Prediction of postoperative visual outcome after pars plana vitrectomy based on preoperative multifocal electroretinography in eyes with diabetic macular edema

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I dedicate this research to my beloved family, especially my wife, Ji Hyun Kim to whom without none could have been accomplished.

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Prediction of postoperative visual outcome after pars plana vitrectomy based on preoperative multifocal electroretinography in eyes with diabetic macular edema

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This study is to evaluate the role of preoperative optical coherence tomography (OCT) and multifocal electroretinography (mfERG) as prognostic factors for visual outcome after pars plana vitrectomy (PPV) treatment of diabetic macular edema (DME)

Thirty-five eyes of 34 patients with DME who underwent PPV with minimum follow-up time of 9 months were retrospectively reviewed. Best-corrected visual acuity (VA) was measured at baseline, and at 3, 6, and 9 months after surgery. Patients were categorized into two groups according to the final VA value. Group 1 consisted of eyes with 0.2 or more logMAR lines of visual recovery, and group 2 of eyes with less than 0.2 logMAR lines or which had worsened at last follow-up visit. Preoperative central macular thickness and mfERG responses (P1 amplitude and implicit time) at central macula, up to 15°, were evaluated and compared between the two groups.

Eighteen eyes (51%) showed improved VA after PPV, and were classified into group 1. Seventeen eyes (49%) were placed in group 2. Among mfERG responses at an eccentricity of 0-15°, P1 implicit time at the central seven

hexagons (eccentricity of 0-5°) was significantly delayed in group 2 patients compared with those of group 1 (P=0.017, Student's *t*-test). However, no significant difference was noted at any other retinal eccentricity. Neither P1 amplitude nor central macular thickness showed any significant between-group difference. There was a modest correlation between preoperative VA value and central macular thickness. The slope of the best-fit line was approximately 0.1 logMAR of improved VA for every 100 μm decrease in macular thickness. No significant correlation was noted between preoperative central macular thickness and mfERG response, at an eccentricity of 0-5°.

In conclusion, preoperative mfERG parameters, especially implicit time, can be useful to predict functional visual outcome prognosis after PPV in patients with DME.

Key words: multifocal electroretinography, pars plana vitrectomy, diabetic macular edema

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I. INTRODUCTION

Diabetic macular edema (DME) is a main cause of visual impairment in patients with diabetic retinopathy.[1,2] The condition is characterized by increased vascular permeability and the deposition of hard exudates at the central retina. Recently, many reports have suggested that pars plana vitrectomy (PPV) might be effective in patients refractory to conventional focal or grid laser macular photocoagulation.[3-13] These studies have shown a significant improvement in vision and reduction of central macular thickness measured by optical coherence tomography (OCT).

Multifocal electroretinography (mfERG) is an objective test which assesses the photopic electrical response in discrete portions of the central 40° of vision. The technique allows simultaneous measurement of multiple retinal responses at different locations and provides a topographic mapping of retinal function. Previous studies have described changes of mfERG values in eyes with DME and showed that mfERG could be used as an objective criterion for evaluation of

DME. [14-16]

In the present study, we obtained preoperative mfERG data, and measured central macular thickness by OCT, in patients with DME, and investigated the relationship between these parameters and postoperative visual acuity (VA) to verify the prognostic utility of mfERG/OCT.

II. MATERIALS AND METHODS

Thirty-four consecutive patients (35 eyes) with macular edema caused by diabetic retinopathy underwent PPV at the Yonsei University Eye and ENT Hospital Vitreoretinal Service (Seoul, Korea) between June 2005 and January 2008. This study was approved by the Yonsei University Hospital Institutional Review Board responsible for research involving human subjects. Informed consent was obtained from each participant after the nature and possible consequences of the study had been explained.

Patients were included in the study if they had (1) diffuse macular edema with attached posterior hyaloid caused by diabetic retinopathy as documented by slit-lamp biomicroscopy with contact lens, and diffuse fluorescein leakage on angiography; (2) a best corrected visual acuity (BCVA) on the logMAR scale of $\geq$0.52 (Snellen equivalent $\leq$12/40); and (3) a minimum follow-up period of 9 months. Exclusion criteria were (1) thickened and taut vitreous membrane or posterior vitreous detachment diagnosed by the presence of a Weiss ring; (2) cataract surgery or intravitreal triamcinolone injection within 6 months before surgery; (3) laser treatment including panretinal photocoagulation, grid macular photocoagulation, or posterior capsulotomy, within 6 months before surgery; or (4) presence of comorbid ocular conditions including vitreous hemorrhage, preretinal hemorrhage, or tractional retinal detachment.

A complete ophthalmic examination including VA measurement, slit lamp biomicroscopy using a 90+ diopter noncontact lens, fluorescein angiography, and color fundus photography, was performed on every patient at baseline, and 3 months, 6 months, and 9 months after surgery. OCT and mfERG data were recorded before surgery. A standard Snellen VA chart was employed to measure BCVA at each examination. For statistical analysis, BCVA measurements were converted to the logMAR scale.

All mfERG data were recorded using the RETI scan multifocal system (Roland Consult, Brandenburg, Germany). Stimulation and recording of

mfERG responses were performed using the m-sequence technique according to ISCEV guidelines.[17] The stimulus, consisting of 103 hexagons covering a visual field of 30°, was presented on a monitor at a frame rate of 75 Hz 24 cm from the patient's eye. The luminance (97% contrast; mean luminance 61.8 cd/m^2) of each hexagon independently alternated between black and white. The amplifier gain was set at 100,000, the lower cutoff frequency was 5 Hz, and the upper frequency 100 Hz. After maximum dilation of the pupil, contact lens ERG-JET electrodes were applied to the topically anesthetized cornea with one ground electrode in the forehead and two temporal reference electrodes. A small black fixation object was placed at the center of the stimulus matrix.

The first-order component of mfERG was analyzed, with reference to the mean response density of P1 amplitude (amplitude per unit of retinal area [nV/deg^2]) and mean implicit time (in milliseconds). The amplitude and implicit time at each four-ring unit were analyzed among the six concentric rings. The central macular response (at an eccentricity of 0-5°) was the summed responses of the most central seven hexagons, thus in the first and second ring.

OCT was performed on every patient using a third-generation instrument (OCT3; Stratus Zeiss Humphrey, San Leandro, CA). After dilation of the pupil, the macula was scanned in the horizontal and vertical meridians using the standard, linear crosshair pattern, with a scan length of 6 mm centered through the fovea, as determined by simultaneous evaluation of the red-free image on the computer monitor of the OCT scanner. The central macular thickness was measured manually in all scans, using the caliper tool built into the OCT software.

The surgical technique was standard three-port PPV. All operations were performed by a single surgeon (HJK). In all eyes, the posterior hyaloid membrane was separated from the retinal surface by applying suction from the vitreous cutter. For internal limiting membrane (ILM) peeling, 0.25% (w/v) indocyanine green was initially applied, with 15 seconds of contact time. When

the ILM became stained, the ILM was cautiously peeled from the macula using a microvitreoretinal blade and intraocular forceps. An intravitreal injection of 4 mg/0.1 mL triamcinolone acetonide (40 mg/mL; Tamceton®; Hanall Pharmaceutical, Seoul, Korea) was always performed at the end of surgery. In patients with mild cataracts, phacoemulsification of the lens with posterior chamber lens implantation was additionally performed.

In the present study, the 'Group 1: favorable outcome' eyes included those in which VA improved by more than 0.2 logMAR lines and the 'Group 2: unfavorable outcome' eyes showed less than 0.2 logMAR lines of improvement or worsened from baseline to the last follow-up examination. Normalized sample distribution was confirmed by Kolmogorov–Smirnov analysis. Baseline demographic and clinical parameters were compared between the two groups.

Statistical analysis utilized SPSS® Version 17.0 (SPSS Inc., Chicago, IL), running on a Windows platform. Numerical variables were subjected to an independent sample *t*-test, and categorical variables were analyzed by chi-square tests to ensure comparability. In all tests, $P<0.05$ was considered to be statistically significant.

III. RESULTS

A total of 35 eyes of 34 patients who completed at least 9 months of follow-up after PPV were included in the study. Of the 35 eyes, 18 (51%) experienced two logMAR lines of visual improvement after surgery and were classified into Group 1. The remainder of the eyes formed Group 2. Demographic data for both Groups are summarized in Table 1. There was no statistically significant difference in baseline characteristics such as age, gender, retinopathy status, number of previous interventions, lens status, or VA, between the two groups. All patients were treated with standard PPV and ILM peeling without any intraoperative complications. Combined cataract surgery was performed in 22 (63%) of 35 eyes. No serious postoperative complication was observed during the follow-up period.

Table 1 Baseline characteristics

Variables	Group 1: Favorable outcome (n=18)	Group 2: Unfavorable outcome (n=17)	P value
Age, year (range)	58.5 ± 8.0 (38-68)	60.4 ± 7.9 (45-75)	0.50*
Gender n (%)			0.21†
Male	9 (50)	5 (29)	
Female	9 (50)	12 (71)	
HTN (%)	12 (67)	9 (53)	0.41†
Status of DR, n (%)			0.23†
PDR	14 (78)	10 (59)	
NPDR	4 (22)	7 (41)	
Lens n (%)			0.93†
Phakic	14 (78)	13 (767)	
Pseudophakic	4 (22)	4 (24)	
Previous grid laser photocoagulation, n (%)			0.53†
Yes	15 (83)	15 (88)	
No	3 (17)	2 (12)	
Previous IVTA injection, n (%)			0.62†
Yes	10 (56)	8 (47)	
No	8 (44)	9 (53)	
Previous Avastin injection, n (%)			0.32†
Yes	4 (22)	6 (35)	
No	14 (78)	11 (65)	
Concomitant cataract surgery, n (%)			0.83†
Yes	11 (61)	11 (65)	
No	7 (39)	6 (35)	
Visual acuity (logMAR) mean ± SD	1.15 ± 0.38	0.93 ± 0.40	0.10*

HTN = hypertension; DR = diabetic retinopathy; PDR = proliferative diabetic retinopathy; NPDR = nonproliferative diabetic retinopathy; IVTA = intravitreal triamcinolone acetonide; logMAR = logarithm of the minimum angle of resolution

* Student's t-test, † Chi-square and fisher exact chi-square test

Values given as means ± standard deviation.

The baseline logMAR of VA (mean ± SD) was 1.15±0.38 in Group 1 and 0.93±0.40 in Group 2 (P=0.10, Student's *t*-test). Figure 1 and Table 2 present the changes in logMAR of VA between baseline, 3 months, 6 months, and 9 months after surgery. Within each group, pairwise comparisons revealed a significant improvement in logMAR of VA at 6 and 9 months in Group 1 (P<0.001), whereas Group 2 showed a significant VA change between all timepoints (P<0.05). Between-group comparisons showed a significant difference in logMAR of VA change from baseline at only 9 months after treatment (P=0.015).

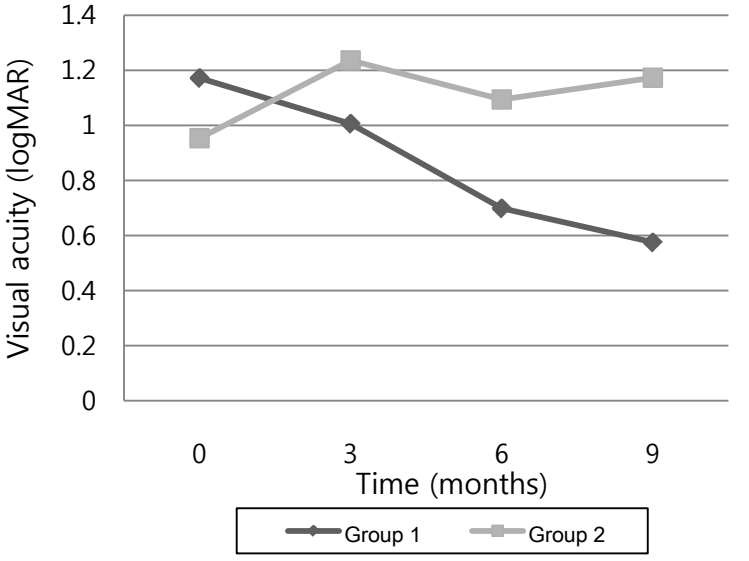

Fig. 1 Changes in visual acuity (VA) after treatment. Significant improvements in logMAR of VA were noted in Group 1 at 6 and 9 months postoperatively (Student's *t*-test, all p values <0.001), and Group 2 showed significant differences from baseline at every follow-up visit (Student's *t*-test, p=0.009, 0.034 and 0.006, respectively).

Table 2 Changes in logMAR of visual acuity between group 1 and group 2

	Time points (months)	Group 1: Favorable outcome (n=18)			Group 2: Unfavorable outcome (n=17)			P value†
		Mean ± SD	P value *	Change vs baseline ± SD	Mean ± SD	P value *	Change vs baseline ± SD	
logMAR VA	0	1.15 ± 0.38			0.93 ± 0.39			
	3	1.04 ± 0.60	0.313*	-0.12 ± 0.48†	1.22 ± 0.49	0.009*	0.29 ± 0.41	0.832†
	6	0.73 ± 0.35	<0.001*	-0.42 ± 0.33†	1.11 ± 0.42	0.034*	0.18 ± 0.31	0.083†
	9	0.62 ± 0.32	<0.001*	-0.54 ± 0.32†	1.18 ± 0.42	0.006*	0.25 ± 0.33	0.015†

logMAR = logarithm of the minimum angle of resolution; VA = visual acuity; SD = standard deviation

* Baseline vs follow up measures within each group; paired *t*-test

† Favorable outcome group vs unfavorable group comparing change of visual acuity from baseline values; student *t*-test

Mean preoperative P1 amplitude and implicit time are shown in Table 3. The P1 amplitude (mean ± SD) at the central seven hexagons, representing an eccentricity of 0-5°, was 32.29±14.57 nV/deg^2 in Group 1 and 24.97±17.48 nV/deg^2 in Group 2. Although the amplitude of Group 2 was less than that of Group 1, the difference was not significant (P=0.187). The P1 implicit time (mean ± SD) at an eccentricity of 0-5° was 42.61±3.31 milliseconds in Group 1 and 45.32±3.03 milliseconds in Group 2. There was a statistically significant delay of implicit time in Group 2 (P=0.017). However, P1 amplitude and implicit time at other eccentricities (5-10°, 10-15°) did not show any significant difference between the two groups. The macular thickness (mean ± SD) at an eccentricity of 0-5° was 474.7±110.9 μm in Group 1 and 499.8±100.2 μm in Group 2. No significant difference was observed between the two groups.

Table 3 Results for preoperative mfERG and retinal thickness at different retinal eccentricities for patients with group 1 and group 2

	Eccentricity 0-5°			Eccentricity 5-10°		Eccentricity 10-15°	
	mfERG		OCT	mfERG		mfERG	
	P1 amplitude ± SD (nV/deg^2)	P1 implicit time ± SD (ms)	Macular thickness ± SD (μm)	P1 amplitude ± SD (nV/deg^2)	P1 implicit time ± SD (ms)	P1 amplitude ± SD (nV/deg^2)	P1 implicit time ± SD (ms)
Group 1 (n=18)	32.29 ± 14.57	42.61 ± 3.31	474.7 ± 110.9	18.53 ± 8.89	41.34 ± 2.70	14.11 ± 7.24	40.32 ± 2.77
Group 2 (n=17)	24.97 ± 17.48	45.32 ± 3.03	499.8 ± 100.2	15.21 ± 11.59	42.90 ± 2.19	11.76 ± 8.45	41.29 ± 1.96
P value	0.187*	0.017*	0.494*	0.346*	0.071*	0.390*	0.272*

mfERG = multifocal electroretinogram; OCT = optical coherence topography; SD = standard deviation

* Student *t*-test

Figure 2 shows preoperative VA plotted against baseline central macular thickness. There was a significant correlation between these parameters, with a correlation coefficient of 0.40. The slope of the best fit line was approximately 0.1 logMAR of improved VA for every 100 μm decrease in central macular thickness. However, there was no statistically significant correlation between preoperative central macular thickness and mfERG response.

No serious vision-threatening complications such as vitreous hemorrhage, retinal detachment, sclera perforation, or infectious endophthalmitis was found in any study eye.

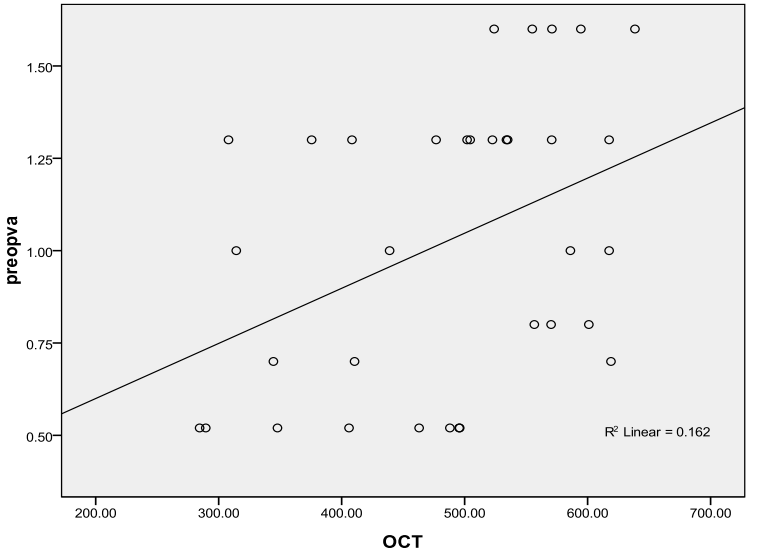

Fig. 2 Scatterplot comparing logMAR of visual acuity and central macular thickness measured by optical coherence tomography (OCT) at baseline. The solid line represents the regression line (y=0.301+0.001x, r=+0.40, p=0.018).

IV. DISCUSSION

Among various interventions for DME that is unresponsive to laser treatment, PPV has shown promising results in recent studies.[3-13] Our previous work on DME patients showed that PPV with ILM peeling was of greater benefit than intravitreal triamcinolone injection.[13] In the cited study, improvement in VA and macular thickness was sustained to 6 months after surgery. However, in some patients, a significant reduction of macular thickness as measured by OCT did not consistently correlate with improvement of VA.[18,19] Kumar and colleagues reported that visual improvement after PPV in DME patients was limited, despite a reduction in macular thickness.[18]

mfERG is a technique for assessing the local ERG from different regions of the posterior retina. Many authors have reported postoperative changes after PPV surgery on DME patients in the morphology and function of the macula, using OCT and mfERG.[14-16] Yamamoto and co-workers also showed that mfERG provided additional evidence of improved physiological function of the macula, and of the safety of PPV.[16]

In the present study, we sought to identify factors affecting visual outcome after PPV, using mfERG to (i) assess DME patients, and (ii) provide appropriate indications for PPV by detecting patients on whom surgery should not be performed because any benefit was unlikely. We categorized patients by change in VA at the final 9-months follow-up, in comparison with baseline values, and analyzed preoperative mfERG data at three different retinal eccentricities to determine whether mfERG information could be used as a prognostic factor.

Our most important finding was a significant delay in P1 implicit time at an eccentricity of 0-5° in Group 2, whereas P1 amplitude did not differ between the two Groups. At an eccentricity of 5-15°, there was no significant between-group difference in either P1 amplitude or implicit time, although implicit time tended to show some between-group variation, more so than did

amplitude. This suggests that preoperative implicit time at the central macula could be used to predict postoperative visual outcome and may be a very sensitive method for measuring macular function. This is consistent with data of a previous report which demonstrated that delayed implicit timing changes were observed in a large area of the retina in DME patients, whereas amplitude changes were not.[20] Bearse and colleagues considered that this might be attributable to the statistical nature of mfERG, which reflects the lower level of inter-subject implicit time variability, unlike the form in which amplitude data are presented. A few studies on the relationship between implicit time and amplitude in early-stage diabetic retinopathy (DR) patients have appeared.[21,22] It is known that the primary generators of mfERG signal, the outer plexiform layer and the bipolar cells, are the first to be damaged, but are not completely silenced, in early-stage DR. Previous histopathologic studies on DME patients have shown that macular edema usually develops at the inner retinal layer (from the outer plexiform layer to the nerve fiber layer) and causes pathologic changes such as necrosis in Müller cells.[24,25] We would thus expect that local retinal responses yielding mfERG signals might be significantly delayed, also in DME patients, but without definite abnormalities of amplitude.

In the present study, PPV led to visual improvement of two or more lines in 51% (18/35) of DME patients. This is similar to the results of other larger studies, that showed a functional benefit in approximately 50% of patients.[3,8,11,12] Group 2 patients had a somewhat worse VA at baseline than did those of Group 1, but the difference was not statistically significant. Preoperative central macular thickness at an eccentricity of 0-5° did not show any significant between-group difference, although the macula was slightly thicker in patients of Group 2. Preoperative macular thickness measured by OCT was of no prognostic value in prediction of visual outcome after surgery. This suggests that macular thickness is just one of several variables that can be used to evaluate the complex macular function.

We also analyzed the relationship between preoperative macular thickness and VA in our 35 eyes with DME. The correlation of OCT measurement with concurrent VA at the central macula was statistically significant, but modest (r=0.40). The coefficient of determination (r^2) was 0.16 and retinal thickness accounted for only 16% of the variability in concurrently measured VA. A wide range of VA was observed in patients with a given level of central macular thickness. Our findings are similar to those of previous studies which reported the coefficient of determination as 0.15 and 0.13.[23,24] Thus, although OCT measurement of macular thickness is a useful method of evaluating macular function, OCT cannot be a good surrogate for VA assessment in treatment of DME patients. No correlation was found between macular thickness and mfERG responses (P1 implicit time or amplitude) at an eccentricity of 0-5°. One possible explanation might be that central macular thickness measured by OCT was not accurately correspond to the ERG response and thus did not reflect only foveal function *per se*.

Some reports on mfERG responses in other retinal vascular diseases have appeared.[25,26] Chung and colleagues showed that preoperative mfERG amplitude was positively related to postoperative ETDRS score after arteriovenous sheathotomy for treatment of macular edema with branch retinal vein occlusion.[27] Those findings imply that the mfERG response can be useful in assessment of objective functional surgical outcomes. Overall, mfERG data may be valuable to predict postoperative visual recovery, especially in patients with retinal vascular disease.

The primary limitation of the present study is the contribution of concomitant cataract surgery at the time of PPV to final VA values. This confounding factor may have influenced our prediction of prognostic factors when the two groups were compared. We performed cataract surgery on 22 eyes (63%) of our patients, but patients with severe cataracts were not included in the study. Also, no significant difference in lens status or number of cataract surgeries was noted

at baseline between the two groups. The development of progressive nuclear sclerosis after PPV in patients with DME has been reported, at high incidence, in several studies.[28,29] However, Hutton and co-workers showed that 37% of patients developed significant cataract progression over 16-108 months after surgery, and Smiddy and associates reported a relatively lower rate of cataract formation after PPV in patients with DR.[30, 31] Thus, the probability of cataract development during the 9 months period after PPV in our present study appeared to be relatively low, and simultaneous cataract surgery was less likely to have an impact on final VA vales when the two groups were compared.

V. CONCLUSION

In summary, our current study showed that 18 (51%) of 35 eyes of patients with DME experienced visual improvement after PPV with ILM peeling. Between-group comparisons also showed that preoperative mfERG parameters, especially implicit time was more useful than amplitude to predict visual prognosis after PPV. However, central macular thickness measured by OCT did not differ significantly between the two groups. Thus, our results provide an appropriate indication of PPV for patients with DME, indicating whether or not patients are likely to benefit from this treatment.

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< ABSTRACT(IN KOREAN)>

당뇨황반부종 환자에서 유리체절제술 후 다국소망막전위도 검사를 이용한 수술 후 시력 예측

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당뇨황반부종은 당뇨망막증으로 인한 시력감소의 가장 흔한 원인으로 알려져 있으며 이에 대한 치료방법으로 레이저 치료, 약물요법, 유리체절제술 등의 여러 방법이 시도되어 왔다. 최근 연구에서는 유리체절제술이 기존의 레이저 치료에 반응하지 않는 당뇨황반부종의 치료로서 효과적이라고 보고하고 있다.

본 연구에서는 수술 전에 시행한 빛간섭단층촬영 및 다국소망막전위도 검사가 유리체절제술 후의 최종시력을 예측하는데 있어서 효과적인지 알아보고자 하였다.

유리체절제술과 내경계막절제술을 동시에 시행한 당뇨황반부종 환자들 중 9개월 이상 경과 관찰이 가능했던 34명 35안을 대상으로 후향적 차트 분석을 시행하였다. 수술 전과 수술 후 3, 6, 9개월째 최대교정시력을 측정하였으며 수술 후 9개월째 시력이 0.2 logMAR 이상 호전된 군을 1군, 0.2 logMAR 이하로 호전되거나 악화된 군을 2군으로 분류하였다. 그리고 수술 전 측정한 중심부 황반두께와 15도까지의 다국소망막전위도 반응 (P1 진폭과 함의점시간)이 두 군 사이에 유의한 차이가 있는지 비교 및 분석하였다.

18안 (51%)에서 유리체절제술 후 시력이 호전되었으며 1군으로 분류되었고 17안은 2군으로 분류되었다. 중심부 7개의

육각형 (0-5도)에서 측정된 P1 함의점시간이 1군에 비하여 2군에서 통계적으로 의미 있는 지연되어있음을 관찰하였다 (P = 0.017, student *t*-test). 하지만 5-15도에 해당하는 망막 부위에서는 두 군 간에 유의한 차이가 없었으며 0-15도에 해당하는 망막부위의 P1 진폭은 두 군 간에 유의한 차이가 없었다. 수술 전에 측정한 중심부 황반두께 또한 두 군 간에 차이가 존재하지 않았다. 전체 35안을 대상으로 한 수술 전 시력과 중심부 황반두께 사이에는 어느 정도의 유의한 연관성이 있었으며 약 100 μm씩 감소하는 황반두께에 대하여 0.1 logMAR 시력의 호전이 있음을 관찰하였다. 하지만 중심부 황반두께와 다국소망막전위도 반응 사이에는 유의한 차이가 존재하지 않았다.

결론적으로 당뇨황반부종 환자에서 수술 전에 측정한 다국소망막전위도 수치, 특히 P1 함의점시간이 진폭보다 유리체절제술 후 최종시력을 예측하는데 있어서 유용할 것으로 생각되며 더 나아가 유리체절제술을 시행함에 있어서 중요한 고려사항이 될 것으로 생각된다.

핵심되는 말 : 당뇨황반부종, 유리체 절제술, 다국소 망막전위도 검사