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Macular buckling versus vitrectomy on macular hole associated macular detachment in eyes with high myopia: a randomised trial

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ABSTRACT

Aim To compare the efficacy of macular buckling (MB) and pars plana vitrectomy (PPV) for full-thickness macular holes (FTMH) and associated macular detachment (MD) in highly myopic eyes.

Methods Prospective interventional case series of eyes undergoing PPV or MB for FTMH and MD.

Main outcome measures Best-corrected visual acuity (BCVA) at postoperative month 24. Other measured outcomes include the initial surgical success rate, macular hole closure rate and the progression of myopic maculopathy.

Results A total of 53 eyes from 53 participants were included in this study (26 participants receiving MB and 27 participants receiving PPV), and finally 49 eyes from 49 participants (25 participants in the MB group and 24 participants in the PPV group) were analysed. At postoperative month 24, the BCVA had improved significantly in those that underwent either MB (p<0.001) or PPV (p=0.04). The difference between the groups was not significant (p=0.653). The surgical failure rate after the primary treatment was significantly higher in the PPV group than the MB group (25.00% vs 4.00%, respectively; p=0.04). The macular closure rate was higher in the MB group compared with the PPV group, but the difference was not statistically significant (64.00% vs 58.33%, respectively; p=0.45). Myopic maculopathy development may be more severe following PPV than following MB surgery.

Conclusion Patients with high myopia obtained anatomical and functional improvements from either MB or PPV. However, MB achieved a significantly higher success rate in retinal reattachment compared with PPV.

Trial registration number NCT03433547.

INTRODUCTION

Macular hole (MH) associated macular detachment (MD) is a common vision-threatening complication that is difficult for vitreoretinal surgeons to treat. The surgical success rate is reported to be limited for MHs in highly myopic eyes,[1 2] possibly due to mechanical traction of the posterior staphyloma, poor function of the retinal pigment epithelium (RPE), a long axial length (AL) and choroidal degeneration. Many surgical approaches to treat MH-associated MD have been proposed, including intravitreal gas injections and pars plana vitrectomy (PPV) with or without internal limiting membrane (ILM) peeling using gas or silicone oil as an internal tamponade.[3–6]

Macular buckling (MB) with scleral imbrications has been established as a successful treatment that increases the success rate of surgery for MH-associated MD. MB is necessary to release both the anteroposterior traction caused by the posterior staphyloma and the tangential traction exerted by the vitreous cortex.[7–9] Recent studies have shown that MB achieved better visual improvement and anatomic recovery than vitrectomy in highly myopic eyes with macular hole-related retinal detachment (MHRD).[7 10–12] Although this newer procedure appears to be promising for the management of MHRD, the effectiveness of the MB technique has not been definitively determined, and further case–control studies are needed.

Thus, the purpose of this study was to compare the efficacy of MB with PPV as the primary procedure for MH-associated MD. To accomplish this task, we compared the postoperative best-corrected visual acuity (BCVA), initial retinal reattachment and MH closure rates between MB and PPV.

METHODS

Trial design

This trial was a prospective, randomised, parallel assignment, single site, open-label trial. This study was registered on the website ClinicalTrials.gov. Patients with high myopia who had MH and concurrent MD were recruited between August 2015 and October 2017 at Zhongshan Ophthalmic Center in Guangzhou, China. Patients who met the inclusion criteria and signed informed consent were randomly assigned to either the MB group or the PPV group.

Surgical failure was defined as the presence of postoperative MH and MD, which required a secondary surgery. It was assumed that the 1 month surgical failure rate would be 2.5% after receiving MB and 36% after receiving PPV, with 85% statistical power and a two-sided test. Thus, to allow for a 4% loss during follow-up, a total of 50 participants were required to participate in this study, with 25 patients in each arm (calculated using G-Power V.3.1.9.2 software).

Inclusion and exclusion criteria

The eligibility criteria for the study included highly myopic patients aged from 18 years to 70 years; AL greater than 26.5 mm or a refractive error (spherical equivalent) less than −8.0 dioptres; presence of full-thickness macular hole (FTMH) and MD on

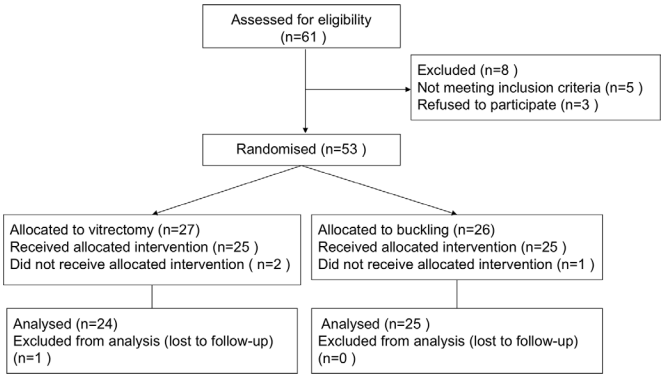

Figure 1 CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

optical coherence tomography (OCT); and clinical evidence of posterior staphyloma that involves the macular area. The exclusion criteria included MD, which extended to the peripheral retina (ie, extension beyond the major vascular arcades in more than one quadrant), a history of PPV or scleral buckling, an active intraocular haemorrhage or inflammation and any media opacity that precluded imaging or clinical evaluation of the macula.

Participants

A total of 61 patients with high myopia who showed FTMH and MD on OCT imaging were screened for this study. Five patients were excluded because they did not meet the eligibility criteria, and three patients refused to participate. Finally, a total of 53 patients were enrolled for randomisation (figure 1).

Randomisation and masking

Using a random number generator, the included participants were randomised with a 1:1 ratio to undergo either the PPV or MB surgical procedures. Given that the patients needed to understand the details of the procedure they were undergoing and any potential complications before providing informed consent, it was not possible to mask the participants or the doctors who performed the surgery. However, the doctors/technicians who performed the BCVA assessment, OCT imaging and intraocular pressure (IOP) measurements were masked.

Surgical technique

The participants in the MB group underwent the surgical procedures of MB, drainage of aqueous fluid and a filtered air injection into the vitreous cavity through the pars plana. The buckling surgery was performed with a silicone sponge-titanium exoplant, as previously reported.[13 14] In addition, 0.2–0.4 mL of filtered air was injected into the vitreous chamber through the pars plana. After surgery, the patients were asked to maintain a facedown position for 3 days.

The participants in the PPV group underwent small gauge vitrectomy, ILM peeling and filtered air tamponade. A transconjunctival 23-gauge or 25-gauge vitrectomy through the pars plana was performed regularly. After removing the core and posterior hyaloid, the ILM was stained with indocyanine green (ICG) and peeled with microforceps. The range of ILM peeling covered the whole macular area and crossed the main vascular arcade. Air-fluid exchange was performed, and the vitreous cavity was filled with filtered air. After surgery, the patients were asked to maintain a facedown position for at least 3 days.

Rescue procedure for surgical failure cases

For the eyes with FTMH and MD present after surgery, PPV combined with air or silicone oil tamponade was performed as a rescue procedure.

Outcome measurements

The included participants were evaluated at postoperative month 6, month 12 and month 24. Outcomes measurements included BCVA, initial surgical success rate, macular hole closure, myopic maculopathy progression and complications. All participants underwent a slit lamp examination, indirect ophthalmoscopy, dilated fundus photography, BCVA test, AL measurements with the Intra Ocular Lens Master, ocular motility assessment and IOP measurements. OCT images were obtained using the SPECTRALIS OCT (Heidelberg Engineering, Germany).

Statistical analysis

The data were processed and analysed with SPSS software for Windows (V19.0). All the data are presented as mean±SD. Comparison of the normally distributed variables was determined using two independent t-tests, while a Mann-Whitney U test was performed to analyse non-normally distributed continuous variables. The preoperative and postoperative logMAR BCVA and AL were analysed using a one-way analysis of variance. Qualitative data were assessed individually using χ^2 tests. A p value of less than 0.05 was considered statistically significant.

RESULTS

A total of 53 eyes from 53 participants were enrolled and randomly assigned to one of the two groups. Twenty-seven participants received PPV, and 26 participants received MB. Two participants in the PPV group and one participant in the MB group did not receive their allocated intervention. One participant in the PPV group was not included in the analysis because of the lack of follow-up after surgery. The participants' demographics and ocular characteristics for the two groups were well matched (table 1).

Comparison of the visual acuity between the groups

We obtained postoperative follow-up data for all the participants at 6 months, 12 months and 24 months. The difference was not significant between the two groups at each time point ($p>0.05$). The BCVA significantly improved in both surgical groups ($p<0.05$). For the eyes with MH closure, the postoperative BCVA improved significantly in both groups ($p<0.05$), and without a significant difference between the groups at each time point ($p>0.05$) (table 2).

Comparison of AL between the groups

The AL in the PPV group was not significantly different after surgery ($p=0.991$), whereas the AL was significantly shortened after surgery in the MB group ($p<0.001$). The difference in AL at each postoperative follow-up point was significant between the two groups ($p<0.001$). Throughout the follow-up period, there was a gradual reduction in surgical indentation in the MB group, which remained stable after 1 year (table 3).

Comparison of initial retinal reattachment and MH closure rate

Within the follow-up period of 24 months, initial retinal reattachment was achieved in 24 (96.00%) eyes in the MB group and 18 (75.00%) eyes in the PPV group ($p=0.04$). All seven failed cases underwent a secondary PPV due to recurrent MH

Table 1 Clinical characteristics of the highly myopic participants of macular hole associated macular detachment who underwent PPV or MB surgery

	PPV	MB	P value
No. of eyes	24	25	
Sex (M:F)	4:20	3:22	0.70
Age (years)	54.60±10.13	54.92±10.10	0.91
AL (mm)	29.03±1.94	29.15±1.78	0.82
RE (D)	−11.03±4.96	−10.58±3.34	0.75
IOP (mm Hg)	14.56±3.26	14.32±2.52	0.24
BCVA preop (logMAR)	1.49±0.53	1.59±0.49	0.53
MM			0.77
C1	4	3	
C2	15	19	
C3	3	2	
C4	2	1	

AL, axial length; BCVA, best-corrected visual acuity; ; IOP, intraocular pressure; MB, macular buckling; MM, myopic maculopathy; PPV, pars plana vitrectomy; RE, refractive error.

and MD after the first operation; among them, four patients had laser photocoagulation around the FTMH during the PPV (figure 2). The final retinal reattachment was 100% in both groups. The MH closure was maintained in 16 eyes (64.00%) in the MB group (figure 3A–E) and 14 eyes (58.33%) in the PPV group (p=0.45) (figure 3F–J) (table 4).

Postoperative myopic maculopathy progression

Preoperatively, 15 (62.50%) eyes had diffuse atrophy in the PPV group and 19 (76.00%) eyes in the MB group. The for patients who underwent laser photocoagulation during the PPV developed a fovea-centred circular macular atrophy (figure 4I–J). Six eyes progressed from diffuse atrophy to patchy atrophy in the PPV group (figure 4A–D), whereas no eyes progressed in this manner in the MB group. However, in the MB group, three eyes showed RPE changes within the buckling area (figure 4E–H) and two eyes showed patchy atrophy at the edge of the buckling area (figure 4K–L).

Comparison of severe complications observed in both groups

No major perioperative or postoperative complications were observed in the PPV group. Almost all of the participants in the MB group exhibited eye movement limitations, diplopia and metamorphopsia. However, the symptoms were reduced or fully resolved spontaneously after the 6-month follow-up. One eye in the MB group underwent buckle removal because of intolerable postoperative diplopia and metamorphopsia. Nine eyes with IOP elevation were observed on the second postoperative day

Table 2 Comparison of the BCVA in myopic eyes with macular hole associated macular detachment between PPV and MB groups

	All			MH closed		
	PPV	MB	P value	PPV	MB	P value
Preop	1.49±0.53	1.59±0.49	0.53	1.79±0.44	1.60±0.48	0.28
6 months	1.11±0.56	1.11±0.56	0.98	1.13±0.68	1.08±0.60	0.71
12 months	1.09±0.55	1.04±0.50	0.74	1.05±0.59	1.02±0.52	0.91
24 months	1.03±0.56	0.96±0.47	0.65	0.92±0.66	0.91±0.50	0.98
P values	0.04	<0.001		0.008	0.005	

BCVA, best-corrected visual acuity; MB, macular buckling; MH, macular hole; PPV, pars plana vitrectomy.

Table 3 Comparison of AL in myopic eyes with macular hole associated macular detachment between PPV and MB groups

	PPV (28)	MB (29)	P value
Preop	29.03±1.94	29.15±1.78	0.82
Half year	28.74±2.13	25.28±2.05	<0.001
One year	28.76±1.99	26.08±2.25	<0.001
Two year	28.82±2.00	26.06±2.23	<0.001
P value	0.99	<0.001	

AL, axial length; MB, macular buckling; PPV, pars plana vitrectomy.

in the MB group, while IOP elevation was not observed in the eyes in the PPV group. After receiving antiglaucoma medication, the elevated IOPs of all participants returned to normal within 2 weeks.

DISCUSSION

This study compared the effect of MB and PPV on FTMH-associated MD. Overall, both MB and PPV enabled postoperative improvement in BCVA; however, MB achieved initial higher anatomic success. This approach changes the macular contour and decreases the AL, vitreoretinal traction and traction induced by posterior staphyloma. As such, it was an effective intervention for FTMH-associated MD in highly myopic eyes. However, the MH closure rate was not improved by the MB and air injection techniques.

MHRD in high myopia is a challenge for retinal surgeons because of severe axial elongation, an abnormally thin retina and chorioretinal atrophy, which causes difficulty with ILM staining, peeling and posterior retinal reattachment. MB is a conventional surgical method for which various types of exoplants and techniques have been developed in recent years, such as the L-shaped and T-shaped silicone sponge that contains titanium, a silicone plate that contains a metal wire, the fibre optic light assisted MB technique and a sterile topical adhesive to fix the buckle.[15–18] Earlier studies that compared PPV with MB in eyes with highly myopic MHRD showed that MB yielded better anatomic and functional outcomes than PPV.[7] The surgical techniques PPV and ILM peeling were associated with a higher surgical failure rate. It has been reported that the retinal reattachment rate

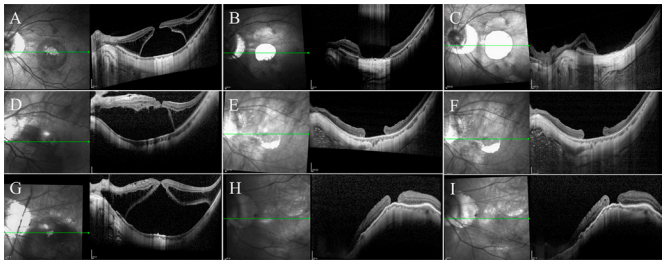

Figure 2 Development of macular atrophy after laser photocoagulation treatment for a recurrent macular hole (MH) and macular detachment (MD). (A–C) The participant underwent a secondary pars plana vitrectomy (PPV) with laser photocoagulation. (A) Preoperative image shows an MH and an MD, (B) the macular atrophy developed at postoperative 8 months, (C) the macular atrophy had enlarged at the 2-year follow-up. (D–F) A participant who was part of the PPV group. (D) A preoperative image shows an MH and an MD, (E) the retina reattached without MH closure at 1 year and (F) 2-year follow-up. (G–I) A participant who was part of the MB group. (G) A preoperative image shows an MH and an MD, (H) the retina reattached without MH closure at the 1 year and (I) 2-year follow-up.

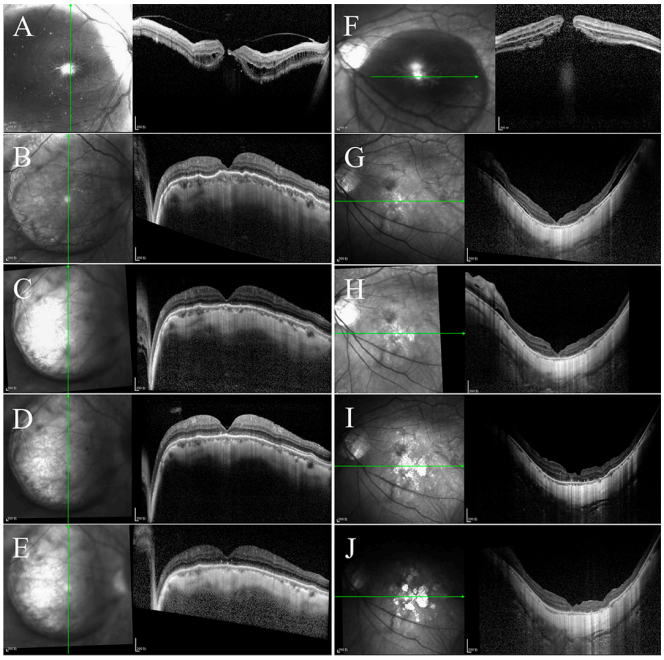

Figure 3 Optical coherence tomography scans of the participants who underwent either macular buckling (MB) or pars plana vitrectomy (PPV) surgery and whose macular hole (MH) was successfully closed. (A) A preoperative image showing an MH and macular detachment (MD) from a participant from the MB group. (B) An image at the 6-month follow-up after MB surgery shows the retina was reattached with MH closure. (C–E) The 1-year, 1.5-year and 2-year follow-up images. (F) A preoperative image showing an MH and an MD from a participant from the PPV group. (G) An image at the 6-month follow-up after PPV surgery shows the retina was reattached with MH closure. (H–J) The 1-year, 1.5-year and 2-year follow-up images; the infrared fundus image shows the appearance and enlargement of patchy atrophy.

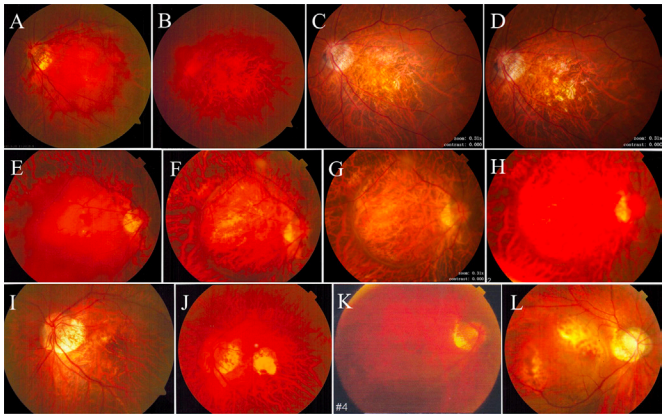

Figure 4 Progression of myopic maculopathy after pars plana vitrectomy (PPV) or macular buckling (MB). (A) A preoperative fundus photograph of a participant who underwent PPV without patchy atrophy. (B–D) The 1-year, 1.5-year and 2-year follow-up fundus photographs showing the development of patchy atrophy. (E) A preoperative fundus photograph of a participant who underwent MB. (F–H) The 1-year, 1.5-year and 2-year follow-up fundus photographs showing the retinal pigment epithelium changes within the buckle area. (I and J) Postoperative fundus photographs showing macular atrophy after laser photocoagulation during PPV. (K and L) Postoperative fundus photographs showing patchy atrophy at the edge of the buckle.

after a vitrectomy and ILM peeling is 50%–100%[3 19 20] and 80%–100%[15 21] after MB in individuals with MHRD. When comparing MB with a combined procedure of PPV and MB, the results showed that MB alone was faster, safer and as effective as the combined surgery.[22] After a vitrectomy, the elongated AL and posterior staphyloma would exert additional traction on the retinal surface, which might impede MH closure.

In the present study, 25% (6/24) of the PPV participants required a secondary procedure that consists of laser photocoagulation of the MH margin, which achieved anatomic success in the majority of the cases. A thermal laser has been shown to stimulate the wound-healing response in highly myopic MHs and promotes macular retinal reattachment.[23] However, a scar can form around the fovea, which may cause the postoperative BCVA to be worse than the preoperative BCVA. The MH closure rate in individuals with high myopia is reported to be 33.3%–63.2% in MH RD after PPV with ILM peeling[2 3 19] and 40%–93.3% after MB.[15] It is possible that MB counteracted the posterior sclera expansion, which accounts for the higher MH closure rate. However, according to our case series, the MH closure rate in the MB group was similar to that of the PPV group. There are several potential reasons: the functioning of the choroid and RPE might be significantly decreased due to progressive atrophy in elderly participants and participants who have high myopia, or the rigid ILM remained in situ after the MB procedure, which might serve as an obstacle for MH closure, whereas ILM peeling could release the traction of the internal vitreous body–macular interface. Inverted ILM insertion[3] and an inverted ILM flap[24] were reported to increase the rate of MH closure to 75%–100%. The ILM flap may induce glial cell proliferation and provide a bridge for cell migration, which enhances MH closure.[25] Further study is necessary to investigate the efficiency of combining the surgical procedures of MB and an inverted ILM flap.

Highly myopic eyes are frequently associated with patchy atrophy and chorioretinal atrophy, which has been described as a poor prognostic factor after PPV for MHRD.[26] The prevalence of macular atrophy in eyes with FTMH (13.2%) and MHRD (30%) was reported to be much higher than macular retinoschisis (3.3%) and foveal retinal detachment (4.4%). It has been speculated that susceptibility to RPE and potential toxicity with ICG can cause macular atrophy.[26] We have also speculated that further myopic maculopathy could be caused by attachment of the retina to the expanded eyeball, which causes RPE or Bruch's membrane damage. Macular atrophy can be a severe consequence of high myopia that accounts for significantly poor visual outcomes, even after successful retinal reattachment. Interestingly, in our study, the progression of myopic maculopathy was less severe in the MB group with only two eyes showing patchy atrophy at the edge of the buckle. It is possible that the buckle reduced the outward expansion of the retina, RPE and choroid, as well as avoided ILM peeling, which slows the progression of myopic maculopathy. One important concern about MB is the long-term effect on the compromised macula from the chronic compression of the buckle. We observed temporal choroidal thickening

Table 4 Comparison of initial success rate and MH closure rate between PPV and MB groups

	PPV (24)	MB (25)	P value
Recurrent MHRD, n (%)	6 (25.00)	1 (4.00)	0.04
MH closure, n (%)	14 (58.33)	16 (64.00)	0.45

MB, macular buckling; MH, macular hole; MHRD, macular hole retinal detachment; PPV, pars plana vitrectomy.

in the early postoperative period and spontaneous recovery in the late postoperative period (figure 3A–E). A possible reason may be the compression of choroid, as previously reported.[27]

Limitations

This study was a single-site study with a small sample size. With the buckling technique, the shortened AL could not be accurately measured during the operation, which might have led to the underestimation of the potential benefits.

A lack of uniform surgical materials, which may cause the outcomes and complications to differ among different studies.

The single MB procedure did not improve the MH closure rate. Considering that the RPE function might be poor and there may be tractions from the staphyloma and vitreous macular interface in individuals with high myopia, FTMH and MD, a combined surgery of MB with PPV and an inverted ILM is worthy of further analysis.

CONCLUSIONS

Both MB and PPV improved the BCVA of the participants. However, our results show that surgeons should consider MB for the treatment of FTMH and MD in patients with high myopia because this procedure enabled significantly more successful retinal reattachments than PPV.

Contributors XH, WM and PL did colour fundal pictures and optical coherence tomography exams of the whole study. XZ and YL collected clinical data and images and edited images. SC and XYwrote the statistical analysis plan, cleaned and analysed the data, and drafted and revised the paper. LL and BL was responsible for clinical treatment of the patients, initiated this study, designed data collection tools, implemented the study and revised the draft paper.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study was approved by the ethics committee of Zhongshan Ophthalmic Center and was conducted in accordance with the Principles of the Declaration of Helsinki and applicable local regulations.

Provenance and peer review Not commissioned; externally peer reviewed

Data availability statement Data are available on reasonable request.

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