‘Comparison of Safety and Performance of Two Ophthalmic Viscosurgical Devices in Cataract Surgery’

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Research Article

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Abstract

Purpose: To compare the safety and performance of two ophthalmic viscosurgical devices (OVDs) Bio-Hyalur SV (Sodium Hyaluronate 3.0%) (Biotech Healthcare Group, Luzern, Switzerland) and Protectalon (sodium hyaluronate 2.0%) (VSY Biotechnology, Turkey) in cataract surgery.

Methods: One hundred twenty eyes of one hundred twenty patients who underwent phacoemulsification surgery were included in the study. Postoperatively sixty eyes using Bio-Hyalur-SV were classified as Group 1, and sixty eyes using Protectalon as Group 2. Patients aged 45 and over, Grade I, II or III unilateral / double stained cataract, healthy eyes creating cataract included in this study. Endothelial cell morphological parameters including endothelial cell density (ECD), cell number, cell area, coefficient of variation (CV) in cell size, cell hexagonality and central corneal thickness (CCT) were measured preoperatively and at postoperative first week, first and third month visits. Intraocular pressure (IOP) was measured with an applanation tonometer at every visit.

Results: There was a statistically significant decrease in the mean ECD all follow-up times when compared with the preoperative visit (p=0.000). In terms of mean ECD levels there was no significant difference between the two groups within three months postoperatively (p=0.616). In the first week after surgery, there was an significant increase in CCT in Group 1 and Group 2 respectively (p=0.000). The IOP was <23 mmHg in all of the patients on the first day after surgery. There was no significant difference in the incidence of IOP peaks between the two groups in every visits. In both groups, a significant increase was observed in the mean IOP at first day, first week, and first month after surgery compared to preoperative values (p=0.000). But no significant difference in IOP increase in Group 1 (P=0.092), Group 2 (P=0.013) compared to preoperative values at third month postoperatively (p <0.001 significant with Bonferrotti correction).

Conclusion: The two OVD’s used in this study during cataract surgery were safe and effective. Both OVD’s resulted in similar rates of transient IOP increases and corneal endothelial damage also provided good anterior chamber depth and were fairly easy to remove.

Introduction

Ophthalmic viscosurgical devices (OVDs) are on a site that is growing in importance in variety of ophthalmic surgeries (1). They allow for manipulations in cataract surgery and protect endothelial cells from potential trauma and damage (2). During phacoemulsification, the instruments and methods used should be well evaluated in order to protect the corneal endothelium from rising temperatures, at this stage OVDs play an important role in the protection of the endothelium (3).

The ideal OVDs should be optically clear, water-soluble, easily injectable and revisable and fully removable. OVD behavior is rheologically dependent on viscosity, pseudopalsticity elasticity and cohesiveness/dispersibility. There is a wide variety of OVDs that differ in split components and are available in various concentrations or chain lengths. According to the Arshinoff classification, OVDs are
classified into two groups: viscosity and cohesion (4). The low molecular weight and short molecular chains of dispersive OVDs allow them to establish a stronger relationship with the cornea and provide more protection during phacoemulsification (5). Cohesive OVDs have high molecular weight and long molecular chains that create potential space and stabilize tissue during surgery (6). Cohesive OVDs provide low protection in the endothelium but because of their high viscosity materials to adhere and entanglement, they can be very comfortable cavity at stages such as capsulorhexis or intraocular implantation and are easy to remove (3).

In this study, we purposed to compare the safety and performance of high viscosity cohesive OVDs according to Arshinoff classification (Table-1) Bio-Hyalur SV (Sodium Hyaluronate 3.0%) (Biotech Healthcare Group, Luzern, Switzerland) and Protectalon (Sodium Hyaluronate 2.0%) (VSY Biotechnology, Turkey).

Methods

One hundred twenty eyes of one hundred twenty patients underwent phacoemulsification surgery were included in this retrospective study. The surgeries were made by same surgeon at Batı Göz Hospital. Sixty eyes using Bio-Hyalur-SV were classified as Group 1, and sixty eyes using Protectalon as Group 2. The study was performed in accordance with the Declaration of Helsinki. The study protocol was approved by the Biruni University Clinical Trials Ethical Comittee in Istanbul, Turkey, 29.01.2021 no:2021/47-38.

Patients aged 45 and over, Grade I, II or III unilateral / double stained cataract, healthy eyes creating cataract included in this study.

History of previous ocular surgery, traumatic cataract, glaucoma or uveitis, cataracts secondary to uveitis, pseudoexfoliation syndrome with glaucoma, proliferative diabetic retinopathy patients were excluded from the study. Endothelial cell density (ECD), cell number, cell area, coefficient of variation (CV) in cell size, and cell hexagonality were analyzed with CEM-530 specular microscope (Nidek Co, Ltd, Gamagori, Japan) and repeated three months postoperatively. Central corneal thickness (CCT) was measured using the Sirius corneal topography system (Costruzioni Strumenti Oftalmici, Firenze, Italy) preoperatively and at postoperative first week, first and third months. Intraocular pressure (IOP) was measured with an applanation tonometer at every visit. The effective phacoemulsification time and average phacoemulsification power were also recorded from patient files.

Statistical Analysis

Statistical Package for the Social Sciences version 20.0 (SPSS Inc., Chicago, IL, USA) program was used to evaluate the data. Student's t-test was used for comparisons between two groups for variables where parametric test assumptions were met, and Mann-Whitney U test was used for comparisons between two groups for variables where parametric test assumptions were not met. Chi-square test was used for comparison of categorical variables. Two-way analysis of variance (Repeated measures ANOVA) was
used for repeated measures in the comparison of repeated measures meeting the parametric test assumptions. A value of p < 0.05 was considered significant.

**Results**

The mean patient age was 64.56±9.29 (46-85) in Group 1 and 65.96±7.63 (52-83) in Group 2.

Table- 2 is a summary of baseline demographic characteristics and cataract grading. There were no statistically significant differences among the two groups. The mean effective phacoemulsification time 45.98±12.78 seconds was in Group 1 and 45.85±11.60 seconds in Group 2 (P=0.983) the average phacoemulsification power was 30.66±8.20 and 30.16±7.18 (P=0.695) respectively (Table-3). The morphological parameters of the two OVD's are listed in Table -4. There was a statistically significant decrease in the mean ECD all follow-up times when compared with the preoperative visit (p=0.000). In Group 1, the mean ECD at postoperative third month was 2149.71±354.48 cells/mm² and 2172.13±289.86 cells/mm² in Group 2. There was no significant difference in mean ECD reduction between the two groups (p=0.616).

First week after surgery, there was significant increase in CCT compare to preoperative values in Group 1 and Group 2 respectively (p=0.000). No significant difference between groups without taking the time factor (p = 0.317). No interaction between independent groups and repeated measures time (p = 0.412). There is a significant difference between repeated measurements in terms of time in the number of cells without taking them within the groups (p = 0.002). No interaction between independent groups and repeated measures time (p = 0.990). Also in cell area and CV in cell size measurements all the visits there wasn’t any difference between the two groups. In both groups, post-operative cell area and CV in cell size values increased statistically significantly at each visit compared to preoperative values (p = 0.000). Preoperative (p= 0.047) and one week after surgery (p=0.020) hexagonality measurement was different between two groups. At the third month after surgery there wasn’t significant difference between two groups (p=0.607). In both groups post-operative cell area and CV in cell size values decreased statistically significantly at each visit compared to preoperative values (p = 0.000). Preoperative (p= 0.047) and one week after surgery (p=0.020) hexagonality measurement was different between two groups. At the third month after surgery there wasn’t significant difference between two groups (p=0.607). In both groups post-operative cell area and CV in cell size values decreased statistically significantly at each visit compared to preoperative values (p = 0.000). Figure-1 shows incidence of IOP peaks at each follow-up. The IOP was <23 mmHg in all of the patients on the first day after surgery. There was no significant difference in the incidence of IOP peaks between the two groups at every visit. In both groups, a significant increase was observed in the mean IOP at first day, first week, and first month after surgery compared to preoperative values (p=0.000). But no significant difference in IOP increase in Group 1 (p=0.092), Group 2 (p=0.013) compared to preoperative values at third month postoperatively (p <0.001 significant with Bonferrotti correction). Therefore although IOP increase in the first postoperative period, it comes to preoperative values in the third month. The cornea was clear for all 120 (100%) eyes at the last follow-up visit.

**Discussion**

OVDs play a crucial role in phacoemulsification to protect intraocular structures from maneuvers during intraocular surgery. The main purpose of OVDs are to stabilize the anterior chamber and protect the corneal endothelium. Dispersive OVDs have lower molecular weight and shorter molecular chains that
protect more from the turbulence of fluid and lens fragments during phacoemulsification and better adhere to corneal endothelial cells (5). Cohesive OVDs are viscoelastics with high molecular weight and long molecular chains that aid in field protection (6).

Short molecular chains make dispersive OVDs more prone to cleavage, resulting in increased postoperative IOP. On the contrary, removal of cohesive OVDs are faster but protection to the corneal endothelium is lower (3).

In this study, we aimed to compare the safety and performance in cataract surgery of two OVDs, each having high viscosity cohesive characteristics. Both groups were operated by the same surgeon and compared in terms of ultrasound energy and other characteristics used in surgery.

The primary goal of OVD is the ability to protect corneal endothelial cells because the corneal endothelium is actively present where optical transparency can be maintained (7,8). The efficiency of OVDs on the corneal endothelium can be evaluated by postoperative endothelial cell concentration (9). The reduction of endothelial cells is compensating by cell expansion, cell shift, rearrangement, and cell fusion (10).

Auffarth et al. (9) in their study they compared the performance of the two ophtalmic devices-Twinvisc and Duovisc which were contain both dispersive and a cohesive OVD in a single device. They were pointing that there were no significant difference in the mean ECD reduction between two grup at three months postoperatively.

Holzer et al. (11) compared five OVDs commonly used during phacoemulsification in terms of ECD loss in a prospective randomized study. They did not confirm that dispersive OVDs protect the endothelium better than cohesive OVDs. In fact, the lowest mean cell loss (6.2±6.5%) was in the Healon 5 (Abbott Medical Optics, Inc., Santa Ana, CA, USA) group, a cohesive agent, and the greatest cell loss was seen in the OcuCoat (Bausch & Lomb, Rochester, NY, USA) group (16.7±10.8%). OcuCoat contains hydroxylpropyl methylcellulose (2.0%) and has dispersive characteristics.

Papaconstantinou et al. (12) assessed and compared the safety and the efficacy of VisThesia (Carl Zeiss Meditec AG, Jena, Germany) and Viscoat in a prospective randomized clinical trial. The mean ECD decrease was 212 cells/mm$^2$ (9.1%) in the Viscoat group and 272 cells/mm$^2$ (11.8%) in the VisThesia group. It was not significant as the difference between the two groups (t-test = 0.18, p> 0.1). They also states that the result is from surgery commensurate with the standard ECD decrease after cataract surgery. Travmatic stress on the endothelium with cataract surgery causes a decrease in ECD and morphological changes in cells. Mechanical reasons such as heat, vibration, micro air bubbles and free radical formation produced by phaco tips and the contact of surgical instruments and nucleus units with the endothelium cause endothelial damage during phacoemulsification surgery (13,14).

Bourne et al. reported a loss of ECD of 16.1% after phacoemulsification surgery in their large series observed for one year (15).
In our study, there is a significant difference between the repeated measurements of the mean ECD in terms of time within the groups (p=0.000). But regardless of the time factor there was no statistically significant difference in the mean ECD reduction between the two groups (p=0.616). As a result, the decrease in ECD was within the physiological limits that should be compatible with the literature.

Dispersif and cohesive viscoelastic substances Twinvisc and Duovisc were compared in a prospective and randomized multicenter study conducted in seven centers in Europe and they showed that mean IOP measurements and incidence of IOP spikes postoperatively the two OVD’s were equally effective. These findings with early postoperative IOP elevation and then returning to baseline values were found to be consistent with the literature (9).

Major reason for the postoperative IOP increase seems to be the amount of remaining OVD at the end of the surgery (16). It is assumed that post-operative OVD is released into the aqueous humor and mechanically inhibits the trabecular outflow tract and reduces its mission (17). It is important to clean the OVD after the operation in order to prevent postoperative IOP increase. Since the OVDs we compared in our study are cohesive with a high viscosity, they are much easier and faster to clean from the forearm, thus enabling us to encounter postoperative IOP spikes. Also Rainer et al. showed that in contrast to the dispersive Viscoat (16), the cohesive Healon caused lower IOP increases than Viscoat 6 hours postoperatively (18,19).

In our study we found statistically significant increase in the mean IOP at postoperative first day, first week and first month after surgery compared to preoperative (p=0.000). However, IOP was <27 mmHg in all patients. This increase in IOP was in the nature of a slight increase that may occur after routine cataract operation and reached preoperative values in the postoperative third month.

Corneal thickness is a parameter that directly reflects the functional status of the corneal endothelium. Postoperative CCT reflects the stress of endothelium caused by US energy and the turbulence of irrigation solution and nuclear fragments (20,21). Auffarth et al. (9) showed that there was an increase of 9.8% and 9.5% in pachymetry 24 hours after surgery in Group 1 and Group 2 when compared with the preoperative values (P! .001), the difference was statistically significant, but the difference between the two groups was not.

In their randomized patient research masked study, Neuyamer et al. (22) found an increase in CCT on the first postoperative day in the Neochrome Cohesive group (a new cohesive OVD) and a discrepancy between low endothelial cell density loss at three months postoperatively. While the difference in endothelial loss between the two OVD groups was not significant, the increase in CCT was moderate. On the contrary, Cheng et al. (23) found a significant correlation between CCT in the immediate postoperative period and the percentage of endothelial cell loss at the 1st and 6th months postoperatively. First week after surgery, there was significant increase in CCT compare to preoperative values in Group 1 and Group 2 respectively (p=0.000). We could not find a relationship between the minimal increase in CCT after surgery and minimal ECD loss in our study. The postoperative clinical reflection was not significant. Cornea was clear in all cases.
In our study there is a significant decrease in the cell number (p=0.002) and hexagonality values (p=0.000) in both groups compared to the preoperative values. Also there is a significant increase in cell area and CV in cell size values compared to preoperative values (p=0.000). There was no significant difference between the groups in all parameters at postoperative third month. These results are the morphological reflections of the damage in the endothelium in routine cataract surgery and were found to be within routine limits. Regarding the limitations of our study, it does not include inflammation, flare and anterior chamber reaction was not examined. This is due to the retrospective nature of our study. As a result, we observed that these two high viscosity cohesive OVDs created a good anterior chamber depth and well preserved endothelial in cataract surgery. We did not encounter any serious complications. Both OVDs can be used safely in the cataract surgery. There is a wide range of OVDs in cataract surgery and comparative prospective studies with other OVDs may be required.

**Conclusion**

The two OVDs used in this study during cataract surgery were safe and effective. Both OVDs resulted in similar rates of transient IOP increases and corneal endothelial damage also provided good anterior chamber depth and were fairly easy to remove.

**Declarations**

**Presentation:** There is no presentation.

**Authors financial or proprietary interest:** None of the authors has a financial or proprietary interest in any of the products, methods, or materials used in this case report.

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**Tables**

*Table 1: Features of Bio-Hyalur SV and Protectalon.*

|                      | BIO-HYALUR SV                     | PROTECTALON                     |
|----------------------|-----------------------------------|---------------------------------|
| RAW MATERIAL         | Sodium hyaluronate (%3.0)         | Sodium hyaluronate (%2.0)       |
| VISCOSITY            | at 1 shear rate – 1.000.000 mPas   | 900.000 mPas                    |
| PH                   | 6.8 to 7.6                        | 6.8-7.6                         |
| OSMOLARITY           | 270-400 mOsm /kg                  | 300-350 mOsm /kg                |
| SOURCE               | Bacterial fermentation            | Bacterial fermentation          |
| MOLECULAR WEIGHT (MILLION DALTONS) | 2,8-3,2 million daltons            | 3,0 million daltons             |
| CONCENTRATION        | 30 mg/ml                          | 20 mg/ml                        |

*Table 2. Summary of patient baseline demographic characteristics.*
Table 3: **Intraoperative parameters.**

|                          | BIO-HYALUR SV     | PROTECTALON     | P değeri |
|--------------------------|-------------------|-----------------|----------|
| **Effective Phaco Time** | 45,98±12,78       | 45,85±11,60     | P=0,983  |
| **Phaco Power**          | 30,66±8,20        | 30,16±7,18      | P=0,695  |
| **Vacum**                | 418,33±51,22      | 416,66±48,42    | P=0,793  |

Table-4: **Morphological parameters of the two OVD's**
|                              | BIO-HYALUR SV  | PROTECTALON  | \(P\) değeri |
|------------------------------|----------------|--------------|--------------|
| **Endothelial cell density (ECD)** |                |              |              |
| Preop                        | 2383,45±288,67 | 2421,43±256,37 | 0,448        |
| Postop 7 days                | 2224,18±344,71 | 2257,65±278,81 | 0,560        |
| Postop 30 days               | 2186,00±359,64 | 2203,30±293,14 | 0,773        |
| Postop 90 days               | 2149,71±354,48 | 2172,13±289,86 | 0,705        |
| **Corneal thickness (CCT)**  |                |              |              |
| Preop                        | 530,63±32,53   | 535,23±31,20  | 0,431        |
| Postop 7 days                | 544,01±36,77   | 551,13±31,34  | 0,256        |
| Postop 30 days               | 539,68±38,25   | 548,25±32,70  | 0,190        |
| Postop 90 days               | 539,65±37,50   | 544,28±41,00  | 0,520        |
| **Cell Number**              |                |              |              |
| Preop                        | 162,11±56,74   | 183,88±68,26  | 0,060        |
| Postop 7 days                | 150,70±52,50   | 173,30±67,71  | 0,053        |
| Postop 30 days               | 150,58±54,22   | 172,91±69,13  | 0,051        |
| Postop 90 days               | 156,53±53,55   | 179,35±70,01  | 0,047        |
| **Cell Area**                |                |              |              |
| Preop                        | 426,10±52,59   | 442,16±52,32  | 0,090        |
| Postop 7 days                | 462,00±97,93   | 474,20±96,02  | 0,265        |
| Postop 30 days               | 470,65±117,41  | 482,86±107,49 | 0,214        |
| Postop 90 days               | 476,63±122,25  | 488,10±113,90 | 0,349        |
| **CV in cell size**          |                |              |              |
| Preop                        | 29,06±5,04     | 29,06±5,19    | 0,910        |
| Postop 7 days                | 30,88±5,79     | 31,25±5,84    | 0,795        |
| Postop 30 days               | 30,91±5,62     | 30,88±5,55    | 0,983        |
| Postop 90 days               | 31,55±4,78     | 30,75±5,28    | 0,263        |
| **Hexagonality**             |                |              |              |
| Preop                        | 68,98±4,87     | 70,58±4,42    | 0,047        |
| Postop 7 days                | 65,78±5,73     | 63,30±5,12    | 0,020        |
|                      | Preop     | Postop 24 hours | Postop 7 days | Postop 30 days | Postop 90 days |
|----------------------|-----------|-----------------|---------------|----------------|----------------|
| **Postop 30 days**   | 65,68±5,65| 64,10±5,13      | 0,127         |                |                |
| **Postop 90 days**   | 63,95±5,12| 64,21±5,33      | 0,607         |                |                |
| **Intraocular pressure (IOP)** |          |                 |               |                |                |
| **Preop**            | 15,20±3,03| 14,79±2,56      | 0,418         |                |                |
| **Postop 24 hours**  | 20,71±3,83| 20,38±3,03      | 0,318         |                |                |
| **Postop 7 days**    | 17,55±3,23| 17,70±2,52      | 0,897         |                |                |
| **Postop 30 days**   | 16,48±2,32| 16,25±2,15      | 0,659         |                |                |
| **Postop 90 days**   | 15,66±2,12| 15,23±2,32      | 0,271         |                |                |

**Figures**
Figure 1

Group comparison of the endothelial cell density (ECD), central corneal thickness (CCT), cell number, cell area, CV in size, hexagonality, intraocular pressure (IOP).