractive outcomes within 0.50 D of their intended target in 82% of the cases (187 eyes), according to the company.¹ This is compared with 57.4% in the DataLink (SurgiVision Consultants Inc.) database (50,000 eyes) and approximately 50% cited in the published literature (Figure 1). Astigmatism was reduced to 0.50 D or less in 78% of cases (63 eyes) by surgeons using the ORA System compared to 65.7% of the cases in DataLink and 62% of cases reported in the FDA trial of AcrySof IQ and Restor IOLs by Alcon Laboratories, Inc. (data on file with company, Figure 2). More clinical data are being generated to validate these outcomes with intraoperative aberrometry, but these early results look quite meaningful.

MICROINVASIVE GLAUCOMA SURGERY

My discussion of the next big things in ophthalmology would not be complete without addressing a major innovation in glaucoma treatment. Collaboration during the past 5 to 10 years between leading glaucoma specialists, comprehensive ophthalmologists, and several early-stage private companies (Glaukos Corporation;

Transcend Medical, Inc.; AqueSys, Inc.; and Ivantis, Inc.) is leading to meaningful innovation in the surgical treatment of glaucoma. By my estimate, more than \$300 million has been invested to date to develop this new field. Substantially more than that will be invested in the coming decade. Investigators have found that elegant microstents placed in various outflow channels can meaningfully decrease IOP for years with minimal

surgical morbidity.² With a few minutes of microsurgical intervention, ophthalmologists may be providing patients with a decrease in IOP equivalent to the use of a glaucoma medication (or two) for the rest of their lives.³ Once these devices are approved, I believe that millions of patients will undergo microinvasive glaucoma surgery in the coming decade.

SUMMARY

Innovation in ophthalmic surgery has led to dramatic advances in the past several decades. Substantial financial, technical, and clinical resources continue to be invested in the field. Outcomes following cataract surgery are improving in clinically meaningful ways. Surgical treatments for glaucoma are entering a new era. These next big things will benefit patients and surgeons as well as industry, entrepreneurs, and investors. Innovation will be rewarded, which bodes well for the future.

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Opportunities for Growth Abound in the Ophthalmic Sector



By Steve Waite, BS, MBA

The ophthalmic surgery market is well positioned for the future despite challenges in the near term related to financial markets, regulatory approval timelines, and reimbursement policies. The market is experiencing fundamental growth, fueled by an aging global population, extended careers, and increased financial prosperity in emerging markets. The aging population is expected to drive a substantial increase in the prevalence of age-related eye diseases, including two markets highlighted in this

article. There are many exciting new products in the pipeline to address these conditions.

LEADING BUSINESSES LOOK TO ACQUIRE NEW TECHNOLOGIES

The ophthalmic sector is supported by leading companies such as Novartis/Alcon Laboratories, Inc., Abbott Laboratories/Abbott Medical Optics Inc., Allergan, Inc., Bausch + Lomb, and Genentech with a propensity to acquire new technology or development-stage companies for growth (outsourced research and development). All of the major players have global businesses and the ability to leverage acquired technology across multiple geographies. Between 2003 and 2010, there were 11 ophthalmic device acquisitions with a combined valuation of more than \$13 billion. Of the anticipated \$8 billion in projected growth in the ophthalmic device market during the next decade, a meaningful portion will be generated by venture-backed companies.

Today, obtaining adequate financing is the biggest challenge facing most early-stage companies. The profound effects of the global financial crisis have resulted in more far-reaching financial regulation and have changed investors' strategies. As a result, fundraising levels in early-stage medical technology are at their lowest levels since 2004.¹ Health care has been particularly hard hit because of increasingly long timelines to exit (the time between investing in a new technology and when it is sold) and growing concerns about slow rates of FDA approvals and limitations on reimbursement. As a result, less capital will be available for developing companies.

PATIENT-SHARED BILLING PROVIDES OPPORTUNITIES

New technologies for premium cataract surgery and the treatment of presbyopia will play significant roles in driving growth in the ophthalmic market. In the United States, patient-shared billing in these markets relieves some of the negative impact on physicians exerted by governmental reimbursement pressure. Key emerging technologies include femtosecond lasers, next-generation accommodating lenses, and corneal inlays. Companies leading these markets have similar profiles: solid managerial teams, substantial financing, strong proof of safety and efficacy, and near-term commercial opportunities with innovative new products. For example, PowerVision, Inc., recently completed \$37 million in financing with Venrock, Medtronic, Inc., Johnson & Johnson, and a strong syndicate of existing investors.² OptiMedica Corporation recently began commercialization of its femtosecond laser for cataract surgery. This market will feature four strong competitors by the

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end of this year. AcuFocus, Inc., recently raised \$65 million³ with Medtronic, Inc., SightLine Health, and Cowen Healthcare Royalty Partners joining a strong syndicate of investors, including Bausch + Lomb. AcuFocus, Inc., has begun commercializing the Kamra corneal inlay in a controlled rollout in more than 50 commercial sites throughout the world.

GLAUCOMA TREATMENT OF HIGH INTEREST

Microinvasive glaucoma surgery (MIGS) offers another exciting near-term marketing opportunity in ophthalmic devices. Sixty-four million patients suffer from glaucoma worldwide. Market Scope, LLC, estimates that this market will generate \$500 million in annual device revenues by 2016. MIGS creates a new drainage pathway or reopens an existing pathway to decrease IOP while reducing or eliminating patients' dependence on medical therapy (and problems with compliance associated with taking medications long term). MIGS can be performed as a standalone procedure or at the time of cataract surgery. MIGS, like presbyopic treatment, is a market that features a number of strong competitors developing novel products. Glaukos Corporation has led the field with respect to its progress toward FDA approval and efforts to establish reimbursement. Other compelling technologies, like those from AqueSys, Inc., Ivantis Inc., and Transcend Medical, Inc., are also making strong progress toward the commercialization of the technologies.

CONCLUSION

Driven by underlying demographics, the importance of vision to individuals' quality of life, and multiple payment alternatives, the overall outlook continues to be favorable for the ophthalmology market. As surgeons look to industry for upgraded therapeutic solutions, their focus should be on companies with experienced managerial teams, proven market opportunities, limited exposure to regulatory (FDA) and reimbursement (Centers for Medicare & Medicaid Services) risks, and the quality of the financial backing to fully support physicians as they adopt new technologies. ■

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1. Pricewaterhouse Coopers/National Venture Capital Association Money Tree Report. December 2011. Data: Thomson Reuters.

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3. AcuFocus raises \$65 million in funding. November 29, 2011. www.eyewiretoday.com/view.asp?20111129-acufocus_raises_65_million_in_funding.