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# **ORIGINAL**

# Long-term outcome of vitrectomy for an idiopathic macular hole performed with the use of indocyanine green

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Abstract: Purpose: To evaluate the long-term outcome and safety of vitrectomy for the treatment of an idiopathic macular hole using indocyanine green (ICG) to peel the internal limiting membrane(ILM). Subjects and Methods: By means of a retrospective study, we evaluated the outcomes of 56 eyes in 56 patients with an idiopathic macular hole who all underwent a primary vitrectomy with successful closure of macular hole. We compared the outcomes of 35 eyes in 35 patients who underwent a vitrectomy with ICG-assisted ILM peeling to those of 21 eyes in 21 patients who underwent the same procedure without ILM peeling. The main outcomes were compared between preoperative and postoperative visual acuities. Results: The periods to achieve the postoperative best visual acuity were 11.1 months in the ILM peeling group and 8.9 months in the non-ILM peeling group. However, there were no significant differences between the two groups regarding the postoperative best visual acuity and the final visual acuity. Complications related to ILM peeling with ICG were not found. Conclusion: These results support the safety of ILM peeling with ICG. J. Med. Invest. 55: 283-286, August, 2008

**Keywords:** idiopathic macular hole, indocyanine green, surgical removal of internal limiting membrane

### INTRODUCTION

Vitrectomy has been regarded as an effective treatment for idiopathic macular hole (MH) since it was first reported by Kelly in 1991 (1, 2). In addition, an internal limiting membrane (ILM) peeling has become popular since Kadonosono reported enhanced visualization of the ILM with the use of indocyanine green (ICG) (3) to stain the ILM.

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However, the ICG toxicity and the injury of the retina by ILM peeling were also reported (4-8). Therefore, we studied the difference in the results of vitrectomy for MH between vitrectomy without peeling off the ILM and that with ICG-assisted ILM peeling.

## SUBJECTS AND METHODS

Informed consents were obtained from all patients before surgery.

A consecutive series of 56 eyes in 56 patients who underwent a vitrectomy for primary macular hole surgery with successful closure of macular hole and were followed up for more than 1 year from January 1998 to April 2005 were analyzed. Their charts were reviewed retrospectively.

Cases with surgical complications which influence the postoperative visual acuity and those involving a recurrence were excluded from the study. The patients were divided into two groups, group 1 of ILM peeling with ICG assistance, and group 2 without ILM peeling.

The characteristics of these two groups are shown in Table 1.

The surgical procedure consisted of a standard pars plana vitrectomy (PPV), removal of the posterior cortical vitreous, peeling of the ILM around the macular hole assisted with ICG staining or without ILM peeling, and a total fluid-air exchange. Perfluoropropane gas was injected at the end of surgery.

The ICG dye was prepared as follows: 25 mg of ICG was mixed with 1.0 ml of distilled water and then mixed in a ratio of 1:9 with balanced salt solution (2.5 mg/ml). The infusion was then turned off momentarily, and a cannula was used to apply ICG in a controlled fashion over the macula to minimize the amount of ICG applied. A subsequent ICG washout was performed within 30 seconds with active extrusion (9). ILM peeling was performed with an ILM forceps as a sheet over the area of the macular hole and its surrounding region

by a continuous fashion. A pars plana lensectomy with posterior chamber intraocular lens (IOL) implantation was also performed for patients whose ages were over 50 years old. After surgery, all patients remained in a face down position for more than 1 week.

The pre- and postoperative visual acuities (VA) in decimal were analyzed using a logarithm of the minimum angle of resolution (logMAR).

We defined a VA change of more than 0.2 to be an improvement or deterioration and the change of less than 0.2 to be unchanged. In addition, the ratio of the VA improvement of more than 0.2 was defined as improved. The best postoperative and the final VAs were thus analyzed.

The analyses of the data were done using an Excel (Microsoft Corp., Japan) and SPSS (SPSS Inc. Japan). A significant difference of 0.05 was used for all statistical tests, and two-tailed tests were applied. Student's *t*-test, chi-square test and Fisher's exact test were used to compare the two groups and the Wilcoxon rank-sum test was used for other variables.

### **RESULTS**

The characteristics of the two groups are shown

Table 1 Comparison of the Baseline Characteristics of the two groups

Group	1: ILM peeling with ICG	2: without ILM peeling	P Value
Age	67.2±6.76 yrs	63.6±9.58 yrs	0.110*
No,of male / female	15/20	11/10	0.489†
Stages			0.331‡
Stage II	9(25.7%)	6 (28.6%)	
Stage III	17(48.6%)	13 (61.9%)	
Stage IV	9(25.7%)	2(9.5%)	
Axial length	$23.3 \pm 1.46$ mm	$23.4 \pm 1.06$ mm	0.790*
Hole diameters	$400{\pm}144\mu\mathrm{m}$	$367\pm82\mu m$	0.327*
Symptom duration	$7.37 \pm 6.11$ months	$6.05\pm7.63$ months	0.478*
Average preoperative logMAR	$0.97 \pm 0.35$	$0.87 \pm 0.33$	0.277*
Pars plana lensectomy with IOL	31(88.6%)	18(85.7%)	1.000§
Postoperative follow-up period	$25.3\pm10.34$ months	$34.2 \pm 21.77$ months	0.091*

Mean± Standard Deviation

ILM = internal limiting membrane

<sup>\*</sup> t-test

<sup>†</sup> Chi-square test

<sup>‡</sup> Wilcoxon rank-sum test,

<sup>§</sup> Fisher's exact test

in Table 1. There were no significant differences between the baselines of these two groups.

The improvement rates in the best postoperative visual acuity in groups 1 and 2 were 77.1% (27 eyes improved out of 35 eyes) and 90.4% (19 eyes improved out of 21 eyes), respectively (Table 2). The average logMAR ratios of the best postoperative visual acuity in groups 1 and 2 were  $0.56 \pm 0.34$  and  $0.65 \pm 0.36$ , respectively. No significant differences between the two groups were seen (P=0.354, t-test). The periods to achieve the postoperative best visual acuity were 11.1 months in the ILM peeling group and 8.9 months in the non-ILM peeling group. There were no significant differences between the two groups (P=0.492, t-test).

While the improvement rates in the final visual acuity in groups 1 and 2 were 74.3% (26 eyes with improvement out of 35 eyes) and 76.2% (16 eyes with improvement out of 21 eyes), respectively (Table 3). The average logMAR ratios of the post-operative final visual acuity in groups 1 and 2 were  $0.46 \pm 0.30$  and  $0.53 \pm 0.43$ , respectively. There were no significant differences between the two groups (P =0.499, t-test). No difference between the two groups on the period to achieve postoperative final visual acuity was seen(P =0.471, t-test).

Complications related to ICG-assisted ILM peeling were not found.

Table 2 Improvement rate in the best postoperative visual acuity

	Group 1	Group 2	P Value
Improved	27/35(77.1%)	19/21(90.4%)	¬ 0.062†
Unchanged	8/35(22.9%)	1/21 (4.8%)	
Deteriorated	0/35(0%)	1/21 (4.8%)	
Average logMAR ratio	$0.56 \pm 0.34$	$0.65 \pm 0.36$	0.354*

logMAR ratio : postoperative logMAR - preoperative logMAR \* *t*-test

Table 3 Improvement rate in the final visual acuity

	Group 1	Group 2	P Value
Improved	26/35(74.3%)	16/21(76.2%)	¬ 0.126†
Unchanged	9/35(25.7%)	3/21 (14.3%)	
Deteriorated	0/35(0%)	2/21 (9.5%)	_
Average logMAR ratio	$0.46 \pm 0.30$	$0.53\pm0.43$	0.499*

logMAR ratio : postoperative logMAR - preoperative logMAR \* *t*-test

#### DISCUSSION

The removal of the ILM using ICG in a vitrectomy for macular hole has been shown to be safe and effective with a good functional outcome (8-14).

The potential for ICG toxicity causing retinal damage after macular hole surgery has also been reported (6, 7). However, in our study retinal pigment epithelium (RPE) atrophy related to ICG was not found. To clarify the adverse effects of ICG-assisted ILM peeling, we analyzed the data in the postoperative best visual acuity and the final visual acuity. The period to achieve the postoperative best visual acuity in the non-ILM peeling group was shorter than that in the ILM peeling group. However, there were no significant differences between the two groups on the best postoperative visual acuity and the final visual acuity. These results were almost as same as those reported by Sheidow (9).

In this study we excluded cases with either recurrence or complications that might affect postoperative visual acuity, because we designed the study to analyze the efficacy of ILM peeling only. Therefore, it seems that it is sufficient to remove the vitreous around the macular hole as completely as possible without removal of the ILM. We obtained good results because of the procedure using triamcinolone acetonide (TA) for visualization of the vitreous. However, ILM peeling was also found to be effective in cases with a macular hole at an advanced stage and also with dense adhesions of the vitreous (12-14). Based on our experience, we, therefore, conclude that an ICG-assisted vitrectomy is thus considered to be a safety procedure to close MH in vitreoretinal surgery.

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