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Foldable Intra Ocular Lens Hydro Implantation Versus Visco Implantation During Phacoemulsification: Comparative Study

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Abstract

Background: Viscosurgical devices created a revolution in the progress of cataract surgery but with great advancement in cataract surgery and their corneal incisions, anterior chamber (AC) and bag stability can be achieved with other methods otherwise viscosurgical devices and the best method is hydroimplantation. Hydroimplantation can achieve the same effect as viscoimplantation with achieving approximate safety on ocular structures especially corneal endothelium and posterior capsule.

Purpose: To compare implantation of a single-piece, foldable intraocular lens (IOL) using hydroimplantation to that of a standard implantation using an ophthalmic viscoelastic device (OVD) in terms of safety, frequency of complications during implantation, influence of the method on endothelial cell density (ECD), and postoperative changes in intraocular pressure (IOP).

Methods: A prospective comparative clinical study was conducted on 120 eyes of 120 patients who underwent uneventful phacoemulsification by the same surgeon. Patients were divided into two groups after the completion of lens cortex removal. IOL implantation was performed with balanced salt solution irrigation in group H (n = 60, hydro-implantation) and with OVD in group V (n = 60, viscoimplantation). The main outcomes measured were postoperative changes in IOP, Corneal endothelium cell characteristics, time of surgery, and the frequency of complications.

Results: Time of surgery was significantly lower in group H than in group V (7.2 ± 1.1 min, 8.0 ± 1.3 min, respectively, $P < 0.001$). There was a statistically significant difference between both groups as regards; postoperative IOP after 1 day and 1 week. There was statistically significant difference regarding IOP spikes; best corrected visual acuity (BCVA) after 1 week.

Conclusions: Hydroimplantation technique is safe and effective in phacoemulsification. Furthermore, reduced time of surgery and reduced cost of OVDs are the advantages of this technique.

Keywords: Endothelial cell density, Hydroimplantation, Intraocular lens, Ophthalmic viscoelastic devices, Phacoemulsification

1. Introduction

Currently, cataract surgery is the most common surgical procedure performed in developed nations.¹ Over the past few decades, there have been significant advancements in surgical methods and the use of additive tools, among other things.² This guarantees a less stressful surgical procedure and considerably lowers the likelihood of complications.

Ophthalmic viscoelastic devices (OVDs), which pressurize the anterior chamber (AC), protect delicate ocular structures, preserve the relationships between ocular structures, create space, enhance visual perception, and provide patients with a quicker, safer procedure with a better visual recovery, are required for modern intraocular procedures.³

Though protecting intraocular structures, particularly corneal endothelium cells (CECs), during

cataract surgery is still one of the key components of OVD usage.⁴

However, if it is not entirely removed, it might potentially result in postoperative intraocular pressure (IOP) increases. During phacoemulsification, if the tip has no fluid space surrounding it, the temperature increase might result in burns on the incision. Additionally, self-sealing may be impeded if OVDs are left inside the corneal incisions.⁵ Because it takes longer to thoroughly insert and remove the injected OVD, using OVDs intraoperatively for IOL implantation extends the duration of the procedure.⁵ Aspiration times can differ according to the specific OVDs used.^{5–7} The CEC loss brought on by the aspiration trauma may also be related to an extended irrigation-aspiration period⁸ and the irrigation solution employed.⁹ These findings show that using OVDs might have negative consequences and could result in CEC loss.

Another drawback is that OVDs are significantly more expensive; as a result, some surgeons implant IOLs without OVDs.

To keep the AC open during IOL implantation, one option is to use an AC maintainer.^{10–12} In this instance, a new side port must be made in order to introduce the maintainer. Filling the AC with an irrigation cannula is another approach to keep it open during an implantation without employing an OVD. Tak was the first to describe this reasonably popular procedure, dubbed hydroimplantation.¹³

Using the left paracentesis, the irrigation cannula of the bimanual irrigation/aspiration device was inserted into the eye (right if the surgeon is left-handed). In addition to providing the eye with exceptional stability and placement, the irrigation cannula ensures enough inflation of the capsular bag and AC for the IOL implantation. A foot pedal-controlled infusion or continuous irrigation mode are both available to the surgeon for use when inserting the IOL.

This study compares the safety, frequency of implantation problems, impact of the procedure on endothelial cell density (ECD), and postoperative changes in intraocular pressure (IOP) of a single-piece, foldable intraocular lens hydroimplantation compared with a typical implantation utilizing an OVD.

2. Patients and methods

2.1. Patients

The study included 120 eyes from 120 participants who had successful phacoemulsification. Patients of both sexes between the ages of 40 and 70 who have

senile lens opacification that has been clinically seen during a slit lamp examination will be included. The degree of lens opacification was rated using the Lens Opacities Classification System III (LOCS III).

2.2. Methods

A prospective comparative clinical study was performed during the period from January 2021 to June 2022.

2.3. Patients divided into two groups

The first group (H) formed of 60 patients use saline irrigation (BSS) during IOL implantation (Hydroimplantation).

The second group (V) formed of 60 patients use an OVD during IOL implantation (Viscoimplantation).

The following tests were performed during a comprehensive eye examination on each person: Snellen chart-based best corrected visual acuity (BCVA); comprehensive Slit-lamp examination of the anterior segment (Keeler 25z); assessment of intraocular pressure using an applanation tonometer (Keeler KAT-T type); Indirect ophthalmoscopy examination of the posterior segment (Keeler- All Pupil II).

2.4. Surgical procedures

Before surgery, the eyes were dilated with phenylephrine HCl 2.5% and tropicamide 1% eye drops. One surgeon used local anesthetic to carry out all cataract operations. In order to fill the AC with viscoelastic hydroxypropyl methylcellulose (Ocucoat 2% HPMC Lifecare Biomedical, LLC), a superior incision of 2.4 mm was made in the clear cornea. To enable free rotation of the nucleus, hydrodissection and hydrodelineation were carried out following capsulorrhexis of around 5–5.5 mm. The quick-chop approach was used for phacoemulsification (INFINITI vision system; Alcon, Novartis). The soft cortex underwent irrigation and aspiration.

In group H, where a hydroimplantation was planned, balanced salt solution (BSS) irrigation was used during IOL implantation (one-piece spherical acrylic intraocular lens (Sensar AAB00, AMO)).

In group V, where the viscoimplantation was planned, an OVD (Ocucoat 2% HPMC) was injected during IOL implantation (one-piece spherical acrylic intraocular lens (Sensar AAB00, AMO)), then irrigation/aspiration was done to remove the viscoelastic material.

Using bimanual irrigation and aspiration canulas, the IOL was centered after IOL implantation

in both groups. Leaks in the wounds were examined, and the surgical incision was hydrated for sealing but no sutures were taken. A 0.5 ml containing 20 mg gentamycin and 2 mg dexamethsone phosphate were injected subconjunctivally in the lower fornix. The eye was then covered with a sterile patch.

The phacoemulsification device was utilized to quickly record intraoperative data such phacoemulsification time and energy, phacoemulsification suction time, and irrigation-aspiration suction time. The timing of the surgery and any potential problems with the implantation, notably any injury to the capsular bag or IOL, were reported.

2.5. Postoperative evaluation

The postoperative IOP was measured using Goldman application at 1 day, 1 week, and 1 month after the surgery.

Using a specular microscope, corneal ECD and corneal endothelium cell size (ECS) were automatically measured preoperatively, one week, one month, three months, and six months following surgery (Topcon SP1–P, Tokyo, Japan).

Reactions in the AC for both groups after 1 day, 1 week, and 1 month.

2.6. Exclusion criteria

We excluded any subject with any type of corneal Pathologies such as cornea guttata or corneal scars, glaucoma, high myopia, Inflammatory diseases, such as iritic or retinitis, evidence of pseudoexfoliation and history of previous intraocular surgeries. Patients who had an AC depth of less than 2.25 mm, a posterior capsule rupture, or who had their cataract extraction changed to an extracapsular cataract extraction during the surgery were excluded.

Additional intraoperative exclusion criteria include total surgical time exceeding 30 min and total phacoemulsification time exceeding 3 min.

2.7. Ethical considerations

Our study was performed following Medical Research Ethical Committee principles at Al-Azhar University as well as the Helsinki Declaration. Informed consents were obtained from patients following guarantee of data confidentiality.

2.8. Data management and statistical analysis

The χ^2 test was used to compare two groups utilizing qualitative data, and the Fisher exact test was used in its stead when the projected count in any cell was less than 5. To compare the two groups, Mann–Whitney and independent *t* tests were used. Two groups were compared using the Wilcoxon Rank test and the paired *t*-test. *P* less than 0.05 statistically significant; *P* less than 0.01: highly significant.

3. Results

In group H (*n* = 60) of the 120 cases, the hydro-implantation procedure was applied, 32 (53.3%) male and 28 (46.7%) female; in group V, where the OVD was utilized for IOL implantation (*n* = 60), 29 (48.3%) males and 31 (51.7%) females had mean ages of 51.800 ± 4.510 , 52.657 ± 3.857 , respectively. In terms of demographic information, there was no statistically significant difference between the analyzed group.

The average operation time was 7.2 ± 1.1 min in group H and 8.0 ± 1.3 min in group V. There was statistically significant increase operation time in group V (*P* = 0.001). The intraoperative parameters between the two groups did not show any significant changes in terms of phacoemulsification time, phacoemulsification energy, or phacoemulsification suction time, indicating that the lens properties were the same in both groups.

In group H the average irrigation–aspiration suction time was 30.3 ± 16.5 s and 36 ± 14.4 s in group V. There was statistically significant increase irrigation–aspiration suction time in group V (*P* = 0.035) (Table 1).

Table 1. Intraoperative parameters of patients assigned to group (H) and group (V).

	Group (H) (<i>n</i> = 60)	Group (V) (<i>n</i> = 60)	<i>P</i> -value
Operation time (minutes)	7.2 ± 1.1	8.0 ± 1.3	0.001
Phacoemulsification time (seconds)	37.0 ± 16.4	37.3 ± 12.1	0.909
Phacoemulsification energy	136.0 ± 104.4	141.3 ± 73.2	0.747
Phacoemulsification suction time (seconds)	43.1 ± 19.6	43.3 ± 14.2	0.948
Irrigation–aspiration suction time (seconds)	30.3 ± 16.5	36.3 ± 14.4	0.035

H, hydroimplantation; n, number; V, viscoimplantation.

Table 2. Comparison between patients assigned to group (H) and group (V) as regard intraocular pressure (preoperative; after 1 day, 1 week, and after 1 month).

	Group (H) (n = 60)	Group (V) (n = 60)	P-value
IOP Preoperative	13.343 ± 2.141	12.857 ± 1.912	0.192
IOP after 1 day	14.371 ± 3.049	16.000 ± 2.364	0.004
IOP after 1 week	13.343 ± 2.115	14.257 ± 1.393	0.024
IOP after 1 month	12.457 ± 2.755	13.229 ± 2.848	0.082
Pre-1 Day			
Paired Test	0.054	0.001	
% of change	7.7%	24.4%	
Pre -1 Week			
Paired Test	1.0	0.001	
% of change	0%	10.9%	
Pre -1 Month			
Paired Test	0.014	0.280	
% of change	-6.6%	2.9%	

H, hydroimplantation; IOP, intraocular pressure; n, Number; V, viscoimplantation.

P less than 0.05 statistically significant; P less than 0.01: highly significant.

Table 3. Comparison between patients assigned to group (H) and group (V) as regard endothelial cell density; (after 1 week, 1 month, 3 months, and after 6 months).

	Group (H) (n = 60)	Group (V) (n = 60)	P-value
ECD Preoperative	2.535 ± 182	2.548 ± 342	0.90
ECD after 1 week	2.375 ± 465	2.407 ± 163	0.99
ECD after 1 month	2.341 ± 240	2.379 ± 896	0.99
ECD after 3 months	2.319 ± 691	2.359 ± 764	0.99
ECD after 6 months	2.312 ± 593	2.354 ± 688	0.98

ECD, endothelial cell density; H, hydroimplantation; n, Number; V, viscoimplantation.

P less than 0.05 statistically significant; P less than 0.01: highly significant.

Table 4. Comparison between patients assigned to group (H) and group (V) as regard endothelial cell size; (after 1 week, 1 month, 3 months, and after 6 months).

	Group (H) (n = 60)	Group (V) (n = 60)	P-value
ECS preoperative	406 ± 58	416 ± 52	0.322
ECS after 1 week	437 ± 82	447 ± 84	0.510
ECS after 1 month	446 ± 92	452 ± 84	0.709
ECS after 3 months	452 ± 64	456 ± 69	0.742
ECS after 6 months	454 ± 51	458 ± 21	0.575

ECS, endothelial cell size; H, hydroimplantation; n, number. V, viscoimplantation.

P less than 0.05 statistically significant; P less than 0.01: highly significant.

The mean IOP in group H was 13.343 ± 2.141 mmHg preoperatively, 14.371 ± 3.049 mmHg on postoperative day 1, 13.343 ± 2.115 mmHg at week 1, and 12.457 ± 2.755 mmHg at 1 month. We did not notice any IOP spike in this group: in group V, these values were 12.857 ± 1.912 mmHg, 16.000 ± 2.364 mmHg, 14.257 ± 1.393 mmHg, and 13.229 ± 2.848 mmHg, respectively. The IOP increase was significantly greater on the first day and first week in group V ($P = 0.004, 0.024$, respectively). Eight patients had an IOP spikes 1 day after surgery.

Intraocular pressure differences between groups H and V were statistically insignificant preoperatively then they became statistically significant 1 day and 1 week postoperatively, but 1 month

postoperatively they became again to be statistically insignificant (Table 2).

Table 3 shows preoperative and postoperative values of ECD in both groups. In group H, the mean central ECD was 2.535 ± 182 cc/mm² preoperatively, 2.375 ± 465 cc/mm² 1 week postoperatively with reduction percentage in ECD of - 6.3%, 2.341 ± 240 cc/mm² 1 months postoperatively with reduction percentage in central ECD of -7.7%, 2.319 ± 691 cc/mm² 3 months postoperatively with reduction percentage in central ECD of -8.5%, and 2.312 ± 593 cc/mm² 6 months postoperatively with reduction percentage in central ECD of -8.8%. In group V, the mean central ECD was 2.548 ± 342 cc/mm² preoperatively, 2.407 ± 163 cc/mm² 1week

postoperatively with reduction percentage in ECD of -5.5% , $2.379 \pm 896 \text{ cc/mm}^2$ 1 months postoperatively with reduction percentage in central ECD of -6.6% , $2.359 \pm 764 \text{ cc/mm}^2$ 3 months postoperatively with reduction percentage in central ECD of (-7.4%) , and $(2.354 \pm 688 \text{ cc/mm}^2)$ 6 months postoperatively with reduction percentage in central ECD of (-7.6%) .

The differences in mean ECD between groups H and V preoperatively and 1, 3, and 6 months postoperatively were not statistically significant.

Table 4 shows that There was no statistically significant difference between both groups as regard ECS after 1 week, 1 month, 3months and 6 months.

The intraoperative problems that occurred during IOL implantation are depicted in Table 5 include flip (H group, 1; V group, 2), haptic breakage (H group, 1; V group, 1), stuck haptic (H group, 3; V group, 1) and sulcus implantation (H group, 2; V group, 0).

This table shows that there was no statistically significant difference between intraoperative characteristics of IOL implantation assigned to group (H) and group (V).

Table 6 shows the visual outcomes in both groups. The mean preoperative BCVA was 0.61 ± 0.43 in group H and 0.52 ± 0.35 in group V ($P = 0.211$). At 1 day postoperatively, the mean BCVA was 0.42 ± 0.18 in group H and 0.44 ± 0.19 in group V ($P = 0.55$). After 1week postoperative, the mean BCVA increased to 0.77 ± 0.16 in group H and 0.73 ± 0.14 in

Table 5. Intraoperative problems of intraocular lens implantation in each group.

IOL implantation problems	Group (H) (n = 60)	Group (V) (n = 60)	P-value
Flipped IOL	1	2	0.437
Haptic breakage	1	1	
Stuk haptic	3	1	
Sulcus implantation	2	0	

H, hydroimplantation; V, viscoimplantation; IOL, intraocular lens; n, Number; P less than 0.05 statistically significant; P less than 0.01: highly significant.

Table 6. Comparison between patients assigned to group (H) and group (V) as regard best corrected visual acuity; (after 1 day, 1 week, and after 1 month).

	Group (H) (n = 60)	Group (V) (n = 60)	P-value
BCVA Pre	0.61 ± 0.43	0.52 ± 0.35	0.211
BCVA after 1 day	0.42 ± 0.18	0.44 ± 0.19	0.55
BCVA after 1 week	0.77 ± 0.16	0.73 ± 0.14	0.147
BCVA after 1 month	0.83 ± 0.18	0.83 ± 0.15	1.00

BCVA, best corrected visual acuity; H, hydroimplantation; V, viscoimplantation; n, Number; P less than 0.05 statistically significant; P less than 0.01: highly significant.

Table 7. Anterior chamber cells in both groups at the postoperative periods.

	Group (H) (n = 60)	Group (V) (n = 60)	P-value
After 1 day	3.2+	3.3+	0.001
After 1 week	1.4+	1.6+	0.001
After 1 month	0	0	NA

There was statistically significant increase in Anterior chamber cells at the postoperative periods in group V ($P = 0.001$ at 1 day and 1 week postoperative).

group V ($P = 0.147$) that was statistically significant. After 1 month postoperative, the mean BCVA was 0.83 ± 0.18 in group H and 0.83 ± 0.15 in group V ($P = 1.00$). The table shows that there was statistically significant increase in BCVA after 1 week in group (H) (Table 7).

4. Discussion

In contemporary cataract surgery, OVDs provide a number of surgical advantages. However, in addition to the surgical advantages of stabilizing the AC during capsulorhexis, enlarging pupils in patients with small pupils, stabilizing the iris in patients with floppy iris syndrome, lowering the risk of posterior capsule rupture, and facilitating IOL implantation,⁵ postoperative issues related to OVDs have only recently come to light, and there is a growing interest among cataract surgeons in finding solutions to these issues.

Residual OVDs in the AC may result in postoperative complications such as IOP spikes, capsular block syndrome, and toxic anterior segment syndrome.^{5,14}

The goal of the current study was to examine the effectiveness and safety of IOL implantation in phacoemulsification with and without the use of an ophthalmic viscoelastic device. There were 120 participants in the current study. Patients divided into two groups; the first group(H) formed of 60 patients use BSS irrigation during IOL implantation (Hydroimplantation) and the second group (V) formed of 60 patients use an OVD during IOL implantation (Viscoimplantation).

Results of the present study showed none significant differences between groups (H) and group (V) regarding age and sex; number of diabetic patients; tamsulosine administration; the mean ECD, average ECS and anterior chamber diameter (ACD); BCVA.

Intraoperative parameters of patients in both groups were determined in the present work; there was statistically significant difference between both groups as regards the mean operation time ($P 0.001$) and the mean irrigation–aspiration suction time. ($P 0.035$).

In contrast to our results Lee et al.,¹⁵ found that the mean operation time (minutes) in OVD group was 17.28 ± 5.67 and 16.45 ± 7.42 in BBS group, there was no significant difference ($P = 0.557$).

During cataract surgery, a number of variables, such as incision size¹⁶ and phacoemulsification method, alter the properties of the corneal endothelium cells.¹⁷

The mean phacoemulsification duration, mean phacoemulsification energy, and mean phacoemulsification suction time between the two groups in the current investigation did not vary statistically significantly. This is consistent with the work by Schulze et al.,¹⁸ which showed that the lens properties were the same for both groups.

In the current study, there was highly statistically significant difference between both groups regarding postoperative IOP after 1 day and after 1 week ($P = 0.004, 0.024$, respectively), but one month postoperatively they became statistically insignificant.

Only in group V there are significant values between IOP differences between preoperative, postoperative values (post 1 day and post 1 week) (P value 0.001) but the results returned to be normal post one month.

All forms of OVD will result in postoperative elevations in IOP if not entirely eliminated.¹⁹

When using greater viscosity OVD, there was a higher rate of postoperative IOP rise.²⁰

Lee et al.,¹⁵ found significant difference between OVD group and BBS group as regards IOP 6 h after surgery ($P = 0.034$). Seven days after surgery, the IOP steadily returned to preoperative values.

In the study by Schulze et al.,¹⁸ mean IOP exhibited substantial changes on each visit following surgery, but baseline IOP levels and IOP differences after 1 day, as well as after 1 and 6 weeks, were not different between the two groups. IOP in the BSS plus group declined between each postoperative visit, whereas in the OVD group, it peaked one day after surgery and gradually returned to presurgical values throughout the duration of the study. Since they were all within normal ranges and the discrepancies were small, it appears that these differences may be overlooked. However, IOP was lower in the eyes allocated to the BSS plus group, suggesting that IOP may have been elevated in the OVD group.

Unlike our findings, Özcürü and Çevik,²¹ found that there was no significant difference in IOP between the two groups 1 day, 1 week, and 1 month after surgery.

With relation to IOP spikes, the current investigation found a statistically significant difference between the two groups ($P = 0.003$).

IOP spikes after intraocular usage of OVDs during phacoemulsifications have been previously documented, and if the OVD was not entirely removed during surgery, they usually take place within the first 24 h.^{5,6}

Lee et al.,¹⁵ also found significant difference between OVD group and BBS group as regard IOP spikes.

After one week, we discovered a statistically significant difference ($P = 0.147$) between the two groups. Postoperative BCVA. After a day and a month, however, there was no statistically discernible change.

According to Schulze et al.,¹⁸ study findings, BCVA considerably increased in both groups after 1 and 6 weeks, and although there were no significant differences at baseline or after 6 weeks, patients in the BSS plus group had much improved BCVA beyond that point.

Phacoemulsification is probably the primary factor contributing to endothelium loss following cataract surgery. Some exclusion and inclusion criteria can help us to study some effect of IOL implantation technique on central ECD and ECS so some similarity in choosing our cases and phacoemulsification time was very important during our study.

The impact of the implantation technique on the postoperative ECD, postoperative ECS, after 1 week, 1 month, 3 months, and after 6 months was not significantly different in our study.

In agreement with our results, Lee et al.,¹⁵ results also showed none significant difference as regards postoperative ECD ($P = 0.945$) three months after surgery and regarding facilitation of intraocular lens implantation.

According to Schulze et al.,¹⁸ there were no significant differences in total ECD between the two groups at baseline, after one week, or after six weeks. Additionally, there were no significant changes in overall ECS between the two groups at any point in time.

There was no statistically significant difference between the two groups in our study's facilitation of intraocular lens insertion. We did, however, run into a few issues when the IOL was implanted. These problems might not be caused by the hydro or viscoimplantation. Flip, haptic injury, hit haptic, and IOL implantation in the sulcus are a few of them.

Overall, there was no discernible difference between the two groups in how simple the surgery was.

The present study results revealed that there was statistically significant increase in AC cells at the postoperative periods in OVD group (V).

The present study results revealed the presence of postoperative refractive myopic shifts in (11.6%) of patients in group (V).

In the study by Iwase et al.,²² statistically significant myopic changes were noticed at 8 weeks following surgery and persisted throughout the follow-up period. While a myopic shift in refraction, defined as at least -0.5 diopters, was seen in 37.1% of individuals in Iribarren and Iribarren's,²³ study.

4.1. Conclusions

Hydroimplantation is an alternative to standard IOL implantation with an OVD.

Compared with the use of OVD for IOL implantation, Hydroimplantation resulted in reduced operative time and costs, no need for OVD removal from behind the IOL optic, no need for additional instrumentation, reduction in postoperative IOP, IOP spikes, and no risk of capsular bag distension syndrome due to the OVD.

IOL hydro implantation with the BSS irrigation line appears to be a practical substitute for straightforward cataract surgeries with lower OVD costs. These, in turn, are advantageous to cataract surgeons as well as patients.

Disclosure

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Conflicts of interest

The authors declared that there were NO conflicts of Interest.

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