Balanced Salt Solution-Assisted Intraocular Lens Implantation in Phacoemulsification Surgery: Intraocular Pressure and Endothelial Cell Effects

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Abstract

Objectives: The purpose of this study was to evaluate the effect of balanced salt solution (BSS)-assisted intraocular lens (IOL) implantation on postoperative intraocular pressure (IOP) and endothelial cells and to compare BSS-assisted IOL implantation with the use of ophthalmic viscosurgical devices during IOL implantation.

Methods: A total of 52 eyes of 40 patients (25 female, 15 male) with a cataract who underwent phacoemulsification surgery with BSS-assisted (26 eyes) or viscoelastic-assisted IOL implantation (26 eyes) were evaluated. BSS-assisted IOL implantation was performed with the aid of irrigation cannula and BSS without using a viscoelastic substance. Viscoelastic-assisted IOL implantation was performed according to standard procedures to facilitate IOL implantation. IOP measurements and endothelial changes after phacoemulsification surgery, as well as the surgical time were noted and compared. The eyes were also evaluated in terms of cataract density preoperatively and phaco parameters were assessed peroperatively.

Results: The mean age of the patients was 67.5±7.8 years in the BSS-assisted group and 67.8±9.4 years in the viscoelastic group. The mean preoperative IOP and postoperative IOP on day 1, week 1, and month 1 was 14.2±2.3, 14.7±3.1, 13.2±1.5, and 13.8±2.7 mmHg, respectively, for the BSS-assisted group and 14.1±2.9, 19.1±3.4, 13.8±3.1, and 13.2±2.9 mmHg, respectively, for the viscoelastic-assisted IOL implantation group. The IOP increase was significantly greater on the first day in the viscoelastic-assisted IOL implantation group (p=0.007). The surgical time was 12.3±2.1 minutes in the BSS group and 14.6±3.1 minutes in the viscoelastic group (p=0.035). The difference in endothelial changes was not statistically significant between groups (p=0.88).

Conclusion: IOL implantation using BSS in phacoemulsification surgery is a reliable technique, and this method has a significantly shorter surgery time and a much smaller postoperative IOP increase. The reduced IOP increase after cataract surgery might be particularly helpful for glaucoma patients.

Keywords: Balanced salt solution-assisted intraocular lens implantation, phacoemulsification surgery, viscoelastic-assisted intraocular lens implantation.

Introduction

Ophthalmic viscosurgical devices (OVDs), or viscoelastic agents, play an important role in the development of new approaches to phacoemulsification (phaco) surgery (1–3). The surgical benefits of OVDs are protection of the corneal endothelium, maintenance of the anterior chamber, and assistance with the implantation of the intraocular lens (IOL) (3, 4). However, in addition to these benefits, OVDs may also cause spikes in postoperative intraocular pressure (IOP) (5). IOP spikes could worsen damage in the fiber layer of the retinal nerve and visual field loss in patients with glaucoma (6). OVDs may also cause inflammation immediately after cataract surgery (7), and if the OVD behind the IOL is not removed completely, it may lead to capsular disten-
sion syndrome (8). To prevent this complication, careful OVD removal should be performed, though this may prolong the surgical time, which may be associated with further endothelial cell loss (9).

To avoid these complications, a technique has been described in literature of IOL implantation using a balanced salt solution (BSS) to maintain the anterior chamber rather than filling the capsular bag with an OVD (10). The results of the technique seem promising, but the data are still insufficient (10–13).

Although the surgical time is known to be shorter with IOL implantation using BSS, it has not been documented, and the relationship of endothelial cell loss with cataract surgery time in BSS-assisted and OVD-assisted IOL implantation is not known.

The aim of this study was to evaluate the effect of BSS-assisted IOL implantation on postoperative IOP, endothelial cells, and surgical time, and to compare these data with OVD-assisted IOL implantation phacoemulsification surgery.

**Methods**

Approval for the study was granted by the Ethics Committee of Istanbul Training and Research Hospital (August 31, 2018; no: 1406). The tenets of the Declaration of Helsinki were observed at all stages of the study and all of the patients were informed about the benefits and potential risks of the procedure. Informed consent was obtained from each patient.

The study included 52 eyes of 40 patients (25 female, 15 male) who underwent uneventful phacoemulsification cataract surgery with BSS-assisted IOL implantation or OVD-assisted IOL implantation.

The inclusion criteria were age between 40 and 80 years and a diagnosis of senile nuclear cataract up to grade 2 according to the Lens Opacities Classification System III. The exclusion criteria were a small pupil, corneal disorder, compromised endothelial cell function, shallow anterior chamber, complication during cataract surgery, glaucoma or preoperative IOP >20 mmHg, pseudoexfoliation, a previous history of eye surgery, or diabetes mellitus. Patients who developed any intraoperative complication were also excluded from the study.

The patients were separated into 2 groups: Group 1 (26 patients) was defined as the BSS-assisted group, and Group 2 (26 patients) was the OVD-assisted group.

The preoperative examination of the patients included a complete systemic and ocular history, as well as routine ocular examinations, such as best corrected visual acuity (BCVA) measured using logarithm of the minimum angle of resolution (logMAR), slit-lamp biomicroscopy, Goldmann applanation tonometry, and fundus examination. Grading of nuclear sclerosis was performed with a slit-lamp examination according to the Lens Opacities Classification System III. The anterior chamber depth was measured with optic biometry (Lenstar LS 900; Haag-Streit AG, Koniz, Switzerland). The number of endothelial cells in the central cornea was measured preoperatively and at 3 months after surgery using a Konan specular microscope (Konan Medical Inc., Hyogo, Japan).

The total ultrasonic time, mean cumulative energy, and surgical time were recorded peroperatively. IOP was measured with a tonopen (Tono-Pen AVIA; Reichert Technologies, Depew, NY, USA) immediately following the conclusion of the surgery.

Postoperative evaluation included BCVA, Goldmann applanation tonometry and slit-lamp biomicroscopy on day 1, then again at 1 week and 1 month after the cataract surgery, and specular microscopy was performed at the end of the third month. The total postoperative refractive error was measured with an autorefractometer (Topcon KR 8800; Topcon, Tokyo, Japan) at the end of the first month. Postoperative IOP was measured at the same time in the morning in all cases.

**Surgical Technique**

All of the surgeries were performed by a single surgeon (E.Y.) under topical anesthesia using proparacaine hydrochloride 0.5% (Alcaine; Alcon Laboratories, Inc, Ft. Worth, TX, USA) and intracameral anesthesia of 0.1 mL preservative-free lidocaine hydrochloride 1% (Jetokain simplex; Adeka Ilac San., Samsun, Turkey). A Stellaris surgical system (Bausch and Lomb, Inc., Rochester, NY, USA) was used for the patients in both groups. The primary incision was made with a 2.8-mm laser-edge steel trapezoidal knife (ClearCut HP; Alcon Laboratories, Inc, Ft. Worth, TX, USA) through the steepest site of the cornea. Two side ports were created at 90° to the main port with a 20-G paracentesis knife (A-OK, V-Lance; Alcon Laboratories, Inc, Ft. Worth, TX, USA) using BSS. The anterior chamber and the capsular bag were filled with OVD (Sodium hyaluronate, Protectalgon 1.6%; VSY Biotechnology, Amsterdam, The Netherlands) and then a continuous curvilinear capsulorrhexis measuring 5.0 to 5.5 mm in diameter was created using capsulorhexis forceps. Hydrodissection was performed to achieve free rotation of the nucleus. Phacoemulsification was completed using the vertical chop technique in both groups. The irrigation/aspiration (I/A) procedure was completed with Buratto Bimanual I/A set tips (Alcon Grieshaber AG, Schaffhausen, Switzerland). In Group 1, IOL implantation was performed using BSS (BSS Plus; Alcon Laboratories, Inc., Ft. Worth, TX, USA) and the anterior chamber and the capsular bag were filled with BSS using I/A cannula from the side port. An IOL (Sensar; Abbott Laboratories, Inc., Lake Bluff, IL, USA) was injected with an IOL injector (Unfolder Platinum 1 Series Implantation System; Abbott Laboratories, Inc., Lake Bluff, IL, USA) into the anterior chamber through the main port.

In Group 2, the anterior chamber and the capsular bag were filled with OVD (Protectalgon), and the IOL was then implanted into the capsular bag with an IOL injector (Un-
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Following the IOL implantation, the IOL was centered using the I/A canula in both groups. Residual OVD was removed as soon as possible. All incisions were sealed with corneal stromal hydration and were checked for leakage with a microspoon.

Before the completion of surgery, 1 mg/mL of cefuroxime (Aksef 750 mg; Nobel Ilac Sanayii ve Ticaret A.S., Istanbul, Turkey) was injected into the anterior chamber as endophthalmitis prophylaxis. The effective phaco time and surgical time was recorded at the end of the procedure.

Statistical Analysis

The analysis to derive descriptive statistics was performed using SPSS for Windows, Version 16.0 (SPSS Inc., Chicago, IL, USA) statistical software. The data obtained from the 2 groups were analyzed using the independent samples t-test, paired samples t-test, and Fisher’s exact test. The relationship between endothelial cell loss and cataract surgery time was evaluated with the Pearson correlation test. A value of p<0.05 was considered statistically significant.

Results

The clinical characteristics of the study subjects are provided in Table 1. The mean age of the patients was 65.5±8.5 years in Group 1 and 66.9±11.4 years in Group 2. There were no significant differences in various preoperative parameters between Group 1 and Group 2 (Table 1).

The mean preoperative BCVA was 0.89±0.13 logMAR in Group 1 and 0.90±0.25 logMAR in Group 2 (p=0.53). At 1 month postoperatively, the mean BCVA was 0.01±0.3 logMAR in Group 1 and 0.01±0.3 logMAR in Group 2 (p=0.60). A postoperative -0.50 diopter (D) myopic refraction was the target. The mean postoperative spherical equivalent was -0.59±0.43 D in Group 1 and -0.57±0.36 D in Group 2 at 1 month. No statistically significant differences were determined between the groups in terms of mean postoperative spherical equivalent (p=0.18).

The phaco parameters of both groups were similar and are shown in Table 2.

In Group 1, the mean IOP was 14.2±2.3 mmHg preop-

| Table 1. The preoperative characteristics of the patients |
|---------------------------------------------------------|
| Group 1 | Group 2 | p   |
| BSS-assisted IOL implantation | OVD-assisted IOL implantation |
| Mean age, years (mean±SD) | 67.5±7.8 | 67.8±9.4 | 0.17‡ |
| Gender (F/M) | 13/8 | 12/7 | 0.73† |
| BCVA (logMAR) (mean±SD) | 0.89±0.13 | 0.90±0.25 | 0.53‡ |
| IOP, mmHg | 14.2±2.3 | 14.1±2.9 | 0.26 |
| ACD | 3.21±0.3 | 3.18±0.2 | 0.35‡ |
| Cataract density* | 2.84±1.2 | 2.78±1.6 | 0.62‡ |
| ECD, cc/mm² | 2535.1±182.4 | 2548.7±342.2 | 0.74‡ |

ACD: anterior chamber depth; BCVA: best corrected visual acuity; BSS: balanced salt solution; ECD: endothelial cell density; F: female; IOL: intraocular lens; IOP: intraocular pressure; LogMAR: logarithm of the minimum angle of resolution; M: male; OVD: ophthalmic viscosurgical device; * according to the Lens Opacities Classification System III.

| Table 2. The peroperative phaco parameters of the patients |
|---------------------------------------------------------|
| Group 1 | Group 2 | p   |
| BSS-assisted IOL implantation | OVD-assisted IOL implantation |
| Surgical Time (min) | 12.3±2.1 | 14.6±3.1 | 0.035† |
| Mean EPT (s) | 4.38±3.98 | 4.25±3.01 | 0.65 |
| Total USG time (s) | 27.9±11.5 | 27.3±12.9 | 0.59 |
| Mean fluid used (mL) | 101.3±29.3 | 93.4±31.7 | 0.03‡ |

BSS: balanced salt solution; EPT: effective phaco time; IOL: intraocular lens; OVD: ophthalmic viscosurgical device; USG: ultrasonography; † Independent samples t-test comparison of Group 1 and Group 2.
eratively, 14.7±3.1 mmHg on postoperative day 1, 13.2±1.5 mmHg at week 1, and 13.8±2.7 mmHg at 1 month. In Group 2, these values were 14.1±2.9 mmHg, 19.1±3.4 mmHg, 13.8±3.1 mmHg, and 13.2±2.9 mmHg, respectively. The IOP increase was significantly greater on the first day in the viscoelastic-assisted IOL implantation group (p=0.007) (Table 3). The surgical time was 12.3±2.1 minutes in the BSS-assisted group and 14.6±3.1 minutes in the viscoelastic-assisted group (p=0.035). The degree of corneal endothelial change was not statistically significant between groups at 3 months (p=0.88) (Table 4). Endothelial cell loss was significantly associated with surgical time in both groups (Group 1: r= 0.91, p=0.029; Group 2: r=0.92, p=0.030).

**Discussion**

OVDs provide many surgical benefits in modern cataract surgery. However, in addition to surgical benefits, such as maintaining anterior chamber stability during capsulorhexis, enlarging pupil size in small pupils, and stabilizing the iris in floppy iris syndrome, decreasing posterior capsule rupture risk, and facilitating IOL implantation (14), postoperative problems associated with OVDs have recently begun to be discussed and there is increased interest in solving these problems among cataract surgeons.

One of the controversial issues is the protection of corneal endothelium cells (CECs). It has been well documented that OVDs protect CECs from contact with intraocular structures, the IOL, and instruments (14, 15). Another beneficial effect of OVDs is the suppression of free radicals during phacoemulsification (16). Furthermore, OVDs may reduce wrinkling of the cornea and mechanical stress on the CECs during implantation of the IOL with injector system (13). In contrast, it has been reported that OVDs increased thermal damage, causing CEC loss (7), for which the possible explanation is that if there is no flow of fluid around the phaco tip as a result of the viscoelastic substance, the phaco tip temperature may increase and burn the cornea, damaging CECs (14). Moreover, prolonged I/A to completely remove the injected viscoelastic for IOL implantation increases the operation time and fluid flow, and thus might affect CEC

| Table 3. Intraocular pressure change in the patients |
|-----------------------------------|
| **Group 1** | **Group 2** | **p** |
| BSS-assisted IOL implantation | OVD-assisted IOL implantation |  |
| Preoperative IOP | 14.2±2.3 | 14.1±2.9 | 0.68 |
| Postoperative IOP | 17.3±3.5 | 17.1±2.5 | 0.72 |
| Postoperative IOP - 1 day | 14.7±3.1 | 19.1±3.4 | 0.007* |
| p | 0.72 | 0.005** |
| Postoperative IOP - 1 week | 13.2±1.5 | 13.8±3.1 | 0.35 |
| p | 0.19 | 0.23 |
| Postoperative IOP - 1 month | 13.8±2.7 | 13.2±2.9 | 0.25 |
| p | 0.13 | 0.14 |

| BSS: balanced salt solution; IOL: intraocular lens; IOP: intraocular pressure; OVD: ophthalmic viscosurgical device; † Independent samples t-test comparison of Group 1 and Group 2; § Paired samples t-test, comparison of IOP changes within groups; ¶ IOP was measured with a tonopen immediately following surgery; **The difference in postoperative IOP increase between groups was significant on day 1; *** The IOP increase was significant in Group 2 on day 1. |

| Table 4. Endothelial cell density change after cataract surgery |
|-----------------------------------|
| **Group 1** | **Group 2** | **p** |
| Preoperative ECD cc/mm² | 2535.1±182.4 | 2548.7±342.2 | 0.74 |
| Postoperative ECD - 3 months | 2302.9±179.4 | 2334.2±401.3 | 0.76 |
| Reduction of ECD (%) | 8.9 | 8.4 | 0.88 |
| p | 0.007 | 0.0001 |

| ECD: Endothelial cell density; † Independent samples t-test, comparison of Group 1 and Group 2; § Paired samples t-test, comparison of preoperative and postoperative ECD. |
characteristics (13, 14). Furthermore, OVD remaining in the eye may induce IOP spikes and inflammation immediately after cataract surgery, which may cause further CEC damage (7, 17). In light of this information, the present study compared changes in CECs using BSS-assisted IOL implantation with the standard method using OVDs during IOL implantation. The results demonstrated that at the end of the third month, the endothelial loss was 8.9% in Group 1 and 8.4% in Group 2. The loss of CECs was comparable with the findings of other studies. Studeny et al. (12) identified CEC loss of 9.76% and 10.7% in a hydro-implantation group and 9.07% and 9.13% in an OVD group at 1 month and 3 months, respectively, after the procedure. Nayak and Jain (11) and Schulze et al. (13) also reported similar results with no significant differences between groups in terms of CEC loss after surgery.

Another concern about using OVDs is increased IOP after cataract surgery. Reports have indicated that OVDs remaining in the eye may cause mechanical obstruction of the trabecular meshwork that may be responsible for early postoperative IOP spikes, particularly within the first 24 hours (18). In the current study, a significantly higher IOP and IOP increase was observed in the OVD group on day 1, although there were no differences between the groups at 1 week and 1 month. The findings of both Lee et al. (4) and Schulze et al. (13) confirmed the results of the present study and demonstrated high IOP levels and spikes within the first 24 hours in the OVD group. In contrast, Studeny et al. (12) indicated that the implantation technique did not influence postoperative IOP changes, and IOP spikes were observed in only 3 patients. Several studies have compared the effects of different types of OVDs on postoperative IOP and have stated that dispersive OVDs are most likely associated with postoperative higher IOP (19, 20). Nayak et al. (11), Studeny et al. (12) and Lee et al. (4) used cohesive viscoelastics (sodium hyaluronate), as in the current study, whereas Schulze et al. (13) used dispersive viscoelastics (hydroxypropyl methylcellulose), and with the exception of Studeny et al. (12), these authors observed an IOP increase postoperatively.

Another possible postoperative problem associated with OVDs is an early form of capsular block syndrome if any of the viscoelastic remains behind the IOL. This has been associated with a distended bag causing anterior formation of the IOL and a myopic shift (21). In the present study, no instances of capsular block syndrome or myopic shift were observed in either group.

The additional surgical time as well as additional I/A time increase intraocular manipulation and fluid flow, which may have an effect on CECs (13). Although the postoperative differences in CECs were similar in both groups of the present study, the surgical time was significantly shorter in the BSS group. Another possible advantage of shorter surgical time is that the possibility of performing a greater number of operations can lead to more cost-effective use of the operating room. Montgomery et al. (22) estimated the cost of operating room use in the USA to be approximately $67.50/minute. In addition, the purchase cost of BSS is less than OVDs, which may also decrease the cost of surgery.

The main limitation of this study is the small sample size and short length of follow-up. Another limitation is the nature of the study; prospective, randomized, double-blind, bilateral comparison studies would provide more valuable information. Complicated cataracts, such as those with a small pupil, shallow anterior chamber, or cases of pseudoexfoliation, were not included our study.

In conclusion, IOL implantation using BSS in phacoemulsification surgery is a reliable technique, and this method provides a significantly shorter surgery time and a smaller increase in IOP in the early postoperative period. The smaller increase in IOP after cataract surgery might be useful for glaucoma patients. Therefore, IOL implantation without the use of an OVD can be recommended in appropriate patients in order to avoid the side effects of devices and to use the operating room more effectively and reduce the cost of surgery.

Disclosures
Ethics Committee Approval: Istanbul Training and Research Hospital, August 31, 2018, no: 1406.
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Authorship Contributions: Involved in design and conduct of the study (EY, BO, MOC); preparation and review of the study (EY, BO, MOC); data collection (EY, BO, MOC); and statistical analysis (EY, BO, MOC).

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