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Pars plana vitrectomy and removal of the internal limiting membrane in diabetic macular edema unresponsive to grid laser photocoagulation

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PURPOSE. *To evaluate the effectiveness of pars plana vitrectomy (PPV) with removal of the internal limiting membrane (ILM) in diabetic patients with macular edema unresponsive to grid laser photocoagulation.*

METHODS. *In this randomized controlled study, 20 eyes of 10 patients with diabetic macular edema unresponsive to grid laser photocoagulation were evaluated. PPV with ILM removal was performed randomly in one eye each of 10 patients and taken as the study group; the untreated fellow eyes were taken as the control group. Main outcome measures were foveal thickness changes measured with optical coherence tomography and preoperative and postoperative visual acuity. Mann-Whitney U, Wilcoxon, and chi-square tests were used in statistical analysis.*

RESULTS. *The mean age of the patients was 61.5±6 years (range 51 to 71). All patients were followed up for 12 months. In the study group, mean foveal thickness was 391.3±91.6 µm preoperatively and 225.5±49.4 µm postoperatively (p=0.009). In the control group, mean foveal thickness was 356.2±140 µm at baseline and 318.4±111.1 µm at 12-month follow-up (p=0.138). Mean decrease in foveal thickness was 165.8±114.8 µm in the study group and 37.8±71.2 µm in the control group (p=0.016). In the study group, best-corrected logMAR visual acuity was 0.71±0.43 preoperatively and 0.54±0.45 postoperatively (p=0.125). In the control group, best-corrected logMAR visual acuity was 0.43±0.44 at baseline and 0.59±0.55 at 12-month follow-up (p=0.235). In the study group, visual acuity improved by two or more lines in 4 eyes (40%) and remained stable in 6 eyes (60%). In the control group, visual acuity improved by two or more lines in 1 eye (10%) and decreased by two or more lines in 3 eyes (30%).*

CONCLUSIONS. *PPV with ILM removal appears to be an effective procedure for reducing diabetic macular edema unresponsive to grid laser photocoagulation. A further study with a large number of patients is required to assess the effectiveness and safety of this procedure. (Eur J Ophthalmol 2006; 16: 573-81)*

KEY WORDS. *Diabetic macular edema, Grid laser photocoagulation, Internal limiting membrane, Pars plana vitrectomy*

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INTRODUCTION

Diabetic macular edema is the major cause of visual loss in diabetic patients and has been shown to occur in approximately 29% of patients with duration of disease of 20 years or more (1). The Early Treatment Diabetic Retinopathy Study Research Group has shown that focal laser photocoagulation reduces the risk of moderate visual loss by 50% in eyes with clinically significant diabetic macular edema (2). In diffuse diabetic macular edema, it has been reported that grid laser photocoagulation stabilizes or improves best-corrected visual acuity in 75.4% of eyes, while 24.6% of eyes experiences loss of vision after 3 years follow-up (3).

Since the observation that eyes with diabetic macular edema have a significantly higher incidence of an attached posterior vitreous than eyes without macular edema, several studies have suggested that pars plana vitrectomy (PPV) decreases macular edema and improves visual acuity (4-7). In recent studies, various authors have performed PPV with removal of the internal limiting membrane (ILM) and have reported diminution or resolution of diabetic macular edema (8-11). However, controlled studies are required to establish the role of PPV with ILM removal in the treatment of diabetic macular edema.

The purpose of this prospective controlled study was to evaluate the effectiveness and safety of PPV with ILM removal in diabetic macular edema unresponsive to grid laser photocoagulation.

METHODS

In this prospective controlled study, 20 eyes of 10 patients with bilateral diabetic macular edema unresponsive to grid laser photocoagulation were evaluated at Haydarpasa Numune Education and Research Hospital between March 2002 and December 2004. This study included eyes that underwent prior grid laser photocoagulation and had persistent macular edema bilaterally during 6 months follow-up. Eyes that met the following criteria were excluded: 1) with unilateral macular edema; 2) treated with grid laser photocoagulation within 6 months; 3) treated with only focal laser photocoagulation; 4) treated with panretinal photocoagulation within 12 months; 5) that underwent vitreoretinal surgery; 6) that underwent cataract surgery within 12 months; 7) with traction retinal detachment, active neovascularization; 8) with media opacity such as cataract or vitreous hemorrhage; 9) with evidence of vitreomacular traction (taut and thickened posterior hyaloid or epiretinal membrane). None of the eyes showed any evidence of vitreomacular traction in preoperative fundus and optical coherence tomography (OCT, Humphrey Instruments, San Leandro, CA) examinations. All patients gave their informed consent prior to inclusion in the study.

PPV with ILM removal was performed unilaterally in 10 eyes of 10 patients, and these eyes were defined as the study group. The untreated fellow eyes were defined as the control group. The eye to be operated on was randomly selected.

Preoperative and postoperative best-corrected Snellen visual acuities were recorded and converted into logMAR (the logarithm of the minimum angle of resolution) units. The visual acuity in all eyes was taken at the same place and under the same conditions by the same investigator who was masked to the study. All patients received an anterior segment examination and biomicroscopic evaluation with both fundus noncontact and contact lenses. Foveal thickness was measured with OCT. Three vertical and horizontal manually assisted OCT scans were obtained at the center of the macula and analyzed from each studied eye by the same experienced ophthalmologist who was also masked to the conditions of the patients.

All of the patients had type II diabetes mellitus. Mean duration of diabetes was 12.9±7.5 years (range 6 to 30). Four patients were treated with oral hypoglycemic medication and 6 patients with insulin. There was no significant difference between the study and control groups preoperatively in terms of the type of diabetic retinopathy, type of macular edema, the duration of visual impairment, the length of time since the diagnosis of macular edema, receiving macular laser photocoagulation, and the number of eyes that had received panretinal laser photocoagulation (Tab. I). Both eyes of seven patients, which had undergone one session of macular laser photocoagulation, had been treated outside our institution, and details concerning these treatments were not available. In these eyes, extensive laser spots were observed in the macular region. The remaining six eyes of three patients, which had been treated in our institution, had undergone two sessions of grid photocoagulation combined with focal laser treatment. Total number of macular laser spots per eye was 441, 354, and 293 (mean 363 spots) in the study group and 390, 412, and 341 (mean 381 spots), respec-

tively, in the control group. None of the patients underwent intraocular surgery previously except one patient who had bilateral cataract operation.

Mean foveal thickness at baseline was 391.3±91.6 µm in the study group and 356.2±140 µm in the control group. The difference between the two groups was not significant (p=0.174, Mann-Whitney U test). Best-corrected logMAR visual acuity was 0.71±0.43 in the study group and 0.43±0.44 in the control group (p=0.084, Mann-Whitney U test).

The surgical procedure performed by the same surgeon (A.Y.) was a standard three-port PPV. After core vitrectomy, posterior vitreous detachment was achieved with a silicone-tipped cannula by active aspiration and then continued 360° peripherally. ILM that was stained with 0.1% (1 mg/mL) indocyanine green (ICG) under intravitreal air was peeled from the macula using intravitreal forceps. At the end of the surgery, subconjunctival injections of dexamethasone (2 mg) and gentamicin (4 mg) were administered.

Patients were examined postoperatively at 1 day, 3 days, 1 week, 1 month, 3 months, 6 months, 1 year, and every 6 months thereafter. OCT measurements were recorded postoperatively at 1 month, 3 months, 6 months, and 1 year. Topical prednisolone acetate was administered six times a day in the first 2 weeks and then four times a day for 6 weeks, ciprofloxacin six times a day for 2 weeks, and tropicamide three times a day for 4 weeks.

Mean outcome measures were preoperative and postoperative visual acuity and foveal thickness changes in the study and control groups as well as intraoperative and postoperative complications. Mann-Whitney U, Wilcoxon, and chi-square tests were used for statistical analysis.

RESULTS

Of the 10 patients, 4 were men and 6 were women. Mean age was 61.5±6 years (range 51 to 71). All patients were followed up for 12 months. Table II shows serial measurements of foveal thickness for each patient. The mean foveal thickness changes in the study and control groups are summarized in Figure 1. In the study group, the mean foveal thickness was 391.3±91.6 µm preoperatively and 225.5±49.4 µm at postoperative 12 months (p=0.009, Wilcoxon test), whereas in the control group it was 356.2±140 µm at baseline and 318.4±111.1 µm at 12-month follow-up (p=0.138, Wilcoxon test).

At 12-month follow-up, the mean decrease in foveal thickness was 165.8±114.8 µm (42.3%) in the study group and 37.8±71.2 µm (10.6%) in the control group.

TABLE I - COMPARISON OF PREOPERATIVE CHARACTERISTICS BETWEEN THE STUDY AND CONTROL GROUPS

	Study group	Control group	p
DR type, n (%)			
NPDR	6 (60)	6 (60)	
PDR	4 (40)	4 (40)	
ME type, n (%)			1.00*
DME	7 (70)	8 (80)	
CME	3 (30)	2 (20)	
Duration of visual impairment (mo), mean ± SD	27.2±18.4	25.4±17.8	0.667†
Time since diagnosis of ME (mo), mean ± SD	28.3±18.4	27.7±18.9	0.614†
Time since macular laser (mo), mean ± SD	22.7±14.9	22.4±15	0.848†
Macular laser treatment, n (%)			
1 session	7 (70)	7 (70)	
2 sessions	3 (30)	3 (30)	
Mean number of macular laser spots/eye (grid/focal x 2) ‡	363	381	§
PRP, n (%)	4 (40)	4 (40)	

*Chi-square test
†Mann-Whitney U test
‡Includes only three patients
§Statistical analysis was not performed because of small number of patients
DR = Diabetic retinopathy; NPDR = Nonproliferative diabetic retinopathy; PDR = Proliferative diabetic retinopathy; ME = Macular edema; DME = Diffuse macular edema; CME = Cystoid macular edema; PRP = Panretinal photocoagulation

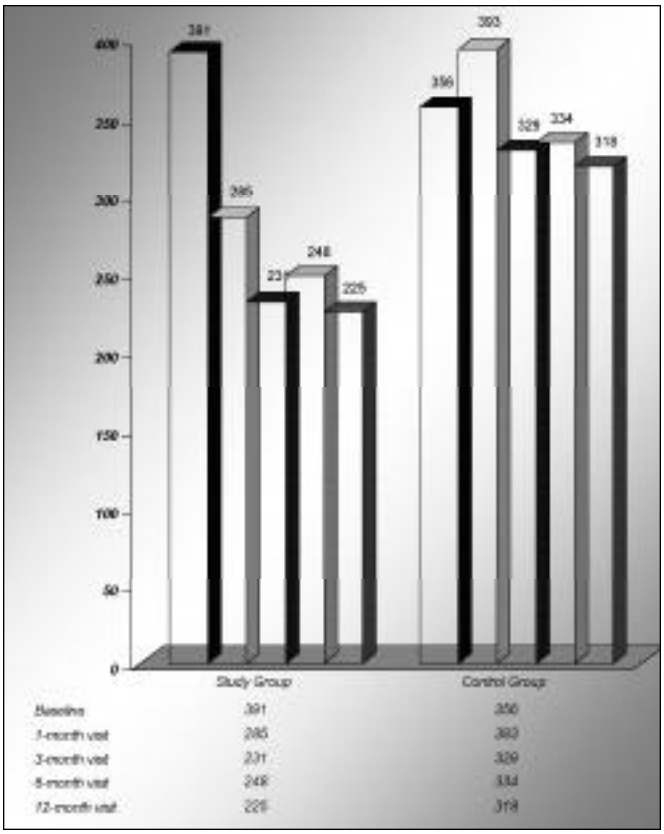

Fig. 1 - *Changes in mean foveal thickness (µm) at baseline and during follow-up period in the study and control groups.*

The difference between the two groups was statistically significant (p=0.016, Mann-Whitney U test). A decrease by at least 20% in foveal thickness was shown with OCT in 8 eyes (80%) of the study group and 4 eyes (40%) of the control group. An increase by at least 20% in foveal thickness was shown in 1 eye (10%) of the study group and none of the control group.

In the study and control groups, the foveal thickness changes between preoperative and postoperative 1 month, postoperative 1 and 3 months, postoperative 3 and 6 months, and postoperative 6 and 12 months are shown statistically in Table III. In the study group, a significant decrease of macular edema was observed at postoperative first month, whereas the decrease during the following months was not significant. In the control group, non-significant changes were observed during the follow-up period.

Table IV shows serial measurements of visual acuity for each patient. In the study group, best-corrected logMAR visual acuity was 0.71±0.43 preoperatively and 0.54±0.45 at postoperative 12 months (Fig. 2). The difference was not significant (p=0.125, Wilcoxon test). In the control group, best-corrected logMAR visual acuity was 0.43±0.44 at baseline and 0.59±0.55 at 12-month follow-up (p=0.235, Wilcoxon test). In the study group, visual acuity improved by two or more lines in 4 eyes (40%) and remained stable in 6 eyes (60%). In the control group, vi-

TABLE II - SERIAL MEASUREMENTS OF FOVEAL THICKNESS FOR EACH PATIENT IN THE STUDY AND CONTROL GROUPS

		Foveal thickness (µm)									
		Treated eye					Fellow eye				
Patient number	Age, yr	Baseline	Follow-up (mo) 1st	3rd	6th	12th	Baseline	Follow-up (mo) 1st	3rd	6th	12th
1	71	355	301	282	257	261	308	296	356	244	221
2	60	330	—	—	168	156	221	—	—	223	257
3	58	260	290	283	317	326	304	290	202	317	337
4	66	544	388	196	297	235	392	506	290	270	274
5	65	259	115	202	189	236	249	305	236	175	216
6	66	442	251	235	223	192	715	654	595	530	565
7	55	448	372	—	312	229	270	425	—	342	196
8	65	385	324	155	175	159	344	384	229	412	377
9	58	425	270	—	257	227	419	311	—	397	356
10	51	465	252	264	280	234	340	364	396	425	385
Mean	61.5	391	285	231	248	225	356	393	329	334	318

sual acuity improved by two or more lines in 1 eye (10%) and decreased by two or more lines in 3 eyes (30%).

No major intraoperative complications were encountered in any of the patients. In the study group, flat peripheral retinal tear was observed in 1 eye (10%) postoperatively. This tear remained attached after laser photocoagulation during the follow-up period. One eye (10%) in the study group showed a transient increase of intraocular pressure. A moderate increase in nuclear sclerosis was observed in 7 (77.7%) of the phakic 9 eyes in the study group and in 2 (22.2%) of the phakic 9 eyes in the control group. Cataract surgery was delayed until after the completion of the study.

DISCUSSION

Macular edema persists and visual acuity decreases in some cases despite grid laser photocoagulation in diffuse diabetic macular edema (3, 12). Although various treatment modalities have been performed in these cases (8, 13-15), no broad consensus has yet been achieved on which procedure is more effective.

In this prospective controlled study, a decrease by at least 20% in foveal thickness was observed in 80% of the eyes treated with PPV and ILM removal, and the decrease (mean 166 µm, 42%) in foveal thickness was found to be

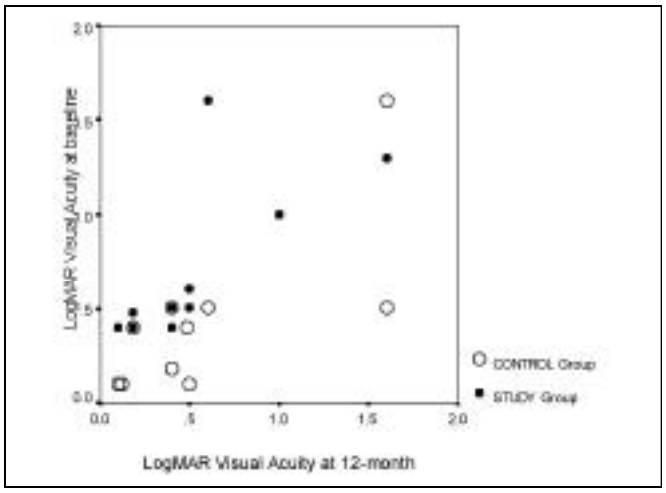

Fig. 2 - *Scattergram showing logMAR visual acuity at baseline versus at 12-month follow-up in the study and control groups.*

TABLE III - STATISTICAL ANALYSIS OF MEAN FOVEAL THICKNESS CHANGES WITHIN EACH GROUP*

	Study group	Control group
Preoperative–postoperative		
1st month	p=0.011	p=0.441
Postoperative1st–3rd month	p=0.237	p=0.091
Postoperative 3rd–6th month	p=0.310	p=0.866
Postoperative 6th–12th month	p=0.093	p=0.507

*Wilcoxon test

TABLE IV - SERIAL MEASUREMENTS OF VISUAL ACUITY (LOGMAR) FOR EACH PATIENT IN THE STUDY AND CONTROL GROUPS

		Best-corrected visual acuity (log MAR)								
			Treated eye				Fellow eye			
			Follow-up (mo)				Follow-up (mo)			
Patient number	Age, yr	Baseline	1st	3rd	6th	12th	Baseline	1st	3rd	6th	12th
1	71	+1.00	+1.00	+0.70	+1.00	+1.00	+0.40	+0.30	+0.18	+0.18	+0.18
2	60	+1.30	—	—	+1.60	+1.60	+0.50	—	—	+1.60	+1.60
3	58	+0.40	+0.40	+0.18	+0.18	+0.18	+0.10	+0.10	+0.10	+0.10	+0.50
4	66	+0.40	+0.18	+0.10	+0.30	+0.10	+0.10	+0.10	+0.10	+0.10	+0.10
5	65	+0.60	+0.60	+0.60	+1.00	+0.50	+0.50	+0.50	+0.48	+0.48	+0.40
6	66	+1.60	+1.30	+1.00	+0.60	+0.60	+1.60	+1.60	+1.30	+1.30	+1.60
7	55	+0.48	+0.30	—	+0.18	+0.18	+0.10	+0.10	—	+0.18	+0.10
8	65	+0.50	+0.60	+0.50	+0.50	+0.50	+0.50	+0.50	+0.50	+0.50	+0.60
9	58	+0.50	+0.50	+0.40	+0.40	+0.40	+0.40	+0.40	+0.40	+0.40	+0.48
10	51	+0.40	+0.40	+0.40	+0.40	+0.40	+0.18	+0.18	+0.30	+0.40	+0.40
Mean	61.5	+0.71	+0.58	+0.48	+0.61	+0.54	+0.43	+0.42	+0.42	+0.52	+0.59

significant. However, a decrease by at least 20% in foveal thickness was observed in 40% of the untreated fellow eyes, and the decrease (mean 38 µm, 11%) in foveal thickness was found to be insignificant. These results suggest that PPV with ILM removal is effective in reducing diabetic macular edema unresponsive to grid laser photocoagulation. A decrease or resolution of macular edema has been reported in 78 to 100% of eyes treated with PPV and ILM removal, as demonstrated by fluorescein angiography or biomicroscopy (8, 9, 16). In studies in which macular anatomy has been assessed by an objective method (OCT), Recchia et al (11) and Yanyali et al (17) have reported that foveal thickness decreases by at least 20% in 73% and 83%, respectively, of eyes that underwent PPV with ILM removal for diabetic macular edema, and mean foveal thickness is reduced by 43% and 50%, respectively, at last follow-up (Tab. V).

Before enrollment in this study, 30% of patients had undergone two sessions of macular laser photocoagulation, while 70% of patients had undergone one session of treatment. The eyes that had undergone only one session of macular laser photocoagulation had fairly extensive laser spots in the macular region. It is not the standard of care to treat only once with laser photocoagulation if the retina is still thickened. It has been reported that macular edema decreases or resolves with supplemental macular laser treatment; however, each additional laser photocoagulation causes a cumulative decrease in the paracentral visual field (3, 18). Progressive enlargement of laser scars, premacular fibroplasia, and subretinal fibrosis have also been reported in eyes treated with grid laser photocoagulation (12, 19, 20). In addition, there is no common point in the treatment of diabetic macular edema unresponsive to grid laser photocoagulation. Previous studies have suggested that PPV with ILM removal is effective in reducing macular edema unresponsive to grid laser photocoagulation (8-11). However, randomized controlled studies are warranted to determine the effectiveness of this surgical procedure. Since our study design was randomized and controlled, and the eyes treated with only one session of macular laser photocoagulation had fairly extensive laser spots in the macula, we did not perform any supplemental macular laser photocoagulation in the fellow eyes.

Visual acuity improvement by two or more lines has been reported in 43 to 92% of eyes that underwent PPV with ILM removal (8-11, 16, 17). In our study, visual acuity improved by two or more lines in 40% of the eyes treated with PPV and ILM removal and 10% of the untreated fellow eyes. Although we observed a significant decrease of macular edema in eyes that underwent PPV and ILM removal, the improvement of visual acuity was not significant. This discrepancy between anatomic and visual outcomes may be due to both the moderate increase in nuclear sclerosis and the irreversible functional damage in macula caused by grid laser spots and longstanding edema. Similarly, Dillinger and Mester have reported a decrease of diabetic macular edema in 93% of eyes treated with PPV and ILM removal, but an improvement of visual acuity by two or more lines in only 43% of eyes (9). In their series, all eyes had a history of macular edema of at least 6 months, and grid laser photocoagulation had been performed previously in most eyes.

Since successful anatomic and functional results have been achieved with PPV in diabetic macular edema with thickened and taut posterior hyaloid membrane (5, 6, 21),

TABLE V - CLINICAL CHARACTERISTICS OF PATIENTS AND RESULTS OF PPV WITH ILM REMOVAL FOR DME WITHOUT EVIDENCE OF VITREOMACULAR TRACTION IN PREVIOUS STUDIES* AND IN THE PRESENT STUDY

	Recchia et al	Yanyali et al	Present study
No. of eyes	11	12	10
Study design	Prospective	Prospective	Randomized controlled
Previous grid laser, n (%)	11 (100)	0	10 (100)
Decrease by ≥20% in foveal thickness, n (%)	8 (73)	10 (83)	8 (80)
Mean decrease in foveal thickness, µm (%)	193 (43)	219 (50)	166 (42)
VA improvement ≥2 lines, n (%)	7 (73)	6 (50)	4 (40)
Follow-up (mo)	6	6	12

*Includes only the studies in which optical coherence tomography examination was performed.
PPV = Pars plana vitrectomy; ILM = Internal limiting membrane; DME = Diabetic macular edema; VA = Visual acuity

there has been an interest in PPV as a treatment for diabetic macular edema without evident vitreomacular traction (7, 22-24). In studies in which macular anatomy has been assessed by fluorescein angiography or biomicroscopy, it has been reported that macular edema decreases in 80 to 100% and visual acuity improves by two or more lines in 48 to 80% of eyes that underwent PPV alone (without ILM removal) for diabetic macular edema without vitreomacular traction (Tab. VI) (22-24). In studies in which macular anatomy has been assessed by OCT, Otani and Kishi (7) have observed a significant decrease in foveal thickness, whereas Massin et al (13) have observed that visual acuity improvement and decrease in macular edema are insignificant.

It has been observed that diffuse macular edema that progresses despite PPV with posterior hyaloid and epiretinal membrane removal for nonresorbing vitreous hemorrhage resolves rapidly after ILM removal (8). This suggests that after spontaneous detachment or surgical removal of posterior hyaloid, tangential traction exerted by the residual cortical vitreous and ILM may play an important role in macular edema. ILM thickening and cell abundance on the vitreous side of the ILM has been observed in eyes with diabetic maculopathy (25). Existence of the residual cortical vitreous that remains attached to the macula after removal of the posterior hyaloid has also been shown during triamcinolone-assisted PPV (26). We observed that ILM was not stained homogenously with ICG in some cases that did not have an epiretinal membrane in preoperative OCT examination. This patchy pattern may be a result of residual cortical vitreous that remains tautly attached to ILM after removal of the posterior hyaloid. Peeling of the ILM removes not only tangential traction exerted by ILM but also residual cortical vitreous. Moreover, postoperative epiretinal membrane formation reported in 10.2 to 13.8% of eyes that underwent PPV (21, 24, 27) has been observed in neither our study nor other studies (8,11,17). It has been found in a retrospective study that PPV effectively reduces diabetic macular edema, but eyes with ILM removal present better results than those without ILM removal (16). However, prospective studies with long follow-up and large series comparing PPV alone with PPV and ILM removal are required to determine which procedure is more effective.

It has been reported that an intravitreal triamcinolone acetonide injection reduces macular edema and improves visual acuity in diabetic patients (28-30). However, a recurrence tendency was observed in relatively short follow-up periods and an intraocular pressure elevation was experienced in many eyes. Thus, further studies are required to assess the long-term efficacy and safety, and the need for retreatment.

The primary limitations of this study are the relatively small number of patients and the use of the Snellen chart for visual acuity measurements. Despite these limitations, since we performed randomly PPV with ILM removal in one eye and took the fellow eye as a control group, individual systemic conditions that may affect macular edema such as type and glycemic control of diabetes, age, blood pressure, serum lipid level, and nephropathy were eliminated. In addition, there was no significant difference between the eyes in terms of type of diabetic retinopathy, the duration of visual impairment, the length of time since the macular edema was diagnosed, receiving macular laser photocoagulation, and presence of panretinal laser photocoagulation. This allowed us to make an unbiased

TABLE VI - CLINICAL CHARACTERISTICS OF PATIENTS AND RESULTS OF PPV ALONE (without ILM removal) FOR DME WITHOUT EVIDENCE OF VITREOMACULAR TRACTION IN PREVIOUS STUDIES

	Ikeda et al	Tachi and Ogino	La Heij et al	Otani and Kishi	Massin et al
No. of eyes	5	58	21	7	8
Study design	Retrospective	Prospective	Retrospective	Prospective controlled	Retrospective
Previous grid laser, n (%)	0	11 (19)	10 (48)	1 (14)	8 (100)
Mean decrease in foveal thickness, μm (%)	NA	NA	NA	353 (57)	94 (18)
VA improvement ≥2 lines, n (%)	4 (80)	31 (53)	10 (48)	4 (57)	2 (25)
Follow-up (mo)	8	12	11	6	18

PPV = Pars plana vitrectomy; ILM = Internal limiting membrane;
DME = Diabetic macular edema; NA = Not available; VA = Visual acuity

comparison between treated and untreated eyes.

In our study, a recurrence of macular edema was observed in one eye (Patient 5) at postoperative 3 months and in another eye (Patient 4) at postoperative 6 months. The postoperative foveal thickness at 12 months remained less than the preoperative foveal thickness in these eyes despite the recurrence. We observed a peripheral retinal tear in 10%, moderate increase in nuclear sclerosis in 77.7% of eyes postoperatively. Previously, the incidence of peripheral retinal tears, postoperative rhegmatogenous retinal detachment, and cataract formation after PPV with or without ILM removal has been reported to be 1.7–20.7%, 1.7–16.6%, 8.3–57.5%, respectively (8, 21, 24, 27). Postoperative epiretinal membrane and lamellar macular hole formation, hard exudate deposits in the center of the macula, and recurrent vitreous hemorrhage have also been reported in recent studies, in which PPV was performed on eyes with diabetic macular edema (21, 24, 27). None of these complications was observed in our series.

In conclusion, macular edema persists and visual acuity decreases in some cases despite grid laser photocoagulation in diffuse diabetic macular edema. PPV with removal of the ILM was observed to be an effective procedure for reducing diabetic macular edema unresponsive to grid laser photocoagulation. A further study with a large number of patients is warranted to assess the efficacy and safety of this treatment.

None of the authors has any financial interest in the study.

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