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Comparison of Rate of Epiretinal Membrane Formation Following Pars Plana Vitrectomy with and without Internal Limiting Membrane Peeling in Advanced Diabetic Eye Disease

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ABSTRACT

Pars plana vitrectomy (PPV) is the standard surgery used to treat the advanced cases of diabetic eye disease, though secondary epiretinal membrane (ERM) formation is a common adverse effect of surgery. **Objectives:** To compare the ERM formation and visual results after PPV in the ILM peel and non-ILM peel groups. **Methods:** A quasi-experimental study was done in the Department of Ophthalmology and comprised 70 patients with tractional retinal detachment that was at risk of affecting the macula. They have been well assessed ophthalmologically and divided into PPV treated with ILM peeling (Group A) and those treated with no ILM peeling (Group B). Clinical examination, OCT, and visual acuity were done as follow-ups at 2 months, 6 months, and 1 year, and analyzed in SPSS version 20.0 ($p \leq 0.05$). **Results:** Clinical ERM was found in 3 of the patients (8.6%) at 6 months of age in Group A and none in Group B (p=0.23). ERM was identified in 11% in Group A at 6 months and 14% at 1 year, with no ERM identified in Group B (p=0.114). The visual acuity in the non-ILM peel group was significantly higher than the ILM peel group at all the follow-ups ($p<0.05$). **Conclusions:** ILM peeling in PPV can decrease secondary ERM and is linked to a better visual outcome after surgery in diabetic eye disease in advanced diabetic patients.

INTRODUCTION

More than 93 million patients around the globe have diabetic retinopathy (DR), and almost a quarter of them have had a serious impairment in their eyesight. Regardless of the use of screening programs, better glycemic control, and positive treatment of proliferative diabetic retinopathy (PDR), a significant number of patients develop severe complications, including tractional retinal detachment (TRD). Around 5 percent of the patients having PDR eventually need pars plana vitrectomy (PPV) despite undergoing pan-retinal photocoagulation treatment [1]. Prolonged hyperglycemia causes endothelial injury, retinal ischemia, and vascular permeability, as well as neovascularization. In more severe DR, fibrovascular tissue infiltrates the vitreoretinal interface and tracts tangentially and anteroposteriorly, resulting in vitreous hemorrhage and retinal detachment that progresses with age [2]. The internal limiting membrane (ILM), which is composed of Müller cell foot plates, serves as a substrate

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to myofibroblasts, fibrocytes, and retinal pigment epithelial cells, which, in the long run, predisposes abnormal vitreomacular traction. Peeling of the idiopathic epiretinal membrane (ERM), chronic macular edema, and macular hole with ILM to alleviate tractional forces has become a regular surgical procedure [3]. The typical surgical treatment of advanced diabetic retinopathy is PPV, which enables the elimination of vitreous hemorrhage, fibrovascular membranes, and the subretinal fluid to reattach the retina [4]. The most common complication after the surgery is ERM formation, though. EMR that has been reported following PPV on PDR is 38.5 to 49 percent, with much lower rates being reported in cases where ILM peeling is done [5]. A number of studies have emphasized the advantages of ILM peeling when used in diabetic vitrectomy. Pehlivanoglu *et al.* managed to report a significant increase in the best-corrected visual acuity (BCVA) and a low rate of secondary ERM among patients who underwent ILM peeling as compared to those without peeling [3]. Jung et al. demonstrated that wide-area ILM peeling improves retinal elasticity and facilitates anatomical reattachment in diabetic TRD [6]. Similarly, Karahan *et al.* found improved BCVA and lower rates of secondary ERM in patients undergoing ILM peeling, with ILM peel emerging as the only factor influencing visual outcomes [7]. Optical coherence tomography (OCT), a non-invasive imaging modality using near-infrared light, provides high-resolution cross-sectional views of retinal layers and is essential for detecting early ERM formation [8, 9]. Optical coherence tomography (OCT) is a non-invasive image modality that utilizes near-infrared radiation, which allows for cross-sectional images of the retinal layers in high resolution and is required to identify early Based on the available evidence, this proposed research will compare the occurrence of secondary ERM development after PPV and after ILM peeling in patients with diabetic TRD by taking into consideration both clinical examination and the OCT at 6 months and 1 year [10-13].
The knowledge of the role of ILM peeling can also be used to further refine the surgical approach and enhance the visual results of advanced diabetic eye disease. This study aimed to compare the ERM formation and visual results after PPV in the ILM peel and non-ILM peel groups.

METHODS

A quasi-experimental study was conducted at the Department of Ophthalmology, Sir Ganga Ram Hospital, Lahore, after getting ethical approval from 5th June 2024 to 5th Dec 2024 (116-FCPS/ERC). By the WHO calculator sample size of 70 was calculated. It used the mean best corrected visual acuity (BCVA) of eyes which belonged to Group A (ILM non-peeling group) (1.69 ± 0.75 LogMAR, p=0.003) vs Group B (ILM peel group) (1.08 ± 0.63 LogMAR) by using the following formula: $n = 2\sigma2\,(Z_{1-\sigma/2} + Z_{1-\beta})^2/(\mu_1-\mu_2)^2$ [7]. Inclusion criteria were patients of all genders, aged 30-65 years, and with TRD threatening the macula. Exclusion criteria were uveitis, age-related macular degeneration, glaucoma, macular hole, and macular edema. Written and informed consent was taken from the patients after explaining the study objectives and procedure. During the initial assessment, patients were undergoing the clinical and ophthalmological assessment, including IOP measurement, anterior and posterior segment examination (for cataract, glaucoma, uveitis, and macular edema), and OCT. Vitrectomy was performed with 23G port system. 3 23G ports were made inferotemporally, superotemporally, and superonasally. The infusion line was secured. Phacoemulsification with intraocular lens implant was done in the presence of cataract. Pars plana vitrectomy was done with the removal of tractional bands with the ILM or ERM peeler. Air fluid exchange done. ILM was stained with brilliant blue dye for 3 minutes. Dye was removed with irrigation and aspiration through a vitrectomy cutter, and ILM was peeled off from the macular area (2-disc diameter) with the Finesse flex loop. Gas tamponade (SF6 or C3F8) was given at the end of surgery. Vitrectomy ports were removed one by one. Ports were closed with vicryl 6/0 suture. Subconjunctival dexamethasone (1cc) was given at the end of surgery for control of postoperative inflammation. There was standardization of surgical procedures where all the operations were done by the same experienced vitreoretinal surgeons under the same standard techniques and protocols. Follow-up visits were scheduled at Day 1 to look for anterior uveitis, 2 weeks for gas absorption and BCVA, 6 months for OCT macula and BCVA, and 1 year for OCT macula and BCVA. The major objective of this research was the formation of the epiretinal membrane at the ages of 6 months and 1 year. The secondary outcome was 6 months and 1-year BCVA. The statistical analysis of this study was done in SPSS version 20.0, where the paired t-test and Wilcoxon signed-rank test were the tests of significance of normally distributed and skewed data, respectively. A p-value of 0.05 was taken as a statistically significant value.

RESULTS

The study involved 70 participants (35 in each group A and B). Participants included 46 male and 24 female. Group A had 22 (62.9%) male and 13 (37.1%) female whereas Group B had 26 (68.6%) male and 11 (31.4%) female. Group A had 11 (31.4%) and Group B had 12 (34.3%) of participants who were ≤50 years of age. Group A had 24 (68.6%) and Group B had 23 (65.7%) of participants who were ≥50 years of age (Table 1).

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Table 1: Demographic Profile and Clinical Characteristics of Patients

Characteristics	Groups		p-value
	Group A (n=35)	Group B (n=35)	
Gender			
Male (n= 46)	22 (62.9%)	24 (68.6%)	0.615
Female (n=24)	13 (37.1%)	11 (31.4%)	
Age Groups			
≤50 Years (n=23)	11 (31.4%)	12 (34.3%)	0.799
>50 Years (n=47)	24 (68.6%)	23 (65.7%)	
Residential Status			
Rural (n= 15)	09 (25.7%)	06 (17.1%)	0.382
Urban (n=55)	26 (74.3%)	29 (82.9%)	
Socioeconomic Status			
Poor (n=24)	10 (28.6%)	14 (40.0%)	0.314
Middle Income (n=46)	25 (71.4%)	21 (60.0%)	
Duration of Diabetes			
Up to 10 Years (n=26)	12 (34.3%)	14 (40.0%)	0.621
> 10 Years (n=44)	23 (65.7%)	21 (60.0%)	
Hypertension			
Yes (n=38)	17 (26.7%)	21 (20.0%)	0.337
No (n=32)	18 (73.3%)	14 (80.0%)	
Side			
Left (n=32)	17 (48.6%)	15 (42.9%)	0.631
Right (n=38)	18 (51.4%)	20 (57.1%)	

At baseline (preoperatively) and at 2 months postoperatively, no epiretinal membrane (ERM) was detected in any patient by either clinical examination or OCT in both Group A and Group B, reflecting a 100% absence rate. By 6 months, clinically detected ERM was present in 3 patients (8.6%) belonging to Group A, while none were detected in Group B patients (p=0.23). OCT-detected ERM at 6 months also showed 4 cases (11.0%) in Group A participants, and none in Group B participants (p = 0.114). Even though these differences were not statistically significant, they suggest a trend toward higher ERM formation in Group A. At 1 year, the clinical detection of ERM increased slightly in Group A to 4 cases (11.4%), while Group B still had no cases (p=0.114). OCT-detected ERM at 1 year showed 5 cases (14.0%) in Group A and none in Group B. It has a p-value of 0.054, indicating a near-significant difference (Table 2).

Table 2: Crosstabulation of ERM Presence by Group Over Time, as Detected Clinically and via OCT

Variable	Category	Group A	Group B	Total	p-value
Preoperative ERM (Clinically Detected)	Non-Detected	35 (100.0%)	35 (100.0%)	70 (100.0%)	NA
	Detected	–	–	–	
2-Month ERM (Clinically Detected)	Non-Detected	35 (100.0%)	35 (100.0%)	70 100.0%)	NA
	Detected	–	–	–	
6-Month ERM (Clinically Detected)	Non-Detected	32 (91.4%)	35 (100.0%)	67 (95.7%)	0.23
	Detected	3 (8.6%)	0 (0.0%)	3 (4.3%)	
1-Year ERM (Clinically Detected)	Non-Detected	31 (88.6%)	35 (100.0%)	66 (94.3%)	0.114
	Detected	4 (11.4%)	0 (0.0%)	4 (5.7%)	
Preoperative ERM (OCT-Detected: Optical Coherence Tomography)	Non-Detected	35 (100.0%)	35 (100.0%)	70 (100.0%)	NA
	Detected	–	–	–	
2-Month ERM (OCT-Detected)	Non-Detected	35 (100.0%)	35 (100.0%)	70 (100.0%)	NA
	Detected	–	–	–	
6-Month ERM (OCT-Detected)	Non-Detected	31 (89.0%)	35 (100.0%)	66 (94.3%)	0.114
	Detected	4 (11.0%)	0 (0.0%)	4 (5.7%)	
1-Year ERM (OCT-Detected)	Non-Detected	30 (86.0%)	35 (100.0%)	65 (92.9%)	0.054
	Detected	5 (14.0%)	0 (0.0%)	5 (7.1%)	

The comparison of BCVA in logMAR units between Group A and Group B at different time points revealed no significant difference preoperatively (p = 0.950), indicating comparable baseline vision in both groups. However, statistically significant differences emerged following surgery. At postoperatively 2months, Group B showed significantly improved visual acuity than Group A (mean ± SD: 0.5500 ± 0.0965 vs. 0.6443 ± 0.0933; p<0.001). Same results continued at 6 months (0.3566 ± 0.0839 vs. 0.4429 ± 0.0864; p<0.001) and 1 year (0.1914 ± 0.0772 vs. 0.2526 ± 0.0901; p=0.003), suggesting that Group B achieved significantly greater improvements in visual acuity over time compared to Group A (Table 3).

Table 3: Difference of Best-Corrected Visual Acuity at Follow-Ups

Time Point	Group A	Group B	p-value
Preoperative	0.89 ± 0.06	0.88 ± 0.05	0.950
2 Months Post-op	0.64 ± 0.09	0.55 ± 0.09	<0.001
6 Months Post-op	0.44 ± 0.08	0.35 ± 0.08	<0.001
1 Year Post-op	0.25 ± 0.09	0.19 ± 0.07	0.003

Note: p-values calculated using independent sample t-tests comparing Group A participants and Group B participants at each time point.

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DISCUSSION

Surgery as a management of diabetic TRDs requires several key factors to achieve positive outcomes. Quick intervention and pre-surgical planning are quite essential, especially when a case is in the process of rapid development. The diabetic tractional retinal detachments (TRDs) continue to be technically challenging to manage [14]. So, this study is done to evaluate the rate of secondary epiretinal membrane formation in ILM peel vs non-LM peel patients of diabetic tractional retinal detachment. The study involved 70 participants (35 in each group A and B). Group A had 11 (31.4%) and Group B had 12 (34.3%) of participants who were ≤50 years of age. Group A had 24 (68.6%) and Group B had 23 (65.7%) of participants who were ≥50 years of age, which is comparable with a study by Pehlivanoglu *et al.* was 60.33 ± 6.90 years in the ILM non-peeling group and it was 56.0 ± 8.62years in the ILM peeling group [3]. However, these age differences may be attributed to each study's inclusion criteria. Regarding gender, our study revealed that Group A had 22 male (62.9%) and 13 female (37.1%). Whereas Group B had 26 (68.6%) male and 11(31.4%) female. While a study by Gelman et al. had 47.9% men in the non-peeling group and 55.9% men in the peeling group enrolled in study [15]. The internal limiting membrane (ILM), which forms the basement membrane of Müller cells, acts as the boundary between the vitreous body and the retinal nerve fiber layer and plays a crucial role in retinal development, structural integrity, and function [16, 17]. Internal limiting membrane peeling has also been applied successfully to treat another type of retinal disorders that include diabetic macular edema, epiretinal membrane, macular hole, and retinal vein occlusion [18]. In current study, at baseline (preoperatively) and at 2 months postoperatively, no epiretinal membrane (ERM) was detected in any patient by either clinical examination or OCT in both Group A and Group B, reflecting a 100% absence rate. By 6 months, clinically detected ERM was present in 3 patients (8.6%) belonging to Group A, while none were detected in Group B participants (p=0.23). OCT-detected ERM at 6 months also showed 4 cases (11.0%) in Group A, and none in Group B (p=0.114). while according to a prospective controlled trial by PY Chang and colleagues showed that at postoperative 6 months, epiretinal membrane (ERM) identified by OCT was present in 10 of 26 eyes (38.5%) in Group 1 (ILM non-peeling) and 0 of 23 eyes in Group 2 (ILM peel) (p=0.001) and in Group 1(non-peeling) ERM was present in 6 eyes (23.1%) at 6 months and in Group 2 [19]. Our study showed that at postoperative 2 months, Group B had significantly improved visual acuity than Group A (mean ± SD: 0.5500 ± 0.0965 vs. 0.6443 ± 0.0933; p<0.001). Same results were noted at 6 months (0.3566 ± 0.0839 vs. 0.4429 ± 0.0864; p<0.001) and 1 year (0.1914 ± 0.0772 vs. 0.2526 ± 0.0901; p=0.003), suggesting that Group B achieved significantly greater improvements in visual acuity over time compared to Group A. Whereas in another study by Michalewska et al. showed that preoperative visual acuity was 0.04 and postoperative visual acuity was 0.27 in both groups (23.4 months in group A, which was the ILM peel group, 60 months in group B, which was the non-ILM peel group [20]. These findings highlight the role of ILM peeling after pars plana vitrectomy to prevent secondary ERM formation in advanced diabetic eye disease patients.

CONCLUSIONS

In conclusion, our study stresses the role of ILM peeling in the prevention of secondary ERM formation and improved BCVA in patients with diabetic TRDs.

Authors Contribution

Conceptualization: MJ
Methodology: MJ
Formal analysis: MJ, HK, NIA, AR, KC, SA
Writing review and editing: MJ, UM

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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