# Unexplained visual loss in silicone oil tamponade for macula-on retinal detachments.

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## Abstract

**Objectives: To assess the effect of Silicone Oil (SO) tamponade on Best-Corrected Visual Acuity (BCVA) when used in macula-on Retinal Detachments (RD).**

**Methods: Retrospective, non-randomised interventional case series of consecutive patients with macula-on RD where SO was successfully used to reattach the retina. The following variables were analysed: hospital site, gender, age, axial length, pre-operative BCVA, presence of vitreous haemorrhage, giant retinal tear, or proliferative vitreoretinopathy, lens status during SO tamponade, duration of SO tamponade, use of perfluorcarbon liquid, an encircling band and the illumination source during Removal of SO (ROSO). The main outcome measure was BCVA at 3 months after ROSO.**

**Results: Twenty-nine patients were included. The mean change in BCVA was -0.18 (0.31) logMAR from pre-operative 0.17 (0.15) to final BCVA of 0.35 (0.29) logMAR after ROSO. Unexplained loss of vision > 2 log MAR lines occurred in 9/29 (31%) patients. Final BCVA was 0.3 logMAR or worse in 15/29 (52%) patients, and only 7/29 (24%) achieved 0.1 logMAR or better at 3 months after ROSO. 1/29 patients remained phakic without significant lens opacification and 28/29 patients were pseudophakic at 3 months follow-up. None of the analysed variables were associated with visual acuity outcome.**

**Conclusion: The use of SO in the surgical repair of macula on RD was associated with a loss of >2 lines in 31% of patients.**

**Keywords:** Silicone oil, Retinal detachment, Visual outcome.

## Introduction

Silicone oils are considered chemically inert and biocompatible, and since their introduction in 1962,1 Silicone Oil (SO) tamponades have remained the only alternative to gas for the treatment of complex Retinal Detachments (RD) that require a longer lasting intraocular tamponade. Several complications due to the physical and chemical properties of SO are well known, including cataract formation, corneal opacification, glaucoma, and deposition of emulsified oil droplets in various intraocular structures. However, in the recent years, reports have emerged regarding unexplained visual loss, both during the time of SO tamponade and following its removal (ROSO). The cohorts in most case series were small and included RD with macular involvement or revisional surgery, 3-4 making it difficult to differentiate the impact of the underlying pathology on the reduced postoperative vision from the effect of the SO tamponade itself. The goal of our study was therefore to analyse the effect of SO tamponade on final visual acuity in primary macula-on RD with good visual potential, and to assess peri-operative parameters that may influence the functional outcome [1].

## Literature Review

Consecutive patients undergoing PPV with SO tamponade for primary macula-on RD at the Hospital rechts der Isar, Technical University of Munich (TUM), Germany and at the Manchester Royal Eye Hospital (MREH), UK between 01/2014 and 06/2020 were included in this retrospective analysis. Inclusion criteria were primary macula on RD anatomically successfully treated with PPV and SO tamponade and a follow-up period of at least 3 months after SO removal. Exclusion criteria were previous RD surgery or any other previous intraocular surgery apart from cataract surgery, pre-existing visually relevant co-pathology apart from cataract and vitreous hemorrhage, and a history of trauma or amblyopia.

All patients underwent full ophthalmologic examination pre and post operatively, including Best Spectacle or Auto-

Refracted Corrected Visual Acuity (BCVA) measured with a Snellen visual acuity (MREH) or a decimal chart (TUM) and then converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analysis [2].

All patients underwent primary standard 23/25 gauge PPV, in some patients combined with cataract extraction by phacoemulsification and intraocular lens implantation into the capsular bag (CE). Some patients had concurrently a 360° encircling band placed. Endolaser and/or cryo-retinopexy were performed to treat retinal tears, and adjunctive Perfluorocarbon Liquids (PFCL) was used or a posterior retinotomy was performed to flatten the retina in some cases. The exchange of fluid to oil was either performed directly or *via* air. All patients were asked to posture face down for at least 24 hours after surgery. ROSO was conducted either by manual aspiration under microscope light or by automated extrusion under endoillumination, combined with CE in some patients. BCVA were recorded while the SO tamponade was in situ and 6 months after Removal of Silicone Oil (ROSO). Statistical analysis was performed using MedCalc® Statistical Software version 19.6.4 and SPSS V.27.0 (SPSS inc, Chicago, Illinois, USA) [3].

Data were analysed using parametric techniques for normally distributed data (presented as means Standard Deviations (SD)) and non-parametric techniques for non-normally distributed and categorical. Multiple linear regression using a step-wise entry of data was used to determine factors that may explain visual outcome following silicone oil removal, with post-operative BCVA at 3 months as dependent variable and the following independent variables: pre-operative BCVA, hospital site, gender, age, axial length, presence of pre-existing Vitreous Hemorrhage (VH), Presence of Proliferative Vitreo Retinopathy (PVR), presence of a Giant Retinal Tear (GRT), lens status (pseudophakic *vs.* phakic) during SO tamponade, concurrent placement of an encircling band, intraoperative use of Perfluorocarbon Liquid (PFCL), intraoperative performance of a retinectomy, type of SO (Centistoke (CS)) and duration of SO tamponade [4].

## Results

A total of 29 cases were included in the study. 22/29 (76%) were male and the median age was 59 (14) years (range 21-76). Underlying pathology included GRT in 10/29 (34%), pre-existent PVR in 7/29 (24%), multiple inferior retinal breaks in 10/29 (34%) and "other" (e.g. poor vision in fellow eye) in 2/29 (10%). In addition, 12/29 (41%) had some degree of pre-existing VH not obscuring visualization of the posterior pole, and imaging (Optical Coherence Tomography (OCT) and /or fundus photography) confirmed a healthy and flat macula. Axial length was available for 19/29 cases with a mean of 25.6 (2.1 mm). Mean pre-operative BCVA was 0.17 (0.15) logMAR (range 0-0.5) and mean final BCVA 0.35 (0.29) (range 0-1.0), with a mean change in BCVA of -0.18 (0.31) (range -0.8 to +0.3). Nine out of 29 (31%) patients experienced an unexplained loss of vision of more than 2 logMAR lines with 6 of them losing vision under oil, 2 at ROSO and 1 at both steps. Final VA was 0.3 logMAR or worse in 15/29 (52%) patients, and only 7/29 (24%) patients achieved 0.1 logMAR or better at 3 months after oil removal [5].

Intra-operatively, 29/29 had endolaser, 19/29 cryotherapy and in 20/29 PFCL was used. One patient had a retinectomy and 16/29 a concurrent encircling band. Sixteen out of 29 were already pseudophakic before primary PPV, 4/29 had combined CE at the initial surgery, 6/29 had combined CE at the time of silicone oil removal and 2/29 later. In total, 20/29 patients were pseudophakic while the SO tamponade was in situ. 1/29 patients remained phakic without significant lens opacification throughout the study and 28/29 patients were pseudophakic at 3 months follow-up. SO viscosity was as follows: 2000 CS (20/29), 5000 CS (1/29) and 1300 CS (7/29) (1 missing data). Intraoperative complications were lens touch (n=1) and localized suprachoroidal peripheral hemorrhage (n=1). All patients were advised various posturing regimes after the first 24 hours face-down positioning of between 1-7 days. Median duration of SO tamponade was 17 weeks (IQR 12-23) (range 2-60). With SO in-situ, 5/29 (17%) patients had at any one time an IOP ≥ 30 mmHg, but none of the patients had persistent IOP spikes. At the time of ROSO, air was used as a tamponade in 27/29 (93%), 1/29 $C_2F_6$ and 1/29 $SF_6$. All cases of SO extraction were performed either using manual extraction under the microscope light or using viscous extraction under endoillumination [6].

There was no significant correlation between post-operative BCVA and the following parameters: age (p=0.29), gender (p=0.82), hospital site (p=0.09), pre-operative BCVA (p=0.34), axial length (p=0.60), the presence of a VH (p=0.41), a GRT (p=0.33), or PVR (p=0.57), the use of cryo-retinopexy (p=0.95), PFCL (p=0.18), use of an encircling band (p=0.47), the type (CS) of SO (p=0.28) used, duration of SO tamponade (p=0.12), the lens status (phakic *vs.* pseudophakic) while the SO was in situ (p=0.10) and whether the SO was removed under microscope light or endoillumination (p=0.09) [7].

## Discussion

Visual dysfunction related to the use of SO is often an unrecognized and underreported phenomenon due to the underlying complexity and macular involvement of retinal detachments where SO is used as a tamponade. Our retrospective analysis of the cohort of patients with SO use in macula-on RDs in the absence of ocular comorbidity allows a measure of visual loss directly related to SO. About a third of patients in our series suffered a loss of VA by more than 2 lines, and more than a half ended up with 0.3 logMAR or worse, a degree of visual loss extremely unlikely to have been caused if gas was used as a tamponade. The results of our study are in line with those of Scheerlinck et al, who found an unexplained vision loss of more than 2 Snellen lines in only 1/151 (0.7%) eyes after gas tamponade, but in 11/37 (29.7%) eyes treated with SO for macula-on RD [8].

SO related visual loss has been linked to various risk factors in different series. Duration of SO tamponade has been shown to have a statistically significant negative impact on visual function in the work by GRTs especially when macula-on have

been implicated in visual loss at the time of SO removal by Moya et al. In our cohort, neither an association with duration of SO tamponade, or presence of GRT was found, nor with any other of the perioperative factors examined. Whilst our study as with others in this field have tried to look for peri-operative risk factors related to visual loss secondary to SO, the answer remains uncertain. The only common theme is the use of SO [9].

The timing of SO related loss of vision can be broadly divided into two categories: reduction in visual function whilst SO is in situ and/or at the time of SO removal. Our series highlights both these categories with the majority of patients experiencing loss of vision under SO. Amongst their 11 pts, Scheerlinck et al. found loss of vision in 8 eyes during SO tamponade and in 3 eyes after ROSO, with a small scotoma within the central 2° on microperimetry. Similarly Herbert et al. documented the development of subjective central scotomas with SO in situ, and Pattern Electroretinography (PERG) suggested macular dysfunction in these patients. Tode et al. presented loss of vision in 8/15 (53%) patients who received SO tamponade for macula on RD from a pre-operative mean of 0.15 logMAR to 0.7 logMAR prior to ROSO and further to 1 logMAR 6 weeks after ROSO. Four of these patients sustained vision loss within the first 6 weeks of SO tamponade, and all of these recovered. In our study 3 patients lost ≥ 5 lines in the first month under SO tamponade with 2 of them recovering 2 lines by 3 months follow-up. Hence early vision loss may potentially have a better prognosis; however, larger studies on this are needed [10].

Different theories have been offered to explain SO related vision loss. Retinal phototoxicity especially at the time of ROSO may have a role.6 We did not find any changes at the level of the retinal pigment epithelium suggestive of phototoxicity on OCT and where available on autofluorescence or Fundus Fluorescein Angiography (FFA) [11]. SO may dissolve fat soluble neuro-protective elements from the retina especially lutein and zeaxanthin, leading to photoreceptor loss. The 'vitreous potassium sink' theory explains visual dysfunction secondary to SO in terms of altered homeostasis, with the small cleft of 5-10 μm of fluid-filled space between macula and SO serving insufficiently as a sink to discard excessive potassium, leading to excitotoxic neuronal cell death. Emulsified SO has been shown to initiate a localized macrophages-mediated inflammatory response, possibly contributing to epiretinal membrane formation and cystoid macular oedema. Patients included in our study, however, did not show corresponding structural abnormalities of the macula on OCT scan explaining the loss of vision (occasional mild retinal thinning and isolated intraretinal fluid cysts were noted in some cases), indicating that damage was more at a cellular level [12].

It is likely that SO mediated visual loss is multifactorial. However, the damage occurs at various time frames, and different studies have failed to find a common peri-operative risk factor related to poor outcome in some cases. The only common incriminating factor is the use of SO itself. Patients having a similar retinal profile and use of SO may end up with varying outcomes, giving rise to the term 'unexplained vision loss related to silicone oil or its removal. One explanation could be that the retinal damage is toxic, and potentially related to the variable safety profile of SO [13].

The safety profile of SO has been loosely regulated because of its approval as a medical device by the US Food and Drug Administration, and not as a medicine. There has been a recent interest in the need for standardization of various SO products especially with regards to purification and stability [14]. Dresp has analysed the purity parameters of SO brands, and concluded that quality characteristics of various products vary significantly, not only amongst different brands, but also amongst batches of the same manufacturer. In particular, it is the different levels of short chain impurities, the oligosiloxanes, which can increase SO emulsification and also diffuse to the surrounding retina causing toxic damage. Such toxic damage would go unrecognized as vitreoretinal surgeons use SO without being fully aware of the safety data of many of these products. Our series focused exclusively on patients with full visual potential, and less than one quarter of them achieved 0.1 logMAR at 3 months following ROSO, which highlights the extent of the problem. Improving the safety parameters of various brands of SO being used as endotamponades is likely to improve functional outcomes in some of these cases [15].

With the limitations of a retrospective study of small numbers and lack of control group, our study aimed to quantify the magnitude of SO related vision loss in eyes with maximal visual potential. It adds to the literature where very few studies have looked at the effect of SO on the functional outcomes of successfully treated macula-on retinal detachments [16].

In conclusion, we present a consecutive case series of 29 patients, where SO was used as tamponade for a macula-on retinal detachment in eyes with no ocular comorbidity. Almost a third of patients experienced 'unexplained vision losses in the absence of corresponding macular or optic nerve abnormality explaining this level of visual dysfunction [17]. None of the peri-operative factors examined was found to be a negative prognostic indicator of final visual acuity. Further studies are needed to look at various parameters which could explain poor functional outcomes with SO. Additionally, there is an imminent need to look at the safety data and stability of various SO products to reduce potential secondary retinal toxicity [18].

## Conclusion

Ethics approval: Approval was obtained from the Ethic Committee at the Technical University of Munich and from the Internal Review Board at the Manchester Royal Eye Hospital. All procedures performed in this study complied with the ethical standards of both institutions and adhered to the Declaration of Helsinki. Informed patient consent was waved due to the retrospective nature of this study in accordance with the legal regulations at both hospitals. Availability of data and materials: The datasets analysed during the current study are available from the corresponding author on reasonable request.

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## Conflict of Interest

M Maier reports speaker honoraria from Novartis, Allergan, Bayer, Heidelberg Engineering and Zeiss outside the submitted work. There are no financial disclosures and no conflicting relationship for any of the other authors.

## Authors Contributions

CB study design, data analysis, writing the manuscript; NP data analysis, writing and review of the manuscript; KK data collection and validation, review of the manuscript; KR data collection and validation, review of the manuscript; TZC data collection and validation, review of the manuscript; MM data collection and validation, review of the manuscript; AJ study design, data analysis, writing and review of the manuscript; All authors read and approved the final manuscript.

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