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ORIGINAL PAPER

Vision-related quality of life after pars plana vitrectomy with or without combined cataract surgery for idiopathic macular hole patients

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Abstract

Purpose To evaluate the influence of vision-related quality of life (VR-QOL) after pars plana vitrectomy (PPV) with or without combined cataract surgery for idiopathic macular hole (IMH) patients.

Methods This prospective consecutive case series study included 53 eyes of 53 consecutive IMH patients who were divided into two groups: 34 eyes underwent PPV combined with cataract surgery (combined group), 19 eyes only underwent PPV (vitrectomy group). Clinical data were collected at baseline and 3 and 6 months after surgery, respectively, including VR-QOL evaluated by The National Eye Institute 25-Item Visual Function Questionnaire (VFQ-25), logarithm of minimal angle of resolution best-corrected visual acuity (logMAR BCVA) using ETDRS chart, severity of metamorphopsia evaluated by M-Charts, contrast sensitivity evaluated by functional acuity contrast test, MH diameter detected by SD-OCT and lens opacity assessment evaluated by Lens Opacity Classification System III (LOCS III). ANOVA and LSD, Wilcoxon signed-rank test were used to compare the difference in logMAR BCVA, metamorphopsia scores, contrast sensitivity, LOCS III scores and VFQ-25 scores between three time points; Spearman's rank correlation test was used to test the correlations between logMAR BCVA, metamorphopsia scores, contrast sensitivity, LOCS III scores and VFQ-25 scores.

Results All eyes had achieved an anatomical success after surgery in both groups. BCVA (logMAR), metamorphopsia and contrast sensitivity were significantly improved at month 3 and month 6 ($p = < 0.005$). VFQ-25 composite and four subscale scores (general vision, near activities, distant activities, role difficulties) were significantly improved in combined group at month 6 compared with baseline ($p = 0.011$, 0.001, 0.003, < 0.001, 0.009). VFQ-25 composite and two subscale scores (general vision, role difficulties) were significantly and negatively correlated with logMAR BCVA ($p = 0.046$, 0.011, 0.012) and metamorphopsia ($p = 0.009$, 0.002, < 0.001) in combined group. VFQ-25 composite and four subscale scores (general vision, near activities, distance activities, mental health) were significantly improved in vitrectomy group at month 3 compared with baseline ($p = 0.014$, 0.047, 0.011, 0.018, 0.037). VFQ-25 composite score and mental

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health score were significantly decreased in vitrectomy group at month 6 compared with month 3 ($p = 0.031$, 0.029) and were significantly and negatively correlated with LOCS III score ($p = 0.047$, 0.017) at month 6.

Conclusion Visual function and VR-QOL were significantly improved after successful macular hole surgery. The fluctuation of VR-QOL after surgery was attributed to the progression of the lens opacity. PPV combined with cataract surgery can help macular hole patients to maintain stable VR-QOL improvement by degrees.

Keywords Macular hole · VR-QOL · Vitrectomy · Cataract

Introduction

The prevalence of idiopathic full-thickness macular hole (IFMH) is about 0.3%, which could induce variable reduction of central vision [1]. Kelly and Wendel [2] firstly reported that pars plana vitrectomy (PPV) could successfully close the macular hole in 1991. Along with operation techniques improved greatly, including internal limiting membrane peeling was widely used [3, 4], the postoperative closure rate greatly increased to 85–100%, and the visual acuity increased approximately 2 Snellen lines in most patients [5, 6]. The most common complication of MH surgery is cataract, the accelerated progression of cataract after the surgery could slow down the recovery of visual acuity [7]. In addition, secondary cataract surgery is generally required within 2 years after the vitrectomy [8, 9].

The effectiveness of surgery was evaluated by tests like visual acuity previously, lack of evaluation of patients' subjective perception [10]. The National Eye Institute 25-Item Visual Function Questionnaire (VFQ-25) had been widely used for the self-evaluation of patients on the diseases including cataract, glaucoma, age-related macular degeneration, proliferative diabetic retinopathy, keratoconus, retinal detachment and epimacular membrane [11–17], as well as the treatment effectiveness. Several studies have used VFQ-25 to investigate the vision-related quality of life (VR-QOL) of the MH patients after PPV [18–22]. Tranos et al. [18], who firstly reported the postoperative VR-QOL of MH patients, pointed out that the VFQ-25 composite and subscale scores were significantly improved postoperatively; although vision acuity was significantly improved, contrast sensitivity was decreased, which was related to the progression of cataract. However, no study had been conducted to investigate the differences of VR-QOL between PPV with or without cataract surgery in MH patients.

The current study aimed to evaluate the influence in VR-QOL of MH patients after PPV with or without cataract surgery and explore the effects of cataract progression to VR-QOL in MH patients after surgery.

Methods

This prospective consecutive case series study had enrolled IFMH subjects who underwent PPV at Beijing Tongren Hospital, between October 2013 and June 2014. The inclusion criteria were as follows: ophthalmoscope examination and OCT confirmed that the patients were with stage 2–4 MH in one eye, the best-corrected visual acuity (BCVA) and the fundus of the contralateral eye was normal. The exclusion criteria were as follows: with secondary or traumatic MH, with other ocular diseases except for slight ametropia or slight cataract, or with a history of PPV. The patients were divided into two groups: patients older than 60 years old underwent PPV combined with phacoemulsification and intraocular lens implantation, which were called the combined group; patients less than 60 years old underwent independent PPV, which were called the vitrectomy group. This study followed the Declaration of Helsinki and was approved by the Ethics Committee of the Beijing Tongren Hospital Affiliated to Capital Medical University (No. TRECKY-012). All subjects had a detailed understanding of the contents and purpose of this study and signed the consent form before the study.

All patients were examined for 3 days before surgery (baseline) and at 3 and 6 months after surgery, including slit-lamp examination, non-contract tonometer measurement, logMAR BCVA, severity of metamorphopsia, contrast sensitivity, MH diameter, lens opacity assessment and VR-QOL.

In this study, Chinese version of NEI VFQ-25 (CHI-VFQ-25) was used to assess patients' VR-QOL with two modifications according to the suggestions

from the initial translators and users [23]: the "Driving" subscales were removed, the subscale "difficulties in going out to watch movies/plays/sporting events" was replaced by "difficulties when watching and enjoying programs on TV." Its reliability and validity have been evaluated and have been applied to study VR-QOL of various diseases in China [24–26].The VFQ-25 composite scores were calculated as the unweighted average response to all 10 items, excluding the "General health" subscale. Higher composite and subscale scores (0–100) represent better VR-QOL. In this study, investigators were asked to introduce the questionnaire to the patients firstly, and then, the investigators would read the questions and the choices to the patients. Patients were asked to select the choice independently, and the selected choices were recorded by the investigators.

ETDRS chart was used to measure the BCVA of the patients, and the logMAR BCVA value was used for statistical analyses.

M-Charts (Inami Co., Tokyo, Japan) were used for measuring severity of metamorphopsia. We chose the two-line M-Charts to avoid the impact of central visual field missing. Metamorphopsia score was measured on vertical and horizontal with three times on each direction; the mean score (average of vertical and horizontal) was calculated and used as the score of metamorphopsia.

Functional acuity contrast test [27] (FACT) (OPTEC 6500, Stereo Optical Co., Chicago, IL, USA) was used for the measurement of contrast sensitivity. FACT uses linear sine-wave grating charts as visual stimulus and could measure 1.5, 3, 6, 12, 18 cpd five spatial frequencies (SF) contrast sensitivity; each SF consists of nine circular patches, decreasing at 0.15 log steps per contrast level. The patients were asked to report the orientation of stripe charts (left, upside or right) in each patches, with the best-corrected visual acuity and the 85 cd/m^2 background light; the number of correct patches for each SF was recorded. [28] As the area under the log contrast sensitivity function (AULCSF) was not invested in this study, the total number of the correct patches in all the five SF was used for the statistical analyses of contrast sensitivity.

OCT (Cirrus HD-OCT Model 4000; Carl Zeiss Meditec, Dublin, CA, USA) was used for the measurement of MH parameters including the basal and minimum diameters.

The Lens Opacity Classification System III (LOCS III) was used for lens opacity assessment [29], by a same trained experienced ophthalmologist under a slit lamp. The opacities of the cortex (C) and posterior subcapsular zone (P), nucleus opalescence (NO) and nuclear color (NC) were evaluated. As previous studies showed that the progression of the opacity of the cortex was not affected by PPV; therefore, the scores of NO and P were added in this study to reflect the lens opacity and was used in the statistical analyses [30].

Surgeries were performed by WL. The surgical technique consisted of standard 23-gauge three-port PPV, peeling of the inner limiting membrane, intraocular gas tamponade (15% C2F6) and postoperative instructions to lie face down for 1 week. Patients in the combined group scheduled a conventional phacoemulsification, and intraocular lens implantation before PPV.

Variables were described with means and standard divisions or median. BCVA, metamorphopsia scores, contrast sensitivity and LOCS III scores between three time points were compared using the ANOVA and LSD. VFQ-25 composite and subscale scores between three time points in each group were compared using the Wilcoxon signed-rank test; the scores between the two groups in the same time point were compared using the Mann–Whitney U test. Spearman's rank correlation test was used to analyze the correlations between BCVA, metamorphopsia scores, contrast sensitivity, LOCS III scores and VFQ-25 scores. $p < 0.05$ was considered statistically significant. SPSS 19.0 was used for the statistical analyses.

Results

Table 1 shows the general characteristics of the patients in two groups. Fifty-three IFMH patients (including 16 males and 37 females) were followed up for three times till 6 months postoperatively. The mean age of the patients was 61.62 ± 7.95 (31–79). Thirty-four patients were in combined group, and nineteen were in vitrectomy group. The closure rate was 100%, and no serious complications such as retinal breaks, retinal detachment, endophthalmitis and secondary glaucoma occurred.

The BCVA, metamorphopsia scores and contrast sensitivity of the combined group are shown in

Table 1 Study demographics

	Combined group	Vitrectomy group	*p*
Number of eyes	34	19	
Age	65.97 ± 4.16	53.84 ± 7.14	0.000
Age range	61–79	31–60	
Gender (male/female)	10/24	6/13	0.872
Eye (right/left)	19/15	8/11	0.345
Stage of MH			
Stage II	3	2	
Stage III	21	17	
Stage IV	10	0	
Minimum diameter of MH (μm)	463.38 ± 178.56	358.53 ± 154.75	0.001
Range of minimum diameter of MH (μm)	152.00–882.00	176.00–760.00	
Scores of LOCS III	3.1*	2.55 ± 0.55	0.001
Range of scores of LOCS III	2.1–4.1	1.1–3.1	

*Date are given as mean ± standard deviation except the scores of LOCS III in combined group, which is given as median

Table 2 BCVA, CS, metamorphopsia at each time point in combined group

	Time point			*p* value		
	Baseline	Month 3	Month 6	Baseline vs. Month 3	Baseline vs. Month 6	Month 3 vs. Month 6
BCVA (logMAR)	0.99 ± 0.50	0.46 ± 0.28	0.39 ± 0.28	0.000†	0.000†	0.293
Contrast sensitivity	3.00 ± 3.36	13.76 ± 7.13	15.68 ± 8.06	0.000†	0.000†	0.077
Metamorphopsia	1.16 ± 0.54	0.56 ± 0.42	0.53 ± 0.47	0.000†	0.000†	0.717

†$p < 0.001$

Table 2. The BCVA, metamorphopsia, scores, contrast sensitivity and LOCS III scores of the vitrectomy group are shown in Table 3. The BCVA, metamorphopsia and contrast sensitivity of the two groups were significantly improved compared with baseline at month 3 and month 6. There were no significant differences between month 3 and month 6 in both two groups.

For the patients in vitrectomy group, 10/19 eyes (52.6%) were with cataract progression after the

Table 3 BCVA, CS, metamorphopsia and LOCS III score at each time point in vitrectomy group

	Time point			*p* value		
	Baseline	Month 3	Month 6	Baseline vs. Month 3	Baseline vs. Month 6	Month 3 vs. Month 6
LOCS III	2.55 ± 0.55	2.60 ± 0.55	3.17 ± 0.96	0.706	0.000†	0.000†
BCVA (logMAR)	0.68 ± 0.41	0.34 ± 0.24	0.35 ± 0.21	0.000†	0.001†	0.874
Contrast sensitivity	5.37 ± 4.89	16.26 ± 8.97	16.95 ± 6.72	0.000†	0.000†	0.709
Metamorphopsia	1.13 ± 0.50	0.56 ± 0.38	0.53 ± 0.47	0.000†	0.002†	0.859

†$p < 0.001$

surgery. NS cataract were found in 2 eyes at month 3 and 10 eyes at month 6, respectively; PSC was found in 1 eye at month 6 (5.3%), which was accompanied by NS cataracts progression. The LOCS III scores in the vitrectomy group are shown in Table 3, comparing with the baseline of 2.55 ± 0.55, 2.60 ± 0.55 and 3.17 ± 0.96 at month 3 and month 6, respectively, there was no significant difference between baseline and month 3, ($p = 0.706$), but significantly decreased at month 6 comparing with month 3 ($p < 0.001$).

VFQ-25 scores of combined group are shown in Table 4, VFQ-25 composite and four subscale scores (general vision, near activities, distance activities, role difficulties) increased from 81.1 ± 12.0, 52.4 ± 16.3, 75.0 ± 22.7, 80.5 ± 17.6, 66.9 ± 28.7 at baseline to 86.0 ± 12.9, 64.6 ± 17.7, 89.5 ± 16.1,90.9 ± 15.2, 80.5 ± 24.1 at month 6 ($p = 0.011$, 0.001, 0.003, < 0.001, 0.009). VFQ-25 composite and two subscale scores (general vision, role difficulties) were significantly negatively correlated with BCVA ($p = 0.046$, 0.011, 0.012) and metamorphopsia ($p = 0.009$, 0.002, < 0.001) at month 6.

VFQ-25 scores of vitrectomy group are shown in Table 5. VFQ-25 composite and four subscale scores (general vision, near activities, distance activities, mental health) increased from 82.4 ± 11.3, 60.0 ± 18.9, 84.4 ± 19.0, 85.1 ± 16.1, 67.8 ± 25.5 at baseline to 88.2 ± 6.1, 69.5 ± 12.2, 95.6 ± 8.5, 94.5 ± 8.6, 79.3 ± 21.3 at month 3 (p = 0.014, 0.047, 0.011, 0.018, 0.037). VFQ-25 composite score and mental health deteriorated from 88.2 ± 6.1, 79.3 ± 21.3 at month 3 to 84.9 ± 9.0, 66.8 ± 21.8 at month 6 ($p = 0.031$, 0.029), which were negatively correlated with LOCS III scores ($p = 0.047$, 0.017) at month 6 (Fig. 1).

Comparison of the VFQ-25 scores at the same time point between the two groups, vitrectomy group was better than combined group in general vision at baseline and in near activities at month 3, combined group was better than vitrectomy group in mental health at month 6, the remaining subscale and composite scores were not significantly different between the two groups, either before or after surgery.

Discussion

With PPV treatment, the current closure rate of IMH has increased to 85–100% [6, 31, 32]. In the eyes with closed hole, visual acuity, contrast sensitivity and metamorphopsia mostly improved after surgery [20, 22]. In recent years, VFQ-25 was used to evaluate

Table 4 VFQ-25 scores at each time point in combined group

	Time point			*p* value		
	Baseline	Month 3	Month 6	Baseline vs. Month 3	Baseline vs. Month 6	Month 3 vs. Month 6
Composite score	81.1 ± 12.0	83.9 ± 13.7	86.0 ± 12.9	0.064	0.011#	0.184
General health	45.6 ± 23.4	44.1 ± 26.2	41.9 ± 25.9	0.462	0.336	0.499
General vision	52.4 ± 16.3	65.9 ± 19.4	64.6 ± 17.7	0.002#	0.001#	0.559
Ocular pain	86.4 ± 17.8	74.6 ± 23.5	84.5 ± 20.1	0.012#	0.837	0.072
Near activities	75.0 ± 22.7	84.0 ± 21.8	89.5 ± 16.1	0.065	0.003#	0.057
Distance activities	80.5 ± 17.6	84.2 ± 21.3	90.9 ± 15.2	0.060	0.000#	0.003#
Social functioning	96.7 ± 10.4	99.3 ± 4.3	99.3 ± 3.0	0.216	0.141	1.000
Mental health	70.4 ± 25.5	83.1 ± 21.6	77.8 ± 25.8	0.023#	0.226	0.068
Role difficulties	66.9 ± 28.7	73.2 ± 31.4	80.5 ± 24.1	0.162	0.009#	0.188
Dependency	86.8 ± 25.8	83.3 ± 22.0	83.8 ± 20.1	0.586	0.420	0.916
Color vision	98.5 ± 6.0	96.3 ± 10.9	96.3 ± 13.9	0.257	0.480	0.891
Peripheral vision	97.1 ± 10.2	94.9 ± 16.0	93.4 ± 15.5	0.480	0.160	0.607

#$p < 0.05$

Table 5 VFQ-25 scores at each time point in vitrectomy group

	Time point			*p* value		
	Baseline	Month 3	Month 6	Baseline vs. Month 3	Baseline vs. Month 6	Month 3 vs. Month 6
Composite score	82.4 ± 11.3	88.2 ± 6.1	84.9 ± 9.0	0.014#	0.334	0.031#
General health	43.4 ± 16.3	50.0 ± 22.1	50.0 ± 28.9	0.132	0.371	0.934
General vision	60.0 ± 18.9	69.5 ± 12.2	63.2 ± 13.8	0.047#	0.776	0.109
Ocular pain	81.5 ± 26.7	80.8 ± 18.6	81.5 ± 18.6	0.860	0.924	0.936
Near activities	84.4 ± 19.0	95.6 ± 8.5	96.1 ± 8.5	0.011#	0.023	0.792
Distance activities	85.1 ± 16.1	94.5 ± 8.6	89.9 ± 13.7	0.018#	0.181	0.065
Social functioning	98.0 ± 6.3	100.0 ± 0.0	100.0 ± 0.0	0.180	0.180	1.000
Mental health	67.8 ± 25.5	79.3 ± 21.3	66.8 ± 21.8	0.037#	0.568	0.029#
Role difficulties	71.7 ± 28.5	80.3 ± 24.1	78.3 ± 28.1	0.365	0.155	0.619
Dependency	83.8 ± 21.4	86.4 ± 21.7	76.8 ± 22.0	0.552	0.242	0.138
Color vision	98.7 ± 5.7	100.0 ± 0.0	100.0 ± 0.0	0.317	0.317	1.000
Peripheral vision	93.4 ± 14.1	96.1 ± 12.5	100.0 ± 0.0	0.589	0.059	0.180

#$p < 0.05$

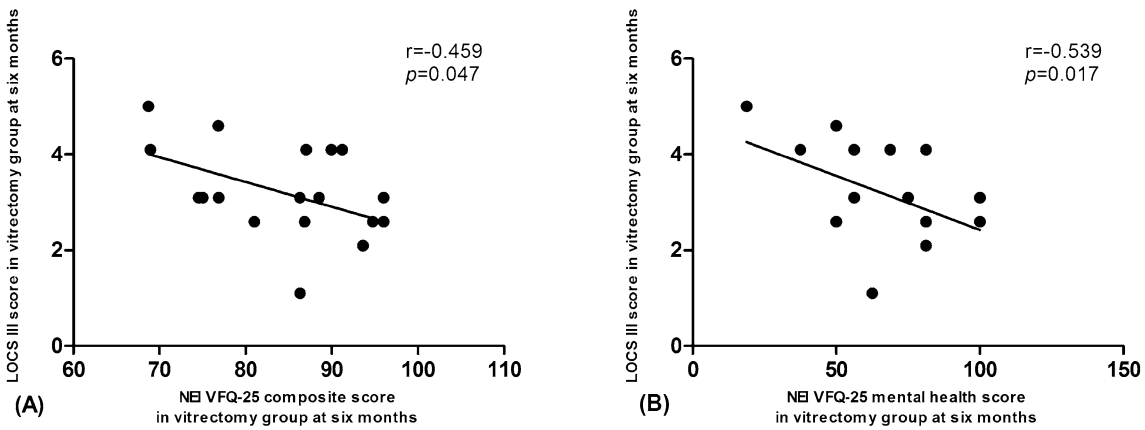

Fig. 1 Correlations between NEI VFQ-25 composite score, mental health score and LOCS III score. **a** NEI VFQ-25 composite scores were significantly negatively correlated with LOCS III score at six months after surgery ($r = -1.459$, $p = 0.047$). **b** NEI VFQ-25 mental health scores were significantly negatively correlated with LOCS III score at six months after surgery ($r = -0.539$, $p = 0.017$)

VR-QOL in patients with MH, and it was shown that VFQ-25 composite and some subscale scores have varying degrees of improvement after PPV [33]. Our study finds that visual acuity, contrast sensitivity and metamorphopsia were significantly improved at 6 months after PPV, regardless of the combination of cataract surgery. VFQ-25 composite score was significantly improved in combined group at month 6, but improved at month 3 and decreased at month 6 in vitrectomy group, this was associated with the increase of LOCS III scores consistent with, suggesting that the progression of cataract reduced the VR-QOL to a certain extent.

PPV can promote the progression of cataract, which has been recognized since 1970 [34]. The progression of cataract after PPV in different types of diseases has

also been reported [35]. With the success of PPV, the progression of cataract postoperatively has become one of the main factors influencing visual recovery. Cheng et al. [36] found that MH patients underwent PPV combined with gas tamponade, 81% of the operated eyes and 18% of the contralateral eyes were with NS cataract progression at 6 months postoperatively, while age was not an influencing factor for NS cataract progression. Previous studies showed that NS cataract progression was the major type of cataract progressions after MH surgery, while progression of PSC was relatively rare [37]. Tranos et al. found that the incidence of NS cataract was 81% and the incidence of PSC was 31% at 4 months after PPV [21]. The current study find that in MH patients, 6 months after PPV, NS cataract progression significantly (10/19 eyes, 52.6%), PSC progressed less(1/19 eyes, 5.3%), and mainly in the period between 3 and 6 months after surgery, which were in accordance with previous findings.

In the combined group, the BCVA and contrast sensitivity increased progressively within 6 months postoperatively, while the increase in metamorphopsia was greater within 3 months postoperatively, but the increase speed decreased after that, which was in accordance with previous findings [20, 22]. VFQ-25 composite and most subscale scores were significantly improved at month 6 compared with baseline, which were in accordance with previous findings [38, 39]. Fukuda et al. [20], Okamoto et al. [22] found that VFQ-25 composite score was associated only with the score and the changes of metamorphopsia before and after PPV. Tranos et al. [18] found that VFQ-25 composite score was associated with the BCVA of the bilateral eyes preoperatively, and associated with BCVA and metamorphopsia of the bilateral eyes postoperatively; in addition, the change inVFQ-25 composite score was not associated with BCVA, metamorphopsia or contrast sensitivity. Lahtelaet al. [38] found that the improvement of BCVA was related to VFQ-25 composite score postoperatively. Duanet al. [39] found that the improvement of BCVA was related to five subscale scores postoperatively. These results are similar to the combined group in the current study, that is, there is a correlation between VR-QOL and BCVA and metamorphopsia.

In the vitrectomy group, the BCVA, metamorphopsia and contrast sensitivity increased progressively within 6 months postoperatively, consistent with the combined group. Only the VFQ-25 composite score and near activities increased significantly at month 3 comparing with baseline, while none of the VFQ-25 scores at month 6 were significantly higher than baseline. In addition, the composite score and general vision, distance activities, mental health, restrictions of social functioning and dependency decreased slightly from month 3 to month 6, but the differences were not statistically significant. Musdlier et al. [7] found that the BCVA in the MH patients who underwent independent PPV at 6 months postoperatively was not significantly different with the preoperative BCVA, while the patients who underwent combined PPV and cataract surgery were with significantly higher BCVA; however, those patients' BCVA also increased significantly after the secondary cataract surgery comparing with preoperatively. Tranos et al. [18, 21] found that although the BCVA in MH patients was increased at 4 months postoperatively, contrast sensitivity was decreased, which could be attributed to cataract progression that causes the poor recovery of postoperative visual function. In the current study, we find that patients who underwent independent PPV, not only BCVA was associated with VR-QOL, but also had a closer correlation between LOCS III score and VR-QOL. There was no study to analyze the correlation between lens opacity and VR-QOL after PPV on MH patients previously. The results suggest that the progression of cataract after MH surgery not only influences the visual acuity and other objective visual functions, but also significantly hinders the recovery of VR-QOL, combined PPV and cataract surgery can help patients to obtain stable improvement of visual function and VR-QOL.

The current study firstly compares the difference of VR-QOL between MH patients who underwent combined PPV and cataract surgery and those underwent independent PPV, follow-up to 6 months postoperatively. Our results further prove the effectiveness of PPV for MH patients, which not only improve the patient's visual function and anatomical structure, but also improve patients' self-evaluation of VR-QOL. However, postoperative cataract progression may severely affect the recovery of vision function and VR-QOL, which have not been reported in previous studies. The current study suggests that PPV combined with cataract surgery may eliminate the need for cataract surgery, and after removing the cataract, the doctor can perform the PPV in a better view.

There were several limitations about the current study. First, the sample size was relatively small, especially the vitrectomy group. The major cause was that IMH is mainly found in aged people; as the patients in the current study were categorized by the age of 60, patients less than 60 years were relatively few. Second, the follow-up time was relatively short. Previous studies showed that the restoration of the functions of macula required more than 1 year after successful closure of the MH [40], while another study showed that the BCVA in the MH patients at 6 months and 1 year after combined PPV and cataract surgery did not change significantly [7]. Third, in order to clarify the effects of changes in the lens on the VR-QOL in MH patients underwent PPV, MH patients with intraocular lens that underwent independent PPV should be included as a control group. Nevertheless, such patients are very rare, thus not included in the current study. Therefore, further research is still needed to prove our findings.

Compliance with ethical standards

Conflict of interest All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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