Advancing MIVS Trends
for Vitreoretinal Surgery in Complex Cases

FEATURING:
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Advancing MIVS Trends for Vitreoretinal Surgery in Complex Cases

Microincisional Vitrectomy for Proliferative Vitreoretinopathy

BY MARÍA H. BERROCAL, MD

Small-gauge instrumentation for microincisional vitrectomy surgery (MIVS) has proved beneficial for all types of retina detachment (RD) cases, including vitrectomy for retinal detachment in patients with proliferative vitreoretinopathy (PVR). There are multiple grades of PVR.

• The first, Grade A, is limited to vitreous cells and/or haze.
• In Grade B PVR, the edges of a tear are either rolled or irregular, or the inner retinal surface has wrinkled.
• Grade C PVR, the most challenging to the retina specialist, is classified by preretinal or subretinal membranes, making repair more difficult.

Grades A and B are more easily manageable and resolved.

PROSPECTIVE STUDY: RD WITH PVR

We performed a prospective study of RD in patients with PVR that included 32 cases in which 10 eyes had mild Grade B PVR, 6 eyes had Grade Ca (anterior to the equator) PVR, and the remaining eyes, 16, had Cp (posterior to the equator) PVR. Preoperative visual acuities (VAs) ranged from 20/40 to light perception (LP); 5 eyes had better than 20/400 visual acuity and 27 eyes had VA worse than 20/400. Thirteen eyes were pseudophakic, 2 were aphakic, and 17 were phakic.

Most vitrectomy procedures (28) were performed using 23-gauge technology with the CONSTELLATION Vision System (Alcon Laboratories, Inc., Fort Worth, TX). Fifteen procedures utilized combined scleral buckle with vitrectomy. We used C₃F₈ gas in 7 cases, C₂F₆ in 4 cases, and silicone oil in 4. Thirteen eyes had a vitrectomy alone, some of which had a previous scleral buckle procedure. We performed 25-gauge vitrectomy for 4 eyes, 1 which also had a vitrectomy/scleral buckle.

RESULTS

The intraoperative complications included 5 eyes with iatrogenic breaks. There were no sclerotomy-associated breaks, which I believe was partly due to the smaller incisions and the trocar cannulas. There was 1 suprachoroidal fluid infusion that resulted from a

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Small-gauge instrumentation for MIVS has proved beneficial for patients with PVR.
trocar cannula that did not adequately stay affixed in
the eye. We saw no cases of retinal incarceration. The
sclerotomies were all sealed at the end of the proce-
dure, and at 3 and 6 months postoperative we observed
no fibrovascular ingrowth (Table 1).

Significant progression of cataract was seen in 7 eyes
during the 6-month postoperative observation period
and 4 eyes had increased intraocular pressure. Recurrent
PVR was seen in 3 eyes and 1 eye developed neovascular
lar glaucoma. No anterior hyaloidal proliferation was
noted in any of the eyes and there was no neovascular-
ization up to 6 months (Table 2).

Postoperative VA ranged from 20/25 to LP with
29 eyes showing an improvement in visual acuity, and
3 eyes unchanged or worse. Twenty-two eyes achieved
better than 20/400, 10 eyes had VA worse than 20/400
(Table 3). Five eyes underwent a second vitrectomy pro-
cedure, 5 had phaco in the 6-month postoperative peri-
od, 2 had laser, and we injected intravitreal anti-VEGF in
1 eye (Table 4).

DISCUSSION

In the past, retinal incarceration in the sclerotomies
and sclerotomy-associated tears and dialysis were
complications that we commonly saw in complex PVR
cases. This was due to infrequent use of cannulas as
well as high pressures used to control bleeding during
the case and frequent exchange of multiple instru-
m ents. Some of these cases developed optic atrophy
because pressures had to be elevated for long periods
of time. Additionally, fibrovascular ingrowth was also
an issue due to multiple reoperations, and iatrogenic
breaks were common while shaving the vitreous base
and membranes with 20-gauge fluidics. In regard to
fluidics on older vitrectomy machines, high flow
would often result in pulling on the vitreous and
 peripheral breaks, which translated into less safe surgi-
cal procedures. Many of these issues have been
resolved with MIVS.

The benefits to MIVS for PVR include reduced sclero-
tomy complications due to the use of cannulas,
 improved IOP control through smaller sclerotomies,
 reduced bleeding intraoperatively, reduced optic atro-
 phy, and increased surgical efficiency. The smaller light
pipes now available result in reduced phototoxicity and
 reduced hypothermal time.

MIVS has distinct advantages over standard 20-gauge
surgery for complex PVR cases, and the technological
improvements and expanded instrumentation have
made it possible to tackle our more complex cases.

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See page 15 for important safety information.
The most important tools that I utilize in surgery to help me maintain a safe, stable surgery include intraocular pressure (IOP) control, improved blades for wound construction, and the valved cannula system on the CONSTELLATION Vision System (Alcon Laboratories, Inc., Fort Worth, TX).

The IOP control on the CONSTELLATION Vision System allows me to maintain the pressure in the eye to the same level as what is preset on the machine—a true pressure inside the eye vs in the bottle. In comparison, there were significantly more pressure fluctuations with the Accurus (Alcon Laboratories, Inc.) during vitrectomy. Once I set the pressure on the CONSTELLATION Vision System, I do not have to think about it again during my procedure.

The EDGEPLUS Valved Cannula Entry System (Alcon Laboratories, Inc.) creates a linear incision (Figure 1). The valved cannulas (Figure 2) can enhance the stability of the IOP during a procedure (Data on file, Alcon Research, Ltd.).

In an experimental eye model, we were able to raise the pressure from 30 mm Hg to 120 mm Hg without inducing any leakage. The red line in Figure 3A shows you that there is not escape of fluid as the pressure is increased. When we removed the 25-gauge vitrectomy probe at 30 mm Hg from the valved cannulas, there was a very light loss of fluid (Figure 3B) but the pressure was immediately maintained. In contrast, when removing the probe from a non-valved cannula the pressure drops to 10 mm Hg of mercury and there is a significant amount of leakage (Figure 3C).

The added stability that the IOP control system offers in conjunction with the linear incision from the EDGEPLUS blade and the valved cannula system have improved my surgical technique for even my most difficult cases.

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Vitreoretinal Dissection Techniques for Diabetic Tractional Retinal Detachment

BY PRAVIN U. DUGEL, MD

The new vitrectomy systems that have become available represent an entirely new generation of machines with advanced fluidics. These improved fluidics have completely changed how I perform surgery compared to 2 years ago, including how I dissect membranes in tractional retinal detachment cases. I now use bimanual dissection for 10% of cases, proportional viscodissection for 15% of cases, and proportional reflux hydrodissection for 75% of cases (Figure 1).

Bimanual dissection has improved due to the availability of a small-gauge chandelier, but I tend to reserve this technique for my most complicated cases. Viscodissection is advantageous in that it allows separation of good tissue from bad, but in the past it required manual injection of viscoelastic and required considerable separation of retinal tissue from fibrous tissue due to the large size of the 20-gauge instruments. The CONSTELLATION Vision System (Alcon Laboratories, Inc., Fort Worth, TX) allows for controlled proportional viscodissection.

SPHERE OF INFLUENCE

The technique that I use most often, proportional reflux hydrodissection, is quick and requires only the click of a foot pedal (no additional consumables are needed). There are some important principles that are associated with proportional reflux hydrodissection. For example, sphere of influence and tissue attraction are essential to the concepts of small-gauge surgery that need to be both understood and utilized. The amount of flow that it takes to cause the tissue to attract is always greater with the larger gauge than with the smaller gauge, so the flow that is required for the tissue to attract is always greater with the larger gauge than with the smaller gauge. Imagine if you were given a handful of M&Ms (Mars, McLean, VA) and one of them was dyed green. The candies are spilled on the floor and you are asked to pick up only the green one,
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representing fibrous tissue, but not all the others, representing normal retina. Would you prefer to use a vacuum hose (eg, 20 gauge) or the small nozzle attachment (eg, 25+ probe)? Not only would the nozzle require less flow to pick up the green M&M, but additionally the chance of inadvertently incarcerating the remaining candies (normal retina) would be much lower than with a vacuum hose (Figure 2). Compare this analogy to the vitreous: lower flow is needed and there is less chance of incarcerating normal 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.

Along with David Bubolz, BSME, MBA, and Jianbo Zhou, PhD from Alcon Laboratories, Inc., I set up a laboratory experiment to evaluate the relationship between gauge selection and tissue attraction. We used a thin wire attached to a synthetic 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.1

Figure 3 shows the flow rate vs the distance for all three gauges. At 0.2 mm to 0.4 mm, less flow was required for the 25+ probe to cause tissue attraction than both 23 and 25 gauge.

**MULTIFUNCTION PROBE AND DUTY CYCLE**

The minimal sphere of influence with the 25+ probe also allows it to be used as a multifunctional tool. By changing the duty cycle settings for the probe, it is convenient for me to use my cutter as I would horizontal and vertical scissors and forceps (Figure 4).

Proportional reflux hydrodissection is similar to viscodissection; however, rather than viscoelastic, water is used to create tissue separation.

Duty cycle is another important principle associated with proportional reflux hydrodissection. In my opinion, duty cycle, which is the percentage of the time that the cutter is open vs closed, is important for modifying the probe into a multifunctional tool, allowing me to use the cutter as horizontal scissors, vertical scissors, and even a phaco fragmatome.

**SUMMARY**

When approaching advanced technique with new-generation vitreoretinal technology, it is crucial to understand both fluidics and parameters that are available with these machines. As my knowledge of these parameters expands, so will the safety and efficiency of my surgical techniques.

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**Note**

See page 15 for important safety information.

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**Figure 3. The flow rate vs the distance for 23, 25, and 25+ gauge.**

**Figure 4. Proportional reflux settings on the CONSTELLATION.**

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Cave exploration is now safer and “cavers undiscovered reaches thanks to innovation.


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
Choose the game-changing performance of MIVS for every challenge.

The MIVS portfolio of micro-incisional tools allows better access and exceptional outcomes for even the most complex cases:

- Faster visual recovery and improved patient comfort\(^1\)
- Linear incisions and optimized wound closure with the EDGEPLUS® blade\(^2\)
- True IOP control via new valved cannulas\(^3\)
- Improved stiffness, flow and versatility\(^4\)
We all know that diabetes is an epidemic that will continue to grow. It is estimated that in 2003, 189 million people worldwide had diabetes, and predicted that by 2025, 324 million people will have the disease. Proliferative diabetic retinopathy (PDR) is the most common complication of diabetes, one which suggests that ophthalmologists and in turn, retina specialists, will be faced with making an increasingly higher number of management decisions in the care of these patients.

The current management of PDR is guided by the findings and recommendations of the Diabetic Retinopathy Study, the Early Treatment Diabetic Retinopathy Study, the Diabetic Retinopathy Vitrectomy Study, and the Diabetes Control and Complication Trial, all which span from 1976 to 1993. Some of the recommendations from these studies include intensive control of blood pressure and glycemic levels, laser photocoagulation, and pars plana vitrectomy (PPV) procedures.

Elliott and Hemeida proposed the following classification system in determining the decision to perform PPV for PDR:

- total posterior vitreous detachment
- focal vitreoretinal attachment(s)
- broad vitreoretinal attachment(s)
- vitreous attachment at the disc, macula, and arcades only
- vitreous attachment at the disc and from the arcades to the periphery only
- complete vitreoretinal attachment

**EVOLUTION OF SURGERY FOR PDR**

The evolution of diabetic surgery runs parallel to the evolution of instruments for surgery. Older techniques involved using scissors to cut the bridges of traction, leaving residual islands of tissue. The remnants of fibrovascular tissue, however, can cause recurrent vitreous hemorrhage, and persistent traction leads to general patient dissatisfaction.

The introduction of MIVS technology and subsequent improvements to instrumentation, such as with handheld MIVS scissors, piks, and forceps, have led to improved delamination techniques.

Membrane delamination has become a popular technique, allowing for complete membrane removal and total relief of traction, particularly with viscodissection (Figure 1). One of the problems with delamination in the past was that it caused bleeding. For this reason, some surgeons began to use perfluorocarbon during membrane removal to stop the bleeding. Perfluorocarbon flattens the detached retina and allows endophotocoagulation using low energy. It stabilizes the retina, allowing fibrovascular membrane removal with good visualization.

**PREOPERATIVE INTRAVITREAL ANTI-VEGF**

More recently, intravitreal anti-VEGF has been used with success in the days prior to surgery to reduce bleeding. Avery et al reported on 45 eyes of 32 patients in whom they used anti-VEGF prior to surgery. All patients with neovascularization as seen on fluorescein angiography (44 of 44 eyes) had complete or partial reduction in leakage within 1 week following injection. Figure 2 shows an eye from that study at baseline, 1 week after, and 6 weeks after injection with intravitreal anti-VEGF.

Another study by Oshima et al evaluated the use of intravitreal anti-VEGF plus microincisional vitrectomy surgery (MIVS) for treating diabetic tractiveal detachment. The authors concluded that these 2 in combination offered comparable success to that with 20-gauge PPV in patients with tractiveal detachment resulting from severe PDR, with shorter intraoperative times and fewer complications.

**CONFORMAL CUTTER DELAMINATION**

In my own experience, using high cuts rates with the ULTRAVIT 25+ probe (Alcon Laboratories, Inc., Fort...
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Worth, TX) allows me to remove large diabetic membranes that cover the posterior pole with only 1 hand. I routinely use a technique called by Steve Charles, MD, conformal cutter delamination, which uses a side-approach rather than approaching from under the epiretinal membrane (ERM), and in which the angle of attack is modulated to feed the ERM into the port and protect the retina (Figure 3).

Of course our maneuvers will vary depending on the clinical findings. For example, there may be only 1 point of adherence between the retina and the hyaloids (Figure 4A), or there may be many points of adherence but the retina is still attached (Figure 4B and C). The worst-case scenario is where the retina is almost detached and the hyaloid is still attached (Figure 4D).

In the first instance, where there is only 1 point of adherence, it can be removed with only the vitrectomy probe. For the second case scenario, where there are many points of adherence, the ULTRAVIT probe can be used for segmentation without the use of other instruments. With more advanced cases of adherence, a bimanual technique should be employed to lift the membrane. With the new probe technology, the cutter can be used as a multifunctional tool. In this case I use the probe to simulate a scissors in one hand and utilizing forceps in the other hand.

For the worst-case scenario, where the retina is almost completely detached and the hyaloid is still attached, I use a bimanual technique using the cutter in one hand and then forceps to carefully remove the retinal attachment.

It is essential in this type of surgery to use anti-VEGF and this new technique of conformal cutter delamination.

**SUMMARY**

The current trend in vitreoretinal surgery is to integrate pharmacological and biological options with surgical techniques to facilitate the operation, improving the overall results. The new high-speed cutters and new techniques in surgery will help to optimize outcomes for patients.

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When managing patients who required a combined vitrectomy/cataract procedures, there are several techniques that can be used: lensectomy without IOL placement, pars plana vitrectomy and IOL placement in front of an intact anterior capsule, or limbal phacoemulsification and IOL placement before or after vitrectomy.

Combined surgery was first described by Coleman and Diamond and Kaplan in 1979, with later reports by Smith et al and Benson et al.

**INDICATIONS FOR COMBINATION SURGERY**

Why perform combination surgery? We know that the incidence of cataract after vitrectomy is high, with the risk increasing 6-fold in patients aged 50 or older, and that the use of intravitreal gas increases the frequency of nuclear sclerotic and posterior subcapsular cataract by 60%.

Although performing combined procedures in the United States is not very common, it is a very common practice around the rest of the world.

In a study of 122 eyes, Demtriades et al described the indications for combined surgery as being macular hole, diabetic retinopathy, retinal detachment, uveitis, and silicone oil removal.

- **Macular Hole.** Idiopathic macular holes are most common in patients older than age 50 and cataract formation is a major cause of patient dissatisfaction after vitrectomy. Additionally, recurrence of macular holes is common after a delayed cataract extraction, with cystoid macular edema (CME) and the use of Nd:YAG laser increasing this risk.

  For patients who cannot maintain a prone position postoperatively, a combination procedure may be the best option; however, we will not perform combination surgery in a traumatic macular hole case unless a traumatic cataract is present. The IOL may be inserted before or after vitrectomy, prior to the fluid gas exchange.

- **Diabetic retinopathy.** In cases of diabetic retinopathy, cataract is frequently associated with the disease and lens opacification is a common postoperative complication. It has also been observed that cataract extraction is associated with an increased incidence of CME after surgery. Combination surgery appears to allow better access to the vitreous base of the peripheral retina and Schiff et al provided evidence of a lower rate of vitreoretinal reoperation when combination surgery had been performed. It is important to note, however, that combination surgery may increase the risk of fibrin formation and an inflammatory reaction with posterior synechia. Thus, when considering combination therapy in eyes with diabetic retinopathy, performing a pars plana lensectomy in an anterior capsule is a preferred technique.

  **Retinal detachment.** The best way to shave the vitreous base in retinal detachment surgery is to remove the crystalline lens and place the IOL after the vitrectomy has been completed. In those cases, there is an important difficult IOL calculation. If extensive PVR is present, we will perform lensectomy with an intact anterior capsule and silicone oil or gas.

- **Uveitis.** Uveitis is frequently accompanied by posterior synechiae and posterior subcapsular cataract. The main indications for combined surgery include idiopathic uveitis, pars planitis, juvenile idiopathic arthritis, and Behçet disease. For intermediate uveitis, approaching the inferior pars plana and periphery with phacoemulsification or lensectomy with small-gauge, either 23- or 25-gauge, instruments is advised.

- **Silicone oil removal.** Surgeons can perform combination surgery with silicone oil removal, because we know that...
Almost 100% of the patients with retained silicone oil will develop cataract, with the exception of pediatric patients. Keppler et al. performed a comparative study of combination surgery vs 2 step vitrectomy and phacoemulsification in 70 cases using 1 of 2 technique: (1) pars plana silicone oil removal, peripheral retina testing, and perform the cataract extraction; or (2) or cataract extraction and silicone oil removal through the posterior capsulorrhexis. These patients have a high risk of extensive fibrosis of the posterior capsule and many require posterior capsulotomy.

**TECHNIQUES FOR COMBINATION SURGERY**

My surgical technique for combined surgery includes infusion cannula placement (first in, last out); this is followed by a limbal beveled phacoemulsification procedure. Peripheral vitreous shaving and a gas or silicone internal tamponade are necessary. I suture the phaco incision, then place 2 additional microcannulas and perform a 23-gauge vitrectomy, after which I insert the IOL and then apply internal tamponade. I then remove the viscoelastic and hydrate the cornea, remove the corneal sutures, and place cefuroxime in the anterior chamber. Finally, I remove the microcannulas and suture the sclerotomies if necessary.

The most common complication with combination cataract extraction and vitrectomy in cases using silicone oil is posterior capsular opacification (PCO). A primary capsulotomy may be required; but it is important to maintain an intact posterior capsule in patients with diabetes or in eyes with silicone oil. PCO has been observed in cases of delayed phaco after vitrectomy.

Another complication is papillary block or capture by the IOL optic, which is more common in eyes that have intraocular tamponade with either gas or silicone oil. In these cases, a small capsulorrhexis can be made to stabilize the IOL, and the patient must maintain a prone position in the first postoperative day. Biometric error can also occur, and is more common in patients with long axial lengths because of myopic shift—it is, however, usually inferior to 1 D. Biometric error can also occur in patients with retinal detachment. For patients with silicone-oil-filled eyes, it is advisable to use noncontact biometry or the IOL Master (Carl Zeiss Meditec, Dublin, CA). The SRK-T formula for IOL calculations should be used in silicone-oil-filled eyes.

**SUMMARY**

Combination surgery can be particularly beneficial for macular surgery because there is a decreased risk of reopening macular holes. The incidence of cystoid macular edema is lower when compared with delayed cataract surgery, and there appears to be a faster visual recovery. Combined surgery is made easier with the new small-gauge instrumentation, and 1 surgery is less invasive than 2 procedures.

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See page 15 for important safety information.
W hen managing a tractional retinal detachment, the goal is to relieve the traction in the posterior pole. If there is a combined traction and rhegmatogenous retinal detachment (RRD), it is imperative that all of the traction is removed, otherwise the retina will not reattach. Several challenges exist when dealing with diabetic retinopathy, in part because almost every case is different. Diabetic retinas are very thin, ischemic and vulnerable to breaks. The fibrovascular tissue tends to have strong adherence and intraoperative bleeding can be a significant problem when this tissue is removed, causing decreased vision. The rhegmatogenous component eliminates any counter traction making removal of the membranes more difficult.

ADVANTAGES OF SMALL-GAUGE INSTRUMENTATION

The advantages of small-gauge instrumentation for diabetic detachments are distinct. The smaller probes can fit under the membranes so you can use them as forceps for dissection, and the reduced flow rates with small-gauge vitrectomy systems, such as the CONSTELLATION Vision System (Alcon Laboratories, Inc., Fort Worth, TX) cause less traction and mobility on the detached retina.\(^1\) The close proximity of the port to the tip of the vitrectomy probe and high cutting rates allow a surgeon to shave the membranes close to the retina, even when it is detached. The probe can be used as not only forceps with suction, but also as scissors and a pik, reducing the need for ancillary instrumentation.

SURGICAL TECHNIQUES

For membrane removal in a case of an attached retina, I like to use a combination of suction and cutting with the 25+ probe because it allows me to come very close to the retina, lift up the membranes and then switch back to cutting mode for membrane removal over the optic nerve.

For RRD, I am able to shave the membrane from the detached retina without causing breaks. With previous 20-gauge technology, large breaks would result.

I use the 25-gauge chandelier for bimanual peeling procedures, as it provides excellent illumination and I am able to use forceps or scissors with one hand and the probe with the other to bluntly dissect the membrane and cut the epicenter (Figure 1).

Intraoperative bleeding makes many cases more challenging. I have found it useful to pretreat with an anti-VEGF agent in cases that are more vascular. The benefits of preoperative anti-VEGF include reduction of intraoperative bleeding. The complications include possible progression of RD; the anti-VEGF also must be injected less than a week prior to surgery.

When, despite preventive measures, bleeding remains an issue during surgery, I am able to use the reflux mode on the CONSTELLATION Vision System to blow the blood from the retinal surface with the vitrectomy probe, switching to aspiration for removal.

When there is a large amount of avascular tissue in complicated tractional RDs or RRDs, I prefer to use viscodissection, using blunt dissection with my probe as I inject the viscoelastic to lift the membranes from the
When, despite preventive measures, bleeding remains an issue during surgery, I am able to use the reflux mode to blow the blood from the retinal surface with the vitrectomy probe.

retina. I simultaneously push the membranes back with the viscoelastic in a simple and quick procedure.

SUMMARY

The availability of small-gauge instrumentation has improved my surgical ability and has resulted in better outcomes for my patients. Using 23- and 25+ technology turns complex cases into more manageable surgical procedures.

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See below for important safety information.

**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:**

- 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 sclerotomies may lead to post operative hypotony.

**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.

**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.
It’s time to rewrite the rules of vitreoretinal surgery.

- Experience the ULTRAVIT® 5000 cpm probe with surgeon-controlled duty cycle to reduce iatrogenic tears and post-op complications\(^1\)
- Trust in integrated and stable IOP compensation\(^2\)
- Enhance patient outcomes and achieve faster visual recovery with ALCON® MIVS platforms\(^3\)
- Improve your OR turnover by 39% with V-LOCITY® E ciency Components\(^4\)

Alcon\(^5\)


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: 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. 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.