TotalVisc™ – A Dual Viscoelastic System

By Mitchell Shultz, MD

Ophthalmic viscosurgical devices (OVDs) can be classified according to their level of viscosity and cohesion into cohesive, dispersive, viscoadaptive, and combined agents/dual viscoelastic systems.

As summarized in Table 1 and Table 2, each classification has advantages and disadvantages. Generally, cohesive OVDs create space, induce/sustain pressure, and are easier to completely remove from the eye at the end of surgery[1-3] Dispersive OVDs coat and protect intraocular structures and break apart during removal.[1-3] Viscoadaptive OVDs have biphasic nature (behaving both as a fluid and solid depending upon environmental conditions), and have been called pseudodispersive.[4]

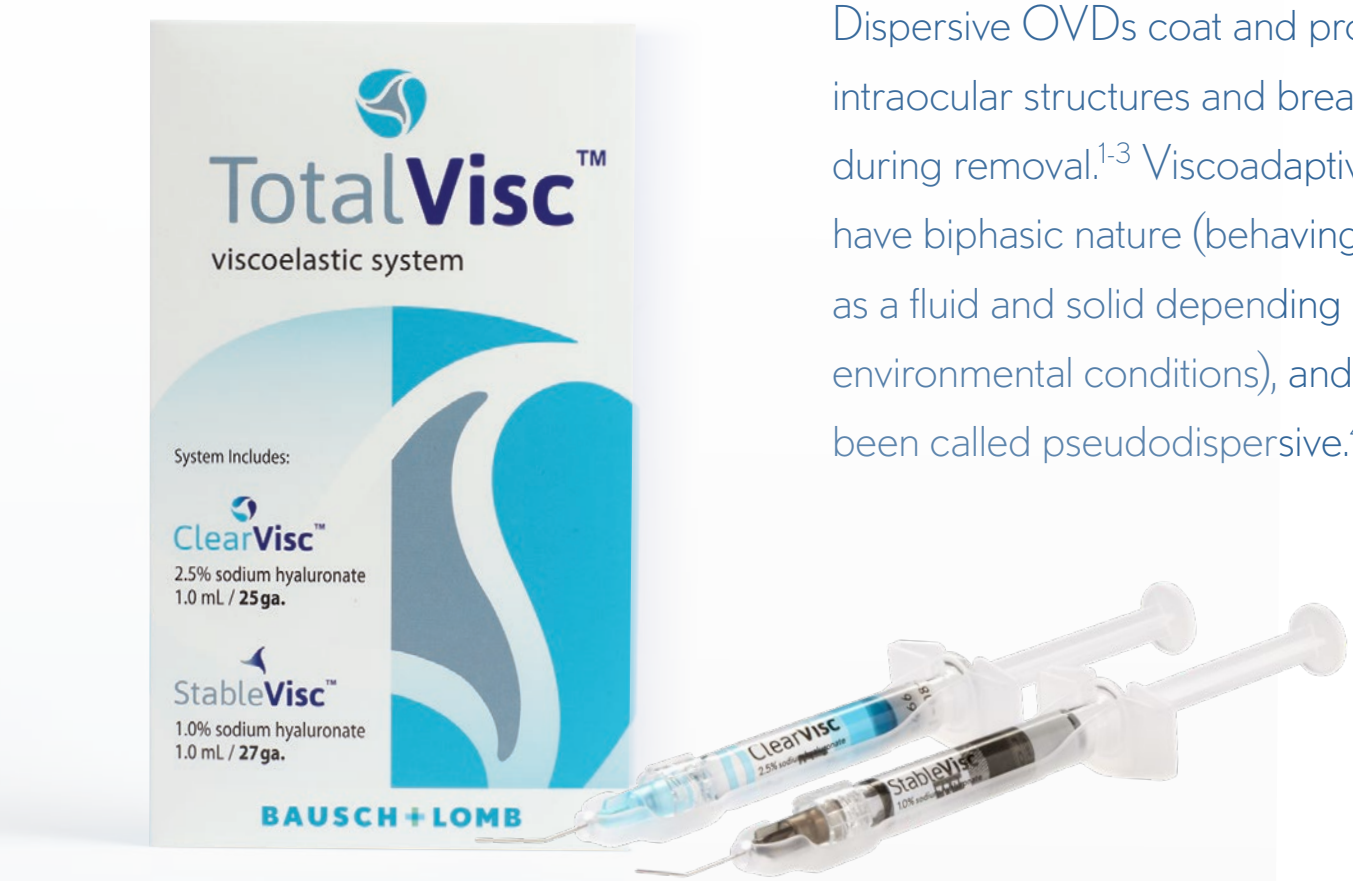

Table 1: OVD Class Advantages[1-3,5,6]

	Cohesive OVD	Dispersive OVD	Viscoadaptive OVD
Maintain space in the eye during surgery	X	X	X
Improve stability to avoid capsular rupture	X	X	X
Easy to completely remove from eye at the end of surgery	X		
Maintains high level of chamber stability		X	X
Provides high degree of endothelial coating/ protection of intraocular structures		X	
Protects intraocular tissue against free radical damage*	X	X	
Reduces risk of collateral damage to delicate intraocular tissues	X	X	X
Enhances visualization of ocular tissue during surgery	X	X	
Liquid enough to be injected through a small-bore cannula	X	X	X
Rheologic behavior during surgery changes depending on conditions of turbulence			X
Well-retained in the anterior segment		X	X

*Depends on the composition of the OVD

Table 2: OVD Class Disadvantages[1-3,5,6]

	Cohesive OVD	Dispersive OVD	Viscoadaptive OVD
Increased risk of IOP elevation attributed to residual OVD obstructing the aqueous drainage system		X	X
Increased risk for unintentional removal during normal irrigation/aspiration = less chamber stability	X		
Increased risk for unintentional removal during normal irrigation/aspiration = reduced protection of intraocular structures	X		
Takes longer to completely remove at the end of surgery		X	X
Breaks apart during removal		X	X
Longer surgical procedures may require additional OVD	X		
More difficult to inject			X

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The Ideal OVD

It is acknowledged that the ideal OVD would (1) be easy to insert and remove from the eye, (2) maintain the anterior chamber, (3) not impair vision by trapping air bubbles, (4) not increase intraocular pressure (IOP), (5) protect the endothelium and eye structures, and (6) have appropriate retention during phacoemulsification and intraocular lens (IOL) implantation.[2, 7] Currently, this ideal OVD does not exist. However, dual viscoelastic systems were designed to have the advantages of both cohesive and dispersive OVDs in attempt to acquire properties of an ideal OVD for each step of the procedure.

OVD types can be used for different purposes and at different stages during surgery. The surgeon may choose a cohesive OVD to help enlarge a small, unresponsive pupil; to smooth the front capsule; and to create space by deepening the anterior chamber.[2, 5] The surgeon may choose a dispersive OVD to protect the corneal endothelium over a longer surgery, to help prepare an IOL, lubricate a cartridge, or fold a lens.[5] It is accepted that the performance of 2 or more OVDs with different properties supersedes the performance of one OVD.[8] (Note: OVDs should not mix or dilute one another.[8]) Thus, a dual viscoelastic system containing both a cohesive and dispersive OVD would combine the advantages of both. In practice, a dual viscoelastic system is used with the soft-shell technique where dispersive plus cohesive or viscoadaptive OVDs are used simultaneously within the chamber to achieve maximum control in the operative environment.[5] Briefly, the soft-shell technique involves first injecting a dispersive OVD into the anterior chamber towards the undersurface of the cornea. Then the cohesive OVD is injected underneath to push the dispersive OVD against the corneal endothelial surface while flattening the anterior capsule to facilitate capsulorhexis creation.[9] Generally, OVD choice may impact ease of surgery and postoperative outcome, which ultimately affect patient satisfaction.[5]

Safety and Effectiveness of StableVisc™

StableVisc™ (Bausch & Lomb) is a cohesive OVD that contains 10 mg/mL sodium hyaluronate (SH) and 40 mg/mL of sorbitol (refer to the full product specifications for additional details).[10] The safety and effectiveness of StableVisc were evaluated in a multicenter, masked, randomized, prospective clinical study and compared to ProVisc cohesive OVD (Alcon Vision LLC), which has similar mechanical properties.[11] Adults (≥ 45 years) with age-related non-complicated cataract considered amenable to treatment with standard phacoemulsification cataract extraction and IOL implantation were included. Patients were randomized to receive either StableVisc (n = 187) or ProVisc (n = 193) during standard cataract surgery. No other OVD was permitted. Changes in mean endothelial cell density (ECD) (an effectiveness parameter) were measured to evaluate how effectively the OVD protects the corneal endothelium. IOP was monitored (a safety parameter) to evaluate how completely the OVD was removed from the eye. Adverse events (AEs) were also monitored.

The StableVisc group was noninferior to the ProVisc group in mean ECD loss from baseline to 3 months ($P = 0.0019$) **(Figure 1)**. The StableVisc group was noninferior to the ProVisc group in the proportion of patients with postoperative IOP ≥30 mmHg at any follow-up visit ($P = 0.003$). Also, the StableVisc and ProVisc groups had a similar mean ± SD change in IOP from baseline to 6 hours (3.8 ± 6.29 mmHg and 4.2 ± 6.87 mmHg, respectively) and 24 hours (2.3 ± 4.57 mmHg and 2.6 ± 4.73 mmHg, respectively) **(Figure 2)**.

StableVisc contains a larger syringe volume than ProVisc (1.0 mL vs 0.85 mL, respectively). Accordingly, a smaller relative volume of the StableVisc was used during the surgery, and fewer patients treated with the StableVisc required 100% of the syringe volume (StableVisc: 26.6% of patients vs ProVisc: 42.9% of patients). In both groups, all eyes had all OVD removed.

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Both groups had similar rates of AEs. The most frequently reported AEs were corneal edema (StableVisc: 7.3%; ProVisc: 5.1%) and increased IOP (StableVisc: 7.3%; ProVisc: 8.2%). Corrected distance visual acuity (CDVA) similarly improved in both groups by 3 months (mean ± SD; StableVisc: 0.04 ± 0.1 logMAR; ProVisc: 0.05 ± 0.1 logMAR). Postoperatively, both groups had similar numbers of anterior chamber cells and presence/severity of anterior chamber flare (markers of inflammatory reactions), and similar proportion of eyes with none to mild corneal stromal edema and corneal wound edema. The mean corneal thickness was similar between groups at baseline and 3 months. Overall, no unexpected safety findings were observed, and no clinically relevant differences in safety endpoints were observed between the groups. The study conclusions were that StableVisc cohesive OVD is safe, effective, and noninferior to the marketed ProVisc cohesive OVD when used in cataract surgery.

StableVisc and ProVisc were also compared in a wet lab study to determine whether surgeons perceived differences between the OVDs in terms of expression, visualization, aspiration, and manipulation.[11] Six surgeons each performed 3 standard cataract surgeries by phacoemulsification on porcine eyes, implanted a silicone posterior chamber IOL in the capsular bag, cleared the anterior chamber via aspiration, and used StableVisc or ProVisc during the surgery. During each surgery, surgeons graded the performance of each OVD on attributes listed in Table 3. Both products were rated "good" to "excellent" for all attributes, with little variation between products. Ranking the scores showed that StableVisc performed slightly better than ProVisc on all tested attributes (but were equally rated for compatibility on OVD use with an inserter) (Table 4). The surgeons remarked that compared with ProVisc, StableVisc had better chamber retention and visualization, and the volume of material in the StableVisc syringe was preferred because it contained more OVD to complete the surgery without having to use a second syringe.[11]

Safety and Effectiveness of ClearVisc™

ClearVisc™ (Bausch & Lomb) is a dispersive OVD that contains 25 mg/mL SH and 40 mg/mL of sorbitol (refer to the full product specifications for additional details).[12] The safety and effectiveness of ClearVisc compared with Viscoat (Alcon Vision LLC) were evaluated in a prospective, multicenter, controlled, randomized study.[13] Patients were stratified by site, age group, and cataract severity. Viscoat is an approved dispersive OVD with properties similar to ClearVisc. Adults (≥ 45 years) with age-related, non-complicated cataract considered amenable to treatment with standard phacoemulsification extraction and IOL implantation were included, and 184 patients were in the ClearVisc group and 188 patients were in the Viscoat group. No other OVD was permitted. The change in ECD was the primary measure of effectiveness and incidence of IOP measurement ≥ 30 mmHg was the primary measure of safety. AEs were also collected.

The ClearVisc group was noninferior to the Viscoat group in mean ECD loss from baseline to 3 months (P = 0.0032) **(Figure 3)**. The ClearVisc group was noninferior to the Viscoat group in the proportion of patients with postoperative IOP ≥ 30 mmHg at all follow-up visits (P = 0.0002). Both groups had a similar mean change in IOP from baseline to 6 hours (9.4 mmHg and 10.0 mmHg, respectively) and 24 hours (4.1 mmHg and 3.9 mmHg, respectively) **(Figure 4)**.

ClearVisc contains a larger syringe volume than Viscoat (1 mL vs 0.75 mL, respectively). Accordingly, a smaller estimated total percent volume of ClearVisc syringes were used during the surgery, and fewer patients treated with the ClearVisc required 100% of the syringe volume (ClearVisc: 19.6% of patients and Viscoat: 29.8% of patients).

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Figure 1: Mean Loss of Endothelial Cell Density from Baseline to 3 Months—StableVisc vs ProVisc

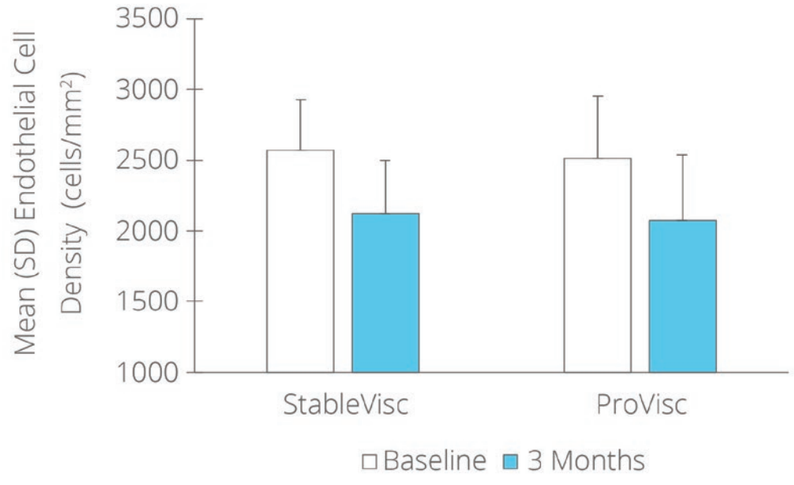

Figure 2: Mean Intraocular Pressure Over Time—StableVisc vs ProVisc

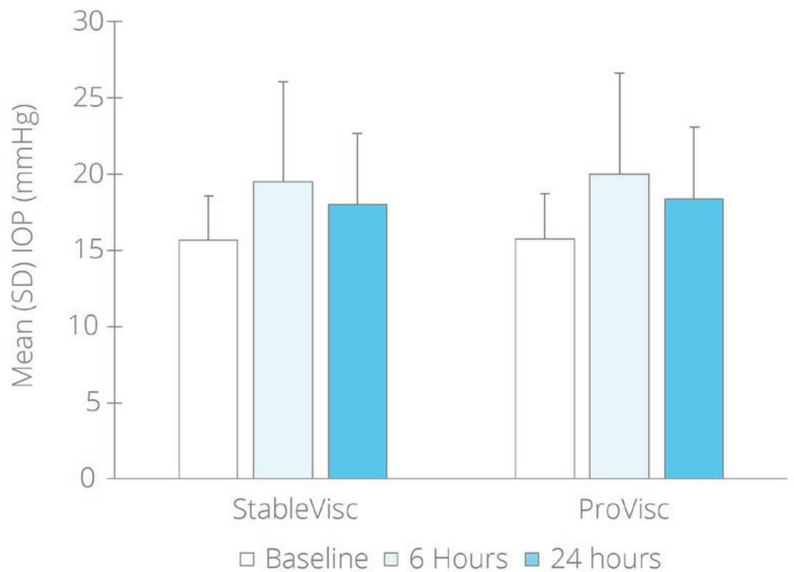

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Table 3: Mean Test Attribute Score – StableVisc vs ProVisc

#	Attribute	StableVisc	ProVisc
1	Ease of OVD extrusion (ie force of expression)	1.2	1.4
2	Ease of movement of cannula in eye (angle and length of needle)	1.1	1.2
3	Ease of distribution within the anterior chamber	1.1	1.3
4	Visualization of ocular tissue through OVD	1.1	1.4
5	Compatibility of the OVD use with an inserter	1.0	1.0
6	Functional use of OVD with IOL delivery	1.1	1.4
7	Chamber space maintenance during IOL delivery	1.1	1.3
8	Ease of OVD removal from the anterior chamber	1.0	1.4
9	Overall performance of OVD against design/expectation	1.1	1.3
10	Comparison against control	1.1	1.3
Scores: 1 = excellent, 2 = good, 3 = acceptable, 4 = poor, 5 = unacceptable			

Table 4: Ranking of Tested Attributes – StableVisc vs ProVisc

#	Attribute	StableVisc	ProVisc
1	Ease of OVD extrusion (ie force of expression)	X	
2	Ease of movement of cannula in eye (angle and length of needle)	X	
3	Ease of distribution within the anterior chamber	X	
4	Visualization of ocular tissue through OVD	X	
5	Compatibility of the OVD use with an inserter		
6	Functional use of OVD with IOL delivery	X	
7	Chamber space maintenance during IOL delivery	X	
8	Ease of OVD removal from the anterior chamber	X	
9	Overall performance of OVD against design/expectation	X	
10	Comparison against control	X	
Performance Value: x = Ranked slightly better on a scale of 1.0 to 1.5.			

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Figure 3: Mean Loss of Endothelial Cell Density from Baseline to 3 Months—ClearVisc vs Viscoat

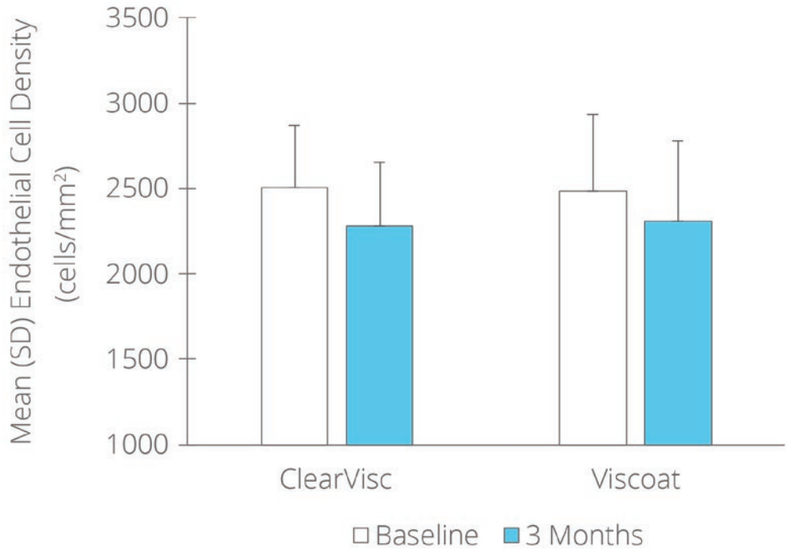

Figure 4: Mean Intraocular Pressure Over Time—ClearVisc vs Viscoat

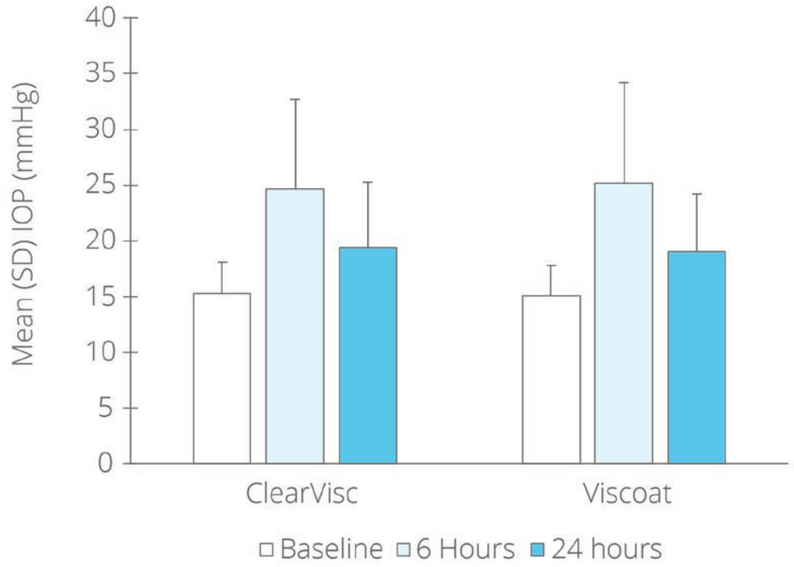

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Table 5: Mean Test Attribute Score — ClearVisc vs Viscoat

#	Attribute	ClearVisc	Viscoat
1	Ease of OVD extrusion (ie force of expression)	1.6	1.4
2	Ease of movement of cannula in eye (angle and length of needle)	1.1	1.2
3	Ease of distribution within the anterior chamber	1.2	1.4
4	Visualization of ocular tissue through OVD	1.3	1.4
5	Compatibility of the OVD use with an inserter	1.0	1.0
6	Functional use of OVD with IOL delivery	1.0	1.3
7	Chamber space maintenance during IOL delivery	1.1	1.2
8	Ease of OVD removal from the anterior chamber	2.3	3.1
9	Overall performance of OVD against design/expectation	1.4	1.7
10	Comparison against control	1.2	1.3

Scores: 1 = excellent, 2 = good, 3 = acceptable, 4 = poor, 5 = unacceptable

Table 6: Ranking of Tested Attributes — ClearVisc vs Viscoat

#	Attribute	ClearVisc	Viscoat
1	Ease of OVD extrusion (ie force of expression)		X
2	Ease of movement of cannula in eye (angle and length of needle)		
3	Ease of distribution within the anterior chamber		
4	Visualization of ocular tissue through OVD	X	
5	Compatibility of the OVD use with an inserter		
6	Functional use of OVD with IOL delivery	X	
7	Chamber space maintenance during IOL delivery	X	
8	Ease of OVD removal from the anterior chamber	X	
9	Overall performance of OVD against design/expectation	X	
10	Comparison against control	X	

Performance Value: x = Ranked slightly better on a scale of 1.0 to 1.5.

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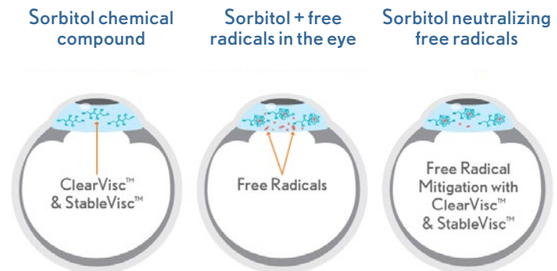
The ClearVisc and Viscoat groups had similar rates of AEs. The most frequently reported AEs were increased IOP (ClearVisc:16.8%; Viscoat: 20.2%) and punctate keratitis (ClearVisc: 9.2%; Viscoat: 6.9%). Mean CDVA similarly improved in both groups to 0.05 ± 0.1 logMAR by 3 months. Postoperatively, both groups had similar numbers of anterior chamber cells and presence/severity of anterior chamber flare, and similar proportion of eyes with none to mild corneal stromal edema and corneal wound edema. The mean corneal thickness was similar between groups at baseline and 3 months. Overall, no unexpected safety findings were observed, and no clinically relevant differences in safety endpoints were observed between the groups. The study conclusions were that ClearVisc has beneficial properties as a surgical aid in cataract extraction and IOL implantation.

ClearVisc and Viscoat were also compared in a wet lab study to determine whether there were any surgeon-perceived differences in expression, visualization, aspiration, and manipulation. Six expert cataract surgeons performed a standard cataract surgery using ClearVisc OVD (test) or Viscoat OVD (control), 3 times each, on porcine eyes mounted under a surgical scope. During the surgery the surgeons graded the performance of each OVD (1 = excellent to 5 = unacceptable) against an attribute list (Table 5). The analyzed data were pooled across 9 wet lab surgical procedures. ClearVisc was "good" to "excellent" for all attributes. Viscoat was rated "good" to "excellent" for 9 of 10 attributes, with "ease of OVD removal from the anterior chamber," scored as "acceptable" to "poor." ClearVisc performed slightly better than Viscoat on 6 of 10 attributes (Table 6). The overall conclusion was that in wet lab conditions, both OVDs performed essentially equivalent; although, ClearVisc was easier to remove and performed slightly better on visualization, IOL delivery, and overall performance.

TotalVisc Viscoelastic System

The TotalVisc™ viscoelastic system (Bausch & Lomb) co-packs 1 mL of StableVisc with 1 mL of ClearVisc, which is a larger fill volume than other OVDs. The combination contains a large total volume to reduce the need for additional syringes of OVD midway through surgery,[11] which reduces waste and cost, and improves convenience. Both StableVisc and ClearVisc were developed to provide mechanical and chemical protection. Namely, the specific molecular weight and viscosity mechanically protect the corneal endothelium, while the sorbitol and SH are free radical scavengers to chemically protect the corneal endothelium (**Figure 5**).[12, 14, 15] Sorbitol and SH work synergistically, and when combined in an OVD they have greater free radical scavenging activity than other commercially available OVDs without the combination.[15] Further, sorbitol provides additional benefits such as helping to maintain the appropriate OVD viscosity, moisturizing the corneal epithelium, and preventing needle clogging when the same syringe is used more than once at intervals during the surgery.[16, 17]

Figure 5: Free-Radical Scavenging Action of Sorbitol



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When comparing the rates of ECD loss in the ClearVisc/Viscoat randomized, controlled study[13] with the rates in the StableVisc/ProVisc randomized controlled study[11] (**Figure 1** and **Figure 3**), the differences between dispersive and cohesive OVDs is apparent. It is important to note that it is well accepted that dispersive OVDs (ie ClearVisc and Viscoat) provide more endothelial protection than cohesive OVDs (ie StableVisc and ProVisc) due to their design.[18, 19] This mechanistic difference supports the added-value of a dual system such as TotalVisc. Likewise, it is well known that dispersive OVDs as compared with cohesive OVDs have an increased risk for post-surgery IOP elevation because dispersive OVDs are harder to completely remove, and residual OVD can obstruct the aqueous drainage system.[1-3] Thus, the IOP results in the randomized controlled studies[11, 13] showing that the ClearVisc and Viscoat groups had higher IOP 6-hours postoperative compared with the StableVisc and ProVisc groups (**Figure 2** and **Figure 4**) are as expected and also support the added-value of a dual viscoelastic system.

Summary

Currently, the ideal OVD does not exist. However, dual viscoelastic systems were designed to have the advantages of both cohesive and dispersive OVDs in attempt to acquire properties of an ideal OVD. TotalVisc is a dual viscoelastic system composed of StableVisc (a cohesive OVD) and ClearVisc (a dispersive OVD). StableVisc and ClearVisc were developed to provide both mechanical and chemical protection of the corneal endothelium through their specific molecular weight and viscosity and by containing both sorbitol and SH. StableVisc and ClearVisc have been shown to be safe and efficacious in randomized, controlled studies with positive surgeon-graded the performance including excellent visualization. TotalVisc contains a large total volume to reduce the need for additional syringes of OVD midway through surgery, which reduces waste and cost and improves convenience.

KEY TAKEAWAYS

- TotalVisc Viscoelastic System, with both cohesive and dispersive devices, provides the advantages of each different OVD class throughout the procedure.
- TotalVisc is a 2-mL dual viscoelastic system composed of 1 mL of StableVisc (a cohesive OVD) and 1 mL of ClearVisc (a dispersive OVD), which is a larger fill volume than other OVDs.
- StableVisc and ClearVisc were developed to provide both mechanical and chemical (benefit of the sorbitol) protection of the corneal endothelium during ophthalmic surgery.
- StableVisc and ClearVisc both contain sorbitol, which is a free radical scavenger to protect the corneal endothelium.
- StableVisc and ClearVisc have been shown to be safe and efficacious in randomized, controlled studies with positive surgeon-graded performance.
- StableVisc and ClearVisc had excellent visualization in a wet lab survey of 6 expert surgeons.

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ORDER NUMBER TVISC20

TotalVisc™ includes one 1.0mL of StableVisc™ and one 1.0mL of ClearVisc™

ORDER NUMBER: DVISC10
SIZE: 1.0mL
VISCOSITY: 40,000
MOLECULAR WEIGHT (DALTONS): <1.0 million
COMPOSITION: 2.5% HA, 4% Sorbitol
COHESION: Dispersive
OSMOLALITY: 330
CANNULA SIZE: 25G

ORDER NUMBER: SVISC10
SIZE: 1.0mL
VISCOSITY: 50,000
MOLECULAR WEIGHT (DALTONS): 2.1 million
COMPOSITION: 1.0% HA, 4% Sorbitol
COHESION: Cohesive
OSMOLALITY: 340
CANNULA SIZE: 27G

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IMPORTANT SAFETY INFORMATION FOR CLEARVISC™, STABLEVISC™ AND TOTALVISC™ OVDS
INDICATIONS FOR USE: ClearVisc™, StableVisc™ and TotalVisc™ OVDs are indicated for use as surgical aids in ophthalmic anterior segment procedures including: Extraction of a cataract; Implantation of an intraocular lens (IOL).
CONTRAINDICATIONS: There are no contraindications to the use of ClearVisc™, StableVisc™ and TotalVisc™ when used as a surgical aid in ophthalmic anterior segment procedures.
PRECAUTIONS: Precautions normally considered during anterior segment procedures are recommended. Pre-existing glaucoma may place patients at risk for increases in intraocular pressure from the OVD during the early postoperative period.
WARNINGS:
Do not use if the sterile barrier has been breached. Sterility cannot be guaranteed, and the patient will be at increased risk for infection.
Do not use the OVD in subjects with known allergies to any of its components.
An excess quantity of OVD should not be used. Excess OVD can cause increased intraocular pressure.
The OVD should be removed from the anterior chamber at the end of surgery to prevent or minimize postoperative intraocular pressure increases (spikes). OVD remaining in the eye can cause increased intraocular pressure.
If the postoperative intraocular pressure increases above expected values, corrective therapy should be administered. Increased intraocular pressure may lead to inflammation or vision loss.
Do not re-use the cannula. Even after cleaning and rinsing, resterilized cannula could release particulate matter as the OVD is injected. It is recommended that a single-use disposable cannula be used when administering the OVD. Reuse may cause eye inflammation.
If any particulate matter is observed, it should be removed by irrigation and/or aspiration. Particulate matter left in the eye may cause increased IOP or Light scattering /obstruction.
Store at 2° to 8°C (36° to 46°F). Protect from freezing. The shelf life of ClearVisc, StableVisc and TotalVisc is not guaranteed if it is not properly stored.
ADVERSE REACTIONS:
Sodium hyaluronate is a natural component of tissues within the body and is generally well tolerated in human eyes. Transient postoperative inflammatory reactions and increases in intraocular pressure have been reported. Inflammation may result from increased intraocular pressure caused by use of the OVD. Intraocular inflammation, i.e., toxic anterior segment syndrome (TASS), has been attributed to OVDs. Furthermore, vision loss may be possible as a result of increased intraocular pressure and inflammation.
ATTENTION: Refer to the Directions for Use labeling for a complete listing of indications, warnings and precautions, clinical trial information, etc.
CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

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