

New OVD optimised for the entire surgical procedure

Dermot McGrath
in Berlin

A NEW ophthalmic viscosurgical device (OVD), DisCoVisc (Alcon Laboratories), combines innovative dispersive and cohesive properties that will enable surgeons to maintain excellent anterior chamber stability during all key phases of cataract surgery, according to Stephen Brint MD.

"This new viscoelastic provides very good corneal protection and excellent space maintenance for all steps of the surgical procedure. It combines the best features of both dispersive and cohesive viscoelastic and is very easy to remove at the end of surgery. More importantly it also provides excellent visibility throughout surgery which is a major plus for any viscoelastic device," he said at the Berlin Technology Summit meeting, an Alcon sponsored event.

Presenting results from a prospective, randomised, FDA phase III clinical trial in which DisCoVisc was tested head-to-head against Healon (AMO), Dr Brint said that Alcon's new OVD performed comparably to Healon in key measurements such as endothelial cell density and IOP control.

However, a subjective arm of the study in which surgeons evaluated the two OVDs based on performance during surgery found that DisCoVisc was judged superior to Healon in practically every major phase of the procedure, noted Dr Brint, associate clinical professor of



Stephen Brint

ophthalmology at Tulane University School of Medicine in New Orleans

The study, which took place at nine investigational sites in the United States, included 249 patients who underwent cataract extraction and IOL implantation, 128 of whom were randomly assigned to DisCoVisc and 121 to Healon. Observers were masked regarding patients' IOP and endothelial cell density in the first arm of the study.

Similar safety profiles

In terms of IOP, no statistical difference was found between DisCoVisc and Healon. Dr Brint noted that six hours after surgery, 13% of patients who received DisCoVisc and 13.3% of those treated with Healon had pressure spikes of more than 30 mmHg.

No treatment was given for these patients and within 24

hours only six percent of patients in both groups had slightly elevated IOP. At one week, no DisCoVisc patient recorded elevated IOP compared to one percent in the Healon group. No patients in either group had elevated pressures at the 30-day and 90-day evaluations.

Endothelial cell counts were also closely matched between the two OVDs, said Dr Brint. At the 90-day evaluation stage, the cell count loss was 6.4% for DisCoVisc versus 8.8% for Healon.

Similarly the results for postoperative ocular signs such as aqueous cells, aqueous flare and presence of corneal oedema found no statistically significant difference between the two OVDs. Measurements of corneal oedema were 13% for DisCoVisc and 18% for Healon at day 1, 5% for both at day seven, and zero at day 30.

The results for visual acuity were good for both groups with no statistical difference between them, said Dr Brint. The number of patients achieving visual acuity of 20/25 or better at day one was 51% for DisCoVisc and 44% for Healon; 67% and 68%, respectively at day seven; 80% and 68% at day 30; and 91% and 83% at day 90.

While the objective data showed little to differentiate the two OVDs in terms of performance, Dr Brint said that the subjective evaluation demonstrated a clear preference for DisCoVisc among the participating surgeons.

"The important question was how well did the two OVDs

maintain the anterior chamber during the procedure. All of the surgeons basically felt that DisCoVisc maintained the anterior chamber much better than Healon during anterior capsulotomy, phacoemulsification and also during IOL insertion," he said.

Surgeons express preference for new OVD

During capsulotomy, a full chamber was maintained 81% of the time with DisCoVisc and 31% of the time with Healon. For IOL insertion, the respective figures were 87% and 48%.

The evaluation of visualisation was also very positive for DisCoVisc, noted Dr Brint.

"I have quite a lot of experience with Viscoat and one of my principal complaints with it is that it can leave a kind of stringy appearance and make visualisation difficult. Healon is very clear and easy to use but most of the surgeons felt that visualisation with DisCoVisc was superior even to Healon," he said.

Ease of injection was also rated as better with DisCoVisc: surgeons stated that DisCoVisc was easy or very easy to inject 98% of the time, compared with 80% for Healon.

Healon fared better than DisCoVisc in terms of ease of aspiration. Surgeons rated Healon as easy or very easy to aspirate 100% of the time compared to 70% percent for DisCoVisc.

Dr Brint said it was interesting to observe the surgeons'

perception of how much of the viscoelastic device was present following the completion of phacoemulsification. They estimated that about 21% of DisCoVisc was still in the anterior chamber coating the cornea following phaco compared to about 6.2% with Healon.

"The difference is significant but of course we would like to have more objective ways of measuring this to be absolutely sure," he said.

When surgeons were asked about their overall satisfaction ratings with the performance of the viscoelastics, 97% said they agreed or strongly agreed that they were satisfied with the performance of DisCoVisc, compared with 35% for Healon.

Summing up, Dr Brint said he had no doubt that DisCoVisc would stake a serious claim as the OVD of choice for routine cataract surgery.

"When this becomes available in the autumn, it will probably be the only OVD that I use because it has the cohesive properties of a viscoelastic such as ProVisc and the dispersive qualities of an OVD like Viscoat. It offers the best of both worlds and will, for me, probably eliminate the use of those two OVDs. It's a big advantage in that I think we can probably use this for every patient without having to notify our technicians about which type of viscoelastic we might need," he said.

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Recent upgrades further enhance safety and efficiency of micro-burst phaco system

Cheryl Guttman
in Lisbon

ICE, a hardware and software upgrade to the Sovereign® system with WhiteStar™ (AMO), features a reshaped ultrasonic wave and improved fluidics that work in concert to make phacoemulsification of all grades of nuclei safer and more efficient, reported William I. Fishkind MD, at the XXIII Congress of the European Society of Cataract and Refractive Surgeons.

ICE, which is an acronym for "Increased Control and Efficiency", delivers waveform-modulated packets of energy characterised by an initial 1.0 microsecond "kicker" at the

beginning of each ultrasound pulse. That ultra-short power burst accelerates transient cavitation and helps to maintain a micro-void between the nuclear material and the phaco tip so that emulsification is carried out without occlusion.

"ICE enhances phaco efficiency and control in several ways. It improves cutting efficiency by increasing transient cavitation, which is the most powerful form of cavitation, and it enhances fragment removal by facilitating pre-occlusion phaco. When the nuclear fragments are held slightly away from the phaco tip, they are emulsified most efficiently, and at the same time, occlusion and surge are prevented," said Dr Fishkind,

clinical professor of ophthalmology, University of Utah, Salt Lake City.

He explained that the end result is that cataract removal can be achieved faster, using less total energy, and with increased anterior chamber stability to decrease the risk of intraoperative complications.

ICE also incorporates new fluidics technology in the form of Chamber Stabilization Environment (CASE) that adds further control of the intraocular environment. CASE is designed to continuously monitor vacuum and adjust it if occlusion occurs, thereby reducing surge and maintaining chamber stability. When the occlusion is cleared, CASE

automatically resets the system to maximum vacuum.

Customisation options

With ICE, surgeons can adjust the duration and amplitude of the initial pulse burst. However, because the technology is so new, Dr Fishkind noted that he has not yet had a chance to experiment extensively with that feature.

"So far I have been using the standard amplitude in which 7% of the preset power comes on in the first microsecond, and a preliminary analysis of my surgical data indicate that approach has resulted in a 30% decrease in my effective phaco time across all categories of nuclei," he said.

Based on the enhanced safety afforded by that reduction in energy use, Dr Fishkind said he has now changed his technique for cataract removal. He still performs a quick chop procedure, but instead of removing the nuclear pieces deeper within the confines of the capsular bag, he now pulls each piece into the iris plane where it is rechopped and removed with great efficiency.

"If surge occurs, there is a safety advantage for working at the iris plane instead of near the posterior capsule or at the equator. There is also a trade-off with working more anteriorly because it increases ultrasound exposure levels for the corneal endothelium and iris. However, I am less concerned about that issue with ICE because of the low amount of energy I am using in my procedures," Dr Fishkind said.

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