

THE MOST NOTABLE TRENDS THAT We've recognized in Crst Europe's Past decade in Print.

BY LAURA STRAUB, EDITOR-IN-CHIEF

Over our first decade in print, **CRST Europe** might have reported a fad or two, but, for the most part, we have done our diligence to highlight serious trends in cataract and refractive surgery. Although some proclaim it better to look forward than backward, here is a historical recap of the top trends we have recognized across five major areas in this space.

- ASTIGMATISM MANAGEMENT

An evergreen topic, astigmatism management has become increasingly important over the years due to a hike in patient demands and expectations. As H.L. "Rick" Milne, MD, pointed out in his article in the November/December 2006 issue, "ignoring the astigmatism is a recipe for later repercussions."¹ Every patient undergoing laser vision correction by Dr. Milne at that time received treatment for astigmatism, whereas only patients with astigmatism who elected a multifocal IOL received treatment at the time of cataract surgery. His preferred methods of correction were limbal relaxing incisions (LRIs) for 1.00 to 2.00 D of astigmatism, laser treatment if the astigmatism was visually influential, and, occasionally, conductive keratoplasty. The next hot era in astigmatism correction, he mentioned, would be "the day when toric multifocal IOLs are available." (As we know, these lenses were available in Europe long before the United States.)

Toric IOLs. Also in the November/December 2006 issue, Georg Gerten, MD, and Omid Kermani, MD, shared their indications for toric IOL implantation: an operable cataract and stable, largely regular astigmatism ranging from 2.00 to 11.00 D (average, 3.75 D). They found that toric IOL implantation reduced astigmatism to a mean $0.84 \pm 0.53 \text{ D.}^2$

Given that surgeons had "become obsessed with the concept of astigmatically neutral surgery"—to borrow a phrase from Charles Claoué, MA (Cantab), BChir, MD, DO, FRCS, FRCOphth, FEBO, MAE—toric IOLs were slow to gain momentum.³ In the July/ August 2009 issue, Dr. Claoué wrote that, although surgeons had done "our utmost to have repeatable, accurate biometry and use appropriate IOL regression formulas with personalized A-constants to correct spherical error, it seems we have bypassed astigmatism correction by adopting aspheric IOLs before toric IOLs." Dr. Claoué said that adding toric IOLs to one's practice is the first step toward offering patients customized IOLs.

Also contributing to that 2009 issue, Rudy M.M.A. Nuijts, MD, PhD; Noël J.C. Bauer, MD, PhD; and Nienke Visser, MD, noted that about 22% of cataract surgery patients had at least 1.25 D of astigmatism, meaning they could potentially benefit from a toric

IOL.⁴ At the time, the minimum available toric IOL power was 1.00 D. "Patients with regular bow-tie astigmatism are the most suitable for toric IOL implantation," they wrote.

Another option for patients with large degrees of astigmatism was a toric phakic IOL, as Alaa El Danasoury, MD, FRCS, pointed out in the February 2010 issue.⁵ "The principal indication [for toric phakic IOLs] is the correction of ... myopic astigmatism beyond the range of LASIK correction," he wrote,⁵ adding that toric phakic IOLs could also be advantageous for patients who presented with risk factors for post-LASIK ectasia or flap complications.

By early 2011, several sophisticated toric IOL alignment technologies were surfacing. Among them was the Callisto Eye (Carl Zeiss Meditec),⁶ a system using video overlay to mark and project parallel lines to aid in lens alignment. "This device collects data from the IOLMaster (Carl Zeiss Meditec), and matches images of the limbus and scleral and/or conjunctival vessels with the operating field, providing automated anatomic recognition," Michel Perez, MD, wrote in the April 2011 issue.

Also available was the Orange Intraoperative Wavefront Aberrometer (WaveTec Vision Systems; now ORA with VerifEye+ by Alcon). "Whereas current toric IOL calculators are conservative on cylindrical power, using the Orange has shown me that a large percentage of patients would benefit from an IOL of the next largest cylindrical power than that chosen preoperatively," Farrell "Toby" Tyson, MD, wrote in that same issue.⁷ "I perform aberrometry again after implanting a toric lens to provide me with the refraction and to indicate the direction of rotation needed to optimize lens placement."

Using rapid data acquisition and real-time data display with wavefront measurements, Holos (Clarity Medical Systems) could also be used for toric IOL alignment, among other applications.⁸ "This technology has the potential to provide intraoperative confirmation of proper IOL power selection and astigmatism reduction," David F. Chang, MD, wrote.

The fourth and final alignment technology described in that 2011 issue was the SG3000 (SensoMotoric Instruments), which,

according to Drs. Visser and Nuijts, provided "a better opportunity to accurately align the toric IOL during implantation."⁹

Perhaps the introduction of toric IOL alignment technologies was in response to an explosion in the toric and toric multifocal IOL market in Europe. In *CRST Europe's* January 2013 cover focus, a group of surgeons shared their experiences with this growing group of lens technologies.¹⁰ Jorge L. Alió, MD, PhD, stated that, with a toric IOL, "the correction of astigmatism is straightforward" and added that, when combined with a femtosecond laser, there were many advantages. Additionally, the patient population potentially benefitting from a toric IOL "is relatively easy to identify," Thomas Kohnen, MD, PhD, FEBO; and Oliver Klaproth, Dlpl-Ing(FH), said. In their practice, patients with at least 0.75 D cylinder were considered for a toric IOL.

In comparison, Roberto Bellucci, MD, said that he considered a toric IOL when a patient's astigmatism was higher than 1.50 D; Tobias H. Neuhann, MD, 2.00 D or more; and Peter Mojzis, MD, PhD, FEBO, greater than 1.25 D.

Dr. Mojzis further said that he would consider a toric multifocal IOL only "if the indications for a multifocal lens are fulfilled," and that he preferred "the stability of four-haptic multifocal toric lenses with the option to implant through a small incision." Dominique Pietrini, MD, also expressed his preference for fourhaptic designs "as they are remarkably stable in the capsular bag."

Incisions for astigmatism management. In an article in May 2008, Achyut Mukherjee, MRCOphth; and Mohammed Muhtaseb, FRCOphth, commented that the increasing use of multifocal and accommodating IOLs required a widespread need to address preexisting astigmatism at the time of cataract surgery.¹¹ Describing their technique of paired 2.6-mm clear corneal incisions (CCIs) created 180° from each other, they reported that "the mean decrease in keratometric astigmatism … was 1.32 D, compared with 0.19 D in eyes that underwent a single on-axis incision and a 0.40 D increase with a superior incision."

In May 2009, José F. Alfonso, MD, PhD; Luis Fernández-Vega, MD; and Begona Baamonde, MD, again advocated for paired opposite CCIs to correct preexisting corneal astigmatism.¹² In a study they described, in eyes in which opposite CCIs were created with an optical zone of 10 mm, astigmatism decreased by 1.00 \pm 0.48 D. "Surgeons should consider opposite CCIs, taking into account the degree of astigmatism to be treated; possible long-term mechanical instability; and variability of postoperative outcomes that are subject to a high number of variables, such as age, magnitude, depth, and length of the incisions," they wrote.

Because eliminating visually significant astigmatism was found to be a key factor in successful premium IOL implantation, many surgeons at this time were circling back to the use of LRIs. In our May 2010 issue, Bartlomiej J. Kaluzny, MD, said that LRIs are "a predictable and effective means of correcting preexisting corneal astigmatism up to 2.00 D at the time of presbyopia-correcting IOL implantation. ... LRIs may increase the percentage of patients who fulfill inclusion criteria for premium IOLs and improve clinical outcomes in these patients."¹³



"CRST Europe instantly connects me to the world's best minds in ophthalmology. It boldly and honestly addresses many challenges and opportunities that we face on a daily basis. One specific piece of advice from Michael Lawless, MBBS, FRANZCO, FRACS,

has really stuck with me: His mentor urged him to keep 1 day each week for planning, innovating, and catching up on emails and other loose ends. I implemented this 1 year ago (a half day is all I can manage at present), and it has made a tremendous difference to my peace of mind and productivity."

Allon Barsam MD, MA, FRCOPHTH

In our September 2010 issue, Eric D. Donnenfeld, MD, offered his technique for LRI construction. He said that he opted to perform LRIs at the beginning of cataract surgery because he prefers "a firm eye, one in which the cornea has not been thinned by dehydration under the operating microscope."¹⁴

The following year, Mark Packer, MD, FACS, CPI, described using the femtosecond laser to make automated LRIs. "The potential for femtosecond LRIs to place the photodisruptive cutting effect at the right orientation and to make cuts of the correct length and depth to create the desired refractive effect should lead to greater consistency of outcomes," he wrote. "Ultimately, our abilities to titrate and enhance precise LRIs may prove superior to outcomes achieved with toric IOLs for most degrees of astigmatic correction."¹⁵

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^{1.} Milne HL. Managing the astigmatic patient. http://crstodayeurope.com/articles/2006-nov/1106_14-php/. Accessed November 9, 2016.

^{2.} Gergen G, Kermani O. Toric IOLs for astigmatic correction. http://crstodayeurope.com/articles/2006-nov/1106_16-php/. Accessed November 9, 2016.

CXL

Although CXL was introduced by Seiler et al¹ nearly 10 years before *CRST Europe* was born, A. John Kanellopoulos, MD, first reported the treatment of post-LASIK ectasia using a combination of CXL to stabilize the cornea and surface ablation for visual rehabilitation in our May/June 2006 issue.² In a 29-yearold patient who experienced myopic and astigmatic regression after unilateral LASIK, Dr. Kanellopoulos used an epithelium-off (epi-off) CXL approach, applying a single application of UV-A radiation at 3 mW/cm² for 30 minutes combined with 0.1% riboflavin in 20% dextran T-500.

"One month after topography-guided treatment, the patient's UCVA was 20/20, and his BCVA was 20/20 with a refraction of +0.50 -5.00 X 160°. The corneal endothelium count had remained stable at 2,700 cells/mm²," Dr. Kanellopoulos wrote.

Amar Agarwal, FRCS, FRCOphth, MS, reported in *CRST Europe*'s July/August 2006 issue that BCVA and maximum keratometry values improved and cessation of keratectasia occurred in approximately 50% of patients he treated with CXL³ Likewise, Roberto Pinelli, MD, and colleagues found that, in all 10 patients who underwent bilateral epi-off CXL, keratoconus progression ceased; that 75% had regressed pathology; and that 80% recorded an improvement in visual acuity.⁴ Furthermore, 40% of eyes showed a 21.9 µm average increase in corneal thickness. Eyes were treated with proparacaine 0.5% for up to 30 minutes before UV-A exposure, followed by riboflavin application for up to 25 minutes before irradiation. UV-A light exposure lasted 30 minutes, with riboflavin reapplied on the cornea every 3 minutes.

"In my opinion, the main goals [of CXL treatment] are to change keratoconus from a disease state into a syndrome and to stop or slow the progression of the pathology. ... The improvement in visual acuity must be considered—and explained to the patient—as a bonus instead of a goal," Dr. Agarwal wrote.³

In a virtual roundtable on CXL in the July/August 2007 issue, Aylin Ertan, MD (now Aylin Kilic), said that topographic improvements in her first short-term results were not as impressive as she had expected but that the "change in visual acuity was far more than ... expected, and it was not parallel to changes in topographic variables."⁵ Dr. Kanellopoulos responded that it could be difficult to compare preoperative and early postoperative topographies because of thicker reepithelialization over the apex of the cone. He also stated that, in using CXL for 4 years, he had reduced his number of PKPs by approximately 50%.

As more surgeons gained experience with CXL, variations of the surgical protocol emerged. In October 2008, Farhad Hafezi, MD, PhD, urged surgeons to stick with the original protocol: "Because crosslinking involves several steps that are potentially harmful to ocular structures ... special attention should be given to the treatment's technical parameters."⁶ Of the currently accepted treatment protocol, which included deepithelialization for efficient penetration of riboflavin into the cornea, he said "this method has been

The Dresden Protocol: Steps and Rationale'

STEPS

- Step No. 1: Mechanical debridement of the corneal epithelium within a 9-mm-diameter zone
- Step No. 2: Application of 0.1% riboflavin every 3 to 5 minutes for 30 minutes
- Step No. 3: UV-A light irradiation for 30 minutes with an intensity of 3 mW/cm² in combination with continual riboflavin application

RATIONALE

- The epithelium, approximately 50 µm in thickness, forms a barrier to both riboflavin and UV-A penetration
- Removing the epithelium allows proper absorption of riboflavin into the cornea and anterior chamber in order for the UV-A light to efficiently illuminate the cornea

1. Wollensak G, Spoerl E, Seiler T. Riboflavin/ultraviolet-A-induced collagen crosslinking for the treatment of keratoconus. Am J Ophthalmol. 2003;135:620-627.

successfully used ... since 1999." (Editor's note: The sidebar directly above outlines the original Dresden protocol for CXL.)

Despite the advice of Dr. Hafezi and others, alternative CXL protocols began to surface, and the debate of epithelium-on (epion) versus epi-off CXL began. To summarize, the key concerns with epi-on CXL are that riboflavin does not penetrate the intact epithelium and that the presence of the epithelium blocks about 20% of the UV-A light from reaching the stroma.

Also in the October 2008 issue, Dr. Pinelli, Tarek El Beltagi, MD; and Antonio Leccisotti, MD, wrote that surgeons "must remember that most complications associated with this procedure, such as infections, slow healing, and subepithelial haze, occur because of deepithelialization. ... In our opinion, the [CXL] treatment of the future will be a less invasive, painless technique that does not require deepithelialization."⁷

Over the years, CXL use continued to increase; however, "safety considerations have yet to be elucidated fully," Sheraz M. Daya, MD, FACP, FACS, FRCS(Ed), FRCOphth, commented in his April 2009 editorial.⁸ Further, in an article in the same issue, Dr. Hafezi offered the following: "As long as the corneal stroma shows a thickness of 400 µm and the irradiance is 3 mW/cm² or less, the endothelium is protected by the riboflavin concentration in the stroma (riboflavin shielding). ... Nevertheless, CXL remains a relatively new method with a potential for complications that is not yet fully understood. CXL should, therefore, be performed only by surgeons with knowledge of corneal wound healing, and only when the indication for CXL is clearly documented."⁹

Another debate that surfaced early in CXL history was whether the treatment can or should be combined with visual rehabilitation techniques. Dr. Kanellopoulos reported in 2009 that superior rehabilitation

of keratoconus was achieved with sequential topography-guided PRK and CXL.¹⁰ "Our findings suggest better results with the performance of partial topography-guided PRK as a therapeutic intervention in extreme corneal irregularity followed by CXL immediately thereafter ... as opposed to CXL followed by PRK."

Arthur B. Cummings, MB ChB, FCS(SA), MMed(Ophth), FRCS(Edin), and Eugene Y.J. Ng, MRCOphth, also reported that they preferred topography-guided PRK followed by CXL, using a procedure they called simultaneous laser correction with CXL (SimLC). "SimLC has produced remarkable improvements in corneal topography. ... [It has] raised the bar even further with a treatment that appears safe and effective."¹¹

Other combination treatments were also shared in a virtual roundtable organized that same year by Jérôme C. Vryghem, MD, PhD.¹² Efekan Coskunseven, MD, stated that he preferred gas-permeable contact lenses for visual rehabilitation or, if the patient could not tolerate the lenses, intrastromal corneal ring segments (ICRSs). Both Drs. Kanellopoulos and Nuijts said that they also used phakic IOLs in combination with CXL to correct large refractive errors.

In a later issue, Dr. Coskunseven provided an update to his use of combined ICRS/CXL treatments.¹³ Performing CXL about 7 months after ICRS implantation, "mean UCVA improved from 0.11 preoperatively to 0.26 after Keraring (Mediphacos) implantation and further improved to 0.32 after CXL," he wrote. Spherical equivalent, cylinder, and mean keratometry also improved following CXL, "demonstrating the efficacy of the combined treatment."

Also in another issue, Victor Derhartunian, MD, and Michael Mrochen, PhD, shared their experience with LASIK plus CXL, stating that the decision to perform the treatment should be based on the patient's risk for developing ectasia according to the Ectasia Risk Score System.¹⁴ "Although the clinical evidence for the effectiveness of LASIK plus CXL is scant, there are promising indications that this combined procedure may ameliorate refractive regression and address the risk of post-LASIK ectasia in carefully selected patients," they wrote.

Other surgeons focused on determining the optimal time interval between CXL and visual rehabilitation. "With sequential CXL followed by ... transepithelial PRK, an interval of at least 6 months should be allowed between the two treatments," according to a 2009 article by Mirko Jankov II, MD, PhD; Sladjana Delevic, MD; Vesna Jovanovic, MD, MS; Dr. Coskunseven; and Slobodan Golubovic, MD, PhD. "Coadjuvant ... transepithelial PRK immediately followed by CXL is more comfortable for the patients; however, it is suitable for thicker corneas or earlier stages of keratoconus."¹⁵

CRST Europe's first report of the use of Keraflex KXL (Avedro), published in the March 2010 issue, included results from the first seven eyes with keratoconus treated with the technique. These very early results showed significant improvements in corneal flattening, smoothness, and regularity, with a mean change in manifest refraction spherical equivalent of 4.39 D (range, 0.50–10.25 D) and mean change in steepest keratometry of -6.00 D. These results suggested the possibility of correcting refractive errors without inducing biomechanical weakening of the cornea. According to author Peter S. Hersh, MD, in addition to improvement in corneal curvature, laboratory investigations indicated corneal strengthening after the procedure.¹⁶

In September 2011, Dr. Cummings shared that he was initially apprehensive about Keraflex, but his reservations later disappeared: "I know of no other modality that can achieve the same degree of corneal flattening and hence visual improvement in such a safe manner," he wrote. "I currently find that, when I use combination treatments, I opt for Keraflex more frequently."¹⁷

In our January 2011 issue, *CRST Europe* published a roundtable discussion with some of the thought leaders in CXL use: Dr. Cummings; Dr. Daya; Dr. Kanellopoulos; Dr. Leccisotti; Professor Mrochen; Roy S. Rubinfeld, MD; Theo Seiler, MD, PhD; Aleksander Stojanovic, MD; and William B. Trattler, MD.¹⁸ Three participants' updates to this article can be found in the feature starting on page 62 of this issue; in short, many of the comments made in 2011 are still relevant today, and the debate of the perfect protocol, including epi-off versus epi-on, continues.

"As long as there are no data, I am not willing to accept that as solid proof that a CXL protocol works," Professor Seiler said in that 2011 roundtable. "One surgeon may crosslink only 55% of the cornea effectively, but he or she happens to be treating patients who do not require 100% crosslinking. The same protocol will not work for the surgeon who is treating advanced keratoconus with CXL. The bottom line is that each surgeon must provide data and be honest as a scientist."

The discussion continued in the March 2013 issue, with Parag A. Majmudar, MD, advocating for epi-on CXL. "I firmly believe that the standardization of riboflavin loading of the cornea and further advances in UV-A irradiation technology will overcome the main objections to [epi-on] CXL," he wrote.¹⁹ "More recent studies have shown support for the efficacy of [epi-on] CXL. Pinelli and colleagues²⁰ reported no significant difference in the analyzed parameters between [epi-on] CXL and standard CXL. Filippello et al²¹ performed bilateral [epi-on] CXL in 20 patients with progressive keratoconus. ... Their conclusion was that [epi-on] CXL treatment appeared to halt keratoconus progression and provide statistically significant improvements in visual and topographic parameters."

On the other side of the argument sat Dr. Cummings and Rebecca McQuaid, MSc. "The reason for performing CXL is to stabilize keratoconus, and the reported clinical outcome and experimental results of epi-on treatments demonstrate reduced efficacy: that is, less biomechanical stiffening of the cornea," they wrote. "Patient comfort is of secondary importance in this situation, and the primary outcome measure is whether or not CXL has been successful in stabilizing or even improving the corneal shape. This is the fundamental thought in the mind of the practitioner of epi-off CXL."¹⁹

Advances in CXL continued to appear in Europe. Two of these, accelerated CXL with higher irradiance output (9 to 45 mW/cm²)



"CRST Europe provides a unique service, through both the publication itself and the publication's website. It is my No.1 method to stay abreast to what is happening in ophthalmology generally and in our subspecialty specifically. What is novel, what

appears to be working, what is relevant to the business of cataract and refractive surgery? The information in *CRST Europe* is typically honest, straight-talking, and from thought leaders and colleagues sharing real-life, firsthand experiences, tips, and advice. There is no other publication that I am aware of that better suits my needs as a cataract and refractive surgeon."

Arthur B. Cummings MB CHB, FCS(SA), MMED(OPHTH), FRCS(EDIN)

and pulsed illumination in which the UV-A beam is turned on and off at specific time intervals, were described by Michael B. Raizman, MD, in the May 2014 issue. "It is my impression that the procedures are well tolerated by our patients, without significant adverse events and with initial efficacy that is at least equal to the traditional protocol," he wrote.²² "The introduction of accelerated CXL and pulsed illumination opens the door to a wide range of applications for CXL beyond the stabilization of keratoconus."

In a 2015 article, Dr. Hafezi wrote that the majority of published data on CXL pertain to 3 mW/cm² for 30 minutes or 9 mW/cm², and that, "for intensities higher than 9 mW/cm², publications are sparse and lack documented stabilization of progression."²³

By early 2016, additional reports on accelerated CXL were available. In a review article, Cosimo Mazzotta, MD, PhD, and Soosan Jacob, MS, FRCS, DNB, said that "the therapeutic window allows treatment in about 20 minutes in all cases with a good balance between efficacy and tolerability for the patient, optimizing the time of surgery without affecting treatment efficacy." They also said that topography-guided treatment protocols "are evolving to achieve a nonablative and nonincisional refractive response without sacrificing the stabilizing effect of the original crosslinking concept."²⁴

Yet another recent CXL innovation is iontophoresis-assisted CXL, a variation of the epi-on procedure. In an article in the October 2015 issue, Luca Gualdi, MD; Federica Gualdi, MD; Veronica Cappello, MD; and Massimo Gualdi, MD, suggested that "CXL assisted by iontophoresis is a potentially valid alternative to standard CXL." After evaluating 18 eyes that completed 2 years of follow-up, their data documented "not only a halting of kerato-conus progression but also a slight tendency to improvement in some cases."²⁵

With all of these variations emerging in recent years, Dr. Hafezi warned in an article in May of this year that none is more

advantageous to the patient than the original Dresden protocol for CXL.

"An abundance of supposedly more sophisticated CXL protocols have been introduced into the field, causing confusion," he wrote. "These approaches, including accelerated CXL, pulsed CXL, contact lens–assisted CXL, [and] epi-on CXL, do provide some biomechanical effect. Ultimately, however, the biomechanical effect of these protocols is still inferior to that of epi-off CXL. Our research group has argued that the primary reason for this is a relative lack of oxygen availability with these and other new protocols."²⁶

Even after 20 years, the history of CXL is just beginning, and a variety of surgical procedures involving the treatment are still being developed. For instance, Dr. Hafezi said, although settings and parameters for corneal CXL "cannot simply be transferred to the sclera," scleral CXL is "a fascinating concept that may someday lead to a therapeutic approach for progressive myopia."²⁷

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- FEMTOSECOND LASERS

It is hard to remember the time when the biggest buzz regarding femtosecond lasers was corneal flap creation, but that is exactly what contributors to *CRST Europe* were talking about in 2006. In March of that year, "blade-free LASIK" was gaining momentum, and, according to an IntraLase (now Abbott) news release, 52% of the refractive surgeons featured in *CRST*'s 50 Most Influential Ophthalmologists list were using the IntraLase for LASIK flap creation.¹

In the November/December 2006 issue, Stephen G. Slade, MD, argued that a sub-Bowman flap created with a femtosecond laser was best. "The advantages to using sub-Bowman flaps include fewer cut nerves; a trend toward improved visual outcomes, particularly with customized LASIK; less required time for creation; a reduced occurrence of post-LASIK dry eye; and less risk of lost suction."

Surgeons' wariness of the femtosecond laser for corneal refractive surgery seemed to die down by early 2007, as the milestone of 1 million procedures performed with the IntraLase was reached. "In spite of the huge capital cost and per-procedure price—a concept Europe is slowly accepting but one our US colleagues are already familiar with—the technology has penetrated widely," Dr. Daya wrote in his April 2007 editorial.² In another editorial, in the November/December 2007 issue, Dr. Daya noted the level of penetration of the technology: "Although 28% to 30% of all LASIK procedures in the United States are performed using IntraLase, the majority of procedures are still being performed using microkeratomes."³

George C. Charonis, MD, and Evgenia G. Konstantakopoulou, MSc, offered one reason for the slow adoption in their article in that same issue: "The \$400,000 investment in an early-generation technology needs thoughtful consideration. Do not throw your trusty mechanical microkeratome in the wastebasket yet!"⁴

In the end, however, outcomes such as those shared by Roberto Montés-Micó, PhD—that LASIK with a mechanical microkeratome was associated with higher values of higher-order aberrations and a higher increase in spherical aberration and that patients treated with femtosecond LASIK achieved more lines of BCVA—helped to establish the femtosecond laser as the gold standard in flap creation.⁵

LASIK volume seemed to remain high until about 2008, when the worldwide economic downturn affected the number of patients seeking refractive correction. For a closer look at this issue, see the sidebar *LASIK Volume Through the Years* on page 50.

As femtosecond laser's place in refractive surgery became generally accepted, other femtosecond-based procedures emerged. In the April 2007 issue, Walter Sekundo, MD, described femtosecond lenticular extraction (FLEX).⁶ After using the VisuMax femtosecond laser (Carl Zeiss Meditec) to treat 32 myopic eyes, Dr. Sekundo noted that a few patients had even achieved 20/10 UCVA 1 day after undergoing FLEX. "FLEX has the potential to revolutionize the entire course of corneal refractive surgery," he wrote. "This is the fascinating procedure of the future." As we know, the FLEX procedure evolved into what is now called small incision lenticule extraction (SMILE). This procedure is covered in more detail in the sidebar *SMILE*: A *Closer Look* on page 52.

In the middle of 2009, the buzz in femtosecond lasers changed dramatically when, for the first time, a femtosecond laser was used in cataract surgery. Zoltan Nagy, MD, reported his results with the LenSx femtosecond laser (now Alcon) for anterior capsulotomy in our September 2009 issue. "When compared with manual capsulorrhexis, the achieved diameter of laser capsulotomies was significantly more reproducible, with 100% of cases achieving the intended diameter," he wrote. "In contrast, only 10% of manual rhexis procedures achieved diameter accuracy of ±0.25 mm."⁷

By late 2010, three companies had developed femtosecond laser technology for cataract surgery: Lensar, LenSx (later acquired by Alcon), and OptiMedica (later acquired by Abbott). "All three platforms use similar concepts and view the market similarly in terms of the platform's appeal," John Vukich, MD, said in an interview with *CRST Europe*.⁸ Later, Technolas Perfect Vision (now a Bausch + Lomb company) entered the space with the only femtosecond laser platform at the time capable of both cataract and refractive techniques.⁹

Around this time, many practitioners were unsure of the femtosecond laser's role in cataract surgery. In an interview with *CRST Europe*, Steve Speares, then vice president of global surgical marketing at Alcon, said that he did not believe "that this technology is going to eliminate phacoemulsification. A femtosecond laser can only complement the procedure, not complete the procedure. I believe any of the investigators will tell you the same thing: Right now, this technology is clearly complementary; it will not displace phaco. Now, if the question is: Can it enhance phacoemulsification? Can it improve the phacoemulsification procedure? Absolutely. It is going to assist surgeons in some of the most difficult and challenging steps of the procedure."¹⁰

Debate over the cost-effectiveness of laser-assisted cataract surgery (LACS) platforms has been a constant theme over the years. In the October 2012 issue, Dr. Daya shared his decision to purchase the Victus femtosecond laser (Bausch + Lomb). "As a habitual 'prosumer,' I am a natural optimist and, I suppose, a risktaker, but I would temper this by stating that I do actually take an analytic view when considering new technologies," he wrote. "For a high-ticket item like this, I would not make an impulsive move if I did not feel it was worthwhile."¹¹

He continued, "I cannot deny that the cost is high, and admittedly I have been trying to figure out the best way forward in terms of a business model. However, I am now convinced that the procedure is better than conventional surgery, and I believe all my patients should undergo the procedure when possible. This means prices have to increase for all, but because the subsequent volume of use will be higher, the cost increase per case will not be as high as it would be if the laser were used

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LASIK Volume Through the Years

By 2009, the worldwide economic downturn, often called *The Great Recession*, had done what many consider permanent damage to the LASIK market. In an exclusive interview with *CRST Europe*, James V. Mazzo, then chairman and CEO of Advanced Medical Optics (now Abbott), shared his thoughts on the decrease in LASIK volume. "There are three principal reasons people choose not to have LASIK. In order of importance, they are (1) fear, (2) awareness—not awareness of the existence of LASIK, but awareness that they are a candidate—and (3) cost. In the current crisis, I am sure that cost has risen in priority in that list, and it could currently be the No. 1 reason, but fear and awareness are still significant factors in people's decisions."¹

Mr. Mazzo further stated: "It is thought that we have treated only approximately 2% to 3% of the eligible patients in the United States with refractive surgery. Why is that? It is because we have not been able to clearly communicate to resolve patients' fear and awareness issues. Fear can be resolved. Your patient should know he is in the hands of the right physician; that is message No. 1. ... In individual practices and in the industry in general, we must get better at educating the consumer on why this may be the right medium for him."

The year 2010 was deemed "The European Year of LASIK" by the European Society of Cataract and Refractive Surgeons (ESCRS), and, in our July/August issue, *CRST Europe* featured an update on LASIK volume around the world with reports from nine surgeons.² To combat the decline in LASIK volume, Karl G. Stonecipher, MD, said, his practice began gearing advertising toward millennials. "More of these patients are coming through the door," he wrote, "but not enough to offset the decline of the aging population."

At 400 to 500 procedures per month, John S.M. Chang, MD, said that his LASIK volume had taken a 10% hit. After a 30% plunge in LASIK cases in the 3 previous years, Francesc Duch, MD, said that his center had entered a plateau phase with a slow trend toward recovery. After a 23% decline the previous year, Michael A. Lawless, MBBS, FRANZCO, FRCOphth, anticipated another decline of about 12% for the following year. He said, however, that "the general decline in LASIK is easing, and individual premium providers offering a full range of refractive options tend to be affected less than those offering only LASIK."

Echoing Dr. Lawless' observation, Arthur B. Cummings, MB ChB, FCS(SA), MMed(Ophth), FRCS(Edin), said that his LASIK numbers had been stable since an initial dive 18 months before, and mostly older patients less affected by the credit crunch were now undergoing LASIK. Furthermore, Eric D. Donnenfeld, MD; Kjell U. Sandvig, MD, PhD; and Ronald R. Krueger, MD, all said that their practices had seen an increase in LASIK volume of about 10% with a return of younger patients with lower levels of refractive error in Dr. Donnenfeld's practice, about 10% in Dr. Sandvig's practice, and about 21% in Dr. Krueger's practice.

In a 2014 article, Stephen Coleman, MD, tried to answer the question: What drives LASIK volume?³ "Naturally everyone has

their own suggestions on how to increase business," he wrote. "My feeling has always been that the key to maintaining or increasing LASIK volume is low enhancement rates. Give me a laser that results in the fewest enhancements, and I will show you a successful practice in which technology can truly be the foundation of ambitious marketing objectives."

In April 2015, Sheraz M. Daya, MD, FACP, FACS, FRCS(Ed), FRCOphth, postulated that price wars and discounts on LASIK provided the public with a confusing message: that the procedure is not serious and is easily available at bargain-basement rates. Unfortunately, even though nearly 100% of eyes achieve 20/20 visual acuity, LASIK volume continued to taper almost worldwide, he said.⁴

CRST Europe took a closer look into LASIK volume in the cover focus of the 2016 July/August issue. Although the content from this cover focus is extremely recent, it is still beneficial to review. Perhaps the biggest take-home message in that issue came from Dr. Donnenfeld, who stated that LASIK is the safest, most successful, and most widely studied elective procedure in the world, with the highest patient satisfaction rate of any elective procedure. He credited the erosion of LASIK's reputation to several myths that are still in circulation today: (1) that physicians would never have LASIK on their own eyes, (2) that contact lenses are safer than LASIK, (3) that LASIK significantly increases the risk of halos and glare, (4) that dry eye is extremely common after LASIK, (5) that the safety of LASIK has not improved, and (6) that complications are commonplace.

"To all the leaders of ophthalmology ... our responsibilities must be to educate patients; to continue to improve patient satisfaction, with 100% of patients seeing the same or better than they did preoperatively; and, most important, to embrace patients who are dissatisfied with their vision following LASIK and never allow them to feel abandoned," Dr. Donnenfeld wrote.⁵

Whatever the cause, it has been clear to many surgeons that actions must be taken to revive the market. In his editorial in April of this year, Dr. Cummings challenged *CRST Europe* readers to put eight points into practice: (1) Share current statistics with everyone who comes through your clinic doors; (2) educate your nonrefractive colleagues; (3) make contact with optometrists; (4) take the opportunity to speak about LASIK at a general ophthalmology meeting in your country; (5) if you offer new procedures, do so with grace and aplomb; (6) fight any attempts to commoditize LASIK; (7) make attempts to remove fear of the procedure; and (8) encourage industry to play its part.⁶

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THE STANDOUTS

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selectively. Cost is also defrayed by its use for refractive surgery and flap creation."

In a counterpoint statement, Khiun F. Tjia, MD, was more reserved. "Why am I waiting to implement [LACS]?" he asked. "The answer is simple: At this time and in this economy, I cannot make a reasonable business case to purchase a laser platform for a procedure that, in my hands, already has exceptionally good results."¹²

These two central arguments persisted. In the February 2014 issue, we reviewed data on the use of LACS for anterior capsulotomy, and surgeons commented on its usefulness in clinical practice.¹³ Some were in favor of the technology in all cases. "In my experience with the FineVision trifocal IOL (PhysIOL), the ratio of enhancements I perform dropped from 11.3% to 3.6% in normal cases with no intraoperative complications. The only difference between my current and previous technique is the use of the femtosecond laser in creating the capsulorrhexis," Erik L. Mertens, MD, FEBOphth, wrote.

Other surgeons felt that the laser's benefits were seen less for capsulotomy than for other indications. "The femtosecond laser's real benefit for patients may not rest with the standard case, regardless of IOL design, but with more niche cases," Jonathan M. Davidorf, MD, commented. Likewise, Oliver Findl, MD, MBA, said that "the femtosecond laser is a fascinating technology for cataract surgery, and its use can perhaps bring increased safety and reduced endothelial cell loss. However, in the context of the capsulotomy, it seems to have a small effect on postoperative outcomes, with little evidence to support claims otherwise."

But others commenting for that 2014 article were even less optimistic of the laser's use for capsulotomy. "There is no study that shows a significant difference in refractive outcomes between a laser anterior capsulotomy and a manual technique; nor would there be any reason to suspect this," Steven G. Safran, MD, wrote. "Most surgeons I speak with report little difficulty in creating a reliable capsulorrhexis by hand, and I know of many surgeons besides myself who cannot remember the last radial tear-out they had. If a surgeon has little difficulty making the incisions, performing the capsulorrhexis, and chopping the lens nucleus effectively and efficiently with his or her manual technique, I do not see the benefit of a femtosecond laser—for the surgeon or for his or her patients."

Some took an even harder stance. "Industry would have us believe that a well-centered and round capsulorrhexis with complete optic overlap is a necessary precondition of predictable refractive outcomes and is heavily invested in convincing surgeons to purchase lasers to achieve this. However, Findl,¹⁴ Davidorf,¹⁵ and Davison¹⁶ come to the opposite conclusion, finding that the capsulorrhexis is not the determining factor in refractive outcomes," commented Richard Schulze Jr, MD, MPhil (Oxon).

Making predictions for November/December 2014 issue, Roberto Bellucci, MD, forecast that, although LACS is still under development, "the femtosecond laser will be increasingly used in cataract surgery."¹⁷ His reasons included better and more efficacious



"One of the most crucial lessons I have learned from reading *CRST Europe* over the years is that it is not only important to remain updated in the science of ophthalmology but also in the art of ophthalmology. This includes many vital

aspects such as developing your soft skills as well as knowing how to market your practice, grow your organization, prioritize your resources, and be an effective team leader. It has been really nice over the years to be able to learn all of these and much more from an easily accessible and trusted source— *CRST Europe*—and I congratulate them for having completed a very successful decade in print."

Soosan Jacob MS, FRCS, DNB

fragmentation patterns, better handling of difficult cases, improving surgeon perspectives, and a forward-thinking industry perspective. H. Burkhard Dick, MD, said he expected that availability of femtosecond-specific IOLs could also influence laser use.¹⁷

According to a survey conducted by Michael Lachman and published in the April 2015 issue of *CRST Europe*, 78% of American-European Congress of Ophthalmic Surgery (AECOS) members who responded to the survey performed LACS at that time.¹⁸ Although 58% described use of the laser as improving surgical outcomes, about 15% felt that it did not, and two respondents said that the laser actually made cataract surgery less safe at that time.

"In terms of the barriers to success and pitfalls to avoid, three items were mentioned in roughly equal numbers. These largely mirrored the pearls for success, viewed from the opposite perspective," Mr. Lachman wrote. "The top three pitfalls were: (1) not taking the time to educate patients and make them aware of the technology, (2) having doubts and uncertainty regarding the clinical benefits and not fully committing to the technology, and (3) operational issues such as poor planning and execution."

Another femtosecond laser-related procedure that *CRST Europe* reported on is immediate sequential LACS. In our July/August 2015 issue, surgeons debated its use, the issues surrounding endophthalmitis, and the proper protocol. "I have been using intracameral antibiotics for 15 years, together with povidone-iodine, and I have a rate of 1 in 12,750 cases of endophthalmitis with this regimen. Based on this experience, the risk of bilateral simultaneous endophthalmitis is extremely low," Dr. Mertens wrote.¹⁹ "I felt confident pursuing the same-day bilateral approach with a LACS technique."

In the same issue, Laurent LaLonde, MD, MSc, FRCSC, reported on the outcomes of 1,142 patients who underwent immediate sequential LACS in his practice, representing 46% of the

SMILE: A Closer Look

We first mentioned small incision lenticule extraction (SMILE), a modification of the FLEX procedure, in the July/August 2010 issue.¹ Of the advantages described by Jesper Hjortdal, MD, PhD, at that time, the biggest were the potential for greater biomechanical stability and a lower risk of corneal ectasia.

Developments in the procedure were slow, but many surgeons continued to think that it was the refractive treatment of the future. In the April 2012 issue, Sven Asp, MD, DMSci, said that ReLEx SMILE had the potential to become the gold standard in refractive correction. The procedure, he said, "is the most significant development in corneal refractive surgery since the introduction of LASIK."²

In a 2015 outlook article, Robert Edward Ang, MD, said that, even with the continuation of the flat LASIK market, LASIK would remain the go-to treatment in most centers. Although "more buzz and data on ReLEx SMILE will surface," he said that the procedure was not yet a must-have.³

Promising results with SMILE had appeared, however. Evaluating the safety of SMILE by calculating postoperative tensile strength, Dan Z. Reinstein, MD, MA, FRCSC, DABO, FRCOphth, FEBO, found that "we can achieve refractive predictability to within ± 0.50 D in about 80% of eyes and within ± 1.00 D in almost all eyes with low to moderate myopia." Using a model to compare the removal of 100 μ m of stroma with an ablation (LASIK or PRK) versus as a lenticule (SMILE) from a 550- μ m thick cornea, he found that "the model calculated the postoperative tensile strength would be 75% of the initial value after SMILE performed with a 130- μ m cap, 68% after PRK, and 54% after thin-flap (100 μ m) LASIK."⁴

Roberta Calienno, MD; Leonardo Mastropasqua, MD; Mario Nubile, MD; and Niccoló Salgari, MD, also reported on clinical advantages of SMILE over LASIK.⁵ Using laser scanning in vivo confocal microscopy to examine the induced alterations and corneal wound healing patterns in myopic eyes after femtosecond LASIK and SMILE, they found "significantly less surgical denervation in SMILE than in [femtosecond] LASIK," and they noted that "significantly faster nerve regeneration also seems to occur."

Jodhbir S. Mehta, FRCS, FRCOphth, said that, with approximately 125,000 SMILE treatments performed globally, results were promising.³ "I believe that, in 2015, we will continue to witness a shift away from conventional LASIK," he wrote. "Patients have also become more aware of the SMILE procedure over the past 2 years."

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"Like many of my colleagues, I am happy that *CRST Europe* is still available in print. The magazine is my companion on the plane and during my holidays. I like the practical tips that *CRST Europe* provides for my practice and for the management

of my center, but I also appreciate all of the scientific articles my colleages write, for example about wavefront and CXL."

Magda Rau MD

cataract surgeries he and colleagues performed between October 2014 and May 2015. "I have elected to complete the cataract procedure in the first eye before performing the femtosecond laser preparation of the second eye (two sittings)," he wrote, adding that other surgeons in his clinic preferred to complete the femtosecond laser preparation of both eyes in one sitting.²⁰ "There were no differences between these two ways of ordering the surgery, with an overall complication rate of 22 of 988 cases (2.2%) in the one-sitting group and three of 154 cases (1.9%) in the two-sittings group."

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- PHACOEMULSIFICATION AND CATARACT SURGERY

The first decade of the 21st century saw rapid advances in phaco technology. Back in 2006—our first year in print—bimanual microincision cataract surgery (MICS) was gaining a following, with advocates arguing that the technique was safer, more effective, and less invasive than coaxial phacoemulfication. However, challengers maintained that their positive results with coaxial and the long learning curve associated with bimanual MICS techniques was more than enough to dissuade them from undertaking the transition.

In an interview with *CRST Europe* in 2006, Professor Alió said that the bimanual approach was "a natural evolution of cataract surgery," and he estimated that 15% of Europeans were using some form of the technique and another 20% was experimenting with it.¹ In the January/February 2007 issue, I. Howard Fine, MD; Dr. Packer; and Richard S. Hoffman, MD, defended their position that bimanual surgery was the superior technique. "We are frequently confronted by criticism ... [but] we believe that bimanual [MICS] is a better procedure, even in the absence of an IOL insertable through these microincisions."²

Later that same year, Dr. Tjia made his case for coaxial microincision (ie, microcoaxial) phacoemulsification; "it does not involve a learning curve," he said, adding that "it is basically identical to the surgeon's own technique, with the exception of a smaller incision" of 2 to 2.2 mm. He also advocated that torsional ultrasound in combination with microcoaxial phacoemulsification should become a new standard of cataract surgery.³ In a later article, Dr. Tjia provided an update on torsional, mentioning that 60% of all phaco machines sold worldwide in the second quarter of 2007 were Infiniti machines (Alcon), up from 50% just 2 years prior. "The 10% increase in sales is undoubtedly due to the introduction of torsional ultrasound," he wrote.⁴

In the following years, competing technologies to torsional ultrasound were introduced, including the Ellips transversal ultrasound handpiece for the WhiteStar (Abbott), a microcoaxial handpiece with longitudinal ultrasound for the Stellaris Vision Enhancement System (Bausch + Lomb), and the 1.6-mm CO-MICS phaco tip (Oertli Instrumente) intended for use with a coaxial technique.

Reporting on his results with microcoaxial phacoemulsification in 2006, Pierre Lévy, MD, asserted that one explanation for its superiority over bimanual was that "keeping the infusion sleeve around the phaco needle prevents the risk of corneal burning and allows for watertight incisions, which ensures preoperative anterior chamber stability."⁵

Whether the technique chosen was bimanual or coaxial, the obvious trend was toward microincisional surgery. "Soon, small-incision lenses that go through these microincisions will be available, and the full promise of increasingly smaller incisions will be realized," Drs. Fine, Hoffman, and Packer wrote.²

In a study conducted by Matteo Piovella, MD; Fabrizio I. Camecasca, MD; and Barbara Kusa, MD,⁶ the researchers found that surgical time with MICS was 35% longer than with traditional phacoemulsification and that, at 1 year postoperatively, the average decrease in endothelial cell count was 14.29% with MICS compared with 6.02% with standard phacoemulsification. They concluded that the "complexity of bimanual microsurgery ... is preparing surgeons for the advent of ultrathin injectable IOLs" and that "the future of cataract surgery may be a coaxial microincisional procedure."

Among his choices of the top 10 phaco innovations in September 2007, Uday Devgan, MD, FACS, listed biaxial and coaxial surgery as No. 7, stating that "surgeons have a choice between biaxial or coaxial microincisional cataract surgery."⁷ He also chose the adoption of retina-style microinstrumentation as No. 6 on his list.

The bimanual versus coaxial MICS debate continued into 2008, when Detlev R.H. Breyer, MD, noted that, despite some obvious advantages of bimanual, the procedure "has never made a break-through into the practices of most high-volume surgeons."⁸ With the CO-MICS tip, Dr. Breyer said he was able to achieve an incision size of 1.6 mm with astigmatic neutrality.

Despite this ongoing debate, however, many surgeons continued to use standard-size incisions and had not yet made the switch to any MICS technique. In his April 2008 editorial, Dr. Tjia noted that "the reality is that the majority of cataract surgeons still operate through a 3.2- to 3.6-mm incision."⁹ That, however, seemed as if it was about to change. In that same issue, Gilles Lesieur, MD, wrote that 5.2% and 18.2% of US and European surgeons, respectively, were using bimanual MICS. However, he said, 45.3% of European surgeons who did not currently practice bimanual MICS expressed interest in the procedure, 30% of whom hoped to begin in the future.¹⁰ "These data may suggest that even if surgeons are not using B-MICS, it may be due to lack of access to the technology rather than not agreeing with the concept," he wrote.

According to Dr. Chang, writing in 2009, the two major advances in ultrasound energy up to that date were the introductions of torsional phacoemulsification and the WhiteStar software (Abbott), which allowed surgeons to shorten the duration of ultrasound pulses and, in turn, increase their frequency.¹¹ "The ability to decrease the duty cycle produces a major reduction in cumulative ultrasound time," he wrote. "Alternating each ultrasonic pulse with rest periods of off-time diminishes the repelling force of the vibrating phaco tip. This in turn reduces the chatter and turbulence of small lenticular particles at the phaco tip that would otherwise bombard the corneal endothelium."

Other technologies introduced around the same time also influenced surgical outcomes. The EQ Fluidics system, six-crystal handpiece, and power modulation software of the Stellaris Vision Enhancement System (Bausch + Lomb) reduced surgical risks, including surgically induced astigmatism, according to Maria Cruz Ciprés, MD. The system "creates a lower mean power as compared with its predecessor, the Millennium," she reported.¹¹



"CRST Europe publishes myriad hot topics from experts in our field ahead of most of the other journals. A rapidly developing specialty such as ours needs a publiation like this one. I like the highlighted take-home messages."

Pavel Stodulka

Another innovation on the CataRhex SwissTech (Oertli Instrumente) allowed surgeons to switch between peristaltic and venturi pumps. The increased internal flow resistance of the machine, combined with a higher vacuum limit, "make the peristaltic pump perform similar to a venturi pump," Rupert Menapace, MD, wrote.¹¹

With all of these innovations becoming available, incision sizes continued to shrink. Comparing results in 15 eyes that had undergone coaxial MICS with a 1.8-mm incision (group 1) to 15 eyes that had undergone coaxial MICS with a 2.2-mm incision (group 2), Leonardo Mastropasqua, MD, and Lisa Toto, MD, found minimal surgically induced astigmatism in both groups at 3 months (0.15 D in group 1 and 0.06 D in group 2).¹² Although more edema was present on postoperative day 1 in group 1, all corneal edema had disappeared by day 30. "In our study, two incision sizes showed low amounts of surgically induced astigmatism, thus demonstrating that for slightly over or sub-2-mm

incisions, induction of astigmatism is negligible," they wrote in the November/December 2009 issue.

In the following years, MICS became common practice, and surgeons offered tips and tricks rather than support or criticism of one or another technique. "MICS has become a reality for an increasing number of surgeons," Jean-Luc Febbraro, MD, wrote in the May 2011 issue.¹³ Furthermore, "MICS does not have to be reserved for standard cataract cases but can be used for complicated cases as well," Alexandre Denoyer wrote in the February 2011 issue. "The improved control of fluidics, which leads to excellent anterior chamber stability, combined with the thinness of the [phaco] tip and cannulas, makes MICS the first-choice technique."¹⁴

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- PRESBYOPIA SOLUTIONS

In his editorial in the January/February 2007 issue, Dr. Daya laid out the state of the art in surgical presbyopia correction: "effective commercial solutions [to presbyopia] are lens-based and of the variety that require a lensectomy." At that time, ablative methods including presbyopic LASIK (presby-LASIK) and corneal implants were investigative, and multifocal and accommodating IOLs and monovision were not yet part of mainstream practice.¹ Since then, however, surgeons have witnessed a surge in available presbyopia-correcting technologies. With that said, all of the solutions available today continue to require some kind of compromise.

Corneal inlays. Regarding the investigation of corneal implants in those earlier days, Richard L. Lindstrom, MD, said that initial data for the AcuFocus inlay (now Kamra; AcuFocus) was impressive at 1 year postoperative, with a typical visual outcome of 20/20 intermediate, J1 near vision, and minimal distance vision loss.² At that time, in January 2007, concerns included delayed visual recovery after the procedure, the potential for mild halos if the pupil dilated beyond the outside diameter of the device, loss of contrast sensitivity with unilateral implantation, and improper function if the inlay was significantly decentered. "Still, of all the devices I have seen, I am most impressed by the outcomes that the AcuFocus intracorneal lens has generated," Dr. Lindstrom wrote. "I believe that this technology has the potential opportunity to rival myopic LASIK."

By January 2009, the thickness of the Kamra had gone from 10 to 5 μ m, and surgeons including Günther Grabner, MD, were reporting that the lens performed the same as the previous generation. "At 3 months, all patients had 20/20 and J2 distance and near UCVA, respectively," he wrote.³ By November/December 2011, "stability has been demonstrated up to 5 years after implantation," George O. Waring IV, MD, wrote.⁴

Minoru Tomita, MD, who has the most experience with the Kamra worldwide, described his use of the inlay in combination with LASIK. At first, the inlay was placed on the corneal bed, under the LASIK flap,⁵ but later it was placed inside a corneal pocket, created at least 200 μ m deep in the cornea and at 100 μ m from the LASIK interface. "We have learned that ... patients experience fewer dry eye symptoms ... which may be

due to fewer peripheral corneal nerves being altered during pocket creation," he wrote. On average, patients achieved J2 near UCVA and maintained a mean 20/20 distance UCVA.

Finally, 10 years after the Kamra received the CE Mark in Europe, it received US FDA approval in April 2015. Although most US surgeons were ecstatic, some experienced concern over the explantation rate. In an article in our July/August 2015 issue, Dr. Tomita explained that most explantations occurred earlier in the history of the inlay, before lamellar pocket implantation was adopted. "I have implanted about 9,000 corneal inlays with the corneal pocket technique, and my overall explantation rate is somewhere between 1% and 2% within 3 years of implantation," he wrote.⁶

Another corneal inlay, the Flexivue (Presbia), using a smart monovision technique, was the first to be implanted via a tunnel created inside the corneal stroma, from the temporal to the midnasal periphery.⁷ "We are studying the visual outcomes and safety of the Flexivue ... using a femtosecond laser for tunnel creation," Dimitrios I. Bouzoukis, MD; Alice Limnopoulou, MD; Ioannis G. Pallikaris, MD, PhD; and Sophia I. Panagopoulou, PhD, wrote. "Our initial reaction is that this combination maximizes precision and customization."

Now known as the Raindrop (ReVision Optics), the PresbyLens, also called the Vue+ corneal inlay for a short time, surfaced in subsequent years. "The ReVision Optics intrastromal corneal inlay seems to have solved the problem of using a hydrogel device to produce consistently good visual results without inducing undue corneal reaction," Enrique Barragan, MD, reported in the November/December 2011 issue.⁸ Later, in our October 2014 issue, Dr. Barragan and Arturo S. Chayet, MD, provided interim 9-month results for 23 patients who received the Raindrop inlay. Bilateral implantation had provided patients with about a 1-line increase in near UCVA over the results with unilateral implantation over preoperative measurements, with more than 80% achieving 20/20 or better binocular UCVA at all distances and follow-ups.⁹

Lens-based correction. Discussing lens-based presbyopiacorrection methods in the January/February 2007 issue, Pascal Rozot, MD, shared that his use of multifocal IOLs for presbyopia correction had risen from 5% to 7% in 2002 to 15% to 20% in 2007. "It remains mandatory to carefully select the patient with a precise and complete ophthalmologic examination, and to eliminate any uncertain case, especially when beginning multifocal [IOL] use," he wrote.¹⁰ Surgeons participating in a roundtable discussion on IOLs published in the May 2007 issue also shared the percentages of patients in whom they implanted presbyopia-correcting IOLs: 15% to 20% for Dr. Chang; 20% to 25% for Samuel Masket, MD; 10% for J.E. "Jay" McDonald II, MD; 22% for Frank Bucci, MD; and 25% to 30% for R. Bruce Wallace III, MD.¹¹

Fast forward to 2010, when Francesco Carones, MD, shared the following statistic: "Most patients who seek treatment ... will walk out with a presbyopia-correcting IOL—approximately 90%, to be more exact. ... My first and foremost target is patient satisfaction, and I believe that the multifocal IOL achieves this



"CRST Europe continues to be one of the leading magazines, and now its online portals have become useful to ophthalmologists across the globe—be it beginner surgeons or experts in their field.

What I like about *CRST Europe* is that it always features innovative and varying themes in the field of cataract and refractive surgery. Being a focused magazine, the reader will generally find all the latest updates and opinions of experts on the featured topic. What I also like about *CRST Europe* is the catchy titles, editorials, and visuals found throughout each issue. The blend of practice, science, and industrydriven content is something that comes across as unique. In a nutshell, I think *CRST Europe* always comes up with the latest in cataract and refractive surgery, packaged in a crisp, concise, appealing, and easy-to-read format."

Abhay R. Vasavada MS, FRCS

target in patients who do not have unnecessarily high demands and who are willing to use spectacles in certain circumstances, such as night driving and reading in dim light."¹²

In 2008, *CRST Europe* contributors started talking about the Light Adjustable Lens (LAL; Calhoun Vision), yet another potentially presbyopia-correcting strategy. Drs. Fine, Hoffman, and Packer wrote: "If this technology can be advanced to sequential adjustability and combined with other technologies, it would dramatically advance the state of [refractive lens exchange]."¹³ *CRST Europe* later interviewed D. Verne Sharma, then CEO and president of Calhoun Vision, who stated that the site with the most commercial experience with his company's lens, the Ruhr Valley Center for Vision Science, had implanted close to 300 eyes with the LAL.¹⁴ At 1 year postoperative, 86% of patients (n=110) achieved 20/20 or better distance UCVA. "That is a phenomenal result, more reminiscent of LASIK than any other kind of IOL," Mr. Sharma said in the interview.

In January 2015, Richard Packard, MD, DO, FRCS, FRCOphth, reported that, after a recent change in the LAL design, the adjustable part of the optic was now a 100-µm posterior layer. "The aim of this and other changes was to decrease the number of postoperative adjustment procedures needed and alleviate the necessity for UV protection," he wrote. "Published results to date are impressive, with achieved correction of up to 2.25 D of sphere and 2.75 D of cylinder."¹⁵ Other modifiable IOL technologies under development at that time included the Precisight (Infinite Vision Optics), the Harmoni Lens (Clarvista Medical), the Acri.Tec AR1, and the Sapphire AutoFocal IOL (Elenza), he said. Extended depth of focus IOLs may just now be coming to the fore, but *CRST Europe* first reported on this concept in our January 2009 issue. At the time, Xceed Imaging was developing the Extended Depth of Focus (EDOF) Technique, an adjunctive technology for use with spectacles, contacts, and IOLs.¹⁶ "Lenses embedded with EDOF technology enable simultaneous high-contrast images of near, intermediate, and distant objects—regardless of astigmatism and with no loss of visual field," Zeev Zalevsky, PhD; Shai Ben Yaish, BSc; Alex Zlotnik, MSc; Ido Raveh, MSc; Oren Yeuezlek, MSc; Karen Lahav-Yacouel, MA; and Michael Belkin, MD, wrote. "Furthermore, the axially continuous-focused image does not have a set of discrete focusing planes, preserving light energy and preventing chromatic aberration."

Testing the EDOF Technique in an IOL with the EDOF profile engraved on its surface, the authors noted a focal depth extension of more than 2.50 D, less glare effect than diffractive multifocal IOLs at 30 cm and at infinity, and better performance at 60 cm and 2.5 m. The lens also functioned well with decentrations of up to 0.5 mm and tilt of up to 10°.

Throughout the years, lens-based options for presbyopia correction have continued to evolve. In our July/August 2013 issue, Francesc Duch, MD, offered the following advice: "Let time and experience redefine your indications for presbyopia-correcting IOL designs."¹⁷ In that same issue, Gerd U. Auffarth, MD, PhD, commented: "With the availability of more presbyopic IOL designs, surgeons should be aware of the performance characteristics of different lens features in order to truly customize lens selection for each patient."¹⁸

Professor Auffarth also provided *CRST Europe* readers with an overview on European trends in multifocal lens use from 2013 to 2015. "In order to discuss the current status of multifocal IOL use and the correction of presbyopia in Europe, we must first consider how the needs and demands of our patients have changed in recent years," he wrote, adding that, over the years, patients have come to learn that their near and intermediate visual needs can be addressed at the time of cataract surgery.¹⁹ "The current trend is to emphasize intermediate vision, with the use of low adds or a trifocal optical approach."

Based on his analysis of German surgeons' practices, the percentage of premium lens implantations in relation to total IOL implantations in 2013 was just more than 5%; the same trend could be extrapolated to the European market in general, he said. "Although usage of multifocal IOLs is increasing, there are competing technologies that can be said to cannibalize the presbyopia-correction market," he said.

Laser treatments. By 2009, several laser-based procedures aimed at presbyopia correction had surfaced. One of these, laser blended vision, introduced by Dan Z. Reinstein, MD, MA(Cantab), FRCSC, DABO, FRCOphth, was described in our January issue that year.²⁰ Dr. Reinstein shared the basic principles of the treatment: a combination of nonlinear aspheric profiles and micro-monovision. With laser blended vision, the targets in the dominant and nondominant eyes are plano and



"CRST Europe always provides a comprehensive overview of new technologies and their economic impacts on our practices. The pros and cons included on such topics provide a wider view than what is included in other journals."

Paolo Vinciguerra MD

slight myopia, respectively, so that the dominant eye provides distance and intermediate vision and the nondominant near and intermediate. "The increase in depth of field is such that the ranges of clear vision achieved by the distance and near eyes overlap at intermediate distances, unlike the traditional monovision approach in which there is a gap in the range of clear vision," Dr. Reinstein wrote. "The major advantage of laser blended vision is the creation of an intermediate and farintermediate distance zone of fusion—allowing the brain to merge images from each eye."

In our April 2010 issue, Patrick Versace, MD, shared that Dr. Reinstein's outcome data showed patient acceptance in greater than 90% of patients.²¹ That data also showed that all patients treated with laser blended vision achieved distance UCVA of better than 20/30, that 95% had distance UCVA better than 20/20, and that 94% of myopic patients achieved binocular vision of 20/20 at distance and J2 at near. "Presby-LASIK treatments using laser blended vision open the possibility of incorporating presbyopia correction into our refractive procedures," Dr. Versace wrote. "The expanded depth of focus it provides makes this a preferable option compared with traditional monovision."

Second-generation presby-LASIK treatments also emerged, such as PresbyMax, a multifocal ablation profile for the Amaris excimer laser (Schwind eye-tech-solutions) designed to provide a near vision add of 1.75 to 3.00 D according to the predicted outcomes for distance and near. "Multifocality, created with biaspheric ablation profiles based on optimized mathematic curves, provides adequate transitions between far and near," David P. Pinero, PhD; and Jorge L. Alió, MD, PhD wrote in the January/February 2009 issue.²² "It is an excellent option for the compensation of initial and intermediate presbyopia in patients with spherical equivalent between 4.00 and -4.00 D."

Although success with the Intracor treatment (Bausch + Lomb) was fleeting, a second-generation treatment, Supracor, seemed to achieve better results. In the July/August 2012 issue, Dr. Mertens wrote that Supracor was his preferred corneal treatment for presbyopia. He explained that it "is an aberration-optimized presbyopic algorithm designed for application in myopic, hyperopic, emmetropic eyes, or post-LASIK eyes."²³ In our October 2013 issue, Robert Edward Ang, MD, shared his experience with the procedure: "When I adopted Supracor, I found that it gave

patients stronger near vision than the [corneal] inlay. Most patients had a near UCVA of J1 postoperatively."²⁴

In 2016, after having amassed 3 years of experience with Supracor and analyzing follow-up through 2 years in myopic and hyperopic presbyopes, Dr. Ang reported that mean manifest refraction spherical equivalent (MRSE) in these groups, respectively, was -0.58 and -0.75 D, distance UCVA was 20/25 and 20/40, intermediate UCVA was 20/20 and 20/25, and near UCVA was J1 and J1. In both groups, mean binocular UCVA was 20/25 for distance and intermediate and J2 for near.²⁵

Another less-studied laser-based method of presbyopia correction is lens softening. In the July/August 2014 issue, Raquel Gil-Cazorla, MSc, PhD, FAAO, FBCLA, FIACLE; Shehzad Naroo, MSc, PhD, FCOptom, FAAO, FBCLA, FIACLE, FEAOO; Harvey Uy, MD; and Sunil Shah, MBBS, FRCOphth, FRCS(Ed), FBCLA, described the procedure. During lens softening treatment, a femtosecond laser makes precise incision patterns within the crystalline lens in order to restore its flexibility. "These incisions create physical sliding planes and soften the lens without opening the capsule," they wrote. "The use of targeted lenticular photodisruption may permit translation of forces exerted by the zonular fibers, resulting in changes in lens shape during accommodating."²⁶ They described the case of a 50-year-old man who experienced significant improvement in median values for near UCVA and for distance-corrected near visual acuity (DCNVA) at 1 month after treatment, improving from 12 to 27 letters and from 53 to 58 letters, respectively.

Two years later, David Smadja, MD, reported results from a preliminary study of the lens softening procedure conducted by Dr. Uy. After treatment, 60 patients who were treated unilaterally had the option to proceed with refractive cataract surgery or to delay lens extraction. Those who decided to delay were followed for 36 months. At 1 month after treatment, objective accommodation had improved in 19.2% of patients, with a mean gain of 0.76 \pm 0.42 D, and subjective accommodation response to the pushdown method was seen in 55.6%, with a mean gain of 0.72 \pm 0.68 D. "It is likely that, in the near future, with the optimization of cutting patterns and laser parameters, we will see laser restoration of accommodation becoming a mainstay treatment for presbyopia."²⁷

Just this year, in our September 2016 issue, Adrian Glasser, PhD; Dr. Shah; and Dr. Uy reported on further study of the procedure.²⁸ In 37 eyes of 37 patients, 33% of patients had improvement in objective accommodation at 1 week postoperatively, 53% showed improved subjective accommodation, and 37.3% had improved DCNVA at 1 week and 40.8% at 1 month, with a 31-letter mean improvement at the latter time point. "Femtosecond laser treatment of the presbyopic lens offers a promising, noninvasive approach to reduce lens stiffness, restore accommodation, and improve DCNVA," they concluded.

Tissue addition. Earlier this year, David Muller, PhD, announced a new kind of presbyopia correction procedure: the shaping and placement of natural corneal tissue allografts on the cornea. According to Mr. Muller, TransForm allogenic tissue can be used as an inlay or an onlay. The inlay would be optically comparable to synthetic corneal inlays such as those described in the outset of the *Presbyopia Solutions* section. "[The inlays] provide great flexibility on optical zone size, can be placed at any depth that is advantageous for getting the proper shape response, and, if they are removed, it is no different than removing native tissue," *Mr.* Muller said.²⁹

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