



Comparative Outcomes of Inverted ILM Flap vs. Flute Needle Assisted Peeling for Large Macular Holes

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Abstract

Purpose: To compare the anatomical and functional outcomes of two techniques for large idiopathic full-thickness macular holes: inverted internal limiting membrane (ILM) flap versus conventional ILM peeling with flute-needle vacuum-assisted closure.

Methods: This prospective randomized study included 100 eyes with idiopathic FTMH (408-1500µm). Group A (n = 50) underwent pars plana vitrectomy (PPV) with ILM peeling plus flute-needle vacuum assisted closure, and Group B (n = 50) underwent PPV with the inverted ILM flap technique. Outcomes included anatomical closure (Type 1 vs Type 2), best-corrected visual acuity (BCVA, logMAR, and outer retinal integrity including external limiting membrane (ELM), ellipsoid zone (EZ) on OCT at baseline and 6 months.

Results: All 100 eyes (100%) in group A and B achieved closure at 6 months. Group A had 45 eyes with type 1 closure and 5 eyes with type 2 closure while group B had 47 eyes with type 1 closure and 3 eyes with type 2 closure. Preoperative BCVA was logMAR 0.685 in group A and 0.677 in group B. At 6 months, BCVA improved to logMAR 0.398 in group A and 0.462 in group B. Mean BCVA gain (0.287 vs 0.215 logMAR) was not significantly different between the groups. The mean diameter of EZ disruption and external limiting membrane disruption were significantly smaller with both surgical techniques.

Conclusions: Both inverted ILM flap and flute-needle-assisted ILM peeling achieved high closure rates and significant visual improvement in large idiopathic FTMH. At 6 months, there were no significant differences in hole closure rates or visual outcomes.

Keywords: Full Thickness Macular Hole; Inverted ILM Flap; Flute-Needle Technique; ILM Peeling

Introduction

Idiopathic full-thickness macular holes (FTMH) cause central visual loss and are a common indication for vitreoretinal surgery. Pars plana vitrectomy (PPV) with internal limiting membrane (ILM) peeling yields high closure rates in small-to-medium holes,

but outcomes are less favorable in large holes (>400 µm), with lower rates of Type 1 closure and limited visual recovery [1].

To improve results, Michalewska, *et al.* introduced the inverted ILM flap technique, which provides a scaffold for Müller cell proliferation and enhances closure rates in large holes. Multiple

subsequent studies have confirmed the technique's efficacy in achieving stable anatomical closure and functional improvement [2].

An alternative adjunctive maneuver is flute-needle vacuum-assisted hole closure, in which gentle suction and centripetal massage under air approximate the hole edges and promote photoreceptor apposition. Reports have demonstrated high closure rates and restoration of outer retinal layers with this approach [3].

Although both techniques show promise, there has been no direct comparison of their outcomes. Determining whether one method offers superior anatomical or visual benefit is clinically relevant for optimizing surgical management of large idiopathic macular holes. The purpose of this study was to compare hole closure rates and functional outcomes of the inverted ILM flap technique versus ILM peeling with flute-needle vacuum-assisted closure in large idiopathic FTMH.

Methods

This was a prospective randomized study conducted at a tertiary center between December 2021 and May 2022. Prior to surgery, the nature and objectives of the study were fully explained to all participants, and written informed consent was obtained from each patient.

Patients with idiopathic full thickness macular hole (FTMH) of size $> 400 \mu\text{m}$ minimum diameter (MD) were included. Patients were excluded from the study if they presented with macular holes exceeding $1500 \mu\text{m}$, traumatic macular holes, myopic macular holes, or any co-existing ocular pathologies that could impair visual outcomes. Additionally, individuals who declined randomization were excluded.

Baseline best-corrected visual acuity (BCVA) was assessed and recorded for all participants at presentation. For the purpose of statistical analysis, baseline and postoperative Snellen visual acuity measurements were converted into the logarithm of the minimum angle of resolution (logMAR). Morphological evaluation of the macula was performed using Spectral-Domain Optical Coherence Tomography (SD-OCT) via the Heidelberg Spectralis platform (Heidelberg Engineering, Inc Heidelberg, Germany) to precisely gauge all FTMH parameters and indices. Scanning protocols included high-definition 5-line raster scans and 3-dimensional 512

$\times 128$ macular cube scans centered on the fovea, acquired both preoperatively and postoperatively.

System-generated random numbers were used to randomize the patients into two groups. Patients in Group A underwent 25-gauge pars plana vitrectomy (PPV) utilizing the inverted ILM flap technique. Patients in Group B underwent 25-gauge PPV combined with standard ILM peeling and flute-needle vacuum-assisted closure.

Surgical technique

For patients in both study arms, the initial intervention comprised phacoemulsification coupled with intraocular lens implantation. This was followed by a same sitting standard 25-gauge pars plana vitrectomy (PPV) and induction of a posterior vitreous detachment (PVD). To facilitate visualization of the internal limiting membrane (ILM), 0.05% brilliant blue G (BBG) solution was used. Using 25G end-gripping forceps, the stained ILM was pinched and stripped circumferentially across an area spanning roughly two disc diameters around the defect to thoroughly alleviate all tangential tractional vectors.

Group A: Flute-needle vacuum-assisted closure

Following complete extraction of the ILM, a fluid-air exchange (FAE) was done. Under an air tamponade, a 25G silicon tipped flute needle was employed to gently massage the perimacular retina in a centripetal, radial pattern (directed from the periphery toward the foveal center) with gentle aspiration of fluid within the hole. The papillo-macular bundle was deliberately avoided during this step. This maneuver served to dehydrate and re-approximate the margins of the macular hole without inducing notable petechial hemorrhages (Figure 1A).

Group B: Inverted ILM flap technique

During the peeling sequence, the outermost margins of the ILM were deliberately preserved and left anchored to the borders of the macular hole. A vitrectomy cutter was utilized to trim the excess tissue, retaining only the precise amount of ILM required for inversion. After fluid-air exchange, this structural flap was carefully manipulated and tucked directly into the macular defect (Figure 1B).

In both cohorts, the FAE protocol was repeated multiple times to achieve thorough fluid aspiration. Care was taken to avoid drawing

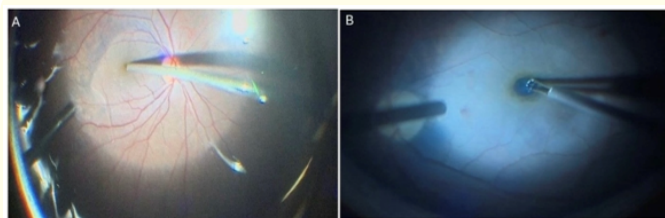


Figure 1: (A) Representative intraoperative image of Group A showing a flute cannula under air, gently massaging/aspirating around the hole. (B) Representative intraoperative image of Group B showing an ILM flap being inverted and tucked into the hole.

the tucked in flap out of the hole in cases where ILM tucking was done. Following this, the cannulae were removed, and conjunctiva manipulated with a cotton bud to cover the sclerotomy ports. 20% Sulfur hexafluoride (SF₆) gas was subsequently introduced via a 30-gauge needle while utilizing the air-infusion line for pressure venting.

Upon flushing the syringe, the infusion line was occluded, and intraocular digital tension was manually evaluated. The inferotemporal line was then removed, ensuring adequate closure of the final sclerotomy site. All patients were counselled to maintain a prone, face-down posture for the initial 48 postoperative hours.

Follow-Up schedule

Postoperative assessments were conducted at scheduled intervals on day 1, month 1, month 3, and month 6. Additional, unscheduled examinations were promptly arranged if any complications were suspected. At each follow-up interval, both best-corrected visual acuity (BCVA) and spectral-domain optical coherence tomography (SD-OCT) imaging datasets were systematically documented (Figures 2A and 2B).

The primary success criteria centered on structural and functional status at 6-months:

- **Anatomical Closure:** Defined broadly as a flattened foveal contour alongside the complete resolution of the surrounding subretinal fluid cuff.

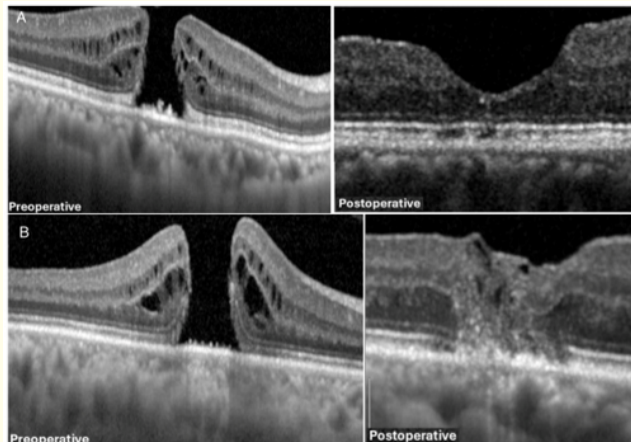


Figure 2: (A) Representative OCT image of group A (ILM peeling flute-needle vacuum-assisted hole closure), patient of full-thickness macular hole seen preoperatively and postoperatively at 6-month follow-up, showing type 1 closure with intact ellipsoid zone and external limiting membrane. (B) Representative OCT image of group B (Inverted ILM flap), patient of full-thickness macular hole seen preoperatively and postoperatively at 6-month follow-up, showing type 1 closure with reconstituted ellipsoid zone and external limiting membrane.

- **Type 1 Closure (Anatomical Success):** Defined as a fully sealed macular defect with complete resolution of the subretinal fluid and total neurosensory retinal (NSR) coverage across the foveal base.
- **Type 2 Closure:** Characterized by incomplete structural sealing of the defect, leaving a bare region of exposed retinal pigment epithelium (RPE).

Statistical analysis

Continuous datasets are presented as mean $\pm$ standard deviation, whereas categorical data are reported as absolute frequencies and percentiles. Inter-group variations for quantitative parameters were calculated using the independent-samples t-test, while longitudinal intra-group shifts (preoperative vs. postoperative) were verified with the paired t-test. Categorical or qualitative associations were analyzed via the chi-square (χ^2) test. Linear relationships between quantitative variables were derived using Pearson's correlation coefficient. Statistical significance

across all tests was predetermined at a threshold of $p < 0.05$. All computational datasets were processed utilizing SPSS software version 24 (IBM Corp., Armonk, NY, USA).

Results

Baseline characteristics

A total of 100 eyes (50 in each group) were included. Baseline demographic and clinical parameters demonstrated homogeneity

across both study arms. The mean basal diameter of the macular hole was $958.6 \pm 335.8 \mu\text{m}$ in Group A and $985.5 \pm 263.8 \mu\text{m}$ in Group B ($p = 0.66$). The mean minimum diameter was $505.4 \pm 171.9 \mu\text{m}$ and $546.8 \pm 186.6 \mu\text{m}$, respectively ($p = 0.25$). The macular hole index (MHI) was 0.597 ± 0.740 in Group A and 0.435 ± 0.143 in Group B ($p = 0.13$) (Table 1).

OCT Parameter (μm)	Group A (n = 50)	Group B (n = 50)	p-value
Basal diameter (BD)	958.6 ± 335.8	985.5 ± 263.8	0.66
Minimum diameter (MD)	505.4 ± 171.9	546.8 ± 186.6	0.25
Macular hole index (MHI)	0.597 ± 0.740	0.435 ± 0.143	0.13

Table 1: Baseline OCT (Optical coherence tomography) parameters of macular hole.
All values are mean $\pm$ standard deviation.

Visual outcomes

Preoperative BCVA was logMAR 0.685 ± 0.240 in Group A and 0.677 ± 0.216 in Group B ($p = 0.88$). At 6 months, BCVA improved significantly in both groups: 0.398 ± 0.261 in Group A and 0.462 ± 0.240 in Group B ($p < 0.001$). Both cohorts demonstrated notable visual recovery; the mean improvement in best-corrected

visual acuity (BCVA) was 0.287 ± 0.258 logMAR for Group A and 0.215 ± 0.266 logMAR for Group B. This difference in functional gains between the two treatment arms did not reach statistical significance ($p = 0.17$) (Table 2).

	Group A (n = 50)	Group B (n = 50)	p-value
Pre-operative BCVA	0.685 ± 0.240	0.677 ± 0.216	<0.001
Post-operative BCVA	0.398 ± 0.261	0.462 ± 0.240	<0.001
BCVA improvement	0.287 ± 0.258	0.215 ± 0.266	0.17

Table 2: Visual outcomes in Group A (ILM peel + flute needle) and Group B (Inverted ILM flap).

BCVA- Best corrected visual acuity in log MAR, postoperative BCVA is at 6-months all values are mean $\pm$ standard deviation.

Anatomical outcomes

All eyes achieved anatomical closure at 6 months (100% overall). Type 1 closure occurred in 45 eyes (90%) in Group A and 47 eyes (94%) in Group B, while Type 2 closure occurred in 5 eyes

(10%) and 3 eyes (6%), respectively. The difference in closure type between groups was not statistically significant ($p = 0.461$) (Table 3).

Closure type	Group A (n = 50)	Group B (n = 50)	Total
Type 1 closure	45 (90%)	47 (94%)	92 (92%)
Type 2 closure	5 (10%)	3 (6%)	8 (8%)
Overall	50 (100%)	50 (100%)	100 (100%)

Table 3: Anatomical outcomes based on OCT.
 $\chi^2 = 0.543$, $df = 1$, $p = 0.461$.

Discussion

In the present study, both techniques achieved excellent anatomical success and significant visual improvement in large idiopathic FTMH. Vitrectomy with ILM peeling, flute-needle vacuum assistant hole closure under air, drying the hole and gas tamponade with face down positioning lead to closure in 90% eyes. The approximation of photoreceptors without glial tissue has the potential to have greater vision improvement since glial tissue is not formed. Release of the tangential traction after ILM peeling makes the previously stiff retina relatively more mobile and amenable to re-approximation of photoreceptors. It is believed that drying the hole thoroughly by performing fluid air exchange from the edges of the hole using the flute needle vacuum assistant hole closure further approximating the photoreceptors.

Vitrectomy with inverted ILM flap technique (IFT) and gas tamponade with face down positioning lead to closure in 96%. Visual improvement continued to occur over 6 months after surgery after which the vision stabilized. It can be hypothesized that glial proliferation over a scaffold, as occurs with the inverted flap, leads to anatomical closure but due to lack of differentiation into photoreceptors, this tissue is unable to perceive light and hence vision improvement is not gratifying [7].

Pathological analyses have verified that the internal limiting membrane, functioning in its native role as a basement membrane, serves as a structural framework that directs glial cell proliferation to facilitate the closure of macular holes [8]. Beyond promoting gliosis, the positioned tissue flap acts as a physical barrier that isolates the subretinal space from the vitreous cavity. This compartmentalization allows the underlying retinal pigment epithelium (RPE) to actively pump out residual subretinal fluid, halting further intraocular fluid ingress and maintaining a dehydrated foveal environment [9]. Laboratory models by Shioda, *et al.* demonstrated that specific native components within the ILM actively trigger the replication and migration of Müller glia *in vitro* [10]. Furthermore, cellular survival may be actively enhanced by neurotrophic molecules and basic fibroblast growth factors (bFGF) that are bound to the flap matrix or generated directly by migrating glial cells [10]. Consequently, the successful repair of large macular holes appears to be driven by a synergistic combination of Müller cell gliosis and localized biochemical signals.

No significant EZ and external limiting membrane disruption were noted in type 1 closure macular holes in both surgical techniques at six months follow up. No significant difference noted in post op visual outcome when comparing both surgical techniques at six months follow up. Visual gains were highly dependent on the morphological configuration of the healed fovea, with Type 1 closures (intact neurosensory retina) yielding far greater visual improvement than Type 2 closures (persistent neurosensory defects). Mechanistically, the preservation of dense neurosensory tissue reflects a healthier, intact foveal microarchitecture, which translates to superior functional outcomes [8].

While historic data frequently correlates baseline macular hole dimensions with both structural closure and functional outcomes. [1,5,11-1], our data specifically emphasizes that the initial diameter is a critical determinant of the final anatomical closure morphology. Specifically, larger macular holes carry a higher predisposition toward incomplete Type 2 closure, whereas compact holes are significantly more likely to achieve optimal Type 1 structural success. These observations underscore the clinical necessity of early surgical intervention for full-thickness macular holes to prevent progressive enlargement. Furthermore, while an extended follow-up window might have allowed our cohorts to achieve greater absolute visual recovery, it is highly probable that the functional disparity between eyes achieving Type 1 versus Type 2 closures would remain distinct over the long term.

In the present series, the eight eyes that manifested a Type 2 closure pattern were predominantly characterized by a protracted duration of visual symptoms, reinforcing chronicity as a major negative prognostic indicator. The chronological lifespan of a macular hole remains a critical predictor of surgical success. Several reports in literature have revealed that the shorter duration of symptoms correlated with better postoperative visual improvement [5,11,13,15,16]. Interestingly, baseline visual acuity did not emerge as a definitive predictor of the final structural closure type in our cohort. While conflicting data exists in the literature regarding the exact relationship between preoperative and postoperative visual performance [12,14,15], our findings failed to substantiate a significant correlation between these two variables. Furthermore, demographic variables—specifically age and gender—exerted no observable influence on either the final anatomical closure morphology or the degree of postoperative visual improvement.

The main limitation of our study is the small number of patients, which limits the ability to detect small differences. Another limitation is the shorter duration of follow up in each group.

Both inverted ILM flap and ILM peel with flute-needle vacuum-assisted closure achieved high success rates in large idiopathic macular holes, with comparable visual outcomes at 6 months. The choice of technique can be individualized, with the primary goal being Type 1 closure, as this predicts superior visual recovery. OCT-based assessment of hole size and chronicity should guide surgical planning.

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