ORIGINAL ARTICLE

Effects of two ophthalmic viscoelastic devices on the corneal endothelium after phacoemulsification

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ABSTRACT

Objective

This study compared the effects of Discovisc (DV) and Amvisc Plus (AP) on the corneal endothelium of patients after phacoemulsification cataract surgery.

Methods

Forty eyes of 36 adult patients were enrolled in this randomized, double-masked clinical trial. They were randomly assigned to receive either DV or AP during phacoemulsification. Both the patients and the evaluators were masked as to which viscoelastic was used during the surgery. The main outcome measures were endothelial-cell loss after surgery, intraocular pressures (IOP), and change in corneal thickness. Differences between the two groups were analyzed statistically.

Results

The mean endothelial-cell loss was 205.5 (9.79%) in the DV group and 450 (18.10%) in the AP group. There was significantly greater endothelial-cell loss among patients who received AP ($p = 0.01$). The mean postoperative corneal thickness and IOP were similar for both groups.

Conclusions

The use of DV resulted in less endothelial-cell loss compared with AP after uncomplicated phacoemulsification in normal eyes. DV, therefore, provided better protection of the corneal endothelium during cataract surgery.

Keywords: *Ophthalmic viscoelastic device, Phacoemulsification, Endothelial-cell count, Intraocular pressure, Corneal thickness*

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PHACOEMULSIFICATION can result in corneal endothelial damage due to localized temperature increase from the ultrasound energy, turbulent flow of the irrigation solution with contact of lens nuclear fragments,[1] air bubbles,[2] or the formation of reactive free-radical species that produce oxidative damage.

Ophthalmic viscoelastic devices (OVDs) stabilize the anterior chamber and protect the corneal endothelium, thereby reducing corneal endothelial damage during cataract surgery. Prior to their use, corneal edema was the most common cause of failed cataract surgery.[3-4]

OVDs were initially classified as either cohesive[5-6] or dispersive.[7-8] The cohesive, high-molecular-weight OVDs maintain the anterior chamber and are removed more easily during phacoemulsification. Dispersive OVDs containing chondroitin sulfate have lower molecular weights and provide better coating of the corneal endothelium, but are harder to remove from the anterior chamber.[8-11] All of these agents showed comparable results in their ability to protect the corneal endothelium with no difference in postoperative best-corrected visual acuity (BCVA) and percent increase in central corneal pachymetry.[8-12] Combining the use of cohesive and dispersive agents during cataract surgery has been advocated by some authors to maximize the benefits of both.[13]

The introduction of DisCoVisc (DV, Alcon Laboratories, Fort Worth, TX, USA) led to an expansion of the classification scheme that considers cohesion-dispersion index (CDI) (rate of removal of the OVD during aspiration in phacoemulsification) independently from zero-shear viscosity.[14] DV is the first viscous dispersive OVD containing 40 mg sodium chondroitin sulfate (4%) and greater-than-17-mg sodium hyaluronate (3%). Its viscous character facilitates excellent space maintenance while its dispersive nature imparts tissue protection. Oshika and coworkers showed that DV has excellent retention during phacoemulsification and easy removal after IOL implantation.[15]

Amvisc Plus (AP, Bausch and Lomb Pharmaceuticals, Irvine, CA, USA) is a viscous cohesive OVD containing 16 mg sodium hyaluronate (1.6%). Its high viscosity results in good space maintenance and tissue manipulation. Because of the high molecular weight of sodium hyaluronate, AP exhibits high zero-shear viscosity and cohesive behavior.[13] It is therefore readily removed from the eye.

Both DV and AP are classified under the same zero-shear viscosity range of 10^5 to 10^6; one is a viscous cohesive, the other a viscous dispersive.[14] Petroll and colleagues used *in vivo* confocal microscopy in quantitatively assessing 3 OVDs in rabbits following phacoemulsification. They showed that DV had better retention and coating of the endothelium than AP.[16]

This study, therefore, compared the effects of DV and AP on the corneal endothelium of patients undergoing phacoemulsification with intraocular-lens (IOL) implantation based on the following parameters: postoperative endothelial-cell count, corneal thickness, and IOP.

METHODOLOGY

Forty eyes of 36 adults with cataracts scheduled to undergo phacoemulsification surgery by one of the authors (HSU) at the Asian Eye Institute were enrolled in this double-masked, randomized, controlled trial. Patients with a history of trauma, corneal pathology, corneal decompensation, glaucoma, and uveitis were excluded. Patients with preoperative intraocular pressure (IOP) over 22 mm Hg by Goldman applanation tonometry, corneal endothelial-cell counts less than 700 cells/mm^2, and corneal thickness of more than 650 µm were also excluded.

All patients underwent preoperative eye examination that included history taking, visual-acuity determination, IOP measurement, and biomicroscopic examination of the anterior and posterior segments. Manifest refraction of both eyes was also done. The following data were collected pre- and postoperatively: BCVA using the ETDRS chart, IOP, central corneal thickness (CCT) as measured by ultrasonic pachymetry (Pachette 2, DGH, USA), and corneal endothelial-cell density as measured by noncontact specular microscopy (SP1000, Topcon Corporation, Japan). A single observer, masked as to the treatment group of the patients, interpreted the specular-microscopy results and determined the endothelial-cell count. Masked observers measured the visual acuity and IOP, graded cataract nuclear density according to the Lens Opacities Classification System II (LOCS II).[17]

The patients were randomly assigned by toss coin to receive either DV or AP. All surgeries were done by a single surgeon (HSU), who was masked as to which OVD was used. Phacoemulsification was performed under topical anesthesia using proparacaine 0.5%. The technique included creating a side port with a 15-degree keratome. The assigned OVD, transferred beforehand to a 1-cc unlabeled syringe, was injected through the side port until the anterior chamber was filled. A clear corneal incision was then made using a 3.0-mm keratome. Continuous curvilinear capsulorhexis was created, followed by hydrodissection and hydrodelineation with balanced saline solution (BSS). Phacoemulsification was performed using the same machine (Millenium Phaco Machine, Bausch and Lomb, USA) for all eyes. Nuclear disassembly was performed using a stop-and-chop technique. The anterior chamber and capsular bag were filled with OVD after removing the remaining cortical material using an irrigation and aspiration (I/A) probe. A foldable acrylic IOL was subsequently implanted. The OVD was removed using I/A until the anterior chamber was cleared of all visible OVD. The phacoemulsification time, ultrasound power, and total operative time were recorded.

The patients were examined 1, 8, and 30 days after surgery. BCVA and IOP were taken and slitlamp biomicroscopy was done at each follow-up visit. Corneal pachymetry and specular microscopy of the involved eye were performed on day 30 postoperation.

All numerical continuous data were summarized using descriptive statistics (percentage, frequency distribution, and measures of central tendency). Categorical variables of the two groups were compared using chi-square and Fisher's exact test. Independent t-test was done to compare main outcome variables. The pre- and postoperative means within each group were computed using the paired t-test. Pearson's correlation was used to correlate the surgical parameters with the main outcomes.

The research was performed in accordance with the guidelines set by the Declaration of Helsinki. Informed consent was obtained from all the patients after thorough explanation of the nature and possible risks and benefits of the study.

RESULTS

A total of 40 eyes (20 for each group) of 36 patients were included in the study. All patients completed the prescribed number of follow-ups. The mean age of the patients in the DV and AP groups were similar (Table 1). Surgical parameters during phacoemulsification were also similar (Table 2).

There was a statistically significant difference ($p = 0.01$) in the mean preoperative endothelial-cell counts between the 2 groups (Table 1), with higher mean cell count in the AP group. There was no significant difference in the postoperative endothelial-cell count between the groups. There was, however, a significantly greater endothelial-cell loss in the AP group ($p = 0.01$) (Table 3).

There was no difference in corneal thickness and IOPs between the two groups postoperatively. The average day 1 postoperative IOPs were under 18 mm Hg for both groups.

There was a significant difference between pre- and postoperative BCVA within each group ($p = 0.000$ for both), but no significant difference between the 2 groups on day 8 postoperatively (Table 3).

There was no significant correlation between phacoemulsification time and IOP ($p = 0.20$), cell count ($p = 0.94$), and corneal thickness ($p = 0.34$). Likewise, no correlation was found between phacoemulsification power and IOP ($p = 0.26$), corneal endothelial-cell count ($p = 0.35$), and corneal thickness ($p = 0.96$). There was also no correlation between surgical duration and IOP ($p = 0.50$), cell count ($p = 0.76$), and corneal thickness ($p = 0.89$).

There was no difference in the amount of postoperative anterior-chamber reaction (cells) ($p = 0.13$) and corneal edema ($p = 0.70$) between the 2 groups.

DISCUSSION

Corneal edema is the most common complication of cataract surgery. To prevent this, protection of the corneal endothelium during surgery is of utmost importance and a good way of ensuring this is with the use of a good ophthalmic viscoelastic. An ideal viscoelastic provides maximum space maintenance, a property of cohesive OVDs, and maximum protection to the corneal endothelium, a property of dispersive OVDs.

DisCoVisc (DV) has both the properties of a cohesive as well as a dispersive viscoelastic. It belongs to the same zero-shear viscosity range 10^5 to 10^6 (hundred thousands) as Amvisc Plus (AP), but DV is more of a viscous dispersive while AP is a viscous cohesive. Several studies have compared the effects of AP on the corneal endothelium with various viscoelastics and showed that they did not significantly affect the postoperative IOP, endothelial-cell count, and corneal thickness after phacoemulsification,[9-11] while a study by Holzer and coworkers showed a significant loss in the endothelial-cell count and increase in IOP postoperatively.[13]

This study demonstrated a significant difference in the endothelial-cell loss between the DV and AP groups, suggesting that DV may provide additional protection to the corneal endothelium during phacoemulsification. The dispersive nature of DV may have afforded added protection to the endothelium during cataract surgery.

Table 1. Preoperative parameters between the 2 groups.

Parameters	Discovisc	Amvisc Plus	*p*
Age (years)	69.00 ± 10.68	68.94 ± 14.29	0.99
BCVA	0.47 ± 0.24	0.51 ± 0.20	0.57
IOP (mm Hg)	15.85 ± 2.56	15.90 ± 2.81	0.95
Corneal thickness (µm)	544.15 ± 33.05	538.85 ± 50.30	0.70
Cell count (cells/mm)	2125 ± 262.45	2392 ± 347.16	0.01

Table 2. **Surgical parameters between the 2 groups.**

Parameters	Discovisc	Amvisc Plus	*p*
Phaco Time (minutes)	0.64 ± 0.39	0.62 ± 0.32	0.84
Phaco Power (%)	10.89 ± 5.33	10.05 ± 4.33	0.59
Surgical duration (minutes)	15.20 ± 3.04	13.90 ± 2.47	0.15

Table 3. **Postoperative parameters between the 2 groups.**

Parameters	Discovisc	Amvisc Plus	*p*
BCVA	0.86 ± 0.16	0.85 ± 0.19	0.86
IOP (mm Hg)	17.20 ± 2.91	16.70 ± 3.74	0.64
Corneal thickness (µm)	558.95 ± 33.26	551.55 ± 50.44	0.59
Cell count (cells/mm)	1919.50 ± 318.94	1942.00 ± 260.60	0.81
Endothelial cell loss (%)	205.5 (9.79)	450 (18.10)	(.01)

No difference in corneal thickness and IOP were seen between the two groups pre- and postoperatively, although a study by Oshika et al. showed a transient rise in IOP after DV was used, which was attributed to the difficulty in removing the OVD during irrigation and aspiration.[15]

No significant correlation between surgical parameters, such as phacoemulsification time, power, and surgical duration, and endothelial-cell count, corneal thickness, and IOP were seen in this study. A decrease in the endothelial-cell count in both groups postoperatively may be due to multiple factors, such as surgical technique and skills, and the severity of cataract.

In summary, this study demonstrated that the use of DV resulted in less endothelial-cell loss compared with AP after uncomplicated phacoemulsification in normal eyes. DV is, therefore, more protective of the corneal endothelium and its use may result in less corneal edema, faster postoperative recovery, and better postoperative vision.

Further studies using DV in cases of decreased endothelial-cell counts (i.e. Fuch's endothelial dystrophy) and during long and complicated surgical procedures (i.e. phacotrabeculectomy) need to be done to elucidate if DV has a superior protective effect on the endothelium of compromised corneas.

References

1. Hayashi K, Hayashi H. Risk factors for corneal endothelial injury during phacoemulsification. *J Cataract Refract Surg* 1996; 22: 1079-1084.
2. Kim E, Cristol S, Geroski DH, et al. Corneal endothelial damage by air bubbles during phacoemulsification. *Arch Ophthalmol* 1997; 115: 81-88.
3. Kaufman E, Katz JI. Endothelial damage from intraocular-lens insertion. *Invest Ophthalmol* 1976; 15: 996-1000.
4. Roper-Hall MJ, Wilson RS. Reduction in endothelial-cell density following cataract extraction and intraocular-lens implantation. *Br J Ophthalmol* 1982; 66: 516-517.
5. Roberts B, Peiffer RL Jr. Experimental evaluation of a synthetic viscoelastic material on intraocular pressure and corneal endothelium. *J Cataract Refract Surg* 1989; 15: 321-326.
6. Harfstrand A, Molander N, Stenevi U, et al. Evidence of hyaluronic acid and hyaluronic acid binding sites on human corneal endothelium. *J Cataract Refract Surg* 1992; 18: 265-269.
7. Arshinoff SA. Dispersive-cohesive viscoelastic soft-shell technique. *J Cataract Refract Surg* 1999; 25: 167-173.
8. Glasser DB, Osborn DC, Nordeen JF, Min Y-I. Endothelial protection and viscoelastic retention during phacoemulsification and intraocular-lens implantation. *Arch Ophthalmol* 1991; 109: 1438-1440.
9. Madsen K, Schenholm M, Jahnke G, Tengblad A. Hyaluronate binding to intact corneas and cultured endothelial cells. *Invest Ophthalmol Vis Sci* 1989; 30: 2132-2137.
10. Maar N, Graebe A, Schild G, et al. Influence of viscoelastic substances used in cataract surgery on corneal metabolism and endothelial morphology: comparison of Healon and Viscoat. *J Cataract Refract Surg* 2001; 27: 1756-1761.
11. Hutz WW, Eckhardt HB, Kohnen T. Comparison of viscoelastic substances used in phacoemulsification. *J Cataract Refract Surg* 1996; 22: 955-959.
12. Koch DD, Liu JF, Glasser DB. A comparison of corneal endothelial changes after use of Healon or Viscoat during phacoemulsification. *Am J Ophthalmol* 1993; 115: 188-201.
13. Holzer MP, Tetz MR, Auffart GU, et al. Effect of Healon 5 and 4 other viscoelastic substances on intraocular pressure and endothelium after cataract surgery. *J Cataract Refract Surg* 2001;27: 213-218.
14. Arshinoff S, Jafari M. New classification of ophthalmic viscosurgical devices–2005. *J Cataract Refract Surg* 2005; 31: 2167-2171.
15. Oshika T, Okamoto F, Kaji Y, et al. Retention and removal of a new viscous dispersive ophthalmic viscosurgical device during cataract surgery in animal eyes. *Br J Ophthalmol* 2006; 90: 485-487.
16. Petroll WM, Jafari M, Lane SS, et al. Quantitative assessment of ophthalmic viscosurgical device retention using in vivo confocal microscopy. *J Cataract Refract Surg* 2005; 31: 2363-2368.
17. Chylack LT, Leske MC, Khu P, et al. Lens Opacities Classification System II (LOCS II). *Arch Ophthalmol* 1989; 107: 991-997.