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Effect of Scleral Flap Size on Intraocular Pressure Outcomes Following Combined Phacoemulsification and Trabeculectomy

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Abstract: ***Aim: To compare intraocular pressure (IOP) outcomes following combined phacoemulsification and trabeculectomy using smaller and larger triangular scleral flaps. Methods: This prospective comparative study included 57 consecutive patients with coexisting glaucoma and cataract. Group A underwent surgery with a 3 × 3 × 3-mm scleral flap and foldable intraocular lens (IOL; n=22), whereas Group B received a 5 × 4 × 4-mm flap and non-foldable IOL (n=35). IOP was assessed preoperatively and at the last postoperative follow-up (4–12 months). Paired and independent-sample statistical tests were used for within-group and between-group comparisons. Results: Mean IOP decreased from 26.27 ± 10.82 to 14.23 ± 3.79 mmHg in Group A and from 24.57 ± 9.85 to 12.50 ± 3.95 mmHg in Group B. Median IOP reductions were 9.5 mmHg (IQR 5.5–17.5) and 10.0 mmHg (IQR 7.0–14.0), respectively (p=0.833). The between-group difference in mean reduction was 0.25 mmHg (95% CI −5.12 to 5.63; p=0.925). Conclusion: Both groups showed substantial postoperative IOP reduction, with no statistically significant between-group difference. However, confounding by IOL type and non-randomized allocation limits conclusions***

Keywords: phacotrabeculectomy; scleral flap; intraocular pressure; glaucoma

1. Introduction

Trabeculectomy is a commonly performed incisional filtering procedure for lowering intraocular pressure (IOP) in patients with glaucoma. In guarded filtration surgery, a partial-thickness scleral flap overlies the sclerostomy and provides resistance to aqueous outflow into the subconjunctival space. Flap construction, thickness, dimensions and suture tension may therefore contribute to postoperative IOP control.

The optimal dimensions of the scleral flap remain uncertain. Starita et al. compared larger and smaller scleral flaps with correspondingly different corneal blocks and reported no significant difference in final IOP or complication rates [1]. In an experimental trabeculectomy model, Birchall et al. also found similar pressure control with larger and smaller flaps [2]. Clinical data specifically examining flap dimensions while keeping the sclerostomy dimensions constant remain limited.

The present study compared postoperative IOP outcomes in patients undergoing combined phacoemulsification and trabeculectomy with two triangular scleral flap sizes: 3 x 3 x 3 mm and 5 x 4 x 4 mm. The full-thickness scleral window was kept at the same dimensions in both groups.

2. Materials and Methods

2.1 Study design and setting

This was a prospective, nonrandomized comparative study of consecutive patients undergoing combined phacoemulsification and trabeculectomy at Glaucoma Eye Hospital, Rajkot, Gujarat,

2.2 Participants and group allocation

A total of 57 consecutive patients with primary open-angle or primary angle-closure glaucoma and coexisting cataract requiring combined surgery were included. Group A comprised 22 patients who received a foldable IOL and a smaller triangular scleral flap measuring 3 x 3 x 3 mm. Group B comprised 35 patients who received a non-foldable IOL and a larger triangular scleral flap measuring 5 x 4 x 4 mm. Flap size was therefore linked to IOL selection and was not randomly assigned.

2.3 Surgical procedure

All patients underwent phacoemulsification using a standard stop-and-chop technique followed by trabeculectomy. A triangular partial-thickness scleral flap was fashioned according to group allocation. A full-thickness scleral window measuring 2 x 1 mm was created in both groups, followed by surgical peripheral iridectomy. The scleral flap was secured with a single apical 10-0 nylon suture, and the conjunctiva was closed using two wing sutures of 8-0 polyglactin (Vicryl).

Intraoperative photographs illustrating the two flap configurations are shown in Figure 1.

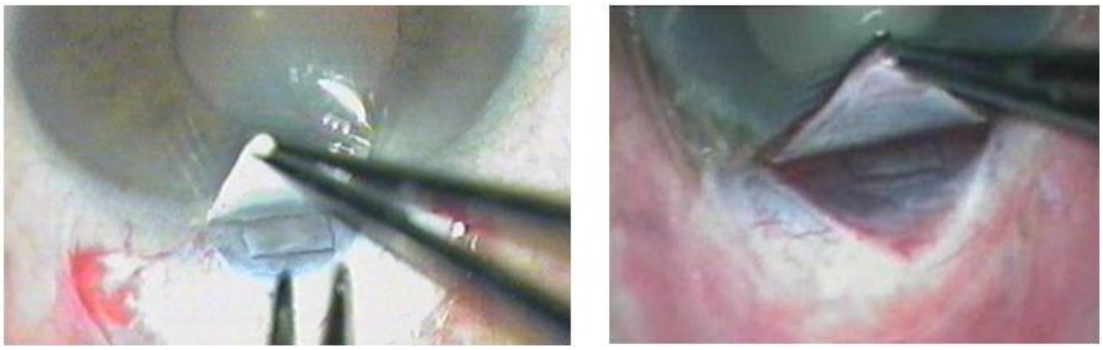


Figure 1: (A) Intraoperative photograph of the 3 x 3 x 3-mm scleral flap. (B) Intraoperative photograph of the 5 x 4 x 4-mm scleral flap. Authors must confirm image accuracy and obtain permission for publication, if required.

2.4 Postoperative management and follow-up

Patients were scheduled for review on postoperative day 1 and at weeks 1, 2 and 6, followed by visits every 3 months. Follow-up ranged from 4 to 12 months. If IOP exceeded 20 mmHg at the first postoperative visit, bleb massage was performed by applying pressure to the sclera posterior to the flap. If IOP remained uncontrolled at subsequent visits, bleb needling with adjunctive subconjunctival 5-fluorouracil (5-FU) was undertaken.

2.5 Outcome measures and statistical analysis

The principal comparative outcome was the change in IOP from the preoperative value to the last recorded postoperative value. Secondary outcomes were final recorded IOP and the number of patients recorded as requiring postoperative bleb needling with 5-FU. IOP values are reported in mmHg.

Continuous data are summarized as mean ± standard deviation (SD) and, where appropriate, median and interquartile range (IQR). Within-group preoperative and postoperative comparisons were assessed using the Wilcoxon signed-rank test. Between-group comparison of IOP reduction was assessed using the Mann-Whitney U test because the reduction values were skewed in the larger-flap group. Welch two-sample t-tests were also used as a sensitivity analysis for differences in means, with 95% confidence intervals (CIs). A two-sided p-value <0.05 was considered statistically significant. One Group B patient without a final postoperative IOP value was excluded from postoperative and paired-change analyses; no imputation was performed.

3. Results

The study included 57 patients: 22 in the 3-mm flap group and 35 in the 5-mm flap group. One patient in the 5-mm flap group did not return after the first postoperative visit and had no final postoperative IOP recorded. Accordingly, final IOP and paired-change analyses included 22 patients in Group A and 34 in Group B.

The mean age was 58.2 ± 10.3 years in Group A and 63.5 ± 9.4 years in Group B. Group A comprised 6 men and 16 women; Group B comprised 16 men and 19 women. Baseline IOP was 26.27 ± 10.82 mmHg in Group A and 24.57 ± 9.85 mmHg in Group B; the difference was not statistically significant (Welch test, p=0.553).

Table 1: Demographic characteristics and IOP outcomes by scleral flap group

Variable	3 x 3 x 3-mm flap (n=22)	5 x 4 x 4-mm flap (n=35; n=34 for final IOP)	Between-group p
Age, years (mean ± SD)	58.2 ± 10.3	63.5 ± 9.4	-
Men, n (%)	6 (27.3)	16 (45.7)	-
Women, n (%)	16 (72.7)	19 (54.3)	-
Preoperative IOP, mmHg (mean ± SD)	26.27 ± 10.82	24.57 ± 9.85	0.553
Last recorded postoperative IOP, mmHg (mean ± SD)	14.23 ± 3.79 (n=22)	12.50 ± 3.95 (n=34)	0.108
IOP reduction, mmHg (median [IQR])	9.5 [5.5-17.5]	10.0 [7.0-14.0]	0.833
IOP reduction, mmHg (mean ± SD)	12.05 ± 10.00	11.79 ± 9.33	0.925

Values are mean ± SD or n (%), unless stated otherwise. Preoperative and final IOP mean comparisons used Welch two-sample t-tests. The primary between-group comparison of IOP reduction used the Mann-Whitney U test; the p-value for the mean reduction is from a Welch t-test. IQR, interquartile range; IOP, intraocular pressure; SD, standard deviation.

Mean IOP decreased from 26.27 ± 10.82 to 14.23 ± 3.79 mmHg in Group A and from 24.57 ± 9.85 to 12.50 ± 3.95 mmHg in Group B. The within-group reductions were statistically significant in both groups (Wilcoxon signed-rank test, p<0.001 for each group). The median reduction was 9.5 mmHg (IQR, 5.5-17.5) in Group A and 10.0 mmHg (IQR, 7.0-14.0) in Group B; the between-group difference was not statistically significant (Mann-Whitney U, p=0.833).

The mean reduction was 12.05 ± 10.00 mmHg in Group A and 11.79 ± 9.33 mmHg in Group B. The estimated between-group difference in mean reduction (Group A minus Group B) was 0.25 mmHg (95% CI, -5.12 to 5.63; Welch test, p=0.925). The difference in last recorded postoperative mean IOP was also not statistically significant (14.23 versus 12.50 mmHg; p=0.108).

Postoperative bleb needling with adjunctive 5-FU was recorded in 7 of 22 patients (31.8%) in Group A and 8 of 35 patients (22.9%) in Group B.

4. Discussion

In this prospective series of combined phacoemulsification and trabeculectomy, IOP decreased after surgery in both scleral flap groups. The magnitude of IOP reduction was similar: the median reduction was 9.5 mmHg with the 3 x 3 x 3-mm flap and 10.0 mmHg with the 5 x 4 x 4-mm flap. No statistically significant between-group difference was detected in either the rank-based comparison of reductions or the comparison of mean reductions.

These findings are broadly consistent with the earlier clinical report by Starita et al., which found no significant difference in final IOP between groups receiving different scleral flap and corneal block dimensions [1]. They are also directionally consistent with the experimental study by Birchall et al., in which large and small flaps supported similar early IOP levels under controlled laboratory conditions [2]. The studies differ in design and surgical details, and the experimental findings should not be interpreted as direct clinical evidence.

The present results should be interpreted cautiously. First, flap size was linked to IOL type: patients receiving foldable IOLs were assigned to the smaller flap group, whereas those receiving non-foldable IOLs received the larger flap. This nonrandomized allocation introduces potential confounding by patient, cataract, surgical and socioeconomic factors associated with IOL selection. Second, the groups were small, and the confidence interval for the between-group mean difference was wide. A nonsignificant p-value does not demonstrate equivalence and does not exclude a clinically important difference. The study was not described as an equivalence or non-inferiority study and no sample-size calculation was available. Third, postoperative follow-up varied from 4 to 12 months, and the precise timing of the final IOP measurement was not supplied for each patient. One patient in the larger-flap group had no final IOP recorded. Fourth, complete data on visual acuity, postoperative medications, bleb morphology, complications or longer-term surgical success were unavailable. In addition, the exact 5-FU regimen requires verification. These omissions limit reproducibility and prevent a comprehensive assessment of safety and efficacy.

The prospective inclusion of consecutive cases and the use of a common sclerostomy size and broadly similar operative steps across groups are strengths. Nevertheless, a larger study with random allocation or an adequately adjusted prospective cohort design, standardized IOP measurement and fixed follow-up time points would be needed to determine whether flap dimensions independently influence clinical outcomes.

5. Conclusion

In this small prospective comparative series, both 3 x 3 x 3-mm and 5 x 4 x 4-mm scleral flaps were associated with postoperative IOP reduction after combined phacoemulsification and trabeculectomy. No statistically significant difference in IOP reduction was detected between groups. Because flap size was linked to IOL type, follow-up was variable and the sample was small, the results should be interpreted as showing no difference detected in this cohort rather than proof that flap size has no effect. Controlled studies with standardized follow-up are warranted.

References

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