



Phacoemulsification Cataract Surgery without Ophthalmic Viscoelastic Devices: A Randomized Controlled Trial

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Abstract

Background: Phacoemulsification is a widely used method for cataract removal. The use of ophthalmic viscosurgical devices (OVDs) in this procedure is common, but their necessity and cost-effectiveness are questioned. This study aimed to determine the outcomes of phacoemulsification cataract surgery with and without OVDs. **Methods:** This prospective, randomized trial included 90 eyes, divided into two equal groups (n = 45 each). Group A underwent cataract surgery with OVDs, while Group B underwent surgery without OVDs. The study was conducted between December 2022 and December 2023 in Iraq. Intraoperative adverse effects, surgical duration, and surgical difficulty were recorded. **Results:** No significant differences were found between the groups in terms of age, axial length, IOL power, pre-operative and postoperative intraocular pressure (IOP), and central corneal thickness (CCT). The mean surgery time was 9.12±8.85 minutes for Group A and 10.80±1.35 minutes for Group B (p=0.791). Surgical difficulty was reported in 17.8% of Group A and 8.89% of Group B. Implantation problems were similar between groups,

including wound leaks, flipped IOLs, haptic breakages, and sulcus implantations. **Conclusions:** Phacoemulsification cataract surgery without OVDs yielded comparable outcomes to surgery with OVDs. This approach may reduce costs and eliminate the risk of increased IOP associated with OVD use.

Keywords: Phacoemulsification, Ophthalmic Viscoelastic Device (OVD), Cataract Surgery, Intraocular Pressure, Surgical Outcomes

1. Introduction

Since its introduction by Charles Kelman in the 1960s, phacoemulsification had remained the most popular surgical procedure for cataract elimination (Kelman, 1967). When contrasted to other methods of cataract removal, phacoemulsification had been linked with faster visual recovery, and patients are able to get back to their usual activities throughout a few days following surgery. Several advances in surgical instrumentation and fluidics for phacoemulsification had resulted in less aggressive and more secure cataract elimination (Dasgupta and Mehra, 2018; Hida et al., 2019; Regina Chandra et al., 2019). Several ophthalmic viscosurgical devices (OVDs) were employed for assisting cataract surgery around the world (Juma., 2023). The benefits of viscoelastic throughout cataract surgery are widely recognized, and phacoemulsification and the implantation of intraocular lens (IOL) without viscoelastic are not routinely carried out in clinical settings (Kuzman et al., 2023; Al-dolaimy et al., 2023; Zaman et al., 2023; Gupta et al., 2023; Hjazzi et al., 2023). However, intraocular pressure spikes, toxic anterior segment syndrome, and

Significance | This study showed phacoemulsification outcomes with/without OVDs, demonstrating cost-effectiveness and safety without increased intraocular pressure.

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capsular bag distension syndrome are all frequently credited on OVDs (Bardoloi et al., 2020; Kashif, 2019).

A previous investigation had revealed that phacoemulsification operation without an OVD took a shorter amount of time and resulted in no major reduction of endothelial cell density (ECD) (Dulger.,2022). Surgeons who feel worried regarding an increased intraocular pressure (IOP) after cataract surgery ought to use the OVD-free technique (Akmaz et al., 2023; Al-Safi and Qasim, 2023; Khursheed et al.,2023; Mansouri ., 2023; Jitendra, et al; Lavanya.,2024).

The purpose of this study was to compare outcomes of phacoemulsification cataract surgery using or without an ophthalmic viscoelastic device.

2. Materials and methods

The current study was a prospective, randomized controlled trial involved 90 cataract-affected eyes (Nizam, M et al.,2023). Participants were assessed after surgery.

2.1 Ethical considerations

To protect the patients' confidentiality, every participant's names were obscured and supplanted with code numbers. Prior to the research was conducted, each participant provided informed consent.

This study included patients with clinically significant cataract with a medium density as determined by the new soft ware Pentacam Nuclear grading System (PNS).(N1-N2). Patients were excluded if they had subluxated cataracts, corneal degeneration, trauma, glaucoma, pseudoexfoliation, uveitis, and prior intraocular operations.

The current study was conducted in the period from December 2022 and December 2023 at Iraq (...) hospital. Patients were divided into two equal groups; group (A) had cataract surgery with OVDs (OVD group) (n=45) using Hydroxy-propyl-methylcellulose 2% implantation. And group (B) had cataract surgery without OVDs (BSS group) (n=45); one-piece acrylic intraocular lens implantation was carried out using normal saline solution (0.9% solution) irrigation.

All participants in the study were subjected to detailed clinical and ophthalmologic investigations. The preoperative examinations included best-corrected visual acuity, IOP assessment by Goldmann applanation tonometer (GAT, Haag-Streit AT 900; Haag-Streit AC, Koeniz, Switzerland), biomicroscopy using slit lamp (Nidek Co., Aichi, Japan), the Lens Opacities Classification System III was used for assessing the level of lens opacification. The central corneal thickness (CCT) measurements had been done twice before and after surgery with noncontact oculus pentacam (Ophthalmicmart Co., Singapore). Time of surgery was recorded. Patients were assessed after surgery. Every patient had an ordinary eye assessment, which included primarily visual acuity, intraocular

pressure, and CCT. The level of difficulty of the surgical procedure as well as any side effects that took place was also recorded.

2.2. Statistical analyses

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard deviation.

3. Results

A total of 90 eyes were included in the research, with 45 (50.0%) undergoing cataract surgery with OVDs (Group A) and 45 (50.0%) undergoing had cataract surgery without OVDs (Group B). Group (A) had a mean age of (55.3±9.4) years, with 23 (51.11%) males. In Group (B), the mean age was (56.2±7.6) years, with 15 (33.33%) males (Figure 1 and Table 1). There was no statistically significant between the two groups regarding age of participants, axial length and IOL power.

Before surgery, there was no statistically significant difference among the two groups regarding the central corneal thickness (P = 0.209), following surgery there was also none statistically significant difference among the two groups (P = 0.128). Table 2

Before surgery, the mean IOP in group (A) was (17.33 ±8.14) mmHg and (18.31 ±7.4) mmHg in group (B). Following surgery; the mean IOP in group (A) was (16.08 ±11.66) and (16.56 ±12.19) in group (B). There was none statistically significant difference (p = 0.709; p=0.702) between both groups regarding preoperative and postoperative IOP. Table (3)

The mean time of surgery in group (A) was (9.12±8.85) minutes and (10.80±1.35) in group (B) (p=0.791). The surgical procedure was difficult in 8 patients (17.8%) in group (A) and 4 patients (8.89%) in group (B). The implantation problems involved wound leak (two patients in each group), flipped IOL (three patients in group A and one patient in group B), haptic breakage (one patient in group A and two patients in group B) and sulcus implantation (two patients in group A and three patients in group B). Capsulorhexis extension was documented in two eyes in group (A) and not any of the eyes in group B. (p=0.344). Table (4); Figures (2, 3)

4. Discussion

Results of the present study showed that group A or OVD group had a mean age of (55.3±9.4) years, with 23 (51.11%) males. The average age in group B without OVD was (56.2±7.6) years, with 30 (66.67%) males. Mohamed et al., (2021) found that; the mean age of all participants was (58.1 ± 6.46) years; (52.5%) of patients were females; whereas (47.5%) were males. In another study conducted by Joshi and Naik, (2020) the mean age of patients in the OVD group was 66.46 ± 10.12, while in the balanced salt solution (BSS)group, the mean age was 67.68 ± 11.22 (p = 0.243).

The current study results showed none statistically significant between the two studied groups regarding axial length (p = 0.269)

Table 1. Comparison between Group (A) and Group (B) regarding demographic data

	Group (A) (n=45)	Group (B) (n=45)	P-value
Age(years) ± SD	55.3±9.4	56.2±7.6	0.214 (NS)
Gender			
Male	23 (51.11 %)	30 (66.67 %)	
Female	22 (48.89 %)	15 (33.33 %)	
Axial length (mm)	28.33±6.89	25.50±9.07	0.269 (NS)
IOL power	25.5±2.08	25.14±1.92	0.635 (NS)

NS: none significant SD: Standard deviation

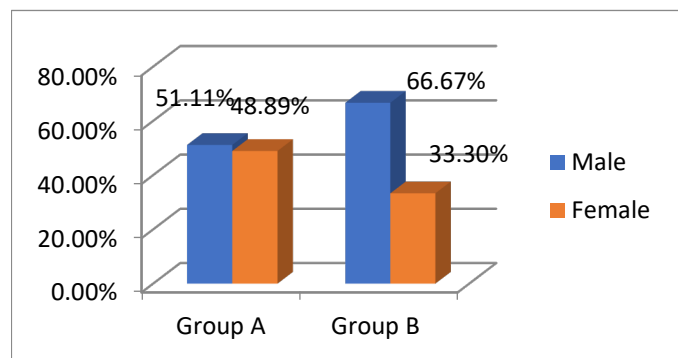


Figure 1. Gender distribution in the study groups

Table 2. Comparison between Group (A) and Group (B) regarding central corneal thickness (CCT) (µm)

(CCT) (µm)	Group (A)	Group (B)	P-value
Pre-operative	584.25 ±52.05	573.70 ±17.2	0.209 (NS)
Post-operative	393.90 ±53.37	570.50 ±40.38	0.128 (NS)

Table 3. Comparison between Group (A) and Group (B) regarding intraocular pressure (IOP) (mmHg)

(IOP) (mmHg)	Group (A)	Group (B)	P-value
Pre-operative	17.33 ±8.14	18.31 ±7.4	0.709 (NS)
Post-operative	16.08 ±11.66	16.56 ±12.19	0.702 (NS)

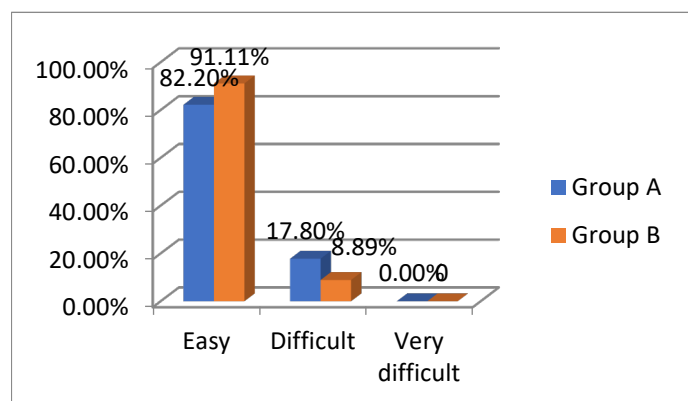


Table 4. Comparison between Group (A) and Group (B) regarding surgical outcomes

	Group (A)	Group (B)	P-value
Time of surgery (minutes) ± SD	9.12±8.85	10.80±1.35	0.791(NS)
Surgical procedure difficulty			
Easy	37(82.2%)	41(91.11%)	1.00(NS)
Difficult	8(17.8%)	4(8.89%)	
Very difficult	0	0	
Implantation problems of intraocular lens			
Wound leak			0.935 (NS)
Flipped intraocular lens	2 (4.44%)	2 (4.44%)	
Haptic breakage	3 (6.66%)	1 (2.22%)	
Sulcus implantation	1 (2.22%)	2 (4.44%)	
	2 (4.44%)	3 (6.66%)	
Capsulorhexis extension (%)	2 (4.44%)	0	0.344 (NS)

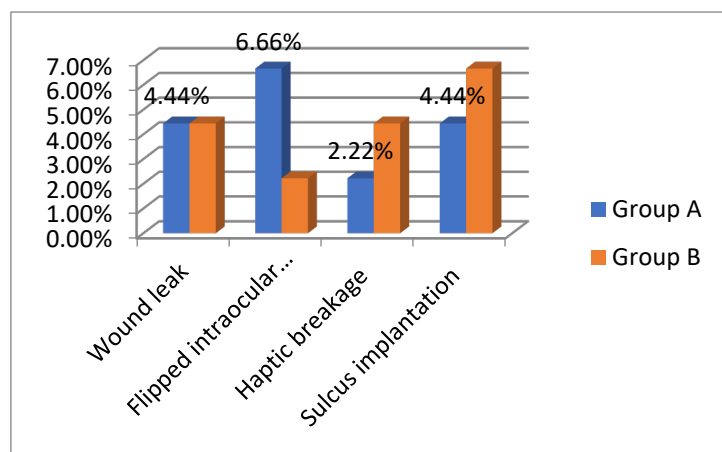


Figure 3. Implantation problems of intraocular lens

and IOL power ($p = 0.635$). Similarly, Joshi and Naik, (2020) found none statistically significant difference in axial length ($p = 0.452$) and IOL power ($p = 0.443$) between OVD and BSS group.

In our study, the comparison among the two groups showed none statistically significant differences in pre-operative IOP and CCT. ($p = 0.209$; $p=0.709$), also there were none statistically significant difference ($p = 0.128$; $p=0.702$) between both groups regarding postoperative IOP and CCT. These results agreed with Mohamed et al., (2021). According to Taşkın and Aslan (2018), the mean preoperative IOP in patients undergoing phacoemulsification surgery with versus without OVDs was 15.7 ± 3.5 and 15.3 ± 4.2 mmHg, respectively. The differences in the groups' mean before surgery IOP and CCT evaluations were not statistically significant. Also, Özcürü and Çevik, (2018) did not find significant difference in preoperative and postoperative IOP or CCT among the hydroimplantation and viscoimplantation groups.

Recently, Akmaz et al., (2023) found that IOP had risen in the OVD group one day after surgery ($p = 0.001$), but there was no difference among the groups three months later ($p = 0.121$).

In our study, the surgical procedure was difficult in 8 patients (17.8%) in group (A) and 4 patients (8.89%) in group (B). Joshi and Naik, (2020) detected that the surgical procedure was difficult in one patient in the OVD group and two patients in the BSS group.

Results of the present study showed that the mean time of surgery in group (A) was (9.12 ± 8.85) minutes and (10.80 ± 1.35) in group (B) with no statistically significant difference ($p=0.791$). This agreed with Joshi and Naik, (2020) they found that in both groups, the overall surgical time was nearly the same; (9.2 ± 3) minutes in OVD group and (9.5 ± 3.5) minutes in BSS group; ($p= 0.521$). On the other hand, Akmaz et al., (2023) reported that operating time in the OVD group was higher than in the OVD-free group ($p=0.011$).

The implantation problems included in the present study were wound leak (2 patients in each group), flipped IOL (3 patients in group A and 1 patient in group B), haptic breakage (1 patient in group A and 2 patients in group B) and sulcus implantation (2 patients in group A and 3 patients in group B). These results are in agreement with previous findings. During IOL implantation, the following issues had taken place in Joshi and Naik, (2020) study: 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).

Results of the current study recorded the presence of capsulorhexis extension in two eyes in group (A) and did not appear in group B. ($p=0.344$). Another study done by Hengerer et al., (2015) looked at intraoperative complications throughout capsulorhexis and phacoemulsification in intumescent white cataracts using two (OVDs) techniques. They found that using two different OVDs and positioning the high-viscosity OVD centrally resulted in secure anterior lens capsule indentation and decreased the likelihood of

continuous curvilinear capsulorhexis (CCC) expansion and capsule tear during surgery (Althomali et al.,2023; Sane et al.,2023; Lafta et al.,2023; Bashar et al.,2022; Lei et al.,2022; Arif et al.,2023; Margiana et al.,2022).

5. Conclusion

Phacoemulsification cataract operation without (OVD) had similar outcomes to surgery with OVD with the advantage of decreased cost and without the risk of increased IOP or the use of additional instruments.

Further studies with larger sample and multiple centers are recommended. We advocate that the variables being investigated be compared among more than one surgical professional.

Author contributions

A.A.F. was solely responsible for the conceptualization, methodology, formal analysis, data curation, software development, validation of results, resources acquisition, funding acquisition, project administration, and supervision. A.A.F. wrote the original draft of the manuscript, reviewed, and edited the final version.

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Competing financial interests

The authors have no conflict of interest.

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