

Ophthalmic Business Forecast for 2011

Industry leaders discuss the market trends for the new year.

BY STEPHEN DAILY, NEWS EDITOR

Each year brings with it several new and exiting technologies in the cataract and refractive surgery market, and many believe 2011 will be an especially important, and in some ways revolutionary, year.

With an ever-increasing baby boom population, more information available to the public, and the growing precision and safety of medical devices and procedures, the global cataract and refractive market is expanding exponentially as each year passes.

Perhaps no new procedure in eye care is as anticipated as femtosecond laser-assisted cataract surgery, a hot topic on the showroom floor at ophthalmology conferences in 2010. Dozens of clinical trial and paper presentations have provided statistical proof of the potential of the new technology. The results show the precision, control, and efficacy of femtosecond lasers to have exceeded manual incisional techniques in just about every measurable category in cataract surgery. The promise and potential of femtosecond lasers will become a reality in 2011, as at least three manufacturers plan to commercially launch their systems, marking what many believe to be the beginning of a paradigm shift in ophthalmology.

Cataract & Refractive Surgery Today reached out to top officials from several of the largest eye care companies, including the leading manufacturers of new femtosecond technology, to gauge what they believe are the most important trends in the cataract and refractive surgery market in 2011, along with an update on what technologies in the pipeline will be launched or advanced in testing.



ROBERT GRANT

Chief Executive Officer and President
Bausch + Lomb's (Rochester, NY) Global
Refractive and Cataract Surgery Business

Can you provide a general outlook of where you see the cataract and refractive surgery market going in 2011? What will be the biggest advances/trends?

The cataract and refractive market is expanding quicker than we have seen in the past few years due to the baby boom population. Extended life expectancies and the growing role of computers in everyday life have increased the importance of near and intermediate vision. We do have an advantage in that regard, because we already have the experience of having several generations of accommodating IOLs. As pressure on the cataract surgeons continues to mount, we see refractive products offering a great opportunity to the surgeon and especially to the patient. Loss of NTIOL [New Technology IOL status] and potential cuts in Medicare reimbursement will cause a major shift in the market. Surgeons who adopt refractive IOLs will see an opportunity to expand their practices. There is also tremendous excitement among cataract surgeons over the all-laser precision, image-guided surgery and its potential to revitalize cataract/refractive surgery. We are just beginning to see the acceleration of new technology as we did with the introduction of phacoemulsification.

What technologies/medical devices/products are in the pipeline at your company that you plan either to launch or advance in testing in 2011?

Bausch + Lomb Surgical has new technologies on the market or in the pipeline in the key segments of cataract and retinal surgery.

The great news is that our new Crystalens Aspheric Optic (AO) has been a real hit. The Crystalens AO provides the highest level of visual quality of all presbyopia-correcting IOLs as well as an improved range of visual acuity without correction.

Recently, we introduced Stellaris PC to the US market. This crossover machine for retinal surgery as well as phacoemulsification provides a significant opportunity in ambulatory surgical centers to bring retinal surgery to their patients.

Bausch + Lomb has once again led the industry with innovative products by introducing the only IOL designed to go through incisions as small as 1.8 mm. The Akreos MICS lens has established the new microincisional standard. B+L will introduce the next tier of IOLs providing long-term material stability. The enVista lens is the only IOL manufactured out of a hydrophobic material, which has been approved by the FDA as being glistening free. This lens is available in Europe and Asia on a limited basis and will be launched globally in the latter part of 2011.

Femtosecond technology is going to be a game changer, and we will participate in that market. Our joint venture partnership with Perfect Vision [Technolas Perfect Vision GmbH, Munich, Germany] is progressing very nicely. They recently announced the introduction of a femto-cataract system.

Quality-of-vision expectations and quality-of-life concerns are more demanding than those of previous generations. Many are willing to pay for, and undergo, surgical procedures to avoid the inconvenience of reading glasses or bifocals. We see ourselves as partners of the ophthalmologist and the technology leader in the ophthalmic market.



STUART RAETZMAN

Vice President of Global Marketing and Area President for the United States
Alcon Laboratories, Inc. (Fort Worth, TX)

Can you provide a general outlook of where you see the cataract and refractive surgery market going in 2011? What will be the biggest advances/trends?

[The year] 2010 was remarkable as femtosecond laser technology for cataract surgery was introduced. There is no question that this technology represents a paradigm shift in how surgeons will approach cataract surgery. We expect the LenSx femtosecond laser to increase precision for key manual steps of the procedure—delivering reproducible, predictable, and improved clinical outcomes through its image-guided visualization and micron-level laser precision, while also offering an improved safety profile. It is truly exciting to be on the threshold of such an important advance in cataract surgery.

In 2011, a trend of continued growth in the global advanced technology IOL market is expected. This growth will be fueled by the adoption of our AcrySof IQ Restor IOL +3.0 D and the AcrySof IQ Toric IOLs. We also should see additional advanced technology IOL growth in Europe, parts of Asia, and Latin America, where we have introduced the AcrySof IQ Restor Toric IOL, enabling surgeons to perform a single surgical procedure for presbyopic and astigmatic correction.

What technologies/medical devices/products are in the pipeline at your company that you plan either to launch or advance in testing in 2011?

In the United States, we anticipate approval in 2011 of our expanded range for the AcrySof IQ Toric IOL—making available [cylindrical] corrections up to 6.00 D at the IOL plane and up to 4.00 D at the corneal plane.

The AcrySof Cachet angle-supported phakic lens continues to launch in markets around the world. It is currently available in CE/non-FDA markets and recently gained approval in countries such as China and Brazil. It is currently under FDA review for approval in the US market.

In the refractive laser market, it is a best-of-times and worst-of-times scenario. On the positive side, we are extremely excited about the introduction of our state-of-the-art WaveLight Refractive Suite that features the new 200-kHz WaveLight FS200 femtosecond laser and the new 500-Hz WaveLight EX500 excimer laser. In addition to forming the world's fastest refractive platform, this system offers a broad range of customization for patient-specific treatments and advanced safety features. We have received approval in most major markets around the world for the WaveLight Refractive Suite and early customer feedback confirms our high expectations.

On the challenging side, we saw a continued decrease in the demand for refractive laser surgery in the United States. Recent Consumer Confidence Index gains provide optimism that 2011 will see a return to growth in demand for refractive laser surgery as more and more consumers seek LASIK treatment.

We anticipate having topography-guided LASIK approved for the US market in late 2011. This will expand our ability to provide more patient-specific treatments, further defining a truly customized approach.

On the refractive laser diagnostic side, we will introduce the Topolyzer Vario into the US market to drive the topography-guided procedure, which we have been offering outside the United States since late 2009.

We expect to see the lines between cataract and refractive surgery continue to merge in the future. [The year] 2011 will be another remarkable [one when] we will continue to bring many new advanced technologies to market for surgeons to help their patients see their best.



GEORGE NEAL

Division Vice President, Global Sales
Abbott Medical Optics Inc. (Santa Ana, CA)

Can you provide a general outlook of where you see the cataract and refractive surgery market going in 2011? What will be the biggest advances/trends?

We see growth in emerging markets as a continuing trend for cataract and refractive technologies in 2011. As economies continue to develop in areas such as China, India, and Southeast Asia, for example, we expect to see the development of new infrastructure, new hospitals, and the training [of] new physicians that will greatly improve much-needed patient access to ophthalmic technologies.

As these economies become more sophisticated, we are also seeing the emergence of a growing middle class that will help drive [procedural] growth in elective procedures such as laser vision correction. With continued technological advancements, education, and awareness, we expect to see further penetration into largely untapped markets.

Another area to watch will be advances in retinal and glaucoma technologies and solutions to address the growing patient need. Since many patients are noncompliant with pharmaceutical treatments for these diseases, there is a tremendous opportunity to advance devices in these areas. For instance, we are exploring the possibility of using a device for the back of the eye that can automatically deliver a drug, similar to today's drug-eluting stents for patients with coronary artery conditions.

Another big trend for 2011 will be the advancement of femtosecond-assisted cataract surgery. We are currently in active development with our technology for femtosecond lasers, which would cover multiple applications, including cataract surgery. With more than 4 million femtosecond procedures already conducted using AMO lasers, we fully expect the capabilities [of] our leading technology to be able to address the ophthalmologist's needs today and well into the future.

What technologies/medical devices/products are in the pipeline at your company that you plan either to launch or advance in testing in 2011?

In our cataract franchise, we received [the] CE Mark on our Tecnis Toric IOL this year and are on track for a full commercial launch in Europe in 2011. Additionally, a US registration trial for this product is ongoing. In Europe, AMO has a particularly strong and broad range of IOLs with the Tecnis 1-Piece, Tecnis Multifocal 1-Piece, and Synchrony accommodating IOLs.

In our refractive franchise, we have received CE Mark approval for our VSS Refractive product with a myopia indication and have engaged in a limited launch in Europe, with a broader launch scheduled for 2011. Additionally, we are targeting late 2011 for the limited launch outside the United States of our iDesign Advanced Wavefront Studio system, which is the next-generation technology to our existing Wavescan Wavefront system. Both of these additions will build on the more than 15 million global excimer procedures performed on our technologies.

Also, we are working on advanced wavefront-guided algorithms to further improve outcomes with CustomVue, and we are developing upgrades to our excimer platform in order to advance outcomes even further.



NICK CURTIS

Chief Commercial Officer
LensAR Inc. (Winter Park, FL)

Can you provide a general outlook of where you see the cataract and refractive surgery market going in 2011? What will be the biggest advances/trends?

The biggest advance will be moving the femtosecond lasers into the early commercialization phase. We anticipate our first commercial system placements in the second half of 2011. Our imaging system with automated biometry, algorithms, and customized treatment programs will really help the surgeon gain confidence with the integration and use in the surgical practice. The early commercialization of this technology, not only from LensAR but also from the other companies, will be the biggest advance and trend toward reshaping the entire cataract market longer term. Providing this technology to our [partnering] surgeons [will] help advance their outcomes and patients' satisfaction in all advanced and [customized] procedures in presbyopia, and astigmatic IOL procedures and grow the private-pay market.

What technologies/medical devices/products are in the pipeline at your company that you plan either to launch or advance in testing in 2011?

One of the very exciting projects we are working on is using the femtosecond laser to soften the nucleus of the lens to treat presbyopia in the natural crystalline lens. To the best of my knowledge, LensAR is the only company to have treated human patients in the correction of presbyopia [in] this way. We have done this in more than 40 eyes and will continue to expand and treat using several more algorithms, with the goal of eventually bringing this treatment to the market. Our intention is for this to be a software upgrade to the existing system.



MARK FORCHETTE

President and Chief Executive Officer
OptiMedica Corp. (Santa Clara, CA)

Can you provide a general outlook of where you see the cataract and refractive surgery market going in 2011? What will be the biggest advances/trends?

[The year] 2011 will mark the beginning of a landscape change in ophthalmology with the introduction of fem-

tosecond laser cataract surgery. New technologies will become available that replace the procedure's most manual steps and offer a whole new level of precision, control, performance, safety, and efficacy to surgeons and patients. We believe these technologies hold the promise [of] better refractive outcomes and are likely [first] to take hold in the growing market for presbyopia-correcting and toric IOLs.

What technologies/medical devices/products are in the pipeline at your company that you plan either to launch or advance in testing in 2011?

OptiMedica expects to launch its Catalys Precision Laser System worldwide in 2011. Developed by an exceptional team of OptiMedica scientists and engineers in close collaboration with leading cataract and refractive surgeons from around the world, Catalys combines a femtosecond laser, integrated optical coherence tomography (OCT) imaging, and OptiMedica's breakthrough pattern scanning technology. Catalys is designed to replace the most manual steps of cataract procedures by providing [customized] control of capsulotomy's size, shape, and position; precise lens fragmentation, including segmentation and softening; exact laser incisions in the cornea to address astigmatism; and meticulously constructed multiplane cataract incisions. Technological hallmarks of the Catalys system include an innovative Liquid Optics Interface that was designed to be an important part of the optical path for the OCT and laser and provide a wide field of view for the surgeon. In addition, Catalys utilizes integrated OCT that is enhanced by sophisticated algorithms—a system called Integral Guidance—which automatically identifies ocular surfaces and establishes safety zones allowing the physician to select and customize treatment, ensuring that the femtosecond laser pulses are delivered precisely to the intended location.

The clinical results achieved with Catalys, which have been published in the peer-reviewed journal *Science Translational Medicine*,¹ have clearly established the numerous benefits the system can bring to cataract surgery. ■

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1. Palanker DV, Blumenkranz MS, Andersen D, et al. Femtosecond laser-assisted cataract surgery with integrated optical coherence tomography. *Sci Transl Med.* 2010;2(58):58ra85.