# Comparison of the Endothelial Protective Effect of Two Different Dispersive Viscoelastics During Phacoemulsification Surgery

## İki Farklı Dispersif Viskoelastik Maddenin Fakoemulsifikasyon Esnasında Endotel Koruyucu Etkisinin Karşılaştırılması

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### ABSTRACT

**Purpose:** To compare the corneal endothelial protective effects of two different dispersive viscoelastics used in phacoemulsification surgery (sodium hyaluronate % 3 [Endocoat®] and chondroitin sulfate % 4.0 - sodium hyaluronate % 3.0 combination [Viscoat®]).

**Material and methods:** The study was comprised of two groups of patients : Both groups 1 and 2 were composed of 40 eyes of 40 patients on which Endocoat and Viscoat were used during phacoemulsification, respectively. Endothelial cell count (ECC) of all patients was measured at postoperative days 1 and 30. The changes in ECC at postoperative day 30 from baseline were compared between the two groups.

**Results:** The preoperative mean ECCs were 2397±410 cells/mm$^2$ in the Viscoat group and 2325±410 cells/mm$^2$ in the Endocoat group. The mean ECC decreased by 297 cells/mm$^2$ (a 12.3 % loss) in the Viscoat group and by 343 cells/mm$^2$(a 14.7 % loss) in the Endocoat group at postoperative day 30, as is illustrated.There was no statistically significant difference in ECC change at postoperative day 30 between the two groups( $p$=0.21).

**Conclusion:** The corneal endothelial protective effects of sodium hyaluronate % 3 (Endocoat$^R$) and the combination of chondroitin sulfate 4.0% and sodium hyaluronate % 3.0 (Viscoat$^R$) during the phacoemulsification were similar.


**Key words:** Phacoemulsification, Viscoelastics, Viscoat, Endocoat, Endothelium.


### ÖZ

**Amaç:** Fakoemülsifikasyonda kullanılan iki farklı dispersif viskoelastik maddenin (sodyum hiyalüronat% 3 [Endocoat®] ve kondroidin sülfat % 4.0 - sodyum hiyalüronat % 3.0 kombinasyonu [Viscoat®]) kornea endotel koruyucu etkisini kıyaslamak.

**Gereç ve yöntem:** Çalışma iki gruptan oluşmaktadır: Grup 1 fakoemülsifikasyon esnasında Endocoat kullanılmış 40 hastanın 40 gözünü, Grup 2 fakoemülsifikasyon esnasında Viscoat kullanılmış 40 hastanın 40 gözünü kapsamaktadır. Bütün hastaların endotel hücre sayısı (EHS) postoperatif 1. ve 30. günlerde ölçülmüştür. Preoperatif ve postoperatif 30. Gün arasındaki fark iki grup arasında kıyaslandı.

**Bulgular:** Preoperatif ortalama EHS Grup 2'de 2397±410 hücre/mm$^2$ iken Grup 1 'de 2325±410 hücre/mm$^2$ idi. Ortalama EHS Grup 2'de 297 hücre/mm$^2$ (% 12.3 kayıp) miktarında azalırken, Grup 1'de 343 hücre/mm$^2$(% 14.7 kayıp) miktarında azalmıştır. Postoperatif 30. günde EHS'de gözlenen azalma iki grup arasında istatistiksel olarak anlamlı değildir ( $p$=0.21).

**Sonuç:** Sodyum hiyalüronat% 3 [Endocoat®] ve kondroidin sülfat % 4.0 - sodyum hiyalüronat % 3.0 kombinasyonunun [Viscoat®] fakoemulsifikasyonda kornea endotel koruyucu etkisi benzerdir.


**Anahtar kelimeler:** Fakoemulsifikasyon, Viskoelastik, Viscoat, Endocoat, Endotel.

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## INTRODUCTION

Since the introduction of Healon (sodium hyaluronate 1%) viscoelastic substances or ophthalmic viscosurgical devices (OVD) with acceptance of Steve Arshinoff's suggestion became indispensable in anterior segment surgery, OVDs had important functions such as adequate intraocular space creation, facilitating surgical maneuvers and protecting corneal endothelium and other ocular tissues from surgical trauma and damage.These benefits of OVDs provided them to be accepted universally and induced the development of numerous OVDs preparations. OVDs are classified mainly in three groups as cohesives with high viscosity, dispersives with low viscocity and viscoadaptives. Cohesive viscoelastics has high molecular weight and their elasticity viscosity, pseudoplasticity and cohesivity are also high. They are used to produce potential space. Dispersive viscoelastics has low molecular weight and their elasticity, viscosity, pseudoplasticity and cohesivity are low. The most important property of dispersive viscoelastics is the possession of low surface tension. They protect endothelium very well by coating it.[1-4] Using a dispersive OVD during the phacoemulsification surgery the endothelial cells and also it suppresses the formation of free radicals.[5] The superiority of dispersive OVDs to cohesive OVDs in protection of corneal endothelium against potential damage during phacoemulsification surgery were shown in various studies.[6-10]

In this study, we purposed to investigate the endothelial protective effects of two different dispersive viscoelastics used in phacoemulsification surgery(sodium hyaluronate % 3 [Endocoat®] and chondroitin sulfate % 4.0 - sodium hyaluronate % 3.0 combination [Viscoat®]).

## MATERIAL AND METHODS

This was a prospective randomized examiner-masked study. The study involved 80 eyes of 80 patients. The study followed the tenets of the Declaration of Helsinki and was approved by the local ethics committee. All participants received oral and written information about the study, and each participant provided written informed consent. The patients older than 45 years who applied to Kayseri Training and Research Hospital with grade 1 to 4 cataract based on the LOCS III classification were involved in the study.

Ocular exclusion criteria for this study were as follows: corneal pathology, ECC lower than 1500 cells/mm$^2$, history of uveitis, glaucoma, ocular trauma, any intraoperative complications, the use of trypan blue during surgery and previous intraocular surgery. Moreover, a history of systemic disease, such as hypertension or diabetes mellitus, pregnancies, and use of any medication also resulted in patients being excluded from the study. The study comprised two groups : Group 1 composed of 40 eyes of 40 patients on which Endocoat was used during phacoemulsification; Group 2 composed of 40 eyes of 40 patients on which Viscoat was used during phacoemulsification.

All operations were performed with Centurion Vision System (Alcon Laboratories Inc., Fort Worth, Tx) by using Ozil Handpiece and 0.9 mm/ 45$^0$ Kelman tip under topical anesthesia. All incisions were done from steep axis or temporal in 2.75 mm long by the same surgeon. Phacoemulsification parameters were torsional pulse mode, phaco power 60% linear, vacum 550 mmHg, bottleheight 90-110 cm and aspiration flow rate 32 ml/min in all patients. In both groups, cumulative dissipated energy (CDE), U/S (ultrasound) total time, average torsional time in position 3 were analyzed.

A clear corneal incision was made on the steep axis. Anterior chamber was constituted with viscoelastics (Viscoator&Endocoat) A 5.0–5.5 mm continuous curvilinear capsulorhexis was made using an utrata capsulorhexis forceps (Katena Products Inc, Denville, NJ). Nucleus was emulsified with quick-chop technique following hydrodissection. After lens removal capsular bag is was filled with sodium hyaluronate % 1(Provisc®) and AcrySof SN60AT lens was implanted into capsularbag with Monarch II cartridge system. The operation was ended with Moxifloxacin hydrochloride% 0.5 (Vigamox®) injection into anterior chamber following hydration of incisions. There was no complication in any operation. The data on the panel computed automatically by the machine were recorded at the end of operation.

Moxifloxacin hydrochloride % 0.5 (5x1, for two weeks), prednisolon acetate % 1 (Pred Forte®), (5x1, for four weeks), and fusidic acid (Fucithalmic®) (2x1, for two weeks) were prescribed to all patients after operation.

Endothelial cell count (ECC), hexagonality (HEX), coefficient of variation (CoV) and standard deviation (SD) of all patients were measured on preoperative and postoperative days 1 and 30 by using specular microscopy (Topcon, SP3000P, Tokio, Japan).

### Statistical analysis

SPSS 20 (Statistical, Package for the Social Sciences, IBM) was used for the data entry and statistical analysis. The data normality was assessed with Kolmogrov-Smirov test. The parameters with normal distribution were compared with independent t test between the groups. The parameters without normal distribution were compared with Mann-Whitney U test between the groups. P value less than 0.05 was accepted as statistically significant.

**Table 1.** *Physicochemical and reological properties of Viscoat and Endocoat.*

| Properties | Viscoat | Endocoat |
|---|---|---|
| Producer | Alcon | Abbott |
| Ingredients | CDS/NaHa | NaHa |
| Concentration (mg/ml) | 4.0% CDS/ 3.0% NaHa | 3.0% |
| Viscosity (mPas) | 40000 | 50.000 |
| Molecular weight (Dalton) | 22500 CDS/>500000 NaHa | 800.000 |
| Osmolarity (mOsm/kg $H_2O$) | 360 | 320 |
| pH | 7.0–7.5 | 6.8 – 7.6 |
| Volume (ml) | 0.5 | 0.85 |

NaHa : sodium hyaluronate; CDS: chondroitin sulfate

## RESULTS

The preoperative and intraoperative data of the two groups are shown on Table 2. There was no significant difference between the two groups in age, preoperative CCT, ECC, HEX, CoV and SD values. There was no significant difference in CDE, U/S total time and torsional time between the two groups ($p$= 0.52, $p$= 0.75, $p$= 0.28).

The mean ages were 65.17±7.61 and 63.18±10.50 years in group 1 and group 2, respectively ($p$= 0.27). Preoperative cataract densities were 2.35±0.78 and 2.49±0.85 in groups 1 and 2, respectively ($p$= 0.35).

The preoperative mean ECC, HEX, CoV and SD values were 2397±410 cells/mm$^2$, 50±6, 36±4 and 163±34 in the Viscoat group and 2325±389 cells/mm$^2$ 49±5, 38±7 and 172±31 in the Endocoat group. The mean ECC decreased by 297cells/mm$^2$(a 12.3 % loss) in the Viscoat group and by 343 cells/mm$^2$(a 14.7 % loss) in the Endocoat group at postoperative day 30 , as is illustrated on Table 3.There was no statistically significant difference in ECC change from preoperative values at postoperative day 30 between the two groups( $p$=0.21). Also, there was no statistically significant difference in HEX, CoV and SD change from preoperative values to postoperative 30$^{th}$ day values between the two groups (p= 0.38, p=0.25 and p=0.12, respectively).

## DISCUSSION

The behaviours of OVDs are related to their rheological, molecular and chemical properties. It is important to realize that rheological properties of any given OVD have a direct impact on the clinical use of that particular material. The rheological characteristics of OVDs that are most relevant when considering their usefulness in ophthalmic surgery are viscosity, elasticity, pseudoplasticity, cohesivity and coating. Coating is the covering of ocular surfaces, surgical devices and intraocular lens. It could be measured with

**Table 2.** *Preoperative, intraoperative and postoperative data of the two groups.*

| | Viscoat group (n:40) | Endocoat group (n:40) | P |
|---|---|---|---|
| | mean±SD | mean±SD | |
| Age (year) | 65.17±7.61 | 63.18±10.50 | 0.27 |
| Total U/S time (min) | 0.47±0.81 | 0.38±0.35 | 0.75 |
| Average torsional time (min) | 0.45±0.69 | 0.38±0.32 | 0.28 |
| Cumulative dissipated energy | 8.15±6.60 | 7.12±3.89 | 0.52 |
| Preoperative CCT (µm) | 535±36 | 515±35 | 0.35 |
| Postoperative CCT (µm) | 541±27 | 528±33 | 0.15 |
| Preoperative ECC (cell/mm$^2$) | 2397±410 | 2325±389 | 0.71 |
| Postoperative 30$^{th}$ day ECC (cell/mm$^2$) | 2100±310 | 1982±335 | 0.58 |
| ECC decrease percentage (%) | 12.32±5.61 | 14.70±5.80 | 0,21 |

ECC : Endothelial Cell Count; CCT: Central Corneal Thickness

surface tension and contact angle. Low surface tension and low contact angle show high coating. OVD with negative discharge becomes neutralized by meeting with eye tissues with positive discharge. Thanks to this, they provide good endothelial protection. They leave trabeculum more easily because of their low molecular weight an deven if they are not cleaned totally from anterior chamber, they cause little intraocular pressure increase.

Viscoat, which is a dispersive OVD with 600.000 dalton weight and 50.000 mPas viscosity, has been widely used in phacoemulsification since early 1990s.It is composed of combination of 2/3 sodium hyaluronate 3.0% and 1/3 sodium chondroitin sulfate 4.0%. It could be injected with 27 G canula. It has low elasticity but it protects tissues with its high adhesivity. It coats endothelium, intraocular lens and surgical devices well. Also, it neutralize spositive discharge on devices with its negative discharge and it decreases endothelial cell loss. Viscoat could be used single or combined with a cohesive OVD as in soft shell technique. A lot of studies have showed that Viscoat protects corneal endothelium better than cohesive viscoelastics.[11-15] The use of Viscoat alone or together with a cohesive agent has been thought as a universally accepted method and newly marketted OVD preparations have been compared with Viscoat in the mean of endothelial protection during phacoemulsification to assess their safety and effectiveness.[6,12,15-19]

Endocoat, a dispersive viscoelastic produced by Abbott in recent years, has 800.000 dalton molecular weight and 50.000 mPas viscosity. It is composed of sodium hyaluronate 3%.Cohesion-dispersion ratio of Endocoat is nearly 3.4 and it is similar to Viscoat. Sodium hyaluronate is prototype of viscoelastic devices and it has been used for long years safely. Its clearance is good and it does not cause inflammation. Also the presence of sodium hyaluronate binding regions on corneal endothelium makes a contribution to endothelium protectiveness of this agent. The new dispersive hyaluronic acid OVD with a low molecular weight showed a greater adherence to the endothelial surface than the standard cohesive hyaluronic acid OVD with a higher molecular weight. The corneal endothelial cell coating of a new dispersive OVD (sodium hyaluronate 3%[HealonEndocoat]) and a standard cohesive hyaluronic acid OVD (sodium hyaluronate 1.4%[Healon GV]) as well as their combination using the soft-shell technique were evaluated and it has been shown that Endocoat, a dispersive viscoelastic with low molecular weight, coats corneal endothelium better than hyaluronic acid.[20]

To our knowledge, there is no study comparing the effects of Endocoat with Viscoat on corneal endothelium in phacoemulsification surgery. This study was conducted to assess the effects of these two regimens on corneal endothelium in patients having cataract surgery. In our study, we found that the endothelial protective effects of Endocoat and Viscoat during phacoemulsification were similar. We thought that Endocoat could be used safely in phacoemulsification as an alternative to Viscoat.

In conclusion, the protective effects of sodium hyaluronate 3% (Endocoat$^{R}$ ) and chondroitin sulfate 4.0% combination and sodium hyaluronate % 3.0 (Viscoat$^{R}$) on corneal endothelium during phacoemulsification were similar.

## CONFILICT OF INTEREST

All authors declared that they had no conflict of interest.

## ETHICAL APPROVAL

Informed consent was obtained from all individual participants included in the study.

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