

Comparison of 1000-Centistoke versus 5000-Centistoke Silicone Oil in Complex Retinal Detachment Surgery

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ABSTRACT

Objective: To compare the efficacy and complications of using 1000-centistoke versus 5000-centistoke silicone oil for complex retinal detachment repair.

Study Design: Case series.

Place and Duration of Study: LRBT Tertiary Eye Hospital, Karachi, from January 2007 to June 2013.

Methodology: Eighty-five eyes (85 patients) presenting with superior rhegmatogenous retinal detachments associated with PVR grades B and C (involving not more than 3 clock hours) were randomized to either 1000 centistokes (n=44) or 5000 centistokes (n=41) silicone oil group. All patients underwent 23-gauge pars plana vitrectomy surgery with silicone oil intraocular tamponade. Patient data was analysed at 18 months post-operatively. IBM SPSS 21 was used for data analysis.

Results: There were 52 male and 33 female patients aged between 22 and 70 years (45.2 ±16.2). After the first surgery, successful reattachment of the retina was achieved in 67 eyes (78.8%); of which 35 eyes were in 1000-centistoke and 32 eyes in 5000-centistoke groups. Mean pre-operative Best Corrected Visual Acuity (BCVA) was 1.63 ±0.54 which was improved to a mean post-operative BCVA of 1.46 ±0.78 (1.42 ±0.74 in 1000-centistoke group; 1.49 ±0.78 in 5000 centistoke group). The 1000-centistoke group had a significantly higher frequency of oil emulsification which necessitated early removal of silicone oil. There were 66 eyes (77%) with at least one complication (34 eyes in 1000-centistoke group; 32 eyes in 5000-centistoke group) including cataract, corneal abnormalities, raised IOP, hypotony, vitreous haemorrhage and retinal redetachment.

Conclusion: Although visual and anatomical outcomes were comparable between the two groups, the 1000-centistoke silicone oil group developed early oil emulsification necessitating its early removal.

Key Words: Retinal detachment. Silicone oils. Vitrectomy. Vitreoretinopathy.

INTRODUCTION

Retinal detachment (RD) is estimated to occur in 0.01% of the general population.¹ Among these patients, approximately 8 - 10% further develop Proliferative Vitreoretinopathy (PVR).² PVR is a potentially blinding complication of retinal detachment which may develop primarily (e.g. in large retinal tears and long standing RD) or secondary to RD surgery. There are multiple factors responsible for the development of PVR, but the underlying mechanism is the dispersion of Retinal pigment Epithelial (RPE) cells and/or breakdown of the blood-retinal barrier, which may subsequently lead to the development of PVR.^{3,4}

With advancements in surgical techniques and development of better vitreous substitutes, PVR surgery realizes much higher success rates today as compared to what it did in its early days.^{5,6} A typical surgical procedure for RD, complicated with PVR, involves

relieving retinal traction via vitrectomy, retinal reattachment by an intraocular air tamponade and then silicone oil or gas exchange. There are a number of advantages of using silicone oil over gas tamponade. Patients are able to see through the silicone oil and air travel is allowed since silicone oil bubble does not expand. While the gas dissolves over a few weeks, silicone oil is not absorbed making it a more suitable choice for use in retinal detachments associated with significant scar tissue that require a longer healing time.

Silicone is a siloxane of repeated units. Silicone oil is a polymer with a backbone of $[R_2-Si-O]_n$ where R₂ are 2 methyl groups, with a siloxane (-Si-O-) repeating unit as their backbone.⁷ Silicone oil is a fluid that is typically inert, thermally stable, has low toxicity and does not support microbiological growth.⁸ Silicone oils used for PVR surgery generally have a viscosity of either 1000 or 5000 centistokes and a specific gravity of 0.97, which is slightly less than that of aqueous (1.00) allowing the oil to float within the eye.⁷ The Silicone Study was a multicentre trial to compare the effectiveness and ocular complications of 1000-centistoke silicone oil with that of an intraocular long-acting gas for the management of RD with PVR. It is concluded that silicone oil to be superior to sulphur hexafluoride gas and comparable to perfluoropropane (C₃F₈) gas in the management of retinal detachment with severe PVR.⁹ However, studies

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comparing 1000 and 5000 centistokes silicone oils are sparse in medical literature.

The objective of this study was to assess the retinal re-detachment rates and visual outcomes encountered using 1000 and 5000 centistokes silicone oils and to report any differences observed. Complications associated with each type of silicone oil were noted as a secondary objective.

METHODOLOGY

A total of 96 patients presenting to the surgical unit of a single tertiary care eye hospital were enrolled for this study, out of which 85 patients made it to the final analysis. This study was conducted from January 2007 to June 2013; whereas, patient enrolment was stopped after June 2011 to allow adequate time for follow-up. The study was reviewed and approved by an Ethics Board before being performed. Written informed consent was taken from each participant in the study.

All patients, aged 21 - 70 years, presenting with rhegmatogenous RD in the superior quadrants, associated with PVR grades B and C were enrolled for this study. In case of PVR-C, only those patients who had the focal sub-type, involving 1 - 3 clock hours, were included. At the time of admission, they were randomly assigned to either the 1000 or 5000 centistokes silicone oil group and only one eye was enrolled in each patient.

Exclusion criteria screened out patients with history of any intra-ocular surgery, pre-existing glaucoma, inflammatory eye condition, traumatic RD, intra-ocular foreign bodies, aphakia and with any pre-existing retinopathy. Also excluded were eyes in which the retina could not be re attached at the time of surgery. In addition, all patients who had a follow-up of less than 18 months or had incomplete records were excluded from the analysis.

Pre-operatively, all the patients underwent the following evaluation: clinical history, measurement of Visual Acuity (VA), Best Corrected Visual Acuity (BCVA), anterior segment examination with emphasis on the state of the cornea and posterior capsule, posterior segment examination, Intraocular Pressure (IOP) measurement via applanation tonometry, assessment of pupil reaction and synechiae, and the state of the fellow eye.

All charts were reviewed in the year 2013. Data recorded included demographic data, pre-operative diagnosis, pre-operative and postoperative VA and BCVA, postoperative complications and BSCVA at 1, 3, 6, 12, 18, 24 months postoperatively.

All surgeries were performed by a single vitreo-retinal surgeon at a single tertiary care hospital under general or local anaesthesia. The operative procedures consisted of pars plana vitrectomy, intravitreal triamcinolone acetonide suspension to identify any proliferative

membrane, relief of epiretinal traction, retinal reattachment by PFCL and simultaneous internal drainage of subretinal fluid, cryopexy or endolaser photocoagulation and fluid-oil exchange. The vitreous cavity was filled with silicone oil to the iris plane. Relaxing retinectomy was done in some cases, if needed.

Postoperatively, all eyes received topical drops containing moxifloxacin 0.5% and dexamethasone 0.1% q2h for first week and then tapered off over eight weeks. In addition, ciprofloxacin 500mg (q12h) and ibuprofen 200 mg (q8h) was given for the first 3 postoperative days.

Patients were examined at first postoperative day, third postoperative day, at the end of first week, then weekly for the first month, and then monthly for the next five months. Examinations included VA, BCVA, IOP measurement, and screening for any postoperative complications. Patients, who presented with pseudohypopyon > 1 mm, as assessed on the slit lamp examination, were considered to have silicone oil emulsification.

Data was recorded manually by the reviewer on a structured questionnaire and was analysed using IBM SPSS Statistics 21. Frequencies, percentages and mean \pm SD were calculated, as appropriate, for the variables. Pearson Chi-Square test and t-test were applied to calculate p-value between both the groups and a p-value < 0.05 was considered significant.

RESULTS

Data was analyzed from 85 eyes of 85 patients, of which 44 (51.8%) patients were in the 1000-centistoke group and 41 (48.2%) patients in the 5000-centistoke group. There were 52 male and 33 female patients aged between 22 and 70 years (mean = 45.2 \pm 16.2 years). Both groups included breaks and atrophic holes with lattice degeneration in the superior quadrants only. Visual acuity and BCVA had been assessed using the ETDRS charts via subjective refraction by optometrists. Patients with visual acuity of counting fingers were considered as a logarithm of the minimum angle of resolution (logMAR) value of 2.0 while those with visual acuity of hand movement or less were given a logMAR of 3.0. The mean follow-up duration was 22.8 \pm 3.2 months. For consistency, all analyses were done on patient data at 18th month postoperatively.

Successful re-attachment of the retina was achieved in 67 eyes (78.8%) with the first surgery and in 79 eyes (92.9%) with the second surgery. Mean pre-operative Best Corrected Visual Acuity (BCVA) was 1.63 \pm 0.54 which improved to a mean postoperative BCVA of 1.46 \pm 0.78, while 59 eyes (69.4%) had at least ambulatory visual acuity (taken as BCVA > 5/200; logMAR < 1.6). At the end of the 18 months follow-up period, BCVA had improved or remained unchanged in 77 eyes (90.6%),

20 eyes (23.5%) had BCVA \geq 20/120 (logMAR \leq 0.8) and 48 eyes (56.5%) had BCVA \geq 20/200 (logMAR \leq 1.0). Mean pre-operative IOP was 14.72 ± 3.7 mmHg which increased to a mean postoperative IOP of 18.33 ± 5.5 mmHg. No statistically significant difference was observed between the two groups or any of these outcomes. Comparison of baseline characteristics and outcomes between groups is given in Table I.

Silicone oil emulsification occurred in 32 eyes (37.6%), significantly more in the 1000-centistoke group than in the 5000-centistoke group ($p = 0.004$), as shown in Figure 1. These patients subsequently underwent surgery for oil removal. Other complications necessitating silicone oil removal were corneal decompensation, uncontrolled intra-ocular hypertension and high anisometropia caused by the presence of silicone oil in the eye. The complications observed are given in Table II. Hypotony was defined as IOP \leq 8 whereas IOP \geq 22 was considered as elevated IOP. Where removal of silicone oil was performed due to complications, the 1000-centistoke group required oil removal at 9.35 ± 2.8 months postoperatively, whereas the 5000-centistoke group had the removal performed at 15.34 ± 3.5 months postoperatively.

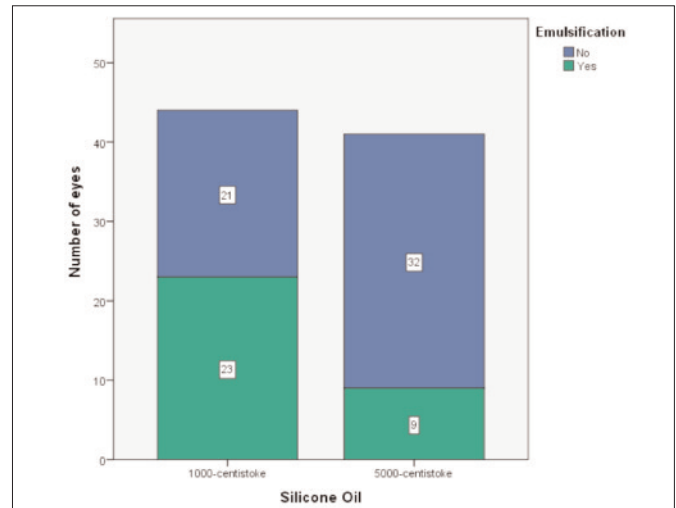


Figure 1: Comparison of silicone oil emulsification between the two groups.

DISCUSSION

While the visual outcomes and retinal reattachment rates were similar between the two groups, a significant difference in emulsification between the 1000-centistoke and 5000-centistoke silicone oils was evident in this study. The 1000-centistoke silicone oil not only had a higher emulsification rate, but it also emulsified earlier than the 5000-centistoke silicone oil. While the 1000-centistoke silicone oil is similar to 5000-centistoke silicone oil in terms of specific gravity (both are lighter-than-water), they differ considerably in their molecular weights.¹⁰ The higher molecular weight of the 5000-centistoke silicone oil increases its shear viscosity, providing greater resistance to deformity. Therefore, higher energy is needed to separate a 5000-centistoke silicone oil bubble into small droplets as compared to a 1000-centistoke silicone oil bubble; hence the lesser tendency of 5000-centistoke silicone oil to emulsify. Once emulsified, silicone oil may migrate into the anterior segment blocking the trabecular meshwork as well as attracting neutrophils, necessitating an additional surgery to remove the oil to prevent damage to the corneal endothelium and glaucoma.⁷

Table I: Comparison of baseline characteristics and outcomes between the two groups.

Results	1000-centistoke	5000-centistoke	p-value
Age (years)	44.43 \pm 16.8	45.98 \pm 15.6	0.662*
Males/females	28/16	24/17	0.630
Pre-op BCVA (logMAR)	1.55 \pm 0.63	1.72 \pm 0.71	0.242*
Pre-operative IOP (mmHg)	14.14 \pm 3.9	15.34 \pm 3.5	0.142*
Duration of RD (days)	88.59 \pm 30.85	88.73 \pm 35.83	0.985*
PVR B / PVR C	24 (54.5%) / 20 (45.5%)	18 (43.9%) / 23 (56.1%)	0.327
Postoperative BCVA (logMAR)	1.42 \pm 0.74	1.49 \pm 0.78	0.662*
Postoperative ambulatory BCVA (logMAR)	31 (70.5%)	28 (68.2%)	0.829
Postoperative IOP (mmHg)	18.30 \pm 5.27	18.37 \pm 5.91	0.954*

Pearson Chi-Square test used to calculate p-values.

* p-value calculated using Independent Samples T-test.

Ambulatory BCVA includes eyes with post-operative BCVA > 1.6 logMAR.

Table II: Comparison of complications observed in the two groups.

Complications	Overall (n=44)	1000-centistoke (n=41)	5000-centistoke	p-value
Redetachment after first surgery	18 eyes (21.2%)	9 eyes (20.5%)	9 eyes (21.9%)	0.866
Redetachment after second surgery	6 eyes (7.1%)	2 eyes (4.5%)	4 eyes (9.7%)	0.349
Cataract formation	48 eyes (56.4%)	22 eyes (50.0%)	26 eyes (63.4%)	0.213
Corneal abnormalities	6 eyes (7.1%)	4 eyes (9.1%)	2 eyes (4.9%)	0.449
Raised intra-ocular pressure	20 eyes (23.5%)	11 eyes (25.0%)	9 eyes (21.9%)	0.741
Glaucoma requiring surgical management	3 eyes (3.5%)	3 eyes (6.8%)	0 eyes	0.089
Hypotony	2 eyes (2.4%)	1 eye (2.3%)	1 eye (2.4%)	0.960
Vitreous haemorrhage	1 eye (1.1%)	0 eyes	1 eye (2.4%)	0.297
Removal of silicone oil required	46 eyes (54.1%)	31 eyes (70.5%)	15 eyes (36.6%)	0.002
Retinal detachment after oil removal	8 eyes (9.4%)	6 eyes (13.6%)	2 eyes (4.8%)	0.613
Eyes with at least one complication	66 eyes (77%)	34 eyes (77.2%)	32 eyes (78.0%)	0.932

Pearson Chi-Square test used to calculate p-values (p-value in bold is significant)

The higher emulsification rate in the 1000-centistoke silicone oil group led to a significantly higher number of patients in this group undergoing removal of the silicone oil as compared to the other group. This, in turn, resulted in a higher number of re-detachments after silicone oil removal in the early postoperative period, although the difference between the two groups could not be statistically proven. This warrants further studies with a larger sample size to verify if a true association exists. The major cause of re-detachment was determined to be re-opening of previous breaks and recurrence of PVR. Since some complex retinal detachments require a longer tamponade, early oil removal causing a loss of this effect may have contributed to the re-opening of breaks after oil removal.¹¹

The mean visual acuity attained at the end of 18 months post-operatively was better for the 1000-centistoke silicone oil group, though statistically insignificant. This could be explained by the worse mean pre-operative visual acuity of the 5000-centistoke silicone oil group (1.72 ± 0.71 compared to 1.55 ± 0.63 for the other group) which subsequently resulted in a relatively lower post-operative visual result for this group. Soheilian *et al.* suggested longer duration of tamponade and the associated pressure effect and subclinical emulsification, with migration of oil droplets into the retina, to be the cause of retinal damage in eyes with the 5000-centistoke silicone oil.¹¹ However, Shen *et al.* studied the results of long term silicone oil tamponade and found no statistically significant effect on the visual outcome.

Scott *et al.* compared 1000- and 5000-centistoke silicone oil in 82 eyes and reported matching results in terms of anatomical success, 80% reattachment in each group.¹⁰ Furthermore, no significant difference was observed in visual acuity outcomes or complications among with the two groups. Using 5000-centistoke silicone oil, Gui *et al.* achieved final reattachment rate of 95.2% (20 out of 21 eyes) in RD associated with choroidal detachment and visual acuity improvement in 19 (90.5%) eyes.¹²

Since its early use, silicone oil tamponade has been associated with a number of complication including cataracts, band keratopathy in corneas with oil-endothelial touch, pupillary block glaucoma, closure of the inferior iridectomy, fibrous epiretinal and subretinal proliferations, pain, oil emulsification and sub-conjunctival deposits of oil.¹³ More recently, a study showed tiny emulsified bubbles to be present intraretinally, subretinally, and underneath epiretinal membranes using SD-OCT.¹⁴ Yilmaz *et al.* showed that the presence of nystagmus may speed up the process of silicone oil emulsification in patients.¹⁵

Visual improvement has been linked to pre-operative visual acuity, macular involvement, extent of retinal detachment, trauma and presence of PVR.^{16,17} Although

the rate of successful retinal reattachment following surgery have improved over the years, PVR still remains the leading cause for post-surgical retinal re-detachment.¹⁸ Mitry *et al.* reported a success rate of 80.8% after a single surgery for RRD, while the presence of PVR increased the odds of surgical failure by 2.4.¹⁶ Abrams *et al.* analysed the long term results of the silicone study and concluded that in the cases with PVR, successful reattachment after the first surgery for PVR was vital for obtaining better visual results and if anatomical and visual outcomes were good at 3 years, the results will be sustained over the long-term.¹⁹

IOP elevation is a known complication of intravitreal silicone oil injection.²⁰ Such patients require aggressive medical management and may go on to need removal of silicone oil, glaucoma implants, or cyclodestructive procedures.²¹ Twenty eyes (23%) in this study developed a raised IOP postoperatively, the majority of which were managed medically. Of these, 3 eyes continued to have a high IOP on anti-glaucoma medications and required removal of silicone oil.

Cataract development and progression is one of the most common complications reported in up to 80% of patients within 24 months postoperative period, thereby leading to advocacy of primary lensectomy along with primary vitrectomy and SO tamponade.^{12,22} However, this carries a risk of increased corneal endothelial cell loss.²³ Fifty-six percent of the patient in the current study developed cataracts or experienced progression of pre-existing lenticular opacities. These patients underwent cataract extraction when needed, starting after the 6-month postoperative visit.

CONCLUSION

In the early postoperative period, visual outcomes were comparable among the two groups. Over longer follow-ups, patients in the 1000-centistoke silicone oil group developed oil emulsification earlier and at a higher rate rather than the 5000-centistoke group necessitating its early removal. Even though the 1000-centistoke silicone oil group had a higher number of re-detachment over an 18 months postoperative period, the results were not statistically significant and further studies with a larger sample size are needed to determine if a true association exists.

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