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Original Article

Inverted flap in the management of idiopathic large macular holes: A comparative study of different techniques.

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Abstract:

Background
Macular holes are vitreoretinal interface disorders due to anatomical defects in the fovea causing poor central vision. The aim of this study was to compare the results of four different variants of inverted flap (IF) technique, for the closure of macular holes larger than 400µm.

Methods
This is a prospective comparative case series. Thirty-six eyes with large macular hole were enrolled: group 1: inserted internal limiting membrane (ILM); group 2: classic IF ILM; group 3: IF without manipulation (Free Flap technique), group 4: temporal IF technique. Best-corrected visual acuity (BCVA), anatomical closure rate, and ellipsoid zone (EZ) and external limiting membrane (ELM) defects were evaluated preoperatively, at 1 month and 3 months after surgery. Odds ratio (OR) and its 95% confidence interval (CI) were used to compare the anatomical and functional results of classic inverted flap ILM peeling (group 2) and modified inverted flap ILM peeling (Group 1,3 and 4).

Results
Mean BCVA improved in all four groups 3 months after surgery. The improvement was significant in group 2,3, and 4 (P=0.001). The rate of successful hole closure ranged from 87.5% to 100% in different groups (P=0.661). The integrity of EZ was achieved in 65.6% and the restoration of the inner layers of the retina in 71.5%.

Conclusion
Inverted flap ILM technique is efficient for the treatment of large full thickness macular hole (FTMH). Different modified inverted flap techniques have been described on the last decade. Through our study, we demonstrated that the inserted flap, may alter outer retinal layer and compromise final functional results despite final closure of the macular hole. The classic IF technique, the temporal and the free flap techniques have finally comparable good functional and anatomical results.

Key words
inverted flap technique, macular hole, surgery, outcomes.

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Introduction

Th standard treatment for macular holes (MH) is surgical. The aim of the procedure is to inhibit all vitreoretinal traction forces (tangential and anteroposterior) [1]. Pars plana vitrectomy with posterior vitreous detachment and internal limiting membrane (ILM) peeling are the main macular hole procedures for many types of vitreoretinal disorders. It allows the release of traction forces and prevents the postoperative epiretinal membrane prevalence [2]. The closure of idiopathic MH is successful in more than 90% of the cases. However, the results are unsatisfactory in cases of large MH with complete closure rate of less than 60% [3,4]. Michalewska et al were the first to describe the inverted internal limiting membrane flap (IF) technique in the treatment of large macular hole >400µm [5]. This technique ensures a macular hole closure in 98% and a significant functional postoperative improvement [6,7]. Nowadays, the IF is the gold standard technique. Several technical variants are described with heterogenous postoperative results. The aim of our study is to assess the results of different variants of IF technique, for the treatment of a large idiopathic MH > 400µm.

Materials and Methods

Study design

In a prospective, interventional and comparative study we included patients with idiopathic large MH larger than 400µm of less than six months duration. This study was conducted in the department of ophthalmology A, Hedi Raies institute Tunis, Tunisia. Our study was carried out in accordance with the principles of the Declaration of Helsinki and was approved by the Ethics Committee of the institute.

Thirty-six eyes of thirty-four consecutive patients, who had large MH and managed in our department from October 2019 to June 2020, were enrolled in our study. Inclusion criteria was patients with idiopathic large MH (diameter>400µm). Exclusion criteria were: Patients with high myopia, traumatic macular hole, macular edema, history of vitreo-retinal surgery, glaucoma or other chronic ocular diseases.

The study sample was divided into 4 groups according to the surgical technique chosen: Group 1: 6 eyes undergoing pars plana vitrectomy (PPV) with inserted flap ILM. Group 2: 16 eyes undergoing PPV with classic inverted flap ILM peeling. Group 3: 8 eyes undergoing PPV with inverted flap without manipulation of ILM flap (free flap technique) and Group 4: 6 eyes undergoing PPV with temporal inverted flap ILM peeling.

Data collection

Preoperative assessment

All patients underwent a complete preoperative ophthalmological examination; with evaluation of the best corrected visual acuity (BCVA) (measured as Snellen fraction converted to LogMAR for statistical analysis), an extended exam of the anterior segment, measurement of the ocular pressure, and a complete fundus exam. A spectral domain optical coherence tomography (OCT-SD) (SPECTRALIS®, Heidelberg Engineering, Germany) was performed systematically. The basal diameter of MH was measured at level of the retinal pigment epithelium and the minimum diameter at the point of minimum distance between the two edges of the MH (figure1). Tomographic data were extracted using the computerized software of the machine (automatic measurement of the size of the macular hole) and recorded in the database.

Postoperative assessment

The follow up was performed at one week, one month and three months after surgery. All patients underwent a complete ophthalmological exam and an OCT-SD.

Main postoperative records were best corrected visual acuity (BCVA), IS/OS line (ellipsoid zone) and retinal nerve fiber integrity then cavitation or cysts on retinal layers. All collected data have been sorted and stored in a database for further processing.

Surgical techniques

All surgical techniques were performed by the same surgeon. This vitreoretinal surgeon was well experienced and trained in these techniques.

Three-port 23-gauge PPV was performed for all patients. A standard vitrectomy with induced detachment of the posterior vitreous, a core and peripheral vitrectomy was performed. Next, a brilliant blue staining was used to color and peel the ILM.

We opted different techniques based on the surgical variety:

Group 1: inserted flap technique: we peeled off > 2-disc areas of the ILM around the hole. The peeled ILM flap was trimmed and placed inside the hole using intraocular forceps.

Group 2: inverted internal limiting membrane flap technique (classic technique): The ILM was grasped with an ILM forceps and peeled off in a circular shape for approximately 2-disc diameters around the MH. During the circumferential peeling, the ILM was not removed completely from the retina but was left attached to the edges of the MH. The ILM was then massaged gently over the MH from all sides until the ILM became inverted (figure 2).

Groupe 3: inverted flap without manipulation (free flap technique): The ILM was grasped with an ILM forceps and peeled off in a circular way for approximately 2-disc diameters around the MH. During the peeling, the ILM was left strongly attached to the edges of the macular hole. Then the vitreous cavity was filled immediately with air, without manipulation of the peeled ILM flap (figure 3).

Group 4: Temporal inverted flap technique: ILM forceps were used to grasp and peel the ILM off at the temporal side of the macular hole in an area of about 2-disc diameters. During this peeling, the ILM was not removed completely from the retina but instead was left attached to the temporal edge of the MH, then inverted and gently coaxed over the macular hole until adequate coverage was achieved (figure 4).

In all techniques, the fluid air exchange was performed with gentle aspiration over the papilla area. Gas tamponade was performed for all patients. We choose the sulfur hexafluoride 20% (SF6) for tamponade. All patients were instructed to keep face down for 3-4 hours a day during the first 3 post-operative days.

Statistical analysis

Statistical analysis was done using SPSS computer software package, version 20.0 (Echosoft Corporation, USA).

Qualitative data were expressed as frequencies and percentages.

Quantitative data were expressed as mean ± standard deviation (SD) for parametric data. Chi square ($\chi 2$) and Fisher exact test were used for the comparative study. Factors affecting functional and anatomical outcomes in each group were assessed using a multiple linear regression analysis (ANOVA test). All tests were two-tailed and considered significant at $p < 0.05$ and highly significant at $p<0.01$. The odds ratio (OR) and its 95% confidence interval (CI) were used to characterize the anatomical and functional success between classic inverted flap ILM peeling (group 2) and modified inverted flap ILM peeling (Group 1,3 and 4). We used the Roc curve to determine the predictive factors of non-closure of the macular hole.

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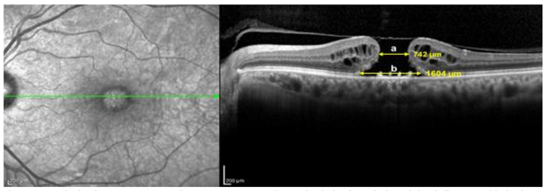

Figure 1: Optical coherence tomography measurements of macular hole size: a) the minimal diameter, b) the base line diameter at the level of the retinal pigment epithelium.

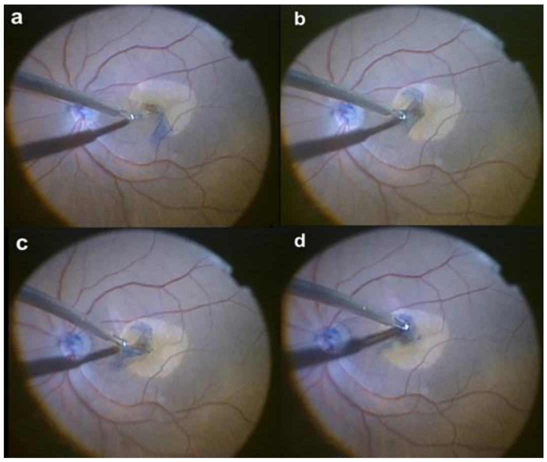

Figure 2: Inverted internal limiting membrane flap technique (classic technique): a/The internal limiting membrane was grasped with an internal limiting membrane forceps and peeled off in a circular fashion for approximately 2-disc diameters around the macular hole. b/During the circumferential peeling, the internal limiting membrane was not removed completely from the retina but was left attached to the edges of the MH. c and d/The internal limiting membrane was then massaged gently over the MH from all sides until it became inverted, that is, upside down such that the surface normally facing the vitreous body now faced the retinal pigment epithelium.

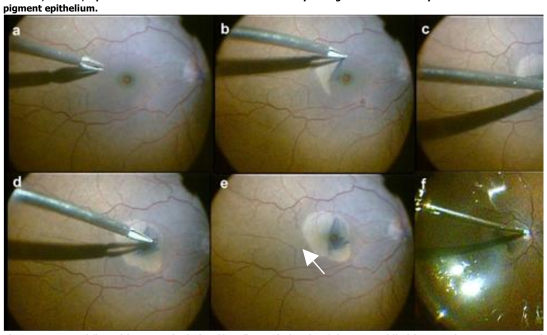

Figure 3: Inverted flap without manipulation (free flap technique): a/The Internal limiting membrane was grasped with an ILM forceps. b-c/The intern limiting membrane was peeled off in a circular way for approximately 2-disc diameters around the macular hole. d-e/During the peeling, the intern limiting membrane was left strongly attached to the edges of the macular hole. f/The vitreous cavity was filled immediately with air, without manipulation of the peeled internal limit in membrane flap.

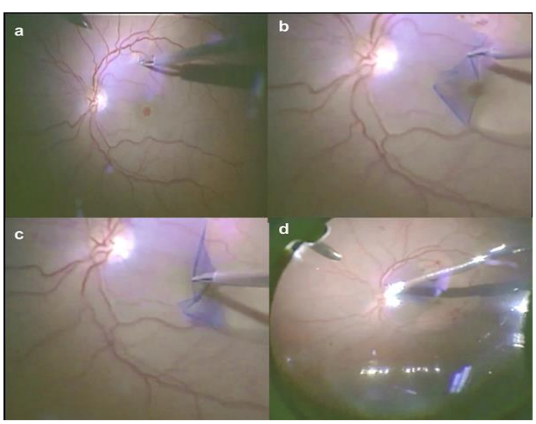

Figure 4: Temporal inverted flap technique: a/ Internal limiting membrane forceps were used to grasp and peel the Internal limiting membrane off at the temporal side of the macular hole in an area of about 2-disc diameters. b/ During this peeling, the internal limiting membrane was not removed completely from the retina. c/ the internal limiting membrane was left attached to the temporal edge of the macular hole. d/ The internal limiting membrane was, then, inverted and gently coaxed over the macular hole until adequate coverage was achieved.

Results

We studied 36 eyes of 34 patients. There were 6 under group 1 (inserted flap), 16 under group 2 (classic inverted flap), 8 under group 3 (free flap technique) and 6 under group 4 (temporal inverted flap). Table 1 summarizes the preoperative clinical data for each group.

The four groups were comparative in terms of age and MH's diameter.

Table1: Pre-operative clinical Data

	G1 (n=6)	G2 (n=16)	G3 (n=8)	G4 (n=6)	P***
Age (years)	57±4	58±8	65±4	64	0.539
Sex (M/F)	4/2	7/9	0/8	4/2	0.032
BCVA* Log MAR	1.25±0,12	0.69±0,42	0.69±0,44	0.69±0,41	0.06
Minimum FTMH**(µm)	469±52	492±71	529±22	531	0.365
Maximum FTMH (µm)	716.5±71	693.12±145	794±64	851	0.428

*BCVA: best corrected visual acuity.
**FTMH: full thickness macular hole.
**** p= p value: significant at p < 0.05 and highly significant at p < 0.01 (Fisher's exact test, chi-square test)

Functional results

Mean BCVA improved in 1 to 3 months after surgery for all groups except the group 1. In this group, the mean BCVA before the surgery was 1.25±0.12 LogMAR, 1.25±0.12 LogMAR at 1 month (p=1) and 1.15±1.16 at 3 months (p=0.8). In group 2, the mean BCVA before the surgery was 0.69±0.42 LogMAR, 0.57±0.37 LogMAR at 1 month (p=0.066) and 0.27±0.16 LogMAR at 3months (p=0.086). In group 3, the mean preoperative BCVA was 0.69±0.44 LogMAR, 0.57±0.37 LogMAR at 1 month after surgery (p=0.066) and 0.27±0.16 LogMAR at 3months (p=0.086). For the fourth group, the mean preoperative BCVA was 1±0.32 LogMAR, 0.77±0.27 LogMAR at 1 month (p=0.213) and 0.38±0.2 LogMAR at 3 months (p=0.236). Table 2 showed the details of the visual acuity (VA) follow up at 1 month and at 3 months.

Macular hole diameter at baseline was not significantly correlated to BCVA at 1 and 3 months (p=0.521 at 3 months).

Table 2: Visual outcomes at 1month and 3 months after surgery

	Visual outcomes at 1month			Visual outcomes at 3months	
	Preoperative BCVA*	**BCVA at 1month**	**P****	**BCVA at 3month**	**P**
Group 1	1.25±0.12	1.25±0.12	**1**	1.15±1.16	**0.8**
Group 2	0.69±0.42	0.57±0.37	**0.01**	0.27±0.16	**0.07**
Group 3	0.69±0.44	0.57±0.37	**0.066**	0.27±0.16	**0.086**
Group 4	1±0.32	0.77±0.27	**0.213**	0.38±0.20	**0.263**

*BCVA: best corrected visual acuity.
** p= p value: significant at p < 0.05 and highly significant at p < 0.01 (Fisher's exact test, chi-square test)

Anatomical results

Overall closure MH rate was 91.6% (33/36). Macular hole diameter at baseline was not significantly correlated to the closure at 1 and 3 months (p=0.521 and p=0.529 respectively). Table 3 summarizes MH closure rate and type of closure in each group. IS/OS line disruption width greatly reduced in group 1, 3 and 4 between baseline and 1 month after surgery (p=0.066). The group 1 showed a poor restitution of the IS/OS line. Cystic changes within the external retinal layers were significantly more prevalent in group 2 and 3 (p=0.04 at 1 month and 0.05 at 3 months). There was a significant correlation between IS/OS defect and BCVA in all groups and at all points in time (3 months; p= 0.02). Table 4 developed the different anatomical results in our study.

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Table 3: Macular hole closure characteristics

		G1	G2	G3	G4	P
Closure	yes	5	14	8	6	0.536
	no	1	2	0	0	
%		93.3	87.3	100	100	
	U	0	9	5	4	
Shape	V	1	3	3	2	0.015
	W	4	2	0	0	

Table 4: Postoperative course

	Follow up 1 month					Follow up 3 months				
	G1 (n=6)	G2 (n=16)	G 3 (n=8)	G4 (n=6)	**P***	G1(n=6)	G2 (n=16)	G3 (n=8)	G4 (n=6)	**p**
Ellipsoid Zone disruption	100%	56.3%	62.5%	66.6%	**0.279**	100%	25%	12.5%	16.6%	**0.02**
Cavitation0	33.3%	43.8%	37.5%	33.3%	**0.956**	16,7%	6.3%	0%	0%	**0.522**
Retina nerve fiber disruption	100%	56.3%	12.5%	33,33%	**0.07**	100%	31.3%	12.5%	0%	**0.01**

The type of closure was defined according to the different postoperative tomographic results. The OCT-SD established the foveal defect of the neurosensory retina, decrease in central retinal thickness with alteration of the different retinal layers and disruptions on the retinal nerve fiber layer. This form of closure was classified as irregular or W-shaped closure of the MH (figure 5). The postoperative OCT-SD demonstrated a significant decrease in retinal thickness with decrease in size and number of cavitations. The IS/OS line was disrupted in the foveal area. The remaining retinal layers were preserved. This type of MH closure is classified as U-shaped closure (figure 6). The V- shaped closure is defined, on macular tomography, as a good thickness of the retina with insignificant defect (disruption) of the IS/OS line on the fovea (figure7). The successful anatomic closure was defined, in our study, as a V-shaped or U-shaped closure. Successful closure was noted on 81.8% (27/33).

For the first group; the W- shaped closure was observed in 80% of closed MH. In the second group; 64.28% of closed MH were closed according to a U-shaped closure Vs 21.42% to a V-shaped closure Vs 14.28% to W-shaped closure. In the third group, the 3-month OCT-SD revealed 37.5% of V-shaped closure and 62.5% U-shaped ones. For the fourth group (figure 8), 66.67% of closed MH were U-shaped Vs. 33.33% V- shaped healing. In the table 3 we summarized the shape of closure in each group. The OCT SD (figure 4) showed a U-shaped closure, with a perfect foveal depression and preservation of all retinal layer (especially the IS/OS line and the retinal nerve fiber layer). The retina has also recovered its usual thickness. Statistically, the regeneration of the photoreceptor layer was diagnosed frequently in the U-shaped closure (p=0.002) (figure 9). Functional success at 3 months was verified in 100% (n =16) of patients in the classic IF group and 85% (n = 20) of patients in the modified IF group. There were no statistical differences between groups: OR = 0.875 (95% CI = [0.32; 2.35], = 0.7). Closure of the MH at 3 months was verified in 87.9% (n =16) of patients in the classic IF group and 95% (n = 20) of patients in the modified IF group. There were no statistical differences between groups: OR = 1.563 (95% CI = [0.125; 19.59], = 0.590). Successful closure (U and V shape) at 3 months was verified in 75% (n=16) of patients in the classic IF group and 75% (n=20) of patients in the modified IF group, with no statistical differences between them: OR = 0,759 (95% CI = [0.256; 2.245], = 0.519). Factors influencing closure and final visual acuity at 3 months (multiple linear regression analysis):

In addition to the surgical technique used and the OCT data (IS/OS line and retinal nerve layer disruptions) other factors were assessed using a multiple linear regression analysis.

There were no correlations between postoperative BCVA at 3months and sex nor maximal diameter of the MH (p=0.836 and p= 0.973 respectively). However, correlation was significant between postoperative and preoperative BCVA and age (p<0.001 and p=0.004 respectively). Likewise, there were no correlations between the closure of the MH at 3months and sex, age and the maximal diameter of the MH (p=0.369 and 0.343 respectively).

Calculating the predictive factors of no closure of the macular hole, only the diameter of the MH was considered as a significant predictive factor. In fact, from a diameter superior to 721µm, the non-closure risk rate of the MH was 100%.

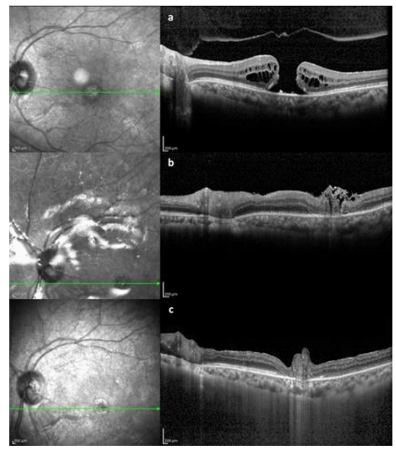

Figure 5: Pre- and post-operative tomography in inserted flap technique: a/ preoperative tomography with a large macular hole more than 400 µm, visual acuity at 2-meters count finger and a central scotoma.
b/ postoperative tomography 1 month after surgery, visual acuity at 1/20 with W shaped closure and disruption of the photoreceptor layer.
c/ 3 months postoperative tomography with large disruption of the photoreceptor layer. Visual acuity at 1/20 and persistent scotoma.

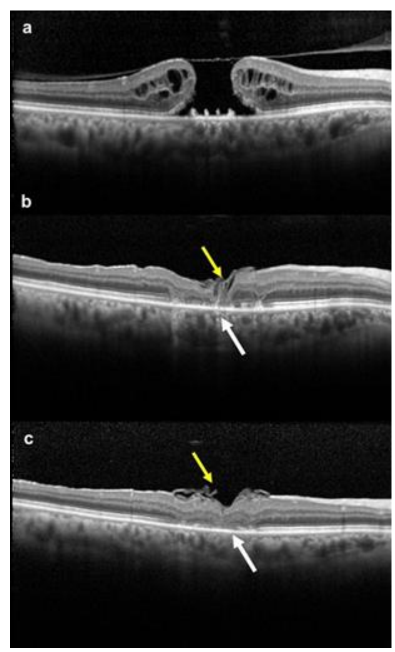

Figure 6: Pre- and post-operative tomography in classic inverted flap technique: a/ preoperative tomography with a large macular hole more than 400 µm, visual acuity at 1/20 and a central scotoma.
b/ postoperative tomography 3 months after surgery, visual acuity at 1/20 with "W" shaped closure; the flap of internal limiting membrane (yellow arrow) and a disruption in the photoreceptor layer (white arrow) are respectively showed on this tomography. c/ a 6 months postoperative tomography showing an incomplete regeneration of the photoreceptor layer and increase in visual acuity to 1/10.

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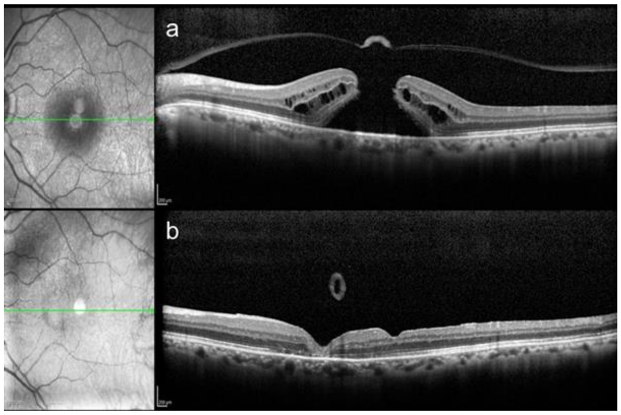

Figure 7: Pre and post-operative tomography in Free Flap inverted flap technique: a/ preoperative tomography with a large macular hole more than 400 µm, visual acuity at 3-meter count finger and a large central scotoma.
b/ postoperative tomography 3 months after surgery, visual acuity at 1/10 with "V" shaped closure; the flap of internal limiting membrane (yellow arrow) and the incomplete regeneration of the photoreceptor layer (white arrow) are respectively showed on this tomography.

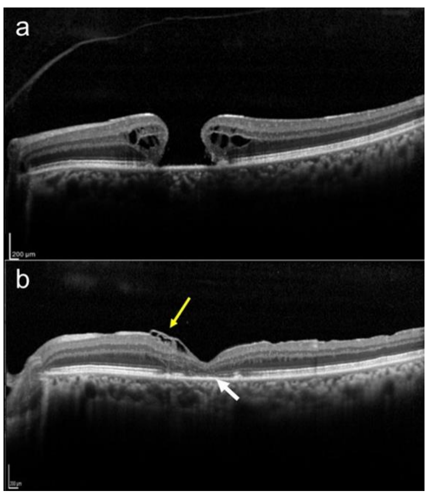

Figure 8: Pre and post-operative tomography in Temporal inverted flap technique: a/ preoperative tomography with a large macular hole more than 400 µm, visual acuity at 1/20 and a central scotoma.
b/ postoperative tomography 3 months after surgery, visual acuity at 2/10 with "U" shaped closure; the flap of internal limiting membrane (yellow arrow) and the incomplete regeneration of the photoreceptor layer (white arrow) are respectively showed on this tomography.

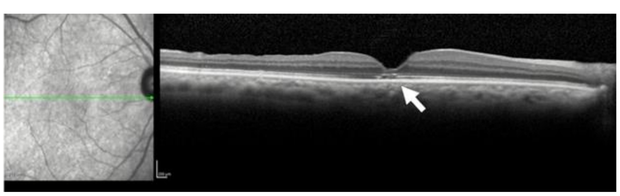

Figure 9: A 6 months post-operative tomography of macular hole treated with free flap inverted flap technique: The arrow shows a regeneration of the photoreceptor layer. The visual acuity is at 4/10 with a U-shaped closure.

Discussion

Through our study, the MH closure rate and the VA improvement rate of large MH (diameter>400µm) was 91% and 88%, respectively, after surgery of inverted flap ILM, for all surgical techniques. The integrity of IS/OS line was achieved in 65.6% and the restoration of the inner liner of the retina in 71.5%; which is consistent with the data in the literature. These results were more significant at 3 months follow up. The assessment is objective only after complete reconstruction and healing of the different retinal layers. For decades, vitrectomy ILM peeling was the golden standard for the management of full thickness macular hole (FTMH), with MH closure rate more than 99% and significant improvement of the visual acuity [6,7]. However, this technique was not efficient for MH larger than 400µm diameter.

The inverted flap technique, introduced by Michalewska and al. at 2010 [5], has radically changed the prognosis. In fact, the authors reported an anatomical and functional success rate of 98% with this technique. According to them the inverted ILM could act as a scaffold for glial cells to proliferate, enhancing then the closure of the MH. the glial cells proliferation provides a suitable environment for the photoreceptors migration near the fovea [5]. Hence, this technique may contribute to reestablish the foveal architecture [9]. Shiod and al, demonstrated, through an experimental MH model in monkeys; that the inverted MLI provides collagen, fibronectin and laminin that accelerate the proliferation of Muller cells, which produce Neurotrophic factors and bFGF. Those may contribute to MH closure [10].

Multiple comparative studies proved the superiority of the inverted flap technique over the simple peeling of ILM for the closure of large FTMH [6]. However, the inverted flap ILM technique have some disadvantages. Michalewska reported the risk of flap detachment at the time of air tamponade or early in the postoperative course.

Some other authors reported a decrease in the VA, an expansion of retinal pigmentary epithelioma atrophy, or the development of dissociated optic nerve fiber layer syndrome (DONFL) due to inverted flap ILM technique [11-14].

In our study, we compared four techniques of inverted flap MLI peeling (the classic inverted flap MLI technique to the inserted flap, the inverted flap without manipulation and the temporal inverted flap). We demonstrated the superiority of both classic inverted flap technique and without manipulation on terms of recovery of the outer and inner retinal layer structure. Unfortunately, the limited number of patients operated on by the "temporal inverted flap" technique (6 patients) does not allow conclusions to be drawn. But this technique, according to the OCT data, appears to be as safe and effective as the classic inverted flap or inverted flap without manipulation.

Rossi et al compared the inserted flap technique to the classic inverted flap (cover technique / fill technique) and concluded that Cover and Fill ILM techniques allowed similar closure rates and post-operative vision at 3 months [7]. The cover group showed better anatomical restoration and vision at 1 month while. the fill technique was more effective in closing larger MH. Parck et al confronted in a non-randomized comparative study including 41 eyes with large MHs the inverted flap technique to the inserted flap. The inserted flap ILM technique was equivalent to the inverted ILM flap technique for the closure of large MH.

However, the classic inverted flap ILM technique showed better recovery of photoreceptor layers and, consequently, better postoperative visual acuity [15]. Casini et al in a comparative prospective single-masked study, compared the classic inverted flap technique to the inverted flap without manipulation.

The study showed no statistical difference in anatomical and functional postoperative results regarding U-shape closure rate, ellipsoid zone defects, and external limiting membrane defects [16].

Retinal layer defect results mainly from micro-traumatisms caused by the ILM peeling. Recently introduced, the temporal inverted flap technique decreases the area of peeled ILM and reduce retinal trauma and DONFL [5,14,17].

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ILM flap could be considered for patients with full thickness MHs, large MHs, traumatic MHs with choroidal rupture and for failure of initial MH surgery. ILM flap technique has many variations, including the difference of the size, shape, number, and the type of MH closure.

These different technique variations may have comparable results. The recommendation is still to proceed on case-based approach. The surgeon is always invited to choose the variant that he controls to ensure best results in such sophisticated procedures [19,20].

Conclusion

In this study we found that inverted flap ILM technique is efficient for the treatment of large FTMH. The inserted flap, as a modified technique, may alter outer retinal layer and compromise final functional results despite final closure of the MH. However, these findings must be demonstrated in a larger group. The comparison needs more randomized controlled trials to rule out objective differences.

Conflict of interest: None

Ethics: The study protocol was approved by the institutional board of the institute of ophthalmology Hedi Raies Tunis, ethics committee.

Author's contribution: All authors contributed to the study conception, design, material preparation, data collection, and analysis. The first draft of the manuscript was written by Dr.Zgolli, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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