• Clinical Research •

Short-term silicone oil tamponade on retinal structure and function in rhegmatogenous retinal detachment: a randomized controlled trial

Zi-Ye Chen, Yu-Qing Wu, Bao-Yi Liu, Yuan Ma, Zhuang-Ling Lin, Run-Ping Duan, Lan Jiang, Chinling Tsai, Zhuo-Jun Xu, Tao Li

State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangdong Provincial Key Laboratory of Ophthalmology Visual Science, Guangdong Provincial Clinical Research Center for Ocular Diseases, Guangzhou 510060, Guangdong Province, China

Co-first Authors: Zi-Ye Chen, and Yu-Qing Wu.

Corresponding to: Tao Li and Zhuo-Jun Xu. State Key Laboratory of Ophthalmology, Zhongshan Ophthalmic Center, Sun Yat-sen University, Guangdong Provincial Key Laboratory of Ophthalmology and Visual Science, Guangdong Provincial Clinical Research Center for Ocular Diseases, No.7 Jinsui Road, Guangzhou 510060, Guangdong Province, China. litao2@mail.sysu.edu.cn; xuzhuojun@whu.edu.cn

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Abstract

● **AIM:** To investigate the effects of shortening the duration of silicone oil tamponade on retinal structure and function in patients undergoing silicone oil removal (SOR) after surgery for primary rhegmatogenous retinal detachment (RRD).

● **METHODS:** A total of 58 eligible patients were enrolled and randomly assigned to two groups based on tamponade duration: the short-term group (30-45d) and the conventional group (≥90d). Comprehensive evaluations were performed before and after SOR, including slit-lamp examination, best-corrected visual acuity (BCVA) measurement, intraocular pressure (IOP) testing, optical coherence tomography (OCT), optical coherence tomography angiography (OCTA), microperimetry, electroretinography (ERG), and visual evoked potential (VEP) assessment.

● **RESULTS:** A total of 33 patients (23 males and 10 females; 33 eyes) were enrolled in the short-term SO tamponade group with mean age of 52.45±9.35y, and 25 patients (15 males and 10 females; 25 eyes) were enrolled in the conventional SO tamponade group with mean age of 50.80±12.06y. Compared with the conventional group, the short-term silicone oil tamponade group had a significantly lower incidence of silicone oil emulsification and cataract progression, with no significant difference in retinal reattachment success rate. Structurally, short-term tamponade was associated with increased thickness of the retinal ganglion cell layer (RGCL) in the nasal and superior macular regions and improved recovery of superficial retinal vascular density in these areas. Functionally, the short-term group showed better BCVA and retinal sensitivity both before and 1mo after SOR; additionally, the P100 amplitude in VEP tests was significantly increased in this group.

● **CONCLUSION:** Shortening the duration of silicone oil tamponade effectively reduces damage to retinal structure and function without compromising the success rate of retinal reattachment in patients with primary RRD.

● **KEYWORDS:** silicone oil tamponade; rhegmatogenous retinal detachment; silicone oil removal; retinal structure; retinal function; prognosis

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INTRODUCTION

Silicone oil (SO) is a macromolecular polymer synthesized with a backbone of repeating siloxane units, characterized by excellent biocompatibility with biological tissues and lacks significant biotoxicity. It is typically a transparent liquid with a refractive index similar to the vitreous body. The low density and high surface tension make it an ideal vitreous substitute, widely used in surgical treatments for retinal diseases[1]. Currently, vitrectomy combined with SO tamponade remains the predominant surgical technique for treating complex rhegmatogenous retinal detachment (RRD) and proliferative vitreoretinopathy.

Air or perfluoropropane (C_3F_8) could be used as alternatives to SO for intraocular tamponade, significantly reducing SO-related complications[2-4]. Nevertheless, comparative studies

indicate that gas tamponades often result in inferior retinal reattachment rates than SO and may not be suitable for complex retinal detachments or in circumstances demanding stable intraocular pressure (IOP), such as during air travel or at high altitudes. Despite the risk of emulsification and associated sequelae, including various forms of keratopathy, secondary glaucoma, cataracts, and neuroretinal damage, SO tamponade is sometimes the exclusive viable option for specific retinal detachment conditions[5-8]. Animal experiments have shown that pathological changes, such as retinal cell apoptosis, thinning of the ganglion cell layer (GCL), and glial cell activation, gradually appear four weeks after SO tamponade[9]. Clinical data also indicate that prolonged SO tamponade may exacerbate SO emulsification and associated retinal damage[10-11]. It suggests that shortening the duration of SO tamponade may be an effective strategy to mitigate SO-induced retinal damage.

The present study was designed to explore the safety of shortening the duration of SO tamponade and its effect on retinal structure and function by comparing the short-term and conventional SO tamponade groups.

PARTICIPANTS AND METHODS

Ethical Approval This study adhered to the principles outlined in the Helsinki Declaration and was reviewed and approved by the Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-sen University (Ethics Number: 2019KYPJ174). Informed consent was obtained from all patients prior to participation.

Study Design This study prospectively enrolled 58 patients who underwent silicone oil removal surgery (SOR) at Zhongshan Ophthalmic Center, Sun Yat-sen University, from January 2020 to March 2021. Follow-up for all participants was initiated immediately upon their enrollment and continued until June 30, 2023, ensuring a uniform duration of follow-up across participants.

The sample size was estimated from retrospective studies due to the lack of existing randomized controlled trial data, with an understanding that this approach carries inherent limitations. This conservative estimate aimed to mitigate the risk of underpowered results stemming from the retrospective nature of the reference data. Although the intention was to enroll participants in a 1:1 ratio for intervention and control groups, practical constraints led to a final distribution of 33 patients in the experimental group and 25 patients in the control group. A computerized random number generator was utilized to produce a 1:1 allocation sequence for intervention and control groups. This task was performed by an independent statistician who had no involvement in the enrollment or assignment of participants. Sequentially numbered, opaque, sealed envelopes containing group assignments were prepared by this statistician to ensure concealment.

Participants were enrolled by study coordinators who screened for eligibility, and upon completion of baseline assessments, the same study coordinators assigned participants to their respective interventions using the prepared sealed envelopes. By separating these duties, we minimized the risk of selection and allocation bias.

Inclusion criteria were as follows: 1) primary RRD involving the macula; 2) age≥18y; 3) proliferative vitreoretinopathy grade≤C1. Exclusion criteria were: 1) concomitant severe ocular diseases, such as corneal leukoma, advanced glaucoma, severe cataract, severe uveitis, advanced diabetic retinopathy, hypertensive retinopathy, ocular tumors, amblyopia, *etc.*; 2) complex retinal detachments, such as macular hole retinal detachment, giant retinal tears, RRD associated with choroidal detachment, *etc.*; 3) history of previous vitreoretinal surgery in the affected eye; 4) monocular patients. Patients were randomly divided into two groups based on the duration of SO tamponade (T): the short-term SO tamponade group (Group 1) with 30d≤T<45d, and the conventional SO tamponade group (Group 2) with T≥90d. After being screened according to the inclusion and exclusion criteria, patients were randomly assigned to either the short-term or conventional SO tamponade group. A computerized random number generator was utilized to produce a 1:1 allocation sequence for intervention and control groups, which was executed by an independent statistician to maintain blinding. The decision to proceed with SOR was based on whether the retina was reattached, as determined by slit-lamp or fundus photography. The decision of whether a patient can undergo an SOR is determined by two experienced vitreoretinal surgeons who were unaware of the duration of SO tamponade at the time of patient evaluation. All surgeries were performed by the same vitreoretinal surgeon (Li T).

After assignment to interventions, all investigators, outcome assessors, and data analysts were blinded to group allocation. However, due to the nature of the interventions, blinding of patients was not feasible. Blinding was maintained by using coded containers and documentation that did not reveal the treatment allocation. Unblinding procedures were only permissible under pre-specified conditions, such as medical emergencies requiring knowledge of the assigned intervention. General demographic data were collected, and detailed ocular examinations were performed before SOR, one month after surgery, and three months after surgery.

Outcome Assessments Optical coherence tomography (OCT) scans (DRI OCT Triton, Topcon, Japan) were performed using the 3D macular mode, with a scanning range of 7 mm×7 mm and a scanning resolution of 512×256 to acquire images. The acquired images were divided into three zones based on the ETDRS grid: the foveal center zone

(diameter 0-1 mm), the inner ring zone (diameter 1-3 mm), and the outer ring zone (diameter 3-6 mm). Retinal thickness was measured in three concentric rings and four quadrants (superior, temporal, inferior, and nasal) of both the inner and outer rings.

Optical coherence tomography angiography (OCTA) scans (DRI OCT Triton, Topcon, Japan) were performed using the OCTA mode, with a scanning range of 3 mm×3 mm and a scanning resolution of 320×320 to acquire images. Two concentric circles were delineated within the foveal center as the center point. The inner circle, with a diameter of 1 mm, was defined as the central zone, while the outer circle, with a diameter of 2.5 mm, was further divided into superior, inferior, nasal, and temporal quadrants. Vessel density (VD) in each region and foveal avascular zone (FAZ) area were measured separately within the superficial layer, automatically identified by the instrument, from the inner limiting membrane to the inner plexiform layer.

The microperimetry (MP-3 Microperimeter, Nidek, Japan) were conducted using the MP1 Macula_12deg mode to measure the retinal sensitivity within a 10-degree range of the macular region.

The electroretinography (ERG) and visual evoked potential evaluations (VEP) examinations (Visual Electrophysiology System, Roland, Germany) were performed in accordance with the international standards recommended by the International Society for Clinical Electrophysiology of Vision.

A detailed slit-lamp examination was conducted before the SOR (pre-SOR) to assess the progression of cataract and SO emulsification. The best corrected visual acuity (BCVA) and IOP examinations, microperimetry, OCT, and OCTA were conducted pre-SOR, 1mo after the SOR (1mo post-SOR), and 3mo after the SOR (3mo post-SOR). The ERG and VEP were assessed pre-SOR and 1mo post-SOR.

Statistical Analysis Data were analyzed using SPSS version 27.0 software. Independent samples *t*-tests were used to compare inter-group differences for normally distributed continuous data. For non-normally distributed continuous data, non-parametric Wilcoxon signed-rank tests were employed. Chi-square tests were applied for binary categorical variables. Data were presented as mean±standard deviation (SD), and $P<0.05$ was considered statistically significant.

RESULTS

Baseline Clinical Characteristics and Primary Anatomical Success Rate A total of 33 patients (33 eyes) were enrolled in the short-term SO tamponade group (Group 1), and 25 patients (25 eyes) were enrolled in the conventional SO tamponade group (Group 2). There were 8 patients of exclusion in Group 2 due to failure to attend scheduled follow-up appointments. All patients in both groups were evaluated preoperatively and determined to have well-attached retinas, making them eligible for SOR. Baseline demographic data and clinical characteristics are summarized in Table 1. There were no significant differences in gender, age, systemic disease, BCVA, IOP, the proportion of high myopia and the status of lens between two groups before retinal reattachment surgery ($P>0.05$). Duration of SO tamponade was 37.88±5.71d in short-term SO tamponade group and 192.16±76.87d in the conventional SO tamponade group, separately ($P<0.001$). No patients in either group experienced a recurrence of retinal detachment within six months following SOR.

Table 1 Baseline clinical data of Short-term (Group 1) and Conventional SO tamponade group (Group 2) Mean±SD, *n* (%)

Characteristics	Group 1	Group 2	*P*
Patients/No. of eyes	33/33	25/25	
Gender			0.442[b]
Male	23 (69.70)	15 (60.00)	
Female	10 (30.30)	10 (40.00)	
Age, y	52.45±9.35	50.80±12.06	0.572[a]
Systemic disease			
Hypertension	8 (24.24)	4 (16.00)	0.443[b]
Diabetes mellitus	2 (6.06)	2 (8.00)	0.773[b]
Stroke	0	0	
Coronary artery disease	0	1 (4.00)	0.246[b]
BCVA, logMAR	1.55±1.10	1.54±1.00	0.826[a]
IOP, mm Hg	11.67±4.01	11.06±4.11	0.632[a]
High myopia	5 (15.15)	7 (28.00)	0.232[b]
Status of lens			0.818[b]
Phakic (no-cataract)	17 (51.52)	15 (60.00)	
Phakic (cataract)	10 (30.30)	7 (28.00)	
Pseudophakic/aphakic	6 (18.18)	3 (12.00)	
Duration of SO tamponade, d	37.88±5.71	192.16±76.87	<0.001[a]

BCVA: Best corrected visual acuity; IOP: Intraocular pressure; SO: Silicone oil. [a]Mann-Whitney *U* test; [b]Fisher's exact test.

Table 2 Rate of cataract progression and SO emulsification before SO removal surgery *n* (%)

Parameters	Group 1	Group 2	*P*
Cataract progression	3 (9.09)	12 (48.00)	<0.001[b]
SO emulsification	13 (39.39)	20 (80.00)	0.002[b]

SO: Silicone oil. [b]Fisher's exact test.

Cataract Progression and Silicone Oil Emulsification The incidence of cataract progression was notably lower in the short-term tamponade group compared to the conventional tamponade group (9.09% *vs* 48.00%, $P<0.001$). Additionally, the occurrence rate of SO emulsification was significantly lower in the short-term tamponade group than in the conventional group, with statistical significance (39.39% *vs* 80.00%, $P=0.002$), as presented in Table 2.

BCVA, IOP and Retinal Sensitivity The results confirmed a gradual improvement in BCVA for the conventional

tamponade group over time, whereas the BCVA in the short-term tamponade group remained stable at a superior level throughout the follow-up period (Figure 1). At different time points, the short-term tamponade group exhibited superior BCVA compared to the conventional tamponade group, with statistically significant differences observed pre-SOR (0.61±0.31 *vs* 1.14±0.74, $P<0.001$) and 1mo post-SOR (0.56±0.28 *vs* 0.74±0.28, $P=0.047$). However, the difference was not significant 3mo post-SOR (0.54±0.33 *vs* 0.67±0.31, $P=0.308$). Additionally, the IOP did not exhibit any significant temporal trends or differences between the two groups at any time point. The microperimetry findings indicated that retinal sensitivity maintained at a relatively high level in the short-term tamponade group, while it showed a gradual increase from a lower baseline level in the conventional tamponade group, as depicted in Figure 2. At each time point, the retinal sensitivity of the short-term tamponade group was superior to that of the conventional tamponade group, but only the difference observed pre-SOR was statistically significant (pre-SOR: 21.34±3.99 *vs* 17.83±5.94 dB, $P=0.011$; 1mo post-SOR: 21.25±3.89 *vs* 19.61±4.06 dB, $P=0.167$; 3mo post-SOR: 21.14±5.51 *vs* 20.20±4.76 dB, $P=0.659$).

OCT and OCTA The OCT results indicated that the short-term tamponade group exhibited significantly greater thickness in the GCL in the superior and nasal sectors of the inner ring (diameter 1-3 mm) compared to the conventional tamponade group 1mo post-SOR (inner-superior thickness: 85.42±10.33 *vs* 72.02±19.26 μm, $P=0.007$; inner-nasal thickness: 85.52±12.04 *vs* 72.60±23.53 μm, $P=0.028$) and 3mo after the SOR (inner-superior thickness: 86.64±22.92 *vs* 69.92±18.93 μm, $P=0.016$; inner-nasal thickness: 87.94±13.08 *vs* 67.44±19.80 μm, $P=0.007$), as shown in Figure 3. However, there were no significant differences in retinal thickness in other regions.

The results of OCTA indicated that the short-term SO tamponade group exhibited significantly higher superficial retinal VD in the superior and nasal regions of the macula compared to the conventional SO tamponade group at 1mo post-SOR (superior VD: 48.64%±3.74% *vs* 46.35%±3.48%, $P=0.037$; nasal VD: 43.84%±3.95% *vs* 41.51%±3.13%, $P=0.011$) and 3mo post-SOR (superior VD: 49.62%±3.55% *vs* 44.44%±4.61%, $P=0.004$; Nasal VD: 44.47%±2.13% *vs* 40.94%±3.98%, $P=0.009$), as shown in Figure 4. There were no significant differences between the groups in retinal VD in other regions or in the FAZ area. These findings are consistent with the OCT results.

ERG and P-VEP The results of ERG demonstrated that, 1mo post-SOR, the amplitude of a-wave and b-wave increased significantly in full-field flash ERG examination compared to their pre-SOR level in both groups. However, no significant intergroup differences were observed at any of the time points.

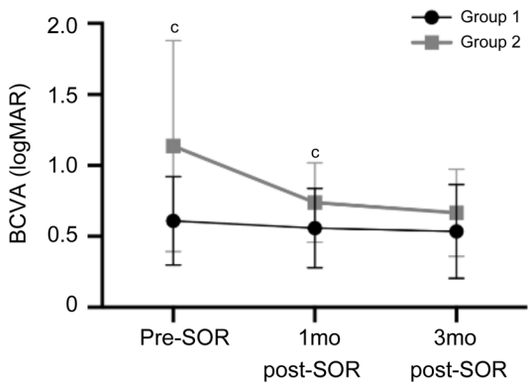

Figure 1 The change of BCVA over time between the two groups $^{c}P<0.05$. BCVA: Best corrected visual acuity; SOR: Silicone oil removal.

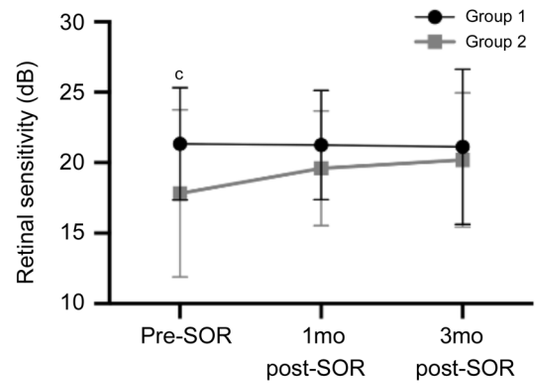

Figure 2 The change of retinal sensitivity over time between the two groups $^{c}P<0.05$. SOR: Silicone oil removal.

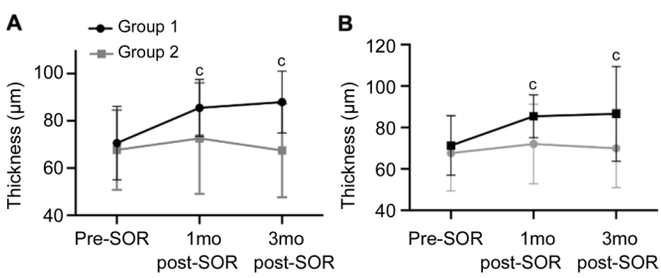

Figure 3 The thickness of GCL measured by OCT examination over time in the two groups A: GCL thickness in the inner nasal quadrant; B: GCL thickness in the inner superior quadrant. $^{c}P<0.05$. SOR: Silicone oil removal; GCL: Ganglion cell layer; OCT: Optical coherence tomography.

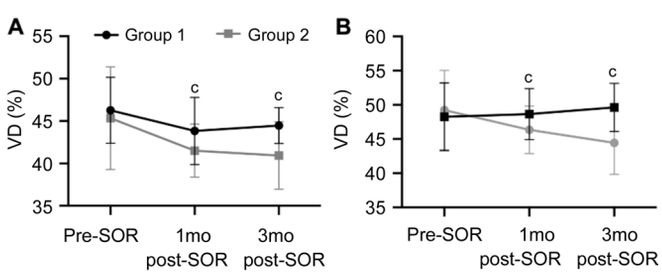

Figure 4 The vessel density measured by OCTA examination over time in the two groups A: Nasal VD of superfical retina; B: Superior VD of superfical retina. $^{c}P<0.05$. SOR: Silicone oil removal; VD: Vessel density; OCTA: Optical coherence tomography angiography.

The results of P-VEP indicated that, 1-month post SOR, the short-term tamponade group exhibited a significant increase in

P100 amplitude compared to their pre-SOR level. However, this change was not observed in the conventional tamponade group. The short-term tamponade group exhibited significantly higher P100 amplitude for both large check sizes (10.08±4.25 *vs* 6.31±2.93 μV, *P*=0.011) and small check sizes (10.18±1.48 *vs* 6.25±2.96 μV, *P*=0.017) compared to the conventional tamponade group. There was no significant difference in P100 latency between the two groups at any time points. Detailed data are summarized in Table 3.

Table 3 Results of P-VEP of both groups at different time point

mean±SD

Parameters	Group 1	Group 2	*P*
Pre-SOR[a], ms			
P100 latency (1D)	110.51±20.35	105.28±24.94	0.436
P100 amplitude (1D)	6.74±3.32	6.31±3.79	0.753
P100 latency (15min)	122.13±11.30	116.94±18.89	0.280
P100 amplitude (15min)	6.60±4.87	7.99±9.53	0.540
1mo post-SOR[a], ms			
P100 latency (1D)	115.36±8.90	122.02±9.94	0.083
P100 amplitude (1D)	10.08±4.25	6.31±2.93	0.011[c]
P100 latency (15min)	122.32±14.27	122.60±10.13	0.951
P100 amplitude (15min)	10.18±5.94	6.25±2.96	0.017[c]

SOR: Silicone oil removal surgery; P-VEP: Pattern-visual evoked potential. [a]Mann-Whitney *U* test; [c]*P*<0.001.

DISCUSSION

Over the past few decades, surgeons have typically assumed that the duration of SO tamponade for diseases such as RRD should be three to six months, or even longer[12-14]. It is generally accepted in the field that the duration of SO tamponade is positively correlated with the incidence of SO emulsification[5-8]. Some researchers have posited that the duration of SO tamponade does not correlate with the rate of primary anatomical success[15]. However, there is insufficient evidence on whether shortening the duration of SO tamponade can reduce the occurrence of SO-related complications.

This study is the first to reduce the duration of SO tamponade to approximately one month and to compare its outcomes with those of the conventional tamponade duration, which typically exceeds three months. We investigated the effects of shortening SO tamponade duration on primary anatomical success rates, visual outcomes, and retinal structure and function in patients after retinal reattachment surgery. During the observation period of more than six months, none of the patients in either group experienced recurrent retinal detachment, demonstrating that shorten the duration of SO tamponade to around one month does not compromise the success rate of retinal reattachment.

The onset timing of emulsification varies across different studies, potentially due to factors related to the SO itself (such as viscosity, manufacturing process, and batch effects), individual patient differences, and variations in the methods used to detect and assess emulsification[16-18]. Our findings indicate that reducing tamponade duration can further decrease the incidence of SO emulsification compared to the conventional tamponade duration, thus potentially minimizing emulsification-related complications.

Cataracts was identified as another complication following SO tamponade[19]. SO tamponade may lead to histopathological changes in the anterior capsule of the transparent lens with the exact mechanism remains unknown[20-21]. This study confirmed that shortening the duration of SO significantly reduced the proportion of cataract progression.

Previous studies have demonstrated that prolonged SO tamponade may lead to thinning of the inner retinal layers, especially the RGC layer, which might be related to impairment of the ganglion cell complex[22-23]. Other studies have also reported reductions in the thickness of the peripapillary retinal nerve fiber layer and the subfoveal choroidal region associated with SO tamponade[24-26]. Numerous studies have confirmed the impact of SO tamponade on retinal blood flow, including reduced foveal blood VD and increased central FAZ area. Notably, some abnormalities in retinal structure and blood supply gradually recover over time following SOR, while others persist as permanent damage[27]. A retrospective cohort study demonstrating that an SO tamponade duration of 6-8mo significantly increases the risk of thinning in the macular fovea and parafovea compared to a duration of 3-4mo[10]. Our data indicated that further shortening the duration of SO tamponade to one month could lead to an increase in retinal RGC layer thickness and superficial VD after SOR, thereby contributing to better retinal structure.

Previous studies demonstrated that the amplitudes of the a-wave and b-wave in ERG examinations increased significantly following the removal of SO. This increase is likely related to the insulating effect of SO on bioelectrical signals, as evidenced by the lack of significant differences between various tamponade durations[28-29]. Additionally, it has been reported that SO tamponade have no significant impact on flash VEP results[30]. In our study, the results of ERG examinations were consistent with these findings. Notably, the pattern VEP results in our study suggested that shortening the duration of SO tamponade could increase the P100 amplitude 1mo after SOR, although the underlying mechanism requires further investigation.

Compared to gas tamponade, SO tamponade might lead to a decrease in retinal sensitivity in RRD patients[31]. However, retinal sensitivity can gradually recover over time after SOR, coinciding with the improvements in BCVA[11,32]. We observed similar findings in the conventional SO tamponade group. Encouragingly, in the short-term SO tamponade group, retinal

sensitivity remained consistently high and did not diminish over an extended postoperative time. BCVA trends paralleled retinal sensitivity alterations in both groups. The conventional tamponade group demonstrated progressive BCVA improvement after SOR, whereas the short-term tamponade group maintained stable and favorable BCVA outcomes. Compared to electrophysiology examinations, microperimetry may better reflect visual function before and after SOR.

The limitations of this study are as follows: First, the sample size is relatively small, and the available data has a short follow-up period of three months. Second, the condition of the contralateral eyes was not included in the analysis, resulting in a lack of normal controls in our study. Nevertheless, the existing data still support the advantages of short-term SO tamponade in the treatment of RRD.

In conclusion, this study demonstrated that shortening the duration of SO tamponade to approximately one month could effectively reduce SO-related damage to retinal structure and function, without compromising the rate of retinal reattachment. Furthermore, shortening the duration of SO tamponade could also reduce the time patients are required to maintain fixed positions, such as face-down positioning, thereby enhancing patient comfort. This approach provided a new perspective for improving the overall outcomes of RRD patients.

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