

**Intraocular pressure and ocular biometrics changes after phacoemulsification in
glaucomatous patients and age matched controls, comparative study**

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Full Protocol

Background and introduction

Phacoemulsification is one of the most commonly performed surgeries in ophthalmic practice. One of the main topics of interest regarding phacoemulsification is its effect on intraocular pressure (IOP) readings whether in glaucomatous or non-glaucomatous eyes by comparing the IOP changes before and after surgery. ^{1,2}

The effect of phacoemulsification on ocular biometrics as the depth of the anterior chamber (ACD) has been previously studied ³. It showed significant results especially in cases of thick lenses or preoperatively shallow anterior chamber (AC) or narrow AC recess as in cases of angle closure glaucoma ².

Changes in the AC angle configuration and the angle opening distance at 500 microns (AOD 500) before and after phacoemulsification have also been studied ³. AOD 500 is defined by UBM as the distance of a perpendicular from the trabecular meshwork on the iris at a point 500 μm from the sclera spur⁴. In primary angle closure glaucoma patients even a clear lens extraction showed a significant increase in AOD 500 after phacoemulsification⁵. However, there is no clear evidence whether preoperative ocular biometrics could predict the amount of this IOP reduction after phacoemulsification and whether further filtering surgeries or medications will be still needed for IOP control.

Some studies have shown a significant decrease in IOP after phacoemulsification⁶, with the effect being more significant and the rate of decrease higher the narrower the angle⁷. However, other studies stated that there's a rise of IOP after cataract removal ⁸ in the first week and it subsides later on. Another study actually proposed there's no

correlation between phacoemulsification and the IOP pre and postoperatively.⁹ Some studies that stated that there's lowering of IOP after phacoemulsification also showed that filtering surgery was eventually needed in the vast majority of glaucomatous cases and in few of them only cataract removal was sufficient.¹⁰

This study aims to evaluate the changes in IOP and anterior segment parameters represented by the central ACD and the AOD 500 measured by UBM before and after phacoemulsification.

In our study we aim to establish a qualitative as well as quantitative relationship between phacoemulsification and the IOP. Also we aim at studying this relationship in non-glaucomatous eyes, open-angle and closed-angle glaucomatous eyes (only appositional type, not synechial angle closure). We want to correlate these changes to the changes in ACD and AOD at 500 pre and postoperatively to establish a quadruple relationship between phacoemulsification on one hand, and the percentage of IOP change, ACD change and AOD at 500 change on the other hand to study the effect in various eyes and a wide spectrum of the population to earn more accurate results than previous studies.

Patients and methods

An estimation of sample size was performed considering a confidence level of at least 80% with an alpha error of 0.05. On the basis of this estimation, a total of 46 patients was considered adequate. We will include 60 patients taking into account the possibility of drop-outs in the postoperative follow up period.

This is an observational, comparative, cross sectional study that will be conducted at Kasr Alainy Cairo University Hospitals. Data collection will adhere to the tenets of the Declaration of Helsinki. Written informed consent will be obtained from all participants. Patients will be recruited from the glaucoma subspecialty and general outpatient clinics if they fulfill the following criteria; Age 40-70 years, visually significant cataracts with best-corrected visual acuity (BCVA) equal to or worse than 6/12, patients candidates for standard cataract surgeries without adjunctive procedure (e.g., pupil stretching or iris hooks). Exclusion criteria include (1) Major intraoperative or postoperative complications from cataract surgery; (2) Peripheral anterior synechiae (PAS) detected by indentation gonioscopy; (3) Uveitis, severe retinal diseases, or congenital Anomalies, (4) History of ocular trauma or any intraocular Surgery

In addition to the routine full ophthalmological examination (Visual Acuity, Auto-refractometer, Slit lamp and fundus examination). All patients meeting the inclusion criteria will have the angle of the anterior chamber assessed by indentation gonioscopy preoperatively to detect whether the angle is opened or closed and to exclude the presence of peripheral anterior synechiae. Also intraocular pressure will be measured using a calibrated Goldman Applanation Tonometry postoperatively. Anterior Chamber Depth & lens thickness will be measured by Optical Biometry (Ienstar 900) as well as measurement of the angle & lens vault using the Ultrasound Biomicroscopy (UBM) before and 1 month after cataract surgery. IOP will be measured pre- & postoperatively on day 7 and 30.

Statistical analysis plan:

All data will be entered into Excel spreadsheets (Microsoft Corporation, Redmond, WA, USA). All statistical analyses will be performed using IBM SPSS version 22.0 software (IBM Corp., Armonk, NY, USA). Descriptive statistics will be summarized as the mean \pm standard deviation for numerical data, frequencies and percentages for categorical data. The ANOVA -test and Pearson moment correlation will be used to compare the means for the numerical data and to identify correlations between them. Chi-square test will be used to compare categorical data. P-values ≤ 0.05 will be considered statistically significant.

References

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