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ORIGINAL ARTICLE

Evaluation of Clinical Outcomes of a Cohesive Ophthalmic Viscosurgical Device

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Abstract

Introduction: To evaluate, the clinical outcomes in patients undergoing cataract surgery with use of sodium hyaluronate 1.4% for its ability to maintain anterior chamber space and protection of corneal endothelial cells.

Methods: This was a single center, retrospective observational study. A total 52 patients (eyes) having age older than 45 years with Grade I to III cataract were enrolled in the study and BIO-HYALUR Plus was used as ophthalmic viscosurgical device (OVD) during the standard cataract surgery procedure. Pre-operative and post-operative day 1, 1 week, 1 month, and 3 months visits, data assessments included: Adverse events observed during the study were also noted for the evaluation of safety.

Results: Intraoperative anterior chamber space maintenance has been well formed for all 52 (100%) patients (eyes). Corneal clarity was observed for all patients. At 3-month follow-up visit, the mean best-corrected visual acuity was improved to 0.9±0.17 (Snellen Decimal). There was decreased in mean ECC, cell density, intraocular pressure, corneal thickness, coefficient of variance in cell size, and cell area compare to pre-operative visits on follow-up period. No adverse events were reported during entire study.

Discussion and Conclusion: BIO-HYALUR Plus OVD cohesive properties and was safe and effective for every stage of cataract surgery without additional toxicity nor result in increased endothelial cell loss.

Keywords: Cataract surgery; endothelial cell count; ophthalmic viscosurgical device

Cataract surgery is performed in a closed, fluid-filled medium, and it is dependent on fluid flow. During cataract surgery, the observed temporary or reversible deformation and permanent or irreversible deformation are within the field of rheology, which is known as the science of materials flow behavior under applied deformation forces [1]. Ophthalmic viscosurgical devices (OVDs) are viscoelastic solutions, which play important role in the success of cataract and various anterior segment surgeries. The main objectives of using OVDs during cataract surgery are to support the anterior chamber volume during surgery, maintain mydriasis and clearance under microscope, and protect the endothelium from phacoenergy. In Faco surgery, it is very critical for ideal OVD to maintain in the eye during the procedure and prevent intraocular pressure (IOP) changes and to be easily removed at the end of the operation [2,3]. OVDs are solutions containing one or more of the following components; hyaluronic acid or its sodium salt, chondroitin sulfate, or methylcellulose. Since these materials are polymeric in nature, they tend to be viscoelastic depending on factors

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such as their properties, concentration, molecular weight, and molecular architecture, as well as interactions between the molecules in the solution [4].

Balazs et al. [5] have first introduced the OVDs in ophthalmic surgeries in 1982. Since then, it has been used extensively in anterior segment surgeries, mostly in cataract surgery with Faco. OVDs are classified as cohesive and dispersive OVDs. Cohesive OVDs are further divided into three types: Viscoadaptive, higher viscosity cohesive, and lower viscosity cohesive. Dispersive OVDs are divided into two types: Higher viscosity and lower viscosity dispersives [4]. Cohesive OVDs are useful in creating and maintaining space in the anterior chamber, which are relatively easy to remove as a bolus at the end of surgery, because cohesive nature tend to hold together as a mass [5,6].

BIO-HYALUR Plus (Sodium hyaluronate 1.4%, Biotech Vision Care, Ahmedabad, India) is a novel OVD, with the properties; viscous cohesive behavior, 1.4% concentration of sodium hyaluronate, bacterial fermentation origin, 2.8–3.2 million dalton molecular weight, 400000 mPas viscosity at zero shear at 25°C, 270–400 mOsmol/kg osmalarity, and 6.8–7.6 PH value at Celsius degrees.

The purpose of this study was to assess the safety, stability, and efficacy of BIO-HYALUR Plus OVD which showed cohesive properties for its ability to protect the corneal endothelial cells and to maintain anterior chamber space in patients during Faco cataract surgery.

Materials and Methods

Study Design and Participants

This was an observational, retrospective study to evaluate clinical outcomes related to protection of corneal endothelial cells and the ability to maintain anterior chamber space with BIO-HYALUR Plus OVD in patients undergoing routine cataract surgery in a university research and education hospital, ophthalmology department. The study was approved by the Local Ethics Committee and performed in accordance with the Declaration of Helsinki.

All the patients, who applied to one skilled surgeon (MSS) cataract clinic for surgery between October 2015 and April 2016, were screened. Total 52 patients who met the following inclusion criteria were included in the study: Unilateral/bilateral diagnosed cataract, patients with age ≥45 years, patients who had undergone surgery for grade 1–3 cataract and used BIO-HYALUR Plus OVD as OVD, and patients who have been followed up for 3 months. Patients who had any of the following criteria were excluded from the study: Patients treated for brown, brunescent, and traumatic or subluxated cataract; patients who had corneal endothelial disease, that is, endothelial cell count <2,000 cells/mm2; patients who had glaucoma, pseudoexfoliation syndrome with glaucoma, iris atrophy, and proliferative diabetic retinopathy at the time of surgery; and patients who had undergone previous intraocular or corneal surgery and participation in any other clinical study.

Surgical Technique

All procedures were performed under topical anesthesia with proparacaine hydrochloride 0.5% (Alcaine 1, Alcon Labs Inc, Fort Worth, TX). Standard pre-operative medications were tropicamide 0.5% (Tropamide 1, Bilim Ilac, Istanbul, Turkey), phenylephrine hydrochloride 0.25% (Mydfrin 1, Alcon Labs Inc, Fort Worth, TX), and nepafenac 0.1% ophthalmic suspension (Nevanac 1, Alcon Labs Inc., Fort Worth, TX) 1 h before surgery for pupillary dilation. One main 2.8 mm and 2 side port clear corneal incision was made. BIO-HYALUR Plus OVD was injected to protect the endothelium. A central, continuous, and curvilinear capsulorhexis, approximately 5.5 mm in diameter was created. Phacoemulsification was performed using INFINITI Vision System (Alcon Laboratories, Inc, Fort Worth, TX). BIO-HYALUR Plus OVD was injected to form the anterior chamber before intraocular lens (IOL) implantation. The aspheric monofocal IOL was then implanted in the capsular bag. BIO-HYALUR Plus OVD was aspirated and anterior chamber was irrigated with BSS solution. The main and side entries were irrigated and checked with sponge for aqueous humor leakage from anterior chamber.

Study Procedure

The data collected during procedure included space maintenance, effective, and total phaco time and power. Noncontact specular microscopes such as the Konan NSP-9900 capture sharp images with sufficient magnification for reliable Endothelil Cell Dansity (ECD) determination or morphometric analysis. The fixed-frame method for determine ECD allows quantitative analysis of cell structure, including ECD, coefficient of variation (CV), and percentage of hexagonal cells. IOP was measured through Goldmann applanation tonometry.

Data collected from pre-operative, post-operative Day 1, 1 week, 1 month, and 3 months visits, assessments included: Best-corrected visual acuity (BCVA) tested with ETDRS charts at 4 m, endothelial cell count, corneal thickness, CV in cell size, cell area, cell density with Cell Check (Konan Medical, California, USA), and IOP.

Statistical Considerations

All statistical analyses were performed using the Statistical Package for the Social Sciences (Chicago, Illinois, USA) version 20.0. For the statistical analysis mean, standard deviation (SD) and frequency of the variables were used. The normality of the data was confirmed using the Kolmogorov-Smirnov test. The independent Student t-test was used to compare variables between groups. $p<0.05$ were considered significant.

Results

Total 52 patients (eyes) were enrolled in the study and included in analysis. Mean age of patients enrolled in the study (age) (±SD) was 65.6 (±12.25) years. Out of 52 patients, 20 (38.46%) and 32 (61.54%) were male and female, respectively. Phacoemulsification was performed without complication in 100% of the eyes. There were no posterior capsule ruptures, no increase in vitreous pressure, no issues in IOL implantation, no uveitis, and no endophthalmitis. Intraoperative evaluation revealed that the anterior chamber was well formed in all 52 (100%) patients. The mean phaco time was 1.9±0.1 min, the mean phaco power was 25.3%±1.2%, and the mean equivalent phaco time was 0.29±0.02 min.

Mean change in endothelial cell count from pre-operative visit (cell/mm^2) (±SD) was −82.9±56.16 (−3.1%), −111.2±63.61 (−4.2%) and −130.2±74.11 (−4.9%) cell/mm2, respectively, at 1 week, 1 month, and 3 months postoperatively. Statistical significant difference ($p<0.0001$) was observed from pre-operative visit to all post-operative visits. Figure 1 shows mean percent decrease from pre-operative visit.

Mean corneal thickness (micron) (±SD) was 556.5±49.39, 560.6±49.11, 556.6±53.35, and 544.7±48.39, respectively, at pre-operative visit and 1 week, 1 month, and 3 month postoperatively. The mean change in corneal thickness was statistically significant ($p=0.0026$) at 3 month postoperatively.

Mean IOP (mmHg) (±SD) was 16.7±2.52, 16.6±3.43, 14.8±2.63, 14.4±2.80, and 13.4±2.31, respectively, for pre-operative, Day 1, week 1, month 1, and month 3 postoperatively (Fig. 2). Mean change in IOP from pre-operative visit to all post-operative visits was −0.1±3.09, −1.9±2.80, −2.3±2.59, and −3.2±2.13 mm Hg, respectively, at Day 1, 1 week, 1 month, and 3 months postoperatively, which was statistically significant ($p<0.0001$) from week 1 onward.

Corneal clarity was observed for all 52 (100%) study patients. Mean BCVA (decimal) (±SD) was 0.9±0.21, 0.9±0.21,

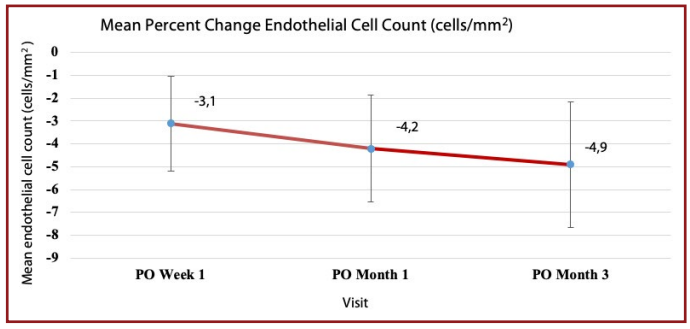

Figure 1. Mean percent change in endothelial cell count (cells/mm^2).
PO: Post Operative.

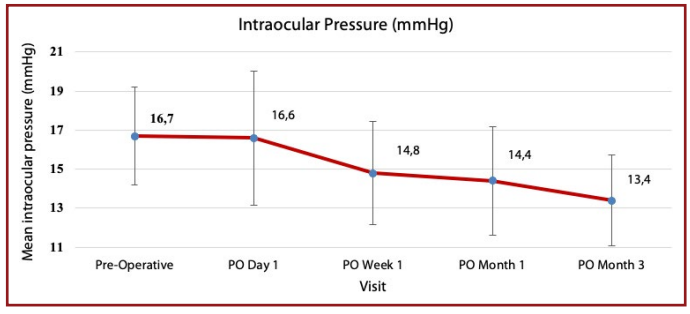

Figure 2. Intraocular pressure (mmHg) changes.
PO: Post Operative.

and 0.9±0.17, respectively, at 1 week, 1 month, and 3 month postoperatively. Mean of CV in cell size (%) (±SD) was 33.8±6.76, 33.2±5.79, 32.8±4.96, and 31.2±2.15, respectively at pre-operative visit and 1 week, 1 month, and 3 month postoperatively. Mean cell area (um2) (±SD) was 381.3±28.66, 382.0±27.26, 380.9±32.25, and 367.5±39.61, respectively, at pre-operative visit and 1 week, 1 month, and 3 month postoperatively. Mean number of cells analyzed (cell/mm2), which was 140.0±11.26, 137.4±11.69, 135.5±12.79, and 135.6±12.58 at pre-operative, 1 week, 1 month, and 3 months postoperatively, respectively. No adverse events or adverse device effects were reported in this study.

Discussion

OVDs maintain adequate intraocular space and stabilize ocular tissue during the operation, especially in the stages of capsulorhexis and IOL implantation [7,8]. OVDs also facilitate any surgical maneuvers and decrease the possible damage of the corneal endothelium due to surgical trauma [9,10]. They are also considered to inhibit the formation of free radicals, which negatively affect the corneal endothelium during phacoemulsification [11,12]. Dispersive OVDs have the ability to coat intraocular structures with their lower viscosity, and this provide to stay in place during the

fluidics of phacoemulsification surgery. Due to these properties, removal of dispersive OVDs requires more effort at the end of surgery. Common dispersive OVDs include Healon D (AMO), Viscoat (Alcon), and OcuCoat (B and L). Cohesive OVDs are able to pressurize the eye and create space with their higher viscosity, and this is important for the easy IOL insertion. They are ideal for flattening the anterior capsule to facilitate capsulorrhexis creation or for deepening a shallow anterior chamber since they are more viscous and solid. Cohesive OVDs tend to stick together. This makes easy removal, they are ideal products to use during capsulorrhexis creation and during IOL insertion. Common cohesive OVDs include Healon (AMO), Healon GV (AMO), Provisc (Alcon), and Amvisc (B and L) [6,13,14]. BIO-HYALUR Plus OVD has cohesive properties; however, we use it on all steps during the cataract surgery and successfully completed all the steps without any adverse effect.

In routine cataract and anterior segment surgery practice, corneal endothelial cell loss still remains a well-known, undesirable side-effect that may, and negatively affect patients' post-operative visual outcomes. In different studies which studied endothelial cell changes, were reported between 0.3% and 20.32% [15-17]. In our study, we observed the mean endothelial cell count was slightly decreased on post-operative period. However, this change was near the low end of ranges found in before.

OVDs should also be able to be easily removed from the anterior chamber at the end of surgery and should have little effect on post-operative IOP rise [14]. In the literature, it is recognized that cataract surgery can help lower IOP, because due to the increased angle opening permitted by the thin IOL as compared with the much thicker lens with cataract. However, there can be fluctuations in the IOP after cataract surgery. Residual OVD left in the eye can clog the trabecular meshwork, leading to a transient elevation in post-operative IOP, particularly in the early post-operative period [14]. In our study, no significant IOP spike was observed till 24 h post-surgery. However, there was statistically significant decrease in IOP from pre-operative visit to post-operative visits, which are compatible with previous results. Furthermore, none of the patients had IOP ≥30 mm Hg, and there was no need for second surgery to clean OVD from anterior chamber during the entire follow-up period.

One key attribute of OVD is the protection of corneal endothelial cells during cataract surgery. Our study showed successfully the protective properties while utilizing BIO-HYALUR Plus OVD for endothelial cells, among its other functions. The data gathered on general and ocular health, IOP, endothelial cell density, and corneal pachymetry were able to conclusively demonstrate safety of OVD. No adverse events or adverse device effects reported in this study. However, lack of comparison group and short follow-up time were our two important limitations. We thought larger patients group with different subgroups comparison mighty enlight more information about the efficacy.

Conclusion

The BIO-HYALUR Plus OVD was evaluated safe and effective for stages of Faco cataract surgery without any additional toxicity nor results in increase endothelial cell loss.

Ethics Committee Approval: This study was approved by the ethics committee of Haydarpasa Numune Training and Research Hospital.

Peer-review: Externally peer-reviewed.

Authorship Contributions: Concept: N.B.C.; Design: N.B.C.; Data Collection or Processing: N.B.C.; Analysis or Interpretation: H.U.Ç.; Literature Search: N.B.C.; Writing: N.B.C.

Conflict of Interest: None declared.

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