

Trailblazing the future with speed and innovation

“Trailblazing the Future with Speed and Innovation” was the theme of the Bausch + Lomb TECHNOLAS

Alliance Meeting, held July 10, 2013, at the Suntec Convention Centre, Singapore. The Alliance was chaired by **Wing Kwong Chan, MD**, senior consultant, Eye & Retina Surgeons, and visiting consultant, Singapore National Eye Centre.

The VICTUS Femtosecond Laser Platform (Bausch + Lomb TECHNOLAS) was the first laser designed for both refractive and cataract applications.

The VICTUS laser offers optimized flap creation. It is easy to dock, creates smooth stromal beds, and achieves accurate and consistent flap thickness (Figure 1).

The VICTUS can also be used for cataract surgery, specifically in challenging cases. Continuous innovations in the VICTUS femtosecond laser have fulfilled the promise of being a versatile, robust combined cataract and refractive platform. There are plans in the works to progress from versatility to even further advanced usability.

SUPRACOR (Bausch + Lomb TECHNOLAS) allows presbyopic patients

who desire spectacle independence and prefer a laser treatment to undergo LASIK for presbyopia. This has been a gap in the market that has now been filled. SUPRACOR simultaneously treats the refractive error and presbyopia in one procedure, and it can be adjusted or reversed.

Another innovation is the TECHNOLAS TENE0 317 Excimer Laser (Bausch + Lomb TECHNOLAS), which is the smallest excimer laser on the market (Figure 2). It is built based on surgeons' feedback from around the world to optimize ease of use, speed, and ergonomics.



Figure 1: VICTUS Femtosecond Laser Platform



Figure 2: TECHNOLAS TENE0 317 Excimer Laser

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VICTUS Femtosecond Laser Platform: Contralateral comparative study

by Gerd U. Auffarth, MD

In the past decade, the femtosecond laser has brought tremendous advancements to the field of ophthalmology. In less than 15 years, it has developed from a flap maker into a universal laser that can do cataract surgery, astigmatic incisions, flaps, presbyopia treatments, and even keratoplasties.

When the femtosecond laser was introduced, it was a refractive laser developed just to make flaps. All of the femtosecond lasers were designed to ablate the surface of the cornea. The TECHNOLAS femtosecond laser, first the Femtec and now the VICTUS laser (Bausch + Lomb Technolas), is the only laser that started with a curved interface and was designed to keep the curved cornea intact.

The VICTUS laser has been approved both in Europe and in the United States for a variety of procedures. In the past two years, it was approved for laser refractive cataract surgery.

In the laboratory, we could show that the femto-capsulotomy is significantly stronger and less likely to tear compared to a manual continuous curvilinear capsulorhexis.¹ This has been demonstrated in many studies.

Phase IV study

We are conducting a Phase IV study on the VICTUS laser. The study is a prospective, contralateral, comparative, single-center study. Preoperatively, analysis of the entire anterior segment included visual acuity (ETDRS), endothelial cell count, slit lamp, flare, wavefront aberrometry, and intraocular pressure. The surgery was randomized to one eye of each patient, and the fellow eye received standard phacoemulsification. A monofocal, aspheric enVista MX60A (Bausch + Lomb) was implanted. This lens is made of hydrophobic acrylate with a diameter of 6 mm and with a power between 10 and 30 D. Intraoperatively, a video was made, and the capsulorhexis was stained. Postoperatively, patients completed a subjective questionnaire. Flare meter and topography were performed, and endothelial cell count was assessed.

Patients will complete six months of follow-up and have currently completed three months. Postoperative follow-up visits are scheduled for one day, one week, one month, three months, and six months. To date, 28 eyes have been treated (14 with VICTUS, 14 with manual phaco). Patients' median age was 72 years (range 45 to 82 years).

Evaluation criteria included visual acuity (corrected and uncorrected), IOP, the difference between the intended and achieved postoperative refraction, flare, effective phaco time, effective IOL position, IOL overlap, and IOL centration.

For the first few days after surgery, patients' uncorrected and corrected visual acuity was comparable. Three months postoperatively, better UDVA results were observed with the VICTUS laser, although the difference was not significant. While this is a small study and these are early results, there appears to be an advantage to laser cataract surgery over manual methods.

When we evaluated intended refraction with a Holladay 1 formula, there were slightly better results with the VICTUS laser, but the difference was not statistically significant. This trend was also seen when we looked at the difference between intended and achieved refraction (Figure 3). It was lower with the VICTUS (0.25 D) compared to the manual procedure (0.51 D).

Even with this small number of patients, there was a significant difference in effective phaco time with less phaco energy applied to the VICTUS group compared to the manual phaco control group (Figure 4).

Additionally, the capsulotomy diameter and the circularity of the capsulotomy were significantly better in the eyes treated with the VICTUS laser.

It is still too early to have significant results with regard to lens position. However, the retroillumination photo is quite beautiful.

Trends

Although these are interim results, we can already see some trends. In fact, the difference in the effective phaco time between the procedures already shows statistical significance. The VICTUS is superior to the manual procedure, at least in certain aspects. There is a free-floating and precise capsulotomy. There were no serious adverse events, and patients achieved good visual outcomes.

Reference

1. Auffarth GU, Reddy KP, Ritter R, Holzer MP, Rabsilber TM. Comparison of the maximum applicable stretch force after femtosecond laser-assisted and manual anterior capsulotomy. *J Cataract Refract Surg* 2013; 39:105-109.

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		Refraction (SE)	
		Victus	Manual
Difference between intended and achieved refraction 1 week postoperatively (n=14 each)	Median	+0.18 dpt	+0.33 dpt
	Minimum	-1.04 dpt	-0.02 dpt
	Maximum	+0.74 dpt	+0.96 dpt
Difference between intended and actual refraction 1 month postoperatively (n=13 each)	Median	+0.10 dpt	+0.15 dpt
	Minimum	-1.41 dpt	-0.25 dpt
	Maximum	+1.24 dpt	+1.08 dpt
Difference between intended and achieved refraction 3 months postoperatively (n=6 each)	Median	+0.25 dpt	+0.51 dpt
	Minimum	-0.49 dpt	-0.37 dpt
	Maximum	+0.61 dpt	+1.58 dpt

Figure 3: Difference in intended versus achieved refraction

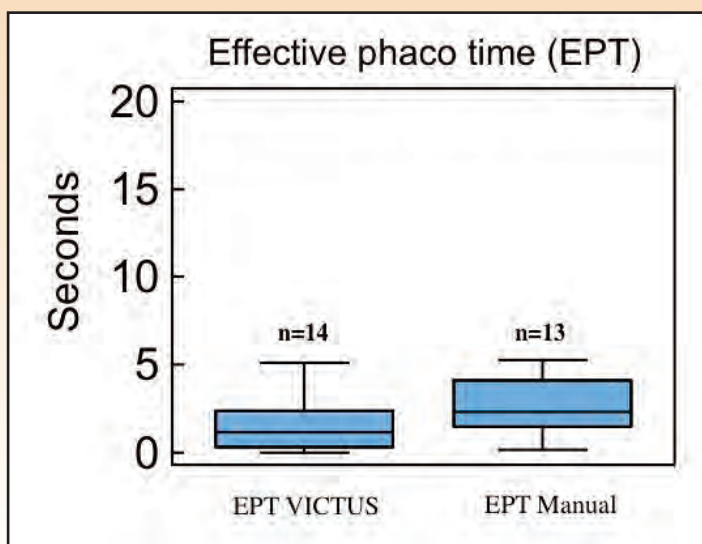


Figure 4: Effective phaco time – VICTUS versus manual

Femtosecond surgery strategies for high-risk cataracts with the VICTUS Femtosecond Laser Platform

by Soon-Phaik Chee, MD

I have a special interest in managing complicated cataract cases, and I have begun using the VICTUS (Bausch + Lomb Technolas) in challenging cases, such as subluxated cataracts and dense posterior polar cataracts. Using the VICTUS in complicated cases can bring unique advantages to cases that cannot be done well, or sometimes at all, with conventional cataract surgery. I have been using the VICTUS since April 2012, and I have performed more than 600 cases with the laser.

Soft cataracts can be difficult because they cannot be cracked. It is helpful to use a laser to segment them, which I prefer over a manual technique. We usually pre-set the diameter of the lens fragmentation pattern to 7 mm. Based on the individual pupil size the diameter is then automatically adjusted to achieve the maximum possible lateral treatment range. Besides that we want to be 700 µm from the posterior capsule, so that if the patient moves, we don't go beyond the posterior capsule.

The other extreme is a brunescient cataract. I typically use a 5-mm capsulotomy; however, beginning surgeons may want to use a larger capsulotomy. The capsulotomy energy and fragmentation energy will need to be increased. Cutting the nucleus into smaller segments makes surgery so much easier. With adequate energy, you can segment very deeply, which makes separating the pieces easy. Nuclei in Asian patients can be very thick, and they may need to be cracked and separated many times for the fragments to come apart cleanly. The laser helps penetrate through the thick, hard nucleus. Even with a brown nucleus, it can be easily done.

With white cataracts, it is important to dock the eye evenly so that the laser actually hits the capsule at the same time, especially if it is intumescent (Figure 5). If one part breaks through before the other, you can get the Argentinian Flag Sign if the pressure intralenticularly is very high.

Also, increase the capsulotomy height that you treat. It should be increased above

the level of the capsule. The fragmentation energy needs to be increased so that it can pass through the white cataract to cut the nucleus. In cases like this, if the surgeon is uncertain whether the capsulotomy is complete, he or she can stain with trypan blue to make sure.

In cases with intumescent cataracts, it is useful to give the patient intravenous mannitol preoperatively. This helps to draw fluid out of the tensely swollen lens and reduce the risk of an anterior capsule rip during the laser procedure.

One of my patients had a Morgagnian cataract and fibrosis beneath the capsule. After staining it with trypan blue, I could see that it was really sticky and the capsule above it had been cut. The fibrotic band could be pulled away nicely because it had been segmented. This is only possible with a femtosecond laser and would not have been possible with a manual capsulorhexis.

Another patient had an inferior coloboma, which made the cataract surgery a challenge. Currently, with the VICTUS, we are using the pupil as a guide to center the capsulotomy. The cataract was intumescent and white, so we had to pretend that the pupil was round. We just put our markings for the pupil as though the pupil was already reconstructed. This patient was a very high myope with astigmatism, so I implanted a toric lens.

We wanted to see if a diseased cornea is a contraindication to using the laser, so we used it on a patient with a hazy cornea and a very dense cataract. The laser actually cut through the very dense, brunescient cataract completely.



Figure 5: White intumescent cataract

I also use the laser in cases with soft posterior polar cataracts. The larger the polar opacity, the higher the risk of capsular rupture. These patients also frequently want a multifocal lens because they are young. However, if I can create a perfectly centered and sized capsular opening that's round, then I have confidence that I can implant a multifocal lens or even a multifocal toric lens because I can always use the capsulotomy to help stabilize the optic in the event of a posterior capsule rupture. The procedure is the same for these patients, except that when positioning the cuts, stay away from the posterior polar opacity. Look at the OCT scan, and mark above the opacity so that the cut doesn't go too deep.

The VICTUS has enhanced my ability to safely handle complicated cases and achieve excellent outcomes.

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Enhancing the VICTUS Femtosecond Laser Platform

by Jochen Kandulla, PhD

Where are we now?

With regard to cataract procedures, VICTUS (Bausch + Lomb TECHNOLAS) is able to perform the following:

- primary and secondary incisions
- capsulotomy
- lens fragmentation
- arcuate incisions/
limbal relaxing incisions

In addition to the cataract indications, VICTUS can be used for penetrating keratoplasties, intracorneal ring segments, and LASIK flaps.

Where are we going?

The VICTUS has versatility and a variety of indications, but we want advanced usability.

We are currently working on a new headrest designed for easier docking. We currently use two joysticks, but we are moving toward using only one. This is a huge improvement.

We are also working on a swiveling bed so that the entire cataract procedure can be performed without moving the patient. Cur-

Optimizing flap creation with the VICTUS Femtosecond Laser Platform

by Robert Ang, MD

In my opinion, the VICTUS (Bausch + Lomb TECHNOLAS) is spectacular when it comes to the capsulotomy and is even more impressive in dealing with very thick cataracts because it can make segmental cuts. However, our center only has one femtosecond laser, so we need it to do both corneal flaps and cataracts. The VICTUS also provides very accurate flap thickness with good postoperative appearance.

For a femtosecond laser to be a good flap maker, it must be easy to use, and it must be easy to dock. In our center, we have nine doctors, but only two of them are refractive surgeons. The laser has to be simple enough for the seven doctors who only do cataract surgery to dock it even though they have never had any experience docking in the eye.

Additionally, the flaps must be easy to open and easy to lift. One criticism of the TECHNOLAS 520F was that the flaps could sometimes be difficult to lift. Stromal beds have to be smooth, the flaps have to be consistent, and the flap appearance has to be nice postoperatively. It has to look good after surgery—almost as good as a LASIK flap created with a blade. So the gutters have to be small, and there has to be minimal haze in the flap edge.

When docking, I start by everting the eyelids. With both the VICTUS and the 520F, I find it easy to dock the patient to the laser via the curved patient interface. Using the intelligent pressure sensors, it is important to be in the green or in the center of the pressure sensor display, which indicates that you're straight when docking the patient. There's no X/Y division. The patient is not looking sideways or downward, so there's no tilt in the eye, which helps to avoid too much opaque bubble layer. It is not only important to be centered in the X/Y axis, but also in the green in the Z axis, to ensure adequate contact of the curved interface on the cornea.

Flap creation

When I create flaps with the 520F, I dissect the entire flap edge to open the flap because

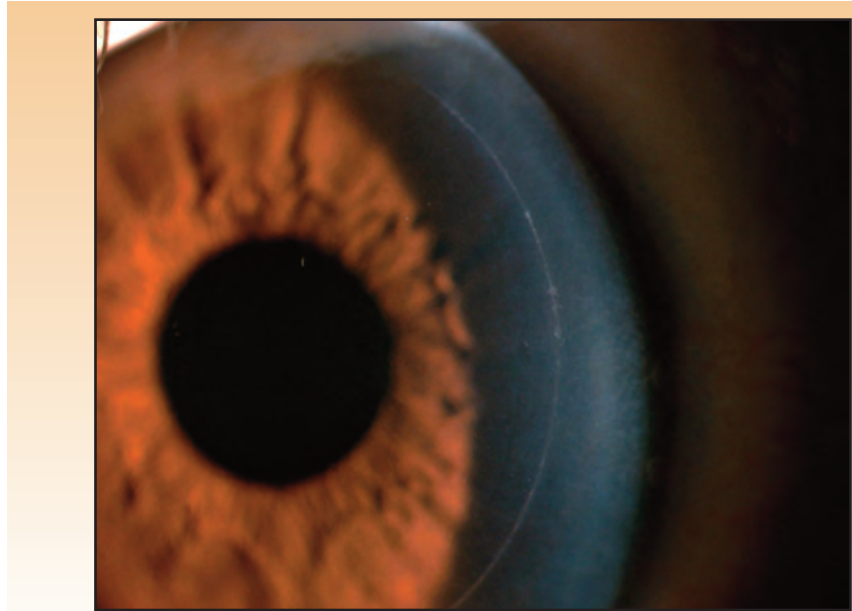


Figure 6: With the VICTUS flaps, there is almost no gutter.

I've noticed that it can be sticky and sometimes hard to open. Then I push all the bubbles away because I need to do iris registration. After iris registration, I insert the dissector slowly, and then I push down and ask the patient to look up. I do a one-handed technique. It's a little sticky, but it works. I have done approximately 2,000 cases with the 520F, and there's never been a flap we could not lift. The beds are typically smooth, but there can be a large opaque bubble layer, and the areas with the opaque bubble layer are the hardest to dissect.

We got the VICTUS in March 2013. While we still sometimes see an opaque bubble layer, it is not as dense as with the 520F. I no longer dissect the flap edge. I just create a pocket and go in. As I go through the other side, I push down without even asking the patient to look up. I use counterforce and just push it down. I still do a one-handed technique. With the VICTUS, the flaps are much easier to lift and the flap beds are smoother than with the 520F.

Flap thickness predictability

Consistency and predictability of flap

thickness is important in computing for residual stromal bed thickness. We use this to determine whether the patient is qualified for LASIK or not so we can reduce the risk of ectasia.

We always try to take a Visante OCT (Carl Zeiss Meditec, Jena, Germany) of the corneas one month after laser. With an intended flap of 120 μm , we compared central flap thickness with the 520F and the VICTUS. With the 520F, our standard deviation is about 14.81 μm , compared to 6.71 μm with the VICTUS.

Additionally, with the 520F, I would usually get a flap gutter. With the VICTUS flaps, there is almost no gutter (Figure 6). They more closely resemble a blade flap.

Femtosecond laser flaps have significantly improved from the 520F to the current VICTUS. Continuous innovations in the VICTUS have fulfilled the promise of being a versatile, robust, combined cataract and refractive platform.

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rently, the VICTUS bed can only swing out by 16.5 degrees or 35 degrees. The upcoming range will allow the bed to swing out by 70 degrees.

We already have real-time OCT, but we are working on faster OCT. It has higher contrast and a faster video frame rate. It will provide real-time imaging during all procedures.

Perhaps most importantly, we are working to improve the software. The aim is to require fewer clicks to see the final results. The software is designed for a more ergonomic flow. It is template based, which is very important because it speeds up the procedure time. With only six screens, the patient can undergo a full cataract treatment,

and with only five screens, a flap can be created. We expect this software to be available in early 2014.

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SUPRACOR presbyopic treatment across all indications

by Robert Ang, MD

SUPRACOR (Bausch + Lomb TECHNOLAS) is a new excimer laser ablation profile that creates a central addition to provide reading vision for patients. I consider it to be the best solution for presbyopia in middle-aged patients because it corrects refractive error and presbyopia at the same time.

SUPRACOR is a varifocal presbyopic treatment. The distance vision is in the periphery, and in between the distance and the near vision is a small transition zone for intermediate vision, which is optimized in the way that minimal unwanted aberrations are induced.

It is not monovision, so one or both eyes can be treated depending on the patient's desires or needs.

This procedure is designed as a full refractive treatment range, for everyone older than 45 years of age (non-cataract presbyopes) who qualifies based on LASIK parameters.

Patient expectations

Among all our patients across all age groups, there is a desire for spectacle independence, including our presbyopic patients. The presbyopic patients are looking for a safe and effective treatment. They want a simple, quick, and pain-free procedure, and they prefer a "laser" treatment over "surgery."

In other words, they want a presbyopia-correcting laser procedure, which we can now provide with SUPRACOR. With declining LASIK numbers globally, this new population of presbyopic patients can help to offset the decline. This market will continue to grow as the population ages, and we can charge a premium price.

At the Asian Eye Institute, patients older than 60 years are the most significant patient population. While they only comprise 36% of all patients, they account for 52% of all examinations. Patients who are 40 or older comprise 67% of all patients, with 79% of all examinations. If practices are not offering a treatment to the 40- to 59-year-old age group, they are missing a significant opportunity for income.

Why offer LASIK for presbyopia?

As you know, there are other treatments for presbyopia. However, our patients' two main requests are spectacle independence and to have a laser procedure, so patient awareness is high. Additionally, this one surgical procedure can treat refractive error and presbyopia. Another advantage is that there is a minimal learning curve for surgeons who are already performing LASIK. This procedure has the same safety profile as LASIK, so surgeons will encounter the same risks, such as flap problems; however, with the femtosecond laser, there are very few flap problems anymore. Patients prefer this procedure because it is minimally invasive and no foreign body is implanted in the eye.

SUPRACOR has been CE-marked for hyperopia since 2011, and more than 20,000 eyes globally have had the procedure in more than 100 clinics. Studies are ongoing in post-cataract and post-LASIK patients, and myopic SUPRACOR is awaiting CE approval.

I recently conducted a retrospective study of my hyperopic SUPRACOR patients. The study included 68 patients: 11 had bilateral SUPRACOR, and 57 had unilateral SUPRACOR. Patients' mean age was 51.7 years.

The refractive target of SUPRACOR ideally is -0.5 D, which is the sweet spot. At the six-month follow-up, my patients were more or less at -0.45 D, which is very close to the target. Many hyperopes have a mean preoperative monocular uncorrected distance visual acuity (UDVA) of 20/40 to 20/50, and after SUPRACOR, they get to up around 20/30 or 20/25, which is where we want them. We don't want them to be 20/20 distance because there won't be enough near vision. The patients in this study achieved uncorrected near visual acuity (UNVA) of J2 to J1 postoperatively compared with mean UNVA of J9 preoperatively. Mean monocular uncorrected intermediate visual acuity (UIVA) also improved from 20/40 to 20/50 preoperatively to 20/20 postoperatively (Figure 7). The interim results of my ongoing clinical studies on SUPRACOR in post-LASIK and pseudophakic patients find the monocular UNVA is greatly improved; it also improves the intermediate vision and maintains the distance vision (Figure 8).

For me, SUPRACOR is the best option for treating refractive error and presbyopia simultaneously in one sitting. In our clinic, we can now offer a laser treatment for all ages. Young patients can have LASIK, middle-aged patients have SUPRACOR, and older patients either have SUPRACOR or VICTUS cataract.

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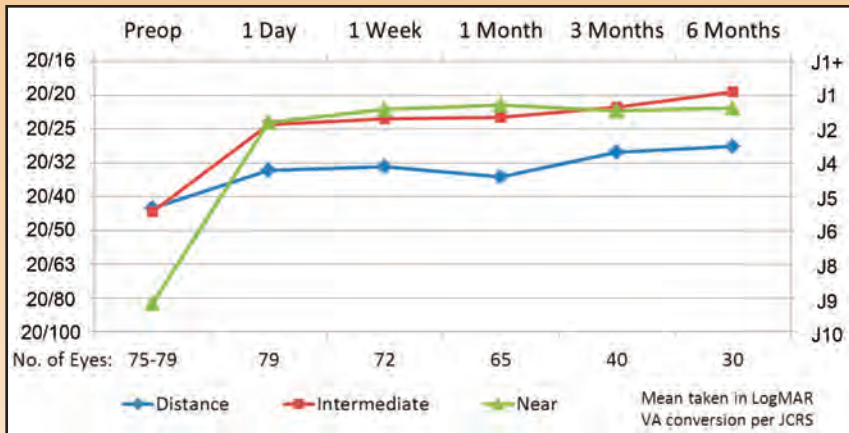


Figure 7: SUPRACOR hyperopia: mean monocular uncorrected VA

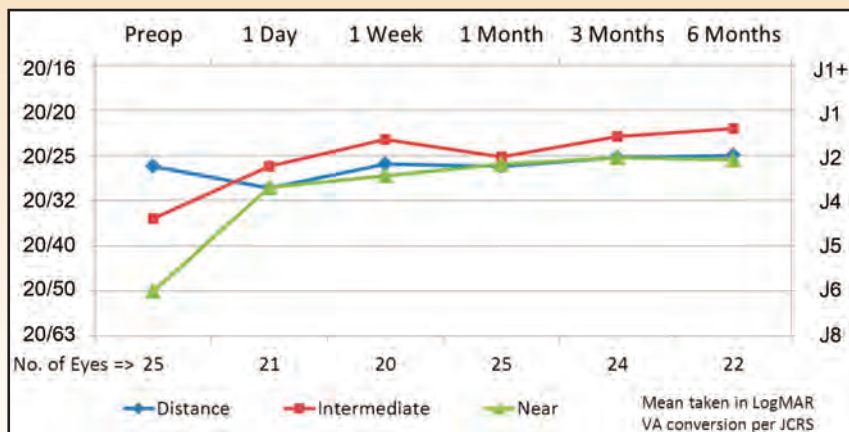


Figure 8: SUPRACOR pseudophakic: mean monocular uncorrected VA

The TECHNOLAS TENEO 317 Excimer Laser has the smallest platform

by Tobias Meythaler, BSc, MSc Physics

The new TECHNOLAS TENEO 317 Excimer Laser (Bausch + Lomb TECHNOLAS) is the smallest laser platform. This was achieved by an innovative design in which the laser head is oriented backward, so the emission goes backward and then comes in the optical beam path at 45 degrees forward. This results in a lot of open space, which provides optimum patient accessibility for both the surgeon and the nurse. Additionally, the 24-cm working distance is designed to help reduce patient anxiety.

The laser is outfitted with the new Zeiss FR1 Pro microscope (Carl Zeiss Meditec, Jena, Germany), which has three different levels of adjustment and can rotate 360 degrees. Being able to adjust the microscope allows surgeons to achieve an optimal ergonomic sitting position.

Advances

While seated at the laser, the surgeon has access to all of the controls on one multi-functional panel. The surgeon can adjust the brightness and magnification levels of the laser.

The laser works with a frequency of 500 Hz and delivers a 1 mm truncated Gaussian beam via a nitrogen-purged sealed beam path. The beam shape is similar to TECHNOLAS' previous units, but instead of using a disposable card, there is now a novel optical element that is permanent in the laser.

The energy to the eye is controlled by three independent energy monitors. This allows for a real closed loop energy delivery.

Treatment planning can be done using an ergonomic touchscreen. During the ablation process, the plume evacuator employs a carbon filter.

The eye tracker now uses digital cameras. The treatment speed of the camera is synchronized with the emission of the laser at 500 Hz.

The system provides X/Y/Z tracking and iris recognition. Furthermore, static rotational compensation using data from

the ZYOPTIX Diagnostic Workstation as well as intraoperative dynamic rotational compensation are included. Additionally, potential pupil shift from your diagnostics is compensated by the laser system.

The system runs on three simple, yet sophisticated, treatment modes: PROSCAN (the non-wavefront aspheric treatment mode); ZYOPTIX HD (wavefront mode that compensates for spherical aberrations); and SUPRACOR.

Safe and effective

The safety and efficacy of the system was recently studied at the Maxivision Eye Hospital in Hyderabad, India. The study included 66 eyes of 34 patients. PROSCAN treatment for distance vision was performed with the new laser, and the target refraction was plano. Outcome measurements included uncorrected and best corrected visual acuity, refraction, and safety. Patients were assessed at one day, one week, one month, and three months postoperatively.

The average refraction was -3.86 with myopia up to 9 D and cylinders up to 2.5 D. At the one-month and three-month visits, the spherical equivalent was virtually zero,

and the standard deviation was very low (less than 0.2 D). Most impressive are the cylinder outcomes. Again, the cylinders at one and three months were virtually zero, and there was a very low standard deviation of 0.13.

There was stability of refraction over time. The refraction was spot on and stable up to three months. With regard to monocular uncorrected distance visual acuity at three months, 95% of patients reached 1.0, and 87.9% of the patients reached 1.2 or better visual acuity at three months (Figure 9).

Additionally, only 1.7% of patients lost one line of monocular best corrected distance visual acuity, no patients lost 2 or more lines, while 34.5% of patients gained one line or more at three months.

In summary, the TECHNOLAS TENEO 317 Excimer Laser is the world's smallest excimer platform, and it was built based on surgeons' feedback from around the world. Its three main benefits are ease of use, speed, and ergonomics.

Mr. Meythaler is the manager of global clinical applications for Bausch + Lomb Technolas. He can be contacted at tobias.meythaler@bausch.com

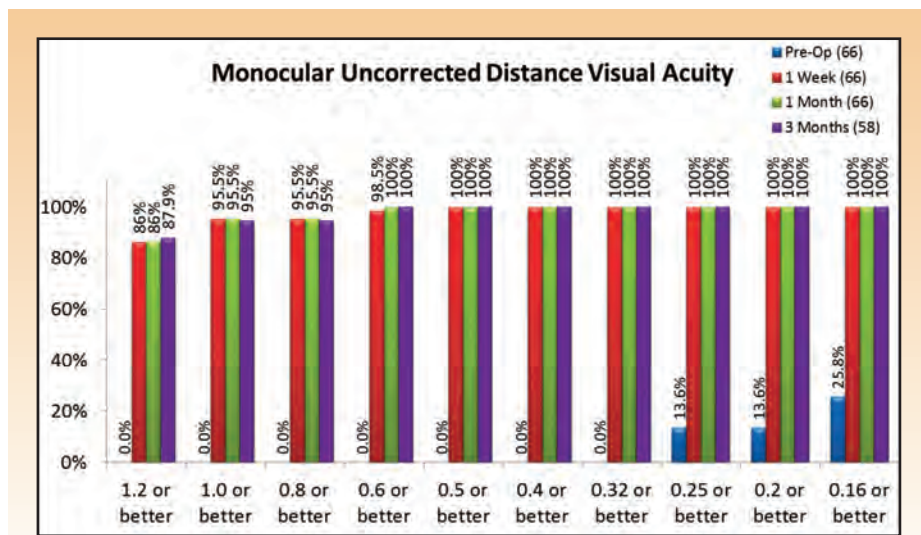


Figure 9: Monocular uncorrected distance visual acuity

The VICTUS Platform has CE Mark for capsulotomy, lens fragmentation, astigmatic keratotomy, corneal incisions, tunnels for intracorneal ring segments, LASIK flaps, INTRACOR and keratoplasty. The TECHNOLAS TENEO excimer laser has CE MARK. SUPRACOR has CE MARK. SUPRACOR for post-LASIK and pseudophakic patients is currently in clinical evaluation. Design and specifications are subject to change without prior notice as a result of ongoing technical development. Indications may vary by country. VICTUS, SUPRACOR, TECHNOLAS, TENEO, ZYOPTIX, and ENVISTA are trademarks of Bausch & Lomb Incorporated or its affiliates.

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