Ozil Phacoemulsification Handpiece versus Phacofragmatome in the Management of Dropped Lens Fragments: A Randomized Controlled Trial

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Abstract

Purpose

In cataract surgery, dislocation of lens fragments into the vitreous cavity is a rare but significant complication. This study compares the effectiveness of the Ozil phacoemulsification handpiece with the traditional phacofragmatome in managing posteriorly dislocated lens fragments to improve patient outcomes.

Methods

A prospective, randomized study was conducted at a tertiary care hospital in eastern India from January to June 2023, involving 40 patients divided into two groups using block randomisation. Group 1 underwent surgery with the phacofragmatome, while Group 2 used the Ozil handpiece. The primary objective was to evaluate the surgical duration and intraoperative complications, with secondary objectives assessing postoperative Best Corrected Visual Acuity (BCVA), incidence of Cystoid Macular Edema (CME), and safety of surgical sites.

Results

The use of the Ozil handpiece significantly reduced surgical duration (110 ± 2.54 seconds) compared to the phacofragmatome (152 ± 2.23 seconds, p < 0.001) and minimized the risk of lens fragments falling onto the retinal surface. No significant difference was found in postoperative BCVA or the incidence of CME between the two groups, indicating similar visual outcomes and safety profiles.

Conclusion

The Ozil phacoemulsification handpiece offers a more efficient and potentially safer alternative for managing posteriorly dislocated lens fragments in cataract surgery compared to the traditional phacofragmatome. These findings suggest the Ozil handpiece could improve surgical outcomes and patient safety.

Introduction

Phacoemulsification stands as the predominant method for cataract surgery, yet it is not without its complications. Among these, the dislodgment of lens nuclei or fragments into the vitreous cavity occurs infrequently but bears significant consequences, with an incidence ranging from 0.1–1.5% of cases [1–3]. The presence of retained lens material, particularly nuclear fragments, poses a spectrum of risks, including persistent intraocular inflammation, secondary glaucoma, corneal edema, cystoid macular
edema (CME), retinal tears or detachments, and endophthalmitis, all culminating in potential permanent vision loss [4–6].

The standard recourse for managing dislocated lens fragments has traditionally been pars plana vitrectomy (PPV) coupled with phacoemulsification [7, 8]. While advancements in phacoemulsification technology have bolstered the efficacy of these procedures, the inherent axial movement of conventional phacoemulsification tips during surgery presents a notable risk of fragment propulsion, thereby heightening the possibility of retinal damage. Moreover, the utilization of perfluorocarbon liquids (PFCL) in these interventions, though beneficial in mitigating retinal damage, concurrently elevates surgical costs and duration, along with the attendant risk of complications stemming from residual PFCL [9].

Our study evaluates the effectiveness of torsional phacoemulsification using a torsional handpiece for managing posteriorly dislocated lens fragments in cataract surgery. Recent literature has highlighted its potential for a safer and more efficient alternative due to its minimized repulsive impact on lens fragments [10, 11]. Notably, prior supporting studies are very few were either prospective case series or retrospective in design, lacking randomized control. Our study distinguishes itself as the first randomized controlled trial in this area, aiming to provide a robust evaluation of its efficacy and safety.

Materials and methods

This was a prospective study conducted in a tertiary care hospital of eastern India from 01 January 2023 to 30 June 2023. Approval of the ethical committee was obtained before the study began. The protocol of the study conformed to the tenets of the Declaration of Helsinki. This was registered with Clinical Trial Registry-India (CTRI/2023/01/049013).

Aim of the Study

To determine the efficacy of the Ozil phacoemulsification handpiece versus traditional phacoemulsification procedures in handling posteriorly displaced lens fragments during cataract surgery.

Primary Objective

To estimate the effectiveness of the Ozil handpiece in reducing surgical duration and minimizing intraoperative complications, especially the displacement of lens fragments onto the retinal surface, compared to the phacoemulsification.

Secondary Objectives

1. To estimate postoperative Best Corrected Visual Acuity (BCVA) and compare the outcomes between patients treated with the Ozil handpiece and those treated with the phacoemulsification.
2. To estimate the incidence of CME post-surgery in patients operated with both surgical methods.
3. To determine the safety of the Ozil handpiece and the phacoemulsification by evaluating the condition of surgical sites postoperatively, focusing on the presence of scleral burns or other related...
Study Participants

Our study enrolled patients having nucleus dislocation during cataract surgery or due to traumatic events. We excluded those having retinal detachment or endophthalmitis. Prior to surgery, each patient underwent thorough preoperative assessments, including detailed ocular examination. Patients having increased intraocular pressure, uveitis, or corneal edema, were treated with topical steroids and anti-glaucoma medications to ensure optimal visualization of the posterior segment during surgery. All included lens nuclei were of LOCS grade II to III \[12\]. The duration of the nucleus dislocation prior to the intervention was noted. Informed consent was obtained from all patients, adhering to ethical standards and ensuring that patients were fully aware of the study's nature. In our study, we enrolled 40 patients. To ensure equal distribution and minimise bias, we employed block randomization with a block size of 4. Consequently, Group 1 and Group 2 consisted of 20 patients each. Group 1 patients underwent surgery using the traditional phacofragmatome, while Group 2 patients were operated upon using the Ozil handpiece (OZiL™, Alcon's Infiniti Vision System).

Surgical technique

All cases were done under local anesthesiа after thorough pre anaesthetic check up by anaesthesiologist. Upon completing a 25-gauge vitrectomy and inducing posterior vitreous detachment, a sclerotomy was performed either superotemporally or superonasally at 3.5 mm using a 20-gauge microvitreoretinal (MVR) blade, depending on whether it was the right or left eye. After this, and following additional vitrectomy at the port site, we inserted a sleeveless OZil handpiece into the sclerotomy. Before the insertion, the infusion pipe of the OZil handpiece was disconnected and then securely sealed with a needle cover (Fig. 1). The nuclear material was then phacoemulsified using a technique similar to the one employed with the phacofragmatome. For all cases, we adopted a consistent set of operational parameters: setting the vacuum at 250 mmHg, the aspiration rate at 30, and the torsional amplitude at 100%. The phaco power was adjusted according to the density of the lens material, ensuring optimal efficacy in lens material removal across various cases. Before closure, the peripheral retina was thoroughly checked for any iatrogenic break. We did not use PFCL in either of the group.

Statistics

Statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS) version 29.0 software. Continuous variables were presented as mean ± standard deviation and categorical variables as percentages. Comparisons between groups were made using independent t-tests for continuous variables and chi-square tests for categorical variables. A p-value of less than 0.05 was considered statistically significant.

Results
Demographics

Out of 40 patients included in the study, 22 (55%) were males, and 18 (45%) were females. The proportion of gender in group 1 were 13 (65%) males and 7 (35%) females. In group 2 were 7 (35%) males and 13 (65%) females. By using Chi-square test the proportion of gender in group 1 and group 2 was not statistically different (p-value = 0.110). The mean (± SD) age of the participants was 62.35 (± 7) years. The mean (± SD) age in group 1 is 61.44 (± 6.4) and mean (± SD) age in group 2 is 63.56 (± 7.5). By using Unpaired t-test there was no statistically significant difference between group 1 and group 2 for mean age (p-value = 0.342).

Surgical Duration

The group 2 demonstrated a superior efficiency with an average surgical duration of (110 ± 2.54) seconds as opposed to surgeries using the Phacofragmatome which took an average of (152 ± 2.23) seconds. The difference in surgical duration was statistically significant (p-value is < 0.001).

Intraoperative Complications

No significant intraoperative complications were reported in either of the groups. Nonetheless, in the group 1, 7 out of 20 cases (35%) encountered a higher frequency of nucleus falling onto the retinal surface, a difference which was statistically significant (p = 0.016) when compared to the OZil group.

Postoperative Best Corrected Visual Acuity (BCVA)

Over the six-month postoperative period, the BCVA, recorded in the logMAR scale, showed no significant disparity between the two groups. The OZil group had an average BCVA of 0.02 ± 0.051 logMAR (range: 0.00-0.05 logMAR), and the Phacofragmatome group revealed nearly similar average BCVA of 0.03 ± 0.054 logMAR (range: 0.00-0.06 logMAR). The difference was not statistically significant (p = 0.55).

Postoperative Cystoid Macular Edema (CME)

CME was diagnosed in 3 out of 20 cases (15%) managed with the Phacofragmatome, while group 2 reported CME in just 1 out of 20 cases (5%). This difference was not statistically significant.

Surgical Site Examination

Postoperative examination of the surgical sites revealed that both groups were devoid of scleral burns or related complications, emphasizing the safety of both interventions.

Discussion

Our study on the use of the Ozil phacoemulsification handpiece shows the significant impact of technological advancements in the evolution of ophthalmic surgery. The results from our study prominently showcase the operational efficiency and enhanced safety profile of the Ozil handpiece in
handling posteriorly dislocated lens fragments. One of the standout aspects of our findings is the marked reduction in surgical duration achieved with the Ozil handpiece compared to the traditional phacofragmatome. This efficiency is complemented by superior followability of lens particles and a reduced likelihood of the nucleus falling onto the retina which is a notable improvement over conventional methods.

The Ozil handpiece distinguishes itself with its unique torsional movement [13]. This innovative approach, which effectively shaves the lens fragments rather than pushing them away, allows for more precise control during surgery. It addresses a common challenge associated with traditional phacoemulsification techniques, where the back-and-forth motion often leads to lens fragments being repelled away from the tip. By mitigating this issue, the Ozil handpiece not only enhances the ease of the procedure but also contributes to the overall safety and success of the surgery.

In our literature review conducted via PubMed, Embase, and Scopus, we found only a limited number of studies regarding the use of the Ozil handpiece as a phacofragmatome. One such study[10] was a prospective analysis of 15 eyes, utilizing the Ozil handpiece. However, unlike our study, they did not include a comparison group. This study reported no scleral thermal burns or retinal damage, endorsing the Ozil torsional handpiece as a safe and effective alternative to traditional longitudinal phacofragmentation. Another study by Garg et al., though retrospective and with a smaller cohort of 12 patients, highlighted similar findings, noting more efficient lens removal with reduced heat and ultrasound power requirements [11]. Chiang et al., also conducted a retrospective case series involving 34 patients [14]. They observed excellent followability of the Ozil handpiece, a finding in line with our study. Notably, their mean total operative time for removing retained lens material, excluding vitrectomy, was 111 seconds, aligning closely with our study's results and demonstrating a faster performance compared to the standard 20-gauge phacofragmatome. Furthermore, the alignment of our results with prior studies adds another layer of credibility to our observations. Our study stands out in the existing literature as it is the only one that adopts a prospective approach along with comparative group. This design adds significant value to our findings, offering a more comprehensive analysis of the Ozil handpiece's efficacy and safety in contrast to the conventional phacofragmatome.

In our study, we also observed several significant benefits of using the OZil handpiece without encountering additional complications. A key strength of the OZil handpiece is its innovative cutting method. Unlike the traditional phacoemulsification process, which relies on a back-and-forth motion, the OZil utilizes a rotational cutting technique. This approach effectively trims the lens fragments in a shaving-like manner, rather than displacing them and thus avoiding the chatter. Consequently, the fragments are more likely to remain near the instrument's tip, significantly reducing the chance of them being pushed away, which is a notable issue with traditional phacofragmatome use. This feature also enhances the followability of lens material, making the procedure smoother. Conventional Fragmatome's tip is longer (22.5 mm) (Fig. 2A) as compared to OZil tip's length (20 mm) (Fig. 2B) that can be inserted into the eye, however, we did not encounter any difficulties in reaching the posterior segment to engage with the lens material [15]. However, we speculate that reaching the posterior segment might be more
challenging in cases of high axial myopia. OZil handpiece shows an advantage in reducing the clogging of the tip. We observed a more pronounced 'milking' phenomenon with the traditional handpieces, which was less evident with the OZil. Also the overall, the OZil handpiece demonstrates an improved efficiency and safety profile in managing dropped lens nuclei compared to standard phacoemulsification techniques.

There are few limitations in our study. It was a single tertiary care hospital study, which may limit the broader applicability and generalizability of the findings to diverse medical settings. Additionally, the study did not investigate the availability and accessibility of the Ozil phacoemulsification handpiece across various healthcare facilities, a factor that could significantly influence its practical use in different ophthalmic surgical contexts. Another notable limitation is the absence of a detailed cost-benefit analysis comparing the use of the Ozil handpiece with the conventional phacofragmatome, particularly considering the requirement for a complete vitrectomy system.

The strengths of our study into the Ozil phacoemulsification handpiece lie in its prospective design. Conducting the study in a prospective manner allowed us to capture real-time data and observations, lending a greater degree of reliability and validity to our findings. The inclusion of a comparison group, juxtaposing the Ozil handpiece with conventional phacofragmatome, is a significant aspect of this study. This comparative approach has provided us with a more comprehensive understanding of the Ozil handpiece's performance in actual surgical scenarios. Furthermore, our study benefited from a demographically diverse patient cohort, ensuring that the results are broadly representative and applicable to varied patient profiles. Stringent data collection and analysis protocols further solidify the robustness of our conclusions, making a compelling case for the effectiveness and potential of the Ozil handpiece in modern ophthalmic surgeries.

In conclusion, our study establishes the Ozil phacoemulsification handpiece as a significant step forward in nucleus drop surgery, noted for its efficiency and safety. Importantly, this study also highlights the potential for its technology, specifically the side-to-side movement mechanism, to be integrated into existing phacofragmatome handpiece. This integration could represent a major advancement in surgical tools for ophthalmologists. Additionally, in scenarios where a phacofragmatome is unavailable or encounters functional issues intraoperatively, the Ozil handpiece stands as a viable alternative. The adoption and adaptation of such technology will not only combine the strengths of both devices but also ensure continued surgical progress and improved patient care.

**Declarations**

**Author contributions** VR, DKS, SB wrote the main manuscript, ANT collected the data, NS carried out statistics, Methodology was advised by MD, AK did formal analysis, reviewing and editing was done by VKS.

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Conflict of interest  The authors report no conflict of interest

Ethical approval  The study has been approved by the Ethical committee of the hospital.

References


**Figures**

**Figure 1**

Shows the Ozil phacoemulsification probe with its sleeve removed, exposing the phaco tip for phacofragmentation, alongside the infusion pipe, which is capped.
Figure 2

A: Illustrates the conventional fragmatome with a phaco tip measuring 22.5 mm, in contrast to the Ozil tip’s length of 20 mm, as depicted in Figure 2B.