SILICONE OIL FLOWABILITY RATES THROUGH A STANDARD 23G VITRECTOMY SYSTEM

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ABSTRACT

Objective: To compare the viscosity of silicone oils made by different manufacturers by comparing the flow rates through a standard 23G millennium vitrectomy system.

Study Design: Quasi experimental study.

Place and Duration of Study: Department of Ophthalmology, Lahore General Hospital Lahore, Pakistan during 2012.

Patients and Methods: Viscosities of silicone oils of 1000cs and 5000cs, manufactured by multinational / national manufacturers in Pakistan, were compared. Oils of 1000cs/500cs were placed in 20 ml syringes, marked randomly and placed in water-VVbaths at 25^0C, to standardize the control environment. Each syringe was then attached to 23G millennium vitrectomy system and time taken to empty 9 ml of oils at pressures of 40 mmHg & 70 mmHg was noted.

Results: Oils of same centistokes manufactured by different manufacturers behaved differently in terms of their flowability and rates of emptying. The emptying times for 1000cs oils ranged from 112.1 seconds to 144.4 seconds at 40 mmHg and 60.2 to 70.3 seconds at 70 mmHg, whereas corresponding figures for 5000cs were between 335.7 seconds and 802.0 seconds at 40 mmHg and between 169.6 seconds and 348.7 seconds at 70 mmHg. The differences at all levels were statistically significant ($p< 0.001$)

Conclusion: Silicone oils of similar centistokes behaved differently in terms of their rates of flow through a standard 23G vitrectomy system under standard conditions indicating better standardization of the viscosity of silicone oils available in the market.

Keywords: Centistokes (CS), Fluid injection System, Silicone Oil, Vitrectomy.

INTRODUCTION

Silicone oil is one of the most widely used fluids in vitreoretinal surgery. Injection of silicone oil after vitrectomy was tried first by Haut in 1976, though Cibis introduced silicone oil in retinal surgery and Scott refined its use[1,2].

Despite the progress in vitreoretinal surgery and the importance of silicone oil as an adjunct for the treatment of complex forms of retinal detachment, controversy still surrounds the issue of selecting the proper oil viscosity for clinical use[3]. Commercially available in various viscosities, oils of 1000 to 5000 centistokes are used in vitreous surgery mostly. Advances in the field of silicone oil (SO) for a product that is easier to inject and at the same time resistant to emulsification had to parallel the rapid advancement in microsurgical small gauge systems[4,5].

SO is available from several manufacturers and the composition of the oil varies depending upon the manufacturing process. Viscosities available for retinal surgery in Pakistan include 1000, 1300, 2000 and 5000 centistokes. Since we had noticed that time taken by oils of similar viscosity prepared by different manufactures to pass through a standard 23G vitrectomy system differed, it was thought worthwhile to undertake a study to compare the viscosity of various brands of SO available in the market. In this study, the rate of injection of silicone oils with a sheer viscosity of 1000 and 5000 centistokes prepared by different manufacturers and available to vitreoretinal surgeons in Pakistan were compared by measuring their flowability through a standard 23G cannula using

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millennium fluid injection system under standard conditions at 40 mmHg and 70 mmHg.

PATIENTS AND METHODS

For this study, silicone oils with a sheer viscosity of 1000 and 5000 centistokes prepared by different manufactures and available in Pakistan were used. All oils were bought from the open market with no funding or donation by any manufacturer. The 1000cs oils included RS-Oil 1000 (Alchimia®, Viale Austria), Ocusil (MSM Industries, LLC), Sil-1000™ (D.O.R.C International® Netherland), Vitreocrom® 1000 (Croma Pharma®, Austria), Oxane® 1300 (Bausch & Lomb®, Rochester, New York). The 5000cs oils used in the study included Siluron 5000™ (Flouron®, Germany), Sil-5000™ (D.O.R.C International® Netherland), Ocu-Sil™ (MSM Industries, LLC), Oxane® 5700 (Bausch & Lomb®, Rochester, New York), RS-Oil 5000™ (Alchimia®, Viale Austria) and PDMS™ (ESS EMM Chemicals®, Mumbai, India). Bausch & Lomb's Oxane® 1300 and Oxane® 5700 were included in the study since the manufacturer produces these oils in the 1000cs and 5000cs categories.

Table-1: 1000 cs silicone oils flow ability at pressure of 40 mmHg.

SO = 1000 cs; Pressure = 40 mmHg

Volume	A	B	C	D	E	*F. Statistics	Significance
1 ml	12.4 ± 0.4	15.1 ± 0.0	15.9 ± 0.0	15.4 ± 0.4	15.4 ± 0.3	595.733	$p < 0.001$
2 ml	12.3 ± 0.1	15.4 ± 0.2	16.0 ± 0.1	15.6 ± 0.0	15.8 ± 0.1	2,823.600	$p < 0.001$
3 ml	12.0 ± 0.1	15.2 ± 0.1	15.8 ±0.1	15.5 ± 0.3	15.3 ± 0.3	1,194.200	$p < 0.001$
4 ml	12.6 ± 0.2	15.2 ± 0.1	16.0 ± 0.0	15.7 ± 0.2	15.7 ± 0.1	929.538	$p < 0.001$
5 ml	12.7 ± 0.3	15.7 ± 0.1	16.3 ± 0.1	15.45 ± 0.4	15.7 ± 0.1	746.390	$p < 0.001$
6 ml	12.5 ± 0.4	15.2 ± 0.0	16.1 ± 0.0	15.5 ± 0.3	15.6 ± 0.3	712.274	$p < 0.001$
7 ml	12.5 ± 0.3	15.3 ± 0.1	16.3 ±0.1	15.7 ± 0.2	15.3 ± 0.2	1,160.080	$p < 0.001$
8 ml	12.3 ± 0.4	15.3 ± 0.2	16.1 ± 0.0	15.3 ± 0.2	15.7 ± 0.1	607.893	$p < 0.001$
9 ml	12.6 ± 0.3	15.2 ± 0.1	15.9 ± 0.1	15.7 ±0.2	15.8 ± 0.1	932.864	$p < 0.001$
Total	112.1 ±0.1	137.6 ±0.5	144.4 ±0.1	140 ±0.2	140.8 ± 1.3	7,341.826	$p < 0.001$

A = RS-Oil 1000, B = Ocusil, C = Dorc, D = Vitreo-Crom 1000, E = Bausch & Lomb oxane,
*Inter-group differences were tested through ANOVA,

Table-2: 1000 cs silicone oils flow ability at pressure of 70 mmHg.

SO = 1000 cs; Pressure = 70 mmHg

Volume	A	B	C	D	E	*F. Statistics	Significance
1 ml	7.6 ± 0.2	7.8 ± 0.1	7.6 ± 0.3	7.7 ± 0.3	7.3 ± 0.3	50.933	$p < 0.001$
2 ml	6.5 ± 0.3	7.8 ±0.1	7.5 ± 0.3	7.8 ± 0.1	7.9 ± 0.1	113.618	$p < 0.001$
3 ml	6.9 ± 0.1	7.6 ± 0.0	7.9 ± 0.1	7.9 ± 0.1	7.5 ± 0.3	67.500	$p < 0.001$
4 ml	6.6 ± 0.3	7.6 ± 0.2	7.8 ± 0.1	7.5 ± 0.3	7.6 ± 0.1	89.424	$p < 0.001$
5 ml	6.7 ± 0.2	7.9 ± 0.1	7.5 ± 0.4	7.4 ± 0.4	7.4 ± 0.3	56.545	$p < 0.001$
6 ml	6.5 ± 0.1	7.8 ± 0.1	7.5 ± 0.1	7.5 ± 0.1	7.6 ±0.2	216.889	$p < 0.001$
7 ml	6.7 ± 0.3	7.8 ±0.1	7.9 ± 0.0	7.4 ± 0.3	7.3 ± 0.1	112.838	$p < 0.001$
8 ml	6.8 ± 0.1	8.0 ± 0.1	7.9 ± 0.1	7.8 ± 0.1	7.6 ± 0.1	89.600	$p < 0.001$
9 ml	6.6 ± 0.1	7.9 ± 0.1	7.7 ± 0.2	7.9 ± 0.1	7.5 ± 0.3	143.059	$p < 0.001$
Total	60.2 ± 0.1	70.3 ± 0.3	69.4 ± 0.6	69.1 ±1.3	67.8 ± 0.3	545.621	$p < 0.001$

A = RS-Oil 1000, B = Ocusil C = Dorc D = Vitreo-Crom 1000 E = Bausch & Lomb Oxane
*Inter-group differences were tested through ANOVA

To standardize the control environment for all oil samples in 1000cs and 5000cs category, the vials were placed in water baths at 25°C. Each vial was then emptied into a 20 ml syringe. In order to stimulate real time surgical conditions. The syringes were attached to a millennium viscous fluid injection system and the desired pressure set in the programme settings. The tests were run on pressure settings of 40 mmHg and 70 mmHg respectively for each oil. These also represent the injection settings in routine vitreoretinal surgery when silicone oils are being infused. One mili litre of oil was discarded from

each syringe and 23 gauge metal cannula was attached. The same reusable 23 gauge needle was used for all experiments in order to rule out internal bore of the cannula as a factor influencing the flowability of the oils. All injection tests were performed in duplicates and fresh oils were used for each run to avoid aeration effects. After each run of oil, the cannula was flushed thoroughly; no detergents were used throughout the injection experiments to clean any piece of equipment. Before each fresh run the cannula were flushed with several ml of the new silicone oil to minimise cross-contamination. The time for each increment of 1 ml of the various silicone oils to be injected were measured using a stopwatch. The injection times for a total of 9 ml for each silicone oil were measured.

For statistical analysis, statistical calculators available at ww.danielsoper.com /statcalc3/ default.aspx were used. Two readings were obtained on each brand of oil at each time interval and different pressures keeping the temperature constant at 25^0C. The mean of two reading was taken and standard deviation (SD) calculated. Inter-group differences were calculated using ANOVA. A p-value < 0.05 was considered as significant.

RESULTS

Injection rates of 9 ml of different multinational brands of silicone oil in 1000cs and 5000cs category through 23 gauge needle using millennium viscous fluid injection system under controlled conditions (temperature 25°C and pressures of 40 and 70 mmHg) were measured. It was possible to inject all the test silicone oils using the millennium viscous fluid injection system with a 23-gauge needle over a clinically relevant time period.

Table-3: 5000 cs silicone oils folw ability at pressure of 40 mmHg.

SO= 5000 cs; Pressure= 40 mmHg

Volume	A	B	C	D	E	F	* F Statistics	Significance
1 ml	62.6 ± 0.1	69.4 ± 0.5	36.9 ± 0.0	72.3 ± 0.3	89.3 ± 0.4	59.9 ± 0.2	6,477.789	p < 0.001
2 ml	61.5 ± 0.7	69.5 ± 0.1	37.5 ± 0.1	72.6 ± 0.5	88.7 ± 0.2	60.5 ± 0.1	4,232.400	p < 0.001
3 ml	62.4 ± 0.7	69.1 ± 0.3	37.5 ± 0.0	72.5 ± 0.1	89.6 ± 0.2	60.5 ± 0.0	5,565.917	p < 0.001
4 ml	62.3 ± 0.0	69.6 ± 0.3	37.2 ± 0.5	72.5 ± 0.3	89.7 ± 0.2	80.7± 0.1	8,167.267	p < 0.001
5 ml	63.1 ± 1.4	69.6 ± 0.1	36.7 ± 0.0	72.6 ± 0.5	88.9 ± 0.2	66.6 ± 0.3	1,478.620	p < 0.001
6 ml	62.5 ± 0.4	69.8 ± 0.0	37.5 ± 0.4	72.4 ± 0.3	88.9 ± 0.0	60.0 ± 0.4	6,047.614	p < 0.001
7 ml	62.4 ± 0.7	69.3 ±0.6	37.2 ± 0.2	72.0 ± 0.3	89.1 ± 0.3	60.4 ± 0.4	2,827.382	p < 0.001
8 ml	62.7 ± 0.3	69.8 ± 0.0	37.2 ± 0.5	72.4 ± 0.0	88.7 ± 0.1	60.4 ±0.2	8,852.554	p < 0.001
9 ml	62.9 ± 0.2	69.6 ± 0.1	37.4 ± 0.5	72.7 ± 0.6	89.6 ± 0.1	60.2 ±0.4	4,261.764	p < 0.001
Total	562.3±0.1	626.0±1.3	334.8±1.2	652.1±0.8	802.8±1.1	543.8 ± 1.1	45,836.057	p < 0.001

*Inter-group differences were tested through ANOVA

A = Siluron 5000, B = Dorc, C = Ocusil, D = Bausch & Lomb Oxane, E = RS-Oil 5000, F = PDMS

Table-4: 5000 cs silicone oils flow ability at pressure of 70 mmHg.

SO = 5000 cs; Pressure = 70 mmHg

Volume	A	B	C	D	E	F	*F. Statistics	Significance
1 ml	30.8 ± 0.1	34.5 ± 0.3	18.9 ± 0.1	32.4 ± 0.5	39.0 ± 0.1	28.5 ± 0.6	757.178	p < 0.001
2 ml	31.0 ± 0.0	34.6 ± 0.5	18.7 ± 0.2	32.7 ± 0.2	38.7 ± 0.1	28.4 ± 0.3	1,298.167	p < 0.001
3 ml	30.75±0.1	34.1 ± 0.1	18.5 ± 0.5	32.9 ± 0.1	38.2 ± 0.2	28.2 ± 0.2	1,515.614	p < 0.001
4 ml	30.2 ± 0.3	34.9 ± 0.0	18.8 ± 0.0	32.8 ± 0.1	38.9 ± 0.1	29.0 ± 0.1	4,680.267	p < 0.001
5 ml	31.5 ± 0.2	34.7 ± 0.7	18.8 ± 0.1	32.7 ± 0.1	38.8 ± 0.1	28.9 ± 0.0	989.400	p < 0.001
6 ml	31.0 ± 0.2	34.3 ± 0.3	18.9 ± 0.0	33.5 ± 0.2	39.0 ± 0.1	29.0 ± 0.0	3,087.133	p < 0.001
7 ml	30.9 ± 0.0	34.6 ± 0.3	18.6 ± 0.0	33.5 ± 0.5	39.1 ± 0.6	28.9 ± 0.1	821.318	p < 0.001
8 ml	31.3 ± 0.3	34.9 ± 0.1	19.0 ± 0.0	32.9 ± 0.0	38.4 ± 0.3	29.1 ± 0.1	2,655.040	p < 0.001
9 ml	31.4 ± 0.3	34.8 ± 0.1	18.5 ± 0.4	32.6 ± 0.5	38.5 ±0.4	28.9 ± 0.1	825.135	p < 0.001
Total	279.0±0.9	311.4 ± 0.2	168.8± 1.1	295.8 ±0.2	348.7 ±0.1	259.0 ±1.1	13,527.360	p < 0.001

A = Siluron 5000, B = Dorc, C = Ocusil, D = Bausch & Lomb Oxane, E = RS-Oil 5000, F = PDMS

*Inter-group differences were tested through ANOVA

Variability in injection rates of different silicone oils was calculated and a statistically significant ($p < 0.001$) difference was found. While analyzing the rate of flow of 1000cs viscosity silicone oils of the selected brands, under similar controlled conditions, we found that RS-Oil 1000™ (Alchimia®, Viale Austria) had the minimum injection time 112.1+0.1 at 40 mmHg (table-1) and 60.2 + 0.1 at 70 mm Hg (table-2). Sil-1000™ (D.O.R.C International®, Netherland) had maximum injection time 144.4 + 0.1 at 40 mmHg while Ocu-Sil™ (MSM Industries, LLC) had the maximum injection time 70.3 + 0.3 at 70 mmHg. The difference was statistically significant ($p < 0.001$). Other silicone oils like Vitreocrom® 1000 (Croma Pharma®, Austria) and Oxane™ 1300 (Bausch & Lomb®, Rochester, New York) showed intermediate resistance to flow at 40 mmHg (table-1) and 70 mmHg (table-2).

The emptying time for 5000 cs ranged between 335.7 seconds and 802.0 seconds at 40 mm of Hg (table-3) while at 70 mmHg, the corresponding figure was between 169.6 second and 348.7 seconds (table-4). The difference was statistically significant ($p < 0.001$). Among the silicone oils of 5000cs viscosity variety we found that Ocu-Sil™ (MSM Industries, LLC) had the least injection time 334.8 sec at 40 mmHg (table 3) and 168.8 ± 1.1 at 70 mmHg (table 4). RS-Oil 5000™ (Alchimia®, Viale Austria) took the maximum time to inject, injection time 802.8 ± 1.1 at 40 mmHg (table-3) and 348.7 ± 0.1 at 70 mmHg (table-4). The inter oil injection time difference was statistically significant ($p < 0.001$).

The results of statistical analysis showed a statistically significant ($p < 0.001$) inter-group difference in the rates of emptying through a standard 23G vitrectomy system under standard and controlled condition of temperature and pressure.

DISCUSSION

Introduced in 1962 as a vitreous substitute, silicone oil has been widely used as an internal temponade for complicated retinal detachment surgery[6]. Pars plana vitrectomy with silicone oil injection is the standard for treating retinal detachments[7].

While performing retinal 23 G trans-conjunctival sutureless surgery we observed that the rate and ease of injection of different brands of silicone oils into the eye was different. This study was designed to statistically analyze this observation. Our results showed a statistically significant difference with a p value of < 0.001, in the inter-group flowability rates of the oils, although all silicone oils were of the same centistokes.

Review of literature for an explanation for this difference in the flow rate threw up limited information. The length of polymer chains and therefore the molecular weight determine the viscosity of SO. For viscosities of 1000cs the average molecular weight is 25,000 and 50,000 for a viscosity of 5000 centistokes. However different samples of the SO of the same viscosity may have different number of short chain molecules and viscosity is determined by the average molecular weight of the chains. Therefore a sample of SO may be composed of a narrow band of different-molecular-weight chains containing only a few short chains whereas another sample of the same viscosity maybe composed of chains with a wider range of molecular weight with more short chains thus effecting the viscosity of oils of similar centistokes and accounting for the difference in the rates of injection of the oils under study[8].

The physical characteristics of silicone oil determine not only the resistance to flow but also the emulsification, surface tension and over the long term rise of intra-ocular pressure. Often silicone oils of higher density are used by retinal surgeons in the hope that they will lead to less emulsification and glaucoma[9]. Although clinical studies comparing silicone oils of different viscosities emphasized the differences in anatomic outcome,[10] they did not look specifically at emulsification[11]. The only consensus thus far has been to use highly "purified" oils with the lower molecular weights removed because they

do tend to cause emulsification[12,13]. Our study has shown that different brands of oils marketed in 1000 or 5000 cs category do not share similar physical characters when compared in terms of their flow rates and may therefore have dissimilar emulsification and intraocular pressure raising properties. Thus selection of a brand of oil may affect the long term outcome of retinal surgery as silicone oil tamponade is maintained for extended period of time.

CONCLUSION

Silicone oils of similar centistokes prepared by different manufacturers behave differently under standard surgical conditions. This calls for strict standardization of the silicone oils available in the country.

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