Comparing surgical outcome between conventional and inverted ILM flap technique for full thickness macular hole repair

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Abstract

Introduction: *Macular holes are primarily managed surgically; either conventional full-thickness Macular Hole (FTMH) repair or the inverted flap technique. Large macular holes (>than 400 micrometers) have poor surgical outcome, with only 44% closure and inverted flap method has resulted better outcome in visual recovery and a higher closure rate.*

Objective*: To compare surgical outcome (anatomical and functional) between conventional and inverted ILM flap technique in macular hole surgery.*

Methodology: *A prospective randomized clinical trial; a longitudinal study with 2 waves of data collection. 154 Pseudo-phakic clients (50-70 years) with full-thickness large macular hole were randomly selected to 2 groups to undergo either technique by same consultant VR surgeon. The approval of Ethics Committee of the National Eye Hospital was obtained.*

Results: *There is 88.3% closure in conventional group and 96% closure in inverted flap technique. However, no significant difference between 2 groups (p>0.05) in the anatomical success and even when compared sub-categorically with U, V, W closure and non-closure. There was a statistically significant improvement in visual acuity (p=0.002) observed in the inverted flap group, but the improvement observed in visual acuity among CG (p=0.18), the improvement in Snellen Chart reading of both groups (p=0.15) and type of closure and surgical technique (p=.369) were not statistically significant.*

Conclusion: *The overall success of anatomical closure following FTMH repair is significantly better compared to literature (92.2% Vs 44%); but there is no statistically significant difference in anatomical success between the two groups. Both groups had a better functional outcome and a statistically significant improvement seen in the ILM-G and CG group.*

Recommendations: *Being the first such study, data gives promising evidence to support the current surgical practice and assist in service development and training.*

Introduction

Background

A full-thickness defect in the centre of the neuro-sensory retina is described as a macular hole. With a 0.8% prevalence and about 8 eyes per 100,000 population annual incidence, it commonly associates advancing age and female gender. Macular holes are primarily managed surgically; the conventional macular hole repair involves 3-port pars plana vitrectomy and peeling off internal limiting membrane (ILM) using gas tamponade. The success rate depends on the diameter of the macular hole, chronicity, and relapsing nature.

Large macular holes (>than 400 micrometres) have poor surgical outcome both anatomically and functionally. Data suggest only 44% closure post surgically. Michalewska and colleagues introduced a modified surgical technique for the conventional macular hole repair, where ILM flap surrounding the fovea is peeled off and inverted over the full thickness hole. This new technique named as 'Inverted ILM flap technique' has resulted better outcome in vision and higher closure rate, mostly in cases with large macular holes. Thus, it has been considered as an alternative to traditional macular hole repair by some surgeon for a better post-operative recovery rate.

The rationale behind the technique is to facilitate closing of the hole by gliosis induced by the Müller cell fragments contained in the ILM pieces. In addition, it is believed that the remaining ILM may serve as scaffolding to enable photoreceptors to re-assemble in their correct position near the fovea.

Justification: Most of the outcome studies on the inverted ILM flap technique describe improvement in both functional and anatomical outcome and reduction in post-operative flat-open appearance. Most of the studies and case series have a small number of sample size. In Sri Lankan setting, there are no studies carried out to assess the prevalence, presenting characteristics or the surgical outcome in either procedure individually or comparison wise. In our clinical practice,

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majority of patients with macular holes present late and found to have full thickness macular holes greater that 400 µm. Thus, assessing a clinical sample for the outcome comparatively (Inverted ILM flap versus Conventional surgery) will assist the management and therapeutic decision making, and ultimately in setting local guidelines based on our own data.

Specific objectives

1. To compare Anatomical success by assessing pre- and post-operative (after 2-months) Optical Coherence Tomography (OCT) in each group: conventional surgery and inverted ILM flap technique.

2. To compare functional Success by assessing pre- and post-operative (after 2- months) visual acuity in each group: conventional surgery and inverted ILM flap technique, and between the 2 groups

Methodology

This study was a Prospective Randomized Clinical trial, a longitudinal study with 2 waves of data collection: macular hole repair with the conventional Method and macular hole repair with Inverted ilM flap technique. Study was carried out at National Eye Hospital of Sri Lanka in March-May 2019.

Inclusion criteria – Patients (50 to 70 y) presenting to the out-patient clinic who were, psuedophakic with full thickness macular holes of more than 400 µm, complaining of reduced vision for more than 1-year, Axial length of less than 22 mm.

Exclusion criteria – Axial Myopia (Axial length more than 22 mm)/ traumatic macular holes/Patients with other macular pathologies – (age related macular degenerations, macular dystrophies etc).

Out of total 154 patients enrolled, 77 equally were randomly selected to undergo either conventional technique or inverted flap technique. All surgeries were done by the same consultant VR surgeon. During the surgery, posterior capsulotomy was done to minimize the effects of posterior capsular opacity affecting final visual outcome.

Both techniques included 23 G brilliant blue assisted vitrectomy, while conventional method with peeling off entire ILM and inverted ILM flap technique with 2-disc diameter peeling around the fovea and remnant ILM attached to the margins inverted on to the fovea. All patients underwent fluid air exchange and C3F8 gas fill followed by 5 days of face down positioning. All patients underwent Spectral Optical Coherence Tomography and Clinical examination in pre-operatively (1st wave of data collection at the admission awaiting surgery) and post operatively (2nd wave of data collection) after 2 months at the follow-up clinic.

Informed written consent was obtained. Data was only used for scientific purposes and confidentiality was always maintained. The participants were informed at the recruitment that they could withdraw or withhold their consent during the study any time and it had no effect on their further management.

The approval from the Ethics Committee of the National Eye Hospital and administrative permission from Director of the National Eye Hospital were obtained.

Risk to research subjects – Both surgeries being invasive procedures carried similar risk of pre- and post-operative complications such as iatrogenic tears, retinal detachment, post-operative high intraocular pressure, vitreous haemorrhage, cataract formation and endophthalmitis. All participants were explained about these complications and details of surgery at the time of recruitment.

Results

1. Pre-op macular hole diameter

Normality tests were carried out prior to the further analysis with hypothetical testing. Shapiro-Wilk test was not significant at 5% critical value for the conventional group (CG)(p=0.07) and inverted ILM flap group (ILM-G).

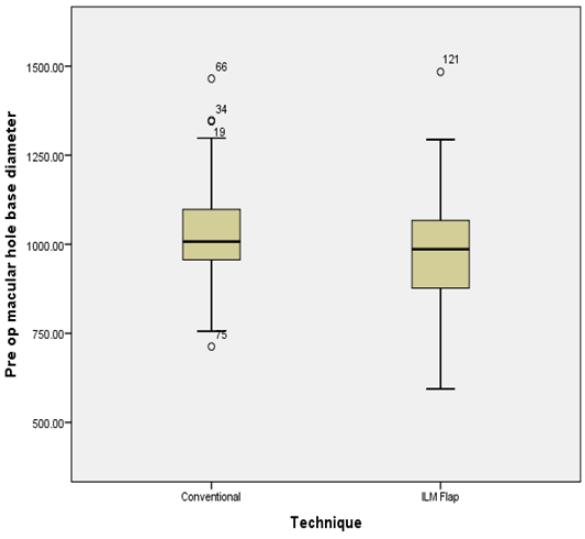

Figure 1. *Pre-op macular hole base diameter between CG and ILM-G.*

Table 1. Mean values of pre-op macular base diameter in CG and ILM -G

Pre-op macular base diameter (micrometre)	*CG*	*ILM-G*
Mean (SD)	1035.55 (156.02)	979.18 (158.94)
Significance	t=2.214, Df=151, p=0.028	

There is a significant difference noted between 2 groups. Patients in the CG has larger macular hole diameters than ILM-G (p=0.028).

2. Anatomical success between the two groups

There is 88.3% closure in conventional group, while 96% closure in inverted flap technique. Two-proportion test was carried out to find out the significance of each type of the macular hole closure between two groups.

Table 2. Comparison between different anatomical closures between CG and ILM-G

Types	*CG Frequency*	*%*	*ILM-G Frequency*	*%*	*P-value*
U	47	61.0	48	62.3	0.86
W	2	2.6	8	10.3	0.081
V	19	24.7	18	23.4	0.65
Non sealed	9	11.7	3	3.9	0.07

There is no significant difference between each type between 2 groups (p>0.05) in the anatomical success.

Table 3. Comparison of type of anatomical closure in CG and ILM-G

Technique	*Type of closure*		*Significance*
	Type 1	Type 2	
CG	51 (66.2%)	26 (33.8%)	0.369
ILM-G	45 (59.2%)	31 (40.8%)	

Even though type 2 closures are high in number in ILM-G group. The type of closure and surgical technique was not statistically significant (p=0.369).

3. Functional success between the two groups

3.1 Comparison of pre-op visual acuity and post-op visual acuity

Non-parametric tests were followed to assess the visual acuity improvement after the surgery. Friedman's test was applied for K-related samples. The null hypothesis was considered as there are no difference of visual acuity among groups. The alternative hypothesis was a significant improvement of visual acuity following the surgery.

Table 4. Visual acuity in CG

The conventional method:

Visual acuity	*Pre-op*	*%*	*Post-op 2 months*	*%*	*Post-op 4 months*	*%*
PL	00	00	00	00	00	00
HM	37	48.1	02	2.6	02	2.6
60	38	49.4	39	50.6	35	45.5
36	02	2.6	25	32.5	27	35.5
24	00	00	04	5.2	06	07.8
18	00	00	07	9.1	07	9.1
12	00	00	00	00	00	00
9	00	00	00	00	00	00

There was a significant difference in visual acuity following conventional method ($p<0.001$).

Table 5. Visual acuity in ILM-G

The inverted ILM Flap technique method

Visual acuity	*Pre-op*	*%*	*Post-op 2 months*	*%*	*Post-op 4 months*	*%*
PL	02	2.6	00	00	00	00
HM	24	31.2	01	01.3	00	00
60	44	57.1	26	33.8	21	27.3
36	09	09.0	32	41.6	29	37.7
24	00	00	12	15.6	15	19.5
18	00	00	06	07.8	09	11.7
12	00	00	00	00	02	02.6
9	00	00	00	00	01	01.3

There was a significant improvement in visual acuity following inverted flap method ($p<0.001$).

3.2 The number of lines improved post-operatively at follow-up when tested using a Snellen chart, in comparison to pre-operative reading

In both groups, most of the patients had 1-line improvement of the Snellen chart (CG (N=36), ILM-G (N=37)). The second-highest number of patients had 2 lines improvement (CG (N=25), ILM-G (N=15)). But patients with 3 lines improvement was more common in ILM-G (N=13), while CG had only 2 patients. Mann Whitney U test was performed to assess the significance of the test results. But there was no statistically significant difference observed ($p=0.15$). Both CG and ILM-G had overall improvement in lines; 1.24 and 1.53 lines respectively, but no statistical significance noted between the 2 groups ($p=0.15$).

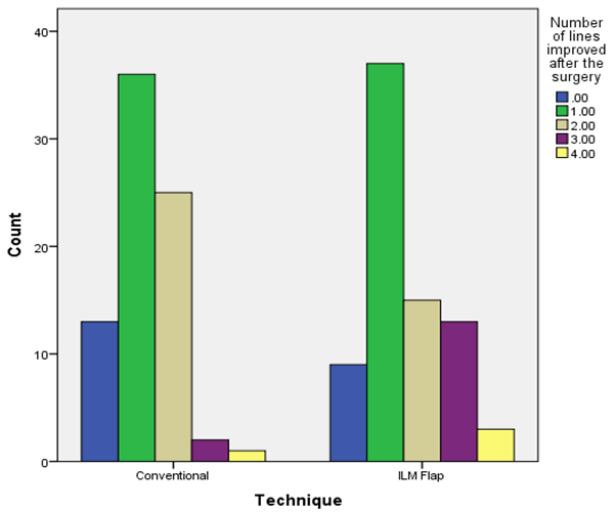

Figure 2. *The number of lines improved in Snellen chart reading post-operatively in CG and ILM-G.*

Discussion

The full-thickness macular hole is not an uncommon clinical finding. However, in the case of large macular holes (size more than 0.4mm), surgical success is poor (around 44%). My study data showed 88.3% (n=68) FTMH closure following the conventional method, which is significantly better than these findings. Compared to FTMH closure rate of 98-100%, this study, ILM-G method had 96% (n=74) (p=.001) success rate, which almost comparable with these findings. The overall post-operative findings showed 92.2% (n=142) successful hole closure rate. Although Michaelewska recommended inverted flap technique for larger FTMH, claiming a better closure, my study revealed no statistically significant difference in anatomical outcome between the 2 groups. There was no significant difference in the non-closure as well (p=0.07). I even compared the closure sub-types: U, V and W. There was no statistically significance found in each subtype among the CG and ILM-G. So, anatomical outcome was overall better than literature. However, both groups had anatomical outcome comparable to each other. No group had a statistically proven superior benefit.

Considering the functional outcome, Michealewska concludes that the visual acuity improved significantly compared to eyes without inverted flap surgery (0.7 vs 0.28). In the present study, there was statistically significant improvement in visual acuity post-surgically in both groups (p<0.001). About 1.5 Snellen chart line improvement was observed in all CG and free flap technique in literature. Both CG and ILM-G had overall improvement in lines; 1.24 and 1.53 lines respectively, with no statistical significance between the 2 groups (p=0.15); 16.9% VS 11.7% with no line improvement; Most of the patients had one-line improvement (46.8% in CG and 48.1% in ILM-G). ILM-G had more patients with 3 lines improvement (n=13) in comparison to the CG (n=2). ILM-G group had outcome comparable to found in literature

Conclusion

The overall success rate of anatomical closure following large FTMH repair is significantly better than data available in literature (92.2% Vs 44%); the outcome of conventional surgery is comparable with outcome of inverted flap method. Even though non closure rate is more with conventional method, it is not statistically significant in comparison. Type of closure does not show a statistical significance difference between the 2 groups.

Both groups have an improvement in visual acuity following surgery which were statistically significant. Average Snellen line improvement is more with ILM-G group (1.53 vs 1.24 in CG) and these results are similar to the findings of other studies (1.5). The functional outcome of each group is not superior to other statistically, however ILM-G had more with 3-lines improvement.

Recommendation

Being the first study conducted to assess the post-operative macular closure rate in Sri Lanka, this gives promising evidence to support the current surgical practice and be a source for the national data as well.

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