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Patient movement may affect FLACS
Pre-op conversation, informed consent are useful strategies

VIDEO Unexpected head movement can lead to suction loss

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A partially regenerated lens behind an IOL post-cataract surgery in a 75-year-old patient. The IOL and large anterior capsular opening limited complete regeneration of the lens.
(Image courtesy of Dr Kang Zhang)
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With the toric version of our unique LENTIS® Comfort lens – the pioneer in modern EDOF-lens technology (Extended Depth of Focus) – you now have the perfect tool to correct astigmatism. The LENTIS® Comfort^toric is available with standard cylinders ranging from 0.75D to 5.25D in steps of 0.75D. Calculating and ordering of this toric lens is done easily in two simple steps using our Easy Toric Calculator at [www.lentistoric.com](http://www.lentistoric.com).

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![Diagram of the Düsseldorf Formula](image)

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Laser cataract surgery amid capsulotomy transformation

Surgeons point to benefits of reproducible and uniform shape, size

By Dr George O Waring IV

In the short time surgeons have been performing femtosecond laser-assisted cataract surgery (FLACS), it has become obvious the technology facilitates creation of a precise and accurate capsulotomy.

As settings continue to be refined, surgeons will almost certainly see further improvements in clinical outcomes with femtosecond laser capsulotomy.

For example, Dr Wendell Scott, has explored the effects of different vertical spacing and incision depth settings on the quality and speed of the laser capsulotomy.1

Work like this mirrors what surgeons saw in the evolution of femtosecond laser LASIK flaps. Early flaps were not superior to manual flaps but as settings were refined and surgeon experience with the lasers grew, laser flaps quickly outpaced what had been previously possible with manual flaps.

The size of laser capsulotomies has been shown to be more uniform and predictable as well as more circular than manual capsulotomies.2 Debate still exists on the overall clinical utility of femtosecond laser-enabled capsulotomies.

Several distinct clinical advantages may result from these attributes. Perhaps the most important benefit may be the increased likelihood of achieving a uniform, 360° anterior capsule-optic overlap which should reduce lens tilt and decentration—both of which are particularly important when implanting tilt-intolerant toric or multifocal lenses. If there is a less-than-perfect or non-circular manual rhexis that extends to or beyond the optic edge, the potential for anterior optic capture (leading to tilt) increases.

Uniform capsulotomy size and shape could also contribute to more uniform capsular contraction, which may be important in controlling for effective lens position (ELP).

However, that may not entirely solve the riddle of ELP. For that, it may be necessary to truly modulate the wound-healing process by eradicating lens capsule epithelial cells or by removing the scaffold for LEC proliferation via primary posterior capsulotomy, as described by Dick and Schultz.3

Although patient and surgical flow issues still remain, the femtosecond laser has the potential to make primary posterior capsulotomies more routine.

Finally, the consistency of the laser capsulotomy can be beneficial in complex cases. Patients with short eyes, tight anterior chambers, and poor dilation benefit from the predictability of the femtosecond laser.

IN SHORT

Femtosecond laser-assisted cataract surgery will continue to lead the transition to a new era in ophthalmology with more precise, customizable, and reproducible capsulotomies.
In the rare event of posterior capsular compromise, the femtosecond-enabled uniform size and shape capsulotomy lends itself well to optic capture, where consistent apposition of the optic and capsule is essential for successful sulcus placement and maintenance of centration and proper positioning of a three-piece lens.

The same line of reasoning applies in the rare event of negative dysphotopsia or a consistently rotating toric IOL, where a patient may benefit from a reverse optic capture maneuver, in which the optic is maneuvered to rest anterior to the anterior capsule. In such a case, a perfectly circular and sized anterior capsule is more likely to capture the optic in a uniform, planar configuration with less chance of tilt.

There is conflicting evidence on the strength of laser versus manual capsulotomies.

Further studies are needed, but I am fairly confident that as laser hardware and settings are optimized—such as increasing the spot and line separation, increasing the laser speed, and with improvement in patient interfaces—the tensile strength of laser capsulotomies should continue to improve from what is already excellent.

**Centration**

Proper centration of IOLs—particularly multifocal IOLs—is key to success. Surgeons and the ophthalmic industry are working to improve IOL centration on a number of fronts, ranging from better centration techniques that rely on the subject-fixated coaxially sighted corneal light reflex (SFCSCLR) to the use of advanced surgical guidance systems.

Femtosecond laser capsulotomies can be beneficial, as well.

In addition to the benefits of uniform capsular overlap described above, the Catalys laser (Abbott Medical Optics) provides the ability to center the capsular opening on the capsule itself, rather than on the pupil.

In my practice, the “scanned capsule” capsulotomy setting has become the default in most cases, except those with very small pupils. It is important to note that in addition to centering on the scanned capsule, multifocal IOLs can be centered on the SFCSCLR intraoperatively I prefer a relatively tight range for the capsule diameter. My ideal capsulotomy is 4.9 mm in diameter, which is easier to routinely achieve with a programmable, automated laser capsulotomy.

My minimum femtosecond enabled diameter in eyes with poor dilation is 4.7 mm, and I will sometimes go as high as 5.1 mm, particularly in mature cataracts.

In eyes with poor dilation due to use of tamsulosin or other medications, it can be challenging to get the desired size capsulotomy with capsule-centered because of the system’s safety zones that prevent encroaching on the iris margin. In such eyes, my default setting is maximized and centered on the pupil.

In cases where sufficient diameter is still not realized, I use a manual override technique to optimise the diameter, in which the captured iris boarder is enlarged to larger than what is captured, which allows the rhexis to expand out to the iris margin when necessary.

The goal is a uniform shape that produces a uniform overlap. Being able to manipulate the laser’s diameter and centration settings helps to avoid decentration.

**Future developments**

Already, much has been learned about the variation of crystalline lens anatomy. Not only is there wide inter-patient and inter-eye variation in capsule dimensions, but there is also the finding that capsule dimensions relative to axial length may be important.

In the future, IOL companies may begin to focus more on the potential for sizing lenses to the capsule in order to improve ELP. The concept of a primary posterior capsulotomy to reduce capsular contraction and possibly primary optic capture techniques is exciting. Much of this is due to the fact that this is now imaged-guided surgery.

Capsulotomy-fixated IOL designs have also been proposed by a number of surgeons, including Dr Julian Stevens; Dr Burkhard Dick; Dr Sam Masket; and Dr Roberto Zaldívar.

**REFERENCES**

Patient movement may interfere with laser-assisted cataract surgery

By Fred Gebhart

Femtosecond laser-assisted cataract surgery (FLACS) is a latest advance in technology that is transforming traditional cataract surgery into a refractive procedure. Multiple studies have shown that laser-assisted cataract surgery can increase precision and reproducibility of the anterior capsulotomy, reduce effective phacoemulsification time, cause less postoperative inflammation to the anterior chamber, and possibly reduce surgically induced endothelial cell damage.

However, it is discussed much less often that the safeguards built into FLACS instruments can fail and allow the femto laser grid pattern to be delivered into the cornea.

“We think this is what happened to one of my patients,” said Dr Sonia Yoo, professor of ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine. “Suction was lost during lens segmentation. The segmentation pattern that was intended for the lens nucleus unintentionally treated the cornea.”

The good news is that the unintentional corneal scoring had no effect on the visual outcome, Dr Yoo noted.

The patient had uncorrected 20/20 vision the day after surgery and still had 20/20 vision on her last exam a year after the incident. But because of the unexpected treatment of the patient’s cornea, she implanted a monofocal lens rather than the planned multifocal lens.

“The patient was quite happy with 20/20 vision,” Dr Yoo said. “Even with the monofocal lens, her vision was so much better than it was pre-op that she was perfectly happy with the result. But this still points out that unexpected head movement can lead to suction loss and displaced laser beam delivery despite safety mechanisms of the femto platform, allowing the femto-laser grid pattern to be delivered into the cornea.”

Misplaced laser beam delivery is not a common occurrence. Dr Yoo said she found just one similar event in literature, submitted by one of the session discussants, Dr Samuel Masket, Founding Partner of Advanced Vision Care and Clinical Professor of Ophthalmology Times Europe

In Short

Though femtosecond laser technology is transforming the surgical arena, it is discussed much less often how safeguards built into such instruments might fail and allow the femto laser grid pattern to be delivered into the cornea. Here are some tips.
Ophthalmology at the Jules Stein Institute, David Geffen School of Medicine, University of California, Los Angeles. The common contributing factor to both events was patient movement. Dr Yoo’s patient was moving so much she needed three attempts to dock and establish suction.

Once suction was established on the third try, the femto platform safety mechanisms should have detected the subsequent loss of suction and blocked the laser pulse. Instead, it appears that the conjunctiva occluded the suction holes, which prevented the platform from detecting the loss of suction and allowing the laser to fire after the eye had moved and delivering the segmentation pattern to the cornea.

Fortunately, the patient had a healthy Bell’s response and the eye had rolled up and out as she began to blink. The laser treatment was limited to the inferior third of the cornea and there was no damage to the central cornea.

“I don’t know if applying the segmentation pattern to the central cornea would have made a difference in post-op vision, but I was relieved we didn’t have to find out,” Dr Yoo said.

“More than a year out, I can still see that grid pattern on her cornea, but there have been no visual sequelae. Dr Masket said he had a very similar case except that the grid pattern on his patient’s cornea faded over time.”

The incident reinforces the need to identify patients who might present difficulties for laser treatment that might not be as significant for traditional phaco. Patients with deep-set orbits or very small eyes could be present challenges to femto laser treatment.

Patients who are unable to hold still can also be problematic. Deeper sedation is not a viable option, Dr Yoo said. Not only must patients be alert, responsive, and able to focus on a bright light as directed during the procedure, they must also be able to move themselves in and out of a lying position for the instrument used in this procedure.

It is also important to realise that laser safety mechanisms can fail. While the laser should not be able to fire once suction is broken, it is possible that the device can sense suction even after the eye has moved if tissues such as the conjunctiva somehow occlude the suction holes.

Modifying the preoperative conversation and informed consent can be a useful strategy to deal with potential misadventures, she continued. The reality is that things do not always go as expected during any cataract surgery, not just FLACS. It particularly important to help the patient understand that surgical plans may change depending on how the procedure evolves.

“It is important to your pre-op discussion with the patient to explain that while you intend to use a laser and to implant a multifocal lens, there may be unforeseen circumstances which preclude the use of either and may require the use a monofocal lens in the interest of safety,” she said. “Safety for the patient is our first concern.”

Dr Yoo did not indicate any financial interest in the subject matter.

www.oturope.com
In the ever-expanding refractive arena, accommodating IOLs that correct both presbyopia and refractive errors are meeting patients’ high postoperative expectations by providing good vision for tasks at all distances.

The performances of two IOLs — the Crystalens AO IOL, labeled as an accommodating IOL, and the Trulign Toric IOL (both from Bausch + Lomb), which corrects presbyopia — were compared by Dr. Jeffrey Whitman in a prospective, non-randomized, two-arm study in which 100 patients received either the Crystalens AO or Trulign Toric IOL. While both IOLs correct presbyopia, the latter also corrects astigmatism. The Trulign IOL is not labeled as an accommodating IOL by the FDA.

The outcomes of the IOLs were compared based on use of a femtosecond laser platform (Victus, Bausch + Lomb) to create the primary incision and capsulotomy and for fragmentation of the nucleus or manual removal of the cataract. The patients were evaluated postoperatively at 1 week and 1 and 3 months.

The two patient groups were similar preoperatively. The mean cataract grades in the femtosecond laser and manual groups were 2.2 and 2.1, respectively, and the mean patient ages were 64.7 and 61.8 years.

Refractive results

At the 3-month evaluation, Dr. Whitman, who is in private practice at the Key-Whitman Eye Center, Dallas, reported that the uncorrected distance visual acuity (UCDVA) was slightly better in the femtosecond laser group than in the manual group. The mean UCDVA levels were 20/28 and 20/30, respectively. In both groups, 28% of patients had 20/20 or better VA; 70% and 62%, respectively, had 20/30 or better; and 88% and 82% had 20/40 or better.

At the same time point, the mean uncorrected intermediate VA (UCIVA) levels were 20/18 and 20/17; 68% and 76% had 20/16 or better UCIVA; 82% and 92% had 20/20 or better; and 96% and 98% had 20/32 or better.

Finally, at the 3-month assessment, the mean uncorrected near VA (UCNVA) levels were 20/28 and 20/26; 26% and 24% had 20/20 or better UCNVA; 74% and 80% had 20/30 or better; and 94% and 96% had 20/40 or better.

The femtosecond laser group had slightly better manifest refraction spherical equivalent results compared with the manual group. Dr. Whitman reported that the respective percentages of patients who were within 0.5 D of the target were 64% and 60%, within 0.75 D 86% and 78%, and within 1 D 94% and 92%.

Based on these results, Dr. Whitman commented, “Both cohorts had an excellent combination of uncorrected distance, intermediate, and near vision. There was no significant difference in the uncorrected vision between the femtosecond and manual cohorts at the 3-month evaluation. The femtosecond laser group had slightly better refractive accuracy. Additional analyses are under way to determine the time to visual stability of the UCVAs and MRSE at 1 week versus 1 month.”

“Both cohorts had an excellent combination of uncorrected distance, intermediate, and near vision.” — Dr. Jeffrey Whitman
Laser capsulotomy studies affirm low rate of anterior capsule tears

Refinement of settings, technique ‘game changers’ for free-floating capsulotomy

Significant evidence in the literature shows that use of a femtosecond laser consistently creates a capsulotomy with precise geometry, circularity, and sizing. Now, data from large studies also establish that the laser procedure is associated with a very low rate of anterior capsule tears, said Dr Tim Roberts.

“These are important points because the quality of the anterior capsulotomy is crucial to the safety and refractive outcome of cataract surgery,” said Dr Roberts, consultant ophthalmic surgeon and clinical senior lecturer, University of Sydney and medical director, Vision Eye Institute Australia.

Dr Roberts and colleagues at the Vision Eye Institute, Chatswood, reported their experience using a femtosecond laser platform (LenSx, Alcon Laboratories). In their prospective, consecutive series of 3,842 eyes, 7 eyes (0.18%) were identified as having a break in the anterior capsule rim.

However, further analyses showed the rate dropped significantly to 0.08% when the new soft contact lens patient interface (SoftFit) replaced the original rigid curved interface (0.08%, 2/3108 eyes versus 0.68%, 5/734 eyes, \( p = 0.004 \)).

Dr Roberts emphasized that the eyes in his group’s series was a consecutive cohort and included complex cases that may be at increased risk for anterior capsule tear—e.g., eyes with floppy iris syndrome, white cataract, pseudoexfoliation, and traumatic zonulopathy.

IN SHORT

› An analysis including almost 3,000 eyes operated on with modern femtosecond laser technology found an anterior capsule tear rate of <0.1%.

“... The anterior capsulotomy is crucial to the safety and refractive outcome of cataract surgery.”
— Dr Tim Roberts

FIGURE 1 Silt lamp images of circular, evenly sized, well-positioned, and intact capsulotomies created with the femtosecond laser.
Reviewing the literature on this topic, Dr Roberts cited a recent paper that similarly reported a very low anterior capsule tear rate of 0.1% when analyzing outcomes for 1,000 eyes operated on at Moorfields Eye Hospital, London, using another femtosecond laser (Catalys, Abbott Medical Optics) [Day AC, et al. J Cataract Refract Surg. 2014;40:2031-2034].

In contrast, an earlier study using the Catalys system reported a high rate of 1.8% in 804 eyes [Abell et al. Ophthalmology. 2014;121:17-24].

Dr Roberts said that the latter paper stirred controversy about femtosecond laser capsulotomy by hypothesizing that treating the capsule with a laser—irrespective of the platform used—may produce a germinative defect, rendering the capsule intrinsically weak.

“The high complication rate in the paper by Abell et al. focused attention on laser settings and surgical techniques used in laser cataract surgery,” he said. “There is no doubt that there will be ultrastructural differences in the capsule when the capsulotomy is created with a laser versus manually, but the important question is: From an evidence-based perspective, what, if any, are the clinical implications of these differences?”

When looking at the most recent published results of nearly 5,000 consecutive laser procedures from their group [Roberts et al. J Cataract Refract Surg. 2015;41:1109-1110] and the Moorfields group, using different laser systems, surgeons can now be confident that optimal laser settings and appropriate surgical technique will result in a perfectly circular, evenly sized and intact capsulotomy in nearly every case, Dr Roberts noted.

He added that the advanced new patient interface for the femtosecond laser platform and refinement of laser settings and surgical technique over time have been “game changers” for achieving free-floating capsulotomies with an extremely low rate of anterior capsule tear.

**Putting it into perspective**

Dr Tim Roberts, MD

E: tim.roberts@visioneyeinstitute.com.au

This article was adapted from Dr Roberts’ presentation at the 2015 meeting of the American Academy of Ophthalmology. Dr Roberts is or has been a consultant to Abbott Medical Optics, Alcon Laboratories, Allergan, Bausch + Lomb, Device Technologies, and Pfizer.

*FIGURE 2* Optical coherence tomography images and laser capsulotomy/lens fragmentation treatment patterns obtained with the femtosecond laser.
In a single-center study, investigators found that a proprietary femtosecond laser (Ziemer Femto LDV Z4) creates corneal flaps of comparable thickness to those of other femtosecond lasers but with a larger range, according to Dr Anam Qureshi. The laser also has a low intraoperative and postoperative complication rate.

“We found that there was variability in terms of the flap thickness with this laser, but we determined that it was probably more due to our measurement tools,” Dr Qureshi said, explaining that the researchers used ultrasound pachymetry, which is an indirect method of calculating flap thickness by subtracting preoperative corneal thickness and intraoperative residual stromal bed values.

Dr Qureshi and colleagues evaluated 159 eyes of consecutive myopic LASIK patients who were treated with the Ziemer Femto LDV femtosecond laser and Alcon Wavelight Ex500 Excimer laser. All procedures were performed by Dr J Bradley Randleman, at the Emory Eye Center, Emory University, Atlanta, Georgia, USA.

At the time of the study, Dr Randleman was a Professor of Ophthalmology at Emory University, while Dr. Qureshi was a Cornea, External Disease, and Refractive Surgery fellow. Dr Randleman is now at the University of Southern California, Los Angeles, while Dr Qureshi will join New York University as an Assistant Professor of Ophthalmology this fall.

Patient characteristics of this study showed that the average preoperative refractive error was –4.1 D. Mean central corneal thickness was 565 μm. The intended flap thickness was 110 μm, and achieved thickness was 104.1 μm (SD 12.5; range 68 to 157 μm) demonstrating a relatively small standard deviation, but wider range of flap thickness values than reported in other studies.

There were no intraoperative complications, and two eyes of the same patient developed diffuse lamellar keratitis. Of particular note was that there were no cases of opaque bubble layer (OBL) to any degree. This finding corroborates other studies.

“This can be partially attributed to the fact that the Femto LDV laser has greater pulse frequency and smaller spot size than other commercially available devices. These settings have been associated with fewer and smaller intrastromal bubbles,” Dr Qureshi said. “OBL can be a significant complication during flap creation due to its interference with pupil tracking, difficulty with flap lifting and possible undercorrection during photoablation. We had no episodes of this complication in our series.”

By Nancy Groves
Reviewed by Dr Anam Qureshi

The Ziemer Femto LDV femtosecond laser creates flaps of comparable thickness but with a larger range than that reported for other femtosecond lasers. This laser does not appear to have any occurrence of opaque bubble layer.
ISSUE FEATURE
femtosecond laser surgery

Femtosecond laser upgrades enhance astigmatism correction outcomes

Technology streamlines automation of several surgical treatment planning values

A proprietary femtosecond laser system (LENSAR Laser System, LENSAR, Orlando, FL, USA) is making astigmatism correction easy, efficient, and more accurate, according to Dr Mitchell A Jackson.

A new software upgrade (Streamline) enables wireless transmission of preoperative topography data and an infrared image of the undilated eye to the laser. Intraoperatively, iris registration automatically adjusts for cyclorotation, eliminating the need to mark the cornea.

Arcuate incision planning using the nomogram the surgeon programmed into the laser is completed at the touch of a button by selecting the “Surgeon’s Table” tab located on the programming screen. The treatment is delivered accurately due to the iris registration, using the system’s software for marking the refractive steep corneal axis and placing precise astigmatic incisions (Intelligent Incisions).

Precise planning

“[This technology] brings automation, customisation, and precision to planning and execution of astigmatism correction,” explained Dr Jackson, founder and chief executive officer, JacksonEye, Lake Villa, IL, USA. “It has allowed me to consistently deliver predictable outcomes.”

Wireless laser integration is only available with the Cassini Corneal Shape Analyser (i-Optics), but compatibility with the OPD-Scan III (Marco Ophthalmics) is coming soon.

The Cassini measures total, posterior, and anterior corneal astigmatism, Dr Jackson said. While the LENSAR software only uses the anterior surface data for astigmatism planning, a future upgrade will let surgeons choose between anterior and total corneal astigmatism values.

“That will be a nice option because we know from work by Dr Doug Koch, and colleagues that the amount of posterior corneal astigmatism can influence outcomes of our astigmatic correction procedures,” Dr Jackson said. “Currently, in cases where I expect that the posterior corneal astigmatism is impacting the total astigmatism, I will adjust my current built-in nomogram accordingly.”

Irrespective of which system surgeons use to obtain preoperative diagnostics information for astigmatic correction, Dr Jackson emphasised the importance of optimising the condition of the ocular surface to assure quality data.

While the LENSAR software only uses the anterior surface data for astigmatism planning, a future upgrade will let surgeons choose between anterior and total corneal astigmatism values

“Garbage in equals garbage out,” he said, adding that he likes to look for agreement between measurements obtained with several different devices. The Cassini also captures an undilated image of the iris that will be used intraoperatively for iris registration, and the software confirms its compatibility in terms of proper focus and absence of any lid obstruction.

“Eliminating the need for corneal ink markings to identify the steep axis is now possible with the iris registration capability of Streamline,” he said.

The diagnostic information guides built-in nomograms for astigmatic correction. Surgeons must choose a reliable nomogram from another

IN SHORT

An experienced user describes the ease and outcomes of astigmatism correction using a proprietary femtosecond laser system.
source when they first start astigmatic incisions with a femtosecond laser.

Widely used options for the LENSAR are those developed by Dr Jackson, Dr Jonathan Solomon, and Dr Rob Weinstock.

“Once the diagnostics data are imported, all the surgeon has to do is press a button and the laser does the rest,” Dr Jackson said. “However, there is also the option to change any of the parameters on the fly.”

With dynamic imaging, there is much less chance of perforation and an increased likelihood the cuts will be made at the true intended depth,” he said.

**More on incisions**

Once the incisions are made, Dr Jackson said he generally leaves them closed and has patients return after 3 to 4 weeks to assess their refractive outcome. Then, with the patient sitting in an exam lane at the slit lamp, he can titrate the astigmatic effect as needed by opening the incisions.

“It is easy to do with a Sinskey hook or similar microsurgical instrument,” he said.

In cases where intraoperative aberrometry is used (ORA, Alcon Laboratories, Fort Worth, TX, USA), the astigmatic incisions are opened intraoperatively to determine if additional deepening or lengthening of the astigmatic incisions are needed.

Using the laser, Dr Jackson said many surgeons treat up to 1.5 D of corneal astigmatism. However, he can set his upper limit to 1.7 D with these techniques. The increased range and predictability lets him to use the laser to correct astigmatism in eyes where he otherwise would implant a toric IOL.

“This shift reduces overhead and so helps enhance my bottom line,” Dr Jackson said.

Over time, surgeons can tweak the nomogram using their own data. The software helps with that task because it captures the information needed, he added.

“Trust the nomogram you start with for the first 50 eyes, and then when you decide to personalise it, change one variable at a time,” he said.

When creating nomograms, surgeons also need to calculate their average surgically induced astigmatism for the right and left eyes. A program developed by Dr Warren Hill is helpful in that regard (www.sia-calculator.com).

Dr Jackson also highlighted the value of the laser’s Scheimpflug imaging systems that allow for dynamic scanning of the cornea and give real-time pachymetric data at the time of femtosecond astigmatic incision creation.

“Corneal hydration is dynamic, and the cornea may become dessicated during the procedure,” Dr Jackson said.

Astigmatic incisions are usually made at 90% depth. If the placement is based on a single preoperative reading, the cuts can go too deep and perforate, he said.

“With dynamic imaging, there is much less chance of perforation and an increased
Regrowing the human lens

Regenerative medicine harnesses capabilities of endogenous stem cells

By Cheryl Guttman Krader; Reviewed by Dr Kang Zhang

Functional lens regeneration may be moving a step closer to reality from hypothesis.

Dr Kang Zhang and colleagues reported results of a clinical trial in which functional lens regeneration was achieved after congenital cataract surgery performed with a novel minimally invasive technique (Lin H, et al. *Nature* 2016;531: 323-28). Dr Zhang is professor of ophthalmology and chief of ophthalmic genetics, University of California-San Diego.

Designed to maintain lens capsule integrity and preserve the lens epithelial stem cells (LECs), the surgical strategy involves removal of the lens contents and/or cortical opacities through a small, 1–1.5 mm, peripheral capsulorhexis using a 0.9 mm phacoemulsification probe.

After demonstrating in rabbit and macaque models that the surgical technique resulted in functional lens regeneration, the research advanced into a pilot clinical trial co-led by Yizhi Liu of the Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangzhou, China.

The randomised study enrolled infants aged 0–1 years with bilateral congenital cataract, and assigned 12 children to be operated on with the new method and 25 children to undergo conventional cataract surgery. The procedure in the control group involved a 6 mm anterior continuous curvilinear capsulorhexis plus a posterior continuous curvilinear capsulorhexis. An intraocular lens (IOL) was either implanted primarily or the eyes were left aphakic and children were fitted with glasses or contact lenses for refractive correction.

After the minimally invasive procedure, the small capsule opening healed within 1 month and a transparent lens structure formed within 3 months.

During follow-up to 8 months, the lens attained central thickness comparable to a normal lens while refractive power and accommodative amplitude increased.

Achieved visual acuity was comparable in the two surgical groups. However, visual axis opacification occurred in only a single eye that underwent the new procedure (4.2%) versus 42 control eyes (84%). Significantly lower rates of other complications also occurred after the new procedure compared with the standard operation, including corneal edema (8.3% versus 30%), anterior chamber inflammation (16.7% versus 74%), ocular hypertension (0% versus 18%), and a need for additional laser surgery (0% versus 84%).

In addition, the life-long glaucoma risk, which is associated with the current congenital cataract surgery, is expected to be significantly lower due to minimal disruption of the ocular structure, although the investigators noted this needs to be verified.

The accomplishment is notable both because of its implications for overcoming current challenges in managing congenital cataract and because it may signal hope for an exciting new era in regenerative medicine, Dr Zhang noted.

“Our hypothesis is that, given the proper environment and stimulation, we can regenerate a lens with visual function.”

– Dr Kang Zhang

IN SHORT

> Functional lens regeneration was achieved in infants undergoing surgery for congenital cataract using a novel minimally invasive technique that maintains lens capsule integrity and preserves lens epithelial stem cells.
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vivo by endogenous stem cells,” Dr Zhang said.

“Since newts can regenerate their own limbs and other organs, latent regenerative capacity should exist in mammals as well,” Dr Zhang said. “If researchers can develop techniques for regenerating tissues and organs using endogenous stem cells, we can envision a future where there is new hope for patients surviving myocardial infarction and those living with hepatic disease, diabetes, degenerative brain diseases, and a host of other conditions.”

LECs as stem cells

The development of posterior capsule opacification (PCO) and Soemmering ring formation after cataract surgery provided the genesis for the idea of retaining LECs as a means for achieving functional lens regeneration after cataract surgery.

Lens regeneration has been contemplated for many years. However, the new approach overcomes some key difficulties. “PCO and Soemmering ring formation are well recognised phenomena after cataract surgery and represent disorganised regrowth of LECs,” Dr Zhang explained. “However, without an intact lens capsule and proper inductive environment, they won’t form a useful lens.”

This novel approach introduces a new way of thinking about visual rehabilitation for congenital cataract.

“Nevertheless, these observations suggest that LECs are stem cells with proliferative potential and the ability to generate mature lens fiber cells,” Dr Zhang said. “Our hypothesis is that, given the proper environment and stimulation, we can regenerate a lens with visual function.”

Initial preclinical experiments confirmed a role for LECs in lens regeneration and showed that loss of LEC homeostasis led to cataract formation.

A look ahead

Despite the favourable safety and efficacy outcomes reported in the published paper, Dr Zhang observed that the new approach does not result in generation of a perfect lens as peripheral cortical changes are seen in some cases.
In addition, it does not address certain underlying causes of cataract, such as genetic mutation, and so the potential for recurrent cataract remains. In fact, opacification is being observed during longer follow-up that ranges up to 18 months in some cases.

“Importantly, however, the visual axis may remain clear during the critical period of vision development so that it would reduce the risk of amblyopia, and buy time while the eye develops to a point where it is possible to implant an IOL powered to provide accurate and long-lasting refractive correction,” Dr Zhang said.

“To date, some children have undergone a second cataract surgery with IOL implantation, and they are doing well during the short-term follow-up,” Dr Zhang said. “So, it appears there is a viable back-up plan if the cataract recurs.”

The decision to develop a technique for promoting functional lens regeneration after congenital cataract surgery recognised limitations of the current surgical procedure for that population, both with respect to techniques used for refractive correction and visual rehabilitation and the associated risks and complications, particularly the lifelong risk of glaucoma.

Dr Zhang said it is tantalising to think about expanding the project to adult cataract surgery, but challenges exist.

The age-related decline in the regenerative potential of LECs is one obstacle, although Dr Zhang suggested they are developing techniques and materials that may augment regenerative capability.

A second issue relates to the fact that adult cataract surgery is already a safe and effective procedure that generally produces a rapid return of functional vision.

“Visual recovery that depends on lens regeneration might take 6 months to 1 year in adults, and so patients would need refractive correction during that period,” Dr Zhang said. “On the other hand, lens regeneration could result in accommodation restoration—thereby providing a solution for the correction of presbyopia, and in a sense, giving a young functional lens back to a patient.”

Dr Kang Zhang
E: k5zhang@ad.ucsd.edu
Dr Zhang did not indicate a financial interest in the subject matter.

See OWLsite.org for details.
Surgical draping for ophthalmic surgery has never been quick or easy—until now. A new design allows the surgeon or scrub nurse to fully drape the patient in seconds. “Even after meticulous cleaning of the lids and conjunctival sac before surgery, there is still a risk of contamination of the surgical field by the bacteria on the eyelashes and the meibomian secretion,” said Dr Takayuki Akahoshi, director of ophthalmology at Mitsui Memorial Hospital, Tokyo. “Appropriate draping to cover the eye lids and lashes completely and blocking the meibomian secretion is extremely important for the prevention of endophthalmitis, but traditional draping is time- and labor-intensive.”

The new design allows for faster draping, which helps Dr Akahoshi perform 10 to 12 cases per hour. In 2015, he performed nearly 10,400.

There are two conventional drapes in common use, he explained, and both pose significant barriers to efficient, painless surgery. One drape has a single window cut into the blue cover material but has no adhesive materials. The surgeon must cut adhesive sheets such as Tegaderm to fix the upper and lower lid. The other drape has an adhesive sheet affixed to the blue cover material. Once the adhesive layer is placed over the eye, the surgeon must cut the sheet along the lid in order to place the speculum, which could damage the cornea.

The new drape has an adhesive patch fixed to the blue cover material with a pre-cut slit. The drape and adhesive is folded in a manner that allows it to be opened quickly and easily over the patient’s face with both the upper and lower lids and lashes completely covered. Dr Akahoshi has applied for a patent on the new drape design. “It only takes ten seconds to drape the patient, something the scrub nurse can do as part of the general preparation,” Dr Akahoshi explained. “We minimized the stickiness of the adhesive to ensure the patient does not feel any pain or pulling of the eyelashes when we remove the drape.”

Speed and ease of draping and undraping are only two advantages of the new system, he continued. The drape has a second window for the non-operative eye which can quickly be opened for anxious or claustrophobic patients. “I have seen many patients who were afraid to cover their entire face during surgery, so I had to use scissors to open a second window so they could see during surgery,” Dr Akahoshi said. “The simple modification made almost everyone more comfortable during surgery, so I added a second window that can be opened very easily if needed.”

The second window is also useful in fixing the operative eye. It can be difficult to fix the eye for some patients because the operative illumination is so bright, Dr Akahoshi said. Because there is no illumination in the second window, it is easier to direct the patient to gaze to the proper position. The second window also helps when operating on children or other patients who might have problems affixing their gaze. Opening the second window allows the surgeon to position a blinking light or some other visual beacon for the patient to focus on, which helps stabilize the operative eye without having to adjust the drape during surgery. The new drape is also more effective in maintaining a clean surgical field. Eyelashes often escape traditional drapes, Dr Akahoshi explained, which can obscure the surgical field.

In cases where the drape does not completely cover the eyelid margin, the oily layer of meibomian secretion on the cornea hinders visibility inside the eye. The surgical assistant can attempt to wash away the oily layer and floaters, but washing often causes the patient to blink, which interferes with the procedure. “The new drape can cover the eyelids completely to enclose the eyelashes and prevent the meibomian secretion, leaving a wide and uniformly clean surgical field,” Dr Akahoshi said. “This allows the surgeon to concentrate on the surgery more fully and more comfortably. By blocking the contaminated meibomian secretion, the new drape helps to diminish the risk of endophthalmitis. In the 15 years we have used this type of drape, we have not encountered any bacterial endophthalmitis at all.”

Dr Akahoshi reports no financial interests the products detailed in this article. Product prototypes were produced courtesy of ASICO. This article was adapted from his presentation at the 2016 American Society of Cataract and Refractive Surgery Symposium and Congress.
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Intracameral antibiotics: Best endophthalmitis prophylaxis?

Early recognition of etiology, prompt treatment can lead to good visual outcome.

Postoperative endophthalmitis remains a potentially devastating complication of cataract surgery. However, good visual outcomes are possible if the infection is recognized early and treated appropriately, according to Dr Harry W Flynn Jr.

He provided an overview of the classification, manifestations, etiology, prophylaxis, and management of post-cataract surgery endophthalmitis.

Endophthalmitis after cataract surgery is divided into acute- and delayed-onset cases, based on whether the event occurs within 6 weeks of the procedure or later, said Dr Flynn, professor of ophthalmology and The J. Donald M. Gass Distinguished Chair in Ophthalmology, Bascom Palmer Eye Institute, University of Miami Miller School of Medicine.

Acute-onset endophthalmitis presents with ocular redness, pain, hypopyon, and fibrin in the anterior chamber.

Despite treatment, there can be infection recurrence in these cases that may necessitate removal of IOL and capsular bag, Dr Flynn noted.

Propionibacterium acnes are the most common cause of delayed-onset endophthalmitis, and fungi, particularly Candida spp., are also important in the etiology of these infections.

Prophylaxis

In the United States, topical antibiotics started before surgery and continued postoperatively are used as endophthalmitis prophylaxis for patients undergoing cataract surgery. Though use of a topical antibiotic may be considered by some to be standard of care for preventing endophthalmitis after cataract surgery, Dr Flynn noted that evidence-based data demonstrating its efficacy is controversial.

There are studies showing topical antibiotics may lower the rates of endophthalmitis by reducing colony counts on the ocular surface, he said.

IN SHORT

- When determining the best course of treatment for endophthalmitis, consider that endophthalmitis after cataract surgery is divided into acute- and delayed-onset cases, based on whether the event occurs within 6 weeks of the procedure or later.
Topical antibiotic treatment could be a relatively expensive option for endophthalmitis prophylaxis. Increasing resistance of endophthalmitis pathogens to commonly used antibiotics is another potential limitation, he noted.

**Delayed-onset endophthalmitis usually follows a course in which inflammation gradually progresses.**

This trend is highlighted by the findings of a study in which Dr Flynn and colleagues analyzed the susceptibility of coagulase negative *Staphylococci* endophthalmitis isolates from patients treated at the University of Miami from 1990 to 2014. Data showed that during the years 2005 to 2014, bacterial resistance rates using ciprofloxacin, moxifloxacin, and levofloxacin were about 60%.

**Intracamerel approach**

Intracameral antibiotic injection is another approach used to reduce the risk of postoperative endophthalmitis. The efficacy of intracameral cefuroxime was demonstrated in the landmark study from the European Society of Cataract and Refractive Surgeons. It has been corroborated by data from other studies comparing cohorts of patients receiving and not receiving intracameral cefuroxime. Large cohort studies are limited by changes in techniques and equipment in earlier years, compared with more recent cases.

Resistance of important endophthalmitis pathogens is also an issue with cefuroxime. Furthermore, there is no commercially available preparation of cefuroxime for intracameral use available in the United States, and the need for compounding the solution for injection introduces risks of dilution errors, contamination, and toxic anterior segment syndrome.

Vancomycin is also being used intracamerally for endophthalmitis prophylaxis. This practice is concerning after recent reports associating it with the development of hemorrhagic occlusive retinal vasculitis and considering the potential to promote bacterial resistance to vancomycin.

With regard to the latter issue, Dr Flynn cited the Centers for Disease Control Hospital Infection Control Practices Advisory Committees Recommendations for Preventing the Spread of Vancomycin Resistance. Its
list of situations in which vancomycin use should be discouraged include both routine surgical prophylaxis and topical application or irrigation.

We are living in an era of antibiotic stewardship where more and more, we are being scrutinized by the government and other healthcare agencies as to antibiotics we utilise during our surgery, Dr Flynn said. We must keep in mind the risks, benefits, costs, and antibiotic stewardship in deciding whether or not to utilise intracameral antibiotics.

Dropless cataract surgery in which triamcinolone plus moxifloxacin with or without vancomycin is injected into the anterior vitreous via a transzonular approach using a long, 27- or 30-gauge cannula represents a novel approach during cataract surgery.

Discussing the potential downsides of this method, Dr Flynn listed concerns about bacterial resistance, compounding errors, steroid-induced glaucoma, lens subluxation and dislocation, and patient complaints of blurred vision for one or more weeks following surgery.

**REFERENCES**


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Confocal imaging system appears promising for retinal diagnostics

By Dr Valentina Sarao

Advances in retinal imaging lead periodically to radical changes in the diagnosis and management of retinal diseases. Confocal imaging systems are at the centre of a revolution that is improving the assessment and management of several retinal pathologies. Recently, the introduction on the market of a true colour confocal scanner (Eidon, Centervue; Padova, Italy) has opened a new window into retinal imaging.

I have tested the device in a large-volume ASC in Udine, Italy (IEMO, Istituto Europeo di Microchirurgia Oculare). I was enthusiastic about its capabilities to provide high-quality and real-colour pictures — allowing a retinal image as it exactly looks when directly observed, and therefore, new opportunities for an early diagnosis of many retinal conditions.

The device uses confocal imaging and white light illumination integrated in a pupil-dilation-free system. This unique combination offers high-resolution images and high-fidelity to real retinal colours, providing a physician with accurate anatomy and all the detailed information needed for an accurate diagnosis and a precise monitoring of particular retinal diseases.

The combination of multiple imaging modalities within a single instrument (true colour, red-free, infrared, autofluorescence) is a key characteristic of this device. Red-free enhances the detail of the retinal vasculature and retinal nerve fiber layer; white illumination is able to provide high-quality true colour imaging; infrared provides information corresponding to choroid, and autofluorescence allows the assessment of the retinal pigment epithelial (RPE) layer. Infrared light images allow a physician to truly capture what is visually not detectable and provide a real-time confocal view of the retina during acquisition.

The system captures 60° in a single exposure, supports single- or multi-field acquisitions, provides seven predefined fields, and allows selection of any non-standard field by displacing the internal fixation target. The device’s optics allow a view angle of up to 110° in automatic mode for more comprehensive retinal documentation. (Figure 1)

Versatility an important feature

The device and its software interface are user-friendly and quick to learn. It ensures minimal operator involvement by automatically aligning the patient’s pupil, focusing the retina, and capturing images in less than one minute using a soft light source that guarantees maximum comfort for patients. Its intuitive commands permit a range from fully automated to fully manual mode.

At any time it is possible to stop the automatic alignment and switch to manual mode using the joystick, offering the ability to customise focusing

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- A novel device provides detailed true colour confocal imaging, giving a retinal image as it looks when directly observed and providing a better chance to an early diagnosis for many retinal diseases. A physician shares early experience with the device.
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and alignment to capture specific pathologies in detail. It works with a dedicated software and operates as a stand-alone unit through the use of a high-resolution, multi-touch, colour-display tablet. No additional personal computer is required.

The device also offers network connectivity for remote data viewing and secure data backup. Images can be shared or printed on the spot with minimal effort.

**Diagnosis, monitoring of disease**

The device represents a significant breakthrough in diagnosing and monitoring retinal diseases compared with fundus camera and scanning laser ophthalmoscope (SLO) systems.

Conventional fundus camera captures colour retinal images over-exposed in red channel, showing an optic disc that looks washed-out and uniform. Acquisitions may be limited by media opacities, such as cataracts or corneal opacities, and the capture flash can be disturbing for the patient. Compared with a conventional fundus camera, this device offers higher-resolution and higher-contrast imaging, enhancing image quality in presence of any media opacities and with a pupil-dilation-free system.

In comparison with other portable non-mydriatic fundus cameras currently on the market, this device also permits a superior accuracy and sensitivity for the detection of posterior pole pathologies. (Figures 2 and 3)

SLO systems are able to achieve better contrast than conventional fundus photography, but typically use a single wavelength laser and provide monochromatic images, unable to extract colour information from the retina.

As previously noted, the widest possible angle is 110°, but some peripheral abnormalities may be difficult to clearly photograph or may be not detected. Moreover, the device is equipped with an optical system that operates within the range of -12D to +15D. In eyes with a myopic refractive error of more than 12 D, the device may be unable to focus the posterior pole and detect retinal conditions related to pathological myopia.

In conclusion, this novel device could be widely used as a screening tool in the primary-care setting for the detection of ophthalmic diseases, such as diabetic retinopathy, glaucoma, and age-related macular degeneration.

Moreover, this device may be introduced in the daily practice for detecting posterior segment diseases and helping retinal physicians in the diagnosis and management of several retinal conditions. It can be easily used by any type of personnel thanks to the automatic mode.

Further studies are needed to evaluate its promising performance in comparison with other devices currently on the market in the field of retinal imaging.

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**DR VALENTINA SARAO**

E: valentina.sarao@uniud.it

Dr Sarao is affiliated with the Department of Medical and Biological Sciences, Ophthalmology, at the University of Udine, Italy, and the Istituto Europeo di Microchirurgia Oculare (IEMO), Udine, Italy. She did not indicate any financial interest.
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Patients with diabetic macular edema (DME) are looking for prompt, consistent, and long-lasting improvement in vision.

A new analysis of an old study suggests early response to agents that block vascular endothelial growth factor (VEGF) can predict longer-term improvement in visual acuity in these patients, said Dr Scott M Whitcup.

“The key finding is that early change in visual acuity, after three injections of ranibizumab [Lucentis, Genentech] is highly predictive of how patients will do over the remaining 3-year study and how consistent their vision response will be,” explained Dr Whitcup, clinical faculty member, Jules Stein Eye Institute, David Geffen School of Medicine, University of California, Los Angeles, USA. “The clinical implication is that patients who don’t respond well after three anti-VEGF injections are generally the patients who will not do well over the longer term.”

Dr Whitcup presented a post hoc analysis of Diabetic Retinopathy Clinical Research Network (DRCR.net) Protocol I data. He was chief scientific officer at Allergan during the DRCR.net Protocol I study that compared ranibizumab plus prompt or deferred laser photocoagulation or triamcinolone plus prompt laser for DME. He is currently founder and chief executive officer of Akrivista and Whitecap Biosciences.

The original analysis of DRCR.net Protocol I found that intravitreal ranibizumab plus laser photocoagulation either within a week of the initial injection or later during treatment provided better anatomic and functional outcomes than laser alone. The original study did not tease out factors that might predict success or failure of treatment. Until this post hoc analysis, physicians often continued using anti-VEGFs without any guide as the likelihood of longer-term improvement in vision.

“Our initial analysis of the data from Protocol I focused on mean values, how the group as a whole did,” Dr Whitcup said. “Patients don’t care about mean improvements, they want to know, ‘How am I going to do?’”

“By the third anti-VEGF injection, you get a very good idea of which patients will do well and which will not.” — Dr Scott M Whitcup

“Physicians want to know the same thing so they can either consider additional interventions or tell patients they are likely to do well on current treatment,” he said.

This analysis included only the two Protocol I cohorts that had been randomly assigned to ranibizumab plus either prompt or delayed laser photocoagulation with observed visual acuity at 12 weeks and three anti-VEGF injections. A total of 340 patients from the original study population of 691 were included.

The patients were stratified into three cohorts based on improvement in best-corrected visual acuity at 12 weeks: less than five letters, five to nine letters, and ten or more letters compared with baseline. Patients were followed for a total study duration of 3 years.

Patients are looking for consistent improvement in vision rather than dramatic swings from better to worse to better that

IN SHORT

> Being able to predict early on whether anti-VEGF treatment will be effective is helpful to both the patient and the physician so an alternative treatment can be planned if necessary.
average out to better vision, Dr Whitcup noted. Researchers assessed consistency of improvement by using a measure of ten or more letters improvement from baseline at 50% or more of visits, 75% or more of visits or all but one visit over the succeeding 33 months.

By the third anti-VEGF injection, you get a very good idea of which patients will do well and which will not,” Dr Whitcup said. “Early response is not a perfect predictor, but based on how well you do by the third injection, there was a very strong indication of how well you would do over the rest of the study period.”

Patients are looking for consistent improvement in vision rather than dramatic swings from better to worse to better that average out to better vision.

At 12 weeks, 135 patients (39.7%) had limited early response of less than five letters, 79 patients (23.2%) had intermediate response of five to nine letters improvement and 126 patients (37.1%) had strong early response of ten or more letters improvement from baseline.

Subsequent rates of consistently good vision were significantly lower in patients with limited early response compared with strong early response, 21.5% versus 81% for ten or more letters improvement on at least 50% of subsequent visits.

The intergroup differences for ten or more letters improvement were even more striking for more consistent improvement.

Only 11.1% of limited early responders showed ten or more letters of improvement on at least 75% of subsequent visits versus 66.7% for strong early responders.

Only 0.7% of limited early responders showed ten or more letters improvement at all but one subsequent visit versus 37.3% of strong early responders.

“By the third anti-VEGF injection, you get a very good idea of which patients will do well and which will not,” Dr Whitcup said. “Early response is not a perfect predictor, but based on how well you do by the third injection, there was a very strong indication of how well you would do over the rest of the study period.”

DR SCOTT M WHITCUP, MD
E: eswhitcup@cox.net

This article was adapted from Dr Whitcup’s presentation at the 2016 meeting of the Association for Research in Vision and Ophthalmology. The source of the data is the DRCR.net, but the analyses, content, and conclusion presented herein are solely the responsibility of the authors and have not been reviewed or approved by DRCR.net.

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The goals when developing new forms of glaucoma surgery include reduction of complications, a long-lasting effect, and improved quality of life for the patient. Any new procedure must be as effective at lowering IOP as trabeculectomy, which remains the reference standard. The desired outcome is a patient who can manage without additional medications, noted Professor Grehn, of the University of Würzburg and Mainz, Germany.

Wound healing is a major challenge with trabeculectomy, with scarring a particularly troubling complication. This can be minimised greatly by reducing fibroblast activity by using antimetabolites and maintaining slow aqueous flow. Frequent post-operative reviews and early massage are essential.

Recently, non-penetrating surgery has become popular because of its reduced complication rates and good preservation of visual acuity, although it is agreed that trabeculectomy remains the most effective means of reducing IOP.

Beyond deep sclerectomy and viscocanalostomy, canaloplasty is now accepted by many glaucoma surgeons. A randomised controlled prospective study of canaloplasty versus trabeculectomy at Professor Grehn’s institution showed that, while trabeculectomy provides significantly better IOP reduction, fewer side-effects and less additional interventions are associated with canaloplasty after 2 years of follow-up, making it of particular value in high-risk cases and worthy of consideration when target pressure requires only moderate IOP reduction. Canaloplasty has been shown to provide good patient satisfaction, with significantly better scores in most measures of visual and non-visual ocular symptoms.

However, trabeculectomy remains necessary to achieve IOPs in the low teens or high single digits, and should be developed further. A new hybrid filtration procedure called filtering trabeculotomy, which combines the techniques of deep sclerectomy and trabeculotomy, has been examined versus trabeculectomy in a controlled matched comparative study. It resulted in IOP reductions equal to those achieved with conventional trabeculectomy. The procedure involves trabeculotomy to remove trabecular resistance; the Descemet membrane is maintained, so there is no need for iridectomy, which reduces the risk of cataract formation.

Tube surgery has become a standard procedure in secondary glaucomas and when previous filtering surgery has failed, but additional medication is often needed and long-term corneal problems are not yet completely controlled. Five-year follow-up of the Tube Versus Trabeculectomy study, which compared tube shunt (350 mm² Baerveldt glaucoma implant) with trabeculectomy with mitomycin C (0.4 mg/mL for 4 minutes), showed a significantly higher rate of additional surgery in the trabeculectomy group; both groups had similar IOP reduction, and rates of late postoperative complications, reoperation for complications and cataract extraction were also similar in both groups. Tube-shunt surgery was associated with use of more glaucoma medications than trabeculectomy with mitomycin C during the first 2 years of the study, but medical therapy equalised with longer follow-up.
CO₂ laser-assisted procedure showing long-term efficacy, safety

Simplified filtration has short learning curve; reduced need for topical drugs

By Cheryl Guttman Krader

Reviewed by Dr Noa Geffen and Dr Michael Mimouni

CO₂ laser-assisted sclerectomy (CLASS, IOPtima) is a safe technique providing long-term IOP control with a reduced need for topical medications, showing findings from follow-up to 5 years in a multinational trial.

“We are fortunate to be caring for patients in an era of glaucoma surgical innovation, and newer microinvasive procedures offer benefits in terms of their safety profiles,” said Dr Michael Mimouni, Department of Ophthalmology, Rambam Health Care Campus, Haifa, Israel. “However most do not provide adequate IOP control over time in eyes with more advanced glaucoma.”

CLASS, developed by Professor Ehud Assia, Department of Ophthalmology, Meir Medical Center, Kfar-Saba, Israel, is a simplified filtration procedure that has a short learning curve.

Outcomes from the studies published by Dr Noa Geffen, principal investigator, and the international CLASS group, show that it can be performed with repeatable efficacy and safety in the hands of different surgeons, Dr Mimouni noted.

“Now we look forward to confirming these promising results with more data,” he said.

More about CLASS

CLASS is performed with a proprietary laser system (IOPtiMate, IOPtima) that includes a 10.6 μm CO₂ laser, a control unit, and a micro-manipulating scanner integrated with the surgical microscope.

After creating a peritomy and half-thickness scleral flap, the laser is used to ablate the zone directly above Schlemm’s canal in order to achieve deep scleral ablation and un-roofing of Schlemm’s canal. The laser ablates tissue layer by layer until percolation of fluid is visualized. CLASS requires a manual creation of a partial thickness scleral flap but overcomes the need to manually create the deeper flap, which is the more challenging step in the standard non-penetrating deep sclerectomy procedures.

“The CO₂ laser was chosen for this procedure because its wavelength effectively ablates dry tissue, but is highly absorbed by water,” Dr Mimouni said. “The laser is used to ablate the deeper scleral layer until percolation is achieved, without perforation.”

IN SHORT

- CO₂ laser-assisted sclerectomy performed with a proprietary laser system is a simplified filtration procedure that is showing good IOP-lowering efficacy and safety in eyes followed to 5 years.
Study results


Patients were eligible for study participation if they had primary open-angle glaucoma or primary exfoliation glaucoma with an IOP >18 mm Hg despite maximum tolerated medical therapy, Shaffer angle > grade 2, no ocular disorders other than cataract, and no surgical intervention in the study eye other than clear corneal cataract surgery. About three-fourths of the study participants had primary open-angle glaucoma.

Mitomycin-C was used in 89% of procedures. During the first year after the laser treatment, there were 12 needling procedures and 18 goniopunctures.

Efficacy results analyzed data from 100 eyes, of which 81 were seen at 1 year, 41 at 3 years, and 21 at 5 years. Mean IOP was 25.8 ± 5.4 mm Hg at baseline, 7.7 ± 6.3 mm Hg on the first day after surgery and averaged 13.8 ± 6.5, 13.5 ± 3.8, 13.0 ± 3.1, 13.8 ± 3.0, 14.2 ± 2.9, and 14.3 ± 2.6 mm Hg at 1, 3, and 5 years, respectively.

Prior to CLASS, patients were on an average of 2.4 ± 1.2 medications daily, and the average number was reduced significantly to 0.1 ± 0.3, 0.2 ± 0.6, 0.3 ± 0.7, 0.5 ± 0.7, 0.7 ± 0.9, and 0.8 ± 0.8 at 1, 3, and 5 years (p < 0.001). (Figure courtesy of IOPtima)

Qualitative success, which was defined using the same IOP criteria but with or without medication, was achieved at rates of 78.5%, 84.8%, and 86.4% at 1, 3, and 5 years, respectively.

Complications were mostly mild without any significant sequelae. The most common procedure-related complications were early wound leak (8.3%), shallow anterior chamber (5.6%), and hyphema (4.6%).

“The CO2 laser was chosen for this procedure because its wavelength effectively ablates dry tissue.”

— Dr Michael Mimouni

“Although some of the patients experienced complications during follow-up, most were transient and mild,” Dr Mimouni said. “In addition, they compared favorably with trabeculectomy if we consider the trabeculectomy arm of the Tube versus Trabeculectomy Study in which 87% of eyes developed at least one complication by 5 years.”
Growing experience with ab-interno canaloplasty (ABiC) shows the minimally invasive glaucoma surgery (MIGS) is very safe and provides significant and sustained reduction of IOP and medication use, according to Dr Mark Gallardo.

Performed through a 1.8-mm, temporal clear-corneal incision and using an illuminated microcatheter (iTrack 250A, Ellex) that provides continual transscleral visualization, ABiC lowers IOP by restoring the natural pathway of aqueous outflow.

Based on its outcomes and benefits, Dr Gallardo now considers ABiC as a first-line option for patients with mild-to-moderate glaucoma whose IOP is uncontrolled on maximum tolerated medical therapy. Because of its potential to reduce or eliminate medication burden, he also sees ABiC as a useful adjunct when performing cataract surgery in patients with mild-to-moderate glaucoma controlled on medications.

Dr Gallardo is in private practice, El Paso Eye Surgeons, El Paso, Texas, USA, and an adjunct clinical faculty member in the department of ophthalmology at University of Texas Health Science Center, San Antonio, and Texas Tech Health Sciences Center, Lubbock.

With passage of the microcatheter through the ostomy in the trabecular meshwork, ABiC uniquely accesses, catheterizes, and viscodilates all sites controlling aqueous outflow. It has been associated with an average IOP reduction of about 35%, and with follow-up available to 18 months in some patients, its benefit is largely maintained, he noted.

“What I love most about ABiC, however, is that it is truly an atraumatic procedure,” Dr Gallardo said.

“With the exception of the small ostomy created in the trabecular meshwork, there is no disruption of tissue throughout the aqueous drainage system,” he said. “Therefore, ABiC has an excellent safety profile—no sight-threatening complications have been associated with its use, and other surgical options remain available if

IN SHORT

- Ab-interno canaloplasty is a minimally invasive glaucoma surgery that accesses, catheterizes, and viscodilates all sites controlling aqueous outflow. When performed alone for uncontrolled glaucoma or with cataract surgery, it can result in reduced IOP and daily medication use at follow-up through 12 months.

““What I love most about ABiC, however, is that it is truly an atraumatic procedure.””
— Dr Mark Gallardo
ABiC is not successful or fails over time.”

The idea for ABiC stems from evidence that good IOP lowering was still achieved in eyes that underwent traditional canaloplasty without placement of the tensioning suture.

“I have a number of patients who had traditional canaloplasty in one eye and then ABiC in the other whose IOP and need for medication is similar in their fellow eyes,” he said.

ABiC can achieve the same outcome as traditional canaloplasty, but is a much simpler and faster surgery because it eliminates the major incisional steps of the ab externo approach and placement of a tensioning suture, he noted.

Outcomes
Dr Gallardo has analyzed results for his patients who have up to 12 months of follow-up. Mean IOP in this cohort was reduced from 18.6 ± 6.4 mm Hg preoperatively (n = 122) to 14.1 ± 3.7 mm Hg at 6 months (n = 65) and to 12.9 ± 2.0 mm Hg at 12 months (n = 28). Mean number of medications used daily was reduced by half from 2.0 to 1.0. About 50% of the patients in his series underwent ABiC alone. In that subgroup, mean IOP was reduced from 21.3 ± 7.4 mm Hg at baseline to 13.3 ± 2.3 mm Hg at 12 months with a 66% reduction in mean daily medication use.

Analysing data
A pooled analysis of data including 106 eyes operated on by Dr Mahmoud A Khaimi, clinical associate professor of ophthalmology, Dean McGee Eye Institute, University of Oklahoma College of Medicine, Oklahoma City, USA, shows that among patients who had combination cataract and ABiC surgery, IOP was reduced from a baseline mean of 17.1 ± 5.0 mm Hg to 13.1 ± 2.1 mm Hg at 12 months with a 50% decrease in daily medication requirement.

Other subgroup analyses in the combined cohort included 161 patients classified having uncontrolled glaucoma (IOP ≥16 mm Hg), 73 patients with uncontrolled glaucoma on maximum medical therapy, and a small number with a history of selective laser trabeculoplasty.

Across all of those subgroups, mean IOP was reduced by about 40% and patients were able to reduce their medication use by at least half. Among 67 patients with controlled glaucoma (baseline IOP ≤15 mm Hg, mean 12.9 mm Hg), average daily medication use was reduced from 2.0 ± 1.0 to 0.0 ± 1.0 at 6 (n = 44) and 12 months (n = 17).

Dr Gallardo acknowledged that ABiC, like all MIGS procedures, is not a replacement for trabeculectomy, but he pointed out that not all patients need a filtering procedure for reaching their target IOP.

Approaches to the management of coronary artery disease (CAD) offer a good analogy, he said.

“When possible, patients needing surgical intervention for CAD will be treated with a minimally invasive approach using cardiac catheterization with a stent or balloon angioplasty rather than undergoing a coronary artery bypass procedure,” he said.

The same premise applies to glaucoma surgery, he noted.

“Trying ABiC first to rejuvenate the natural drainage system in appropriately selected patients is a minimally invasive procedure that can be very successful but leaves the opportunity to perform a procedure that bypasses the natural drainage system if it is unsuccessful,” Dr Gallardo said.
A newly introduced high-definition imaging device for evaluation of meibomian glands (LipiScan, TearScience) measures lipid layer thickness and evaluates blink dynamics with an efficient, easy-to-use device for clinical practices, said Dr Preeya K Gupta, assistant professor of ophthalmology, Duke University, Durham, North Carolina, USA.

“Despite being smaller and easier to accommodate in a clinic, it still takes very high-resolution meibomian gland images,” Dr Gupta said. “I use it as a screening tool in my office to help identify patients who might have meibomian gland dysfunction (MGD) or who may have been misdiagnosed or underdiagnosed in the past.”

She also uses it to screen both refractive surgery and cataract surgery candidates to identify co-existing MGD that can lead to dry eye.

Before the development of imaging devices specifically for evaluation of the meibomian glands, it was difficult to determine if a patient had gland atrophy and other signs of gland dysfunction, such as dilation or tortuosity, Dr Gupta said.

“Now you can identify anatomically whether or not there is gland dysfunction or atrophy,” she said. “As a clinician it has provided a lot of information about the meibomian glands that we really didn’t have access to in the past.”

**IN SHORT**

A new compact, portable device for rapid, high-definition meibomian gland imaging (LipiScan, TearScience) is an efficient screening tool for patients with complaints of dry eye and/or candidates for surgical procedures in which pre-existing dry eye could affect outcomes.
It is not only helpful for making a diagnosis, but also for framing treatment expectations in discussions with patients, she added. For example, if the images showed very severe gland atrophy, she could explain that the treatment goal is to preserve the few remaining glands, and that it could be an uphill battle. But if the patient had relatively minor gland atrophy accompanied by symptomatic dry eye or MGD, she could outline the specific treatment steps likely to produce improvement.

The device uses a patented technique that takes high-definition images of the glands using a transilluminator and near-infrared technology, said Joseph Boorady, OD, president and chief executive officer of TearScience. The device and its predecessor (LipiView, TearScience) have a transilluminator, which everts the eyelid and uses a proprietary infrared light source to image the lid. The infrared light allows the camera on the lid to take very high-quality, high-definition images of the glands, he said.

“In order to accurately diagnose MGD, which still today is vastly misunderstood and underdiagnosed, you need to look at two things: structure and function,” Dr Boorady said. “Look at the structure of the meibomian glands and [whether they are] secreting lipid or not.”

**Traditional procedure**
Historically, physicians would transilluminate the eyelid and use a slit lamp to evaluate the meibomian glands when they wanted to look at the structure.

However, the imaging technology developed by the company provides a high-resolution view of the glands in under 10 seconds per lid, Dr Boorady said. Function can then be assessed using the slit lamp along with the company’s handheld meibomian gland evaluator or by manual expression.

Until relatively recently, tools for evaluating the meibomian gland had largely been found in research settings and tended to be more sophisticated and complex than was necessary for the typical clinical practice, Dr Boorady said. The new product was developed in response to demand for a dedicated, smaller, and less-expensive device that produced high-quality images.

“It’s been an easy instrument to integrate into clinical practice because it’s not invasive and it’s easy for technicians to use and become familiar with,” Dr Gupta said. “As a clinician, what I’m focused on is whether a device going to give me good images, and also [whether] it easy for my staff to use. I would say this device definitely captures excellent images . . . but it’s much more portable and compact and easier to integrate, especially into higher-volume practices and busy clinics.”

Dr Gupta noted that the device is less expensive than one of the company’s previous developments (LipiView II), and clinicians could purchase multiple devices for different office locations or more than one in a large clinic. The device’s small footprint also makes it unlikely to disrupt patient flow, regardless of the practice size and number of devices on site.

“I believe [physicians] are looking for an easy and cost-effective way to get images so that they can screen a lot more patients in their offices,” Dr Boorady said. “We believe we’ve filled that niche. More screening and more identification of MGD will lead to more treatment, which is why we want to help [physicians] identify this dysfunction.”

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**FIGURE 1**

**LEFT** Truncated meibomian glands alter the tear film and can ultimately cause damage to the ocular surface if left untreated.

**RIGHT** Normally functioning meibomian glands secrete oil which prevents the tear film from evaporating. (Photos courtesy of TearScience)

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**DR PREEYA K GUPTA, MD**

E: preeya.gupta@duke.edu

Dr Gupta is a consultant to TearScience.
Modern cataract surgery can provide good visual outcomes for most patients, thanks to developments in surgical technique, instrumentation, and IOL technology.

Unfortunately, despite advances in lens design and material, clinicians cannot always prevent the main complication associated with cataract surgery: posterior capsule opacification (PCO).

The use of neodymium-doped yttrium aluminum garnet (Nd:YAG) laser capsulotomy allows for a safe and non-invasive method of managing PCO.

Use of the Nd:YAG laser is not limited to capsulotomies. It is also frequently used to undertake peripheral iridotomies in patients with acute and narrow angle-closure glaucoma. Nd:YAG lasers are also used by some surgeons to vaporise symptomatic vitreous floaters. Not surprisingly, the Nd:YAG laser has become an essential feature of most ophthalmology clinics.

Laser choice

The Nd:YAG laser has come a long way since it was first demonstrated in the 1960s, and there are now several Nd:YAG devices available. Our department recently incorporated a new system (OptoYag M, Optotek Medical; Ljubljana, Slovenia).

The main reason we chose this particular laser was because it enables the best treatment results using lower energy and fewer shots.1

Although Nd:YAG capsulotomy is known to have a good safety profile, there is a small risk of complications, including retinal tears and detachment, cystoid macular oedema, IOL damage, iritis, and transient or persistent elevation of IOP.

Findings from numerous studies suggest that side-effects are more pronounced when a high single-pulse energy is used. Consequently, many surgeons perform Nd:YAG capsulotomies at the lowest possible energy level.2,3 One of the most helpful features is the system’s ability to deliver 30 different energy levels between 0.5 mJ and 10 mJ.

This allows me to precisely adjust the energy in order to match the specific needs of the particular treatment and the patient’s eye response.

The system also features a repetition rate of 3 Hz, which affords faster treatment. This feature is not only beneficial for practice productivity, it also increases patients’ comfort levels.

Another feature that supports patient ease is the LED slit lamp incorporated into the device. Unlike many other slit lamps, it emits minimal heat, which is important for patient comfort, particularly in those with dry eye.

I have also found this device allows accurate, repeatable, and consistent delivery of energy. Some YAG lasers can be temperamental, particularly in terms of accuracy, but this system has proven to be reliable thanks to the incorporation of pulse-to-pulse stability (PPS) technology which delivers a stable energy output.

“The Nd:YAG laser plays a key part in ophthalmology. However, it is important to select a device that enables the best treatment results using lower energy and fewer shots.” — Masoud Teimory
output that exceeds current industry standards (Figure 1).

Enhanced accuracy and stability of laser energy not only helps to improve safety, it also increases treatment efficacy.

Because the system has a red diode aiming beam with continuous power adjustment that allows precise focusing of the YAG laser, I find I don’t need to use a contact lens in most cases, further simplifying the procedure.

Another advantage is that the system has a convenient portable design.

Because the electronics box is positioned under the table, the system can be moved freely to another worktop and is therefore instantly ready to use.

**Clinical experience**
We’ve used the system in hundreds of patients for both capsulotomies and iridotomies. I find that I can achieve a successful capsulotomy at an energy level between 1.0 mJ and 1.6 mJ, typically using only 10 to 12 shots.

For an iridotomy, I tend to use an energy level of 2.5 mJ at two pulses. A study undertaken by Hawlina and Drnovšek-Olup at the University Medical Centre Ljubljana, Slovenia, showed that Nd:YAG laser capsulotomies could be successfully undertaken using the system at an energy level of 1.6 mJ.

In this study, which included 53 eyes of 44 patients (mean age, 76.49 years; range, 59 to 89 years), all procedures were performed with an energy level of 1.6 mJ and an average total energy of 104.72 mJ (range, 27.2 mJ to 320 mJ).

The average number of pulses used was 65.5, ranging from 17 to 200. All treatments were successful.1

Although I haven’t conducted a formal study of this laser, my capsulotomy patients generally report immediate improvements in PCO symptoms.

Moreover, I haven’t had to repeat the procedure in any patient and there have been no serious complications.

**REFERENCES**

Topcon delivers 10,000th OCT device

Topcon, an ophthalmic instrumentation company based in Oakland, NJ, has announced that it has shipped its 10,000th optical coherence tomography (OCT) device. OCT devices provide important insights and aid in the management of retinal disease. This non-invasive technology is significant in its ability to provide micrometre-level imaging of the internal structure of the eye. This milestone reflects the growing global market demand for OCT systems.

The introduction of the first spectral domain OCT in 2006 marked a significant revolution in eye care diagnosis and dramatically expanded the use of OCT. With the introduction of the 3D OCT-1 Maestro, Topcon has created a comprehensive OCT system that is easy to use, automatically providing full colour fundus images in the same patient-friendly exam.

Topcon has introduced several new technologies, including fully automated scanning, rapid scanning speeds, high-resolution images in the deep retinal layers, multimodality, and integration of swept source technology. “Swept source adds a new dimension to OCT,” said Dr Paulo E Stanga, consultant ophthalmologist, vitreoretinal surgeon, and professor of ophthalmology and retinal regeneration at the Manchester Royal Eye Hospital in Manchester, UK. “The TOPCON DRI Swept Source OCT is easy to use, provides unique clinical information, and has improved my practice. For the first time, we can in-vivo visualise not only the vitreoretinal interface but also the cortical vitreous, which is important at a time when more and more therapies are delivered via intra-vitreal injections. Deeper imaging brings choroidal thickness, helping guide my clinical decisions. Seeing more helps guide my therapy and allows me to treat more effectively. I find Swept Source an essential tool to look for biomarkers of disease regression or progression.”

For more information, go to http://www.topcon-medical.com/eu

Geuder launches new instruments for cataract and LASIK surgery

Geuder has an extended product range of femto laser instruments for LASIK and cataract surgeries. Designed especially for cataract surgery, a double-ended spatula has been developed in cooperation with Professor Bernhard Dick of Bochum, Germany. This sharp spatula is used for the opening and special preparation of laser paracentesis, as well as for the mobilisation of lens fragments. A femto laser eye speculum can be universally used for all patient interfaces. For LASIK surgery, a double instrument with a semi-sharp spoon has been designed in cooperation with Dr Detlev R H Breyer of Düsseldorf. The instrument serves to laminate the stroma lenticule for minimally invasive LASIK Surgery. In Particularly designed for ReLEx Surgery, Geuder also has tube-guided forceps for the minimally invasive removal of the lenticule.

For more information, go to www.geuder.com
CenterVue SpA announces launch of EIDON AF, introducing autofluorescence capability

CenterVue SpA has announced the launch of a new device, EIDON AF, introducing autofluorescence capability to EIDON technology.

The new EIDON AF represents a unique combination of advantages from different technologies, providing autofluorescence retinal images with higher contrast than conventional fundus camera systems, thanks to its confocal technology based on scanning line. It is also provided with the highest pixel resolution for a confocal system to guarantee high details and resolution.

EIDON AF captures 60° autofluorescence images with a single flash of light, so it is able to provide high fidelity without image averaging and improving patient comfort. Based on the EIDON technology, it is a fully automated device that can take a 110° of the retinal autofluorescence thanks to the Mosaic function.

EIDON AF is now an extraordinary tool for improving the patient flow and for obtaining multiple types of high-value information from multiple imaging modalities: white illumination is able to provide high-quality TrueColor imaging; red-free is useful to enhance the detail of the retinal vasculature and retinal nerve fibre layer; infrared light provides information corresponding to the choroid; and autofluorescence allows the assessment of the Retinal Pigment Epithelial (RPE) layer.

For more information, go to www.centervue.com

Carl Zeiss Meditec recruits new head of its newly consolidated ophthalmology organisation

James V Mazzo will join Carl Zeiss Meditec as Global President of Ophthalmology, with responsibility for the new Strategic Business Unit Ophthalmology as well as its US Sales and Service Centre. He spent over 20 years leading Allergan’s North American and European eye care organisations, and led the public spin-off of AMO as Chairman and CEO. In 2009, Abbott Labs purchased AMO and Mazzo was selected as EVP to lead Abbott’s global ophthalmology business. He left Abbott in 2013 to become executive chair and CEO of AcuFocus and Executive Chair of Neurotech.

In a joint statement by the Executive and Supervisory Board of Carl Zeiss Meditec AG, Dr Ludwin Monz, President and CEO, and Dr Michael Kaschke, Chairman of the Supervisory Board, comment: "We are excited to have Mr Mazzo, one of the best experts in the ophthalmology industry join the Zeiss family. The re-organisation and new leadership of the ophthalmology business will allow Carl Zeiss Meditec to extend the offering for ophthalmology and optometric customers globally. We see particular opportunities in extending the business in North America and parts of Asia."

Mr Mazzo said "I am privileged and honoured to be joining Carl Zeiss Meditec. The company has been an innovative leader in the industry for over 100 years. The broad line of technology and commitment to our industry is exciting. I look forward to continuing this excellence and building Zeiss into the premier ophthalmic franchise."

For more information, go to www.zeiss.com/med
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