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CLEAR - Lenticule Extraction

Experience, reviews, and visual outcomes

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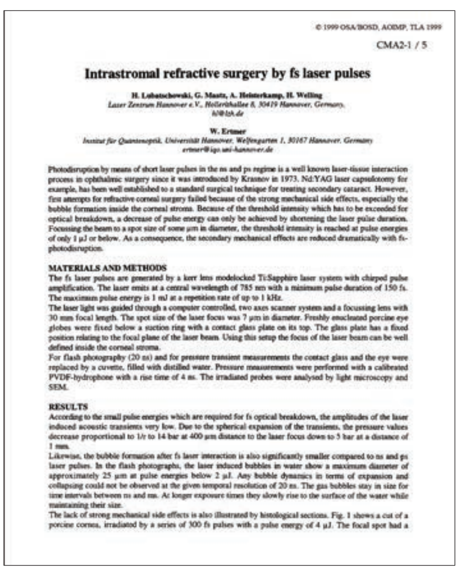
A Brief History of Low-Energy Lasers and Lenticules

Ziemer is the pioneer in low-energy femtosecond lasers.

BY HOLGER LUBATSCHOWSKI, PHD

Refractive surgery has a rich history. In 1975, Krasnov introduced the concept of photodisruption of ocular tissue with short laser pulses in the nanosecond and picosecond range.[1] The energy required for the laser pulses at the time, however, led to mechanical side effects, mainly bubble formation, which prevented successful completion of the procedure. Over time, incremental improvements in laser technology, especially in the shortening of pulse durations to femtoseconds made it possible to overcome the obstacle of high pulse energy, making refractive corneal surgery a reality.

Today, femtosecond laser systems are routinely used to perform lens and corneal-based procedures, including lenticule extraction. I have been involved with the development of lenticule extraction since the early days of the technique and have published extensively on the topic of lenticule extraction with a low energy laser system.[2-4] This article describes the multiple advantages of low energy and provides a brief history of lenticules.



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Intrastromal refractive surgery by fs laser pulses

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Photodisruption by means of short laser pulses in the ns and ps regime is a well known laser-tissue interaction process in ophthalmic surgery since it was introduced by Krasnov in 1973. Nd:YAG laser capsulotomy for example, has been well established to a standard surgical technique for treating secondary cataract. However, first attempts for refractive corneal surgery failed because of the strong mechanical side effects, especially the bubble formation inside the corneal stroma. Because of the threshold intensity which has to be exceeded for optical breakdown, a decrease of pulse energy can only be achieved by shortening the laser pulse duration. Focussing the beam to a spot size of some µm in diameter, the threshold intensity is reached at pulse energies of only 1 µJ or below. As a consequence, the secondary mechanical effects are reduced dramatically with fs-photodisruption.

MATERIALS AND METHODS

The fs laser pulses are generated by a kerr lens modelocked Ti:Sapphire laser system with chirped pulse amplification. The laser emits at a central wavelength of 785 nm with a minimum pulse duration of 150 fs. The maximum pulse energy is 1 mJ at a repetition rate of up to 1 kHz.

The laser light was guided through a computer controlled, two axes scanner system and a focussing lens with 30 mm focal length. The spot size of the laser focus was 7 µm in diameter. Freshly enucleated porcine eye globes were fixed below a suction ring with a contact glass plate on its top. The glass plate has a fixed position relating to the focal plane of the laser beam. Using this setup the focus of the laser beam can be well defined inside the corneal stroma.

For flash photography (20 ns) and for pressure transient measurements the contact glass and the eye were replaced by a cuvette, filled with distilled water. Pressure measurements were performed with a calibrated PVDF-hydrophone with a rise time of 4 ns. The irradiated probes were analysed by light microscopy and SEM.

RESULTS

According to the small pulse energies which are required for fs optical breakdown, the amplitudes of the laser induced acoustic transients very low. Due to the spherical expansion of the transients, the pressure values decrease proportional to 1/r to 14 bar at 400 µm distance to the laser focus down to 5 bar at a distance of 1 mm.

Likewise, the bubble formation after fs laser interaction is also significantly smaller compared to ns and ps laser pulses. In the flash photographs, the laser induced bubbles in water show a maximum diameter of approximately 25 µm at pulse energies below 2 µJ. Any bubble dynamics in terms of expansion and collapsing could not be observed at the given temporal resolution of 20 ns. The gas bubbles stay in size for time intervals between ns and ms. At longer exposure times they slowly rise to the surface of the water while maintaining their size.

The lack of strong mechanical side effects is also illustrated by histological sections. Fig. 1 shows a cut of a porcine cornea, irradiated by a series of 300 fs pulses with a pulse energy of 4 µJ. The focal spot had a

Figure 1. Professor Lubatschowski's first publication on intrastromal refractive surgery and lenticule extraction in 1999.[2]

BACKGROUND

Just before the turn of the millennium, in 1998, our group began to experiment with intrastromal refractive surgery and the idea of lenticule extraction (Figures 1 and 2). I remember being inspired by the early work of Kurtz and Juhasz, who in 1997 showed that femtosecond lasers could be used to cut tissue below the cornea much more precisely than picosecond lasers.[5] Their work was so exciting because many of us were looking for alternatives to ablation with excimer lasers. Some colleagues tried to use the erbium laser for ablation, which was cheaper and smaller, but the results were not as good as what excimer lasers could produce. The need for better procedures in refractive surgery was clear.

Their idea to use ultrashort pulses to cut tissue below the surface was literally disruptive and at the same time right under our noses—for some time, femtosecond lasers were used in our laboratories to process glasses. It did not take long for the ophthalmic industry to recognize the advantages of intrastromal refractive surgery, and several manufacturers began to develop femtosecond lasers that could be used to perform refractive procedures below the corneal surface. The first generation lasers used a comparatively high pulse energy to generate the cutting process.

Several of my colleagues and I saw it as a scientific challenge to take the concept of intrastromal disruption that was established in the literature and optimize the process. We knew that extremely short pulse duration and focal volume (ie, spot size) could still produce very high intensities with the application of low energy only, and we postulated that it could be used to create a lenticule that could achieve refractive correction.

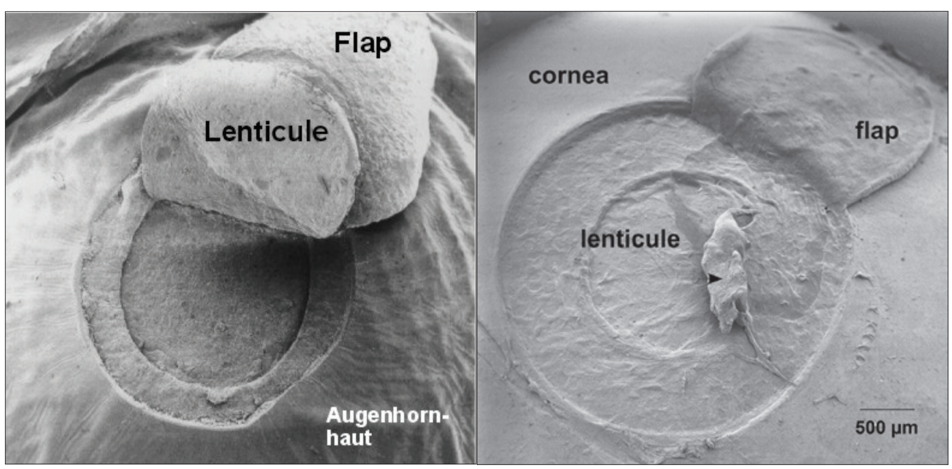

Figure 2. Scanning electron microscopy of one of the first flaps and lenticules created in a pig eye at 1.2 µJ pulse energy (1998).

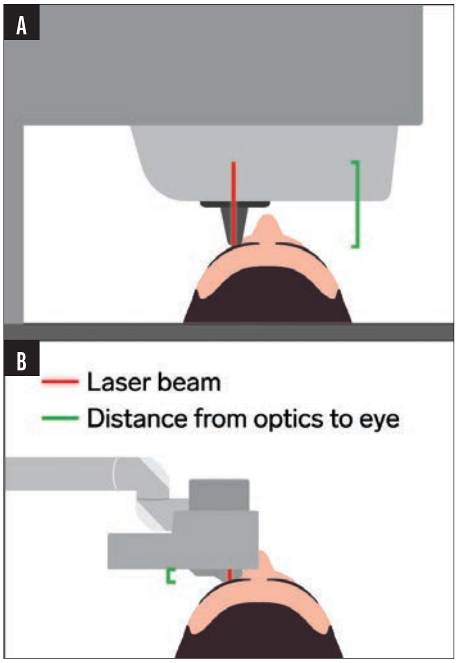

Figure 3. Conventional femtosecond lasers without a handpiece (A) have a long working distance to the eye whereas the small handpiece of Ziemer works from a short distance (B).

In 1999, we presented our concept for low-energy intrastromal refractive surgery at several conferences and wrote and published many studies. The first peer-reviewed paper was published in *Graefes Archive for Clinical and Experimental Ophthalmology* in 2000.[4] Thereafter, we partnered with Ziemer in the development of a laser system that could separate tissue with the lowest amount of pulse energy not reached by any other laser system. This was possible due to a handpiece design from Ziemer with specially developed microscope optics with a very short focal distance (Figure 3).

INTRODUCTION OF THE FEMTO LDV

In 2005, the FEMTO LDV (Ziemer) became commercially available. This device was smaller than other femtosecond lasers, and it had a lower pulse energy and higher repetition rate, which has many advantages over higher pulse energy femtosecond lasers. Higher pulse energy causes unwanted mechanical side effects like tissue rupture, cavitation, shockwaves, and bubble formation that can lead to opaque bubble layers in the stromal tissue. Lower pulse energy, on the other hand, helps to protect the adjacent ocular tissue and produces higher precision. Last but not least, low-energy pulses can also be generated using a much more compact and robust laser system that promises true mobility.

Because the cutting process with a low pulse energy laser is naturally slower than lasers that use high pulse energy, an increase in the repetition rate is required to achieve a similar cutting rate. The current FEMTO LDV Z8 platforms operate with a repetition rate of up to 20 MHz. Further, the small spot size and overlapping spots delivered with the Ziemer laser produce complete tissue dissection and eliminate tissue bridges. The FEMTO LDV is therefore, by design, the most precise laser for cutting cornea. As a result, new applications with higher precision requirements—such as the creation of lenticules—can be easily installed via software. No hardware modification is required.

The FEMTO LDV is designed with a flat patient interface for most corneal surgeries. Combined with a controlled vacuum system, this provides maximum precision and control over the patient's eye. Suction loss is therefore not an issue.

THE INTRODUCTION OF LENTICULE EXTRACTION

LASIK is a well-established procedure. The ablation is extremely precise—it is one-quarter of a micrometer per pulse—and the way in which ocular tissue reacts to an excimer laser ablation is well known. A flapless, intrastromal refractive procedure such as lenticule extraction, however, is attractive to surgeons and patients alike because it avoids some of the challenges associated with LASIK, including flap-related complications and the risk for dry eye disease postoperatively.

The lenticule extraction procedure only requires a small keyhole incision through which the lenticule can be removed. The lenticule extraction application is available as a software upgrade to the FEMTO LDV Z8 and FEMTO Z8 NEO, both of which can also be used to perform cataract surgery, LASIK, tunnels for rings, pockets for inlays, and keratoplasty procedures.

CONCLUSION

Lenticule extraction is an exciting evolution in the history of refractive surgery. The procedure is currently indicated for myopic correction, and future applications are in development.

The future of femtosecond laser applications in ophthalmology is low energy, and Ziemer is blazing the trail. ■

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Clinical Impressions After 3 Years of Experience With CLEAR

The procedure effectively expands the indications for vision correction surgery.

BY LUIS IZQUIERDO JR, MD, PHD

Low-energy laser treatments have many advantages. They maximize precision, minimize tissue damage and the inflammatory response, and aid in fast visual recovery. Corneal lenticule extraction for advanced refractive correction (CLEAR) can be performed with two low-energy laser platforms, the FEMTO LDV Z8 and FEMTO Z8 NEO (both by Ziemer).

I started performing CLEAR more than 3 years ago and continue to be impressed with the results my patients have achieved at every stage of the laser's development. This article recaps how and why the indications for the CLEAR procedure have expanded over the years and discusses a new bioptics treatment option that combines lenticule extraction with implantation of a phakic IOL.

EXPANDING INDICATIONS

Early in the lenticule extraction procedure's lifecycle, many surgeons—myself included—positioned the procedure as an option mainly for patients who were contraindicated for other refractive surgery procedures, such as those with high myopia or a thin cornea. Very quickly, however, we started to realize it was advantageous in a larger group of patients other than those in whom we wanted to avoid removing too much corneal tissue.

My very first CLEAR procedure was performed in April 2019. The patient, a 27-year-old man, presented with myopia and blurred vision. There were no significant findings at the slit lamp and no personal history of relevance. The refraction was -5.00 -0.50 x 180º OD. After counseling, the patient decided to undergo CLEAR. On postoperative day 1, UDVA was 20/40 and CDVA was 20/30. At 3 months postoperative, the patient achieved a UDVA of 20/20 and CDVA of 20/20. At his last follow-up, which was at 3 years, the patient's refraction was stable. He is still very happy with his vision.

Today, my indications for CLEAR have expanded to include patients with higher levels of myopia (-8.00 to -10.00 D) and for patients with astigmatism.

GREAT RESULTS FOR SURGEONS OF ALL EXPERIENCE LEVELS

One of the trickiest parts of performing lenticule extraction is determining if you are in the correct corneal plane. It can be challenging to differentiate between the anterior and posterior surfaces of the cornea.

Compared to other lenticule extraction procedures, both Z8 laser systems can be programmed to create two guiding tunnels, one for the anterior surface and another for the posterior surface of the lenticule, for easy lenticule separation. In other words, the surgeon can program the laser to create two incisions, which is helpful early in the learning curve, or one incision, which surgeons can progress to after gaining experience with and increasing their comfort in the procedure.

The use of two guiding tunnels is preferable in my clinic because we are a teaching institution, and oftentimes our fellows and residents are either observing or assisting in surgery. It is a great way for them to learn CLEAR in a safe and effective way.

A NEW APPROACH TO BIOPTICS

The promising experience I have had with CLEAR over the years has led me to new and exciting treatment possibilities. One of them is combining CLEAR with phakic IOL implantation in a bioptics procedure. Bioptics can be used to address refractive error by combining the use of corneal and lenticular techniques. I believe that it is more precise to correct the cylinder on the cornea versus the lens, and therefore I favor bioptics procedures to the implantation of toric phakic IOLs.

In the past, I performed bioptics by first using LASIK to address the astigmatism and, about 1 month later, implanting a phakic IOL to address the refractive error. Now, however, I perform CLEAR before I implant the phakic IOL. The advantage of using CLEAR instead of LASIK is that it avoids the need for

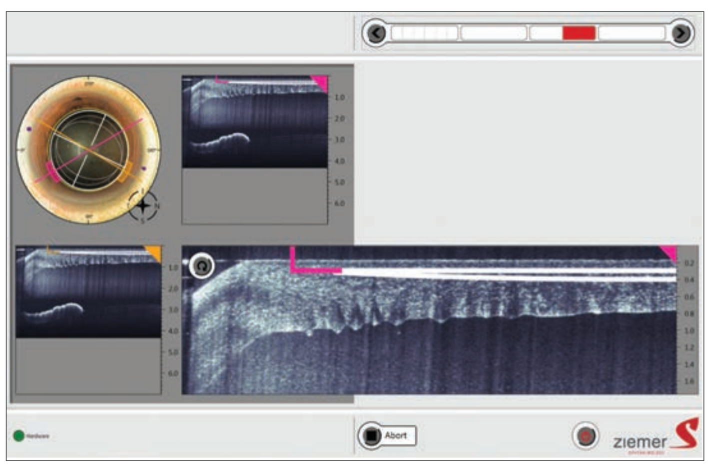

Figure 1. Example of a planned CLEAR/phakic IOL bioptics procedure.

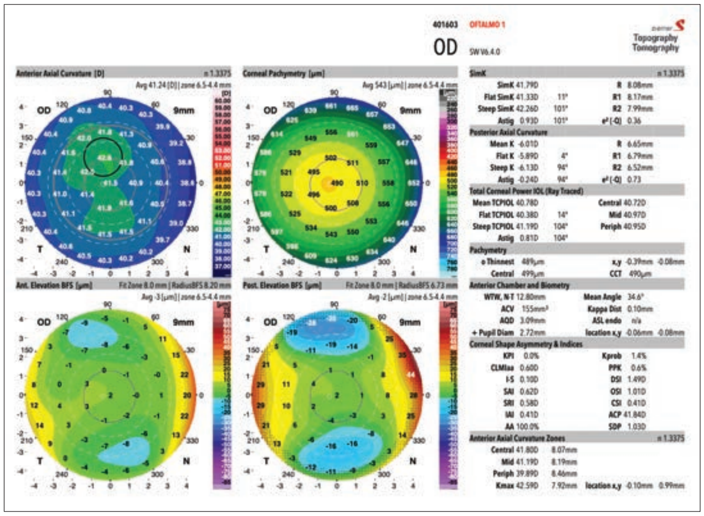

Figure 2. Preoperative corneal topography/tomography (GALILEI).

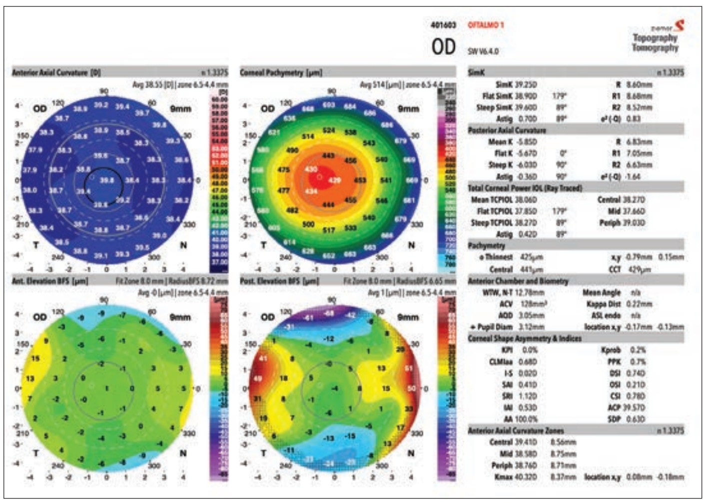

Figure 3. Postoperative corneal topography/tomography (GALILEI).

a corneal flap and therefore the risk of flap dislocation during phakic IOL implantation.

CLEAR and phakic IOL implantation are currently staged about 1 month apart, but eventually the hope is that phakic IOL implantation can be performed immediately after the CLEAR procedure. Additionally, it is to be hoped that the combined CLEAR/phakic IOL bioptics procedure can be indicated not for only phakic eyes but also for aphakic eyes.

Figure 4. FEMTO Z8 NEO and FEMTO LDV Z8.

This is a new concept in bioptics, and at the time this article was written, I had only performed the procedure in five patients. Thus far, however, results have been great and patients are happy with their visual recovery and the quality of their vision (Figures 1-3).

A VERSATILE LASER PLATFORM

I am a cornea surgeon by nature, and to me the FEMTO LDV Z8 and FEMTO Z8 NEO (Figure 4) are fantastic laser platforms because they are so versatile. In addition to CLEAR, I can use either platform to create pockets for intrastromal corneal ring segments and allograft corneal inlays for keratoconus, as well as for corneal transplants.

The intraoperative OCT function is also a useful tool, not only for corneal surgery but also for cataract surgery. I use the Z8 every day for both standard procedures and the new bioptics procedures because it is not only precise but it supports a faster visual recovery and minimal tissue damage and inflammatory response. There is no other laser system that can do what the Z8 platforms can do. ■

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The CLEAR Advantage for Corneal Aberrations

The CLEAR lenticule extraction procedure does not create a significant increase in spherical aberration postoperatively.

BY JODHBIR S. MEHTA, BSC (HONS), MBBS, PHD, FRCOPHTH, FRCS(ED), FAMS

Refractive surgery is booming. This is, in part, due to the negative effects of COVID-19 such as mask wear and increased computer use from working from home. In short, patients are motivated to improve their quality of life and now have the financial means to make their desires a reality. There is no doubt that refractive surgery is life-changing. It provides patients with the opportunity to achieve spectacle independence and a better quality of vision than they've ever experienced. With that said, it is important to understand the nuances of each procedure so that the right decision is made for every patient.

I have extensive experience with many refractive surgery procedures, including LASIK, PRK, phakic IOLs, and lenticule extraction. All have their place depending on patients' needs and ocular anatomy, and we shouldn't discredit one procedure over the other.

One important consideration when selecting the right procedure for patients is postoperative spherical aberration. The literature has shown that flap-based procedures are associated with an increase in corneal aberrations after surgery.[1,2] Testing with low-contrast charts and with dilated pupils indicates that the overall image quality can degrade in response to the increased aberrations in the optical system.[3,4] Corneal aberrations do not, however, describe the overall optical quality of the eye. This is for several reasons. First, the optical changes that are induced by refractive surgery occur on the cornea. Second, other parameters including lens position, lens thickness, the refractive index, axial length, and pupil centration are integral components of image formation. Nevertheless, the presence of excessive spherical aberration, for some patients, can lead to poor visual performance.

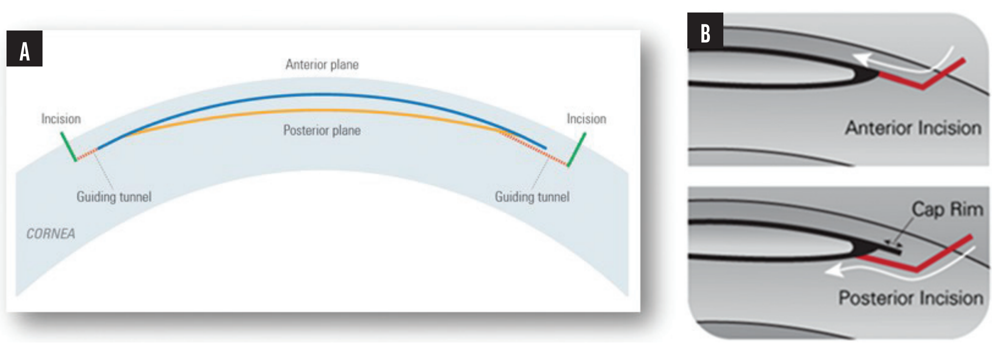

Figure. Schematics of the guiding tunnels to the anterior and posterior surfaces (A, B).

SPHERICAL ABERRATIONS

Lenticule extraction procedures induce only a minimal increase in spherical aberrations after surgery.[5] So far what we have found with Corneal Lenticule Extraction for Advanced Refractive Correction (CLEAR) using the FEMTO LDV Z8 (Ziemer) is that there has been little change in the spherical aberration. More importantly, there has been minimal induction or change in vertical coma after surgery, which can result when the treatment is incorrectly centered on the visual axis. In my experience, it is easier to accomplish treatment centration with CLEAR. This device allows me to place the creation of the lenticule directly on the visual axis or the central corneal light reflex rather than on the center of the pupil, which is routine with other lasers.

Centration of the CLEAR treatment is simple. It is performed after the patient interface of the Z8 is docked. The lenticule is automatically centered, but it can be adjusted if needed. Perfect centration results in a smaller risk for the induction of vertical coma. Furthermore, the lenticule is rotated automatically, according to the marking of the horizontal axis, for cyclotorsion control. There is no risk of suction loss.

The ability to rotate the lenticule to achieve adequate torsional control gives me more confidence in the CLEAR procedure. The Z8 automatically detects the corneal markings. In the very near future, the centration and rotation will be automated with a link to the GALILEI (Ziemer) diagnostic system.

CLEAR ADVANTAGES

Lenticule extraction procedures require a very different skill set to LASIK. Surgeons must recognize the shape and the demarcation line of the lenticule, they must understand whether they are above or below the lenticule, and of course they must learn how to perform surgery through a keyhole incision. The CLEAR procedure boasts several advantages over other lenticule extraction procedures.

Guiding tunnels. One advantage of the CLEAR procedure is that two small tunnels can be created to guide the instruments into the correct lenticule plane. As an extended part of the incisions, one tunnel guides you to the anterior surface, and the other tunnel guides you to the posterior surface (Figure). The tunnel size can be customized to as small as 1.5 mm, and the position of the tunnel can be customized depending on the surgeon's hand dominance. I typically create the first guiding tunnel at about the 11 o'clock position and the second at about the 1 or 2 o'clock position. The use of guiding tunnels also decreases the intrastromal manipulations and therefore reduces the amount of inflammation in the eye.

The use of two tunnels compared to one can also shorten the learning curve. I find that I no longer need to create two tunnels due to my level of experience with CLEAR; however, my colleagues sometimes still create two tunnels because the second acts as a safety net in case they run into problems during surgery.

Intraoperative OCT shows the positioning of the guiding tunnels in relation to the lenticule creation.

Less risk for formation of an opaque bubble layer. The venting tunnels of the CLEAR trajectory are created in such a way that gas can escape during the creation of the lenticule. This reduces the risk for an opaque bubble layer (OBL) to form. OBL can affect the dissection and therefore refractive outcome as well.[6]

A thinner lenticule. The shape of the CLEAR lenticule is slightly thinner at the edge compared to the lenticules that are created by other laser platforms. Because there is no sidecut, it is easy to navigate into the posterior plane to complete the dissection. If there is any problem, the guiding tunnels can be useful to determine which plane you are in.

Ease of centration. Centering the lenticule with the Z8 is easy. The eye is marked at 0º and 180º on the horizontal axis, followed by the center of the corneal light reflex. The latter is determined by where the patient fixates at the slit lamp.

I also check angle kappa with the Orbscan (Bausch + Lomb). If the angle kappa is large, the lenticule is decentered about 300 µm away from the center of the pupil toward the angle kappa intercept. If it is small, then the lenticule is centered on the visual axis.

After centration, cyclotorsion control is performed by automatically rotating the lenticule into position. The Z8's software has a built-in feature to warn the surgeon if the lenticule is decentered or too close to the applanation zone.

In the near future, an exciting development should be available—automated centration and cyclotorsion. This will be achieved by linking the Z8 femtosecond laser to the GALILEI diagnostic system (Ziemer), allowing full automation of two of the key steps of the CLEAR procedure.

SURGERY ON A COLLEAGUE

In my early experience with CLEAR, the results have been encouraging. Here, I share one example of a case in which CLEAR was the best choice for my patient. It also highlights benefits of the CLEAR procedure in terms of inducing minimal spherical aberration and vertical coma.

In one of our ongoing clinical studies, one of my staff members participated in the study and is thrilled with her results in the CLEAR eye. She had moderate myopia and large eyes and presented with dry eye disease. She was prescribed omega-3 fatty acids, lubricants, and topical cyclosporine for 6 weeks before surgery. She also received punctal plugs to optimize the ocular surface before surgery. For any lenticule extraction procedure, it is crucial to make sure the cornea is well hydrated before surgery. Surgery was uncomplicated. At 3 months postoperative, her UDVA was 20/20+ OU. (To read the patient's perspective, see the article on page 8.)

CONCLUSION

CLEAR has many advantages over other lenticule extraction procedures. For those who are just starting with the procedure, the use of two guiding tunnels to help ensure the instruments are in the correct plane is helpful, increasing the accuracy and ease of the procedure. ■

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On the Other Side of the Laser: My Surgical Experience With CLEAR

From operating technician to patient.

BY NURULHUDA BINTE SUAINI

Prior to undergoing refractive surgery, I had worn contact lenses for more than 13 years to correct moderate myopia and astigmatism. Over the years, however, I grew tired of wearing contact lenses. As an operating technician, I knew of the myriad benefits of refractive surgery and had long contemplated undergoing some sort of laser vision correction. Here, I share my rationale for selecting CLEAR and detail my personal experience with the procedure.

PERSONAL EXPERIENCE

In addition to the inconveniences of wearing contact lenses, including the risk of infection, I also wanted to eliminate the long-term cost of contact lenses.

After assisting Professor Mehta in performing CLEAR numerous times, I decided the procedure might be a good option for me. I was specifically drawn to CLEAR because it has a very low risk of complications and a minimal risk for suction loss. A preoperative evaluation performed at Singapore National Eye Centre confirmed that I was a good candidate for CLEAR (Figure 1), and the procedure was scheduled for February 2022.

Because I have seen the CLEAR procedure performed countless times, I am well acquainted with the entire surgical process. Even so, experiencing it as a patient was eye-opening. I was nervous before the surgery yet excited about the end result. The docking of the laser was slightly uncomfortable, but it was quick. During surgery, Professor Mehta calmed my nerves and kept me focused on the necessary steps, such as looking at the light during fixation. I finally understood what surgeons mean when they explain to patients that the red light will disappear, but it's nothing to worry about. Halfway through the laser treatment, my vision went dark, and I could not see for a few seconds. But here I am now with clear vision. I felt a slight pressure, but I did not feel any pain during surgery.

Before I knew it, I was in the postoperative recovery room and Professor Mehta was checking my eyes to ensure everything went well. My eyes were not red or painful after surgery. I experienced some tearing, but it only lasted about 1 hour. After CLEAR, my UDVA is 6/6 (Figure 2).

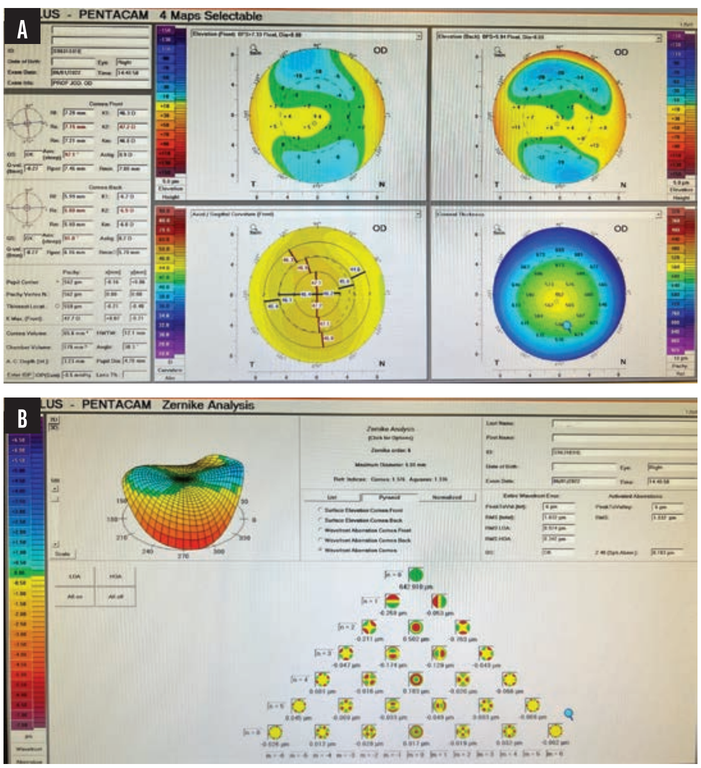

Figure 1. Preoperative examinations.

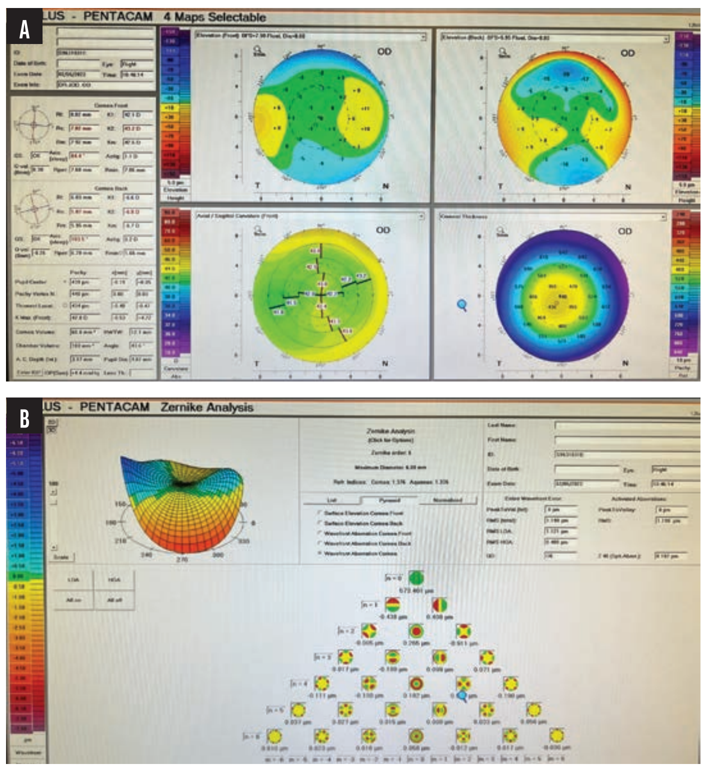

Figure 2. Postoperative examinations.

Figure 3. Ms. Suaini with Professor Mehta after he performed the CLEAR procedure.

SHARING MY EXPERIENCE

In addition to speaking with my friends and family members about my CLEAR surgery, I also share my experience with patients in our practice. I explain to them what they can expect during the procedure, how long the recovery time is, and if they had dry eyes preoperatively why it is important to treat them before surgery. I have always told patients that the 20-minute procedure will give them a lifetime of freedom, but it is mind-blowing to experience it for yourself (Figure 3).

CONCLUSION

I will never forget the euphoric feeling I had the next morning after surgery when I woke up to clear vision. It was life-changing, and it confirmed that undergoing CLEAR was the best decision I made this year. Now, I enjoy my life with true freedom from contact lenses and have never looked back. The convenience of not having to wear contact lenses and glasses for the rest of my life made everything worthwhile. ■

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- Financial disclosure: None

Practice Makes Perfect: Our Experience With CLEAR

Optimize your settings for superb results.

BY ARTURO CHAYET, MD, AND DENISSE PINKUS, MD


There are more options than ever before for patients who desire correction of their refractive errors. Most recently, intrastromal procedures such as lenticule extraction have become a popular treatment choice for patients because they avoid flap-related complications and reduce the risk of dry eyes after surgery.

We started performing corneal lenticule extraction for advanced refractive correction (CLEAR) with the FEMTO LDV Z8 (Ziemer) in January 2020, just before the COVID-19 pandemic. It took us a little bit of time to gain significant experience with the procedure simply because of the related lockdown and, after our practice reopened, patients' reluctance to return to their health care providers in the height of the pandemic. Once our surgical volume returned to near-normal levels, however, we saw an increased interest from our patients in the CLEAR procedure.

TWO INCISIONS ARE BETTER THAN ONE

To date, we have performed more than 150 CLEAR procedures. We both had previous experience with lenticule extraction using a different laser platform. The learning curve with the CLEAR technique was therefore straightforward and fast. Regardless of a surgeon's level of experience with lenticule extraction, one thing that can help shorten the learning curve is creating two guiding tunnel incisions through which the CLEAR procedure can be performed. One incision leads directly into the anterior plane and the other into the posterior plane to ensure the instruments are placed in the correct plane and to decrease the number of manipulations that are required. As you get more confident with the procedure, CLEAR can be performed with just one incision.

In order to build our experience with CLEAR and improve our surgical technique, we scheduled several days in which we would perform between 20 and 40 cases. This helped us to titrate things including the size of the suction ring and the amount of energy

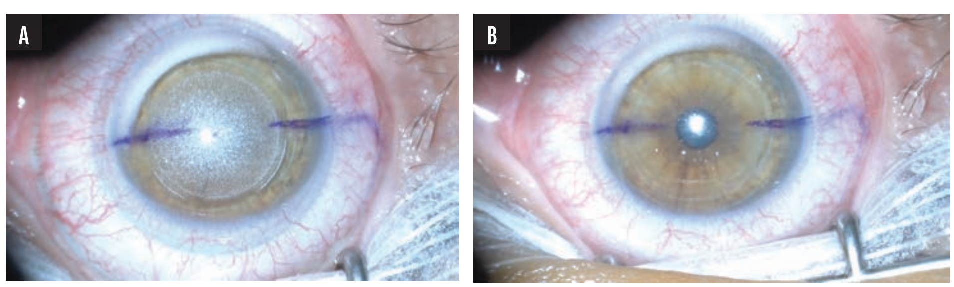

Figure 1. The eye before the lenticule is dissected (A). The eye immediately after the removal of the lenticule (B).

applied. Optimizing our settings has helped us to produce superb visual results for our patients. Now, more than 80% of the eyes are 20/25 on day 1 postoperative. That's very exciting.

From our first cases, we were pleasantly surprised at the simplicity of docking the laser and dissecting the lenticule (Figure 1). To date, neither of us have experienced any complications during dissection such as an incomplete lenticule or suction loss. We also have never had to abort any cases. This is also true for our fellows, who had no prior experience with lenticule extraction. So, in terms of safety, CLEAR is an extremely safe way of performing lenticule extraction.

CASE PRESENTATION

A 26-year-old woman presented for a refractive surgery evaluation. She had a manifest refraction of -4.00 -0.50 x 177° OD and -3.00 -0.75 x 7° OS. Her CDVA was 20/20 OU. Preoperative diagnostic imaging is shown in Figure 2. After counseling, the patient decided to undergo CLEAR surgery, and the procedure was scheduled for October 2022.

On postoperative day 1, the patient's UDVA was 20/25 OD and 20/20 OS with a manifest refraction of 0.00 -0.75 x 8° OD and 0.00 0.00 x 0° OS. CDVA was 20/20 OU. By 1 month postoperative, UDVA had improved to 20/16 OU. The manifest refraction was 0.00 -0.50 x 7° OD and +0.25 0.00 x 0° OS. CDVA further improved to 20/16. The patient was extremely satisfied with her results (Figures 3–5).

PRACTICE MAKES PERFECT

It can take time to gain comfort and confidence with any new surgical procedure, and CLEAR is no different. It can feel foreign at first to dissect the lenticule, but watching videos and live surgeries and doing wet labs is helpful to hone your technique. The right surgical tools are also essential.

One of the most important early steps of the CLEAR procedure is to make sure that you separate the anterior plane, or the roof of the cap, before dissecting to the bottom. It is also important to perform the dissection 360º to the periphery.

Patient selection is also crucial, especially in early cases. We recommend beginning first with spherical treatments for at least -3.00 to -4.00 D of myopia. In these eyes, the thickness of the lenticule allows easy separation of the planes and extraction. Another helpful tip is to place marks on the cornea to center the treatment to the visual axis and align the axis to compensate for cyclotorsion.

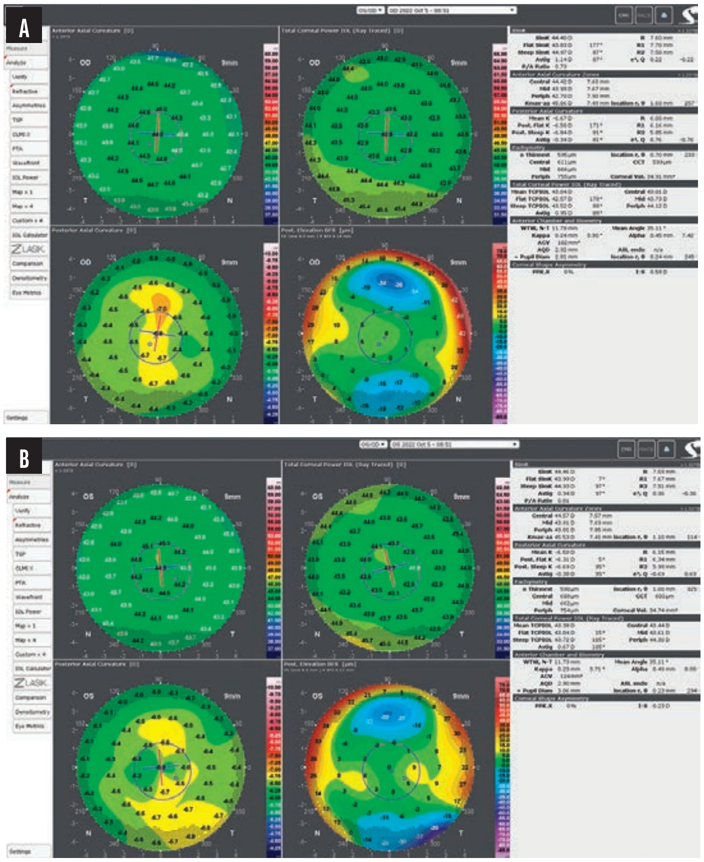

Figure 2. Preoperative corneal topography/tomography (GALILEI) for the right (A) and left (B) eyes.

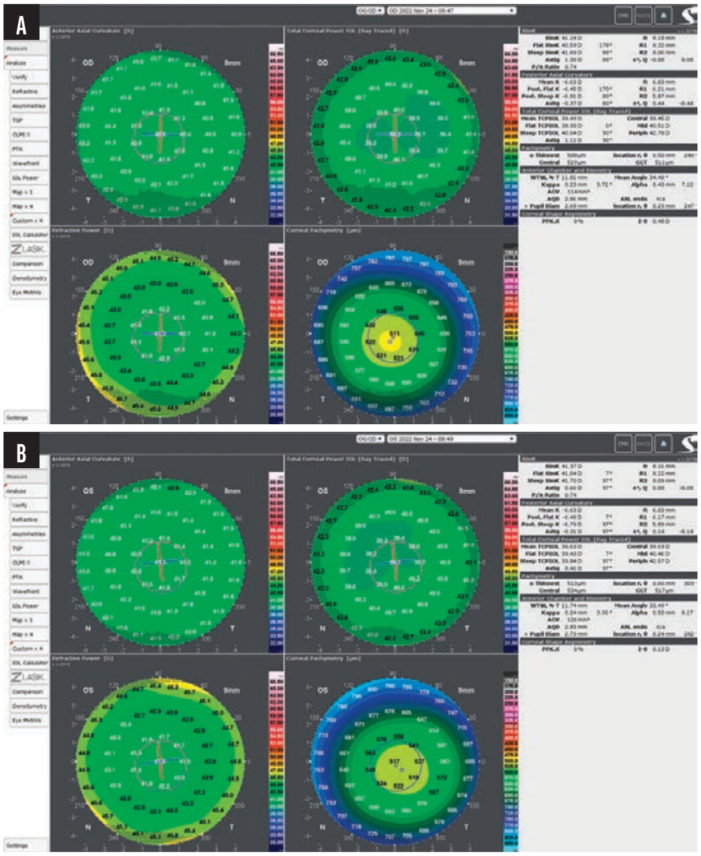

Figure 3. Postoperative corneal topography/tomography (GALILEI) at 1 month for the right (A) and left (B) eyes.

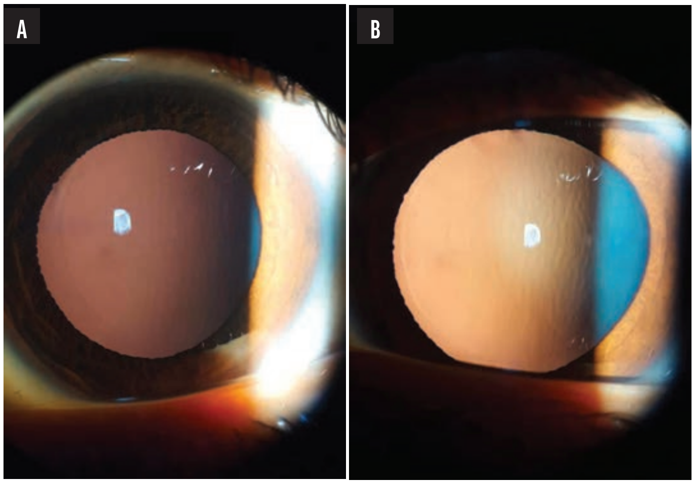

Figure 4. Corneal interface in retroillumination after dilatation at 1 day postoperative for the right (A) and left (B) eyes.

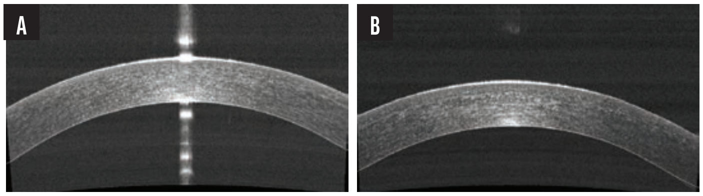

Figure 5. OCT images showing well-apposed, smooth, and regular interfaces at 1 month postoperative for the right (A) and left (B) eyes.

DOCKING

In more than 95% of eyes, we can get good suction and perfect positioning the first time. If needed, the treatment can be easily recentered and the marks on the laser screen can be aligned after docking. This also allows excellent centration and alignment for astigmatism correction.

VISUAL OUTCOMES

Visual rehabilitation after lenticule extraction can be slightly slower than after LASIK. With LASIK, most of our patients are 20/20 on day 1, especially for corrections of -6.00 D or less. With lenticule extraction, day 1 vision might not be as crisp, but by 1 month postoperatively, typically that line of vision is gained and most patients maintain a visual acuity of about 20/20.

Setting expectations is important. When patients understand that their vision might not be crisp on the first day but will get better over time, they are less anxious that something has gone wrong. It is also important to explain the advantages of not having a flap with the CLEAR procedure.

In our opinion, patient selection for CLEAR is similar to that for LASIK. We do not recommend performing CLEAR on eyes with thin corneas and asymmetric astigmatism. For patients who have a little bit of dry eye, it's possible that lenticule extraction is more suitable than LASIK. The main advantage that we see with CLEAR versus LASIK is that the procedure can be performed through a small incision versus needing to create a large opening of the cornea. This increases the safety of the procedure and can decrease the healing process.

CONCLUSION

CLEAR is an exceptional procedure with proven excellent results. Regardless of your experience level, the learning curve with this technique for lenticule extraction is short. Our residents and fellows have all felt comfortable performing CLEAR within their first few cases. ■

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Visual Outcomes With CLEAR Lenticule Extraction

Early results with the procedure were safe, efficient, and stable.

BY SHADY T. AWWAD, MD, AND YARA BTAICHE, MD

Since the introduction of refractive lenticule extraction for the correction of myopia and myopic astigmatism in 2011,[1,2] significant improvements have been made on the surgical and technological aspects of the procedure. Lenticule extraction has gained significant momentum, claiming its place as a mainstream refractive surgery procedure. Currently, the lenticule extraction landscape is being shaped by four different manufacturers that are developing dedicated femtosecond laser modules for the procedure. Corneal lenticule extraction for advanced refractive correction (CLEAR) is a new form of lenticule extraction performed with the Z8 femtosecond laser systems (Ziemer).

THE LASER

FEMTO LDV Z8 is a low-energy laser—working at the nanojoule level—with a solid track record of performing smooth flaps for femtosecond LASIK (femto-LASIK), customized tunnels for intrastromal corneal ring segments, deep anterior lamellar keratoplasty, Descemet-stripping endothelial keratoplasty, penetrating keratoplasty (PKP), arcuate keratectomy, and femtosecond laser-assisted cataract surgery (femto-phaco). The Z8's intraoperative OCT ensures safety while performing the aforementioned procedures and allows the surgeon to view real-time corneal applanation that is generated by the system. Femto-phaco and PKP, however, use a liquid interface system with zero corneal compression to avoid mechanical deformation.

The CLEAR module of the Z8 builds on the advantages of the laser's low energy source, ensuring smooth lenticule dissection.[3] Additionally, the laser can center the treatment on the corneal vertex and adjust for cyclotorsion, all intraoperatively, thanks to the device's corneal applanation feature. We have been using the Z8 for more than 4 years and have been performing CLEAR procedures for about 5 months at the time of this writing with great outcomes.

STUDY DESIGN

Patient population and examinations. This article reviews our 1- and 3-month retrospective data of the first 46 eyes treated with CLEAR. All eyes had myopia or myopic astigmatism and a preoperative corrected distance visual acuity (CDVA) of 20/25 or better. The mean age of patients was 26 ±5.94 years (range, 18–43 years) and the mean preoperative manifest refraction spherical equivalent (MRSE) and manifest cylinder were -3.78 ±1.53 D and -0.62 ±0.55 D, respectively. The planned optical zone was 6.5 ±0.13 mm. The complete preoperative data is represented in the Table.

Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), objective and subjective refraction, topography, tomography, ocular aberrometry, and

TABLE. PREOPERATIVE DESCRIPTIVE VALUES

Demographics	n	
Number of eyes Number of patients	46 24	
	Mean ± SD	Median [Range]
Age (y) Gender (M:F)	26 ± 5.94 13:11	24 [18, 43]
Visual		
Sphere (D) Cylinder (D) MRSE (D) UDVA (logMAR) CDVA (logMAR)	-3.47 ± 1.47 -0.62 ±0.55 -3.78 ±1.53 1.04 ±0.27 -0.014 ±0.04	-3.25 [-6.25, -1.25] -0.5 [-2.75, 0] -3.43 [-6.625, -1.625] 1.1 [0.3, 1.3] 0 [-0.1, 0.1]
Aberrometry (optical zone at 6 mm)		
RMS total Total HOA Vertical coma Horizontal coma Spherical aberration Vertical trefoil Horizontal trefoil	1.16 ± 0.48 0.39 ± 0.14 -0.05 ± 0.16 0.02 ± 0.13 0.22 ± 0.07 -0.04 ± 0.13 -0.02 ± 0.11	1.03 [0.45, 2.58] 0.39 [-0.25, 0.84] -0.06 [-0.51, 0.27] 0.01 [-0.28, 0.38] 0.25 [0, 0.35] -0.03 [-0.31, 0.4] -0.01 [-0.25, 0.24]
Pachymetry		
Thinnest corneal thickness (μm)	552.9 ± 33.2	550 [494, 626]
Surgical parameters		
Cap thickness (μm) Optical zone (mm) Suction ring (mm)	122.6 ± 7.65 6.50 ± 0.13 9.5 ± 0	120 [110, 140] 6.5 [6.3, 7]

Abbreviations: SD, standard deviation; RMS, root mean square; MRSE, mean refractive spherical equivalent; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; HOA, higher-order aberrations; CCT, central corneal thickness

Figure 1. Limbal markings performed at the slit lamp.

biomicroscopic examination were performed on all patients preoperatively and postoperatively at 1 day, 1 week, and 1 and 3 months.

Surgical technique. The procedure was performed under topical anesthesia with standard prepping and draping. Limbal markings were initially done at the slit lamp (Figures 1 and 2A) and were checked for accuracy using the toriCAM smartphone application (Graham Barrett) on iOS devices. Consequently, the limbal markings were extended under the microscope using a three-pronged instrument that acted as a crosshair (Awwad 3-Blade Marker for CLEAR, Epsilon Ophthalmic Surgical Instruments; Figures 2B and 2C). The instrument's corneal markings were centered on the fixation light reflex, approximating the corneal vertex. Extension of preoperative markings onto the cornea allows them to be recognized by the automatic centration and cyclotorsion system of the Z8 (Figure 2D). Centration and cyclotorsion can be further readjusted manually by the surgeon if needed.

At the time of this writing, Ziemer presented a software patch on the Galilei that was fed to the Z8, allowing it to automatically detect the corneal vertex and compensate for cyclotorsion without any markings. The CLEAR software also allows adjustments to the number and size of the incisions as well as programming target refraction, optical zone, and energy settings.

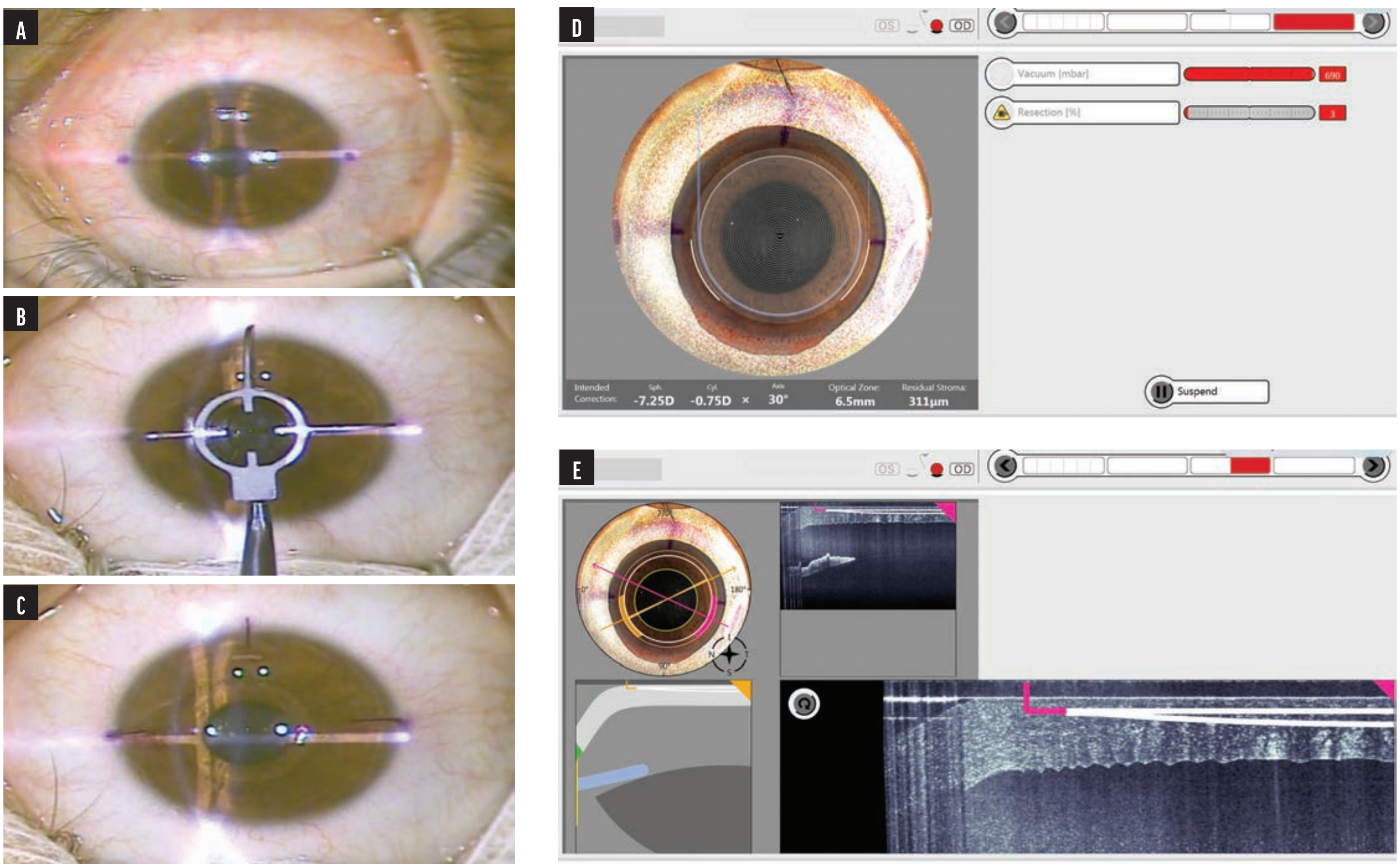

Figure 2. Intraoperative video snapshots. Two limbal dots are marked by gentian violet on the slit lamp (A). A three-pronged instrument is centered on the fixation light (ie, visual axis) and is meant to extend the two marking dots into the cornea (B). The three marked lines act as a crosshair on the light reflex, approximating the corneal vertex (C). Image from the Z8 display screen after eye docking. The laser software automatically recognizes the three marked lines and rotates and centers the treatment accordingly. There is room for the surgeon to recenter and control the location should the surgeon need further alignment (D). Image from the Z8 display screen showing an intraoperative OCT (E).

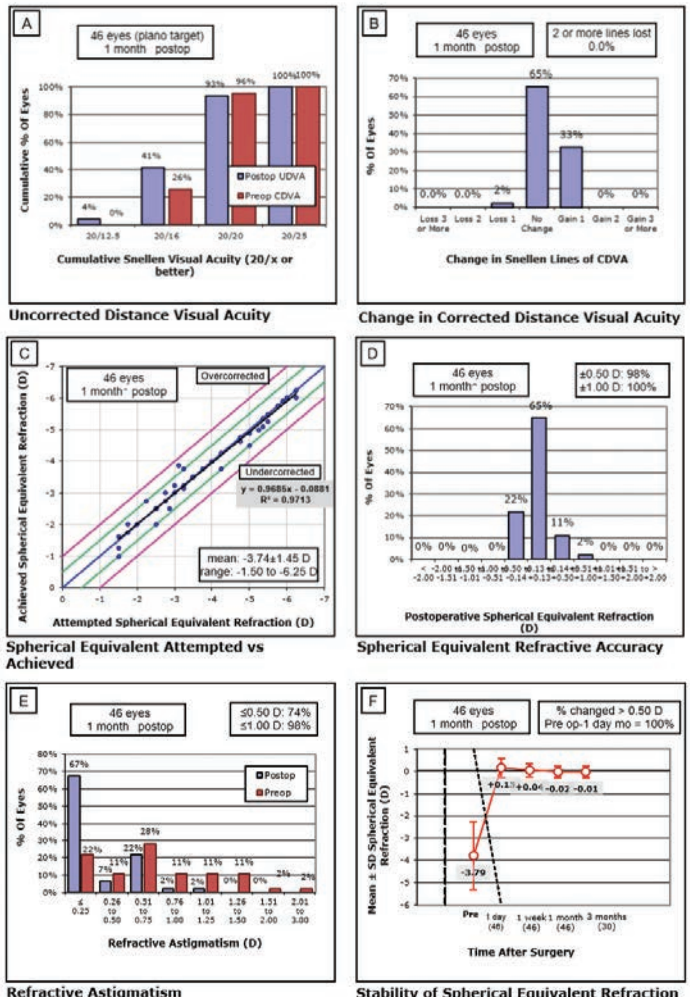

Figure 3. Six standard graphs for reporting refractive surgery showing the visual and refractive outcomes for 46 eyes treated with CLEAR.

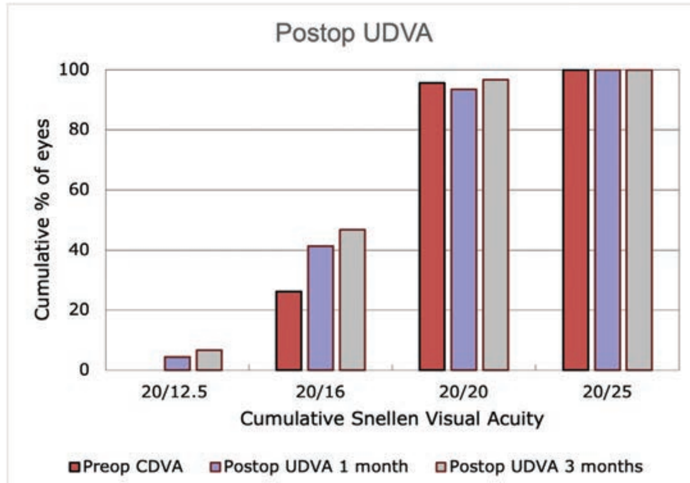

Figure 4. Postoperative UDVA at 1 and 3 months.

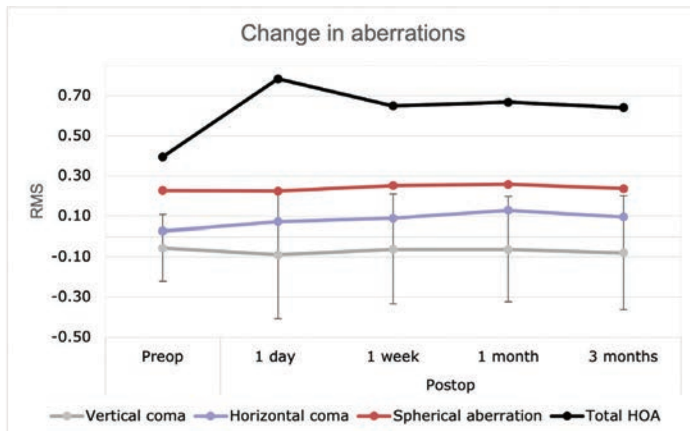

Figure 5. Total corneal HOA changes at different postoperative intervals.

STUDY OUTCOMES

Efficacy. At 1 month postoperatively, 93% of eyes had an UDVA of 20/20 or better, and 97% had an MRSE within ±0.50 D of the intended target (Figure 3A). At 3 months, 96% of eyes had an UDVA of 20/20 or better, and 100% had an MRSE within ±0.50 D (Figure 4). Figures 3B and 3C show the change in corrected distance visual acuity and attempted versus achieved spherical equivalent, respectively. Manifest cylinder changed from -0.63 ±0.56 D preoperatively to -0.16 ±0.26 D at 1 month ($P < .001$) and -0.2 ±0.30 D at 3 months ($P = .049$) postoperatively (Figure 3E). The correlation of attempted and achieved MRSE indicated good accuracy over the whole range of planned treatments with no obvious under- or overcorrection (Figure 3C). Figure 3F shows the stability of the spherical equivalent refraction.

Aberrometry. Changes in total corneal aberrometry at a 6-mm optical zone are shown in Figure 5. Spherical aberration was almost unchanged from 0.22 ±0.07 µm preoperatively to 0.24 ±0.18 µm at 3 months postoperative ($P = .013$). Vertical coma also remained relatively stable while horizontal coma slightly increased from 0.03±0.13 µm to 0.13±0.19 µm after 1 month ($P = .003$). Total higher-order aberrations (HOAs) increased at 1 day but then decreased at 1 week and remained stable at 3 months.

Stability. As expected for lenticule extraction procedures, patients had a relatively slower visual recovery than what is customary for femto-LASIK, especially on day 1. However, visual results significantly improved over time. The percentage of eyes achieving an UDVA of 20/20 or better was 52.2% on day 1, 76.1% at 1 week, 93% at 1 month, and 96% at 3 months postoperatively. Mean MRSE changed from -3.79 ±1.53 D preoperatively to 0.04 ±0.29 D at 1 week postoperatively ($P < .001$). At 1 and 3 months, respectively, it further improved to -0.02 ±0.251 D ($P < .001$) and -0.01 ±0.26 D ($P < .001$).

Safety. Only one eye (3.3%) lost one line of CDVA at 3 months postoperatively. No patient experienced a loss of 2 lines or more

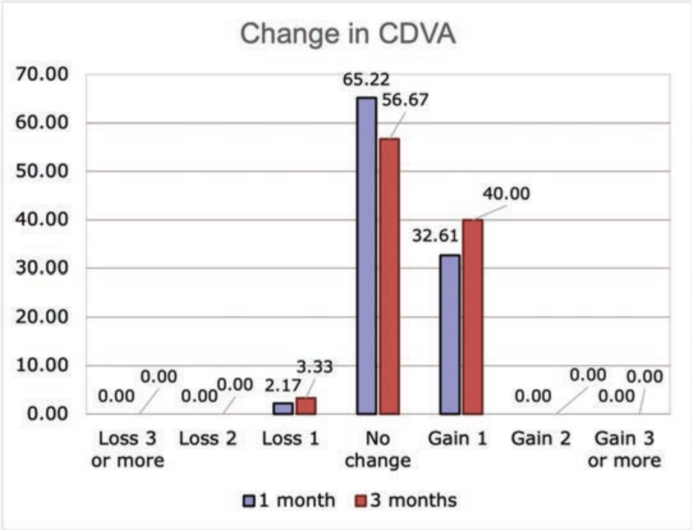

Figure 6. Lines of CDVA gained or lost at 1 and 3 months postoperatively.

(Figure 6). For CDVA, at 1 month, 33% gained 1 line and 65% experienced no change (Figure 3B). No aborted cases, no suction loss, and no cases of lenticule tears were encountered.

DISCUSSION

Given that the sample study was the first series of CLEAR procedures performed by one of us (STA), there was a significant improvement in UDVA, MRSE, and refractive astigmatism and an excellent aberrometry profile postoperatively. The mild increase in coma mirrors the results of other studies[4,5] and is possibly due to manual centration. This can be mitigated currently by using a large optical zone. In the near future, the Z8 will provide automated centration and cyclotorsion technique.

We believe the reason for the minimal induction of coma was the adoption of the three-pronged marker to aid in accurate treatment centration and cyclotorsion correction. The minimal induction of spherical aberration underlines the large functional optical zones achieved.

Previous studies of the aberrations after femto-LASIK and corneal wavefront-guided PRK have shown that HOAs, notably spherical aberration, increase postoperatively.[6] This pattern, however, has been shown to be better with lenticule extraction procedures.[7-12] Maintaining a large functional optical zone can therefore curb the increase in HOAs and spherical aberration postoperatively.

The relatively slower recovery observed after lenticule extraction compared to flap-based procedures can be in part attributed to the undulations in the Bowman layer created by lenticule dissection and the time needed for flattening and repositioning of the cap until visual results are achieved. Microdistortions in the Bowman layer have been reported in various procedures of lenticule extraction.[13] The low energy profile of the Z8 is key to providing the optimal visual recovery.

CONCLUSION

CLEAR is a great lenticule extraction procedure that offers safe, efficient, and stable results. The results reported in this article represent our initial experience with the first series of eyes. We are confident that further refinement of the energy profiles and additional surgeon experience will enhance the procedure's results.

CLEAR induces less spherical aberration. This is ideal in eyes with moderate to high myopia. The procedure also ensures the integrity of the nerve plexus, which is important to preserve the ocular surface while having less biomechanical impact on the cornea compared to flap-based procedures. ■

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The FEMTO LDV Z8 is CE marked and FDA cleared. Lenticule extraction application is CE marked but not yet FDA cleared for use in the United States. For other countries, availability may be restricted due to regulatory requirements. Please contact Ziemer for details.