• Clinical Research •

Analysis of the rates of emulsification in intraocular silicone oil tamponades of differing viscosities

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Abstract

● **AIM:** To investigate the rates of emulsification in silicone oil (SO) tamponades of differing viscosities used during pars plana vitrectomy (PPV) in the treatment of complicated vitreoretinal diseases.

● **METHODS:** This study was a prospective randomized clinical trial. Totally 290 cases with greater likelihoods of secondary detachment were included and randomly grouped into either Siluron 2000 (*n*=143) or Siluron 5000 (*n*=147) SO tamponades with 23-gauge PPV. Patient follow-ups and data analyses were conducted 1, 3, 6, and 12mo post-surgery.

● **RESULTS:** The time of the SO emulsification ranged from 1 to 17mo, with a mean of 7.3±4.2mo. The Siluron 5000 group showed a slower emulsification rate in comparison to the Siluron 2000 group. The Siluron 2000 group took a shorter time to show signs of emulsification, necessitating earlier SO removal. However, there were no significant differences in the occurrence of complications, including secondary retinal detachment, cataract, corneal abnormality, high intraocular pressure and hypotony.

● **CONCLUSION:** The Siluron 2000 SO tamponade shows a faster rate of emulsification than the Siluron 5000 SO, necessitating earlier removal. Both groups show similar results in terms of anatomical success and visual acuity outcome, and there is no significant difference between the SOs regarding the occurrence of complications.

● **KEYWORDS:** silicone oil; emulsification; viscosity

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INTRODUCTION

Intraocular tamponade has become an essential technique in the treatment of retinal detachment (RD)[1-2], providing intraocular support and facilitating reattachment to achieve anatomical success. Silicone oil (SO) is a popular choice of tamponade as it is able to prevent fluid from entering the subretinal space, thus promoting adhesion between the retinal layer and the retinal pigment epithelium (RPE), especially there is no inert gas can be used in China. Surgical intervention has become a common form of treatment for an increasing number of complicated cases, including, but not limited to, proliferative diabetic retinopathy (PDR), proliferative vitreoretinopathy (PVR), giant retinal tears[3], cytomegalovirus retinitis, and trauma. There is an expanding need for the use of intraocular SO tamponade.

In comparison to other forms of tamponade, SO can be retained for a longer period, allowing more time for reattachment of the retina. However, shear forces acting upon the SO can cause dispersion into tiny droplets, a process known as emulsification. Emulsified SO often migrates into the anterior chamber[4] causing inflammation, cataract, glaucoma[5], keratopathy, and corneal decompensation[6]. Several factors influence the rate of SO emulsification, including oligosiloxanes, hydroxy-end groups[7], blood constituents[7], phospholipids and lipoproteins[7], remnant metal ions from catalysts, and interfacial tension[8]. However, current studies have shown that resistance to emulsification is highly dependent upon the viscosity of the SO. Substances with lower viscosities require less energy for a large bubble to be dispersed into small droplets. However, a low-viscosity SO has greater fluidity. Therefore, an SO with a viscosity of 1000 mPas is more fluid and easier to inject and remove than a SO with a viscosity of 5000 mPas. However, low-viscosity SO leads to a faster emulsification rate[9-13]. As SO emulsification can lead to postoperative anterior segment complications, such as keratopathy, cataract, and glaucoma[14-17], it has been recommended that SO is removed between 3 to 6mo post-surgery. Despite its necessary removal, there is still no definite

agreement about the optimal time to remove SO due to scarce knowledge of the *in vivo* emulsification process and the high variability among individuals.

There has been an ongoing conflict about the choice of what types of SO tamponade. On one hand, advancements of smaller gauge vitrectomy create a greater need for SO of higher fluidity that can be more easily introduced and removed through smaller gauge sclerectomies, using finer instruments and cannulae. On the other hand, low-viscosity SO has a faster rate of emulsification and requires earlier removal, which may affect the success of surgical treatment. This study aims to investigate the natural course of SO emulsification *in vivo* in Siluron 2000 and Siluron 5000 SOs and evaluate the effects and the feasibility of using these SOs in treating RD. The intraocular SO tamponade was retained as long as possible until the first signs of emulsification were observed to better understand the emulsification process.

SUBJECTS AND METHODS

Ethical Approval This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of the Zhongshan Ophthalmic Center (2017KYPJ059), registered at the International Standard Randomized Controlled Trial registry (ISRCTN53986599). Written informed consent was obtained from all of the participants before surgery.

Study Design and Patient Eligibility This study was conducted as a prospective randomized clinical trial. Totally 290 consecutive patients who underwent pars plana vitrectomy (PPV) and intraocular SO tamponade due to complicated RDs between Aug. 2016 and Dec. 2017 were included in the study. Indications for the use of SO tamponade include complicated RD associated with Grade C or Grade D advanced PVR, PDR, macular hole with RD in highly myopic eyes, severe trauma, RD combined with choroidal detachment, and giant retinal tears extending more than ninety degrees.

All procedures were performed by a single surgeon (Lu L), using similar surgical procedures and techniques. Surgery involved a 23-gauge, 3-port pars plana approach (Constellation® Vision System, Alcon Laboratories, Inc., Fort Worth, TX, USA), detachment of the posterior hyaloid face, vitrectomy, endolaser photocoagulation around the tears or peripheral retina, and an exchange of fluid with air followed by an exchange of air with SO. SO with a viscosity of 2000-centistoke (Siluron 2000, Gueder, Fluoron GmbH, Neu-Ulm, Germany) and 5000-centistoke (Siluron 5000, Gueder, Fluoron GmbH, Neu-Ulm, Germany) were used according to the random grouping of patients by the random number table method. In sixty cases with severe PVR (20.7%), an additional scleral buckling was performed, while the remaining 230 cases (79.3%) did not have such a procedure. In thirty-seven cases, SO removal was combined with cataract extraction and intraocular lens (IOL) implantation. At the end of the surgery, the fundus was examined under a noncontact wide angle microscope to ensure that the retina was attached, and no large SO bubbles remained in the vitreous cavity.

The main indications of SO removal included a complete anatomical reattachment of the retina, first signs of SO emulsification, reverse hypopyon, and other SO-related complications, such as ocular hypertension, keratopathy, or oil-corneal touch, occurring within the duration of SO tamponade. The prolonged retention of SO tamponade was indicated in complicated conditions, such as advanced PVR, RD after a severe ocular trauma, macular hole with RD in highly myopic eyes, and giant retinal tears. SO removal was performed using an infusion tube and 23-gauge trocar-cannulas[18], follow by fluid-air exchange.

All cases were followed-up on the first day after operation and 1, 3, 6, and 12mo post-surgery. All patient examinations were performed by two independent investigators (Liu BQ and Li YH) who were blinded in terms of types of SO. Ocular examinations included measuring best-corrected visual acuity (BCVA), a slit-lamp examination of the anterior segment, an intraocular pressure (IOP) measurement, and a dilated fundoscopy.

The anatomical outcome was considered successful only for the cases when the retina remained attached after a single procedure on the eyes that were treated with PPV and SO tamponade, or after SO removal at the twelve-month follow-up interval. Otherwise, some developed secondary RD or progressive local RD despite adequately performed laser coagulation, which was considered to be recurrent RD. The BCVA was converted to a logarithm of the minimum angle of resolution (logMAR). Improvement or worsening in BCVA was determined as at least a 0.3 logMAR (doubling or halving the decimal visual acuity) change of visual acuity. In our study, glaucoma was defined as an IOP of more than 25 mm Hg or higher than 20 mm Hg with topical or systemic anti-glaucoma medication. Treatment with drugs to lower IOP was administered when the IOP was higher than 25 mm Hg, and, for the majority, stopped after SO removal. Hypotony was defined as an ocular hypotension status lower than 5 mm Hg. According to the Silicone Study[19], SO-associated keratopathy included bullous keratopathy, calcific band keratopathy, corneal endothelial decompensation, corneal edema, endothelial degeneration, and opacification. First signs of emulsification represent the emulsified SO was seen in the anterior chamber, vitreous and epiretinal.

Statistical Analysis Patient baseline and follow-up data were analyzed by SPSS software 16.0 (SPSS for Windows, Rel. 16.0; SPSS, Inc., Chicago, IL USA). A two-sample, two-

sided *t*-test was used to compare interval level variables, while a Fisher exact test, or the χ^2 test, was performed among the categorical variables. By calculating the conventional percentages of the available number of cases, the rates of complications, visual outcomes of the same follow-up period were obtained and analyzed by the Fisher exact test.

RESULTS

The mean age of patients was 46.58±15.97y, and the ratio of female to male was 34:111. Totally 244 cases were phakic, whereas 32 cases were pseudophakic. The indications for the use of SO were complicated RDs associated with Grade C or Grade D advanced PVR (64 eyes, 22.1%) and rhegmatogenous detachments with PVR of Grade B (152 eyes, 52.4%). Cases were graded according to Machemer *et al*'s[20] proposed classifications. The indications for the use of SO tamponade for other cases were PDR (42 cases, 14.5%), RD in highly myopic eyes (36 eyes, 12.4%), and eyes with giant retinal tears extending more than ninety degrees (34 eyes, 11.7%). In the preoperative period, a detailed ophthalmic examination was carried out. Patients were randomized into two groups: the Siluron 2000 and Siluron 5000 groups. There were no significant differences between the two groups in terms of demographic characteristics and the causes of RD (Table 1).

The duration of SO emulsification ranged from 1 to 17mo, with a mean of 7.3±4.2mo. As can be seen from Table 2, Siluron 2000 showed a faster emulsification rate than Siluron 5000, in terms of the first signs of SO emulsification and reverse hypopyon.

The rate of recurrent RD was higher in the Siluron 2000 group than the Siluron 5000 group, but the differences were not statistically significant at each of the investigated follow-up intervals (Table 3). There were no significant differences between the two groups in respect to change in BCVA (Table 4). An increase in BCVA was combined with continued improvement in retinal function after successful retinal reattachment, cataract extraction, and reduction in the optical effects of the SO bubble after the SO was removed.

There were no significant differences between the two SO-viscosity groups regarding the occurrence of SO-related complications. Cataract formation was observed mostly within the first half of the postoperative year in the 159 cases that had clear, phakic lenses pre-surgery. In these cases, cataract surgery was combined with SO removal to improve functional rehabilitation. During the period of SO tamponade, the rate of elevated IOP (higher than 25 mm Hg) between the two groups showed no significant differences. After SO removal, these temporary changes returned to normal in all the affected patients. There were no significant differences in hypotony and corneal abnormalities between the two groups (Table 5).

Table 1 Demographic characteristics of subjects *n* (%)

Variables	2000-Centistoke SO	5000-Centistoke SO	*P*
No.	143	147	
Age (y)	45.23±16.24	47.85±15.79	0.998
Gender (female:male)	30:113	38:109	0.328
BCVA (logMAR)	1.76±0.55	1.78±0.54	0.808
IOP (mm Hg)	11.16±5.31	11.61±4.47	0.747
Choroidal detachment	18	26	0.226
Lens status			0.744
Aphakic	4 (2.8)	7 (4.8)	
Phakic	121 (84.6)	123 (83.7)	
Pseudophakic	17 (11.9)	15 (10.2)	
Lens subluxation/dislocation	1 (0.7)	2 (1.4)	
Follow-up, mean±SD	10.2±4.3	10.4±5.1	0.121
Median (range), mo	8 (1-17)	7 (1-15)	
RD etiology			
RRD	102 (71.3)	114 (77.6)	0.224
Recurrent RD	24 (16.8)	20 (13.6)	0.451
PDR	24 (16.8)	18 (12.2)	0.272
High myopia	16 (11.2)	20 (13.6)	0.553
Giant retinal tear	18 (12.6)	16 (10.9)	0.652
Choroidal detachment	25 (17.5)	27 (18.4)	0.844
VH	28 (19.6)	24 (16.3)	0.470
Retinectomy	17 (11.9)	20 (13.6)	0.661
Combine encircling band	27 (18.9)	33 (22.4)	0.453

BCVA: Best corrected visual acuity; IOP: Intraocular pressure; RD: Retinal detachment; RRD: Rhegmatogenous retinal detachment; PDR: Proliferative diabetic retinopathy; VH: Vitreous hemorrhage.

Table 2 Compared rates of SO emulsification for all cases between two groups *n* (%)

Variables	Siluron 2000	Siluron 5000	*P*
First sign of emulsification			
1mo	14 (9.8)	2 (1.4)	0.002
3mo	45 (33.1)	22 (16.8)	0.002
6mo	63 (52.1)	26 (22.4)	<0.001
12mo	94 (83.2)	58 (56.9)	<0.001
Reverse hypopyon			
1mo	6 (4.2)	1 (0.7)	0.064
3mo	21 (15.4)	8 (6.1)	0.014
6mo	33 (27.3)	12 (10.3)	0.001
12mo	53 (46.9)	32 (31.4)	0.020

DISCUSSION

The emulsification of SO is influenced by several factors, but mainly by viscosity and interfacial tension. High-viscosity SO tends to have higher stability in terms of emulsification resistance and fills the vitreous cavity more completely. 2000-centistoke SO is easier and faster to inject and remove from the vitreous cavity, especially when using small-gauge instruments, such as 25- or 27-gauge[21-24]. This study

Table 3 Retinal redetachment rates by type of oil and length of follow-up *n* (%)

Follow-up	Redetachment rate		*P*
	Siluron 2000	Siluron 5000	
1mo	12/143 (8.4)	7/147 (4.8)	0.212
3mo	17/136 (12.5)	9/131 (6.9)	0.121
6mo	21/121 (17.4)	11/116 (9.5)	0.076
12mo	20/113 (17.7)	10/102 (9.8)	0.095

Table 4 Change in visual acuity by types of SO during follow-up *n* (%)

Follow-up	Change in visual acuity			*P*
	Worse	Stable	Improved	
1mo				0.559
2000	19 (13.3)	61 (42.7)	63 (44.1)	
5000	17 (11.6)	73 (49.7)	57 (38.8)	
3mo				0.308
2000	26 (19.1)	54 (39.7)	56 (41.2)	
5000	24 (18.3)	43 (32.8)	64 (48.9)	
6mo				0.875
2000	23 (19.0)	53 (43.8)	45 (37.2)	
5000	25 (21.6)	44 (37.9)	47 (40.5)	
12mo				0.665
2000	24 (21.2)	54 (47.8)	35 (31.0)	
5000	22 (21.6)	44 (43.1)	36 (35.3)	

Table 5 Complications due to the SO used as endotamponade by follow-up visit *n* (%)

Complications and type of oil	Follow-up			
	1mo	3mo	6mo	12mo
Elevated IOP, >25 mm Hg				
2000	16 (11.2)	13 (9.6)	11 (9.1)	5 (4.4)
5000	22 (15.0)	12 (9.2)	8 (6.9)	6 (5.9)
P	0.341	0.911	0.534	0.628
Hypotony				
2000	2 (1.4)	3 (2.2)	2 (1.7)	0
5000	1 (0.7)	2 (1.5)	2 (1.7)	0
P	0.546	0.682	0.966	
Corneal abnormality				
2000	8 (5.6)	9 (6.6)	11 (9.1)	9 (8.0)
5000	12 (8.2)	11 (8.4)	11 (9.5)	13 (12.7)
P	0.388	0.581	0.917	0.248
New cataract[a]				
2000	12 (14.3)	19 (24.1)	23 (37.1)	31 (55.4)
5000	12 (16.0)	21 (30.9)	25 (39.7)	30 (55.6)
P	0.763	0.353	0.766	0.629

[a]Of 159 cases with clear, phakic lenses preoperatively.

presents an analysis of the *in vivo* emulsification process of SO tamponade. As expected, a significantly higher degree of emulsification was observed in the Siluron 2000 group compared to the Siluron 5000 group in the same amount of time. The time taken for the emulsified SO droplets to first appear epiretinally, in the vitreous or on the surface of the posterior lens capsule was much shorter in the Siluron 2000 group than the Siluron 5000 group. Emulsified SO droplets in the anterior chamber were also observed earlier in the patients with Siluron 2000 tamponade. Hence, patients in the Siluron 2000 group generally needed an earlier removal of the SO. These results confirm previous studies that have demonstrated greater SO emulsification in low-viscosity SO than in high-viscosity SO[7,10].

Several factors affect SO emulsification rates, such as how much the SO fills the vitreous chamber and the effects of indentation from the encircling scleral band[25-26], if any. Studies reported an improvement in BCVA in patients with an attached retina after SO removal. The improvement of BCVA after the SO removal was caused by the reversal of refractive changes, the gradual healing of the reattached retina, the removal of the emulsified SO bubbles, and the removal of opaque lenses through cataract surgery and IOL implantation. The results of this study indicated that anatomic and BCVA outcomes were similar between the Siluron 2000 group and Siluron 5000 group. Ambulatory vision and retinal reattachment were achieved in most eyes in both groups at each follow-up interval during the investigation, with the retina completely attached in approximately 90.2% of the eyes in the Siluron 5000 group and 82.3% in the Siluron 2000 group. Ambulatory vision was achieved in approximately 80% of the eyes in each group at the one-year follow-up interval. There may be a tendency for recurrence in the Siluron 2000 group. The rate of recurrent RD was higher in the Siluron 2000 group than the Siluron 5000 group, although the difference was not statistically significant. The possible reason may be that the surface tension of Siluron 2000 SO is weak and the emulsification time is early which needs to be removed earlier than Siluron 5000 SO.

There are several limitations in our study. First, the patients enrolled were heterogeneous. Second, SO emulsification was decided by slit-lamp ophthalmoscope which could be subjective. Third, the time of SO removal was generally earlier in the Siluron 2000 group than the Siluron 5000 group.

In conclusion, there were no significant differences in the anatomic and BCVA outcomes and the complication rates between the two groups. Retinal reattachment and ambulatory vision was achieved in most of the eyes that had undergone repairs for complex RD with either 2000- or 5000-centistoke SO tamponade. Although emulsification occurred earlier in the Siluron 2000 group, there were no significant differences among the patients with elevated IOP at each of the follow-up intervals. Siluron 2000 SO can be a better choice for uncomplicated cases as it is easier and faster to inject and remove from the vitreous cavity. However, for the complicated

cases that have high risks of retinal redetachment and require extended periods of SO tamponade, Siluron 5000 still proves to be a better choice, especially for SO-dependent eyes.

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