Long-term complications according to silicone oil type. A single center cohort study.

ABSTRACT

Purpose: To study the incidence of macular edema (ME), ocular hypertension (OHT), emulsification and migration to the anterior chamber (AC) of silicone oil (SO) in patients after complex retina surgery, stratified by SO type.

Methods: Retrospective, cohort study. Patients who underwent retina surgery with SO injection and extraction in our center were included. We compared the complication rates of ME, OHT, emulsification and migration to the AS according to SO type (1300cSt, 5700cSt and heavy SO). Data on age, sex, emulsification time, duration of the tamponade, previous retina surgeries and diagnosis were also gathered and included in a multivariate analysis.

Results: We included 163 patients (mean age of 64.8 years; mean duration of the tamponade: 11 months). Rates of emulsification, ME, OHT and SO migration to the AC were similar in all groups (p=0.998, 0.668, 0.915 and 0.360). ME was the most frequent complication (33.3-47.8%), which resolved after SO extraction in 77.6% of cases. The majority of cases with OHT persisted (61.7%). Emulsification was related to younger age (OR 0.94) and longer duration of the tamponade (OR 1.04). The odds of SO migration to the AC increased with emulsification (OR 2.78), recurrent retinal detachment (OR 0.99) and aphakia (OR 4.05).

Conclusions: We propose SO extraction as the preferred treatment for ME during SO tamponade. SO extraction should be performed sooner in younger patients to avoid emulsification. In selected patients, we suggest a longer duration of the tamponade up to 11 months with a reasonable safety profile, regardless of the SO type.

INTRODUCTION

The choice of silicone oil (SO) as a tamponade agent in retina surgery is made by surgeons depending on several factors. Extensive proliferative vitreoretinopathy (PVR) (grade C) and pathology affecting the inferior retina are common indications for its use, as well as giant retinal tears, ocular trauma, viral retinitis or endophthalmitis. SO is also the preferred tamponade in patients unable to maintain a specific postoperative position.[1] Application of gas or air in these particular cases is not recommended, as the rapid gravitational change in location depending on patient posture and even in compliant patients can result in increased postsurgical failure rates due to PVR.

SOs are generally categorized by their density: Light SOs have lower density than water, causing them to accumulate in the superior part of the vitreous cavity for up and about patients with upright posture. Light SOs are divided into two groups based on their viscosity: 1000/1300cSt and 5000/5700cSt. Heavy SOs (often mixed with semi-fluorinated agents) are heavier than water, making them sink relative to the aqueous, so they accumulate at the inferior retina for up and about patients with upright posture.[2] According to their gravitationally induced distribution in the vitreous cavity, light and heavy SOs are normally used for treating superior and inferior retinal pathology, respectively.

Despite their convenient delivery and safety, SOs can lead to glaucoma, cataract, keratopathy [2,3] or macular edema (ME) [4], in many cases as a result of SO emulsification. Therefore, SO should be extracted, generally after 3-6 months[5,6], although there are more recent reports suggesting that removal time may be extended up to a year for

selected patients under close monitoring.[7] Density and viscosity may affect SO emulsification rate. [1]

Here, we perform a retrospective single center cohort study of 163 patients treated with 1300cSt, 5700cSt and heavy SO.

MATERIAL AND METHODS

We retrieved and reviewed all electronic clinical charts of patients undergoing retina surgery between 2017 and 2021 in our center. We performed an automatic search of the surgical report including the terms “silicone oil”. Inclusion criteria included SO extraction performed in our center, and a follow-up period of at least 6 months after the extraction. Exclusion criteria were loss of follow-up and SO injection or extraction performed in another center.

Primary outcomes were the presence of SO emulsification, ME, ocular hypertension (OHT) and SO migration to the anterior chamber (AC), stratified by SO type. Secondary outcomes were months until SO emulsification, duration of SO tamponade or time until SO extraction (months), lens status (phakic, capsular bag IOL, sulcus IOL, iris-claw IOL and aphakia), number of previous retina surgeries, and retinal disease that precipitated the surgery. Data on age and sex was also gathered.

After SO injection, patients were followed-up on the first post-operative day, after two weeks and then monthly or bimonthly until SO removal. Main criteria to remove the silicone oil were attached retina without any sign of PVR after 4-6 months, high intraocular pressure not controlled with topical medication, SO emulsification, corneal endothelium contact with SO and ME. After SO extraction, patients without complications were followed up on the day after extraction, two weeks after the

surgery, then monthly during the first 3 months, then every 3 months. In every follow-up visit an ultra-widefield retinography (Optos® California) was performed, together with a macular radial OCT (DRI-Triton, Topcon, Japan), biomicroscopy examination and intraocular pressure measurement. All surgeries and follow-up visits were performed by three retina specialists (JMB, EPP, MCDE), using the same operation procedures and techniques. The presentations of SO used were Oxane®1300, Oxane®5700cSt and Oxane®HD (Bausch+Lomb, Vaughan, Canada).

In those patients who underwent more than one surgery with SO injection, data from the last surgery were collected.

Variables and outcomes were stratified by SO type and compared between: 1300cSt light SO, 5700cSt light SO and high density SO.

Also, we hypothesize that emulsification, ME and OHT can be predicted by SO type, duration of the tamponade, diagnosis, age and sex. Also, SO migration to the AC can also be predicted by emulsification and lens status.

This study was conducted in accordance with the tenets of the Declaration of Helsinki and was approved by the institutional review board (ID number: PI-117)

Statistical analysis

We performed a multiple logistic regression for each of the main variables studied: emulsification, ME, OHT and SO migration to the AC. In the multivariate analysis we included data on age, sex, duration of the tamponade, SO type, diagnosis (recurrent retinal detachment) and lens status. The goodness of fit of the model is shown as the area under the ROC curve.

Silicone oil types were compared using ANOVA test for the quantitative variables and the Chi-square test for the categorical variables. A Kaplan-Meier survival analysis was performed for analyzing the time until silicone oil emulsification in each group, using Mantel-Cox log-rank test for group comparison. There was no evident violation of the proportional hazards assumption such as crossing of the Kaplan-Meier curves. A p-value < 0.05 (two-sided) was considered statistically significant. Quantitative variables are represented as mean +/- standard deviation and categorical variables as proportion and 95% confidence interval (CI 95%) if not indicated otherwise. The purpose of this study is purely exploratory and no corrections for multiple comparisons were performed.

All statistical tests were computed using Prism9 (version 9.5.0, GraphPad Software, LLC).

RESULTS

Demographics and clinical characteristics

After reviewing a total of 231 clinical charts, 163 patients were included in the study (Figure 1). Forty-two were excluded due to loss of follow up and 26 because either the SO injection or SOE were performed in another center.

Most patients received 1300cSt light SO (n=125, 76.7%), while only few patients received 5700cSt light SO (n=15, 9.2%) or heavy SO (n=23, 14.1%). The overall mean age was 64.8 (range 18-90) years. Ninety-nine were male (60.7%). The overall mean duration of the tamponade (or SOE time) was 11 (range 2-82) months (Table 1). We did not detect

large differences in clinical variables between SO groups with the potential limitation of low sample.

SO emulsification

SO emulsification occurred in a total of 45 cases (27,6%), with a similar distribution within groups (Table 2, p=0.457). To test the hypothesis that emulsification can be predicted by the following factors: type of SO, duration of the tamponade, age and sex; a multiple regression analysis was used. Results show a significant effect on duration of the tamponade and age (mean age of patients with SO was 55.3 years vs 68.4 years in patients without emulsification). Holding all the other variables constant, the odds of emulsification increased by 4% (95%CI 1-7) for each additional month of SO tamponade. Also, for each year of increasing age, the probability of emulsification decreased by 9.4% (95%CI 9.2-9.7). Also, recurrent retinal detachment increased the risk of emulsification by 4% (95%CI 1.8-8.8). The goodness of fit of the model was good, with an area under the ROC curve of 0.787 (Figure 2).

We also studied the time until emulsification in each group. The mean emulsification time of 10.4, 16.6 and 10.7 months in 1300cSt, 5700cSt and HSO groups, respectively. We also performed a survival analysis to depict the tendencies among groups. The Kaplan-Meier curve (Figure 3) showed that the median emulsification time was lower in the group of 1300cSt compared with the rest (22 vs 33 months, p=0.457), suggesting that 1300cSt light SO might emulsify sooner, although the differences were non-significant.

Macular edema

Macular edema (ME) occurred in 67 patients (41,1%), with similar distribution across SO types (Table 2, p=0.668). Of all patients that suffered ME during SO tamponade, 52 resolved after SOE without the necessity of any intravitreal or periocular treatment (77,6%). None of them had a previous diagnosis of ME.

In the multivariate analysis, all variables included in the model showed no significant effect (SO type, duration of the tamponade, age and sex)(Table 3). The goodness of fit of the regression analysis suggests that we cannot accurately predict the odds of ME with our model (Area under the ROC=0.596) (Figure 2).

Ocular hypertension

Ocular hypertension (OHT) appeared in 60 patients (36,8%) during SO tamponade, with a similar group comparison according to SO type (p=0.915) (Table 2).

After SOE, 37 patients (61.7% of the OHT group, 22.7% of total) maintained antihypertensive eye drops as chronic treatment. Of these, 7 patients had a prior diagnosis of glaucoma but more medication had to be added to control intraocular pressure after SOE. Four patients required glaucoma surgery.

None of the variables included in the multivariate analysis showed a significant effect, including duration of the tamponade, age, sex and presence of emulsification (Table 3), although the goodness of fit of the model was not very high, suggesting that these results should be interpreted with caution (area under the ROC 0.629) (Figure 2).

SO migration to the anterior chamber

Migration of SO to the anterior chamber (AC) occurred in 34 patients (20,9% of total). The regression analysis showed, with a good goodness of fit (area under the ROC

0.7738, Figure 2), that SO emulsification might increase the odds of migration to the AC by 2.78 (95%CI 1.05-7.50). Of all lens status possibilities, only aphakia showed a significantly positive effect, suggesting that the odds of SO migration to the AC increases by 4.05 in aphakic patients (95% CI 1.04-15.86). The effect of the other variables including type of SO, duration of the tamponade, diagnosis, age and sex, were non-significant (Table 3).

DISCUSSION

In this study we investigated the complication rates including macular edema, ocular hypertension, SO emulsification and migration to the AC according to SO type. We found no group differences in complication rates by SO type. Macular edema was the most frequent complication (40.8-47.8%), and it resolved after SOE in 77.6% of patients, whereas the majority of patients that suffered from OHT persisted (61.7%). Younger age, the diagnosis of recurrent retinal detachment and longer duration of the tamponade might increase the odds of emulsification. We also suggest that aphakia and emulsification increase the odds of SO migration to the AC.

Emulsification is one of the most frequently-reported complications after SO injection and usually determines the time point of SO extraction or exchange. The emulsification rates found in our cohort were 28%, 30% and 29% (1300cSt, 5700cSt and HSO, respectively). A recently published meta-analysis showed a much lower emulsification rate (9,2%).[8] Our center is a tertiary referral center for complex retina surgery, with a high population of previously treated patients with high risk of re-

detachment, so the longer duration of tamponade in our cohort might explain these differences, as we suggest in the multivariate analysis. Emulsification rates reported by recently-published studies vary greatly from previous works. While Federman et al. described an emulsification rate of 100% in patients after 1 year in a study conducted in 1988,[9] Toklu et al. showed in a more recent study that SO tamponade can last safely up to more than one year in selected cases.[7] Further studies with a higher number of patients are needed to confirm these findings, preferably with prospective randomized designs, but we suggest that better and safer commercially-available SOs might have an important role.

It is also important to mention how fast the SO emulsifies. We report a median emulsification time of 22 months in 1300cSt and 33 months in 5700cSt group. It was undefined for HSO because more than 50% of cases were non-emulsified at the last time point. These outcomes may indicate that although the comparison among groups were non-significant, HSO may emulsify later than light SO. We also calculated the mean emulsification time of each group (10.4, 16.6 and 10.7 months in 1300cSt, 5700cSt and HSO groups, respectively) for a better comparison with other studies. Zhao et al. reported in a similar study a longer emulsification time in the 5000 cSt group compared with 2000 cSt, with a mean time of 7.3 months.[10] Mean age of their cohort being younger than ours (46.58 vs 64.8 years) may explain these differences. In our cohort, younger age was a significant factor in SO emulsification. An explanation to this might be that younger people tend to be more physically active and have higher inflammation rates. Eye movement can induce emulsification by increasing shearing, while pro-inflammatory mediators and fibrin can act as surfactant agents. [11,12]

ME is a well-known complication after intraocular surgery, which usually resolves spontaneously or with topical treatment.[13] We found an overall rate of 41.1% of ME during SO tamponade, which spontaneously resolved after SOE in 77.6% of cases. We can then infer that SO may have a role in ME development, as previously reported by other authors.[14,15] We found no statistically significant differences in ME rate among type of SO or age. Duration of the tamponade was also non-significant, mainly because ME was one of the criteria we used to indicate surgery for SO extraction.

We also explored OHT, a critical adverse event of SO tamponade as it can potentially cause irreversible blindness secondary to retinal ganglion cell and nerve fiber layer degeneration. Other authors have reported the association between OHT and SO, mainly due to SO emulsification.[16] When the SO emulsifies, micro-droplets can cause inflammation of the trabecular meshwork, leading to a chronic secondary glaucoma. However, we did not find any statistically significant relationship between OHT and SO emulsification, probably due to our small sample. In other cases, there is a transitory IOP rise after surgery with SO tamponade. This can be due to pupillary block or SO overfilling.[17] We did not record these IOP spikes, only the incidence of intraocular pressure in the late postoperative period during a longer follow-up and the necessity of anti-hypertensive treatment during tamponade.

Whereas 36.8% of patients required anti-glaucomatous medication at some point during SO tamponade, the incidence of secondary, long-standing glaucoma that was maintained after SOE was 22.7% of the whole cohort. There were no differences according to SO type. Similarly, Moussa et al. reported that Densiron (HSO) was not related with higher glaucoma surgery rates compared with light SO.[18] Branisteanu et al.

reported an incidence of 16.32% secondary glaucoma. The duration of SO tamponade was lower than in our cohort (5.46 vs. 11 months), which might explain the differences.[19] Although we did not find a significant effect of SOE time on OHT, probably due to the low goodness of fit of the model and a relatively low sample, the OR is positive (OR 1.02). Based on these results and supported by previous studies, SOE can be sometimes enough for lowering IOP and should be the first approach when possible, but in other cases extensive medical treatment or even surgery is necessary.[16,20,21]

Many complications of SO are secondary to AC migration. Emulsified droplets can alter trabecular meshwork causing glaucoma, as explained above. Also, SO bubble in contact with corneal endothelium can cause keratopathy, leading to vision loss.[22,23] Besides, it can be a cause of retina surgery failure due to vitreous cavity underfilling. Thus, it is of utmost importance to avoid the SO to pass into the AC. This is more likely to happen when the eye compartmentalization is lost, such as in zonular dehiscence, aphakia or posterior capsulotomy. Our results supported this, as the odds for SO migration to the AC are increased by aphakia (OR 4.05) and emulsification (OR 2.78). However, according to our results, group distribution was very similar among SO types.

Limitations of this study include its retrospective design and the relatively low sample especially in the groups of 5700cSt and Heavy SO. Also, the majority of patients were affected by a retinal detachment. Results can vary in other conditions and this must be taken into account when interpreting our results. Besides, emulsification was assessed clinically by one observer, in most cases without gonioscopy, so it is possible that we might have underestimated the emulsification rate.

While our study was too small to assess the exact frequencies of complication rates according to SO type, it suggests that there are no striking differences in complications supporting the current clinical practice. In these cases, the choice of SO type should be done depending on retinal pathology, mainly between light SO and Heavy SO. When light SO is the most correct choice, 5700cSt SO increases surgical time compared with 1300cSt, as they both appear to have similar complication rates. Emulsification might depend on age, so shorter SOE times should be considered in younger patients regardless of the SO type. Macular edema was a frequent complication in our cohort, but it usually resolves spontaneously after SOE. In order to minimize all of the complications aforementioned, it is important to avoid the use of SO as much as possible in non-complicated cases.

DECLARATION OF CONFLICTING INTERESTS

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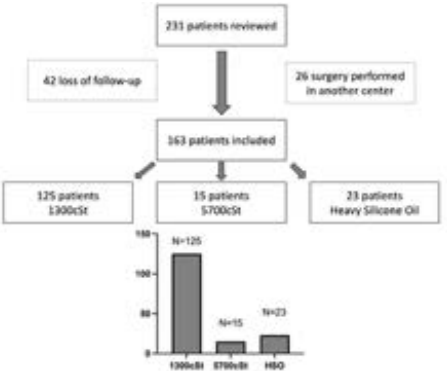
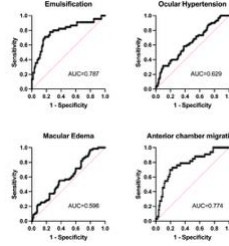
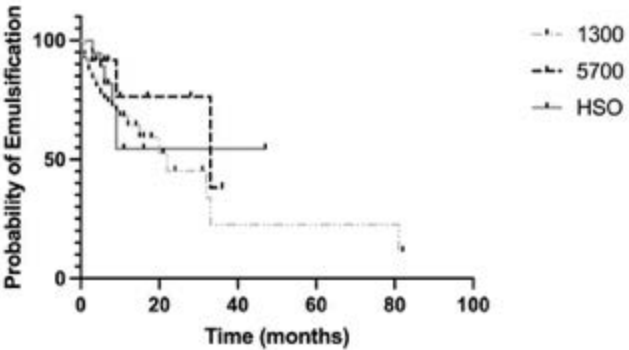

231 patients reviewed
42 loss of follow-up
26 surgery performed in another center
163 patients included
125 patients 1300cSt
15 patients 5700cSt
23 patients Heavy Silicone Oil
N=125
N=15
N=23
1300cSt
5700cSt
HSO


Emulsification
Sensitivity
1 - Specificity
AUC=0.787
Ocular Hypertension
Sensitivity
1 - Specificity
AUC=0.629
Macular Edema
Sensitivity
1 - Specificity
AUC=0.596
Anterior chamber migration
Sensitivity
1 - Specificity
AUC=0.774


Probability of Emulsification
100
50
0
0
20
40
60
80
100
Time (months)
1300
5700
HSO

	1300cSt N=125		5700cSt N=15		Heavy SO N=23		p-value
Diagnosis	**N**	**%**	**N**	**%**	**N**	**%**	0.710
Naïve RD	54	43.2	5	33.3	9	39.1	
Recurrent RD	60	48	9	60	13	56.5	
Macular hole	4	3.2	0	0	0	0	
Proliferative DR	5	4	0	0	1	4.4	
SC Hemorrhage	1	0.8	0	0	0	0	
Melanoma	1	0.8	1	6.7	0	0	
Lens status	**N**	**%**	**N**	**%**	**N**	**%**	0.422
Phakic	23	18.4	2	13.3	5	21.7	
Capsular bag IOL	89	71.2	11	73.3	12	52.2	
Sulcus IOL	5	4	0	0	1	4.3	
Iris-claw IOL	2	1.6	0	0	1	4.3	
Aphakia	6	4.8	2	13.3	4	17.4	
Age (years)	65 (18-90)		63.2 (22-90)		64.8 (46-88)		0.912
Duration of the tamponade (months)	10.4±12.9		16.6±17.5		10.7±9.97		0.269
Sex (M/F) %	76/49 (60.8/39.2%)		10/5 (66.7/33.3%)		13/10 (56.5/43.5%)		0.741

Table 1. Patient characteristics according to silicone oil subtype. Diagnosis and lens status are expressed as number of patients and percentages; age as mean and range; Duration of the tamponade as mean ± standard deviation. *RD: retinal detachment, DR: diabetic retinopathy, SC: suprachoroidal suprachoroidal, IOL: intraocular lens, SO: silicone oil. cSt: centistokes.*

	1300cSt N=125		5700cSt N=15		HSO N=23		p-value
Complication	**N**	**%**	**N**	**%**	**N**	**%**	
ME	51	40.8	5	33.3	11	47.8	0.668
OHT	47	37.6	5	33.3	8	34.8	0.915
Emulsification	36	28.8	4	26.7	5	21.7	0.998
AC migration	23	18.4	4	26.7	7	30.4	0.360

Table 1. Rates of macular edema (ME), ocular hypertension (OHT), emulsification and SO migration to the anterior chamber (AC). Distribution among groups of silicone oil (SO) type (1300cSt, 5700cSt and heavy silicone oil (HSO)). Values are expressed as absolute numbers and percentages of complications in each group. All comparisons were non-significant. cSt: centistokes.

Multiple logistic regression parameters of migration to the anterior chamber			
Variable	**OR**	**95% CI**	**p-value**
Intercept	0.55	0.04-7.56	0.655
SO type (1300cSt)	0.55	0.18-1.88	0.321
So type (5700cSt)	0.79	0.15-3.97	0.781
Duration of the tamponade (months)	1.02	0.99-1.05	0.203
Age (years)	0.98	0.95-1.01	0.247
Sex (Male)	1.44	0.6-3.67	0.430
Emulsification	2.78	1.05-7.50	0.04*
Lens status (phakic)	0.25	0.03-1.11	0.104
Lens status (sulcus IOL)	3.15	0.37-20.51	0.242
Lens status (aphakia)	4.05	1.04-15.86	0.041*
Lens status (iris-claw IOL)	13.49	0.47-389.7	0.085
Diagnosis (recurrent RD)	0.99	0.41-2.40	0.984
Multiple logistic regression parameters of macular edema			
Variable	**OR**	**95% CI**	**p-value**
Intercept	0.43	0.07-2.44	0.344
SO type (1300cSt)	0.53	0.21-1.3	0.166
So type (5700cSt)	0.44	0.11-1.71	0.245
Duration of the tamponade (months)	0.98	0.95-1.01	0.218
Age (years)	1.02	1-1.04	0.083
Sex (Male)	0.97	0.5-1.89	0.931
Diagnosis (recurrent RD)	1.05	0.55-2	0.885
Multiple logistic regression parameters of emulsification			
Variable	**OR**	**95% CI**	**p-value**
Intercept	9.4	1.07-88.78	0.040*
SO type (1300cSt)	1.68	0.55-6.15	0.390
So type (5700cSt)	0.97	0.15-5.81	0.974
Duration of the tamponade (months)	1.04	1.01-1.07	0.014*
Age (years)	0.94	0.92-0.97	<0.0001*
Sex (Male)	1.08	0.48-2.48	0.849
Diagnosis (recurrent RD)	0.40	0.18-0.88	0.025*

Multiple logistic regression parameters of ocular hypertension			
Variable	**OR**	**95% CI**	**p-value**
Intercept	0.49	0.07-3.34	0.471
SO type (1300cSt)	1.62	0.62-4.64	0.339
So type (5700cSt)	1.07	0.24-4.52	0.930
Duration of the tamponade (months)	1.02	1-1.06	0.124
Age (years)	0.99	0.97-1.01	0.365
Sex (Male)	1.1	0.56-2.18	0.791
Emulsification	1.74	0.78-3.89	0.175
Diagnosis (recurrent RD)	1.03	0.53-2.05	0.923

Table 1. Parameters of the multivariable analysis for silicone oil (SO) migration to the anterior chamber, macular edema, emulsification and ocular hypertension. *cSt: centistokes, OR: odds ratio. CI: confidence interval, IOL: intraocular lens. RD: retinal detachment *: p-value<0.05.*