Intraoperative Evaluation of Phacoemulsification Cataract Surgery with and without the Use of Ophthalmic Viscosurgical Devices

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Abstract:

PURPOSE: The purpose of this study was to compare the efficacy and safety of cataract surgery by the phacoemulsification technique with and without the use of ophthalmic viscosurgical devices (OVDs).

SETTING: This study was conducted at a tertiary eye care center in a rural area of Central India.

DESIGN: This was a prospective, randomized, observational study.

METHODS: In this study, 220 patients underwent phacoemulsification for cataract surgery with OVDs (OVD group) or without OVDs (BSS group) \( n = 110 \) in each group. Patients with operable, nuclear Grade 2–4 cataracts were included in the study. The study was conducted from June 2017 to September 2018. The frequency of intraoperative complications, surgical time, and ease of the surgical procedure (easy, difficult, or very difficult) were recorded.

RESULTS: There was no statistically significant difference in the nuclear opalescence, axial length, and intraocular lens (IOL) power between the two groups. Capsulorhexis extension was seen in two eyes in the OVD group and none of the eyes in the BSS group. The problems that occurred during IOL implantation included flip (OVD group, 2; BSS group, 1), haptic breakage (OVD group, 1; BSS group, 1), sulcus implantation (OVD group, 0; BSS group, 2), and stuck haptic (OVD group, 1; BSS group, 3). The total surgical time was almost equal in the two groups (OVD group, 9.2 min ± 3; BSS group, 9.5 min ± 3.5; \( P = 0.521 \)). None of the patients had iris trauma or posterior capsular rupture.

CONCLUSIONS: OVD-less phacoemulsification surgery is a safe and effective technique for treating age-related cataracts that requires no additional instrumentation and saves the cost of the OVD.

Keywords: Ophthalmic viscosurgical device, phacoemulsification, viscoless cataract surgery

Introduction

Phacoemulsification has become the technique of choice for cataract extraction. With the introduction of ophthalmic viscosurgical devices (OVDs) in the market, the safety of cataract surgery has improved. The main function of a viscoelastic is to protect the corneal endothelium and maintain the stability of the anterior chamber throughout the surgical procedure. OVDs have been used in various ophthalmic surgical procedures, such as viscoanalostomy, post trabeculectomy shallow anterior chamber,[1] mechanical stretching of the pupil (viscomydriasis),[2] posterior capsular rupture to tamponade the defect in the posterior capsule, retrieval of a partially dislocated nucleus after posterior capsular rupture,[3] and anterior capsular staining with dyes.[4]

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However, removal of the OVD is mandatory after the completion of phacoemulsification; leaving the OVD or parts of it behind in the anterior chamber can cause increased intraocular pressure, capsular block syndrome, and toxic anterior segment syndrome.\[5,6\] Retained OVD behind the intraocular lens (IOL) after phacoemulsification in patients with implanted toric IOL can cause rotation of the IOL and misalignment of the predetermined axis of placement of the IOL. To solve these problems, Tak described a hydroimplantation technique for the insertion of posterior chamber IOLs without the use of OVD.\[7\] Chen et al. also compared two techniques for toric IOL implantation: one with hydroimplantation and the other with OVDs.\[8\] Various studies have reported the safety of hydroimplantation of IOL.\[9‑11\] Kugu et al. studied the safety and efficacy of using OVDs versus balanced salt solution (BSS) during capsulorrhesis and IOL implantation and concluded that using OVDs improved the safety and efficacy of phacoemulsification.\[12\]

Taskin and Aslan studied postoperative outcome of cataract surgery with and without OVDs and have found that there was no difference in final clinical outcomes between two groups.\[13\] However, there have been no intraoperative comparative evaluations of the phacoemulsification procedure with and without an OVD.

The present case series examines the safety and efficacy of the phacoemulsification technique with and without an OVD in a prospective and randomized manner.

### Materials and Methods

**Sample size**

To find a 25% difference (control group, 35%, and rotation group, 10%) with 80% power, a significance level of 5%, and 10% loss to follow-up, the necessary sample size in each group was determined to be 55 eyes.

**Patient selection and study design**

The present study adhered to the tenets of the Declaration of Helsinki. The medical ethics committee of the hospital approved the study. Informed consent was also obtained from all the participants.

This prospective, comparative, and randomized case series included patients with senile cataracts who were scheduled for phacoemulsification and hydrophilic IOL implantation from June 2017 to September 2018. The study’s exclusion criteria were glaucoma, pseudoexfoliation, uveitis, previous intraocular surgeries, subluxated cataracts, trauma, monocular vision, corneal degeneration, and poor pupillary dilation. The preoperative assessment included best-corrected visual acuity, slit-lamp examination, intraocular pressure by a handheld tonometer (Perkins, Haag-Streit United Kingdom Limited, UK), retinal evaluation, A-scan biometry (Axis-II PR Biometer, Quantel Medical, France) for axial length measurement, and IOL power calculation. The degree of lens opacity was graded by means of the Lens Opacities Classification System III.

The simple randomization by toss method was followed for the assignment of patients to groups. Heads were assigned to the intervention group (BSS group) and tails to the control group (OVD group).

### Surgical technique

1. For the OVD group, a single surgeon performed all the surgeries. Patients were operated under 0.5% topical proparacaine hydrochloride eye drops that were instilled twice every 10 min before the surgical procedure. A 20G side-port incision was created on the appropriate side as required. Viscoelastic (2% hydroxypropyl methylcellulose, Appavisc, Appasamy Ocular Devices, Puducherry, India) was injected through the side port with a 23G blunt-tip cannula. A 2.8-mm clear corneal temporal incision was performed. Continuous curvilinear capsulorrhesis (CCC) was completed using Utrata forceps under viscoelastic conditions. Hydrodissection was performed with BSS. In patients with posterior polar cataracts, hydrodelineation was done. The nucleus was managed by the direct chop method. The settings for the nucleus chop were power 90% (linear), vacuum 350 mmHg, and aspiration flow rate 34 cc/min. The parameters were the same for all the cases and were not changed until the last fragment was emulsified. Thorough cortical cleanup was accomplished by irrigation and aspiration. The anterior chamber was filled with viscoelastic. A single-piece hydrophilic IOL (Acryfold, Appasamy Ocular Devices, Puducherry, India) with a 6-mm optic diameter, dual haptics, 12.5-mm overall length, biconvex optic design, and square edge design was used. Thorough anterior chamber wash was given to clear the viscoelastic. Stromal hydration of the side port and the main incision was completed with BSS [Video 1]

2. For the BSS group, the surgical steps were similar to those of the OVD group until the creation of the side port. After the creation of the side port, a 23G irrigation cannula was introduced through the side port. Another side port was made on the opposite side. A clear corneal 2-mm temporal incision was made. Capsulorrhesis was done with the help of microrhexis forceps under irrigation. Incision was enlarged to 2.8 mm. Hydrodissection was performed. The phaco probe was introduced through the main incision with continuous irrigation. At this point, the irrigation probe was removed from the side port and the chopper was
introduced. Phacoemulsification was completed in the capsular bag with the same parameters as described above. The chopper was taken out and the irrigation probe was introduced through the side port. The phaco probe was taken out and the aspiration probe was introduced through another side port. Cortical cleanup was accomplished. While keeping the irrigation on through the side port, a foldable IOL was inserted into the capsular bag and the ports were hydrated [Video 2]. A drop of trypan blue was put over the wound to test for wound leaks. Dilution of the dye was suggestive of wound leak, and if there was a leak, a 10-0 nylon suture was taken [Video 3].

Surgical time was noted from the creation of side port to the hydration of ports from the recording of each case. After each surgery, the surgeon noted the ease of the surgical procedure (easy, difficult, or very difficult) and any complications that occurred during each case.

**Correction of intraocular lens flip**

To correct IOL flip, the anterior chamber was deepened with an OVD. A 23G cannula was passed through the side port and placed at the backside of the optic and the Sinskey hook through the main incision and placed at the edge of the optic. To correct the flip, the Sinskey hook was raised toward the cornea and the 23G cannula was pushed posteriorly.

**Broken haptic management**

The incision was enlarged to 3 mm. A broken haptic was exteriorized and grasped with lens-holding forceps. With the help of Vannas scissors, the optic was cut to 3 mm from the edge, the IOL was swiveled out, and a new IOL was implanted.

**Statistical analysis**

The data were entered into an Excel® sheet (software version 14.1.0 [110310]/2011) (Microsoft Corporation, Redmond, WA, USA), and statistical analysis was performed with SPSS version 13.0 (SPSS Inc., Chicago, IL, USA). The Chi-squared test and *t*-test were used for categorical and continuous variables, respectively. The values are expressed as mean ± standard deviation and percentage where appropriate. *P* < 0.05 was considered statistically significant.

**Results**

A total of 110 eyes were included in the study (the OVD group had 26 males and 29 females; the BSS group 29 males and 26 females).

The mean age of the participants, at the time of surgery, in the OVD group was 66.46 ± 10.12, whereas in the BSS group, it was 67.68 ± 11.22 (*P* = 0.243). There was no statistically significant difference in the nuclear opalescence, axial length, or IOL power between the two groups. The demographic data of all the participants are presented in Table 1.

The intraoperative characteristics of the surgical steps in the studied groups are depicted in Table 2. Capsulorhexis extension was seen in two eyes in the OVD group and none of the eyes in the BSS group. The hydroprocedure, nucleus chopping, and cortical aspiration were uneventful in both the groups. Shallowing of the anterior chamber was noted in two patients in the OVD group and four patients in the BSS group.

Two patients (OVD group) had anterior-posterior tilt of the IOL and one patient (BSS group) had total posterior

| Table 1: Demographic data in each study group |
| Parameters | OVD group | BSS group | *P* |
|-----------|-----------|-----------|-----|
| Age±SD    | 66.46±10.12 | 67.68±11.22 | 0.243 |
| Gender (male/female) | 26/29 | 29/26 | 0.324 |
| N02/NO3/NO4 | 16/17/22 | 17/18/20 | 0.543 |
| Axial length (mm) | 22.55±1 | 22.99±0.88 | 0.452 |
| IOL power | 23.5±0.56 | 24.10±0.45 | 0.243 |

OVD: Ophthalmic viscosurgical device, BSS: Balanced salt solution, SD: Standard deviation, IOL: Intraocular lens, NO: Nucleus opalescence

| Table 2: Intraoperative characteristics of surgical steps in study groups |
| Surgical steps | OVD group | BSS group | *P* |
|----------------|-----------|-----------|-----|
| Capsulorhexis (%) | Extension - 2 | Extension - 0 | 0.342 |
| Hydroprocedure | No complications | No complications | - |
| Nucleus chop | No complications | No complications | - |
| Cortical aspiration | No difficulties | No difficulties | - |
| Surge (%) | 2 | 4 | 0.683 |
| IOL implantation | Flipped IOL | 2 | 1 | 0.834 |
| Haptic breakage | 1 | 1 | |
| Sulcus implantation | 0 | 2 | |
| Stuck haptic | 1 | 3 | |
| Wound leak (%) | 1 | 1 | - |
| Ease of surgical procedure | Easy (%) | 54 (98.2) | 53 (96.4) | 0.653 |
| Difficult | 1 | 2 | |
| Very difficult | - | - | |
| Conversion to other procedures | Nil | Converted to OVD - 4 | - |
| Surgical time (min) ± SD | 9.2±3 | 9.5±3.5 | 0.521 |

OVD: Ophthalmic viscosurgical device, BSS: Balanced salt solution, SD: Standard deviation, IOL: Intraocular lens
rotation of the IOL, wherein the posterior surface of the IOL faced anteriorly. The position of the IOL was corrected subsequently, and all patients had uneventful delivery of the leading and trailing haptic in the bag.

The surgical procedure was difficult in one patient in the OVD group and two patients in the BSS group. Four patients in the BSS group required conversion to the OVD group (1 flip of IOL, 1 haptic break, and 2 sulcus implantations). In each group, one patient had a wound leak, which was sutured with 10-0 nylon.

The total surgical time was almost equal in the two groups (OVD group, 9.2 min ± 3; BSS group, 9.5 min ± 3.5; P = 0.521).

None of the patients had iris trauma or posterior capsular rupture during the implantation and manipulation of the IOL. Fixation of the globe was also not a problem in the two groups.

Discussion

Protection of the corneal endothelium during cataract surgery is of prime importance for the long-term preservation of visual acuity. Since the inception of OVDs, the safety of cataract surgery has increased; however, with the many benefits of OVDs come certain disadvantages. To eliminate the problems related to OVDs, numerous devices have been recommended. These include the anterior chamber maintainer (ACM),[14] trocar,[15] irrigation cannula of the irrigation and aspiration probe,[7] and Simcoe cannula.[16] Most of the studies associated with the use of an ACM focus on the implantation of the IOL. There is a sparse literature on the intraoperative analysis of the complete OVD, with and without the use of OVDs, in the phacoemulsification of age-related cataracts.

Cataract surgery is currently performed by the phacoemulsification technique under topical anesthesia.[17] However, the stability of the globe and the cooperation of the patient throughout the procedure are crucial. The procedure described in this study was carried out under topical anesthesia in both the groups. The stability of the globe was achieved using a 23G cortex-aspirating cannula with a blunt tip in the OVD group and an irrigation probe (20G) in the BSS group.

CCC was performed with the help of Utrata forceps in the OVD and microrhexis forceps in the BSS group. Extension of the CCC occurred in two eyes in the OVD group. In general, the OVD maintains the configuration and the depth of the anterior chamber but not its physiological pressure. In contrast, continuous irrigation of BSS creates high intraocular pressure, which pushes the lens and iris diaphragm backward, reducing the tension over the anterior capsule and thereby preventing the capsular tear from extending to the periphery. Making a small cut to the other side of the anterior capsule and then completing the capsulotomy managed the extended CCC. Fluctuations in the anterior chamber can lead to extension of the CCC to the posterior capsule.[18] Continuous irrigation of fluid during CCC prevented extension to the posterior capsule. No complications occurred during nucleus management and cortical aspiration in these cases. Blumenthal et al. have shown that continuous irrigation of BSS during CCC helps the surgeon to identify the cut edge of the anterior capsule in the absence of red glow in eyes with dense cataracts.[19]

No difficulties were encountered during the hydropreparatory, nucleus chopping, and cortical aspiration. In patients with posterior polar cataracts, hydrodelineation was performed through the main incision. In the BSS group, the bottle height was lowered during hydrodelineation to prevent the sudden blowing up of the posterior capsule.

The quick-chop technique was performed in all cases. The parameters were in the linear mode and were not changed until the last nuclear fragment was emulsified. Soft, nuclear Grade 2 cataracts were emulsified with aspiration. Ultrasonic power was used to break the occlusion.

Surge was experienced in four cases in the BSS group and two cases in the OVD group. In the BSS group, surge occurred momentarily during the removal of the irrigation probe and the placement of the chopper through the side port and during removal of the chopper. In the OVD group, surge occurred during the emulsification of the last fragment due to a sudden occlusion break; however, none of the patients had posterior capsular rent or fragment drop. Sharma and Agarwal et al. advocated the use of ACMs during phacoemulsification. ACM use may help to compensate for the loss of fluid during surge and the placement of the IOL.[14,15] A fourth port may be needed for the aspiration of the subincisional cortex; in our case series, three ports were sufficient.

Instead of using irrigation probe throughout the procedure, irrigation chopper is another modality for the irrigation as well as chopping of the nucleus.[20] However, it is bulky and has sharp edge. For Grade 2 cataract, it may not useful. The occurrence of the surge may cause posterior capsular rent. Therefore, we used irrigation probe and chopper may be selected depending on the grade of cataract.

ACMs have been in use for the implantation of the IOL for many years.[7‑10,16,21] Tak studied the implantation of a
foldable IOL under BSS. The intraoperative advantages of this technique include reduced surgical time, increased efficiency, no need to remove the OVD from behind the IOL, and no need for additional instrumentation.\[^7\] We also experienced similar advantages when using the hydroimplantation technique in our study. However, we experienced a few problems during implantation of the IOL. These difficulties may not be attributable to the hydro- or viscoimplantation. These include flip, haptic damage, struck haptic, and sulcus implantation of the IOL.

IOL flip occurred in two eyes in the OVD group and one eye in the BSS group and was recognized after the optic of the IOL became unfolded in the anterior chamber. To correct the flip in the BSS group, the anterior chamber was filled with an OVD. The frequency of flip in various studies ranged from 1% to 1.3%.\[^12,23\]\[^23\] The present study dealt with hydrophilic IOL with dual haptics; the procedure may not be different if it occurs with a hydrophobic or multipiece IOL.

Broken haptic was seen in one eye in each group. A new IOL was implanted in place.

Stuck trailing haptic was seen in one eye in the OVD group and three eyes in the BSS group. The type of procedure may not have anything to do with the occurrence of stuck trailing haptic but instead may be due to an IOL injector cartridge problem.

Sulcus implantation of the IOL was seen in two patients in the BSS group and none of the patients in the OVD group; sulcus implantation could be due to BSS pushing the IOL up and preventing its haptic from going inside the capsular bag. The OVD was used to deepen the chamber and the IOL was manipulated inside the bag with the help of a Sinskey hook.

Overall, there was no significant difference in the ease of the surgical procedure between the two groups. Four cases in the BSS group required the use of OVDs due to minor problems associated with the IOL implantation (1 flip of IOL, 1 haptic break, and 2 sulcus implantations). There was no significant difference in the total surgical time between the two groups.

The drawback of the study was that very hard cataracts were not included in the study. Only one type of OVD (2% hydroxypropyl methylcellulose) was used in this study. Therefore, extrapolation of the data to other types of OVDs is not possible.

An expert assistant was required who could switch over the irrigation line and the phaco probe during the surgical procedure. An IOL needed to be folded before the start of the surgical procedure in the BSS group. A single surgeon was involved in the study, which omits any comparison of skills in the surgical technique. We recommend a comparative evaluation of the studied parameters between two or more surgeons.

The BSS technique for cataract surgery by phacoemulsification is safe, useful, and effective in the management of age-related cataracts. No additional instrumentation is needed to perform the procedure and saves the costs of using OVDs.

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**Conflicts of interest**

There are no conflicts of interest.

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