



CASE SERIES NO. 2

OVD System Provides Essential Support for Cataract Surgery

DuoVisc Viscoelastic System helped protect the eye for an excellent outcome in a patient with prior surgical complications.

BY BRANDON D. AYRES, MD



Over the past 5 or 6 years, there have been advances in every step of cataract surgery: lasers, IOLs, and intraoperative aberrometry, as well as that first step in cataract surgery that we have long taken for granted, viscoelastic. Viscoelastic holds and stabilizes space in the anterior chamber during cataract surgery, protecting the endothelium so we may more safely perform critical parts of the procedure.¹⁻⁶

I would like to review a case where safety was a particular concern, so careful selection of the right ophthalmic viscosurgical device (OVD) was of key importance. The patient had already undergone cataract surgery in one eye that was complicated by a posterior capsular tear and retained lens fragments. The patient had to be returned to the operating room for a pars-plana vitrectomy to remove retained lens material. The prolonged recovery and multiple surgical procedures left the patient with a best vision of 20/100. Understandably, the patient was very concerned about having surgery in the contralateral eye. I was tasked with performing surgery on the second eye, which would receive standard cataract removal and monofocal IOL implantation using intraoperative aberrometry.

I wanted to do everything as safely as possible; control of the procedures was of the utmost importance. Safety starts with anesthesia and making sure the patient does not feel discomfort. In this case, we were using IV sedation and intracameral lidocaine as well as intracameral phenylephrine and ketorolac (Omidria; Omeros). Two paracentesis were created to allow bimanual technique. My choice of OVD was the DuoVisc Viscoelastic System (Alcon), which includes both VISCOAT and ProVisc OVDs. Injected at the beginning of surgery, VISCOAT has a triple negative charge with hyaluronic acid and chondroitin sulfate, which allows that viscoelastic to disperse, stick to the endothelium, and remain throughout the case, helping to reduce endothelial cell loss (Figure 1).^{1,2,4} Later in the case, I



Figure 1. Brandon D. Ayres, MD, uses VISCOAT at the beginning of a surgery.

planned to switch to the more cohesive viscoelastic, ProVisc, which is validated for use with the ORA SYSTEM (Alcon). In my experience, this space-filling viscoelastic is relatively easy to remove at the end of the case.⁷

To begin the procedure, I used VISCOAT dispersive viscoelastic to stick to and protect the endothelial cells throughout the case. The dispersive nature helps to maintain the anterior chamber because it resists expulsion through the wounds with surgical manipulation of the eye. VISCOAT's ability to maintain the anterior chamber helped me safely create the capsulorhexis.⁵

At every step of this surgery, I worked a bit more slowly and cautiously because there was no room for error in a patient who already had a problem in one eye. My preferred technique for removal of the cataract is a horizontal chop using Nagahara chopper and the Centurion Vision System (Alcon) with Active Fluidics, coupled with the INTREPID Micro-Coaxial System and its Balance tip. As I began the chop procedure, the VISCOAT dispersive viscoelastic held the anterior chamber open, allowing me to see where I was embedding the chopper as I broke up the lens. I like to use a cross-chop procedure, so I embed and break

Please see pages 3 and 4 for important information about the products mentioned in this insert.

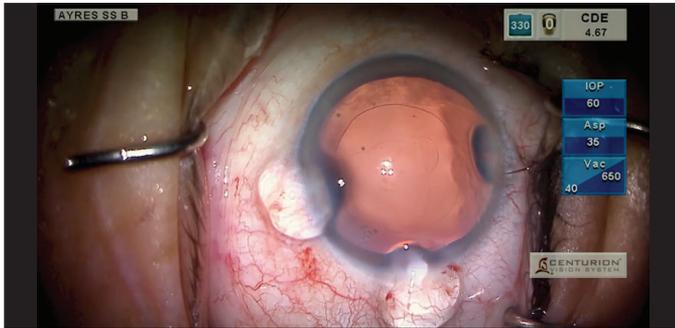


Figure 2. Brandon D. Ayres, MD, fills the capsular bag and anterior chamber with ProVisc before obtaining intraoperative aberrometry.

in one direction and then make another chop 90° away. This gives me two quadrants that can be easily removed with minimal manipulation or energy.

Early in the case, one of the quadrants drifted more anterior than I prefer, and some of the lens fragments were in close approximation to the corneal endothelium, but the dispersive viscoelastic protected that energy from being transferred to the endothelium, thus protecting the cornea.⁵ When needed, additional VISCOAT was added to keep nuclear fragments at the iris plane. The additional OVD helped protect the cornea and kept the posterior capsule away from the phaco.

After nuclear removal, I transitioned to the INTREPID Transformer I/A Handpiece (Alcon), a coaxial that converts easily into a bimanual by removing the back portion of the I/A handle. One of the more common times to experience a complication is during removal of subincisional cortical lens fibers. After the majority of the cortex was removed, leaving the subincisional area, instead of risking the capsular bag, I detached the aspirator and placed it through the side port incision, taking advantage of the bimanual mode. This allowed me to see very well in the subincisional space and remove subincisional cortical material without a struggle.

Next, I removed the majority of the VISCOAT with the Transformer I/A Handpiece and filled the capsular bag and anterior chamber with the cohesive viscoelastic, ProVisc

(Figure 2). ProVisc is validated for use with the ORA SYSTEM intraoperative wavefront aberrometry without altering IOL calculations.⁷ I used the ORA SYSTEM to help ensure accuracy of preoperative biometry and verify selection of the correct implant.

I put the IOL into the capsular bag and prepared to place the lens, and then I removed the viscoelastic. Continuing to use the Transformer I/A Handpiece, I switched to coaxial mode and went underneath the IOL. The cohesive viscoelastic worked beautifully, coming out from underneath and above the IOL. It kept the lens in place while enabling me to remove all the viscoelastic so we did not have a pressure spike on day 1.

Using the DuoVisc OVD combination to implant a monofocal IOL with the aid of intraoperative aberrometry, I was able to achieve the patient's target refractive outcome. At the beginning of the case, VISCOAT dispersive viscoelastic helped protect the endothelial cells, and in the aberrometry portion and IOL insertion, cohesive ProVisc viscoelastic helped promote success. Fortunately, in this case our patient did very well, achieving 20/25 uncorrected distance vision. ■

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DUOVISC® OVD IMPORTANT PRODUCT INFORMATION

DESCRIPTION: DUOVISC® Viscoelastic System is designed to give two Viscoelastic materials with different physico-chemical properties that can be used differently and/or sequentially to perform specific tasks during a cataract procedure. DUOVISC® Viscoelastic System consists of VISCOAT® Ophthalmic Viscosurgical Device and PROVISC® Ophthalmic Viscosurgical Device.

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

DESCRIPTION: VISCOAT® (Sodium Chondroitin Sulfate – Sodium Hyaluronate) Ophthalmic Viscosurgical Device **INDICATIONS:** VISCOAT® OVD is indicated for use as an ophthalmic surgical aid in anterior segment procedures including cataract extraction and intraocular lens (IOL) implantation. VISCOAT® OVD maintains a deep anterior chamber during anterior segment surgeries, enhances visualization during the surgical procedure, and protects the corneal endothelium and other ocular tissues. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery. **WARNINGS:** Failure to follow assembly instructions or use of an alternate cannula may result in cannula detachment and potential patient injury. **PRECAUTIONS:** Precautions are limited to those normally associated with the surgical procedure being performed. Although sodium hyaluronate and sodium chondroitin sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material. **ADVERSE REACTIONS:** VISCOAT® OVD has been extremely well tolerated in human and animal studies. A transient rise in intraocular pressure in the early postoperative period may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. It is therefore recommended that VISCOAT® OVD be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of surgery

to minimize postoperative IOP increases. Do not overfill anterior chamber.

ATTENTION: Please refer to the directions for use for a complete listing of indications, warnings and precautions.

DESCRIPTION: PROVISC® (Sodium Hyaluronate) Ophthalmic Viscosurgical Device **INDICATIONS:** PROVISC® OVD is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation. Ophthalmic viscoelastics serve to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. They help push back the vitreous face and prevent formation of a flat chamber during surgery. **PRECAUTIONS:** Postoperative increases in intraocular pressure have been reported with sodium hyaluronate products. The IOP should be carefully monitored and appropriate therapy instituted if significant increases should occur. It is recommended that PROVISC® OVD be removed by irrigation and/or aspiration at the close of surgery. Do not overfill anterior chamber. Although sodium hyaluronate is a highly purified biological polymer, the physician should be aware of the potential allergic risks inherent in the use of any biological material; care should be used in patients with hypersensitivity to any components in this material. Cannula assembly instructions should be followed to prevent patient injury. **ADVERSE REACTIONS:** Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastics, as well as incidents of corneal edema, corneal decompensation, and a transient rise in intraocular pressure. It is therefore recommended that PROVISC® OVD be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of surgery to minimize postoperative IOP increases. Do not overfill anterior chamber. **ATTENTION:** Please refer to the directions for use for a complete listing of indications, warnings and precautions.

CENTURION® VISION SYSTEM IMPORTANT PRODUCT INFORMATION

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

As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.

INDICATION: The CENTURION® Vision System is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert® IOL Injector Handpiece is indicated for use with the AcrySof® lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

WARNINGS: Appropriate use of CENTURION® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage,

power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage. Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AES/COMPLICATIONS: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use for the accessories/consumables and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

ORA SYSTEM® IMPORTANT PRODUCT INFORMATION

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

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

INTENDED USE: The ORA SYSTEM® uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS AND PRECAUTIONS: The following conditions may make it difficult to obtain accurate readings using the ORA SYSTEM®.

- Patients having progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that the physician deems would interfere with patient fixation;
- Patients having corneal pathology such as Fuchs', EBMD, keratoconus, advanced pterygium impairing the cornea, or any other pathology that the physician deems would interfere with the measurement process;
- Patients for which the preoperative regimen includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics;
- Visually significant media opacity, such as prominent floaters or asteroid hyalosis, will either limit or prohibit the measurement process; or
- Patients having received retro or peribulbar block or any other treatment

that impairs their ability to visualize the fixation light.

- Use of iris hooks during an ORA SYSTEM® image capture will yield inaccurate measurements.

In addition:

- Significant central corneal irregularities resulting in higher order aberrations might yield inaccurate refractive measurements.
- Post refractive keratectomy eyes might yield inaccurate refractive measurement.
- The safety and effectiveness of using the data from the ORA SYSTEM® have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.
- The ORA SYSTEM® is intended for use by qualified health personnel only.
- Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure. Do not operate the ORA SYSTEM® in the presence of flammable anesthetics or volatile solvents such as alcohol or benzene, or in locations that present an explosion hazard.

ATTENTION: Refer to the ORA SYSTEM® Operator's Manual for a complete description of proper use and maintenance, as well as a complete list of contraindications, warnings and precautions.

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09/17

US-VIS-17-E-2134