·Clinical Research·

Visual function and vision-related quality of life after vitrectomy for idiopathic macular hole: a 12mo follow-up study

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Abstract

• AIM: To investigate the visual function and the relationship with vision-related quality of life (VRQOL) after macular hole repair surgery.

• METHODS: Prospective case series. Thirty-six consecutive eyes in 36 patients who underwent pars plana vitrectomy (PPV) and internal limiting membrane (ILM) peeling were included. The 25-item National Eye Institute Visual Function Questionnaire (VFQ-25) was answered by the participants before and 3 and 12mo after operation. Follow-up visits examinations included best-corrected visual acuity (BCVA), clinical examination, and central macular thickness (CMT) measured by optical coherence tomography (OCT).

• RESULTS: Macular-hole closure was achieved in 35 of 36 eyes (97.2%). At baseline and months 3 and 12, the logMAR BCVAs (mean±SD) were 1.15±0.47, 0.68±0.53 (P<0.0001 versus baseline), and 0.55±0.49 (P<0.001 versus baseline, P=0.273 versus month 3), respectively; the CMTs (μm) were 330±81, 244±62 (P<0.001 versus baseline), and 225±58 (P<0.001 versus baseline, P=0.222 versus month 3), respectively; the median preoperative VFQ-25 composite score of 73.50 (63.92-81.13) increased postoperatively to 85.50 (80.04-89.63) at 3mo (P<0.001) and 86.73 (82.50-89.63) at 12mo (P<0.001) respectively. The improved BCVA was correlated with improvements in five subscales (r=-0.605 to -0.336, P<0.001 to P=0.046) at 12mo.

• CONCLUSION: PPV with ILM peeling improved anatomic outcome, visual function, and VRQOL. The improved BCVA was an important factor related to the improved VRQOL.

• KEYWORDS: idiopathic macular hole; vitrectomy; quality of life; National Eye Institute Visual Function Questionnaire
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INTRODUCTION

Idiopathic macular hole (IMH) is characterized by a full-thickness neuroretinal break or defect of the macula. Surgical closure of IMH was first reported in 1991 by Kelly and Wendel [1]. Since then, the surgical procedure has continued to be evolved, and now it contains vitrectomy[2] and internal limiting membrane (ILM) peeling[3-4]. The anatomical closure rate approaches 78.7% to 100% in different stages according to the Gass classification system [5]. And so far, favorable postoperative visual outcomes have been reported[6,7]. In general, visual acuity and morphological parameters are used as major outcome parameters to assess the visual function of macular hole surgery. However, the results lack the needful survey of the impact on patients' quality of life.

The 25-item National Eye Institute Visual Function Questionnaire (VFQ-25) was designed to assess patients' perception of their vision-related quality of life (VRQOL)[8]. The purpose of our study was to evaluate the effects on VRQOL after MH surgery and to assess the relationship between visual function and VRQOL for up to 12mo postoperatively.

SUBJECTS AND METHODS

Study Design In all, 36 eyes of 36 Chinese patients with IMH were enrolled consecutively over a 12-month period. At the study entry, all patients provided informed consent that followed the tenets of the Declaration of Helsinki. All patients were recruited from the Department of Vitreoretinal Diseases (Tianjin Eye Hospital, Tianjin, China) between April 2012 and August 2013. The study was approved by Ethics Committee of Tianjin Eye Hospital. The IMH was diagnosed through slit-lamp biomicroscopy with a 90 diopter lens, funduscopy and optical coherence tomography (OCT).

Inclusion and Exclusion Criteria Eligibility criteria included evidence of stage 2 to 4 full-thickness IMH and symptoms that had been present for less than 1y. Exclusion criteria included traumatic macular hole, high myopia ≥6D, severe cataract hindering satisfactory evaluation of the macula, previous vitreoretinal surgery, and other retinal diseases, disagree to sign informed consent, and loss of follow-up.

Surgical Procedures All macular holes were treated by the same experienced surgeon. The surgical procedures consisted of standardized 23-gauge three-port pars plana vitrectomy (PPV), ILM peeling, and intraocular gas tamponade (14% C_3F_8 gas mixture) as reported previously[9]. For the procedure, a posterior vitreous detachment was created firstly. Then, the ILM was peeled off in a circular mode for about 2 optic disk diameters around the MH after staining with the indocyanine green (0.125% solution of indocyanine). After fluid-air exchange, the air was then replaced through the use of C_3F_8 gas. A combined phacoemulsification and intraocular lens implantation were performed on all the phakic eyes. The patients were asked maintain a prone position for at least 1wk after surgery.

Clinical Evaluation The patients were assessed before surgery and at 3mo and 1y following surgery. At each visit, the best-corrected visual acuity (BCVA), full ocular examinations and OCT imaging were performed. Central macular thickness (CMT) was recorded. The BCVA was measured using a Snellen visual acuity chart and converted to the logarithm of minimal angle of resolution (logMAR) BCVA. The CMT in the central 1-mm diameter subfield was measured using the Cirrus HD-OCT (Carl Zeiss Meditec, Dublin, CA, USA) with an area scan covering a 6×6-mm macular region (128 lines, 512A scans per line). CMT was analyzed using a circular Early Treatment Diabetic Retinopathy Study type-grid positioned on the center of the fovea. If there was error in automated recognition of the inner or outer boundaries as the ILM or retinal pigment epithelium, CMT was measured with a caliper manually.

Vision -related Quality of Life Questionnaire The VFQ-25 was self-administered at baseline and 3 and 12mo postoperatively. It contains 12 subscales: overall health, overall vision, ocular pain, difficulty with far- and near-vision activities, mental health due to vision, role limitations due to vision, social functioning limitations due to vision, driving difficulties, peripheral and color vision, and dependency because of vision. The score is from 0 to 100 in each item, and a composite score can be calculated as the mean score of all items, except for general health items[10]. The VFQ-25 has been proven to be a reliable and valid instrument to measure VRQOL[11-13].

Table 1 Patient demographics *n*=36

Parameters	Baseline characteristics
Age (a)	
Range	47-72
$\bar{x} \pm s$	61.2±5.2
Gender	
M	3
F	33
Lens states	
Phakic	34
Pseudophakic	2
logMAR BCVA	
Range	0.22-2.00
$\bar{x} \pm s$	1.154±0.473
Stage of macular hole	
Ⅱ	19
Ⅲ	13
Ⅳ	4

logMAR BCVA: Logarithm of minimal angle of resolution best-corrected visual acuity.

Statistical Analysis Quantitative variables were expressed appropriately as means (SD) or as medians (range). The logMAR BCVA and CMT were compared between each pair of three time points using the one-way ANOVA and LSD. Each VFQ-25 subscale and the composite scores were compared with Wilcoxon signed-rank test. Continuous dependent variables were tested for normality by Kolmogorov-Smirnov test (D test) and Shapiro-Wilk test (W test). The relationships between changes in the VFQ-25 scores and changes in logMAR BCVA and CMT were analyzed using the Spearman's rank correlation test. Statistical significance was set at P<0.05. Data analysis was performed using SPSS Version 19.0 (SPSS, Inc., Chicago, IL, USA).

RESULTS

Table 1 summarizes the baseline data of the 36 eyes of 36 consecutive subjects in this prospective study. There were 34 phakic eyes enrolled and each received combination cataract surgery and PPV with MH repair; the remaining 2 pseudophakic eyes received only PPV with MH repair. Anatomic closure of IMHs was achieved in 35 of 36 eyes (97.2%) after one surgery; the ILM was removed successfully in all subjects; no serious complications, such as retinal detachment, retinal breaks, or endophthalmitis, occurred intra- and postoperatively. All patients completed the follow up examinations at months 3 and 12. Figure 1 shows fundus and OCT images of 4 typical patients: Patient 1, a 48-year-old woman (Figure 1A-1D). Her visual acuity (VA) was 0.05 in her left eye. Fundus photograph showed a full thickness macular hole (FTMH) with a cuff of subretinal fluid (Figure 1A). OCT also showed FTMH with cystic spaces in her left eye (Figure 1B). OCT showed closure of

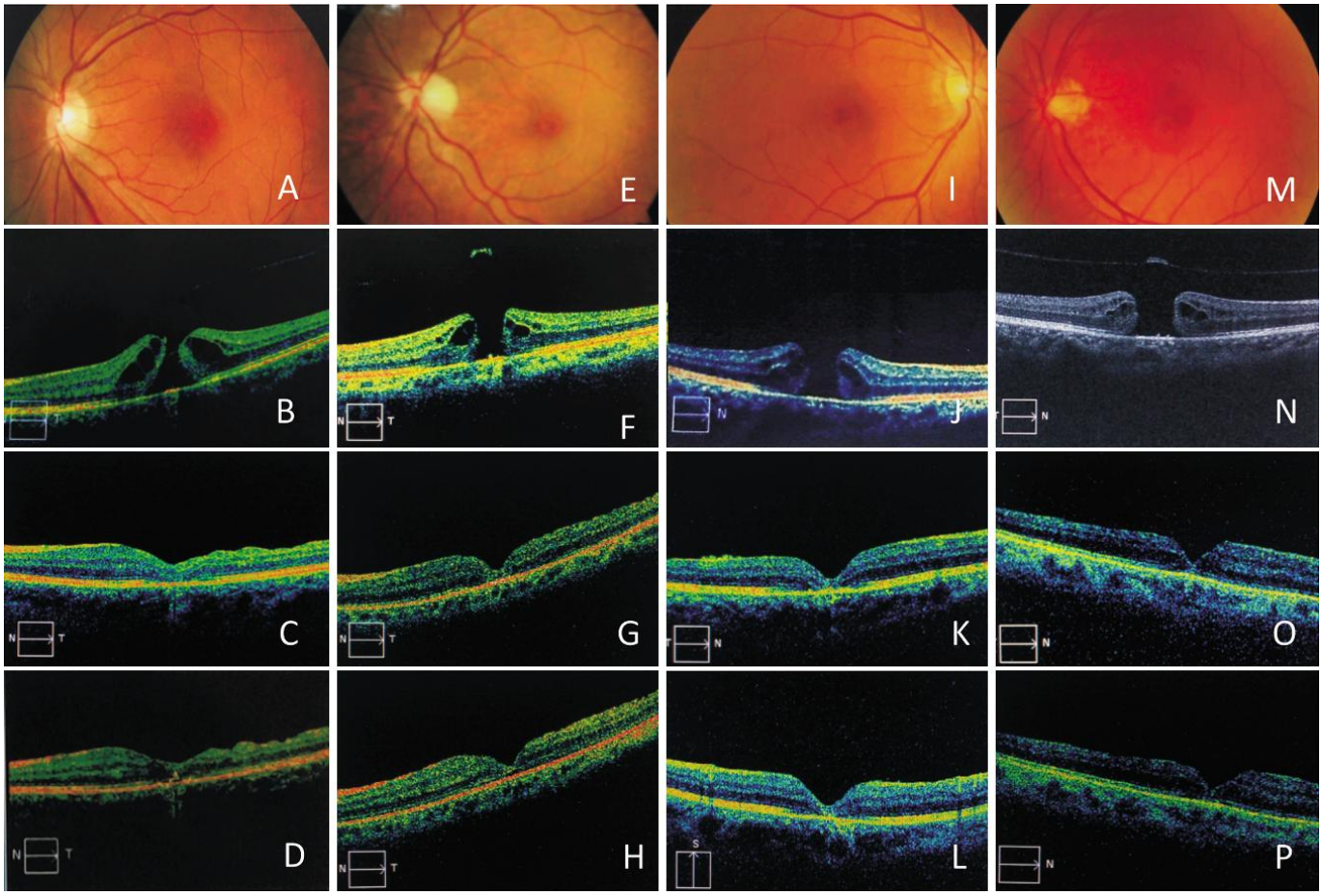

Figure 1 Color fundus photographs and Cirrus OCT images from 4 cases The images in first row (A-M) show fundus photographs of 4 IMH patients before surgery, respectively; OCT images in the second row (B-N) demonstrate the same eyes before surgery, respectively; OCT images (C-O) reveal nearly normal macular configuration 3-month after surgery, respectively; and OCT images (D-P) show clear contour of the fovea, respectively.

but IS/OS junction was still defect (Figure 1K). At 12mo after surgery, the IS/OS junction defect had become smaller, the VA maintained at 0.2 (Figure 1L). Patient 4, a 61-year-old woman (Figure 1M-1P). Her VA was 0.04 in her right eye. A clear FTMH was obtained in fundus photograph (Figure 1M). OCT also showed a FTMH with a fluid cuff and a pseudo-operculum attached to vitreofoveal separation (Figure 1N). At 3mo postoperatively, her VA increased to 0.2, OCT showed macular hole had closed (Figure 1O). By 12mo after surgery, OCT showed nearly normal foveal contour (Figure 1P). The VA slightly increased to 0.3.

Best-corrected Visual Acuity A significant improvement in BCVA between 3mo and preoperation, and between 12mo and preoperation was recorded (P<0.001, respectively; Figure 2). However, no statistically significant changes were observed between 3mo and 12mo after operation. There was no significant difference in BCVA of the fellow eye before and after surgery, the function of the fellow eye was always stable.

Central Macular Thickness CMT was assessed by OCT; Table 2 shows the CMT value at each time point. The mean CMT from baseline to 3mo and 12mo were 330 μm, 244 μm and 225 μm respectively. It significantly reduced at 3 and 12mo after surgery (P<0.001, respectively).

Vision-related Quality of Life The distribution of the VFQ-25 data at baseline, 3 and 12mo postoperation is presented in Table 3. The median preoperative VFQ-25 composite score of 73.50 (63.92-81.13) increased postoperatively to 85.50 (80.04-89.63) at 3mo (P<0.001) and 86.73 (82.50-89.63) at 12mo (P<0.001) respectively. Also there was an increase of composite score between 3mo and 12mo (P<0.001). Overall, the median scores for the 12 subscales of the VFQ-25 improved 3 and 12mo after surgery except "general health" (P>0.05), respectively. As the missing rate of driving subscale was rather high (27/36, 75%), we omitted this subscale in the calculation of composite score and further analysis according to the suggestion of previous research [14]. Furthermore, comparing the scores obtained 3 and 12mo postoperatively, the analysis revealed a long term significant benefit from macular hole surgery in the following: the composite score and the scores of subscale general vision, ocular pain, distance activities, mental health, role difficulties, and dependency (P<0.001, P=0.001, 0.023, 0.028, 0.007, 0.016, 0.042, respectively).

Table 2 Changes in logMAR BCVA and CMT in the study before surgery and at 3mo and 12mo follow up period postoperatively $\bar{x} \pm s$

Serials	Time point			*P*		
	Preop.	3mo postop.	12mo postop.	Preope. *vs* 3mo postop.	Preop *vs* 12mo postop.	3mo *vs* 12mo postop.
logMAR BCVA	1.15±0.47	0.68±0.53	0.55±0.49	<0.001	<0.001	0.273
CMT (μm)	330±81	244±62	225±58	<0.001	<0.001	0.222

logMAR BCVA: Logarithm of minimal angle of resolution best-corrected visual acuity; CMT: Central macular thickness.

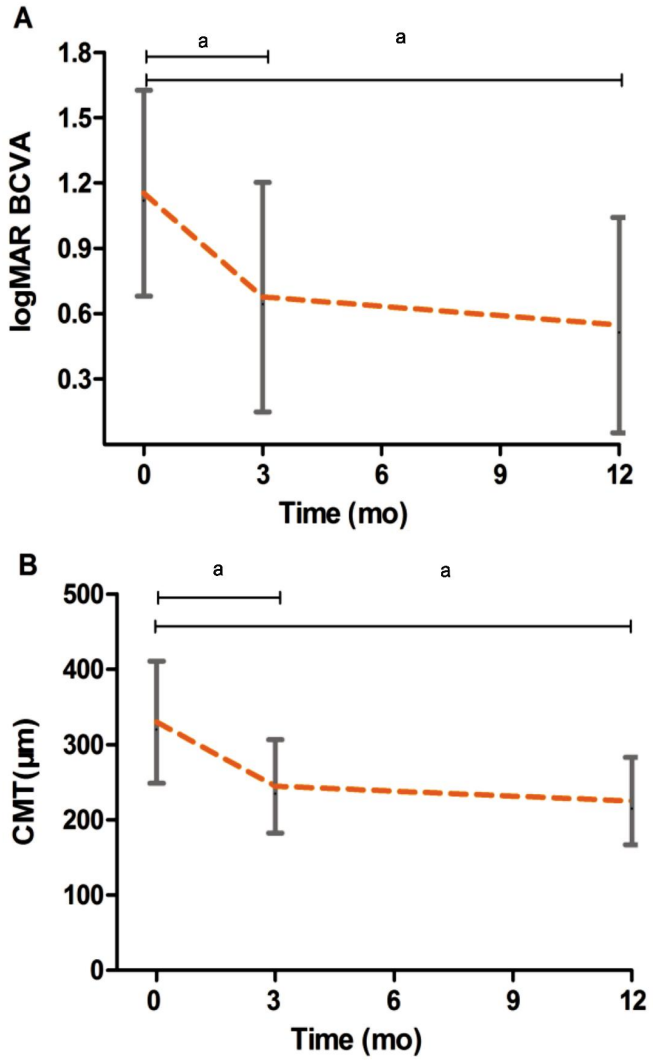

Figure 2 Changes of logMAR BCVA and CMT from baseline to 3-month and 12-month after macular surgery for IMH patients [a] P<0.05.

Correlation Between Changes in VFQ-25 Scores and Changes in LogMAR Best-corrected Visual Acuity and Central Macular Thickness Table 4 shows the correlations between the changes in VFQ-25 scores, logMAR BCVA and CMT. At 3mo and 12mo follow up, no correlations between each VFQ-25 score and the two parameters reached significance. Encouragingly, the postoperative improvement in logMAR BCVA was correlated with the improvements in general vision (r=-0.605, P<0.001), ocular pain (r=-0.336, P=0.045), mental health (r=-0.362, P=0.030), dependency (r=-0.444, P=0.007), peripheral vision (r=-0.341, P=0.042), and composite score (r=-0.448, P=0.006).

DISCUSSION

Many previous studies estimated the VRQOL for patients undergoing vitreoretinal surgery, mainly included age-related macular degeneration, epiretinal membranes and proliferative diabetic retinopathy [11-13]. There are only a few reports about visual quality of life after macular hole operation. In our present study, pre- and postoperative VRQOL were assessed using VFQ-25 in the patients with IMH. The VFQ-25 used in our study was a Chinese version, with modifications to suit the culture and lifestyle of Chinese. The modified VFQ-25 questionnaire has been assessed for reliability and validity, and it has been shown to accurately measure VRQOL in Chinese individuals [14,15]. To our knowledge, this is the first study which evaluated the VRQOL of IMH patients using VFQ-25 in mainland China so far.

Rayat *et al* [16] showed an improvement of VRQOL on IMH patients after vitrectomy in a case-series with a follow-up time of one month. However, some studies showed that the full functional recovery after vitreomacular surgery may take up to one year or more [11, 17]. Therefore, we investigated the VFQ-25 values at two different time points at 3 and 12mo after surgery. In this study, congruent results were obtained with other previous studies[16, 18]. However, our study provided a Chinese perspective on VRQOL after MH repair surgery; previous studies were based on European and Japanese patients [19-21].

Previous studies have reported that the BCVA continued to improve for up to more than one years after macular hole repair surgery [20, 22]. The logMAR BCVA was significantly improved 3 and 12mo postoperatively (P<0.001, 0.001, respectively). Of the 36 eyes, only 4 showed decreased postoperative visual acuity following MH surgery. Of these eyes, 2 eyes were stage 4 holes, 1 eye of macular hole persisted. Correspondingly, studies of Stage 4 holes have had lower closure rates [23]. We found the patient's macular hole unclosed, and we advised him to conduct second operation 6mo after operation. However, he did not because he could not afford the cost. Nevertheless, he visited the hospital every half year. His retina of the affected eye was in normal position. Nevertheless, visual acuity improved in the present study as a whole. These results agreed well with the results of the current study (Figure 1).

Likewise, our results showed a significant improvement in the VFQ-25 composite score and at least in some VFQ-25

Table 3 Median composite and subscale scores for VFQ-25 in the study before surgery and at 3mo and 12mo follow up period postoperatively

VFQ-25 questionnaire scale	Time point			*P*		
	Preop. median (25^{th}-75^{th} percentile)	3mo postop. median (25^{th}-75^{th} percentile)	12mo postop. median (25^{th}-75^{th} percentile)	Preop. *vs* 3mo postop.	Preop. *vs* 12mo postop.	3mo *vs* 12mo postop.
General health	60.00 (50.00-65.00)	60 (44.38-65.00)	60.00 (50.00-65.00)	0.388	0.278	0.102
General vision	35.00 (30.00-45.00)	60 (50.00-65.00)	65.00 (55.00-75.00)	<0.001[a]	<0.001[a]	0.001[a]
Ocular pain	100.00 (75.00-100.00)	100 (87.50-100.00)	100.00 (100.00-100.00)	0.002[a]	0.001[a]	0.023[a]
Near activities	83.33 (46.25-98.96)	95.83 (75.00-100.00)	95.83 (80.21-100.00)	<0.001[a]	<0.001[a]	0.102
Distance activities	72.92 (46.87-83.33)	85.42 (70.83-91.25)	87.50 (70.83-91.67)	<0.001[a]	<0.001[a]	0.028[a]
Social functioning	91.67 (77.08-100)	100.00 (91.67-100)	100.00 (100.00-100.00)	0.002[a]	0.001[a]	0.180
Mental health	65.00 (51.25-78.75)	80.00 (70.00-88.75)	80.00 (76.25-90.00)	<0.001[a]	<0.001[a]	0.007[a]
Role difficulties	56.25 (43.75-75.00)	81.25 (62.50-87.50)	81.25 (68.75-87.50)	<0.001[a]	<0.001[a]	0.016[a]
Dependency	68.75 (50.00-85.94)	87.50 (70.31-92.19)	87.50 (81.25-92.19)	<0.001[a]	<0.001[a]	0.042[a]
Driving	70.83 (50.00-91.67)	100 (75.00-100.00)	100.00 (75.00-100.00)	0.002[a]	0.002[a]	1.000
Color vision	100 (81.25-100.00)	100 (100-100)	100.00 (100.00-100.00)	0.005[a]	0.005[a]	1.000
Peripheral vision	75.00 (50.00-100.00)	87.50 (75.00-100.00)	100.00 (75.00-100.00)	0.001[a]	0.001[a]	0.102
Composite score	73.50 (63.92-81.13)	85.50 (80.04-89.63)	86.73 (82.50-91.18)	<0.001[a]	<0.001	<0.001[a]

[a]$P<0.05$.

subscales (general vision, ocular pain, distance activities, mental health, role difficulties, and dependency) when comparing 3 and 12mo postoperatively (Table 3). This suggests that macular hole repair surgery has an impact not only on visual function but also on other sides of health, such as emotional and social aspects, even if the visual acuity in the fellow eye is excellent.

In the light of the above anatomical and functional results recorded postoperatively, we studied the correlations among the changes between VFQ-25 scores and the two variables. At 3mo and 12mo follow up, compared with preoperation, no correlations between each VFQ-25 score and the two parameters reached significance. Encouragingly, from 3mo to 12mo, the improvement in BCVA was correlated with the improvements in general vision (r=-0.605, P<0.001), ocular pain (r=-0.336, P=0.045), mental health (r=-0.362, P=0.030), dependency (r=-0.444, P=0.007), peripheral vision (r=-0.341, P=0.042), and composite score (r=-0.448, P=0.006). It indicates that better vision means a better quality of life. No correlations between the VFQ-25 scores and CMT reached significance at 12mo time point after surgery.

There were several limitations in our current study. First, the sample size was relatively small, and that may affect the scores of the VFQ-25. Second, the improved BCVA in phakic patients could be attributed partly to the combination of cataract surgery and vitrectomy, so it was difficult to ascertain the relative contribution of each procedure to the outcome. However, the effects of such a bias would have become weaker at month 12 than soon after the surgery at 3mo. Finally, our prospective design did not include a control group, as patients with macular hole who underwent only cataract surgery should be the optimal controls that can cancel the bias in cataract itself and the follow-up effect on improvement of VRQOL. However, it would be not consistent with the ethical requirements if we performed cataract surgery alone on patients with macular hole and followed them for a long time. So it is difficult to include such a group, this is the reason why the control group was absent in this and previous studies[12, 18].

In conclusion, our current study indicated that MH repair surgery improved visual function and VRQOL. The evaluation of VRQOL helps to provide a more complete overview of patients' experiences and satisfaction with surgery than do the use of visual and anatomic outcomes alone.

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