

The efficacy of vitrectomy combined with internal limiting membrane flap in the treatment of macular hole with age-related macular degeneration

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Abstract

Objective: To observe Pars Plana Vitrectomy (PPV) combined with Internal Limiting Membrane (ILM) flap in the treatment of Macular Hole (MH) with Age-related Macular Degeneration (AMD).

Methods: A prospective study. A total of 44 eyes of 44 MH patients with AMD who were treated in the Affiliated Eye Hospital of Nanchang University from May 2021 to May 2023 were included in the study. Among them, 23 eyes of 23 patients underwent PPV combined with ILM peeling, and 21 eyes of 21 patients underwent PPV combined with ILM flap. All patients underwent Best Corrected Visual Acuity(BCVA), Optical Coherence Tomography(OCT) and microperimetry before surgery and 1, 3, 6 and 12 months after surgery. The structure and function of the macula were compared between the two groups.

Results: A total of 44 patients (44 eyes) were included and followed up. There were 23 patients (23 eyes) in the ILM peeling group and 21 patients (21 eyes) in the ILM flap group. There was no significant difference in age, BCVA, MH size, visual acuity, IS/OS loss length and ELM loss length between the two groups before operation ($P > 0.05$). The times of anti-VEGF therapy during and after operation were 3.48 ± 0.51 in ILM peeling group and 3.38 ± 0.49 in ILM flap group. There was no significant difference between the two groups ($P > 0.05$). At the last follow-up, 18 eyes (78.26%) in ILM peeling group and 16 eyes (76.19%) in ILM flap group had stable AMD. There was no significant difference between the two groups ($P=0.58$). At the last follow-up, 18 eyes (78.26%) in the ILM peeling group and 17 eyes (80.95%) in the ILM flap group had complete MH closure, and the difference was not statistically significant ($P=1.0$). Compared with pre-operation, the diameter of MH decreased and the BCVA increased in the two groups after operation, and the differences were statistically significant ($P < 0.05$). In postoperative 1 month, 3 months and 6 months, the diameter of the MH in the ILM flap group was smaller than ILM peeling group, statistically significant difference ($t = 5.372, 5.121, 3.438, P < 0.001, < 0.001, 0.001$). At 3 months and 12 months after operation, the BCVA of the ILM flap group was higher than that of the ILM peeling group ($t=2.28, 2.19; P=0.027, 0.034$). At each follow-up time point after operation, the missing length of IS/OS and ELM in the two groups was significantly lower than that before operation, and the visual acuity was improved, and the difference was statistically significant ($P < 0.001$). There was no significant difference in the missing length of IS/OS and ELM between the two groups at each follow-up time point after operation ($P > 0.05$). At 3 months, 6 months and 12 months after surgery, the visual acuity of the ILM flap group was significantly higher than that of the ILM peeling group ($t=2.132, 2.924, 4.177; P=0.039, 0.006, < 0.001$).

Conclusion: PPV combined with ILM flap is more effective in the treatment of MH with AMD. It can not only improve the structure of the macula, promote the closure of the macular hole, but also improve the BCVA and macular visual acuity of the patients.

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Background

Macular hole (MH) is a condition characterized by an abnormality at the vitreoretinal interface, involving partial or complete loss of the retinal neuroepithelium, primarily affecting central vision and currently being one of the leading causes of visual impairment. MH predominantly occurs in women over 50 years of age, with an annual incidence rate of approximately 0.441%^[1]. Although the exact mechanism underlying MH formation remains unclear, it is widely believed that traction from the vitreous cortex leads to dysfunction of Müller cells at the fovea and rupture of Müller cell cones, playing a significant role in MH development^[2]. Age-related macular degeneration (AMD) is a multifactorial disease associated with genetic, aging, and environmental factors, primarily affecting the retinal pigment epithelium and characterized by drusen-like deposits in the retinal basement membrane^[3]. With the aging population, the prevalence of AMD continues to rise. Complications such as macular atrophy, choroidal and subretinal neovascularization, and retinal pigment epithelial tears secondary to AMD have become major causes of vision loss among middle-aged and elderly individuals over 50 years old^[4]. Both AMD and MH are age-related conditions that affect the macula. Historically, MH occurring in conjunction with AMD was considered rare; however, advances in optical coherence tomography (OCT) have led to increasing reports of such cases and a clearer understanding of their pathogenesis. Currently, reports on MH associated with AMD are mostly sporadic cases occurring following intravitreal anti-vascular endothelial growth factor therapy^[5-7]. Kim et al. used OCT to identify four main mechanisms underlying MH formation in patients with AMD: 42.9% due to vitreomacular traction (VMT), 22.9% resulting from retinal atrophy caused by subretinal drusen deposits and retinal pigment epithelial detachment, 20% attributable to extensive subretinal hemorrhage, and 14% arising from a combination of vitreomacular traction and retinal thinning^[8].

Currently, pars plana vitrectomy (PPV) combined with internal limiting membrane (ILM) peeling is the primary surgical approach for treating idiopathic macular holes (IMH). Faria and Chang et al. demonstrated that PPV with ILM peeling achieves a 100% postoperative closure rate for IMH, improves visual function, and reduces the recurrence rate of epiretinal membranes^[9-10]. However, Kim et al. reported that the closure rate of MH was only 80.5% when using PPV with ILM peeling in MH associated with AMD^[8]. These studies indicated that this technique is less effective for MH with AMD compared to IMH. Studies have shown that for refractory or large-diameter MH, PPV combined with ILM flap is superior to PPV with ILM peeling^[11]. Therefore, this study investigates the efficacy of PPV combined with ILM flap in treating MH associated with AMD, aiming to provide clinical reference for the treatment and management of such patients.

Method

General Information: Prospective study. 44 patients (44 eyes) with MH complicated by AMD, who were treated at the Affiliated Eye Hospital of Nanchang University between May 2021 and May 2023, were enrolled in this study. Of these, 23 eyes underwent PPV combined with ILM peeling (ILM peeling group),

while 21 eyes received PPV combined with ILM flap (ILM flap group). All participants underwent comprehensive preoperative ophthalmological examinations, including best corrected visual acuity (BCVA), optical coherence tomography (OCT), microperimetry, intraocular pressure, slit-lamp examination, and dilated fundus evaluation. All patients included in the study were operated on by the same experienced vitreoretinal surgeon. Patients were followed up for 12 months, with BCVA, OCT, and microperimetry assessments conducted at 1, 3, 6, and 12 months postoperatively. The study adhered to the Declaration of Helsinki and was approved by the Ethics Committee of the Affiliated Eye Hospital of Nanchang University (approval number: YSL202101228). Informed consent was obtained from all participants prior to enrollment.

Inclusion criteria: 1. Confirmed as full-thickness MH by OCT; 2. Diagnosed as active exudative AMD according to the standards of the Age-Related Eye Disease Study and no previous related treatment (including laser, anti-VEGF, etc.)^[12]. According to the literature^[13] meeting 3 out of the following 5 indicators defines an active case: (1) BCVA has decreased by ≥ 5 letters compared to the previous follow-up; (2) Retinal fluid or subretinal fluid persists or appears in the retina; (3) The macular retinal thickness has increased by 50 μm compared to the previous follow-up; (4) New hemorrhagic lesion appear in the fundus; (5) Active lesions or new lesions are detected by FFA, ICGA examinations.

Exclusion criteria: 1. Diagnosed as dry AMD according to the standards of the Age-Related Eye Disease Study; 2. AMD that occurred after the diagnosis of MH; 3. Lamellar MH; 4. Intraocular lens implantation or aphakic eye; 5. Combined with other eye diseases that cause vitreomacular traction (glaucoma, retinal detachment, vitreous hemorrhage, diabetic retinopathy, etc.); 6. History of ocular trauma; 7. History of intraocular surgery (such as cataract surgery, retinal detachment surgery, etc.); 8. Cases with incomplete case data or unclear imaging data due to lack of regular follow-up.

Surgical procedure: The vitreous was removed from the central part to the posterior pole and base. After vitrectomy, 0.25% brilliant blue was injected into the vitreous cavity to stain the ILM for 10 seconds. In the ILM flap group, the nasal side macular area with a diameter of approximately 2DD was peeled off using ILM forceps, while the temporal side ILM flap was retained. Cover the hole in the macula with the lenticular-like ILM. In the ILM peel group, the ILM with a diameter of approximately 2DD in the macular area was directly removed. The gas or silicone oil was injected into the vitreous cavity according to the size of the MH of the patient. According to previous research reports, silicone oil is filled in the vitreous cavity in patients with medium to large diameter MH (i.e., diameter $> 500\mu\text{m}$), while gas is used for filling in other cases^[14-15].

Imaging examination: The microperimetry test was conducted in a dark room. All patients underwent adequate pupil dilation before the examination. The same functional examination technician used the microperimetry instrument to examine the patients. During the examination, the central fixation point was automatically aligned with the center of the MH and the retina was automatically tracked. The visual acuity within a 12° range of the macular area was tested. The stimulus cursor size was the Goldmann III visual target, the stimulus intensity range was from 0 to 34 dB, the background brightness was 10 cd/m^2 ,

and the stimulus duration was 200 ms. The microperimetry instrument automatically recorded the visual acuity within the 12° range of the macular region.

Statistical methods: Statistical analysis was conducted using SPSS 24.0 software. Measurement data were tested for normal distribution using the S-W test, and homogeneity of variance was tested using Levene's test. If the data satisfied normal distribution and had homogeneity of variance, two repeated-measure data comparisons were performed using analysis of variance, and pairwise comparisons were conducted using the least significant difference t-test. If the data did not satisfy normal distribution, the Mann-Whitney test was used. If the data satisfied normal distribution, approximate t-tests were used when the variance was not homogeneous. The results of measurement data were presented as mean ± standard deviation ($\bar{x} \pm s$). The comparison of count data was performed using Fisher's exact test. It was considered that $P < 0.05$ was statistically significant. The age, BCVA, MH size, visual acuity, the length of the inner and outer segments (IS/OS) of photoreceptors, and the length of External Limiting Membranes (ELM) in the two groups all had homogeneity of variance and conformed to normal distribution.

Results

General Information In the ILM peel group, there were 23 cases (23 eyes), including 7 males (7 eyes) and 16 females (16 eyes), with 11 left eyes and 12 right eyes. In the ILM flap group, there were 21 cases (21 eyes), including 5 males (5 eyes) and 16 females (16 eyes), with 11 left eyes and 10 right eyes. The age of the ILM peel group was (72.57 ± 5.12) years, ranging from 61 to 79 years, while the age of the ILM flap group was (71.90 ± 4.70) years, ranging from 63 to 79 years. Before the surgery, there were no statistically significant differences between the two groups in terms of age, BCVA, size of MH, visual acuity, length of loss of IS/OS of photoreceptors, and the loss of length of ELM ($P > 0.05$) (Table 1). The number of anti-VEGF injections during and after the surgery: the ILM peel group was (3.48 ± 0.51) times, and the ILM flap group was (3.38 ± 0.49) times. The difference in the number of anti-VEGF injections between the two groups was not statistically significant ($P > 0.05$). At the last follow-up, 18 out of 23 eyes in the ILM peel group had stable AMD, and 16 out of 21 eyes in the ILM flap group had stable AMD. The difference between the two groups was not statistically significant ($P = 0.58$).

Table 1: Comparison of general preoperative data of the two groups of patients

category	ILM peel group	ILM flap group	t	P
Age (years)	72.57±5.12	71.90±4.70	0.45	0.66
BCVA∕LogMAR∕	4.21±0.28	4.20±0.29	0.11	0.91
The Size of MH∕um∕	690.39±111.76	707.67±127.31	-0.479	0.634
Visual Acuity∕dB∕	15.05±2.67	14.87±2.67	-0.22	0.826
IS/OS∕um∕	334.60±85.55	334.48±86.81	0.005	0.996
ELM∕um∕	374.09±84.74	389.76±71.98	-0.658	0.514

Notes:BCVA:Best Corrected Visual Acuity;LogMAR:Minimum Resolvable Angle Logarithmic Visual Acuity;MH:Macular Hole;ELM:External Limiting Membranes;P < 0.05 indicates that the difference is statistically significant.

Comparison of the diameters and lengths of MH

At the last follow-up, complete MH closure was achieved in 18 eyes (78.26%) in the ILM peel group and in 17 eyes (80.95%) in the ILM flap group.The difference was not statistically significant (P=1.0).The diameter lengths of MH in both groups decreased over time (F=460.45, P<0.001), and the difference was statistically significant. Compared with before the operation, the diameters of MH in both groups decreased after the operation, and the difference was statistically significant (P < 0.05). When comparing the two groups, the diameters of MH in the ILM flap group were smaller than those in the ILM peel group at 1 month, 3 months, and 6 months after the operation, and the differences were statistically significant (t=5.372,5.121,3.438,P<0.001,<0.001,0.001)(Figure1).

Comparison of BCVA

The BCVA of both groups of patients improved over time (F= 39.60, P< 0.001). Compared with before the surgery, the BCVA of both groups significantly increased at each time point after the surgery, and the difference was statistically significant (P< 0.001). When comparing the two groups, at 3 months and 12 months after the surgery, the BCVA of the ILM flap group was higher than that of the ILM peel group, and the difference was statistically significant (t=2.28, 2.19; P=0.027, 0.034) .

Comparison of the continuity between ELM and IS/OS:

The missing lengths of IS/OS and ELM in both groups decreased over time, and the differences were statistically significant (F=201.95,295.15; P<0.001,<0.001). Compared with the preoperative, the missing lengths of IS/OS and ELM in both groups were significantly reduced at each follow-up time point after surgery, and the differences were statistically significant (P<0.001). When comparing the two groups, the differences in the missing lengths of IS/OS and ELM at each follow-up time point after surgery did not have statistical significance (P>0.05).

Comparison of visual acuity:

The visual acuity of both groups of patients increased over time, and the difference was statistically significant ($F=210.16$, $P<0.001$). Compared with before the surgery, the visual acuity of both groups of patients at each follow-up time point after the surgery was significantly improved, and the difference was statistically significant ($P<0.001$). When compared between the two groups, at 3 months, 6 months, and 12 months after the surgery, the visual acuity of the ILM flap group was significantly higher than that of the ILM peel group, and the difference was statistically significant ($t=2.132, 2.924, 4.177$, $P=0.039, 0.006, < 0.001$) (Table 2).

Table 2: Comparison of 12° visual acuity of the macula in the two groups of patients

Category	ILM peel group	ILM flap group	t	P
Pre-operation	15.05±2.67	14.87±2.67	-0.22	0.826
1 month after operation	16.12±2.83	17.32±2.88	1.38	0.174
3 months after operation	16.76±2.77	18.52±2.69	2.13	0.039
6 months after operation	17.40±2.83	19.83±2.67	2.92	0.006
12 months after operation	17.96±2.79	21.28±2.48	4.18	0.001

Notes:ILM:Internal Limiting Membranes,A P value less than 0.05 indicates that the difference is statistically significant.

Discussion

In AMD, the symbiotic relationship among the components of the RPE-Bruch membrane-photoreceptor complex has changed. Studies have shown that AMD leads to RPE cell apoptosis and loss of the outer layer of the retina, resulting in disruption of intercellular adhesion and instability of the fovea, thereby making the fovea more prone to form MH^[16-17]. Similarly, previous studies have observed that the retinal changes caused by AMD precede the formation of MH, suggesting that pathological RPE may have induced retinal damage, while choroidal neovascularization may contract and accelerate the tangential traction on the subretinal side, and in MHs with AMD, there are a large number of inflammatory cells at the vitreoretinal interface, all of which may contribute to the formation and development of MH^[18-19]. Kim et al. classified MH with AMD based on OCT results into four types: VMT, subretinal drusen membrane or pigment epithelial detachment(PED), numerous subretinal hemorrhage, or mixed type (VMT with gradually thinning retina caused by subretinal drusen membrane or PED), and their study also indicated that the type of MH with AMD is not correlated with the visual acuity of the postoperative patients ^[20].

At present, there are not many studies on the treatment of MH patients with AMD. The results of this study indicate that in terms of structure, there is no significant difference in the closure rate of MH between the two surgical methods. However, compared with ILM peel surgery, ILM flap surgery has a smaller diameter of MH at 1 month, 3 months, and 6 months after surgery, suggesting that ILM flap surgery can close MH more quickly in the short term. Both surgical methods can restore the continuity of ELM and IS/OS after surgery, but there is no significant difference in the recovery of the continuity of ELM and IS/OS between the two surgical methods. In terms of visual function recovery, the results of this study show that compared with before the surgery, both groups of patients can significantly improve BCVA and increase visual acuity after surgery. At 3 months and 12 months after surgery, the BCVA improvement of the ILM flap group is more significant than that of the ILM peel group. This indicates that ILM flap surgery for MH with AMD can better improve visual function than ILM peel group. PPV combined with ILM peel is considered a common surgical method for MH, and it can well restore the structure and function of the macula in IMH. However, the efficacy of ILM flap surgery in secondary MH with AMD is unclear. Studies have shown that for the treatment of large refractory MH, ILM peel surgery will cause many complications such as exposure of the retinal pigment epithelium layer, loss of photoreceptor cells, etc., and poor visual function recovery after surgery. However, ILM flap surgery is superior to ILM peel surgery in terms of MH closure rate and visual function recovery^[21-22]. This is consistent with the results of this study. Similarly, some studies have shown that compared with ILM peel surgery, ILM flap surgery can increase the closure rate of larger MH, but it is still uncertain whether it affects the visual function after surgery^[23-24]. Nene et al. studied that ILM flap surgery can promote the proliferation of glial cells such as Müller cells and restore the tangential traction force, promote the proliferation of photoreceptor cells, and improve BCVA and macular visual acuity^[25]. We speculate that the possible reason why ILM flap surgery is superior to ILM peel surgery is that the ILM flap closing the MH can prevent the fluid in the vitreous cavity from entering the hole, provide a favorable environment for the proliferation of glial cells, and help to recover the central foveal structure more quickly^[26].

As far as we know, this study is the first to investigate the treatment of MH with combined PPV and ILM flap in patients with AMD. This study found that the efficacy of combined PPV and ILM flap in treating MH with AMD is superior to that of combined PPV and ILM peel. However, this study still has some limitations: 1. Studies have shown that PPV not only does not accelerate the progression of AMD, but can also slow down the formation of AMD and geographic atrophy^[27]. At the same time, studies have also shown that PPV has no significant effect on the progression of AMD^[28]. The short follow-up time of this study did not observe the effect of PPV surgery on AMD. 2. This study did not observe the changes in the microcirculation of the macula. 3. The sample size observed in this study was small, the follow-up time was short, and it was only a single-center study. In the next step, we will conduct a large-sample multi-center study to explore the effects of combined PPV and ILM flap on the macular microcirculation and the progression of AMD in patients with MH.

Conclusion

The combined use of PPV and ILM flap for treating MH with AMD has better therapeutic effects. It not only improves the structure of the macula, promotes the closure of macular holes, but also enhances the BCVA and macular visual acuity of the patients.

Declarations

Disclosure statement

No potential conflict of interest was reported by the author(s).

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Figures

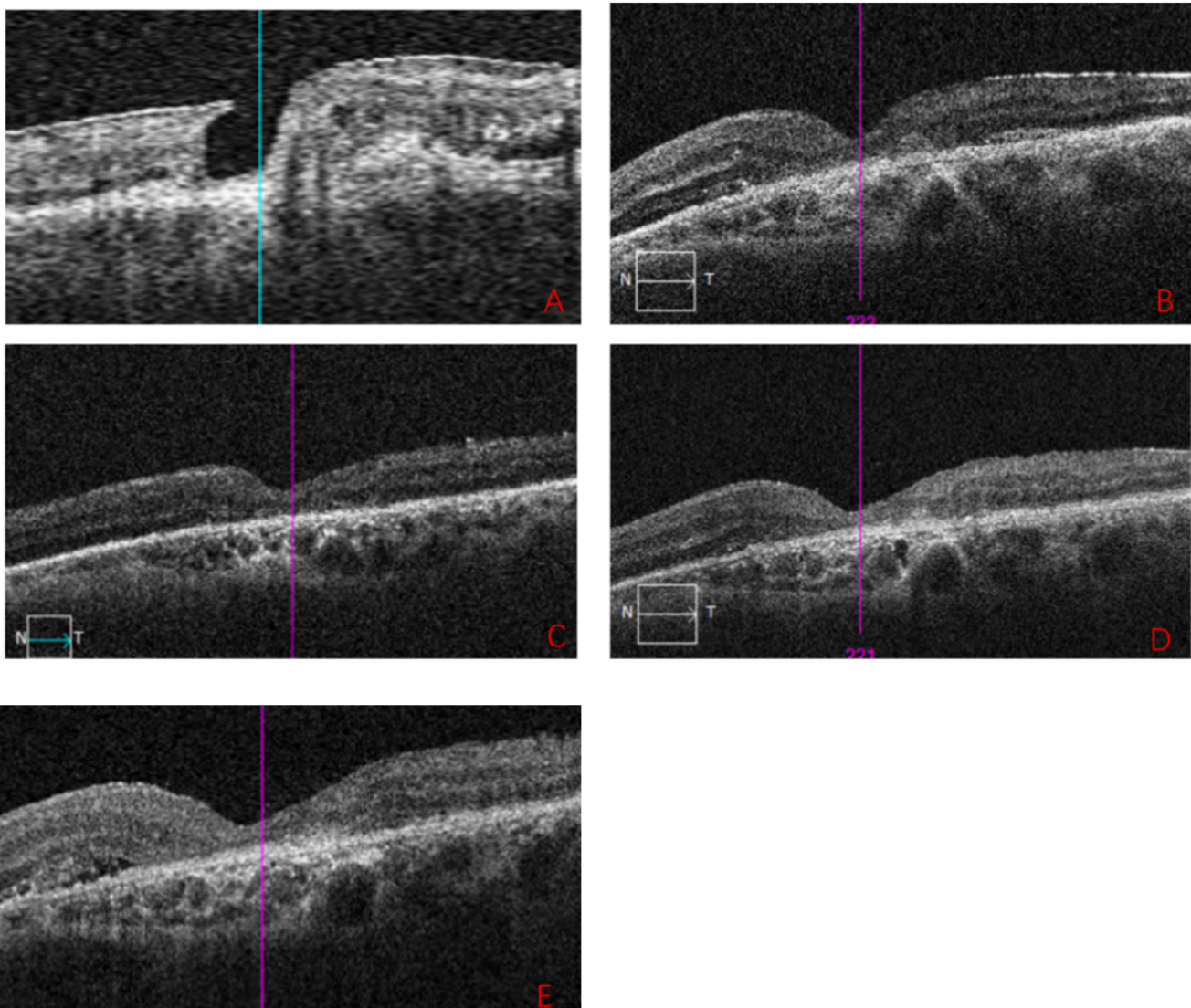


Figure 1

A shows the OCT image of the left eye macula of a 75-year-old male patient, which reveals macular hole and wet age-related macular degeneration. After admission, a left eye vitrectomy combined with ILM flap surgery was performed. During the operation and after the surgery, a total of 3 injections of Conbercept intravitreal injection were administered. B-E show the OCT images of the patient's macula at 1 month, 3 months, 6 months, and 12 months after the surgery. It is shown that the macular hole was closed at 1 month after the surgery, and no recurrence of the macular hole was observed during the 1-year follow-up. The subretinal neovascularization, hemorrhage, and subretinal fluid of wet age-related macular degeneration improved significantly compared to before the surgery.