

MACULAR HOLE: CONVENTIONAL ILM PEELING VERSUS ILM FLAP TECHNIQUE

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ABSTRACT

Background: The study was conducted to compare the outcomes with conventional ILM peel and inverted flap technique for full thickness macular hole (FTMH). **Materials and Methods:** This prospective randomised control study included 48 eyes of idiopathic FTMH stage 3 and 4 conducted at tertiary health care centre. They were randomly divided in two groups of 24 patients each as conventional ILM peel and inverted flap technique. Best corrected visual acuity (BCVA) in both eyes were recorded in logMAR, applanation tonometry, slit-lamp biomicroscopy, posterior segment evaluation and spectral domain optical coherence tomography (SD OCT) was performed. Statistical analysis was performed in SPSS software using Anova test and unpaired t test. **Result:** Out of 48 patients 29 (60.04%) were females and 19 (39.96%) were males. Mean age of patients in conventional technique was 60.1 and Inverted ILM flap technique 58.8 years. Preoperative mean LogMAR visual acuity of conventional technique was 1.5 and 1.4 for Inverted flap technique which has improved to 1 and 0.7 respectively at postop day 90. On OCT, 21 (87.5 %) macular holes were sealed in conventional technique while in Inverted flap technique 22 (91.7 %) were sealed. In conservative technique 16 (76.2 %) patients achieved type 1 closure while in inverted flap group 21 (95.5 %). **Conclusion:** Visual acuity results obtained in macular hole surgeries are better in Inverted flap ILM technique in comparison to Conventional ILM technique. Macular hole closure are better achieved in Inverted flap technique but difference is not statistically significant.

INTRODUCTION

Prevalence of macular hole is 10.2 per 1000 population according to blue mountains study.^[1] Full thickness macular hole more common in female (female: male=3: 1) and in 6th decade of life.^[2,3]

The main pathogenesis behind the formation of idiopathic macular hole is a tangential as well as antero-posterior traction exerted by the posterior vitreous cortex on the neurosensory retina at the fovea.^[4] Tangential traction may be the result of contraction of the prefoveal vitreous cortex following invasion and proliferation of Muller cells.^[5] Antero-posterior traction may occur from dynamic tractional forces on an abnormally persistent vitreo-foveal attachment following perifoveal vitreous separation.^[6]

A cone-shaped, zone of Muller cells, the 'Muller cell cone' forms the central and inner part of the fovea centralis and appears to confer Structural support, serving as a plug to bind together the foveolar photoreceptor cells. Vitreo-foveal traction may result in disinsertion of the Muller cell cone from underlying Foveolar photoreceptor cells and in the

formation of a foveal schisis or "cyst". A dehiscence develops in the roof of the foveal cyst that may extend by centric or pericentric fashion, to form a crescentic hole that progresses to a horse-shoe tear.

Complete avulsion of the cyst roof results in a fully detached operculum that is suspended on the posterior vitreous cortex in the prefoveal area. Opercula primarily comprise vitreous cortex and variable amount of foveal tissue and glial elements. The photoreceptor layer, which is no longer supported by the Muller cell cone at the foveola, undergoes passive centrifugal retraction to form a full-thickness retinal dehiscence. The edge of the full thickness hole becomes progressively elevated and a cuff of subretinal fluid develops.

Pars plana vitrectomy (PPV) and fluid gas exchange have been treatment modality for Full thickness macular hole since 1991. Before the introduction of PPV spontaneous closure rate for Full thickness macular hole is 4%. With the introduction of PPV closure rate increased up to 58%.³⁸ Nowadays given the improvements in diagnostic and surgical techniques and instrumentation closure rate increase to high as 90%.^[7]

Recently the inverted ILM flap was introduced which shown increase the success rate in large FTMH and in refractory FTMH and FTMH with high myopia.^[8] Indication for surgery in full thickness macular hole:

- Stage 2 or 3 or 4 macular hole.
- Macular hole associated with epiretinal membrane.
- Macular hole persisted from long time.
- Macular hole with visual acuity 6/36 or worsen.
- Macular hole in younger patient.

Two techniques use for macular hole surgery:

1. Internal limiting membrane peeling technique:^[9]

In this technique surgical repair of macular hole includes relief of all tangential traction and anteroposterior traction and use vitreous substitutes. Three 23-gauge PPV ports are made for infusion canula, illumination pipe and vitreous cutter and core vitrectomy done. 0.1 ml of 4mg/ml is injected in front of the posterior pole for clear visualization of the vitreous cortex. 23-gauge vitreous probe is used and firm aspiration and detachment of the posterior hyaloid. Aspirating the vitreous fibres at the Weiss ring, lifting the vitreous cortex en bloc, and then extending detachment to the equator in all quadrants is the most effective method. ILM peeling done and closed with gas temponade.

2. Inverted ILM flap techniques:^[10]

In this technique instead of removal of complete ILM one edge of ILM flap is left attached to the edge of hole and after trimming ILM flap inverted into the hole.

The inverted ILM which contains muller cell fragments is said to induce glial cell proliferation, thereby filling the Macular hole and supporting Macular hole closure. It also Work as a scaffold for tissue proliferation so finally improve postoperative anatomical and functional outcome.

MATERIALS AND METHODS

A prospective, randomized observational clinical study was conducted at a tertiary eye care hospital from October 2022 to June 2024 on 48 eyes. The study followed the tenets of the Declaration of Helsinki and applicable guidelines for good clinical practice.

Our study included 48 eyes of 48 patients with idiopathic macular hole stage 3 or 4 (gass classification). All patients were above age 18 with full thickness macular hole.

Patients were excluded if they had:

- Paediatric age group patient with full thickness macular hole
- Lamellar macular holes.
- Full thickness macular hole secondary to retinal vascular diseases
- Patient with history of previous retinal surgery.
- Patients with reopening of macular hole and patients with re-surgery were excluded.
- Traumatic macular hole.

The detail and aims of study and type and possible complication of surgery explained to the patients. Patients were enrolled in the study after informed written consent taken from each patient and inclusion and exclusion criteria assessed.

Preoperative Workup: A detailed pre-operative ophthalmic workup of patients were done which included Demographics and baseline characteristics such as age, sex occupation. Patient's chief complaints including duration of vision loss was documented. Any significant family history or past history of retinal detachment, cataract surgery, details of YAG capsulotomy and personal history of trauma or systemic illness were noted.

Best corrected visual acuity (BCVA) in both eyes were recorded on snellen's chart and converted to logMAR chart for statistical analysis. The intraocular pressure was measured with goldmann applanation tonometry. A thorough examination of the anterior segment was conducted using slit-lamp biomicroscopy and Detailed evaluation of the posterior segment was performed utilizing binocular indirect ophthalmoscopy.

Additionally spectral domain optical coherence tomography (SD OCT) was Assessed Preoperatively. All the patients were randomized for surgical technique either by internal limiting membrane peeling technique or inverted flap technique.

Surgical Procedure: All the patients were operated under local anaesthesia with peribulbar block given and close monitoring of vitals by anaesthetist. The eye was prepared by cleaning with 5%povidone iodine and instillation of drop inside the eye and then patient eye was draped. In both technique 23G pars plana vitrectomy (PPV) ports made followed by induction of posterior vitreous detachment. Internal limiting membrane was then stained with 0.05% solution of brilliant blue dye for 1 minute after air fluid exchange. Internal limiting membrane peeling was done using pinch and pee technique in a circular fashion approximately 2-disc diameters around macular hole.

In the internal limiting membrane peeling technique whole ILM removed. In the inverted flap technique, the margins of the ILM left attached to the edge of the hole. The margins were letter trimmed with cutter. Adequate amount of Internal limiting membrane required to tuck into the hole was retained. Fluid gas exchange with 12-14% perfluoro propane(C3F8) was then performed. 23G Pars plana vitrectomy port removed and the digital tension of the globe was assessed. All port site sealed with cautery or suture. Subconjunctival injection of gentamicin, dexamethasone and mydriatic agent given. Pad and patch with antibiotic steroid eye ointment. Post operative prone position explained.

Post-operative workup- Postoperatively all the patients were evaluated for the following on post-operative day 1, and patient is evaluated at subsequent follow up visits at intervals of day 7,1 month and at 3 months.

Statistical Analysis: Statistical analysis was performed using the SPSS software (version 22.0 Armonk, NY: IBM corp.) The study data was evaluated using descriptive statistical methods (mean and standard deviation) and comparison of different parameters at different time interval and intergroup comparison of parameters was done by Anova test and unpaired t test. The results were assessed within a 95% confidence interval and significance was accepted at $P < 0.05$.

RESULTS

Total 48 patients of Full Thickness Macular Hole (FTMH) stage 3 and 4 were enrolled in the study and they were divided in two groups of 24 each. One group underwent conventional Internal Limiting Membrane (ILM) method procedure and another group underwent ILM inverted flap technique procedure and following results were observed for both techniques. Out of 48 patients 29 (60.04%) were females and 19 (39.96%) were males. Mean age of patients in conventional technique was 60.1 years and Inverted ILM flap technique was 58.8 years. In our study, conventional technique 10 (41.7%) out of 24 patients had phakic eye and remaining 14 (58.3%) out of 24 patients had pseudophakic eye. In inverted flap technique group, equal proportion (50%) was observed for phakic and pseudophakic lens in eyes Table one shows stages of macular hole at preoperative status. In conventional technique, 6 (25.0%) patients out of 24 were of stage 3 macular hole and in inverted flap technique, 8 (33.3%) patients were of stage 3 macular hole. In conventional technique 18 (75.0%) patients were of stage 4 macular hole and in inverted flap technique 16 (67.3%) patients were of stage 4 macular hole diagnosis based on SD-OCT.

Graph one shows comparison of Log-MAR visual acuity at different stages of operative procedures between Conventional technique and inverted flap technique. During preoperative stage mean visual acuity of 1.5 was observed for conventional technique and 1.4 for Inverted flap technique. After operative procedure day 1, mean visual acuity for both groups patients had decreased to 1.9 for conventional and 1.8 for Inverted flap group. Further post operative period of time value increases and at the day 90 mean visual acuity of conventional group was 1.0 and for Inverted flap group it was 0.7.

ANOVA test was applied to correlate statistical significance in Log-MAR findings overtime. Obtained p value was 0.000 which was highly statistically significant.

On applying unpaired t test statistically significant difference was found between both group mean visual acuity on post operative day 30 and 90 (p value 0.03 and 0.006 respectively)

Table two represents Optical Coherence Tomography (OCT) findings on post operative day 90 for checking status of macular hole. In conventional technique out of 24, 21 (87.5%) macular holes were sealed and 3 (12.5%) were not sealed while in Inverted flap technique 22 (91.7%) were sealed and 2 (8.3%) were not sealed.

Table three shows type of closure after surgical approach. In conservative technique 16 (76.2%) out of 21 patients achieved type 1 closure and 5 (23.8%) out of 21 patients achieved type 2 closure while in inverted flap group 21 (95.5%) out of 22 patients achieved type 1 closure and 1 (4.5%) out of 22 patients achieved type 2 closure.

On comparison of Log MAR vision between Conventional and Inverted flap group in Type 1 and Type 2 closure. Statistically significant difference was observed between pre operative and post operative 90th day in Conventional and Inverted flap group. No statistically significant difference was observed between Conventional and Inverted flap group at preoperative and post operative day 90. In type 2 closure statistically, significant difference was observed in conventional group at preoperative period and post operative 90th day.

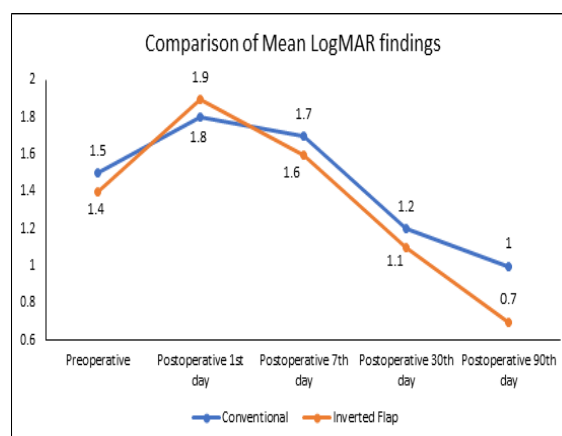


Figure 1: Comparison of Log MAR vision findings of conservative and inverted flap technique

Table 1: Stages of Macular Hole

	Conventional tech.	Inverted Flap tech.	Total
Stage 3	6 (25.0)	8 (33.3)	14 (29.2)
Stage 4	18 (75.0)	16 (66.7)	34 (70.8)
Total Patients	24 (100.0)	24 (100.0)	48 (100.0)

Table 2: Status of Macular Hole at Post operative Day 90

	Conventional tech.	Inverted Flap tech.	Total
Sealed	21 (87.5)	22 (91.7)	43 (89.6)
Not sealed	03 (12.5)	02 (8.3)	05 (10.4)
FTMH	03	01	04
FTMH With SRF	00	01	01

Table 3: Type of closure of Macular Hole

	Conventional tech.	Inverted Flap tech.	Total
Type 1 closure	16 (76.2)	21(95.5)	37 (86.0)
Type 2 closure	05 (23.8)	01 (4.5)	06 (14.0)
Total	21(100.0)	22 (100.0)	43 (100.0)

DISCUSSION

Present study was conducted on 48 patients with full thickness macular hole and they were randomly divided in two groups of 24 each. One group underwent surgery with conventional internal limiting membrane technique and one group underwent surgery by ILM inverted flap technique. Outcome was measured by Log-MAR visual acuity at time interval of preoperative, post operative 1st day, post operative 7th day, post operative 30th day and post operative 90th day and sealing of macular hole with type of sealing.

In present study 60.4 % patients were Female and 39.6% were male. In study done by Stanislao Rizzo et al,^[11] female proportion was higher (72. 7%) in comparison of male which is line with the present study. In another study done by Naresh Babu Kannan et al,^[12] almost similar male-female proportion was observed in which 53. 4 % patients were female and remaining patients were male.

In present study Mean age of patients in conventional technique group was 60.1 years while in Inverted flap technique mean age was 58.8 years. Study conducted by Naresh Babu Kannan et al,^[12] shows mean age group in conservative technique was 61.17 and in Inverted flap group it was 59.37 years which similar to present study. In a study done by Stanislao Rizzo et al,^[11] mean age group for study patients was 70.23 years which is slightly higher than the present study. Above two findings suggests that female patient's proportion was slightly higher in all the studies and predominantly higher age group individuals (above 50 years) were reported in all of the studies.

In present study mean LogMAR visual acuity measured at preoperative time, post operative 1st day, post operative 7th day, post operative 30th day and on postoperative 90th day.

In conventional technique group, at pre operative stage mean log-MAR visual acuity was 1.5. On post operative day 1 mean Log-MAR visual acuity was 1.8 which gradually increase as time passes. On Post operative 30th day Log-MAR visual acuity was 1.2 and at the end of 90th day mean log-MAR acuity was 1.0.

In case of inverted flap group, at pre operative stage mean log-MAR visual acuity was 1.4. on post operative day 1 mean Log-MAR visual acuity was 1.9 which gradually increase as time passes. On Post operative 30th day Log-MAR visual acuity was 1.1 and at the end of 90th day mean log-MAR acuity was 0.7.

A study done by Naresh Babu Kannan et al.,¹¹ shows that in conventional technique, Mean baseline logMAR acuity was 0.79 and visual acuity after 1st month postoperative period was 0.68 and after 6th

month it was 0.65. similarly in inverted flap technique Mean baseline logMAR acuity was 0.75 and visual acuity after 1st month postoperative period was 0.54 and after 6th month it was 0.53.

In study done by Carmen Baumann et al,^[13] mean preoperative logMaR visual acuity in conventional technique group was around 1.2 and following operative procedure at 3, 6 and 12 months it was 0.8, 0.7 and 0.4 respectively. In case of Inverted flap group logMaR visual acuity was around 1.0 at pre operative stage and following operative procedure at 3, 6 and 12 months it was around 0.7, 0.6 and 0.5 which shows similar trend with the present study.

In a study done by Michalewska et al,^[14] in conventional technique group, pre operative visual acuity was 0.92 and poste operatively it was 0.77 in Inverted flap technique group pre operative visual acuity was 1.10 and post operatively it was 0.55 In another study done by Chakrabarti et al,^[15] pre operative visual acuity in inverted flap technique was 1.0 and poste operatively it was 0.5.

All of this study findings suggests visual acuity improves after operative procedure in both conventional ILM technique and Inverted flap ILM technique which is also established in present study by applying ANOVA test at different time interval in both the groups. But improvement in visual acuity by inverted flap technique was better in compare to conventional technique.

Regarding closure of the macular hole in present study, Optical Coherence Tomography (OCT) findings on post operative day 30 suggests that in conventional technique out of 24, 22 (91.7 %) macular holes were sealed and only 2 were not sealed. Same findings were observed in Inverted flap technique patients and OCT findings on day 90 suggests that in conventional technique out of 24, 21 (87.5 %) macular holes were sealed and 3 (12.5 %) were not sealed while in Inverted flap technique 22 (91.7 %) were sealed and 2 (8.3 %) were not sealed.

In patients with sealed macular hole in conservative technique 16 (76. 2 %) out of 21 patients achieved type 1 closure and 5 (23.8 %) out of 21 patients achieved type 2 closure while in inverted flap group 21 (95.5 %) out of 22 patients achieved type 1 closure and 1(4.5 %) out of 22 patients achieved type 2 closure. There have been some studies comparing the anatomical and functional outcome of Inverted Flap Technique with conventional ILM technique. However, there is no conclusive evidence that suggest superiority of the any technique. There are few studies like kocak N.et al,^[16] Avci R et al,^[17] which suggest that Inverted flap technique is better than conventional ILMP.

Michalewska et al,^[14] found that anatomical closure rate was 98% in Inverted flap technique(IFT) group

and 88% in ILMP group Type 1 anatomical closure rates in the IFT and ILMP groups were 96 % and 69% respectively and at the similar time post-operative BCVA was significantly higher in the IFT group. Similarly, Manasa et al,^[18] showed that both the anatomical and the functional outcome was statistically better in the IFT group (95.6%) than the ILMP group (78.6%) In contrast with above findings a study done by Narayanan et al,^[18] in their retrospective analysis of 36 eyes found no statistically significant difference in either the anatomical or the functional outcome between the two groups. Their results showed 88.9% closure rate in IFT group and 77.8% in ILM peeling group which is in line with the present study.

All findings described above suggest that visual acuity results obtained in macular hole surgeries are better in Inverted flap ILM technique in comparison to Conventional ILM technique which is significant and regarding macular hole closure, results are better achieved in Inverted flap technique but difference is not statistically significant and different studies have their contradictory view on results as described above.

CONCLUSION

Visual outcome improved with both technique but inverted ILM flap technique gives better result as compare to conventional ILM peeling technique for large macular hole. Anatomical outcome (hole closure rate) is better with inverted ILM flap (91.7%) technique as compare to conventional ILM peeling technique (87.5%). Type 1 closure which is associated with good visual acuity is more achieved with inverted ILM flap technique (95.5%) as compare to conventional ILM peeling technique (76.2%). Inverted ILM flap technique and conventional ILM peeling technique both were safe with minimal complication in postoperative period.

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