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Original Research Article

Visual and anatomical outcome of inverted ILM flap technique for large macular hole surgery

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ABSTRACT

Background: A new study finds that in about 14-16% of macular hole repairs using the inverted internal limiting membrane (ILM) flap technique, the hole actually closes itself thanks to a thin layer of the ILM left behind, not the full flap itself. This suggests a potentially simpler closure mechanism for this surgery.
Objective: This study was conducted to investigates both the physical results (anatomy) and vision improvements experienced by patients who underwent large macular hole surgery using the inverted internal limiting membrane (ILM) flap technique.
Materials and Methods: 20 patients with significant macular defects participated in the research from January 2019 to December 2019 at the Ispahani Islamia Eye Institute and Hospital. Idiopathic large macular lesions were analyzed in the study using optical coherence tomography (OCT) and biomicroscopy. Exclusion criteria excluded macular holes measuring less than 400 μm and those resulting from other etiologies. Demographic and clinical information was collected, including age, gender, best-corrected visual acuity (BCVA), and intraocular pressure. Slit-lamp biomicroscopy was performed on the anterior region and fundus, and spectral-domain optical coherence tomography (OCT) was used to verify the presence of macular holes. Approval from the institutional ethical committee was obtained, and surgical procedures were performed after informed consent. The final best-corrected visual acuity was documented, and a comprehensive ocular assessment was conducted during appointments.
Results: In this study half (50.0%) of patients belonged to those aged≥51 years. The mean age was 41.40±17.87 years with ranged from 20 to 60. Here it was observed that the mean BCVA pre-operative was 1.39±0.65 and the mean BCVA (3 months after surgery) was 0.50±0.16. In OCT all (100.0%) patients had macular holes before surgery and 100.0% closure of MH after surgery. Here ERM is formed in only 1(10.0%) patient.
Conclusion: The study found a 100% closure rate for macular holes and superior functional outcomes. Further research is needed to assess the efficacy of this approach with a larger sample size and longer follow-up duration.

1. Introduction

A macular hole (MH) is a structural abnormality located in the fovea of the retina, resulting in significant vision impairment. Idiopathic full-thickness macular holes are observed in individuals between the age range of 50

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to 60 years, with a higher incidence rate in women, occurring three times more frequently than in men.[1,2] Patients commonly report experiencing impaired central vision accompanied by metamorphopsia as their primary concern. These modifications may manifest either gradually or suddenly. The surgical procedure known as vitrectomy, which was initially documented in 1991 as a viable therapeutic intervention for macular holes, has undergone numerous subsequent revisions. Macular hole (MH) was previously considered an incurable condition with a dismal prognosis until the pioneering work of Kelly and Wendel in 1991 when they first described the use of vitrectomy as a treatment for MH.[3] The success rate of macular hole (MH) surgery experienced a notable increase to 98%[4–6]in a significant number of cases following the implementation of internal limiting membrane (ILM) peeling, as introduced by Eckardt et al.[7] This particular surgical technique has been widely regarded as one of the most efficacious techniques.[8] However, the probability of attaining anatomical success for macular defects exceeding 400 μm is considerably diminished, as closure rates as low as 40% have been documented.[9,10] This holds irrespective of the removal of the internal limiting membrane (ILM) during vitrectomy. Initially, the inverted internal limiting membrane (ILM) flap technique was implemented to treat large macular lesions (MH) by Michalewska et al.[11] This innovative approach has been shown to result in reasonably high rates of closure for MH. Nevertheless, the probability of attaining anatomical success for macular defects exceeding 400 μm is considerably diminished, as closure rates as low as 40% have been documented.[9,10] This holds irrespective of the removal of the internal limiting membrane (ILM) during vitrectomy. However, the low availability of solid evidence to support such a position can be attributed to various factors, including the absence of proper controls, uncontrollable components, or insufficient sample sizes in the majority of these investigations.

2. Materials and Methods

The current study was carried out within the Vitreo-retina department of Ispahani Islamia Eye Institute and Hospital, spanning from January 2019 to December 2019. The study will include all patients who satisfied the predetermined inclusion criteria and did not satisfy any of the exclusion criteria. A sample size of 20 patients will be chosen by the successive sampling technique, specifically targeting individuals with significant macular holes. The study included patients who were diagnosed with idiopathic giant macular holes based on biomicroscopy and optical coherence tomography (OCT) imaging. The exclusion criteria encompass macular holes measuring less than 400 μm and macular holes resulting from other etiologies. Demographic and clinical information was gathered for all participants, encompassing variables such as age, gender, best-corrected visual acuity (BCVA), and intraocular pressure. Additionally, slit-lamp biomicroscopy was conducted using a +90 D lens on the anterior region and fundus. The investigation confirmed the existence of macular defects in every subject by employing spectral-domain optical coherence tomography (OCT). The methodology comprised the assessment of the macular fissure's minimum linear diameter (MLD). The approval of the ethical committee of the institution was acquired. Following the acquisition of informed permission, surgical procedures were performed on all of the patients. The final best-corrected visual acuity (BCVA) was documented, and a comprehensive ocular assessment was conducted, including optical coherence tomography (OCT) imaging, during all the appointments.

2.1. Surgical technique

Employing a 23G cannula and local anaesthetic, every surgical procedure was performed. To commence the vitrectomy procedure, an infusion cannula was initially inserted through the inferior temporal sclera. Subsequently, two cannulas were inserted through the super temporal and super nasal regions. A triamcinolone acetonide (TA) injection was administered into the vitreous cavity after the extraction of the central vitreous to enhance the visibility of the posterior vitreous detachment (PVD). In the absence of pre-existing peripheral vascular disease (PVD), a PVD was induced. Following the induction of posterior vitreous detachment (PVD) and subsequent removal of peripheral vitreous, the internal limiting membrane (ILM) flap was inverted with the use of brilliant blue dye. A limited quantity of per fluorocarbon (PFCL) was administered during the process of inverting the flap. After the surgical procedure, a fluid-air exchange (FAX) was conducted. The FAX procedure was executed with a delicate approach, ultimately resulting in the removal of PFCL. To finish the surgery, a special gas (perfluoropropane) was injected to help hold the retinal flap in place. Then, all the tiny incisions were closed. Notably, only one experienced eye surgeon performed the entire procedure Patients were given instructions to lay face down for five days following surgery to promote appropriate healing.

2.2. Data analysis

The data analysis in this study employed SPSS V20, a statistical software often used in the social sciences. Following the study's objectives, a p-value of less than 0.05 was deemed to indicate statistical significance. Before doing the final analysis using SPSS, the process of data cleaning was performed in Excel.

2.3. Ethical clearance

The study protocol was approved by the ethical review committee of Ispahani Islamia Eye Institute and Hospital. The study adhered to the tenets of the Helsinki Declaration. The findings of the study will be shared through publication in peer-reviewed journals or presentations at conferences

3. Results

Table 1 presents the baseline characteristics of the patients included in the study. It was noted that 50.0% of the patients were aged 51 years or older. The mean age was 41.40 ± 17.87 years, ranging from 20 to 60 years. The proportion of female patients was 60%. The study findings revealed that a total of 4 patients (20.0%) were identified to have DM. Approximately 30.0% ofthe exhibited hypertension. It was noted that the average BCVA before surgery (referred to as pre-op) was 1.39±0.65. The data reveals that a significant proportion, specifically 40.0%, of patients exhibited an IOP of 10. The average intraocular pressure (IOP) was 11.00±1.05. 50.0% of the patients had a C: D ratio of 0.3 with an average C:D ratio was found to be 0.36±0.07.

Table 1: Baseline characteristics of the study patients (n=20)

Baseline Characteristics	
Age (in years)	
Mean ± SD	41.40±17.87
Range (min-max)	20-60
BCVA BCVA Pre-op (Before surgery)	1.39±0.65
IOP	
Mean ± SD	11.00±1.05
Range (min-max)	10-13
C: D	
Mean ± SD	0.36±0.07
Range (min-max)	0.30-0.50

Figure 1 demonstrates the state of the patients' cataracts and intraocular lenses who were part of the study. The numbers show that 40.0% of the patients had clear cataracts.

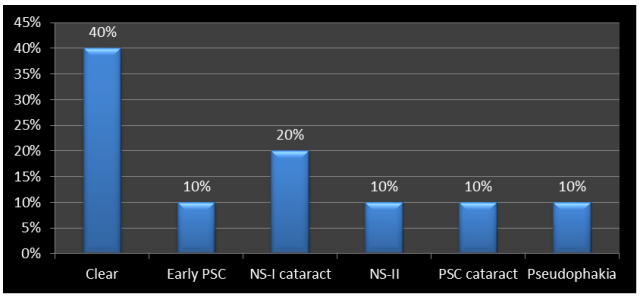

Figure 1: Distribution of the study patients by Cataract/lens (n=20)

Table 2 presents the best-corrected visual acuity (BCVA) of the patients involved in the study. It was noted that the average BCVA before surgery (referred to as pre-op) was 1.39±0.65. The average best corrected visual acuity (BCVA) at 3 months post-surgery was 0.50±0.16. BCVA change (logMAR) was-0.89±0.49.

Table 2: Distribution of the study patients by BCVA (n=20)

BCVA	**Mean ± SD**
BCVA (3 months-After surgery)	0.50±0.16
BCVA change (logMAR)	-0.89±0.49

Table 3 presents the OCT status of the patients included in the study. It was discovered that all patients (100.0%) had a macular holebefore surgery. There was a complete closure of MH after surgery in 100.0% of cases.

Table 3: Distribution of the study patients by OCT (n=20)

OCT	**Frequency (n)**	**Percentage (%)**
Before surgery		
Macular Hole	10	100.0
After surgery		
Closed	10	100.0
Not closed	0	0.0

Figure 2 shows the issue (ERM formation) of the patients in the study. One patient (10%) had ERM formation.

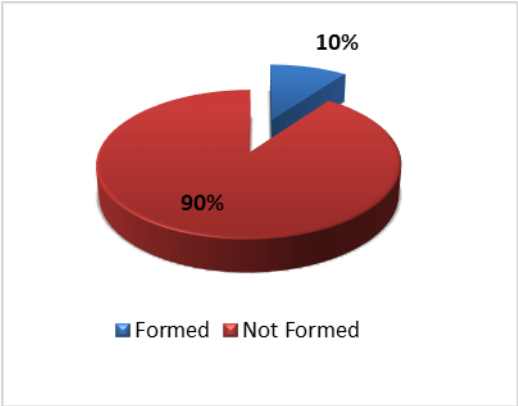

Figure 2: Distribution of the study patients by complication (ERM formation) (n=20)

4. Discussion

The primary objective of the present research was to assess the structural and visual consequences of two discrete surgical methodologies employed in managing substantial macular defects. The examination was conducted at the Ispahani Islamia Hospital and Eye Institute. Significant improvements have been observed in the morphological and functional success of vitreo-retinal surgery as a result of the technique advancements and instrumentation refinement that have occurred. The study conducted by the Vitrectomy

for Treatment of Macular Hole Study Group showed a significant advantage in terms of closure rates and ultimate visual acuity when comparing surgical intervention to observation for macular holes at stages III and IV.[12] The size of the aperture is the primary determinant of surgical results, exhibiting the highest degree of reliability. Several studies have demonstrated a strong correlation between the minimum linear dimension (MLD) of the hole and the rate of anatomic success. Moreover, previous studies have demonstrated that superior visual recovery is closely linked to higher levels of initial visual acuity.

The anatomical closure rate was found to be 100% following the implementation of the inverted internal limiting membrane (ILM) flap technique in cases of giant macular holes (MH) within our study. Based on recent randomized control trials (RCT), it has been observed that the inverted internal limiting membrane (ILM) flap technique demonstrates the highest rate of anatomical success and improved functional outcomes. However, it is important to note that although this difference is notable, it did not reach statistical significance.[13] In their study, Michalewska et al. (year) reported a success rate of 98% for large macular holes (> 400 μm) using the ILM-flap approach. Only 2% of these cases exhibited flat-open configurations. Investigated is the notion of stimulating closure-promoting retinal gliosis within the macular defect by employing the flap of the internal limiting membrane (ILM) by Michalewska et al. and Morizane et al. Furthermore, this method not only eliminates all conventional forces exerted on the retinal surface but also facilitates greater preservation of the internal limiting membrane (ILM), hence mitigating some physiological consequences associated with significant ILM ablation.[14,15]

Surgeons performing the ILM flap inversion technique for giant macular holes face challenges due to their technical complexity. Their experience plays a crucial role, particularly in preventing the flap from dislodging from the macula. This study proposes delaying flap inversion until the very end of the surgery, just before the fluid-air exchange. Furthermore, the authors recommend conducting the exchange with extreme caution, minimizing fluid removal and air pressure.

The study employed a prospective design to assess the anatomical and visual outcomes of the ILM flap technique.

5. Conclusion

Our study findings demonstrate a 100% success rate in closing retinal holes using this method, with equally impressive functional benefits. Nevertheless, to thoroughly evaluate the effectiveness of this method, it is important to carry out a more extensive investigation including a larger sample size and a longer duration of follow-up.

6. Source of Funding

There was no institutional funding.

7. Conflicts of Interest

The authors declare no conflicts of interest.

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