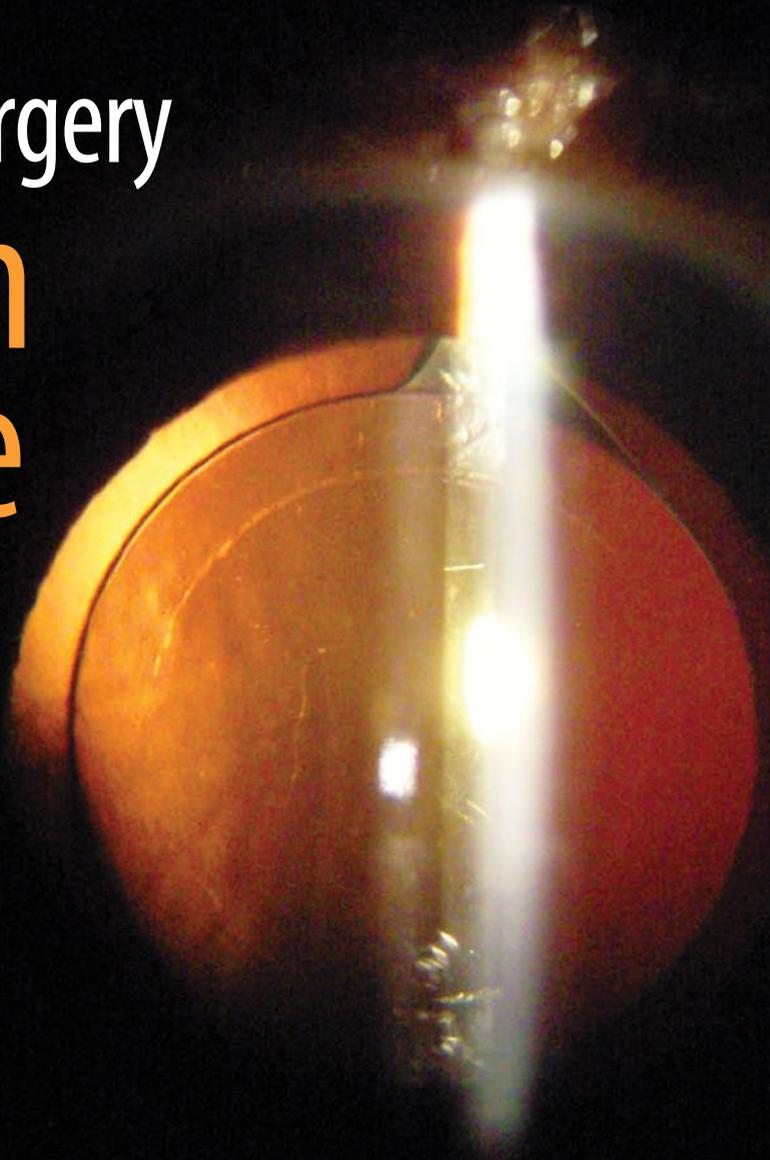


Cataract & Refractive Surgery TODAY

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Laser Cataract Surgery Delivers On Its Promise

Our Experience With
the Catalys Precision
Laser System



BY PAUL MANN, MD
WILLIAM F. WILEY, MD
ROBERT P. RIVERA, MD
PROFESSOR H. BURKHARD DICK, MD, PhD
JEREMY KIEVAL, MD

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Our Experience With the Catalys Precision Laser System

BY PROF. H. BURKHARD DICK, MD, PhD; JEREMY KIEVAL, MD; PAUL MANN, MD; ROBERT P. RIVERA, MD; AND WILLIAM F. WILEY, MD

The Catalys Precision Laser System (OptiMedica, Inc.) (Figure 1) was designed with the purpose of improving and standardizing the least predictable and most technically demanding steps of cataract surgery. To this end, the laser incorporates several innovative features that together optimize the safety and control of all four steps of the laser cataract procedure. This monograph is the first of a two-part series that will explore the technology behind the Catalys Precision Laser System, why we chose it for our practices, and our experience with the system to date. This first part focuses on the laser itself—its technology, capabilities, and clinical performance. Part 2, which will print in April, will focus on our experiences integrating the Catalys into our practices.



Figure 1. The Catalys Precision Laser System.



H. Burkhard Dick, MD, PhD, Full Professor, is the chairman of Ruhr University Eye Hospital, Bochum, Germany. Professor Dick is a member of the *CRST Europe* Editorial Board and of the medical advisory board for OptiMedica, Inc. Professor Dick may be reached at +49 234 299 3101; burkhard.dick@kk-bochum.de.



Jeremy Kieval, MD, is the director of cornea, refractive, and anterior segment surgery at Lexington Eye Associates Inc. in Massachusetts. He is a speaker for Allergan, Inc., and Alcon Laboratories, Inc., and a consultant to Alcon and SARcode Bioscience. Dr. Kieval may be reached at 781-862-1620; jkieval@lexeye.com.



Paul Mann, MD, is in private practice at the Mann Eye Institute and Laser Center in Houston. He is a consultant for OptiMedica, Inc. Dr. Mann may be reached at (713) 580-2568; paul.mann@manneye.com.



Robert P. Rivera, MD, is director of clinical research, intraocular lens & refractive surgery, at Hoopes Vision in Draper, Utah. He is a consultant for OptiMedica, Inc. Dr. Rivera may be reached at (602) 955-1000; rpriveramd@aol.com.



William F. Wiley, MD, is medical director of the Cleveland Eye Clinic and is an assistant clinical professor of ophthalmology at University Hospitals/Case Western Reserve University in Cleveland. He is a consultant for OptiMedica, Inc. Dr. Wiley may be reached at (440) 840-2020; drwiley@clevelandeyeclinic.com.

AN OVERVIEW OF THE CATALYS PROCEDURE—CUSTOMIZED, PRECISE, AND PATIENT-FRIENDLY

Performing laser cataract surgery with the Catalys Precision Laser System involves four steps: planning, engaging, visualizing/customizing, and the treatment itself.

Planning

The Catalys laser offers intuitive, template-based planning software (Figure 2) that enables surgeons to preplan patients' treatments with just a few touches of the screen. This touch-screen software streamlines the procedure and minimizes the time that the patient is under the laser.

Engaging

Catalys features a proprietary Liquid Optics Interface (Figure 3) that docks the patient's eye to the laser via a gentle, fluid-filled approach that minimizes increases in IOP, raising it by only 10 to 15 mm Hg.¹ In fact, Catalys is not contraindicated in glaucomatous eyes. The lens does not contact or appanate the cornea. The Liquid Optics Interface creates a wide field of view that allows all of the laser's cuts to be performed in a single dock. The interface also reduces contact with the sclera, so there is less redness after the procedure.

Visualizing/Customizing

The Catalys laser is guided by an integrated, proprietary imaging system called Integral Guidance (Figure 4) that is powered by full-volume 3D optical coherence tomography (OCT). The system images from the anterior cornea through the posterior lens (Figure 5), then its sophisticated algorithms accurately map the ocular surface and designate safety zones around the iris and other important ocular structures that the laser must avoid. Based on this information regarding the patient's ocular anatomy and orientation of the eye, the surgeon can create a customized treatment plan, confirm the plan, and then deliver the laser treatments precisely to the intended locations (and within the safety zones).

The Treatment

The capsulotomy, lens fragmentation, and corneal incisions maps are displayed on top of the full-volume 3D OCT and video images of the eye according to the selected centration method (Figure 6). The system automatically centers the capsulotomy on the pupil and adjusts for any tilt. The laser is a proprietary fiber laser created specifically for laser cataract surgery. The surgeon can implement multiple fragmentation and softening patterns. As a safety measure, there are four sensors to tell if the patient is becoming agitated during the treatment, although patients typically find the laser procedure comfortable and speedy.

WHY WE CHOSE THE CATALYS FOR OUR PRACTICES

Paul, Mann, MD

Here at the Mann Eye Institute and Laser Center in Houston, my partners and I have been using femtosecond lasers in LASIK surgery since 2003; ours was one of the first practices to adopt the Intralase FS femtosecond laser (Abbott Medical Optics, Inc.) when it came out. A few years later, it became apparent that femtosecond lasers had several potential applications beyond just cutting corneal flaps. So, in 2009, I attended the 2nd annual International Conference on Femtosecond Lasers in Ophthalmology in Bordeaux, France, and had my first



Figure 2. The touch-screen planning software on the Catalys Precision Laser System.



Figure 3. The Liquid Optics Interface.



Figure 4. Powered by full-volume OCT imaging, the Catalys system's proprietary Integral Guidance system accurately maps ocular surfaces and designates safety zones to ensure laser pulses are delivered only where intended.

(courtesy of Prof. H. Burkhard Dick, MD, PhD, Bochum, Germany.)

(Courtesy of Prof. H. Burkhard Dick, MD, PhD.)

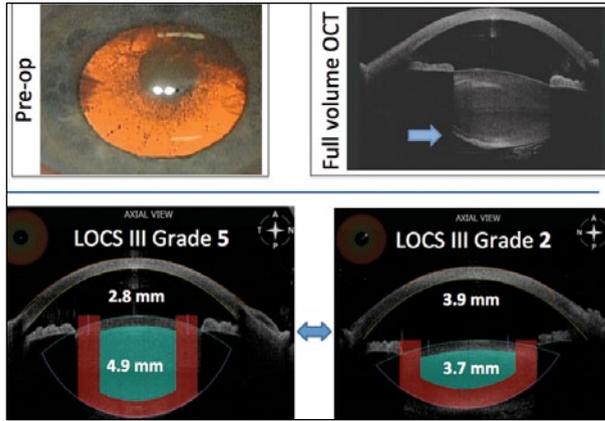


Figure 5. The OCT visualization of the eye's intraoperative anatomy informs the surgeon's decision making.

introduction to using femtosecond lasers in cataract surgery as well as other areas. After that experience, my father, Michael Mann, MD, and I explored the companies that were developing femto-cataract technology for the United States. We attended the major US ophthalmic meetings and learned that Alcon Laboratories, Inc., was likely to be the first to market with the LenSx laser; we also thought that OptiMedica, Inc., was likely to be close in time to market with the Catalys Precision Laser System. Although most Alcon products have a superb reputation, we were more impressed with the technology on the OptiMedica system. It seemed to us that the LenSx was just a converted flap maker, whereas the Catalys system was designed from the ground up for laser cataract surgery.

Subsequently, I traveled to the Dominican Republic in December 2011 and watched physicians there perform cataract surgery with the Catalys laser. I was very impressed with the system's capsulotomies and phaco-fragmentation. In the same month, I went to Fort Worth to watch a colleague perform surgery with the LenSx system, and I thought there was a big difference between the two lasers' ability to phaco-fragment the nucleus. Also, the Catalys' capsulotomies seemed to be much more accurate and more often free-floating.

In January of last year, I traveled to Germany to watch Prof. H. Burkhard Dick, MD, PhD, perform some cases with the Catalys, and I was amazed by how little ultrasonic energy he was using to remove the cataracts. While I was in Germany, my father and our administrator, Dana Ondrias, OD, were in California touring the LenSx facility. When we compared notes, we decided to choose what we believed was the better technology. This decision felt somewhat risky because Alcon is known for establishing the gold standard of care in our field, and we knew the LenSx would come with plenty of customer support. We were confident with our decision, however, after meeting with the OptiMedica team, and we continue to be confident with the attentive service we have received.

(Courtesy of Prof. H. Burkhard Dick, MD, PhD.)

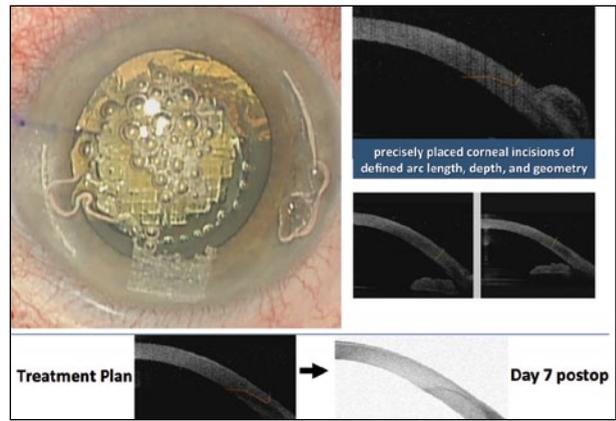


Figure 6. The Catalys' intraoperative OCT image guidance enables the precise placement of corneal incisions.

William F. Wiley, MD

My partners and I followed a similar approach in our research and selection of Catalys at the Cleveland Eye Clinic. When we were deciding whether to adopt laser cataract surgery, we polled our patient base and determined that our patients did want the laser option. So, we began to evaluate the available platforms: the LenSx (Alcon Laboratories, Inc.), the LensAR Laser System (LensAR Inc.), the VICTUS (Technolas/Bausch & Lomb), and the Catalys Precision Laser System (OptiMedica, Inc.).

After a fairly extensive review of these systems (Figure 7), I concluded that all of the laser cataract systems can give practices a marketing edge by virtue of the laser technology, but that the performance of some of the platforms at the time of our evaluation did not appear to provide a clinical advantage. My partners and I placed a high priority on clinical performance and the potential for an easy, complication-free learning curve. We wanted a femtosecond laser that could provide a true clinical improvement for our patients—we would not tolerate a device that increased our potential for surgical complications.

We chose the Catalys Precision Laser System for two main reasons. First, it is the only laser built exclusively for laser cataract surgery from the ground up. Second, the laser's imaging capability was very important to us—we wanted to be able to image the ocular structures clearly before applying the laser, and we were impressed by the Catalys system's Liquid Optics Interface and state-of-the-art Integral Guidance full-volume 3D OCT imaging system. These two systems work in concert to map out the patient's laser treatment, and this technology was the deciding factor in our choosing the Catalys laser.

Jeremy Kieval, MD

The selection process for our surgery center (Lexington Eye Associates in Massachusetts) took about a year. My partners and I vetted all of the laser cataract systems, but we decided fairly early on to focus our attention on the LenSx laser (Alcon Laboratories, Inc.)



Figure 7. Dr. Wiley's research for a laser cataract system.

and the Catalys Precision Laser System (OptiMedica, Inc.).

Once we observed the LenSx laser, we began to understand the potential benefits that a femtosecond laser could bring to the cataract procedure. However, we witnessed several cases in which a loss of suction caused the surgeon to speed up the procedure, and others in which the surgeon chose not to perform the corneal incisions out of fear of losing suction with that laser. We also learned that capsulotomies were not always complete with the LenSx laser. For these reasons, we started to question whether the technology was really ready for our patients.

Then, we observed surgeries performed with Catalys, and our minds were completely changed. The system's precision and performance were nothing less than exceptional, and it was also incredibly easy to use.

Robert P. Rivera, MD

My experience is somewhat unique in that my partners and I purchased and installed the LenSx laser (Alcon Laboratories, Inc.) in September 2011, with great anticipation. Unfortunately, we experienced quite a number of shortcomings with the LenSx system. It was difficult to dock patients' eyes to the laser, it produced incomplete capsulotomies, and its treatment of the nucleus did not seem to offer us any real advantages. I felt that the LenSx system required surgeons to be more proficient than usual with making capsulotomies so they could correct those made by the laser. Furthermore, conversations with colleagues nationally and internationally have made me aware that this experience with the LenSx laser is apparently quite commonplace. In fact, some of my colleagues in South America have had such a poor experience that they have

unfortunately concluded that laser cataract surgery is not viable, and they have abandoned the technology.

After using the LenSx system for nearly 1 year, our procedural volume remained flat. However, my partners and I knew that other femtosecond cataract laser platforms were available, and we researched our options. We took particular interest in the Catalys Precision Laser System. I especially liked the way that the Catalys system treated the nucleus and rendered it into microfragments (Figure 8A–C). So, even though we had already invested in the LenSx laser, we reserved a Catalys system when it gained US FDA clearance, and we took delivery of the Catalys in August 2012.

Naturally, after spending money on a second platform, I worried whether we would experience any of the same issues we did with the LenSx laser. (Incidentally, we still have both lasers, sitting side by side.) From the very first case, however, Catalys proved that it is an entirely different machine. My partners and I have been so impressed with the Catalys Precision Laser System's treatment of corneal incisions, capsulotomies, and the nucleus that we now recommend laser cataract surgery with this system to all of our surgical candidates. We are so pleased with the performance of this system and its outcomes that we currently do not use our LenSx laser (Table 1).

SYSTEM PERFORMANCE

Prof. H. Burkhard Dick, MD, PhD

I acquired the Catalys laser in December 2011, and my experience with it has convinced me of the superiority of laser cataract surgery versus the traditional procedure. First, it has unquestionably improved my capsulotomies with a level of reproducibility that is unattainable with the manual technique. More than 99% of the capsulotomies I make with the Catalys system are complete and have a perfect diameter, position, shape, and centration, and a perfect 360° overlap of the lens.

Capsulotomies are not the laser's only capability, however; it is adept at (and FDA cleared and CE marked for) precise corneal primary and sideport incisions, arcuate incisions, and lens fragmentation as well. Moreover, the laser's lens softening ability enabled me to eliminate my use of ultrasound in 40% of the first 850 cases I performed.

Catalys also performs beautifully in the area of IOP rise. My staff and I evaluated 100 eyes that had undergone



Figure 8A–C. The Catalys' signature cuts—unparalleled performance in capsulotomy and lens fragmentation.

(Figure 8A courtesy of Jason Jones, MD, Sioux City, Iowa. Figure 8B courtesy of the Iahis Group Alliance, Alliance, Spain. Figure 8C courtesy of Howell M. Findley, DO, Lexington, KY.)

TABLE 1: DR. RIVERA'S PERSONAL COMPARISONS WITH THE CATALYS PRECISION LASER SYSTEM AND THE LENSX LASER

	Catalys	LenSx
Docking	Easy docking, with no mechanical pressure on the cornea (no contraindications for glaucoma patients) ¹	Difficult docking that creates an IOP spike (contraindicated for glaucoma patients)
Capsulotomy Integrity	All capsulotomies have been 100% free-floating to date, with no complications	Free-floating capsulotomies were rare
Capsulotomy Time	Capsulotomy time = 1.5 secs	Capsulotomy time = approx. 6 secs
Complications	Minimal complications; no subconjunctival hemorrhaging	Radial tears, posterior capsular tears, loss of nucleus, subconjunctival hemorrhaging, broken corneas

successful tonometry and laser cataract surgery with Catalys, measuring absolute IOP preoperatively and postoperatively. Mean preoperative IOP was 15.6 mm Hg \pm 2.5 SD and rose to only 25.9 \pm 5.0 mm Hg after application of the suction ring and vacuum. The IOP remained constant even after the cataract laser procedure. After the suction ring was removed, the mean IOP was 19.1 \pm 4.4 mm Hg, and 1 hour after surgery, the IOP did not significantly differ from preoperative values. These results are in contrast to other studies demonstrating a higher IOP rise with alternative applanation interfaces.

Similar results of low IOP rise were achieved in a separate study recently published in the *Journal of Cataract and Refractive Surgery*.² In this study of 25 eyes, femtosecond laser pretreatment with Catalys was associated with a mean peak increase in IOP of 18.5 mm Hg from baseline, with the authors concluding the pretreatment was safe and well tolerated.

Finally, an additional aspect of Catalys that I find valuable is the system's full-volume 3D OCT technology; the degree of intraoperative visualization it affords allows me to make informed surgical decisions, such as detecting pre-existing posterior perforations or posterior polar cataract, that would necessitate a change in the treatment plan.

Dr. Wiley

I have been quite pleased with the Catalys laser's performance. The system has allowed me to reduce the amount of ultrasound I use during cataract surgery dramatically (up to 99%), as has been the case in other centers around the world (Figure 9). In fact, in many cases, I have achieved zero phacoemulsification. In those cases where we do still use ultrasonic energy, it has been at a greatly reduced level, even with using our older Venturi-style phaco system. Furthermore, my team and I have a 99% complete capsulotomy rate. The corneal incisions are very precise and accurate, and they are delivered exactly where intended.

In addition, my personal complication rate since obtaining Catalys has been impressively low. In our first 109 cases, my staff and I achieved 108 free-floating capsulotomies; we had one tag due to an existing corneal scar. In our 400+

subsequent cases, we have had no dropped nuclei, anterior or posterior capsular tears, or any other significant complication.

Dr. Rivera

I tell colleagues that the Catalys system makes a good surgeon better and an excellent surgeon perform at the top of our field. The degree of surgical accuracy that the Catalys system provides by standardizing the surgical incisions, including arcuates, improves cataract surgery for everybody.

Docking patients' eyes with the Catalys laser is noticeably easier and less traumatic than our experience with the LenSx laser. The Catalys laser does not applanate the cornea or contact the cornea, but instead it uses a very soft process of docking that does not flatten, crease, or alter the biological shape of the cornea.

Two of the most important features unique to Catalys are its Liquid Optics Interface and Integral Guidance full-volume 3D OCT imaging system. The Liquid Optics Interface is designed to dock the laser to the patient's cornea without applying mechanical force. By not distorting the cornea, this docking system creates a clear path for the Integral Guidance OCT imaging software to capture a full-volume 3D image of the cornea, identify the treatment area, and establish a safety zone around the treatment. Thus, the full-volume 3D OCT image that the system obtains is as physiologic as it can be, which in turn enables the treatment pattern to be as predictable as possible. In addition to the precision and safety aspects of this laser, my staff and I have found that the Liquid Optics Interface does not cause marked subconjunctival hemorrhaging, as we have experienced with the LenSx laser. Catalys patients emerge from the surgical procedure with a white eye, and I no longer have concerns about postoperative redness or increases in IOP.

It is worth noting that the LenSx's new SoftFit interface is an improvement over the system's original one, yet it is still a one-piece, curved interface, and the system remains contraindicated for glaucoma. In my opinion, the newer interface has not improved the learning curve or ease of docking (Figure 10A and B). The single-piece interface still

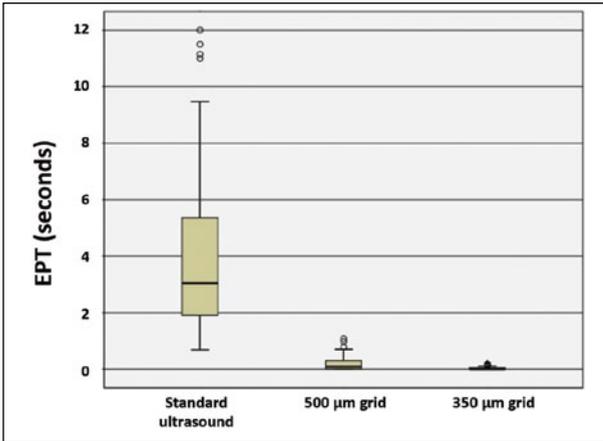


Figure 9. Reduction of ultrasound with Catalys. Prof. Dick demonstrated a 96% reduction in ultrasonic energy using Catalys' 500-µm lens fragmentation grid, as compared to a manual technique; and an additional 77% reduction when using the 350-µm grid. Moreover, he said that 40% of the first 850 Catalys cases in his clinic required no ultrasound (LOCS III grade=3.2 ±0.9; 350-µm grid). (Data adapted from: Conrad-Hengerer I, Hengerer FH, Schultz T, Dick HB. Effect of femtosecond laser fragmentation on effective phacoemulsification time in cataract surgery. *J Cataract Refract Surg.* 2012;28(12):879-883.)

creates decentered docking, which exaggerates the natural tilt of the lens. The interface does not compensate for lens tilt in the lens treatment. In addition to the new SoftFit interface, Alcon recently updated the LenSx's imaging; and in my experience, it still has OCT artifacts (Figure 10B) and still needs manual manipulations—it is not automated and integrated with the laser, as it is on the Catalys.

In our practice, the Catalys Precision Laser System really does produce perfectly circular, 100% free-floating capsulotomies in 1.5 seconds, and they are as easy to lift off the capsule as lifting a napkin off the dining table. Also, the

“In my opinion, Catalys lens softening is the greatest advancement in the field of cataract surgery since the development of phacoemulsification itself.”

—Dr. Rivera

laser's reproducibility allows us to measure the effect of using different sizes of capsulotomies. This type of information will help us gain even greater surgical excellence, such as the best effective lens position.

My favorite part of the Catalys system's technology, however, and what I believe really sets this laser apart, is how it approaches nuclear fragmentation and emulsion. The femtosecond energy emulsifies the nucleus so exquisitely that my staff and I can actually remove many nuclei (even substantial ones) without phacoemulsification (using I/A only). This technology is so effective that I believe it will generate a paradigm shift in cataract surgery to what we will begin to refer to as “femto-emulsification.” In fact, surgeons new to the Catalys platform quickly find that the learning curve is short and easy. Instead of using phacoemulsification to carve the nucleus, we are now using it simply to clear the port on the phaco handpiece. Thus, the total amount of ultrasonic energy that laser cataract surgery uses in the eye is markedly less than the conventional treatment, if any is required at all. It has reduced our overall use of phacoemulsification dramatically, like the other centers. Corneas look very clear postoperatively, and patients' vision recovers that much faster.

The dramatic reduction in phacoemulsification that the Catalys lens softening allows has been documented by many practices around the world. For example, the results of a 400-eye comparative study conducted in Australia³ showed that the large reduction of ultrasound reduced

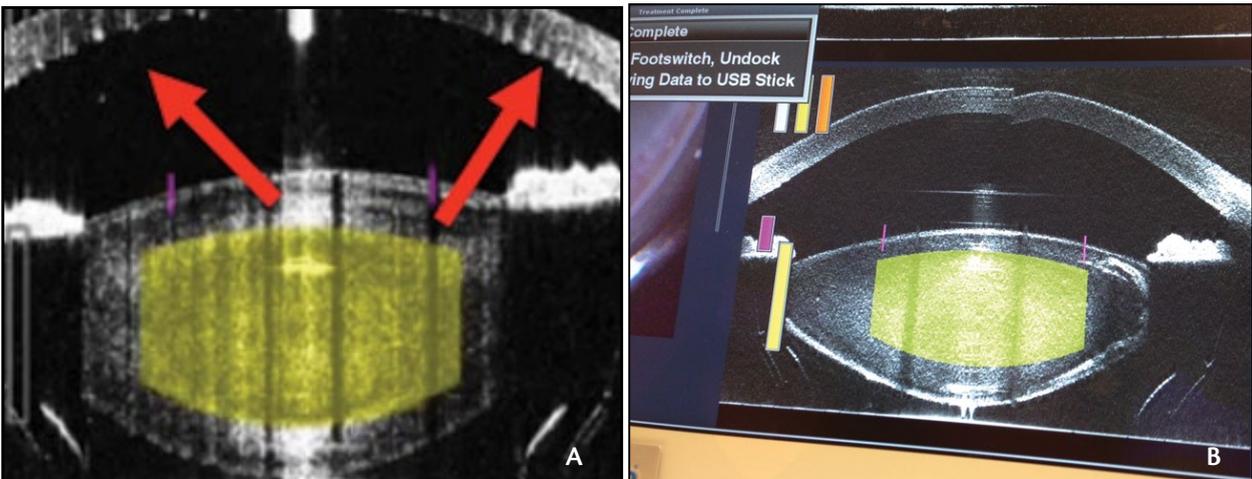


Figure 10. Dr. Rivera has witnessed corneal folds with the LenSx laser's original docking system (A). With the LenSx's new imaging and interface (SoftFit) system, he is still experiencing OCT imaging artifacts (B).

“The Catalys Precision Laser System has far exceeded our projections for break-even case volumes.”

—Dr. Wiley

endothelial cell loss in the 200 eyes that were treated with Catalys as compared to the 200 eyes treated with conventional cataract surgery. In my opinion, Catalys lens softening is the greatest advancement in the field of cataract surgery since the development of phacoemulsification itself.

Dr. Mann

Since obtaining the Catalys laser, I have been using much less ultrasound than I do in the non-femto cases I currently perform. Our patients’ corneas are noticeably clearer immediately after surgery compared with the traditional technique, and their anterior chambers are so much quieter that they recover their visual acuity faster.

Dr. Kieval

I adopted laser cataract technology with a fairly skeptical view. I knew I could already make a great capsulorhexis, but my early experience with Catalys showed me that nothing I could do manually could ever duplicate the precision of the laser-delivered capsulotomy. In addition, I have found that laser lens fragmentation with Catalys makes the lens so much easier to emulsify and aspirate. It’s almost a completely different feel. There’s really no phacoemulsification needed; it’s almost all aspiration. The arcuate incisions are also incredibly beautiful. As with the capsulotomy, no manual technique could match the precision of Catalys and how truly accurately the laser makes its incisions.

OVERALL IMPRESSIONS

Dr. Rivera

In my experience, the Catalys system gives precise outcomes, even in challenging eyes such as those with advanced Fuch’s dystrophy. These types of cases are contraindicated on the LenSx platform, because that system’s applanating plate elevates IOP to a greater extent. I treated such a patient who had advanced Fuch’s dystrophy and advanced cataracts. On her first eye, I used the traditional manual technique for the capsulorhexis; I did not even recommend that she undergo laser cataract surgery with the LenSx system. For her second eye, however, we had obtained the Catalys laser, and she and I decided that we would try that system. The difference in this second eye was remarkable. By the first postoperative day visit, that cornea looked as crystal clear as the manually treated eye looked at 1 month.

Dr. Wiley

From the business perspective, the Catalys Precision Laser System has far exceeded our projections for break-even case volumes. Therefore, it has already been a very good investment in the short time we have had it.

Prof. Dick

Considering all of the surgical benefits I have experienced from the Catalys laser, I am convinced that laser cataract surgery is here to stay. With a short learning curve, automated processes, improved reproducibility, superb intraoperative viewing and ergonomic comfort for the patient and surgeon, I have yet to experience any drawbacks with Catalys. I continue to be impressed with this system.

Dr. Mann

What most impresses me about the Catalys laser is the perfectly circular capsulotomy we are able to achieve every single time, and the femtofragmentation and resultant decrease in the amount of ultrasonic energy needed to extract cataracts. I am excited to continue using the laser and to optimize treatments for patients. My partners and I are very pleased with the way Catalys has enhanced our surgical outcomes.

Dr. Kieval

I think some surgeons fear adopting technological changes that may not make much of a difference for patients. Frankly, that was my opinion of laser cataract surgery before I experienced the Catalys Precision Laser System. My feeling now is that this technology is definitely here to stay; it will only become more and more widely used. Lower-volume surgeons who have not yet acquired the technology do not necessarily need to become early adopters, but they must build it in to their future practice plans. As laser cataract technology becomes more broadly used, patients will start to seek it out, and surgeons who are not offering it will fail to advance their skill set and eventually hurt their practices.

Dr. Rivera

Ophthalmology is currently in the early days of adopting laser cataract surgery with femtosecond lasers, and we should expect all platforms to continue to improve to reveal new opportunities for making cataract surgery faster and safer. In my opinion, the Catalys system has entered the market so far ahead of the competition that I anticipate it will be one of the drivers of this new technology. ■

1. Schultz T, Conrad-Hengerer I, Hengerer FH, Dick HB. Intraocular pressure variation during femtosecond laser-assisted cataract surgery using a fluid-filled interface. *J Cataract Refract Surg.* 2013;39(1):22-27.
2. Kerr NM, Abell RG, Vote BJ, Toh TY. Intraocular pressure during femtosecond laser pretreatment of cataract. *J Cataract Refract Surg.* 2013 Jan 8. [Epub ahead of print].
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The accompanying article reflects the views of the respective authors, and they are responsible for its content. The OptiMedica® Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. For more information regarding the device visit www.optimedica.com.