

CLINICAL SCIENCE

A clinical comparison between DisCoVisc and 2% hydroxypropylmethylcellulose in phacoemulsification: a fellow eye study

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OBJECTIVE: This study sought to compare the effects and outcomes of two ophthalmic viscosurgical devices, 1.6% hyaluronic acid/4.0% chondroitin sulfate and 2.0% hydroxypropylmethylcellulose, during phacoemulsification.

METHODS: This prospective, randomized clinical trial comprised 78 eyes (39 patients) that received phacoemulsification performed by the same surgeon using a standardized technique. Patients were randomly assigned to receive either 1.6% hyaluronic acid/4.0% chondroitin sulfate or 2.0% hydroxypropylmethylcellulose on the first eye. The other eye was treated later and received the other viscoelastic agent. Preoperative and postoperative examinations (5, 24 and 48 hours; 7 and 14 days; 3 and 6 months) included measurements of the total volume of the ophthalmic viscosurgical device, ultrasound and washout times to completely remove the ophthalmic viscosurgical device, intraocular pressure, central corneal thickness and best-corrected visual acuity. The corneal endothelial cell count was measured at baseline and at six months postoperatively. ClinicalTrials.gov: NCT01387620.

RESULTS: There were no statistically significant differences between groups in terms of cataract density or ultrasound time. However, it took longer to remove 2.0% hydroxypropylmethylcellulose than 1.6% hyaluronic acid/4.0% chondroitin sulfate, and the amount of viscoelastic material used was greater in the 2.0% hydroxypropylmethylcellulose group. In addition, the best-corrected visual acuity was significantly better in the hyaluronic acid/chondroitin sulfate group, but this preferable outcome was only observed at 24 hours after the operation. There were no statistically significant differences between the two ophthalmic viscosurgical devices regarding the central corneal thickness or intraocular pressure measurements at any point in time. The corneal endothelial cell count was significantly higher in the hyaluronic acid/chondroitin sulfate group.

CONCLUSION: The ophthalmic viscosurgical device consisting of 1.6% hyaluronic acid/4.0% chondroitin sulfate was more efficient during phacoemulsification and was easier to remove after IOL implantation than 2.0% hydroxypropylmethylcellulose. In addition, the corneal endothelial cell count was significantly higher following the use of hyaluronic acid/chondroitin sulfate than with hydroxypropylmethylcellulose, which promoted an improved level of corneal endothelium protection.

KEYWORDS: Cataract; Viscoelastic Agent; Intraocular Lens.

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INTRODUCTION

Ophthalmic viscosurgical devices (OVDs) play an important role in modern cataract surgery. They maintain adequate space, facilitate intraocular lens (IOL) implantation and surgical maneuvers, and they protect the corneal endothelium during various stages of cataract surgery (1-3).

Transient corneal edema, however, is a common complication of cataract surgery that delays visual improvement, especially in the early postoperative period (4,5).

Many viscoelastic substances are available for cataract surgery and differ depending on their physical and chemical properties (6). The OVD 2.0% hydroxypropylmethylcellulose (2.0% HPMC) has low zero-shear viscosity and dispersive characteristics (7). This commonly used OVD is more likely to be retained in the eye than DisCoVisc but has the disadvantages of poorly maintained spacing and occasional difficulties with its removal (8,9).

DisCoVisc (1.6% hyaluronic acid/4.0% chondroitin sulfate), which combines the rheological behaviors of highly viscous and dispersive OVDs, was the first viscous dispersive viscoelastic to become available. The viscous properties of

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DisCoVisc facilitate space maintenance, while its dispersive properties impart tissue protection (3,10).

This prospective study was performed to compare the effects and outcomes of DisCoVisc (Alcon Laboratories, Inc., Fort Worth, TX) and 2.0% HPMC (Celoftal, Alcon Laboratories, Inc., Fort Worth, TX) during phacoemulsification.

MATERIALS AND METHODS

This prospective, randomized study with intra-individual comparisons comprised 78 eyes from 39 patients who received bilateral phacoemulsification. The Institutional Review Board approved the study, and all patients provided informed consent before enrollment. The inclusion criteria consisted of bilateral age-related cataracts from grades 1 to 3 based on the lens opacities classification system (LOCS III), and no other ocular pathology or condition and pupil dilation that was greater than 7.0 mm. The exclusion criteria consisted of black, brunescient, traumatic or subluxated cataracts; coexisting corneal endothelial disease (endothelial cell count $<2,000$ cells/mm²); glaucoma; uveitis and pseudo-exfoliation. Patients who had undergone previous ocular surgery were also excluded.

Preoperative and postoperative examinations measured the best-corrected visual acuity (BCVA), central corneal thickness (CCT), graded cataract density using a slit lamp, Goldmann applanation tonometry and corneal endothelial cell count. The corneal thickness was measured by ultrasonic pachymetry using the OcuScan system (Alcon Laboratories, Inc.). Three acceptable values were generated for each eye, and a mean value was obtained. Visual acuity was measured using the Early Treatment of Diabetic Retinopathy Study charts under photopic conditions (target luminance of 85 cd/m²).

The same experienced surgeon performed all surgeries under topical anesthesia. Phacoemulsification was performed with the Infinity Vision System (Alcon Laboratories, Inc.) using a standardized surgical technique (stop-and-chop). A 2.4-mm-wide, 2-step corneal incision was fashioned, and a continuous curvilinear capsulorhexis was made using a forceps under viscoelastic protection. The lens nucleus and cortex were hydrodissected with a balanced salt solution. This dissection was followed by 1-handed irrigation and aspiration (I/A) to ensure that the cortex was completely removed. A 3-piece, foldable, acrylic IOL (Alcon Laboratories, Inc.) was implanted in the capsular bag. The rear section of the IOL surface was aspirated to completely remove the OVD under the IOL.

An envelope system was used to randomly assign all enrolled patients to an OVD regimen. Sequenced and sealed envelopes containing the first type of OVD (2.0% HPMC or DisCoVisc) were prepared before surgery. An unscrubbed observer in the operating room opened the envelopes and assigned each patient to the prescribed option. The second eye was treated later and received the other viscoelastic agent for all steps of the phacoemulsification.

The following components were measured intraoperatively: the total volume of the OVD used; cumulative dissipated energy (CDE), ultrasound time during phacoemulsification and washout time to remove the OVD.

Postoperatively, the patients were administered 0.5% moxifloxacin four times per day for one week and 0.1% dexamethasone four times per day for one week and three times per day for an additional two weeks.

After surgery, each patient was examined at 5, 24 and 48 hours, 7 and 14 days and 3 and 6 months postoperatively. The corneal endothelial cell count was measured preoperatively and at six months postoperatively.

During all examinations, the patient and the observer were masked concerning the OVD used in each eye.

Statistical analyses were performed using SPSS for Windows (version 11.5; SPSS, Inc., Chicago, Illinois, USA). For the primary outcome measures, the statistical tests were conducted at a level of $p < 0.05$. For the statistical analysis of visual acuity, the logarithm of the minimal angle of resolution acuity value was used. The analysis was based on a non-normal distribution of the data. The two OVDs were compared between eyes intra-individually. The statistical analyses were performed using the unpaired t-test, ANOVA, chi-square test, Fisher's exact test and the Mann-Whitney U-test.

RESULTS

Seventy-eight eyes from 39 consecutive patients (13 men [33.3%] and 26 women [66.7%]) were enrolled in the study. The mean age of the patients was 71.5 ± 7.9 years. No significant differences were observed between groups regarding the mean IOL power ($p = 0.597$), cataract density ($p = 0.363$), preoperative BCVA ($p = 0.695$) or endothelial cell count ($p = 0.676$). No eyes experienced intraoperative or postoperative complications.

Table 1 lists the intraoperative variables measured. It took significantly more time to remove the 2.0% HPMC (0.22 ± 0.09 min) than the DisCoVisc (0.17 ± 0.06 min) ($p < 0.001$), and the amount of viscoelastic material used was greater with 2.0% HPMC (1.35 ± 0.20 ml) than DisCoVisc (0.89 ± 0.11 ml) ($p < 0.001$). No significant difference was found between groups regarding the mean ultrasound time ($p = 0.456$) or CDE ($p = 0.401$).

The mean preoperative central corneal thickness was 535.3 ± 33.9 μ m in the DisCoVisc group and 538.2 ± 35.9 μ m in the 2.0% HPMC group ($p = 0.756$) (Table 2). The corneas had increased in thickness at 5 hours after the operation ($p < 0.001$) but began to decrease by 24 hours, reaching preoperative levels at three months post-surgery. No

Table 1 - Intraoperative variables.

	DisCoVisc	2.0% HPMC	p-value
Amount of viscoelastic used (mL)			
Mean \pm SD	0.89 \pm 0.11	1.35 \pm 0.20	0.001*
Median	0.9	1.50	
Range	0.70–1.00	0.75–1.50	
CDE			
Mean \pm SD	17.28 \pm 8.92	15.57 \pm 9.11	0.401
Median	16.31	15.41	
Range	4.22–39.06	0.20–42.64	
Ultrasound time (min)			
Mean \pm SD	0.61 \pm 0.38	0.56 \pm 0.45	0.456
Median	0.47	0.40	
Range	0.16–1.40	0.10–2.30	
Washout time of viscoelastic (min)			
Mean \pm SD	0.17 \pm 0.06	0.22 \pm 0.09	0.001*
Median	0.15	0.20	
Range	0.10–0.36	0.12–0.51	

*statistically significant; CDE=cumulative dissipated energy; HPMC=hydroxypropylmethylcellulose.

Table 2 - Primary outcome variables (DisCoVisc versus HPMC 2.0%).

Variables	DisCoVisc Mean \pm SD	2.0% HPMC Mean \pm SD	p-value
Corneal Thickness (μm)			
Preoperative	535.3 \pm 33.9	538.2 \pm 35.9	0.756
Postoperative			
5 hours	620.7 \pm 72.6	628.4 \pm 59.2	0.634
24 hours	605.5 \pm 74.8	605.9 \pm 58.1	0.896
48 hours	583.7 \pm 51.3	588.2 \pm 49.6	0.698
7 days	574.5 \pm 57.8	572.4 \pm 46.9	0.860
14 days	558.9 \pm 38.5	560.2 \pm 45.6	0.897
3 months	543.2 \pm 36.8	543.8 \pm 39.5	0.943
6 months	538.6 \pm 36.0	541.3 \pm 36.6	0.744
Intraocular Pressure (mmHg)			
Preoperative	13.4 \pm 2.3	13.5 \pm 2.1	0.756
Postoperative			
5 hours	14.3 \pm 3.6	14.4 \pm 3.8	0.951
24 hours	13.5 \pm 3.9	14.3 \pm 3.6	0.325
48 hours	13.1 \pm 3.0	12.9 \pm 2.8	0.813
7 days	12.9 \pm 2.4	13.1 \pm 3.9	0.780
14 days	13.0 \pm 3.1	12.6 \pm 3.3	0.645
3 months	12.6 \pm 2.2	12.6 \pm 2.3	0.880
6 months	12.2 \pm 1.8	12.5 \pm 2.3	0.510
Endothelial cell count (cells/mm²)			
Preoperative	2,358 \pm 334	2,364 \pm 358	0.758
Postoperative			
6 months	2,214 \pm 372	2,032 \pm 460	0.001*

* statistically significant; HPMC = hydroxypropylmethylcellulose.

statistically significant difference was found between the OVDs at any postoperative time point ($p = 0.533$).

At five hours postoperatively, all groups had increased IOP ($p < 0.001$), which gradually decreased to the preoperative levels by seven days post-surgery. The highest mean IOP values were observed in the 2.0% HPMC group (14.4 ± 3.8 mmHg) at 5 hours postoperatively ($p = 0.951$). The mean IOP values obtained at all examinations are shown in Table 2. There was no statistically significant difference between OVDs at any examination point ($p = 0.834$). Only 1 eye (1.2%) demonstrated an IOP less than 5 mmHg (in the DisCoVisc group at 24 hours), and no IOP spike greater than 30 mmHg was measured in either group (Table 2).

There was a statistically significant difference between OVDs in terms of the postoperative mean BCVA, but only at 24 hours post-surgery (0.35 ± 0.28 and 0.53 ± 0.43 logMAR in the DisCoVisc and 2.0% HPMC groups, respectively [$p < 0.0001$]). At 6 months, the mean BCVA was 0.02 ± 0.07 logMAR in the DisCoVisc group and 0.05 ± 0.10 logMAR in the 2.0% HPMC group ($p = 0.104$).

The mean extent of corneal endothelial cell loss at six months postoperatively was $1.0 \pm 8.6\%$ in the DisCoVisc group and $3.5 \pm 8.2\%$ in the 2.0% HPMC group ($p < 0.001$). Table 2 shows the distribution of corneal endothelial cell counts over time.

DISCUSSION

This contralateral eye study was conducted to analyze the overall clinical performance of two OVDs during phacoemulsification. The clinical usefulness of DisCoVisc in cataract surgery has not been reported previously, with the exception of a few clinical studies that compared DisCoVisc to a soft-shell technique using 3.0% sodium hyaluronate/4.0% chondroitin sulfate (Viscoat) and 1.0% sodium hyaluronate

(Provisc) (11) or to 2.3% sodium hyaluronate (Healon5) (12,13).

In the present study, we compared DisCoVisc to 2.0% HPMC in operations where a single surgeon performed all surgeries using the same standardized technique.

Clinically significant elevations in IOP following uneventful cataract surgery occur in a small percentage of cases. This IOP increase rarely exceeds 30 mmHg in nonglaucomatous eyes and is transient in most cases (14-16), which is in agreement with our results.

We found no significant difference in postoperative IOP between the use of DisCoVisc and 2.0% HPMC with topical anesthesia. Five hours postoperatively, all groups had increased IOP ($p < 0.001$), which gradually decreased to preoperative levels at 7 days post-surgery. Holzer et al. (17) analyzed five OVDs and showed that all groups demonstrated increased IOP at 4 hours postoperatively and that no significant difference was found between groups. Rainer et al. (9) observed IOP spikes more often with 2.0% HPMC than with 1.0% sodium hyaluronate during the 2-hour postoperative period, whereas in our study, no IOP exceeded 30 mmHg in any group. The OVDs were removed with great care from the anterior chamber as well as from behind the IOL at the end of the surgeries, which may indicate that both OVDs were effectively and successfully washed out in our study. Another previous study showed that 4.0% chondroitin sulfate/3.0% sodium hyaluronate (dispersive OVD) caused a significantly higher IOP increase and significantly more IOP spikes than 2.0% HPMC (18).

It is widely assumed that the peak of postoperative IOP increase occurs 4-7 hours after surgery (19), which is in agreement with our results. However, these findings are not in complete agreement with the results of others studies (9,20). The main reason for the postoperative IOP increase seems to be the amount of remaining OVD at the end of the cataract surgery.

We observed an increase in CCT after phacoemulsification in both groups. Following this increase, the CCT decreased continuously in both groups, reaching preoperative levels at three months post-surgery. The absolute difference in CCT did not vary significantly between the groups preoperatively or at any time postoperatively, which may be attributed to the fact that the OVDs used in both groups have dispersive properties and because this study was conducted in patients with simple age-related cataracts with no other ocular complications.

Praveen et al. (11) performed a study to evaluate the safety and efficacy of DisCoVisc and found no significant difference in CCT measurements preoperatively and at seven days or one month postoperatively compared to the use of 3.0% sodium hyaluronate/4.0% chondroitin sulfate and 1.0% sodium hyaluronate. Davis et al. (6) also found no difference in postoperative CCT measurements when comparing 1.6% sodium hyaluronate (Amvisc Plus), 4.0% chondroitin sulfate/3.0% sodium hyaluronate and 2.0% HPMC.

The ability of OVDs to remain in the eye and their ease of removal are important issues during cataract surgery (10). As shown in the present study, the removal time of the OVD was significantly shorter with DisCoVisc. In addition, the results of previous studies have demonstrated that the removal time of DisCoVisc was shorter than that of 2.3% sodium hyaluronate (11) but longer than that of 1.0% sodium hyaluronate in porcine eyes (21). The study by Bissen-Miyajima et al. (10) further analyzed the in vitro

behavior of OVDs and showed that the removal time for DisCoVisc was between those of cohesive (1.0% sodium hyaluronate) and dispersive (3.0% sodium hyaluronate/4.0% chondroitin sulfate) OVDs.

The current study found that corneal endothelial cell loss was significantly lower in the DisCoVisc group, which was most likely due to its superior retention compared to 2.0% HPMC during phacoemulsification. The study by Oshika et al. (12) also demonstrated better endothelium protection with DisCoVisc.

Considering the amount of viscoelastic material used during phacoemulsification, a significantly larger quantity of 2.0% HPMC was needed to perform all steps of the surgery, which implies that DisCoVisc was a more efficient OVD. In addition, Praveen et al. (11) found that a single injection of DisCoVisc was a safe and effective alternative to the use of multiple OVDs.

Our study did not include eyes with dense sclerosis, as dense cataract emulsification is cited as a risk factor for excessive cell loss (22,23). Furthermore, there were no statistically differences between the two OVD groups in terms of cataract density, ultrasound time or CDE (Table 1), thus eliminating any potential effects of these variables. The fact that this study utilized a contralateral comparison minimized intra-individual factors that could have interfered with the outcomes.

However, one limitation of this study was that only simple cataract cases were included. One previous study (24) evaluating DisCoVisc in complex ocular environments showed that this OVD facilitated good intraoperative performance in complex cases and was effective in simple cataract surgeries; however, this study was observational and non-comparative.

In conclusion, the viscous, dispersive OVD DisCoVisc was more efficient during phacoemulsification and was able to be more rapidly removed after IOL implantation compared to 2.0% HPMC. The degree of corneal endothelial cell loss was also significantly lower with DisCoVisc than with 2.0% HPMC, which promoted improved corneal endothelium protection at 6 months postoperatively.

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AUTHOR CONTRIBUTIONS

Espindola RF designed, conducted and managed the study, and was also responsible for the data collection and interpretation, review and preparation of the manuscript. Castro EF designed and conducted the study, and was also responsible for the data collection and interpretation, and review of the manuscript. Santhiago MR managed the study and was also responsible for the data interpretation and review of the manuscript. Kara-Junior N designed, conducted and managed the study and was also responsible for the review of the manuscript. All authors participated sufficiently in this work to take public responsibility for appropriate portions of the content.

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