Indications for Use: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery. The PUREPOINT® Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including: Proliferative and nonproliferative retinopathy (including diabetic); choroidal neovascularization secondary to age-related macular degeneration; retinal tears and detachments; macular edema, retinopathy of prematurity; choroidal neovascularization; leaking microaneurysms.
- Iridotomy/Iridectomy for treatment of chronic/primary open angle glaucoma, acute angle closure glaucoma and refractory glaucoma.
- Trabeculoplasty for treatment of chronic/primary open angle glaucoma and refractory glaucoma.
- And other laser treatments including: internal sclerostomy; lattice degeneration; central and branch retinal vein occlusion; suturelysis; vascular and pigment skin lesions.

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Contraindications: Patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber of vitreous humor) are poor candidates for LIO delivered laser treatments.

Complications: Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

Warnings and Precautions:

- The disposables used in conjunction with Alcon instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.
- Attach only Alcon supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.
- Mismatch of consumable components and use of settings not specifically adjusted for a particular combination of consumable components may create a patient hazard.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- The closed loop system of the CONSTELLATION® Vision System that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. If the surgeon believes that the IOP is not responding to the system settings and is dangerously high or low, this may represent a system failure. Note: To ensure proper IOP Compensation calibration, place
infusion tubing and infusion cannula on a sterile draped tray at mid-cassette level during the priming cycle.

- Leaking sclerotomy may lead to post operative hypotony.
- Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD4 or above at 532nm, when the system is in Standby/Ready mode as well as during treatment. The doctor protection filter is an OD greater than 4 at 532nm.

Important Safety Information: Warnings and Cautions: A complete listing is available in the CONSTELLATION® Vision System Operators Manual. To obtain a copy, please contact Alcon Customer Service.
Attention: Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

Micro-Incisional Vitrectomy System (MIVS)

Indications for Use: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

Caution: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Warnings and Precautions:

- Attach only ALCON® supplied products to console and cassette luer fittings. Improper usage or assembly could result in a potentially hazardous condition for the patient. Mismatch of surgical components and use of settings not specifically adjusted for a particular combination of surgical components may affect system performance and create a patient hazard. Do not connect surgical components to the patient’s intravenous connections.
- Each surgical equipment/component combination may require specific surgical setting adjustments. Ensure that appropriate system settings are used with each product combination. Prior to initial use, contact your Alcon sales representative for in-service information.
- Care should be taken when inserting sharp instruments through the valve of the Valved Trocar Cannula. Cutting instrument such as vitreous cutters should not be actuated during insertion or removal to avoid cutting the valve membrane. Use the Valved Cannula Vent to vent fluids or gases as needed during injection of viscous oils or heavy liquids.
- Visually confirm that adequate air and liquid infusion flow occurs prior to attachment of infusion cannula to the eye.
- Ensure proper placement of trocar cannulas to prevent sub-retinal infusion.
- Leaking sclerotomies may lead to post operative hypotony.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- Minimize light intensity and duration of exposure to the retina to reduce the risk of retinal photic injury.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings, precautions, complications and adverse events.
María H. Berrocal, MD is a paid consultant for Alcon.
Pravin U. Dugel, MD is a paid consultant for Alcon.
John S. Pollack, MD has no financial interest in the products discussed.
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Peter K. Kaiser, MD is a paid consultant for Alcon.

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Surgical Maneuvers With Microincisional Vitrectomy Surgery

FEATURING ARTICLES BY:
MARÍA H. BERROCAL, MD • PraVin U. DUGEL, MD • JOHN S. POLLACK, MD
STANISLAO RIZZO, MD; AND FEDERICA GENOVESI-EBERT, MD
LIHTEH WU, MD; AND ERICK HERNÁNDEZ-BOGANTES MD
FOR THE PAN AMERICAN COLLABORATIVE RETINA STUDY (PACORES) GROUP
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Expanding Indications for MIVS for Complex Cases

BY MARÍA H. BERROCAL, MD

Proliferative vitreoretinopathy (PVR) is a common complication in retinal detachment, which increases the surgical complexity of the procedure and adversely affects anatomical and visual outcomes. Traditionallly, PVR has been managed with 20-gauge vitrectomy surgery. Frequent complications of 20-gauge vitrectomy have been retinal incarceration in sclerotomies, sclerotomy-associated tears and dialysis, and iatrogenic breaks from traction from the vitreous cutter at the vitreous base. In complex vitrectomies, it is often necessary to utilize high pressures to control bleeding, and to undergo multiple exchanges of instruments through the sclerotomies. This can result in retinal breaks near the sclerotomies, and postoperative optic atrophy and fibrovascular ingrowth (Figures 1A and B).

Twenty-gauge vitrectomy, due to the larger cutter opening and the high flow rates through the cutter causes instability inside the eye with traction on the vitreous base and the detached retina.

I have been using microincisional vitrectomy surgery (MIVS) with good success for complex diabetic traction cases, and so sought to evaluate the effect of using 23- and 25-gauge surgery on complicated retinal detachment surgery with PVR.

METHODS

We conducted a prospective, consecutive series of surgeries in 32 eyes that had a retinal detachment with PVR. There were 18 men and 14 women in the study group and the ages of the patients ranged from 27 to 86 years of age, with a mean age of 57 years. The PVR grades of the patients in the study group are seen in Table 1.

Six of the patients had previous scleral buckling surgery; two patients had scleral buckle plus vitrectomy; five had previous LASIK; 13 had phaco; and two underwent prior pneumatic retinopexy. Preoperative visual acuity ranged from 20/40 to light perception; five eyes had better than 20/400 vision and 27 eyes had vision equal to or

<table>
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<th>TABLE 1. PVR GRADING.</th>
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<tbody>
<tr>
<td>B: 10 eyes</td>
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<tr>
<td>CP: 22 eyes</td>
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<td>CP1 quadrant: 10 eyes</td>
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<tr>
<td>CP2 quadrants: 8 eyes</td>
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<td>CP3 quadrants: 4 eyes</td>
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<tr>
<td>CP4 quadrants: 4 eyes</td>
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<td>CA: 6 eyes</td>
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Figure 1. Injection of PFO liquid through 25-gauge cannula.

Figure 1. Fibrovascular ingrowth in vitreous base: 20 gauge (A). Vascular ingrowth through sutured 20-gauge sclerotomy (B).
worse than 20/400. Thirteen eyes were pseudophakic, two were aphakic, and 17 were phakic.

**PROCEDURES**

Twenty-eight eyes underwent 23-gauge vitrectomy using the CONSTELLATION Vision System (Alcon Laboratories, Inc., Fort Worth, TX). Fifteen eyes underwent 23-gauge scleral buckle plus vitrectomy surgery. C$_3$F$_8$ was used in seven of these eyes, C$_2$F$_6$ in four, and silicone oil in one. Thirteen eyes had 23-gauge vitrectomy only; C$_3$F$_8$ was used in four of these eyes, C$_2$F$_6$ was used in seven, SF$_6$ was used in one, and silicone oil in one. Four eyes had 25-gauge vitrectomy, one eye had 25-gauge scleral buckle and vitrectomy using C$_2$F$_6$ and three had vitrectomy only, two for which C$_3$F$_6$ was used (Figure 2). Surgery times ranged from 25 to 95 minutes.

**COMPLICATIONS**

Intraoperatively, we encountered suprachoroidal infusion in two eyes, extrusion of trocar cannulas in two eyes, and four iatrogenic breaks. We had no incidence of sclerotomy-associated breaks or retinal incarceration.

Patients were examined at the end of the procedure and then again at 3 and 6 months postoperative. Postoperative complications included cataract of progression in seven eyes, increased intraocular pressure in four eyes, recurrent PVR in three, and neovascular glaucoma in one eye. There were no cases of anterior hyaloidal proliferation, of neovascularization in sclerotomies.

Five eyes (16%) required a subsequent vitrectomy, five eyes required phaco, two had laser photocoagulation, and one eye was injected with intravitreal bevacizumab (Avastin, Genentech).

**RESULTS**

At 6 months postoperative, 29 eyes had visual acuity improvement (90%), while three eyes (10%) were unchanged or worse. Twenty-two eyes (69%) had visual acuity better than 20/400 and ten eyes (31%) had visual acuity equal to or worse than 20/400.

**THE BENEFITS OF A MICROINCISION FOR PVR**

The benefits of using MIVS for PVR surgery are numerous. Using 23- and 25-gauge surgery allows for reduced traction on the detached retina and the closer proximity of the port to the tip allows for closer shaving of membranes at the vitreous base (Figures 3A-C).

The cutting speeds on the CONSTELLATION System are faster and the vitrector ports are smaller. The trocar system and smaller incisions results in fewer sclerotomy complications, reduced retinal incarceration and tears near the sclerotomy sites. Additionally, IOP control is improved from the smaller sclerotomies and IOP is lower during the procedure.

Using a smaller incision has the added advantages of reduced intraoperative bleeding, reduced optic atrophy, increased surgical efficiency, and reduced phototoxicity as a direct result of the smaller light pipes employed.

Other benefits of MIVS include:
- reduced hypothermia time;
- reduced retinal and optic nerve damage;
- more efficient and complete vitreous removal;
- minimal traction on the detached retina;
- increase safety in vitreous base dissection;
- and with the probe opening closer to tip, it can be used as both a pic and forceps.

**SUMMARY**

MIVS has distinct advantages in PVR and complex cases; the technological advances, such as on the CONSTELLATION Vision System, have enhanced and expanded instrumentation making it possible to tackle these difficult cases with optimized outcomes with reduced complications. Future improvements to the CONSTELLATION Vision System will include expanded MIVS instrumentation including fragmentomes, optimized chandeliers, and lighted infusions.

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How do we define efficiency in vitreoretinal surgery? Efficiency is often mistaken to be a term that is interchangeable with speed. Although speed is a component of efficiency, it is in fact only a minor component. The dictionary defines efficiency as the safe production of the desired effects or results with minimum waste of time, effort, and skills. Thus, safety is, above all, the primary component of efficiency.

In vitreoretinal surgery, safety often depends on two main factors: fluidics stability and tissue separation. In terms of fluidics stability, what we take out must match what is coming in. Therefore, we do not want a lot of fluid movement. We neither want a soft eye nor do we want a very hard eye. We want the least amount of fluid movement possible. Therefore, we want the least amount of flow possible to do the job. Regarding tissue separation, we must be able to separate the good tissue from the bad, simplifying the removal of the bad tissue (eg, fibrous tissue).

It is certainly possible to achieve both goals using the 20-gauge system. We have done so for decades. However, it is easier with 23 gauge. Herein, I hope to show you why it is easiest with the 25+gauge.

**FLUIDICS STABILITY**

Fluidics stability comes down to this simple formula:

\[
\text{length of pull of collagen fibril (vitreous traction)} = \frac{\text{flow rate}}{\text{lumen area} \times \text{cut rate}}.
\]

If the flow rate is increased, the length of pull of collagen fibril is increased, vitreous traction is increased, decreasing safety. Conversely, if you increase the cut rate, you decrease length of pull of collagen fibril, decrease the vitreous traction, and increase safety. This is not a new concept, rather, it was first introduced by Steve Charles, MD, years ago—he termed it “port-based flow limiting.” Regardless of what we call it, this concept requires low flow with ultra-high cutting for maximum fluidics stability and maximum safety.

**TISSUE SEPARATION**

When I switched to the 25+ probe, I was able to address tissue in a manner in which I previously could not. I can use the cutter as a multifunctional tool and as a result, I use scissors and forceps far less frequently.

Along with David Bubolz, BSME, MBA, and Jianbo Zhou, PhD, I set up a laboratory experiment to study the relationship between gauge selection and tissue attraction. We used a very thin wire attached to material to mimic tissue membrane. Twenty-, 23-, and 25+gauge probes were placed at various distances with varying parameters, and we measured the tissue attraction based on the deflection of the wire with high-speed cinematography. From this experiment, we accumulated a large amount of data, but of particular interest was what was discovered about the amount of flow required for tissue attraction.

Figure 1 shows the flow rate vs distance for all three gauges. Figure 2 shows the vacuum required for tissue attraction for all three gauges. At 0.2 mm to 0.4 mm, it is clear that less flow is required for the 25+ probe to cause tissue attraction than both 23 and 25 gauge. These results are intuitive. Imagine if you were given a handful of raisins and one of them was dyed red. The raisins are spilled on the floor and you are asked to pick up only the red raisin, representing fibrous tissue, but not all the other raisins, representing normal retina. Would you prefer to use a vacuum cleaner (eg, 20 gauge) or a straw (eg, 25+ probe)? Not only would the straw require less flow to pick up the raisin, but additionally...
the chance of inadvertently incarcerating the remaining raisins (normal retina) would be much lower than with a vacuum cleaner. Compare this analogy to the vitreous: lower flow is needed and there is less chance of incarcerating retina with the smaller gauge. With the 25+ probe, the sphere of influence is smaller. The term, “the sphere of influence,” is, I believe, of paramount importance.

The minimal sphere of influence with the 25+ probe also allows it to be used as a multifunctional tool. It is convenient for me to use my cutter as I would horizontal and vertical scissors and forceps. The 25+ probe combined with the CONSTELLATION Vision System (Alcon Laboratories, Inc.) has also allowed me to revive previously abandoned techniques, such as viscodissection, and allowed me to create entirely new dissection techniques, such as proportional reflux hydrodissection.

**PROPORTIONAL REFLUX HYDRODISSECTION**

Viscodissection makes a good deal of sense for tissue separation—viscoelastic is injected to separate good tissue from bad (eg, retina from fibrous tissue). Unfortunately, the amount of viscoelastic needed to create the necessary separation for the 20-gauge was so large that the injection itself often resulted in tears, and many surgeons abandoned the technique. Applying a similar technique with the smaller 25+ probe requires less separation because of the smaller gauge and smaller sphere of influence. Proportional reflux dissection is surgeon-controlled hydrodissection (the use of water to create tissue separation instead of viscoelastics). The CONSTELLATION Vision System allows for an exquisitely controlled reflux parameter, which produces surgeon-controlled proportional reflux with hydrodissection: instead of a viscoelastic creating tissue separation, water from the cutter port will do the same in a tightly controlled manner.

I recently performed proportional reflux hydrodissection on a patient with combined tractional rhegmatogenous retinal detachment. For this difficult case, I would normally employ MPC or horizontal scissors and a bimanual technique. With the 25+ probe, however, I used my cutter to dissect the tissue at 5000 cpm. When I encountered thicker tissue, I lowered my cut rate to 100 cpm and switched my duty cycle to “shave”, in which the cutter is closed the majority of the time, reducing the risk of retinal incarceration. The shave duty cycle acts as vertical scissors, negating the need for instrument exchange. I am also able to use a foldback technique, in which I approach the tissue from a reverse angle and fold it back into my cutter.

**SUMMARY**

In my hands, the 25+ probe affords me the greatest amount of efficiency because it allows for the best fluidic stability and tissue separation with low flow and ultra-high cut rates and with a reduced sphere of influence. The cutter can act as a multifunctional tool, requiring fewer instrument exchanges. Additionally, entirely new dissection techniques can be introduced to the surgical arena, most notably proportional reflux hydrodissection.

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Preventing 23-gauge Vitrectomy Wound Leaks

BY JOHN S. POLLACK, MD

Although 23-gauge surgery is, in theory, a sutureless procedure, in certain situations leakage can still occur. The rate of leakage in 23-gauge surgery varies widely, largely because of varying trocar designs, differing insertion angles (9°, 20°, 45°, 5/30°, 30/90°) and differing personal criteria in the determination of “no need” for sclerotomy sutures. Some surgeons are comfortable leaving sclerotomies unsutured as long as the anterior chamber is formed and there is no visible stream of fluid emanating from the sclerotomy. Others leave sclerotomies unsutured as long as the anterior chamber is formed and the final intraocular pressure (IOP) feels “reasonable” to finger palpation.

We hypothesized that 1) the need for 23-gauge sclerotomy sutures can be reduced by utilizing a relatively flat cannula insertion angle, and 2) postoperative hypotony can be minimized by objectively assessing the structural integrity of sclerotomies after removal of cannulas and suturing all sclerotomies that fail to maintain a normal and stable IOP.

METHODS

To test these hypotheses, we performed a retrospective review of 98 eyes that had undergone 23-gauge vitrectomy performed by me and two vitreoretinal fellows, Sachin Mudvari, MD, and Michael Davis, MD. All of the surgeries had been performed using the same standardized 23-gauge technique that employs an approximately 9° insertion angle, the Alcon single-step trocar/cannula assembly (Fort Worth, TX), and scleral fixation with 0.12 forceps. It is sometimes useful to think of the 9° insertion angle as 10% of a 90° angle (Figure 1).

Cannulas were removed at roughly the same flat angle as insertion and the sclerotomy tunnel was compressed with a cotton-tip swab to collapse and close the tunnel. A standardized technique for assessment for sclerotomy wound leak and standardized management of the leakage immediately following cannula removal was employed in all cases. Brief elevation of IOP to 60 mm Hg, while compressing the sclerotomy tunnel with a cotton-tip swab, was performed when an immediate sclerotomy leak did not cease with cotton-tip swab compression alone. In all cases in which the sclerotomies were unable to maintain a final intraoperative IOP of between 15 mm Hg to 21 mm Hg, as measured by a Terry-Barraquer applanation tonometer, leaking sclerotomies were identified and sutured (Figure 2). Fellows operated under my direct supervision, maximizing the likelihood of that all three

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<th>TABLE 1. ALCON 23-GAUGE INCISIONS</th>
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<td><strong>Eyes</strong></td>
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<td>Surgeons</td>
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<td>Insertion</td>
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<td>Sutured Eyes</td>
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<td>Sutured Sclerotomies</td>
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<td>Hypotony (POD #1)</td>
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<th>TABLE 2. DORC 23-GAUGE INCISIONS</th>
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<td>Surgeons</td>
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surgeons adhered to the same standardized 23-gauge surgery technique. All cases utilizing silicone oil were excluded from the study because sclerotomies were routinely sutured in these eyes.

RESULTS

Suturing was required for 2.4% (7/292) of sclerotomies and 5.1% (5/98) of eyes. The prevailing risk factor for sutures appeared to be a very small, tight orbit, which were noted in 50% of the sutured eyes and 67% of the sutured sclerotomies. On postoperative day 1, 1% (1/98) of patients had hypotony (<7 mm Hg). No patients had hypotony after the first postoperative day. The average preoperative IOP was 16.9 mm Hg and the average postoperative IOP was 17.6 mm Hg. Sixty-two percent of patients received gas injection for macular hole or retinal detachment; 67% of the sutured sclerotomies were in gas-filled eyes. There were no choroidal detachments or cases of endophthalmitis. While only 4% of eyes were recorded as having tight orbits, 71% of sclerotomies requiring suturing were recorded in eyes with this characteristic.

Tables 1 and 2 compare data from this study to other studies evaluating 23-gauge vitrectomy systems produced by Alcon Laboratories, Inc., and DORC (Zuidland, Netherlands). The current study’s postoperative hypotony rate is lower than other studies evaluating the Alcon 23-gauge one-step entry system and compare favorable to studies evaluating the DORC two-step 23-gauge cannula entry system.

SUMMARY

The results of our study demonstrate that the Alcon single-step cannula system can produce leak-free wounds over 97% of the time when using the standardized insertion and removal technique described in this study. A relatively flat cannula insertion angle, combined with compression of the sclerotomy tunnel after canula removal produces a final sclerotomy wound architecture that minimizes the risk of persistent sclerotomy leaks and postoperative day 1 hypotony. Excellent scleral fixation with 0.12 forceps was found to be an important aid to cannula insertion at relatively flat angles. Confirmation of sclerotomy leak status is most reliably performed by the objective measurement of the eye’s ability to maintain normal IOP at the end of surgery. Finally, persistent sclerotomy leaks that fail to seal with appropriate manipulation should be sutured to reduce the risk of postoperative hypotony.

John S. Pollack, MD, is an Assistant Professor of Ophthalmology at Rush University Medical Center in Chicago, and practices at Illinois Retina Associates in Joliet, IL. He states that he has no financial relationships to disclose. Dr. Pollack can be reached at +1 815 744 7515; fax: +1 815 744 7661; or via e-mail at pollackjs@aol.com.

1. Pollack JS. How to Prevent 23G Vitrectomy Wound Leaks. Paper presented at Vail Vitrectomy 2010; March 13-17, 2010; Vail, CO.
Comparative Study of the Standard 25-gauge Vitrectomy System vs the New Ultra-high–speed Vitrectomy System

BY STANISLAO RIZZO, MD; AND FEDERICA GENOVESI-EBERT, MD

Vitreoretinal surgical technology has evolved dramatically over the last few years. One of the more recent developments has been the ability to cut the vitreous at ultra-high–speed rates. Although we live in an age where faster is almost always considered better, is it true for vitrectomy? Unfortunately, there is an absence of experimental models and no clinical data on high-speed vitrectomy systems to answer this question.

Thus, we conducted a randomized prospective controlled trial that was designed to compare the efficiency and safety of the new 25-gauge ultra-high–speed CONSTELLATION vitrectomy system (Alcon Laboratories, Inc.) using 5000 cuts per minute (cpm) with the currently used 25-gauge ACCURUS system (Alcon Laboratories, Inc.) using 1500 cpm for diseases requiring vitreous surgery.1

METHODS

One hundred-twenty patients affected by various vitreoretinal disease were enrolled from October 2008 to April 2009 and divided in two semi-randomized groups. Sixty eyes were operated on using the 25-gauge CONSTELLATION vitrectomy system and 60 were operated on using the current-generation 25-gauge ACCURUS system.

Patients who required surgery for epiretinal membranes, macular holes, retinal detachment, and complications of diabetic retinopathy were included in the study. Patients were excluded if they had undergone previous vitrectomy, scleral buckling surgery, and cases requiring silicone oil tamponade.

The main outcome measures were vitrectomy time, number of tools that had to be exchanged during the procedure, and intra- and postoperative complications.

Complete pars plana vitrectomy was performed on all patients using preservative-free triamcinolone acetone (Triesence injectable suspension, Alcon Laboratories, Inc.) as a vitreous highlighter. Dye-assisted (Brilliant Peel, Ulm, Germany) ILM peeling was employed when required, as were endolaser treatment and gas endotamponade. If gas was not used, the eyes were left filled by air. All surgeries were performed by a single surgeon.

RESULTS

Vitrectomy times using the ultra-high–speed vitrectomy system were significantly lower than for standard system (P<.0001; figure 1).

Induction of PVD during vitrectomy results in a significantly higher incidence of intra- or postoperative retinal breaks, or both.2

Figure 1. Vitrectomy times for ultra-high speed were significantly lower than for standard (P<.0001).

Figure 2. No statistically significant difference was indicated between UHS and STD with respect to rates of induction of PVD (P=.8695). The rates tended to vary among the procedure types.
the standard system with respect to rates of induction of PVD ($P=0.8695$; figure 2); however, the rates tended to vary among the procedure types.

It has been cited that retinal breaks occur in 15.8% of operations.3 The rate of retinal breaks was significantly lower for the ultra-high–speed vitrectomy system than for the standard system ($P=0.0006$; figure 3). On average, tools required exchange 27 (+9) times in the cases using the ultra-high–speed vitrectomy system, compared to 53 (+12) in the cases using the standard vitrectomy system.

CONCLUSIONS

Based on the results of the study, we concluded that the new-generation vitreous cutter may provide a new paradigm of high flow, and smaller diameter instrumentation increasing the efficiency of the 25-gauge vitrectomy technique and the overall safety of the surgery.

Stanislao Rizzo, MD, and Federica Genovesi-Ebert, MD, are at the U.O. Chirurgia Oftalmica, Azienda Ospedaliero Universitaria Pisana in Pisa, Italy. Dr. Rizzo states that he has received honoraria from Alcon Laboratories, Inc., Allergan, Inc., Bausch + Lomb, I-Science, Merck Inc., Novartis, and Thrombogenics. Dr. Rizzo is a member of the Retina Today Editorial Board and may be reached via e-mail at stanislao.rizzo@gmail.com.

Infectious endophthalmitis remains one of the most dreaded postoperative complications of any ophthalmic procedure because it often leads to severe visual loss. The incidence rates vary from procedure to procedure. For example, the 10-year incidence rate of postoperative endophthalmitis at the Bascom Palmer Eye Institute was 0.082% following cataract extraction, 0.178% following penetrating keratoplasty, 0.124% following glaucoma procedures, and 0.046% following pars plana vitrectomy (PPV). The rates of post-PPV endophthalmitis have decreased over the years. In 1984, Ho and Tolentino reported a 0.15% incidence rate. More recent series have reported rates between 0.03% to 0.05% for conventional 20 gauge PPV.

Recent innovations in vitreoretinal surgery include the development of minimally invasive transconjunctival microincision vitrectomy surgery (MIVS) with 23- and 25-gauge instruments. In this technique, flexible thin self-retaining cannulas are placed through sharp trocars that are used to pierce the conjunctiva, sclera and pars plana. Instruments are placed through the cannulas to perform the vitrectomy. Once the surgery is finished, the cannulas are removed and the wounds are often left unsutured because it is thought that the wound is self-sealing. Potential advantages to 25-gauge transconjunctival MIVS include a shorter surgical procedure, improved postoperative comfort, less postoperative inflammation, less conjunctival scarring and a faster visual rehabilitation. Presumably these advantages are secondary to the self-sealing sclerotomies that obviate the need for scleral and conjunctival suturing. The lack of rigidity and increased flexibility of the first generation 25-gauge instruments are some of the disadvantages of 25-gauge PPV. In order to overcome the flexibility issues found with 25-gauge instruments and maintain the benefits of transconjunctival MIVS, Eckardt introduced 23-gauge transconjunctival instruments in 2005. Since then, the popularity of minimally invasive transconjunctival MIVS has risen. Any time a new technique or device is introduced into clinical practice, safety is of paramount importance. That is why the vitreoretinal community became concerned when the first reports of increased rates of endophthalmitis following 25-gauge vitrectomy were reported. Kunimoto and Kaiser reported that the incidence rate of post-PPV endophthalmitis at the Wills Eye Institute Retina Service was 12-fold higher in 25-gauge vitrectomy (0.23% / 7/3103 eyes) as compared to 20-gauge vitrectomy (0.018% / 1/5498 eyes). Similarly in a multicenter retrospective study, Scott et al found that the incidence rates of endophthalmitis were 28 fold higher in the 25-gauge vitrectomy group (0.84%; 11/1307 eyes) when compared to the 20-gauge vitrectomy group (0.03%; 2/6375 eyes).

PREDISPOSING FACTORS FOR ENDOPHTHALMITIS

Potential predisposing factors for endophthalmitis following minimally invasive vitrectomy surgery have been discussed at length in prior articles and include the inoculation of bacteria into the vitreous cavity of patients with a relative immune compromise, vitreous wick in the sclerotomies, the absence of subconjunctival antibiotics, less vitreous removal during small gauge vitrectomy, lower infusion rates in 25 gauge vitrectomy and perhaps more importantly wound related issues. Taban et al have shown that wound construction plays an important role in preventing sclerotomy leakage. In their study all straight incisions led to open wounds regardless of the intraocular pressure. In contrast, even on postoperative day 1, oblique-angled incisions led to adequate wound apposition.

In an editorial by Martidis and Chang, they caution that the potential for cluster bias exists when studying in a retrospective fashion a rare event such as post-PPV endophthalmitis.

The potential for cluster bias exists when studying in a retrospective fashion a rare event such as post-PPV endophthalmitis.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Incidence 20 gauge</th>
<th>Incidence 23 gauge</th>
<th>Incidence 25 gauge</th>
<th>Years</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ho &amp; Tolentino</td>
<td>(4/2,817) 0.14%</td>
<td></td>
<td></td>
<td>1970-1981</td>
<td></td>
</tr>
<tr>
<td>Bacon, et al</td>
<td>(11/7,333) 0.15%</td>
<td></td>
<td></td>
<td>1986-1990</td>
<td></td>
</tr>
<tr>
<td>Eifrig, et al</td>
<td>(6/15,326) 0.04%</td>
<td></td>
<td></td>
<td>1984-2003</td>
<td></td>
</tr>
<tr>
<td>Sakamoto, et al</td>
<td>(1/1,886) 0.05%</td>
<td></td>
<td></td>
<td>2002-2003</td>
<td>Triamcinolone assisted vitrectomy</td>
</tr>
<tr>
<td>Kunimoto, et al</td>
<td>(1/5,498) 0.02%</td>
<td>(7/3,103) 0.23%</td>
<td></td>
<td>2004-2006</td>
<td>12 Fold increase in Endophthalmitis</td>
</tr>
<tr>
<td>Scott, et al</td>
<td>(2/6,375) 0.03%</td>
<td>(11/1,307) 0.84%</td>
<td></td>
<td>2005-2006</td>
<td>28 Fold increase in Endophthalmitis</td>
</tr>
<tr>
<td>Mason, et al</td>
<td>(2/2,642) 0.08%</td>
<td>(1/1,906) 0.053%</td>
<td></td>
<td>2004-2007</td>
<td>No difference between gauges</td>
</tr>
<tr>
<td>Hu, et al</td>
<td>(0/1,948) 0%</td>
<td>(1/1,424) 0.07%</td>
<td></td>
<td>2002-2008</td>
<td>No difference between gauges</td>
</tr>
<tr>
<td>Chen, et al</td>
<td>(1/3,046) 0.03%</td>
<td></td>
<td>(1/431) 0.23%</td>
<td>2002-2006</td>
<td>No difference between gauges</td>
</tr>
<tr>
<td>Parolini, et al</td>
<td>(1/3,078) 0.03%</td>
<td>(0/943) 0%</td>
<td></td>
<td>2003-2008</td>
<td>No difference between gauges</td>
</tr>
<tr>
<td>Shimada, et al</td>
<td>(1/3,592) 0.03%</td>
<td>(1/3,343) 0.03%</td>
<td></td>
<td>2000-2004 (20G) 2004-2007 (25G)</td>
<td>No difference between gauges</td>
</tr>
<tr>
<td>PACORES</td>
<td>(4/18,928) 0.02%</td>
<td>(3/10,192) 0.03%</td>
<td>(1/4,605) 0.022%</td>
<td>2005-2009</td>
<td>No difference between gauges</td>
</tr>
</tbody>
</table>
Our study supports the notion that small-gauge MIVS with either 23- or 25-gauge does not increase the rates of post-PPV endophthalmitis.

The aim of the study was to compare the rates of post-PPV endophthalmitis in eyes operated on with 20-gauge, 23-gauge and 25-gauge vitrectomy. Patients who had a follow-up of less than 3 months; patients who underwent PPV for trauma or endophthalmitis; and patients who had combined cataract extraction and PPV were excluded.

We identified a total of 35,427 cases of PPV that satisfied the inclusion criteria during the 2005 to 2009 period. Of these, 19,865 cases were operated with 20-gauge vitrectomy, 10,845 cases were operated with 23-gauge vitrectomy, and the remaining 4,717 cases with 25-gauge vitrectomy. The 5-year post-PPV endophthalmitis incidence rates were 0.021% (4/19,865) for 20-gauge vitrectomy, 0.028% (3/10,845) for 23-gauge vitrectomy, and 0.021% (1/4,717) for 25-gauge vitrectomy (P=0.9685).

Limitations of the current study include all those that are inherent in any retrospective study. Because of the retrospective design of our study, we were unable to determine how many sclerotomies had to be sutured in our 23- and 25-gauge cases. Furthermore, in the 25-gauge cases, we could not determine how many of the incisions were straight or at an angle. However, the point to make is that when in doubt suture. If the surgeon is unsure if the wound is leaking or not then it is probably best to suture.

To the best of our knowledge, our study represents the largest comparative case series evaluated during the longest period of time, which minimizes potential for cluster bias. Despite all the limitations, we believe that our study supports the notion that small-gauge MIVS with either 23- or 25-gauge does not increase the rates of post-PPV endophthalmitis.

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Recent enhancements include better trocar blades, valved cannulas, and collagen plugs for sclerotomy closure.

**BY PETER K. KAISER, MD**

Microincision technology has changed the face of vitreoretinal surgery since its introduction during the past decade. Minimally invasive surgery in an outpatient setting offers patients convenience and the possibility of faster recovery and visual rehabilitation. The field has changed quickly from the early 25-gauge systems, with their too-flexible instruments and longer vitrectomy times, to 23-gauge instrumentation that overcame many of these compromises, and now with newer 25-gauge systems with stiffer instruments, better fluidics, and improved lighting. Microincision surgery has been quickly adopted by the retina community.

Several recent advances in instrumentation for microincision surgery make the technology even better and promise to increase the ease of surgery, reduce complications, and hopefully improve results for our patients. These enhancements include new trocar blade designs to ease incision creation, valved cannulas to prevent fluid leakage during surgery, and collagen plugs to aid closure of sclerotomy sites.

**TROCAR BLADE DESIGN**

Currently available beveled trocar blades represent a significant improvement over the earlier needle-style trocars, reducing the amount of force required for tissue penetration and cannula insertion. However, they result in a chevron-shaped rather than linear incision. It is harder to ensure closure with a chevron-shaped incision than with a linear incision.

A new trocar with a flatter, more linear edge similar to a microvitreoretinal (MVR) blade has recently been introduced (EDGEPLUS Trocar Blade, Alcon, Fort Worth, TX). This blade creates linear incisions while maintaining reasonable penetration forces.

In order to understand the importance of blade design, we can look at the earliest 23-gauge system from Dutch Ophthalmic USA (Exeter, NH). This system used a two-step procedure with a bent MVR type stiletto that made a linear incision, followed by insertion of a blunt cannula through the incision. The system produced excellent wounds, but many surgeons preferred the one-step insertion technique offered by Bausch + Lomb (Rochester, NY) and Alcon’s trocar system rather than the two-step procedure. This new blade design allows us to use a one-step technique, but with the advantage of achieving a linear rather than chevron incision (Figure 1). This gives us the best of both worlds: good incision mechanics with a one step insertion.

We assessed these new blades in an animal model of vitrectomy.1 Under general anesthesia, 12 New England white rabbits (24 eyes) underwent a 5-minute timed three-port pars plana vitrectomy using the Alcon EDGEPLUS 23-gauge trocar blade, with infusion set at 30 mm Hg throughout the procedure. The eyes were enucleated on postoperative day 7, and histopathology was performed.

Histopathologic examination showed excellent wound closure with the new blade and a cleaner histopathologic appearance compared with eyes operated on with the older blade design and assessed at the same postoperative time point (Figure 2).

In addition to this animal work, a retrospective analysis of our own surgical cases at the Cole Eye Institute shows a significant reduction in wound leak and need for sutured closure of sclerotomies with the newer blades.

**VALVED CANNULAS**

Fluidics control during microincision surgery has been improved with the introduction of valved cannulas. Historically with non-valved cannulas, large fluid shifts could occur during surgery when the instruments were introduced and removed, and irrigating fluid was wasted by egress through these open ports. Valved cannulas allow the surgeon to maintain a formed eye during instrument exchanges, which offers several advantages. First, in older,
hypertensive patients the risk of choroidal hemorrhage due to sudden fluid shifts is reduced. Second, with less loss of fluid, it is rare to require a second bottle of irrigating fluid, even in a long case. Third, the risk of pulling out a strand of vitreous due to suction from instrument removal is greatly reduced with a valved cannula.

Two companies, Alcon and Dutch Ophthalmic, currently offer valved cannulas. With the advantages these devices offer, other companies are sure to quickly follow suit with their own offerings.

COLLAGEN PLUGS

Another recent innovation is the development of a collagen plug (InSitu Therapeutics, Menlo Park, CA) to aid in sclerotomy closure. These plugs are made of non-cross-linked 99.9% ultrapure collagen; 96 to 98% consists of type 1 collagen, and the remainder is type 3. The rate of biodegradation of the plugs is adjustable from 2 to 4 weeks.

The plug is inserted into the cannula at the end of surgery, where it swells rapidly upon exposure to fluid. The cannula is then retracted using a special tool, and the plug remains in place beneath the conjunctiva, becoming a soft collagen wound dressing.

This device was assessed in the same animal model described above.1 The incisions in the rabbit eyes were made either with straight or angled 23-gauge incisions and the wounds received collagen plugs at the end of the timed three-port vitrectomy.

Leakage and signs of adverse events were monitored over the next week, with none being seen. After 7 days, on histopathology the wounds were nicely closed with essentially no inflammation around the plugs in any wound. The appearance of these specimens was suggestive of a healing process (Figure 3).

Another study using India ink in cadaver eyes was also performed to evaluate the potential for ingress of fluid from the surface of the eye into sclerotomy wounds.1 India ink was chosen because its particles are of a similar size to bacteria; if India ink could penetrate the eye with these plugs in place, potentially bacteria could also get in.

The study demonstrated rapid wound closure with collagen plugs irrespective of wound architecture. The ink did not penetrate, even in eyes with a 23-gauge straight incision that would be considered poor wound construction.

This work was done using a 23-gauge cannulated system, but the same plugs can be used in any gauge procedure, including 20-gauge non-microincision surgery. The device enhances wound closure, making up for any lack of technique in wound construction.

Future possibilities in the development of collagen plugs for sclerotomy closure include the potential to impregnate the plugs with drugs such as antibiotic, anti-inflammatory, or anti-angiogenesis agents to facilitate postoperative healing.

CONCLUSIONS

Instrumentation for microincision vitreoretinal surgery will continue to evolve as the ingenuity of surgeons and manufacturers is brought to bear on the challenges of performing delicate maneuvers in a closed space under a microscope. Recent improvements in instrumentation and lighting that allow bimanual small-gauge procedures will change the way we do surgery, and that in turn will change our requirements and needs for instrumentation in the future.

The addition of better trocar blades, valved cannulas, and collagen plugs for sclerotomy closure to our armamentarium will undoubtedly improve the efficiency and safety of the procedures we perform.

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