PARS PLANA VITRECTOMY WITH AND WITHOUT INTERNAL LIMITING MEMBRANE PEELING FOR DIABETIC PATIENTS WITH MACULA INVOLVED TRACTIONAL RETINAL DETACHMENT

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Purpose: To evaluate the effect of internal limiting membrane (ILM) peeling on anatomical and functional results in pars plana vitrectomy performed eyes with tractional retinal detachment affecting the macula because of diabetes mellitus.

Methods: Patients without ILM peeling were considered as Group 1, and patients with ILM peeling were considered as Group 2. The main outcomes were the best-corrected visual acuity at 6 months and the rate of epiretinal membrane formation within 6 months. The rate and the indications for resurgery were determined. Parameters affecting the final best-corrected visual acuity were determined by regression analysis.

Results: Final best-corrected visual acuity was significantly better in eyes with ILM peeled off than in eyes with no peel-off ($P = 0.012$). Less secondary epiretinal membrane was formed in Group 1 ($P = 0.009$). There was no difference between groups in resurgery rates ($P = 0.143$). The need for resurgery because of epiretinal membrane was higher in Group 1 rather than Group 2 ($P = 0.001$). The only factor affecting the final best-corrected visual acuity was ILM peeling.

Conclusion: In patients with tractional retinal detachment affecting the macula because of diabetes, ILM peeling in addition to pars plana vitrectomy and membrane excision does not affect the need for resurgery but contributes positively to anatomical and functional outcomes.

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Diabetic retinopathy (DRP) is an important cause of blindness worldwide and its importance is increasing as a serious public health problem.[1] Satisfactory functional results can be achieved as a result of panretinal laser photocoagulation in proliferative DRP and anti–vascular endothelial growth factor (anti-VEGF) applications in diabetic maculopathy.[1] However, some patients with DRP continue to experience severe vision loss. Tractional retinal detachment (TRD) is the most difficult group of patients among patients with DRP.[2]

In most of the patients with severe proliferative diabetic retinopathy (PDR), pars plana vitrectomy (PPV) could be performed successfully. In PPV, it is aimed to separate the vitreoretinal tractions from retinal surface and obtain a reattached, healthy retina. However, in a significant proportion of cases, epiretinal membrane (ERM) develops after PPV by covering the macular surface and disrupting the macular anatomy, resulting in poor visual success. Depending on the degree of visual impairment, it could be necessary to perform revision surgery in some of these patients.[3–5]

Internal limiting membrane (ILM) peeling is recommended as an effective method to reduce ERM formation after PPV in these patients.[6] Internal

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limiting membrane can act as a scaffold for glial and retinal pigment epithelial cells, especially in patients with a pathologic vitreoretinal interface. If dense cell accumulation occurs on ILM, the adhesion between the ILM and the posterior vitreous increases, and thus, the ILM contributes to the pathophysiology of macular diseases.[7] Peeling of the ILM from the retinal surface may lead to the disappearance of this scaffold, thereby reducing the incidence of postsurgical ERM.[8,9] Although ILM peeling reduces the recurrence of ERM and macular edema, it may damage not only the Müller cells but also other retinal cells histologically. Indeed, the structure of the macular region has reportedly changed after ILM peeling.[6,10]

There have been studies examining whether ILM peeling affects the prognosis of the patients who underwent PPV for TRD because of PDR, but patients with and without macular involvement were evaluated together in these studies.[8,9] The goal of the current study was to compare the postoperative anatomical and functional results of diabetic patients who had PPV with and without ILM peeling in patients with severe TRD with macular involvement.

Materials and Methods

In this study, the medical records of 89 patients who underwent PPV for TRD secondary to PDR at Balıkesir University Faculty of Medicine between May 2019 and May 2021 were reviewed retrospectively. Those who had previously undergone PPV for any reason, had inaccurate perioperative and postoperative data, had ophthalmologic diseases other than DRP and cataracts that could cause vision loss, and had no follow-up for >6 months were excluded from the study. Eyes that had no macular involvement of fibrovascular proliferation were also excluded. Finally, 69 eyes of 60 patients were included. All participants provided written informed consent to participate in the study. The study adhered to the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Balıkesir University Hospital (Registration Number: 2021/104).

Patients' age, gender, diabetes mellitus (DM) duration, preoperative hemoglobin A1c level, lens status, characteristics of the fibrovascular tissue detected during surgery, complications in the surgery, and the type of tamponade were noted. Patients were divided into 2 groups: cases who had surgery without concomitant ILM peeling between May 2019 and June 2020 were accepted as Group 1, and patients in Group 2 had ILM peeling after the removal of fibrovascular proliferation between July 2020 and May 2021. PPV was performed in all patients with a 23-gauge EVA (Dutch Ophthalmic Research Center, DORC, Zuidland, the Netherlands) system, using a wide-angle noncontact viewing system (EIBOS-2, Haag-Streit Surgical, Germany). The patients were examined on the first day, first week, first month, third month, and sixth month postoperatively. Controls were continued every 3 to 6 months in patients who did not encounter any problems after the sixth month visit. Findings in the sixth month after PPV were accepted as the final findings in the study. In 18 eyes of 15 patients in Group 1, intravitreal anti-VEGF therapy was being administered, although not regularly. In 12 eyes of 11 patients in Group 2, anti-VEGF therapy was being administered in the presurgery period. None of the patients had received anti-VEGF therapy within 3 months before the decision for surgery. After the surgery decision was made, intravitreal bevacizumab 0.05 mL/1.25 mg was administered 3 to 7 days before surgery in patients who did not have any contraindications because of the side effects of anti-VEGFs. In the postoperative period, macular edema was followed and intravitreal anti-VEGF or dexamethasone 0.7 mg implant application was performed in patients if necessary.

At each visit, patients underwent a complete ophthalmologic examination, including best-corrected visual acuity (BCVA), intraocular pressure measurement (with Goldmann applanation tonometer), slit-lamp examination, and dilated fundus examination. Intraocular pressure values >30 mmHg and <6 mmHg were considered as hypertonia and hypotonia, respectively; complications such as postoperative retinal detachment and endophthalmitis were determined. Revision surgery was performed according to the surgeon's preference in cases of macula involved TRD or rhegmatogenous retinal detachment, vitreous hemorrhage that did not resolve spontaneously within 3 months, and clinically significant ERM development on the retina. Epiretinal membrane affecting only the macula was present in patients who underwent surgery for ERM; none of these eyes had macula involved TRD or rhegmatogenous retinal detachment. Semitransparent opaque premacular tissue with stretching and distortion of retinal vessels or surface wrinkling on biomicroscopic examination was accepted as clinically evident ERM. The tomographic findings of the eyes that could be adequately evaluated with optical coherence tomography (OCT) were also noted. Optical coherence tomography images were obtained at the first-, third-, and sixth-month follow-ups. Evaluation of the presence of ERM with OCT was not reflected in the statistics in the eyes that could not obtain the desired quality OCT image in none of these follow-ups.

Surgical Procedure

The bimanual method was used in all patients. A twinlight chandelier was implanted between superotemporal and superonasal trocars after three trocars were placed. A central vitrectomy was performed in all eyes. After core vitrectomy, 360° vitreorrhexis was applied to the vitreous tissue around the traction area, the appropriate area was determined at the vitreoretinal interface, and all the supraretinal membranes were peeled off from the retina, starting from this area. Intravitreal triamcinolone (40 mg/mL, Kenacort; Bristol-Myers Squibb, New York, NY) was used in all patients for better visualization of the posterior vitreous. After all the membranes were removed, the infusion was interrupted and membrane blue (MembraneblueTM 0.15% Trypan Blue Ophthalmic Solution syringes of 0.5 mL; Dutch Ophthalmic Research Center, DORC, Zuidland, the Netherlands) was injected rigorously to the retinal surface and waited for 2 minutes. The ILM was peeled from the retinal surface to a width of at least 3 disc diameters. Eyes with insufficient previous panretinal laser photocoagulation had additional intraoperative panretinal laser photocoagulation. Phacoemulsification, ocular tamponade, intraocular lens implantation, intravitreal injection of an anti-VEGF, and intravitreal or posterior sub-Tenon's triamcinolone acetonide injection were performed based on the surgeon's determination. In eyes treated with silicone oil (SO) endotamponade, SO (SILIKON TM 1000; Alcon, Fort Worth, TX) was injected after fluid–air exchange. All surgeries were performed by one experienced surgeon (E.K.). A standardized postoperative treatment scheme including topical moxifloxacin 0.5% eye drops (Vigamox; Alcon Laboratories, Fort Worth, TX) and topical dexamethasone 1% (Maxidex; Alcon Laboratories) therapy was administered 4 times daily for 1 week and 1 month, respectively. Main outcome measures were BCVA, anatomical success, and development of ERM at the final follow-up.

Statistical Analysis

Snellen visual acuity was converted into logMAR for statistical analysis. Statistical analyses were performed using the Statistical Package for Social Sciences, for Windows V.20 (SPSS, Inc, Chicago, IL). All values were reported as mean ± SD. Categorical variables were expressed as proportions (n, %), and group differences were analyzed using Chi-square or Fischer's exact test. The normality of the data distribution was evaluated by Shapiro–Wilk test. The paired *t*-test was used for the difference between the parameters in the preoperative and postoperative examinations in groups, and Chi-square test was used for parametric values. For the differences of parametric values between the two groups, *t*-test for independent groups was used. The relationship between the parameters was evaluated by regression analysis. *P*-values < 0.05 were considered statistically significant.

Results

Group 1 included 41 eyes of 35 patients and there were 28 eyes of 25 patients in Group 2. Table 1 demonstrates the baseline clinical characteristics of all participants. No significant differences existed between two groups regarding age, gender, duration of DM, and basal hemoglobin A1c level. No significant difference was found in the extent of fibrovascular proliferation and the lens status between two groups.

There were no differences between groups regarding preoperative laser or anti-VEGF application rate, type of tamponade, rate of combined surgery, the occurrence of iatrogenic retinal tear, and follow-up time (Table 2). Combined surgery was performed in 5 of 30 phakic eyes in Group 1 and 6 of 18 phakic eyes in Group 2. During the sixth-month follow-up period, uncomplicated cataract surgery was performed in 6 eyes of Group 1 and in 1 eye of Group 2. There was no difference between two groups in the final lens condition ($P = 0.189$). During the 1-, 3-, and 6-month follow-up period, intravitreal anti-VEGF and/or dexamethasone implant treatment was performed in 6 eyes in Group 1 and 5 eyes in Group 2 because of macular edema ($P = 0.568$).

Mean preoperative BCVA was 1.76 ± 0.46 in Group 1 and 1.82 ± 0.39 in Group 2 ($P = 0.277$). At the final visit, mean BCVA was 1.30 ± 0.59 in Group 1 and 0.92 ± 0.67 in Group 2 at the final visit ($P = 0.012$). Final BCVA was better than hand motions in 28 of 41 eyes in Group 1 and in 23 of 28 eyes in Group 2 ($P = 0.157$). Final BCVA was ≥20/200 in 19 of 41 eyes (46.3%) in Group 1 and 21 of 28 eyes (75.0%) in Group 2 ($P = 0.016$) (Figure 1).

Multivariate linear regression analysis revealed that the only predictor of visual outcome was whether the ILM has been peeled. Any other parameter was not found associated with visual outcome (Table 3). Retinal attachment was achieved in 90.2% of Group 1 and 89.3% of Group 2 ($P = 0.600$). Sixteen eyes (39.0%) in Group 1 developed clinically significant ERM, whereas 3 eyes (10.7%) in Group 2 had clinically significant ERM ($P = 0.009$) within 6 months (Figures 2 and 3). Optical coherence tomography images could be obtained in 24 of 41 eyes in Group 1 and 19 of 28

Table 1. Baseline Demographics and Clinical Data of the Patients

	Group 1 (n = 35 Patients, 41 Eyes)	Group 2 (n = 25 Patients, 28 Eyes)	*P*
Gender			
Male	17	12	0.879
Female	18	13	
Age, years (mean ± SD)	53.3 ± 6.9	56.2 ± 9.1	0.165
Hemoglobin A1c (%; mean ± SD)	8.1 ± 1.1	8.3 ± 0.9	0.457
Duration of diabetes mellitus, years	11.7 ± 6.3	10.8 ± 8.2	0.568
Lens status			
Phakic eyes (%)	30 (73.1)	18 (64.3)	0.300
Pseudophakic eyes (%)	11 (26.9)	10 (35.7)	
Preoperative panretinal laser (%)	56.1	60.7	0.448
Preop anti-VEGF (%)	66.7	56.9	0.330
Fibrovascular proliferation involving quadrant (mean ± SD)	2.5 ± 0.7	2.6 ± 0.8	0.643
Extent of fibrovascular proliferations (n/n) (Grade 1/2)*	18/23	12/16	0.321
Preoperative visual acuity, logMAR (mean ± SD)	1.76 ± 0.46	1.82 ± 0.39	0.605

*Grading of the extent of fibrovascular proliferation was defined as follows: Grade 1 focal adhesions only; Grade 2 broad adhesion ≥1sites.

eyes in Group 2. In Group 1, regular OCT scans could not be performed in 8 eyes because of vitreous hemorrhage or retinal detachment requiring reoperation, in 4 eyes because of VH that did not require surgery, and in 5 eyes because of cataract. In Group 2, regular OCT images could not be obtained because of vitreous hemorrhage or retinal detachment requiring surgery in 7 eyes, vitreous hemorrhage not requiring surgery in one eye, and cataract in one eye. Epiretinal membrane was present in 18 of those 24 eyes (75.0%) in Group 1 and in 5 of 19 eyes (26.3%) in Group 2 ($P < 0.001$). The mean central retinal thickness was 378 ± 126 μm in Group 1 and 269 ± 87 μm in Group 2 ($P < 0.001$). Nine patients in Group 1 and 5 patients in Group 2 required ocular antihypertensive agents for temporary intraocular pressure elevation that resolved within 3 months ($P = 0.345$). Nine eyes (22.0%) in Group 1 and 5 eyes (17.8%) in Group 2 had vitreous hemorrhage postoperatively ($P = 0.189$). Fourteen of 41 eyes (34.1%) in Group 1 and 7 eyes in Group 2 (25.0%) had resurgery ($P = 0.143$). The reason for resurgery was ERM in 6 eyes of Group 1; none of the eyes were operated for recurrent ERM in Group 2 ($P = 0.001$). In Group 1, 3 eyes were reoperated for tractional and accompanying rhegmatogenous retinal detachment and 1 eye was reoperated for fibrovascular proliferation affecting the macula. Reoperation was performed for tractional and accompanying rhegmatogenous

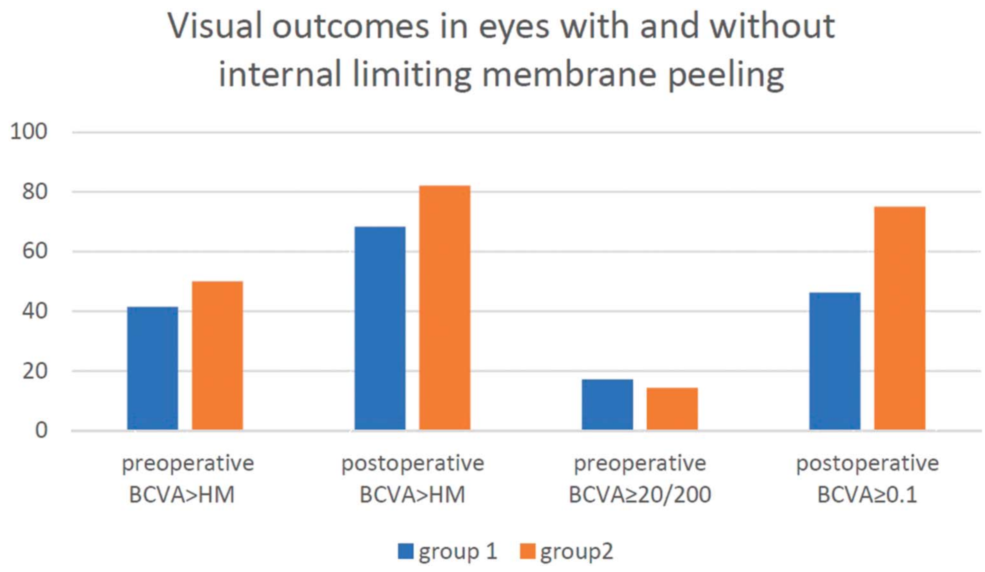

Fig. 1. Visual outcomes in eyes with and without internal limiting membrane peeling.

retinal detachment in 3 eyes in Group 2. No additional ILM peeling was performed in these eyes other than cleaning the membranes on the macula. Table 4 demonstrates the causes of resurgeries in the groups.

Discussion

In patients with TRD affecting the macula, the prognosis is extremely poor if surgery is not performed. However, even with completely appropriate surgery, some of these patients cannot achieve the desired functional results. The surgical success rate in diabetic TRD has increased significantly compared with previous years. In recent studies, anatomical success has been reported as around 90% and the rate of patients with severe visual impairment is below 25%.[8,9,11] Whereas, in a study that reports the outcomes of vitrectomy for TRDs, only 66% of eyes achieved successful reattachment of the retina and 41% of patients had visual acuity worse than 20/800.[12]

A significant cause of inadequate visual acuity levels is ERM developed after PPV. The epiretinal membrane could occur after PPV for any indication, but it occurs more frequently after PPV for PDR, and some patients require revision surgery because of clinically significant ERM.[13,14] In this group of patients, the risk of ERM is high because of the activity of retinopathy, the presence of dense fibrovascular tissues on the retina, and the development of vitreous hemorrhage after surgery.[15] The microscopic remnants remaining on the retina after surgery act as a mold, and the membrane on and around this mold becomes dense and widespread.[15] In the current study, 27.5% of our study group had clinically significant ERM 6 months after surgery. Revision surgery was needed in six (8.6%) of these cases.

Data about the positive effects of ILM peeling in surgeries for macular holes, idiopathic ERM, and diabetic macular edema has taken its place in the literature.[9,10,16] There is a paucity of studies to show whether the positive effect of ILM peeling is valid for PDR patients.[12] Postoperative ERM formation could be decreased by ILM removal because ILM removal provides removal of proliferating astrocytes and myofibroblasts over ILM tissue.[17,18] In addition, ILM peeling ensures that posterior hyaloid is precisely separated from the macular surface. It has been shown by transmission electron microscopy that residual posterior hyaloid can still be found on the ILM despite using triamcinolone-assisted vitrectomy.[19] The purpose of the ILM peeling procedure is the complete removal of fibrous tissue residues located on the ILM surface together with the ILM and vitreous

Table 2. Peroperative and Postoperative Results of Vitrectomy With or Without Internal Membrane Peeling

	Group 1 (n = 41 Eyes)	Group 2 (n = 28 Eyes)	*P*
Type of tamponade (%)			
None	22.0	25.0	0.239
Air	26.8	14.3	
SF_6	9.8	28.6	
C_3F_8	4.9	7.1	
Silicone oil	36.6	25.0	
Combined surgery (%)	5 (12.2)	6 (21.4)	0.242
Final lens status			
Phakic eyes (%)	19 (46.3)	11 (39.3)	0.189
Pseudophakic eyes (%)	22 (53.7)	17 (60.7)	
Iatrogenic retinal tear (%)	12.2	10.7	0.584
Intravitreal treatment for macular edema (%)	14.6	17.8	0.568
Single-surgery anatomical success (%)	65.9	75.0	0.453
Final anatomical success (%)	90.2	89.3	0.600
Resurgery (%)	34.1	25.0	0.143
Mean BCVA at the final visit, logMAR	1.30 ± 0.59	0.92 ± 0.67	0.012
Change in BCVA			
Improved ≥2 lines	45.9	70.6	0.135
Stable	45.9	17.6	
Decreased ≥2 lines	8.2	11.8	
BCVA ≥20/200 at the final visit	46.3	75.0	0.016
No light perception vision at the final visit (%)	9.7	7.1	0.467
Follow-up time (months)	13.1 ± 4.2	12.2 ± 3.6	0.438

Table 3. Results of Multivariate Regression Analysis of Factors Affecting the Final Visual Acuity

	Beta	t	*P*
Preoperative BCVA	−0.066	−0.511	0.612
Age	0.120	0.811	0.421
Type of DM	−0.154	−1.097	0.277
Final lens status	0.192	1.447	0.153
Preoperative laser	0.150	1.183	0.242
Preoperative anti-VEGF	−0.079	−0.545	0.588
Fibrovascular proliferation involving quadrant	0.184	1.608	0.113
Extent of fibrovascular proliferations	−0.074	−0.660	0.512
Iatrogenic retinal tear	0.152	1.307	0.197
Retinal tamponade	0.118	0.976	0.333
Combined surgery	0.122	0.917	0.363
ILM peeling	−0.368	−0.3242	0.002

residues because of vitreoschisis. When the peeled ILM tissues in diabetic patients were examined, it was observed that they were thicker and had much more cell content than nondiabetic patients.[19] Moreover, addressing the ILM within the macular region can ensure or assist the surgeon in obtaining a reasonable dissection plane and devoid of adherent posterior hyaloid.

Although ILM peeling could reduce the incidence of ERM development, there might be deleterious consequences of ILM peeling in regard to retinal anatomy. Damage to the skeleton of the retina may be caused by ILM peeling. Secondary to epiretinal traction, an increase in the expression of the intermediate filament protein glial fibrillary acidic protein occurs, which increases gliosis and adhesions between the intraretinal cells and the ILM.[6] Damage to gliotic Müller cells through ILM peeling may result in collapse of intraretinal tissues and atrophy of the outer retinal layers.[6]

In the study of Chang et al, patients who underwent PPV for TRD because of DRP were divided into two groups as ILM peeled and nonpeeled patients. The rate of ERM that could be identified by OCT was 38% in those without ILM peeling and 0% in those with ILM peeling. It was determined that the only factor associated with poor visual prognosis was the nonpeeled ILM.[8] In our study, it was also determined that the only important factor affecting visual prognosis was ILM peeling. Mehta et al reported that ERM formation and necessity of revision surgery were significantly reduced through ILM peeling after diabetic vitrectomy. The clinically evident ERM formation was significantly lower in ILM-peel group (4% vs. 20%), and fewer revision surgeries were required in ILM-peel group (2% vs. 14%). Visual acuity in the ILM-peel group was significantly better than the control group at 3 months (0.35 vs. 0.50).[9] In our study, it was determined that less ERM developed in the ILM peeled patients, none of the ILM peeled patients required revisional PPV for ERM, and finally, better visual gain was obtained in ILM peeled patients. According to the results of our study, it was concluded that it was a correct approach to peel the ILM additionally after the posterior hyaloid was removed and the tractional membranes peeled in patients whose macula is affected by tractions. In the above-mentioned previous studies that compare the patients with and without ILM peeling, patients with and without macular involvement were evaluated together.[8,9] However, it would be more appropriate to evaluate patients with and without macular involvement separately because ERM incidence would be different in eyes with and without macular involvement. To the our best knowledge, our study is the first to evaluate only patients with macular detachment secondary to

Table 4. Reason for Resurgery in Eyes With or Without Internal Membrane Peeling

	Group 1 (n = 41)	Group 2 (n = 28)	*P*
Total number of resurgery (%)	14 (34.1)	7 (25.0)	0.143
Macula involved TRD or rhegmatogenous retinal detachment (%)	4 (9.7)	3 (10.7)	0.349
Vitreous hemorrhage (%)	4 (9.7)	4 (14.3)	0.121
Epiretinal membrane (%)	6 (14.6)	0 (0.0)	0.001

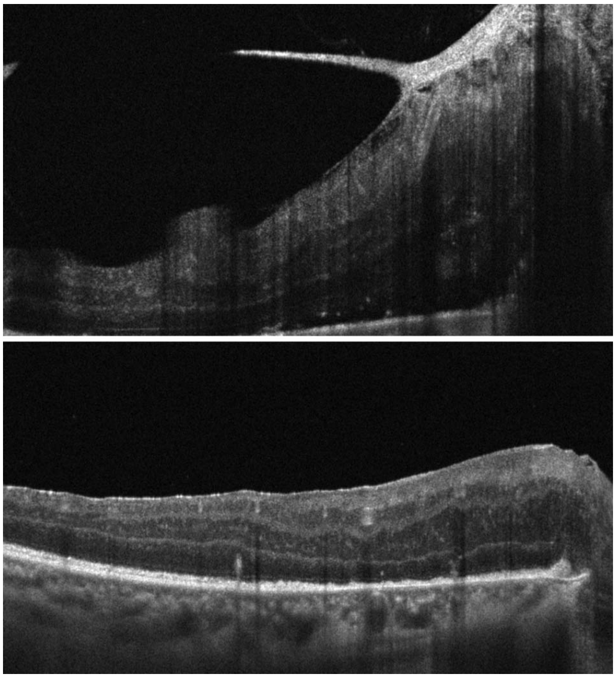

Fig. 2. The preoperative (top) and postoperative (bottom) OCT images of a non–ILM peeled patient. In preoperative sectional image, the tractional membrane and tractional retinal detachment are displayed. In postoperative period, the retina is visualized as attached, and the foveal contour was unavailable.

tractional forces and exclude eyes without macular involvement.

As a matter of fact, ERM evaluation with biomicroscopic examination alone is not sufficient. With OCT, both postoperative ERM formations are better observed and intraretinal edema or residual vitreous remnants can be detected better. In our study, when the patients who could be evaluated with OCT were examined, ERM was detected at a rate of 75% in the non–ILM-peel group and 26.3% in the ILM-peel group. Central retinal thickness at sixth examination was significantly thinner in the ILM-peel group. The thinner macula might be because of damage to the endoskeleton of the retina as a result of ILM peeling. However, when our functional results were evaluated, the healthy vitreomacular interface obtained by ILM peeling might be more important than atrophy of the macula because it would not be possible to achieve such good visual results if macular atrophy was the main reason for retinal thinning. Undoubtedly, to reach this conclusion, the degree of ischemia in the macula needs to be evaluated in detail. Without determining the degree of ischemia, it is not possible to reach a conclusion about the visual results by only looking at the anatomical condition of the macula. In addition, a detailed examination of the photoreceptor, inner nuclear, and ganglion layers of the macula will enable a complete determination of functional success. In patients with and without ILM peeling, the proportion of patients whose light sensation disappeared in the final examination was found to be close to 10%. Retinal nerve fiber analysis in the preoperative period could not be performed completely because of intense tractions. Considering that a significant portion of the patients was not treated regularly, it can be thought that some of these patients had glaucomatous damage that was not treated in the preoperative period. Because of the retrospective nature of the study, it was not possible to reach a definite conclusion on this subject.

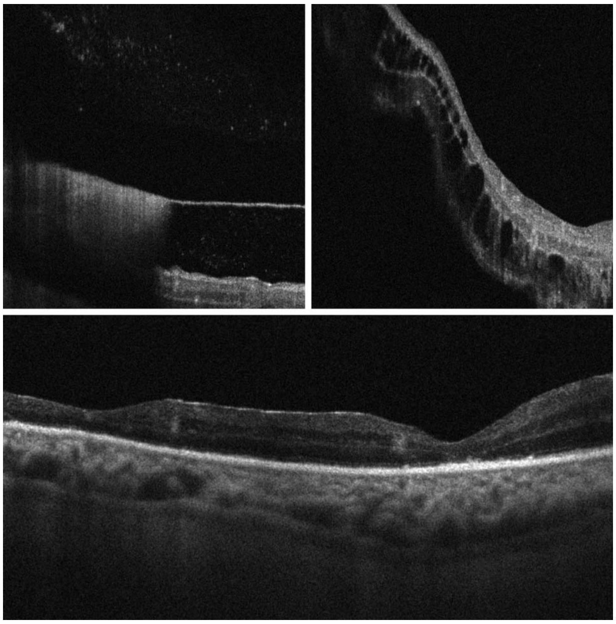

Fig. 3. Preoperative tractional membranes (upper left) and tractional retinal detachment (upper right) are displayed in an ILM peeled patient. In postoperative OCT images, the appropriate foveal contour was available (bottom).

The most important limitation of our study was retrospective design. Real randomization was not performed for the decision of ILM peeling. The poor quality of OCT images in some of the patients made it impossible to perform a healthy OCT evaluation. In addition, the inadequate evaluation of the macular ischemia through fundus fluorescein angiography and OCT angiography weakens our results in the reliability of functional outcomes.

As a result, patients with TRD because of DRP and whose macula is affected are the most difficult group to treat among DRP patients. In our study, it was determined that ILM peeling in addition to routine surgery had a positive effect on postoperative results in these patients. Prospective studies are needed to evaluate the effect of ILM peeling on functional outcomes in this specific group of patients.

Key words: diabetic retinopathy, epiretinal membrane, internal limiting membrane, macula surgery, pars plana vitrectomy, tractional retinal detachment.

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