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ORIGINAL PAPER

Corneal endothelial cell loss and intraocular pressure following phacoemulsification using a new viscous-cohesive ophthalmic viscosurgical device

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Abstract

Purpose To compare results of two ophthalmic viscosurgical devices (OVDs)—Viscoat (a dispersive OVD, Alcon) and FR-Pro (a viscous-cohesive OVD, Rayner), in phacoemulsification surgery.

Methods A prospective randomized controlled study. Patients undergoing phacoemulsification were randomly assigned to receive one of the two OVDs. Exclusion criteria were age under 40, preoperative endothelial cell count (ECC) below 1,500 cells/mm^2 and an eventful surgery.

The primary outcome was change in ECC from baseline to postoperative month one and month three. Secondary outcomes were the difference between ECC at postoperative month one and month three, changes in IOP and occurrence of an IOP spike ≥ 30 mmHg after surgery.

Results The study included 84 eyes—43 in the Viscoat group and 41 in the FR-Pro group. Mean cell density loss at month one and month three was 17.0 and 19.2%, respectively, for the Viscoat group and 18.4 and 18.8%, respectively, for the FR-Pro group, with no statistically significant difference between the groups ($p = 0.772$ and $p = 0.671$, respectively). The mean ECC difference between the month one and month three visits was 50.5 cells/mm^2 and was not statistically significant ($p = 0.285$). One eye in each group had an IOP spike ≥ 30 mmHg, both normalized by postoperative week one.

Conclusions Viscoat and FR-Pro have comparable results following phacoemulsification surgery, suggesting that while FR-Pro is not a dispersive OVD, its endothelial cell protection may be comparable to one, perhaps due to the addition of sorbitol. Furthermore, a one-month follow-up of ECC seems sufficient in such trials.

Keywords Cataract · Phacoemulsification · Ophthalmic viscosurgical device · Endothelial cell count

Introduction

Corneal endothelial cells are inadvertently lost during routine phacoemulsification cataract removal surgery, with reports ranging between 1 and 18% of cells lost [1–11].

Ophthalmic viscosurgical devices (OVDs) are used during surgery with the aim of reducing this loss and have many other properties advantageous for intraocular surgery, such as maintenance of the anterior chamber and facilitation of surgical maneuvers [12, 13].

Based on the rate of removal from the eye during aspiration, referred to as the cohesion-dispersion

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index (CDI), OVDs can be broadly divided into two groups—cohesive OVDs (CDI ≥ 30 (%aspirated/mmHg)) and dispersive OVDs (CDI < 30 (%aspirated/mmHg)) [14]. Cohesive OVDs are high molecular weight materials and are made up of long molecular chains which tend to interlock and intertwine. This structure allows these materials to maintain the stability of the anterior chamber during surgery and facilitates their rapid evacuation at the end of surgery. Dispersive OVDs are low molecular weight materials and are made up of short chains that tend to slide over each other. These materials tend to coat and protect structures inside the eye. Their disadvantage is the difficulty of evacuating them at the end of surgery [15]. In concordance with these properties, dispersive OVDs have been shown to have superior protective effect on the corneal endothelium, when compared with cohesive OVDs [3, 16, 17].

Viscoat® (Alcon), a dispersive OVD, is widely used and its protective effect on corneal endothelial cells has been demonstrated in many studies [1, 6–8, 10]. Ophteis® FR-Pro (Rayner), a viscous-cohesive OVD, has added sorbitol that acts as a free radical scavenger and, to the best of our knowledge, has yet to be compared to another OVD [18]. Properties of the two OVDs are presented in Table 1 [18, 19]. In this study we compared the effect of Viscoat and FR-Pro on corneal endothelial cell loss and intraocular pressure (IOP), following uncomplicated phacoemulsification cataract surgery.

Table 1 Properties of the two OVDs

Property	Viscoat	FR-Pro
Ingredients	3% NaHa, 4% CDS	2% NaHa, 4% Sorbitol
Molecular weight (dalton)	22,500 CDS, > 500,000 NaHa	1,800,000
Viscositiy at zero shear rates (mPa*s)	40,000	500,000

OVDs Ophthalmic viscosurgical devices, *NaHa* Sodium hyaluronate, *CDS* Chondroitin sulfate, *mPa*s* Millipascal second

Methods

Study design and population

This was a prospective randomized control study performed in the Department of Ophthalmology, Samson Assuta Ashdod University Hospital, Ashdod, Israel, between November 2020 and November 2021. The protocol was reviewed and approved by the institutional review board, and it followed the tenets of the Declaration of Helsinki. All patients provided a written informed consent before entering the trial.

The study was designed to compare two OVDs—Viscoat and FR-Pro. Patients were blinded to the OVD used. The surgeon was not blinded, as the two substances have typical identifying features.

The inclusion criteria were patients aged 40 years or older who had uncomplicated phacoemulsification cataract removal with intraocular lens implantation in the capsular bag. Exclusion criteria were age under 40 and preoperative endothelial cell count (ECC) below 1,500 /mm^2.

Sample size calculation—based on a minimal detectable difference for ECC of 200 cells/mm^2, standard deviation for ECC of 250 cells/mm^2, power of 80% and a significance level of 0.05—the minimal recommended number of patients in each group was 25.

Preoperative, intraoperative and postoperative assessments

All eyes were assessed at least once preoperatively, including – ECC, central corneal thickness (CCT), axial length (AL), anterior chamber depth (ACD), best corrected visual acuity (BCVA), IOP measurement and slit lamp biomicroscopy assessment of the eye (including nuclear sclerosis grading).

Intraoperative parameters recorded were—type of OVD used, total surgery time, average ultrasound power (AVE), actual phaco time (APT) and effective phaco time (EPT)—which is the multiplication of AVE by APT. Any out of the ordinary occurrences were recorded.

Postoperative assessment occurred at postoperative day one, week one, month one and month three with recording of IOP and ECC, depending on the visit.

ECC was measured on the SPM-700 specular microscope by Rexxam.

CCT, AL and ACD were measured on the OA-2000 optical biometer by Tomey.

Best corrected visual acuity (BCVA) was measured using a standard visual acuity chart (Snellen equivalent) and was converted to the logarithm of the minimum angle of resolution (logMAR) for analysis.

IOP was measured using Goldmann applanation tonometry.

Nuclear sclerosis was assessed by slit lamp biomicroscopy examination and was graded between 1 and 4.

Outcomes

The primary outcome was change in ECC from baseline to the postoperative month one and month three visits. The secondary outcomes were the difference between ECC at postoperative month one and month three, changes in IOP and the occurrence of an IOP spike ≥ 30 mmHg on postoperative day one and week one.

Statistical analysis

Statistical analyses were performed with IBM SPSS Statistics 28.0 and managed on Excel spread sheet.

The Kolmogorov–Smirnov Test was used to assess the normality of distribution. ECC, AL, ACD and AVE passed the test while age, IOP, logMAR, CCT, APT, EPT and total surgery time did not.

Quantitative variables were reported in terms of mean and standard deviation (SD) and/or median and interquartile range (IQR), and qualitative variables were reported in terms of number and percentage of each modality.

The differences in baseline characteristics and outcomes between the two groups were compared by the student t test for independent samples for variables with a normal distribution and the Mann–Whitney test for independent samples for variables that did not have a normal distribution. To assess the change in time in ECC, the Student t test for paired samples was used.

A p-value <0.05 was considered statistically significant.

Surgical technique

All surgeries were performed by a single experienced surgeon (YP) using the same standard technique.

Preoperatively, pupils were dilated with topical application of cyclopentolate 1%, phenylephrine 10% and tropicamide 0.5%, each applied every 10 min for 30 min. At the start of each surgery, topical anesthesia consisting of oxybuprocaine hydrochloride 0.4% and tetracaine hydrochloride 1% were instilled.

After standard cleaning and draping protocol, a 2.2 mm clear corneal incision was made followed by two side-port paracenteses. An OVD, either Viscoat or FR-PRO, was injected into the anterior chamber and a continuous curvilinear capsulorhexis was created. Hydrodissection was carried out followed by phacoemulsification and irrigation/aspiration (I/A) of the cortical residues. An anterior chamber maintainer attached to Balanced Salt Solution (BSS) was placed, and an intraocular lens was implanted into the capsular bag. Surgical wounds were hydrated with BSS and checked for leakage. Antibiotics were injected into the anterior chamber, and a drop each of oxybuprocaine hydrochloride 0.4%, povidone iodine 5% and dexamethasone 0.1% was administered.

Postoperative treatment consisted of dexamethasone 0.1% six times a day with a taper over five weeks, ofloxacin 0.3% four times a day for one week and nepafenac 0.1% three times a day for one month.

Results

Baseline characteristics and intraoperative data

The study included 84 eyes randomly assigned to one of the two OVDs, with 43 in the Viscoat group and 41 in the FR-Pro group.

Baseline characteristics and intraoperative data are presented in Table 2. There were no statistically significant differences found between the groups. The mean $\pm$ SD preoperative ECC was 2267.1 ± 236.2 cells/mm^2 and 2277.9 ± 258.0 cells/mm^2 in the Viscoat ($n=43$) and FR-Pro ($n=41$) groups, respectively ($P=0.842$). Mean $\pm$ SD IOP was 14.9 ± 3.1 mmHg and 15.1 ± 3.4 mmHg in the Viscoat ($n=43$) and FR-Pro ($n=41$) groups, respectively. For EPT, the mean $\pm$ SD was 7.1 ± 5.1 s and

Table 2 Baseline characteristics and intraoperative data

Variable	Viscoat ($n=43$)	FR-Pro ($n=41$)	p-value
Age (years)			
Mean ± SD	72.7 ± 7.5	73.9 ± 6.0	0.700
Median (IQR)	73.0 (69.0–79.0)	74.0 (69.5–79.0)	
Male: Female ratio	51:49	54:46	0.820
ECC (cells/mm^2)			
Mean ± SD	2267.1 ± 236.2	2277.9 ± 258.0	0.842
AL (mm)			
Mean ± SD	23.7 ± 1.7	23.4 ± 1.3	0.356
ACD (mm)			
Mean ± SD	3.2 ± 0.4	3.3 ± 0.6	0.633
IOP (mmHg)			
Mean ± SD	14.9 ± 3.1	15.1 ± 3.4	0.623
Median (IQR)	14.0 (13.0–17.0)	15.0 (12.0–17.0)	
Visual acuity logMAR			
Mean ± SD	0.76 ± 0.85	0.72 ± 0.72	0.756
Median (IQR)	0.40 (0.30–0.70)	0.48 (0.30–0.70)	
CCT (µm)			
Mean ± SD	528.5 ± 29.0	521.8 ± 30.4	0.284
Median (IQR)	531.0 (505.0–556.0)	516.0 (498.0–544.0)	
NS grading (% of eyes)			
+ 1	31	22	0.418
+ 2	40	46	
+ 3	21	20	
+ 4	7	12	
AVE (%)			
Mean ± SD	11.5 ± 4.5	11.4 ± 4.7	0.954
APT (sec)			
Mean ± SD	57.0 ± 28.3	54.5 ± 37.3	0.326
Median (IQR)	54.6 (32.7–77.7)	45.1 (24.4–70.2)	
EPT (sec)†			
Mean ± SD	7.1 ± 5.1	7.1 ± 6.5	0.476
Median (IQR)	6.3 (3.2–12.3)	4.3 (2.0–11.3)	
Total surgery time (min.)			
Mean ± SD	30.5 ± 16.5	30.8 ± 16.0	0.795
Median (IQR)	25.5 (20.8–38.3)	26.0 (22.0–35.0)	

n Number of eyes, *SD* Standard deviation, *IQR* Interquartile range, *ECC* Endothelial cell count, *AL* Axial length, *ACD* Anterior chamber depth, *IOP* Intraocular pressure, *logMAR* Logarithm of the minimum angle of resolution, *CCT* Central corneal thickness, *NS* Nuclear sclerosis, *AVE* Average ultrasound power, *APT* Actual phaco time, *EPT* Effective phaco time

†$n=39$ for Viscoat, $n=41$ for FR-Pro

7.1 ± 6.5 s in the Viscoat ($n=39$) and FR-Pro ($n=41$) groups, respectively ($P=0.476$).

Pupillary abnormalities (poor dilation and intraoperative floppy eyelid syndrome (IFIS)—some necessitating the use of a Malyugin ring) were seen in five eyes in the Viscoat group and six eyes in the FR-Pro group. Zonulopathy (causing changes in AC depth and poor lens stability – some necessitating the use of a capsular tension ring) was seen in three eyes in each of the OVD groups.

Endothelial cell count

ECC measurements decreased after surgery in both groups with no statistically significant difference between the groups in any of the follow-up visits. Changes in ECC are presented in Fig. 1 and are detailed below.

The mean ± SD postoperative ECC at one month in the Viscoat group ($n=33$) was 1882.7 ± 260.8 cells/mm^2, corresponding to a mean cell density loss of

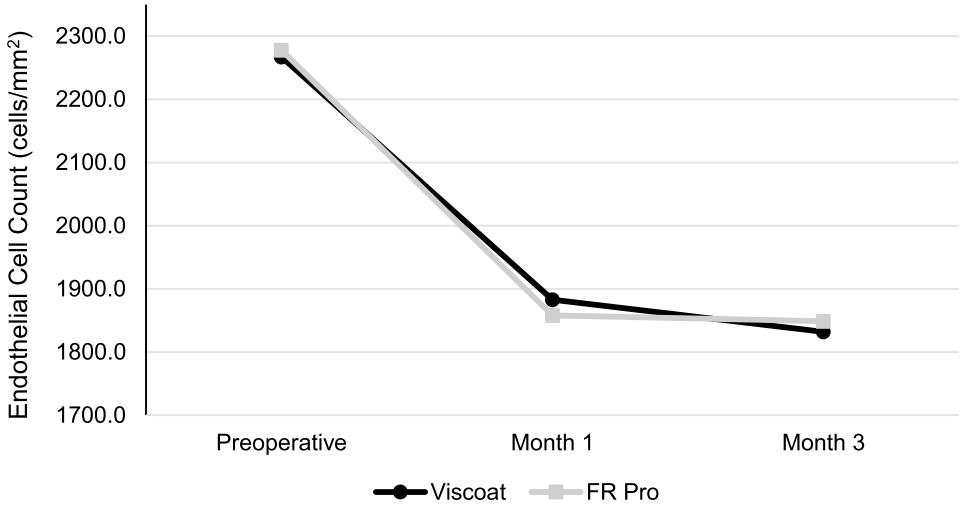

Fig. 1 Endothelial cell count (cells/mm^2) in the two groups—preoperatively and on postoperative month one and month three

17.0% from baseline. The mean ± SD postoperative ECC at one month in the FR-Pro group ($n = 32$) was 1857.9 ± 337.8 cells/mm^2, corresponding to a mean cell density loss of 18.4% from baseline. There was no statistically significant difference between the groups ($P = 0.772$).

The mean ± SD postoperative ECC at three months in the Viscoat group ($n = 19$) was 1831.8 ± 277.5 cells/mm^2, corresponding to a mean cell density loss of 19.2% from baseline. The mean ± SD postoperative ECC at three months in the FR-Pro group ($n = 19$) was 1848.7 ± 280.5 cells/mm^2, corresponding to a mean cell density loss of 18.8% from baseline. There was no statistically significant difference between the groups ($P = 0.671$).

In a sensitivity analysis excluding cases with poor pupillary dilation, IFIS or zonulopathy—similar ECC changes were seen in both groups. Mean cell density loss at one month was 14.5% ($n = 26$) and 19.8% ($n = 24$) for Viscoat and FR-Pro, respectively, and at three months was 22.2% ($n = 16$) and 19.1% ($n = 14$) for Viscoat and FR-Pro, respectively. There was no statistically significant difference between the groups at either time period ($P = 0.209$, $P = 0.551$, respectively).

With both OVD groups put together, there were 34 eyes which had an ECC performed both at the one month and at the three-month follow-up visits. Mean ± SD ECC was 1890.7 ± 319.1 cells/mm^2 and 1840.2 ± 283.3 cells/mm^2 at one and three months, respectively. The mean difference between the visits was 50.5 cells/mm^2 and was not statistically significant ($P = 0.285$).

Intraocular pressure

Table 3 shows the preoperative and the postoperative IOP measurements in both groups. After surgery, IOP initially increased and then gradually declined. No statistically significant difference in IOP was seen between the groups at any of the follow-up visits.

An IOP spike ≥ 30 mmHg was measured on postoperative day one in two eyes—one in the Viscoat group (IOP = 31 mmHg) and one in the FR-Pro group (IOP = 32 mmHg). Both eyes received topical IOP lowering medication and IOP normalized by

Table 3 Changes in intraocular pressure over time

Time period	Viscoat	FR-Pro	*p* value
Preoperative mean ± SD IOP (mmHg)	14.9 ± 3.1	15.1 ± 3.4	0.623
Postoperative day one mean ± SD IOP (mmHg)	17.1 ± 4.7	17.4 ± 4.5	0.578
Postoperative week one mean ± SD IOP (mmHg)	14.2 ± 3.4	14.1 ± 2.9	0.777
Postoperative month one mean ± SD IOP (mmHg)	13.3 ± 2.5	13.3 ± 2.1	0.858
Postoperative month three mean ± SD IOP (mmHg)	11.8 ± 1.7	11.9 ± 2.8	0.943

IOP Intraocular pressure

postoperative week one (with consequent cessation of the medication).

Discussion

This study compared Viscoat, a dispersive OVD, to FR-Pro, a viscous-cohesive OVD, and found a similar reduction in ECC after surgery, with no statistically significant difference between the groups. As presented previously, due to their properties, cohesive OVDs traditionally are used for maintaining stability of structures, while dispersive OVDs traditionally have a superior protective effect on the corneal endothelium [3, 16, 17]. This study suggests that although FR-Pro is not a dispersive OVD, its endothelial cell protection may be comparable to one, perhaps due to the addition of sorbitol.

While the number of eyes at the postoperative month one visit was sufficient for statistical significance, the number of eyes at the month three visit was not. An analysis including only eyes which had data available from both these visits showed a mean difference in endothelial cell density loss of 50.5 cells/mm^2. This difference was not statistically significant ($P=0.285$), and in our opinion, it is not clinically important.

Mean cell density loss after one and three months ranged between 17.0–19.2%. This is a relatively high loss compared to previous studies but was similar between groups and could be explained by the broad inclusion criteria—this study did not exclude eyes with pseudoexfoliations, glaucoma, shallow anterior chambers, poor dilation, Malyugin ring use, IFIS, zonulolysis with insertion of a capsular tension ring and many other criteria that might have excluded eyes in previous reports. A sensitivity analysis was performed in an attempt to overcome some of these points but revealed similar results indicating that these may be only partial explanations, and there are more unknown reasons for the relatively high ECC loss in this study (surgeons' technique, equipment used, population related characteristics or other causes). In both groups, IOP slightly increased on postoperative day one, then gradually decreased and by the three-month postoperative follow-up visit reached an IOP 3–4 mmHg lower than the baseline IOP. This pattern is compatible with previous reports [20–23]. There was no statistically significant difference in the change in IOP measurements in the two groups at any of the follow-up visits. Only one eye in each group had an IOP spike ≥ 30 mmHg, both eyes normalized within a week.

It is worth noting that while patients were blinded to the OVD used, the surgeon was not, and this serves as a limitation to this study.

In conclusion, when used during uncomplicated phacoemulsification cataract surgery, Viscoat, a dispersive OVD, and FR-Pro, a viscous-cohesive OVD, have a comparable protective effect on corneal endothelial cells and a comparable effect on IOP. This suggests that although FR-Pro is not a dispersive OVD, its endothelial cell protection may be comparable to one, perhaps due to the addition of sorbitol. Furthermore, we would like to propose that in similar trials in the future, a one-month follow-up of ECC is sufficient.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by KW. The first draft of the manuscript was written by KW and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors have no conflict of interest to declare.

Ethics approval The study's protocol was reviewed and approved by the institutional review board, and it followed the tenets of the Declaration of Helsinki.

Consent to participate Written informed consent was obtained from all individual participants included in the study.

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