



## Efficacy of ILM Peeling 1 DD Versus 2 DD for Treatment of Large FTMH Evaluated by a Pilot Randomized Controlled Clinical Trial

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### Oral

**Objective:** To evaluate the anatomic closure rate and visual outcome in patients undergoing PPV with ILM peeling 1DD and 2 DD for treatment of large FTMH and identify the predictive factors determining surgical success.

**Method:** This study was a Randomized Clinical Controlled Trial. Forty six patients with large FTMH (>500  $\mu$ m) were randomized to ILM peeling 1 DD or 2 DD in addition to PPV. Primary outcome was BCVA at 6 months after surgery. Secondary outcomes include closure rate, complication and identify factors predicting surgical success. Preoperative, intraoperative, and post-operative variables were evaluated.

**Result:** Thirty five patients (76.09%) completed the 6-month follow-up. 27 (77.14%) were females and 8 (22.86%) were males. The average age of patients was  $59.7 \pm 14$  years old. Duration of symptom was detected  $10.63 \pm 8.36$  months preoperatively. The size of macular hole was  $643.20 \pm 118.96 \mu$ m. The baseline characteristics were not significantly different between the two groups. The majority of cases (80%) had

anatomical success with one operation. Due to the significant cataract, phacoemulsification was also done in three patients. Only one patient with unclosed FTMH needed the second operation. No statistically significant difference in distance visual acuity (VA) at 6 months were found between groups (95%confidence interval [CI], -5.33 to 2.51;  $p = -0.71$ ). No statistically significant difference in closure rate at 6 months were found between groups (95%confidence interval [CI], 0.25 to 2.23,  $P = -0.48$ ). Complications included hyphema and iatrogenic retinal breaks were found in three patients (8.57%). Multivariable regression analysis identified that preoperative visual acuity and hole size were significant predictors of surgical success.

**Conclusion:** PPV with ILM peeling 1 DD may be sufficient for the treatment of large FTMH (> 500  $\mu$ m). Preoperative VA and macular hole size can predict the surgical related quality of life after surgery. Further study of more cases and longer follow-up are needed.

**Key words:** macular hole, internal limiting membrane

