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Visionary Cataract and Refractive Techniques: Explore With Us

Who is really at the leading edge of refractive and cataract surgery? Bausch + Lomb puts forward its case.

Contributors

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Indications and approvals may vary by country. Please contact your local Bausch + Lomb representative for further details.
Legal Manufacturer of the VICTUS Femtosecond Laser Platform and the TECHNOLAS TENEO 317 Model 2: Technolas Perfect Vision GmbH, Messerschmittstr. 1+3, 80992 München, Germany.

In a technology-led industry like eyecare, almost everyone is shouting that their products are the latest and greatest in the market; the biggest and best. To be fair, there's a lot of advanced technology to shout about in cataract, refractive and corneal surgery, including femtosecond and excimer lasers and advanced IOL materials and designs. Who really is at the leading edge of ophthalmic innovation in the anterior segment and what else is on the horizon? Surgeons Sheraz Daya, Tobias Neuhann, Thomas Poole and Luis Cardarso share their experiences with Bausch + Lomb's advanced laser and IOL offerings.

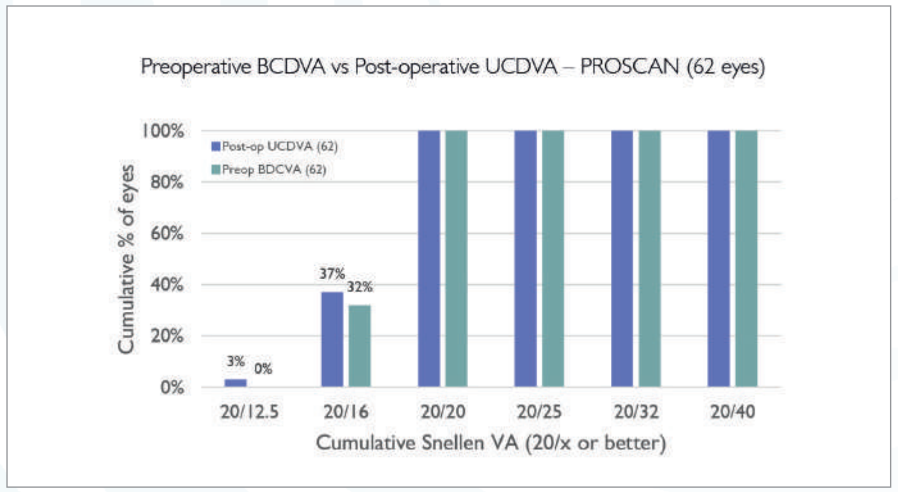


Figure 1. Preoperative BCDVA and postoperative (1 month) UCDVA in 62 eyes treated with PROSCAN†, on the TENEO 317 Model 2.

Inclusion criteria: Pre-op BCVA was 20/25 or better, Pre-op Refraction: Sphere up to -7.5 D and cyl. up to -5.25 D, Treatment target was plano ± 0.25 D; treated optical zones 5.5 mm or bigger, 1 month follow ups, if data for UCVA, BCVA and manifest refraction were available. Exclusion criteria: one case with post-op striae as a flap complication has not been considered; treatments targeting for monovision have been excluded. †Data courtesy of J. Castanera, S. Daya, P. Levy and F. Nouira.

SHERAZ DAYA, Medical Director, Centre for Sight, East Grinstead, Sussex UK

I've been a happy user of the Technolas TENEO 317 Model 1 excimer laser for over three years now… but I recently moved to the Model 2. So what's changed? Are patients experiencing better outcomes? Was the upgrade worth it? Let's take a look. The short answer is, unsurprisingly, yes, and there are a number of features that come together that are helping drive better outcomes and speedier and more efficient procedures (Box 1). Let's start with how easy it is to use: like my Tesla Model S, almost everything is presented and controlled from a large, 24" touchscreen, with a simple, clear and functional graphical user interface. Everything from magnification changer control settings to energy check counters are there, and again, like my Tesla, most of these parameters can be customized to the surgeon's own preferences. The TENO 317 Model 2 has a built-in video camera; unlike my Tesla (which has many cameras, but came with no Dashcam feature!), the footage is easily obtained from the system.

Simpler is better

The new microscope (sourced from Zeiss) integrates well with the touchscreen to switch between the five basic magnification levels (2.5×, 4×, 6.5×, 10× and 16×) and to deploy the 50 percent booster option (providing 10 settings in all), plus it incorporates a slit lamp, helping you to ensure that you've cleaned all the debris and confidently conclude the procedure. Like the Tesla, not everything is controlled by the touchscreen. It makes little sense to control the car's indicators from a central display, so there are indicator stalks; in the TENEO 317 Model 2, we have a joystick to control the bed, and the new bed is stable and easy to position too. Everything is user-friendly, convenient, and centered around helping surgeons and their teams accomplish what they need to achieve in the simplest manner possible.

Ticking the options list

Again, like my Tesla, the performance is swift! With the Model 2, you get what's probably the highest repetition rate for a multi-dimensional eyetracker laser platform on the market, with a 1,740 Hz sampling rate along with cyclotorsion control, dynamic rotation tracking and pupil shift compensation. Importantly, the system features a digital coaxial camera. Older systems had a problem: if the patient's eye moved in the Z-axis, it could result in a slight decentration. The coaxial camera is used to eliminate that possibility. But the fast-tracking speed is matched with a fast laser, and this allows fast and efficient surgery. A -6.00 D, using a standard treatment takes only around 1.0 second per diopter (1) – in other words, 6 seconds from start to finish; an astigmatic eye of -4.00, -2.00 requires only 6.0 seconds too. Less demanding cases are done in 3–5 seconds, and this speed can be tremendously useful if you deal with high patient volumes.

The laser technology manages to achieve this by using an optimal system: an energy delivery at the sweet-spot of 200 mJ/cm² (2), a pulse distribution algorithm that employs optimised entropy (i.e. disordered) laser pulse sorting, and a single nozzle design for plume evacuation, which I can assure you is patient-friendly and surgeon-friendly: it doesn't get in the way during surgery.

Key features of the TENEO Model 2.

Road test results

But the real work happens in the Tesla where the rubber hits the road. And the true test of the TENEO 317 Model 2 is patients' outcomes – and data on the first LASIK outcomes with the Model 2 are now available. Records came from four sites: ours, the Centre for Sight in East Grinstead (UK)*†, the Clinique de la vision in Montpellier, France*; the Centre Ophtalmologique de Laser Excimer en Tunisie in Sousse, Tunisia*†, and the Instituto Castañera Oftalmología in Barcelona, Spain*, where the lead surgeons were myself, Pierre Levy, Fethi Nouira and Jorge Castanera, respectively. This was a real-life, retrospective analysis, not an investigative study. All patients received LASIK, and were given either PROSCAN® (n=62) or Zyoptix HD† (wavefront aspheric, n=64) treatments; assessments were made pre-operatively and at 1 day, 1 week, and 1 month post-operatively. In the Zyoptix HD group, 95 percent of eyes achieved 20/20 UCDVA versus pre-op BCDVA of 94 percent, showing good efficacy of the procedure; similarly, 100 percent of eyes were within 0.5 D of the intended value (in spherical equivalent), indicating its good predictability. In the Proscan group, 100 percent of eyes achieved 20/20 UCDVA (Figure 1) and 100 percent of eyes within 1.0 D and 97 percent were within 0.5 D of the intended value (in spherical equivalent).

This model does more

So what have I gained by upgrading from the Model 1 to the Model 2? The Model 2 does everything the Model 1 can do, but far faster, with greater ease, and, I believe, with a potentially higher level of accuracy. But there is more to come: our current work is examining the feasibility of using the Model 2 for transepithelial PRK and topography-guided LASIK.

Why use it for transepithelial PRK? Because it turns the procedure into an all-laser ablation – you don't touch the cornea at all. This "no-touch laser" approach appears to give more consistent removal of the epithelium; it's customizable, faster and healing should be faster too. Regular corneas should experience less pain, because only the epithelial area affected is where the laser ablation takes place, and in turn, corneal nerve endings are lasered – unlike regular PRK, there is no removal of excess epithelium and exposed nerve endings outside the area of laser ablation.

Our own work, which followed a feasibility study indicated that the average OCT-measured corneal thickness was 54 µm and was similar centrally and in the mid and far peripheral areas. Transepithelial PRK initially removes the epithelium, which takes 14 seconds. That's less than half the time required to delaminate epithelium by putting alcohol in the eye for 30 seconds alone, never mind the time to scrape the epithelium and then allowing the surface to dry before laser ablation! When performing PRK, the actual treatment requires only 2 seconds for a refraction of +1.00 and -1.50 astigmatism. Not only is the Transepithelial PRK very rapid, but subsequent healing is potentially too. Visual outcomes appear to be excellent – a contact lens is placed after the procedure, epithelialization typically completes within three days. In essence, the new procedure turns Transepithelial PRK from a two-step treatment to a one-step treatment process.

What is the rationale for topography-guided LASIK or PRK? Simply put, it's likely to further improve refractive outcomes in hyperopes, those with high astigmatism and other instances such as decentered pupils where the visual axis is not aligned with the center of the pupil. In addition, topography-based guidance should help correct coma, irregular astigmatism, decentration and poor distance visual acuity resulting from previous ablations to an even greater standard than before, and in the right cases, can be used in patients with forme fruste keratoconus for the treatment of photopic symptoms such as glare, halo and distortion.

Conclusion

The Teneo 317 Model 2 is fast and responsive, intuitive to use, and in my opinion, the initial results have provided good outcomes. There's more to come, and we're really looking forward to innovations and features like transepithelial PRK and topo-guided treatments coming to the market. Much like my Tesla, the Model 2 has significantly improved our efficiency and speed, and it is a delight to have!

References

1. *Based upon a standard myopic treatment and 6 mm optical zone*
2. *RR Krueger, SL Trokel, "Quantitation of corneal ablation by ultraviolet laser light", Arch Ophthalmol, 103, 1741–1742 (1985). PMID: 4062643*

Therapeutic Indications and Latest Technology on the VICTUS® Femtosecond Laser Platform

TOBIAS NEUHANN, Medical Director, AaM Augenklinik Marienplatz Munich, Germany

Femtosecond lasers for cataract surgery have been on the market for over five years now, but the questions for me are: has the technology advanced over this period, and if so, what advances have been made?

I have been using the latest B+L VICTUS femtosecond laser platform for over a year now, and I can tell you that it has a number of key features that are really improving my patients' outcomes. The feature list is long, and I appreciate the VICTUS' ability to create LASIK flaps and perform different kinds of keratoplasty, but in terms of cataract surgery, there are three key ones that I want to focus on as they are the most important in terms of improving patient outcomes.

The OCT is central to centration on the visual axis

The first is the latest Swept Source OCT system (Figure 1). It has a very high resolution, it displays a live OCT image throughout the procedure and performs 50,000 A-scans per second – I view it as almost having a "filmic" quality! The system also has enhanced contrast sensitivity compared with previous instruments, and the new software offers the automatic recognition of the pupil, lens thickness and the anterior and posterior capsule.

There's a long list of features, so let's get that out of the way: various software optimizations, not least an advanced identification management system; an improved OCT capability; soft docking, which is quite important for cataract surgery; and, perhaps most impressive of all, the new apex centration system – all of which can be seen in a surgical video of mine, available here: https://youtu.be/-6VkDF0G7gQ.

Figure 1. The new Swept Source OCT system: 50,000 A-scans per second enhanced contrast sensitivity, plus automatic recognition of the pupil, lens thickness and the anterior and posterior capsule. See the OCT in action online as part of femtosecond laser-assisted cataract surgery at: youtu.be/-6VkDF0G7gQ

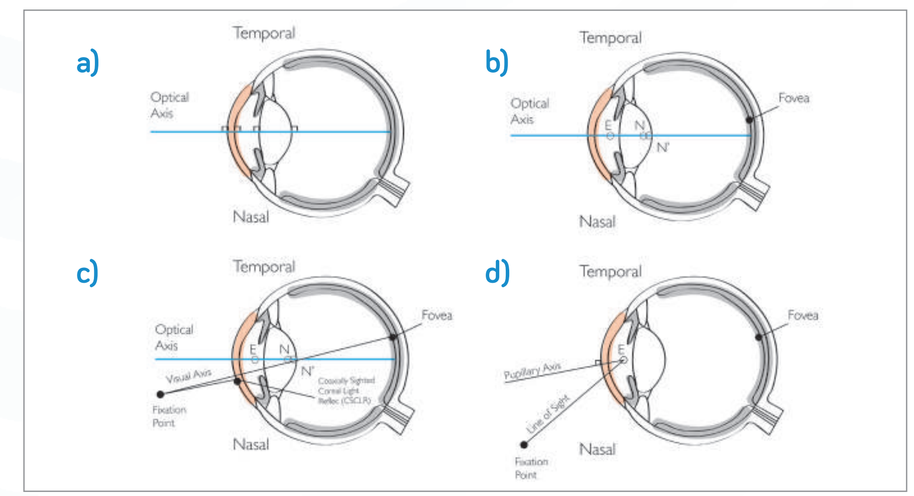


Figure 2. a. The optical axis of the eye (a purely theoretical construct where the surfaces of the cornea and crystalline lens are rotationally symmetric and their centers of curvature lie on a common line). If a point source was shone into the eye, there would be a point where all the Purkinje images coincide – the line from the point source through each Purkinje image would define the optical axis. In real eyes, the Purkinje images do not align and the surfaces are not rotationally symmetric, so no true optical axis of the eye exists. Occasionally, the optical axis is defined as the line that minimizes the deviation of the Purkinje images; b. The fovea, the center of the pupil, E, and the nodal points N and N'; c. coaxially sighted corneal light reflex (CSCLR), where the line from the fixation point that is normal to the cornea defines the CSCLR; d. The pupillary axis (perpendicular to the cornea, found by aligning the first Purkinje image with the center of the pupil) and the line of sight (connecting the fixation point to the center of the entrance pupil).

With all of the axes in the eye (Figure 2), it can be hard to decide how to center your laser capsulotomies (or even more so, manual capsulorhexes). I strongly believe that it's best to center the capsulotomy on

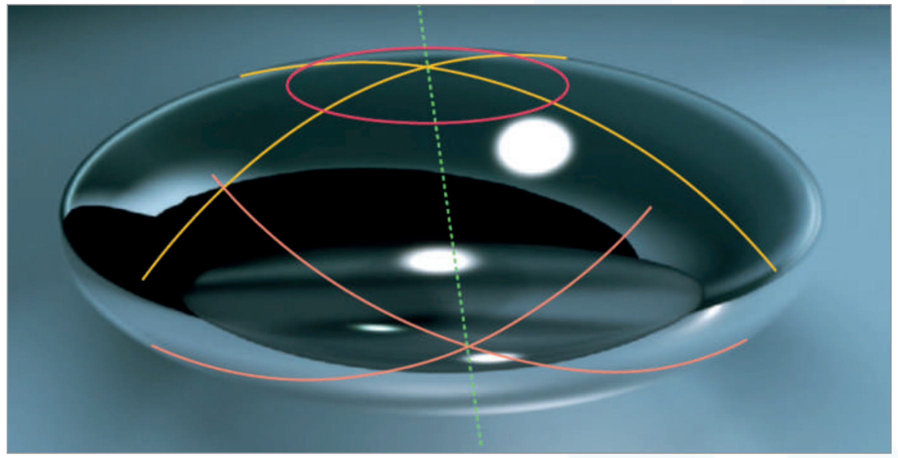


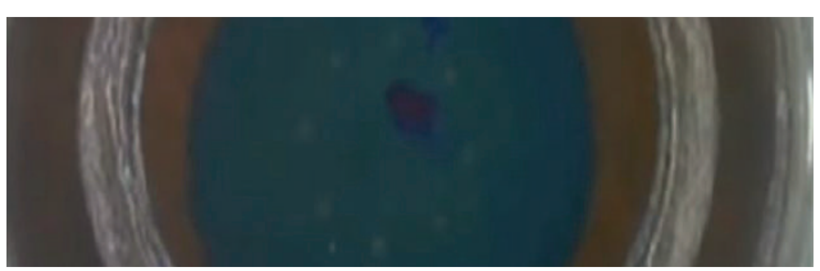
Figure 3. VICTUS' OCT enables you to center the capsulotomy on the visual axis by calculating 0° and 90° on the surface of the anterior and posterior capsules. You center the capsulotomy where the lines cross, enabling you to find the apex of the lens.

Box: Using the VICTUS for DALK

One of the best features of using the VICTUS for DALK is the entirely atraumatic nature of incising the donor cornea: you don't press the trephine against the cornea; you just dock the donor cornea and divide the corneal tissue with the laser. It's not only gentle, but very fast too – at least as fast as performing a manual trephination – and it results in a perfect edge in the donor button.

It's then a case of proceeding with the DALK as normal: putting the donor button in medium, creating a big bubble in the patient's eye with a 30 G needle, and cutting a flap in the deep stroma without damaging the Descemet's membrane, then you're at the stage where you insert the donor into the recipient eye. To finish, you simply stitch the donor transplant in place.

But is the future of DALK no longer a circular transplant, but a decagonal one? Back in the 1960s, Barraquer tried transplants with four edges, so there is a precedent: he figured that the edges would stop the donor from rotating (as can be the case with circular transplants). It's only really now, with femtosecond lasers, that we can construct a decagonal transplant with an outstanding fit to the patient. Hopefully, the software that permits this will be broadly available soon.



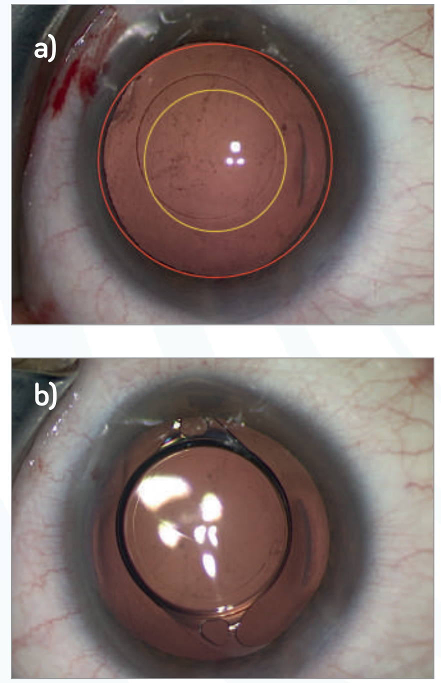
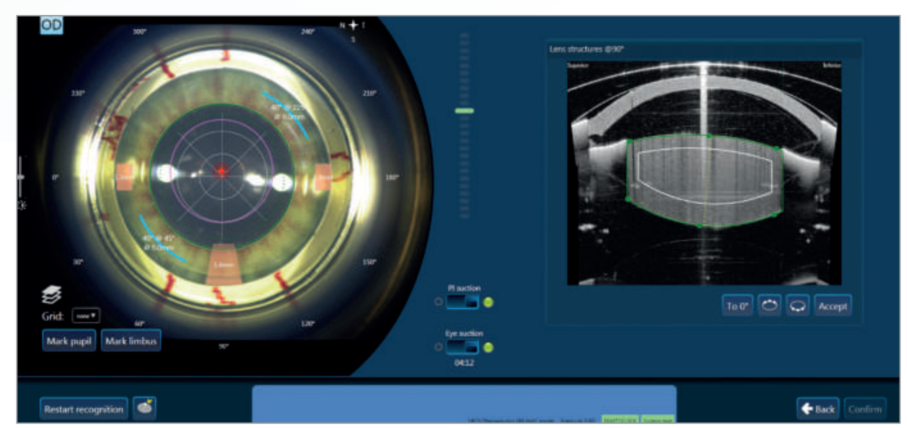


Figure 4a. The difference between a capsulotomy centered on the pupil (red and yellow circles) and the apex of the lens (actual capsulotomy) as determined by OCT; b. The same eye once the IOL is implanted. The IOL looks decentered – but is not! The symmetry between the edge of the anterior capsule and the edge of the implant proves that an apex-centered capsulotomy is superior to a pupil-centered capsulotomy.

the visual axis, and the OCT supports this by calculating 0° and 90° on the surfaces of the anterior and posterior capsules. Where the lines cross (Figure 3), you center the capsulotomy – which enables you to find the apex of the lens. Without this, most of us would center the capsulotomy on the pupil center (which is easiest) – but there is a noticeable difference in positioning (Figure 4). But, in my experience, the result of using the VICTUS' OCT-guided method is that the center of the lens is optimally positioned in the capsular bag, centered on the visual axis. This is particularly important for aspheric, toric and multifocal lenses, and it's now easy to do something that was previously very difficult – and it's all thanks to the VICTUS apex centration capability.

VICTUS: Applications

		Commercially available? CE	Commercially available? USA
Cataract	Capsulotomy Lens Fragmentation Arcuate Incisions Corneal Incisions	Yes	Yes
Therapeutic Applications	Penetrating Keratoplasty Intracorneal Ring Segments Lamellar Keratoplasty Corneal Crosslinking	Yes	No
Corneal Flap		Yes	Yes



The Victus and its simple, clean user interface.

"Fixating the IOL on the anterior capsule means it is closer to the iris and hence will not create any negative dysphotopsia."

The 'conditio sine qua non' for next-gen IOLs

The optics of IOLs are becoming increasingly sophisticated, and apex centration should now be considered a mandatory tool for sophisticated IOLs such as aspheric monofocal, multifocal or trifocal toric IOLs. The latest VICTUS system's high-resolution OCT is definitely superior to a Purkinje image and will be the 'conditio sine qua non' for the next generation of IOLs. It will enable more patients to benefit from the advantages of these IOLs, should help avoid the specter of negative dysphotopsia (especially the outer dark arc which patients often complain about and for which there is no real solution), and events like capsular phimosis and post-operative toric IOL rotation. When you look at some of the most recent IOLs to come to the market with a groove in the optic edge, that "hooks" the lens in place at the anterior capsule; you start to see the benefits of the femtosecond-laser rhexis approach: when you implant this lens in a standard eye, via an apex-centered capsulotomy, phimosis can't occur, because the anterior capsule sits inside the lens, and the lens cannot rotate. Fixating the IOL on the anterior capsule means it is closer to the iris and hence will not create any negative dysphotopsia. I have no doubt that this will be the next generation of IOL optics.

The VICTUS® Femtosecond Laser Platform in a Public Hospital Setting

THOMAS POOLE, Consultant Ophthalmic Surgeon at Frimley Park Hospital, Frimley, Surrey, UK

I work in the UK's National Health Service (NHS) in a 750-bed acute hospital near London. We employ 25 ophthalmologists, including six trainees, and cover all major subspecialties. Naturally, we are subject to the same cost containment pressures as any other NHS unit – but does that preclude the purchase of FLACS instruments? Not necessarily – you just need to think about the way you apply the technology within the constraints of your economic environment.

In operating theatre economics, there are fixed costs (mainly related to nurses and surgeons) and variable costs (primarily consumables per operation) – but there is also income per operation. What that means is that anything that helps you perform more operations per unit time may pay for itself – provided it does not also generate excessive increases in consumables costs. We decided that a laser could be a cost-effective purchase – our projections indicated that a femtosecond pathway would allow two extra patients on each cataract list.

Making it work: theory

Our predictions suggested that having access to two operating theatres was a key enabling factor. With a single laser feeding two theatres, we expected to be able to really benefit from process efficiencies. But we also knew we had to allow for the increased pressure on ward space implied by the increase in operations per unit time: this involved some pathway redesign in readiness for the laser. We also decided to move to Mydriasert + Flurbiprofen for pupil dilation, which we knew would save nurse time on the ward.

We also expected that stakeholder buy-in and careful teamwork would be fundamental to the successful introduction of the new system – hence the principle that the femto laser would be for everyone, from the most junior ophthalmologists all the way up to senior consultants. Also, remember that in a public health setting there is often more than one surgeon on the operating list – we figured that would enable us to have one surgeon in the laser room all the time.

To ensure that we could enjoy the cost benefits of the laser, we planned to move to cataract-only operating lists – local anesthetic only, avoiding complicated cases such as uveitis or traumatic cataract, and avoiding small pupils and toric lenses where possible. There was another key consideration: avoiding patients require a long time to be hoisted onto the operating table – for example, the very frail. So by eschewing cases which would slow us down, streamlining our processes – and, importantly, by retaining adequate theatre staffing levels, we thought we would maintain high operating throughput and see laser-associated cost efficiencies… and outcomes.

> "If you achieve a really good docking on the femto, you get a fantastically quick capsulotomy."

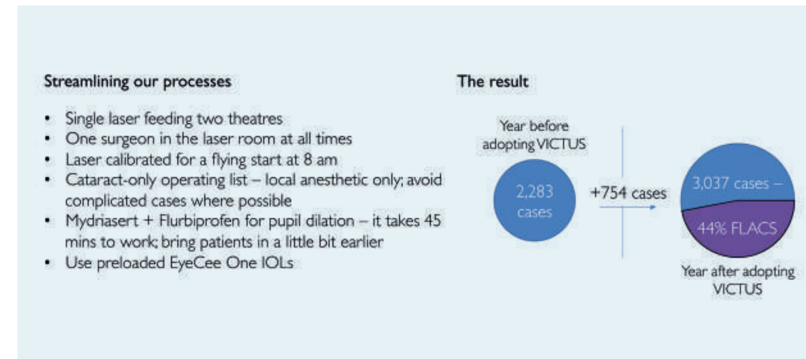
As always, there are real-world practical issues to contend with: getting somewhere to install the VICTUS required the cataract service to reclaim an injection room from the medical retina service – a rare victory! In terms of the day-to-day practicalities, I was initially concerned that our more elderly patients might not actually get under the laser, as the bed doesn't have the same degree of movement as an ordinary operating table – but in fact that kind of problem is very rare, as the VICTUS table head is actually quite flexible.

We also found that timing is very important: for example, Mydriasert requires 45 minutes to take effect, so we need to bring in our patients a little bit earlier. We also need the laser properly calibrated for a flying start at 8 am in the morning – that really helps. Our femtosecond laser with the latest software and setup has also contributed to overall efficiency: if you achieve a really good docking on the femto, you get a fantastically quick capsulotomy, and that gives you greater confidence because you know you are not going to get a tag. The latest laser setup has also improved the frag step: nuclear segments cleave more easily during phacoemulsification. Another pertinent development has been our adoption, this year, of the EyeCee One lens. By using this preloaded device, we save further time, as you don't need to spend an additional minute or so loading a lens into the injector: over ten patients, this saves you the time for a coffee break!

Making it work… in practice

So how have these changes affected our operational throughput? The results are very clear: 2,283 cataract operations in the year preceding laser adoption vs. 3,037 in the following year (Box 1). This represents an extra 754 cases, which was a 25% increase in capacity. Of the 3,037 operations carried out in the year after laser purchase, only 44% were carried out with the laser; I'd hoped for a higher percentage, but it's inevitable that some surgeons will prefer to do things as they did before, and that some patients will not meet the criteria for the FLACS list. I expect a higher proportion of laser surgeries next year.

Box 1. By adopting VICTUS and streamlining our processes to accommodate it, we managed to perform 754 more cases in the year after adopting the femtosecond laser than in the year before.



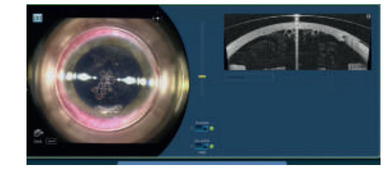
Data courtesy of Thomas Poole

On a day-to-day basis, throughput improvements depend on what trainee I have with me. If I have a very junior trainee, a pre-laser list of 6 cataracts might get bumped up to 8 with the laser; with a more senior trainee with me, a pre-laser list of 8 might get pushed up to 10. In all cases, the patient flow is critical: we achieve our best efficiencies by having three surgeons operating at the same time – one surgeon in each operating theater, and one surgeon in the laser room feeding his two colleagues. Our experience is that the femtosecond surgeon easily keeps ahead of the two phaco surgeons. The bottom line is: after all of this planning, we have a fast and efficient process: from the treatment time with the laser, to the phaco, to the lens insertion.

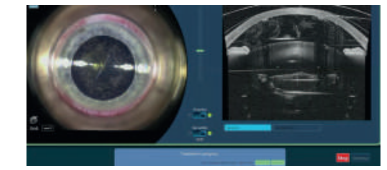
Special cases

The VICTUS isn't just limited to standard cataract cases. Arcuate incisions are very easy to do with the VICTUS – with live OCT you can adjust the arcuate incision depth for the optimal outcome. It only adds another two minutes to the laser room cataract surgery. And the beauty of VICTUS is that you can use it in cases of very low delta k: so if somebody has an 'against the rule' of 0.75 D, I may do a couple of little arcuate incisions to get their cylinder down. But similarly, a 90-year-old patient who wishes to wear glasses post-operatively, and who has a high cylinder – maybe 3 to 3.5 D – can also be treated with the laser to reduce that cylinder to 1 D. So the VICTUS gives us another option – we don't necessarily need to insert a toric lens. Indeed, while we perform arcuate incisions in 21 percent of FLACS operations, in the year before VICTUS we used 133 toric lenses – but only 75 in the year after VICTUS. This 44 percent reduction in toric lens use provides not only a small saving in costs, but also savings in theater time and surgeons' administrative time for toric lens ordering.

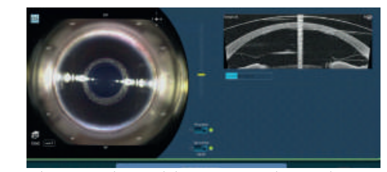
Box 2. View the VICTUS-in-action videos.



a. Laser arcuate incisions. Visit: youtu.be/MeWsx9X70XA



b. Lens fragmentation. Visit: youtu.be/4KmddPiT6A8



c. Intrastromal corneal ring segment pocket creation. Visit: youtu.be/4quGERQ2k7A

Videos courtesy of Thomas Poole

Finally, we've also been using the VICTUS for corneal surgery – it's very versatile! I used to cut my corneal ring inserts by hand, but now I do them with a femtosecond laser, which is a heck of a lot easier! We have also been doing penetrating and deep lamellar grafts, which has been great fun.

In summary, the VICTUS has enabled significant efficiency improvements in my NHS ophthalmology unit; it has been the catalyst which enabled us to achieve more productive and cost-effective surgical procedures and theater processes. When used correctly with a team of surgeons, FLACS is fast, accurate, and efficient.

Clinical Experience with enVista®

LUIS CADARSO, Medical Director at the Clínica Cadarso, Vigo, Spain

When you're choosing IOLs to offer your patient, there are a number of fundamental aspects you need to consider before making that decision: an excellent biomaterial, high-quality optics, and crucially, in the case of astigmatic patients, excellent rotational stability of the lens. I regularly offer the enVista IOL to my patients – so let's consider whether enVista fulfills these needs or not.

enVista lenses are made from cross-linked homogeneous, hydrophobic acrylic material, with excellent dimensional and thermal stability. It has a high refractive index – which is important (especially in toric versions) as it makes the lens very thin – although it also has a high modulus, meaning that the lens maintains its mechanical properties, despite its svelte dimensions. It has durable optical surfaces, which both resist both scratches during implantation, and Nd:YAG laser damage (1). It comes supplied pre-hydrated in 0.9% saline to equilibrium, and therefore has optimized water content. But most importantly for me, the material has been shown over a number of years now to be stable and glistening-free – in fact, it was the first clinically-proven glistening-free hydrophobic acrylic IOL brought to market (2,3).

Let's examine the optics. Here, we have some advanced optics with aberration-free surfaces, which should result in reduced post-operative spherical aberration with no image degradation with decentration, a lens that is less sensitive to tilt, and with an enhanced depth-of-field, and that includes axis marks.

Let's examine the haptics. The enVista haptic design (Box 1) enables a wide contact angle within the bag – maxing out at 56°, for post-operative stability and less risk of ovalization of the capsular bag. Fenestration holes limit the transfer of capsular contraction forces into the optic – and improve intraoperative handling (especially for the toric versions). We all know postoperative rotational stability is crucial for maintaining the performance of toric IOLs (e.g. 10° off axis will reduce correction by 30 percent; 30° off axis abolishes any astigmatism correction; 90° off axis doubles astigmatism). enVista's FDA submission clinical study shows that the lens is rotationally stable – in the best-case analysis set, 92 percent of eyes exhibited 5° or less of rotation between operative day and the 4- to 6-month post-operative visit. The haptic design brings another advantage: the small anterior offset relative to the optic (~0.2 mm), that has been designed to vault the optic posteriorly for direct contact with the capsular bag, along the sharp-edged (R~10 µm) 360° posterior square edge (Figure 1), helping the lens guard against PCO – one study showed that the incidence of Nd:YAG capsulotomy rates over 3 years was only 2.2 percent (5/126 eyes) (4).

As a cataract surgeon, you'll know that some IOLs are easier to inject and handle than others – I found that injecting and implanting the lens is very easy; unfolding is smooth, and it is very easy to rotate the IOL inside the before the lens is completely unfolded – once the IOL is completely unfolded, it becomes very stable on the axis.

The IOL plane corrects for the corneal plane in a standard ratio, determined by the effective lens position (ELP) – but we should know that in non-standard ELP calculations; for example, in extreme eyes, we may over or under correct. In eyes where the ELP is shorter, this decreases this ratio: flatter corneas and short axial lengths result in overcorrection; larger ELPs increase this ratio (deeper corneas and long axial length result in under correction) – but these issues are only really relevant for non-standard/ highly astigmatic eyes. In any event, there is an online enVista toric cylinder power calculation website that takes into account pre-operative corneal astigmatism and combines it with predicted surgically-induced astigmatism to calculate the expected post-operative corneal astigmatism and recommend an IOL cylinder power. I do also use other online calculators that use the ELP of the patient to calculate cylinder power, and I have to say that I have never one used a lens that wasn't suggested by the enVista toric calculator.

I had the opportunity to participate in the EU enVista toric registry, with the following study design:

- Standard of care
- No patient selection
- No specific endpoint
- Routine assessment

Box 1. enVista toric registry study design.

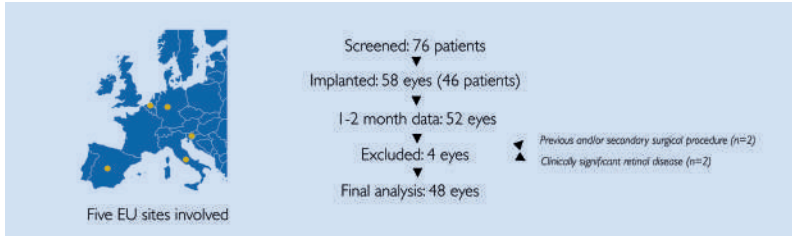


Table 1. Pre-operative refractive patient/ eye characteristics (52 eyes, 41 patients).

Measurement	Value	
IOL spherical equivalent power	15.5 to 25.50	Median: 21.50
IOL cylinder power	1.25 D (n=28) 2.0 D (n=11) 2.75 D (n=13)	
Gender	13 males/ 28 females	
Age category	<60: 4.9%	60–69: 19.5%
	70–79: 53.7%	≥80: 22.0%
Incision size	2.2 to 3.0 mm	
Incision on steep axis	45.8%	
Preoperative corneal astigmatism	1.57 D (0.61)	Range: 0.85 to 2.95 D
Expected postoperative residual cylinder	0.20 D (0.16)	Range: 0.00 to 0.68 D

Data on file, B+L Study #792_2012.

Table 2. Uncorrected distance visual acuities (UDVAs) at 3–6 weeks postoperatively.

UDVA	3–6 weeks (n=47)
20/25 or better	51.1%
20/32 or better	78.7%
20/40 or better	87.2%

Data on file, B+L Study #792_2012.

Table 3. Final manifest refraction spherical equivalent (MRSE) predictability at 3–6 weeks postoperatively.

MRSE: accuracy to target refraction	3–6 weeks (n=44)
± 0.50 D	75.0%
± 1.00 D	95.5%

Data on file, B+L Study #792_2012.

Table 4. Effectiveness of the intervention – proximity to targeted refraction and cylinder.

	3–6 weeks (n=44)
Residual manifest refractive cylinder	-0.55 ± 0.39 D
% within 1.0 D of the target	93.2%
Mean reduction in cylinder in percentage	75.2%

Data on file, B+L Study #792_2012.

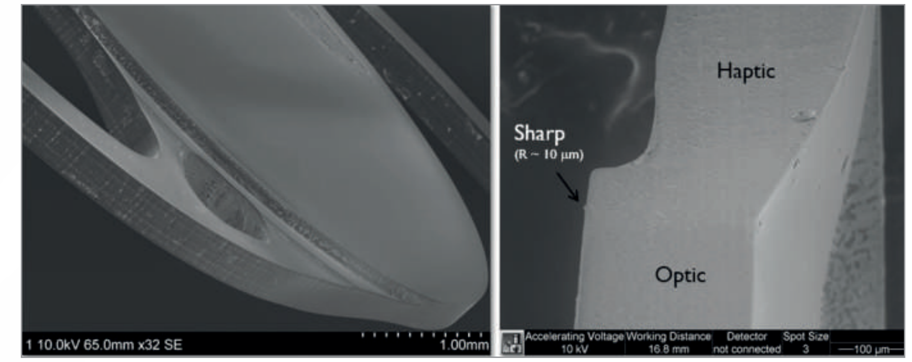


Figure 1. Anti-PCO features of the enVista IOL haptics and optics: a Continuous 360° posterior square edge, a sharp edge radius (R ~ 10 µm), an anterior offset of haptics relative to the optic, designed to vault the optic posteriorly for direct contact with the capsular bag. Images courtesy of David Spalton.

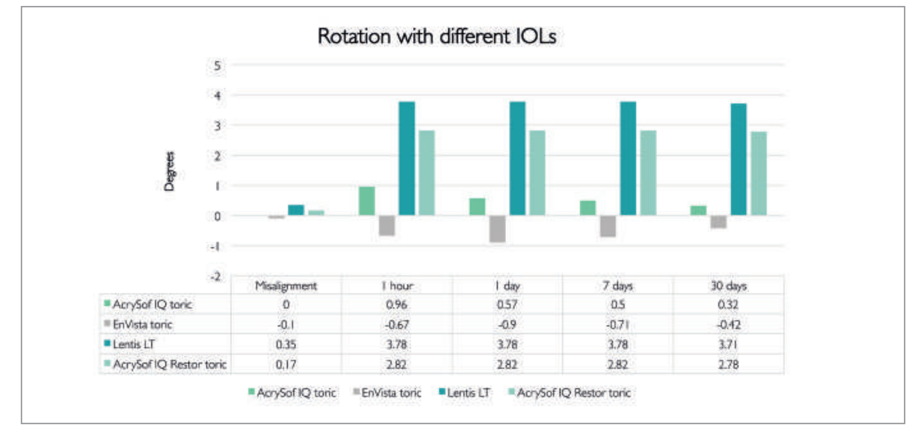
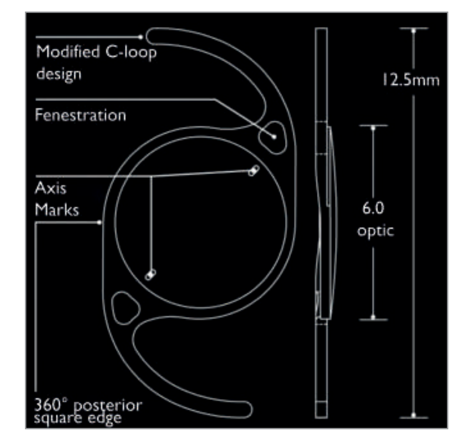


Figure 2. A comparison of toric IOL rotation 1 hour after surgery (6). Negative values indicate anti-clockwise rotation and positive values indicate clockwise rotation.



Box 1. enVista toric lens specifications. Note the modified C-loop haptic design that increases contact with the capsular bag and minimizes rotation and the 360° posterior square edge that minimizes PCO formation.

Five EU sites were involved, from Spain, Germany, the Netherlands, Slovenia and Italy; 77 patients were screened, 56 eyes (from 44 patients) implanted; 52 eyes from 41 patients were included in the analysis. Four eyes were excluded from the analysis: one eye, because of a secondary glaucoma surgery, one eye with lens haptic damage during the injection procedure, and two eyes because of clinically significant retinal disease (CDVA less than 20/32) (Box 1).

Tables 1–4 show what we found. These are good results (5) – and they're supported and reinforced by the work of Garzón et al., (6) who found that 90.5 percent of patients implanted with enVista toric after 30 days were within less than 5° of rotation (Figure 2). Packer et al. found that 92 percent of eyes exhibited 5° or less of rotation between implantation and 4-6 months later (7). My personal outcomes are similar – at 3 months, 88 percent of patients were within ± 0.5 D, and 91 percent of patients within less than 5° of rotation.

So what have we learned? The enVista is a high-quality aspheric toric IOL, made from glistening-free hydrophobic acrylic material. It is easy to implant through a 2.2 mm incision and has a high safety (3,7) and effectiveness profile, plus excellent stability with regards to rotation centration and tilt thanks to its advanced haptic and optic design. What's most interesting about this lens, though, is that it was launched seven years ago; it was the first glistening-free IOL to the market, and there's now a wealth of clinical experience to back up this claim. It's a testament to the engineers that their innovative designs and material have stood the test of time.

References

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