Complications associated with the use of silicone oil: A systematic review

Complicaciones asociadas al uso de aceite de silicona: revisión sistemática

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Abstract

Purpose: To identify and assess the available information regarding the frequency of complications following the use of silicone oil (SO). **Methods:** A systematic search was conducted in PubMed/Medline, Cochrane and Embase, up to June 2020. The reference lists of identified studies and relevant reviews were also reviewed. We included studies in Spanish and English, with no publication date limits, of all types of methodology, with populations over 50 eyes, with patients previously diagnosed with tractional retinal detachment, proliferative diabetic retinopathy, giant retinal tears, traumatic retinal detachment and patients with proliferative vitreoretinopathy from any cause, with a minimum follow-up of 6 weeks. The quality assessment of the studies was conducted according to the Centre for Evidence-Based Medicine classification of levels of evidence. **Results:** A total of 13 studies were included, most of which were retrospective, with a level of evidence 2b. Cataract (median: 90, interquartile range [IQR]: 80-100%), silicone oil emulsification in the anterior chamber (median: 64.5; IQR: 46.5-82.25%), ocular hypertension (median: 23.3; IQR: 22.15-35.1%) and retinal redetachment (median: 22; IQR: 18.5-30%) were the most frequent complications; while pupillary block (median: 4.3; IQR: 3.8-4.8%), subconjunctival silicone oil deposits (median: 4.15; IQR: 3.75-4.57%), and expulsive suprachoroidal hemorrhage (median: 1; IQR: 0.95-1.05%) were the least frequent. **Conclusions:** The most frequent complications reported in decreasing order were cataracts, silicone oil emulsification in the anterior chamber, ocular hypertension, retinal redetachment, keratopathy, hypotonia, subretinal silicone oil migration, rebleeding, secondary glaucoma, unexplained visual loss, pupillary block, subconjunctival silicone oil deposits and expulsive suprachoroidal hemorrhage.

Key words: Silicone oil complications. Silicone oil removal. Systematic review.

Resumen

Objetivo: Identificar y evaluar la información disponible sobre la frecuencia de las complicaciones tras el uso del aceite de silicona. **Método:** Se realizó una búsqueda sistemática en PubMed/Medline, Cochrane y Embase, hasta junio de 2020. Las listas de referencias de los estudios identificados y de las revisiones relevantes también fueron revisadas. Se incluyeron estudios en español e inglés, sin límite de fecha de publicación, de cualquier metodología, con una muestra mayor de 50 ojos, con pacientes con diagnóstico previo de desprendimiento de retina traccional, retinopatía diabética proliferativa, des-

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garros gigantes, desprendimiento de retina, por trauma, y pacientes con proliferación vitreorretiniana independientemente de la causa, con un seguimiento mínimo de 6 semanas. La evaluación de la calidad de los estudios se realizó según la clasificación del Centre for Evidence-Based Medicine. **Resultados:** Se incluyeron 13 estudios, la mayoría retrospectivos, con un nivel de evidencia 2b. La catarata (mediana: 90; rango intercuartílico [RIC]: 80-100%), la emulsificación en la cámara anterior (mediana: 64.5; RIC: 46.5-82.25%), la hipertensión ocular (mediana: 23.3; RIC: 22.15-35.1%) y el redespndimiento de retina (mediana: 22; RIC: 18.5-30%) fueron las complicaciones más frecuentes, mientras que el bloqueo pupilar (mediana: 4.3; RIC: 3.8-4.8%), el depósito conjuntival de aceite de silicona (mediana: 4.15; RIC: 3.75-4.57%) y la hemorragia expulsiva (mediana: 1; RIC: 0.95-1.05%) fueron las menos reportadas. **Conclusiones:** Las complicaciones más frecuentes en orden decreciente fueron cataratas, emulsificación en la cámara anterior, hipertensión ocular, redespndimiento de retina, queratopatía, hipotonía, migración de aceite de silicona subretinal, resangrado, glaucoma secundario, pérdida visual inexplicable, bloqueo pupilar, depósitos conjuntivales de aceite de silicona y hemorragia expulsiva.

Palabras clave: Complicaciones por aceite de silicón. Retiro de aceite de silicón. Revisión sistemática.

Introduction

The use of silicone oil (SO) in the vitreous cavity dates back to the late 1950s, when Stone¹ showed in rabbit eyes that oils of different viscosities were well tolerated for a period of 2 years. The first human study was conducted in the early 1960s by Cibis, et al.², who used SO in 33 patients as retinal tamponade, demonstrating good retinal tolerance for a period of 7 months. Since then, the use of SO has been preferred for those cases with a high risk of retinal redetachment (reRD), such as complex retinal detachments associated with proliferative vitreoretinopathy (PVR), giant tears (GT) and tractional retinal detachments (TRD) associated with proliferative diabetic retinopathy (PDR), trauma or viral retinitis³.

SO is an important tool in vitreoretinal surgery because it has the ability to displace aqueous humor and maintain retinal adhesion; furthermore, it is a good tamponade agent for retinal lesions without traction. Although its use today is associated with good anatomical results, several complications have also been described that can affect almost all ocular structures and include cataract formation, ocular hypertension (OHT), anterior chamber oil emulsification, secondary glaucoma, reRD, hypotonia, pupillary block, SO subretinal migration, unexplained visual loss, subconjunctival deposits of SO, rebleeding and expulsive hemorrhage³⁻³⁰. The frequency of these complications varies considerably between different studies, and they can have a great impact on the visual health of the patient. Another important consideration in the use of SO is the need for an additional surgical procedure for its removal once the anatomical stabilization of the retina has been achieved; however, to date there is no consensus regarding the appropriate time to remove SO based on possible complications¹⁰⁻¹⁷. Considering the diversity

and severity of the complications reported, as well as the heterogeneity of the existing reports, we decided to conduct a systematic review to assess the frequency of complications after the use of SO.

Methods

Search strategy and selection of studies

A systematic search was carried out in the PubMed/ Medline, Cochrane and Embase of publications up to June 2020, using the keywords “silicone oil removal”, “outcome of silicone oil removal” and “silicone oil complications”. Additionally, the reference list of identified studies and relevant reviews on the subject were assessed, looking for other possible studies that could be included.

Randomized clinical trial studies, cohort studies and case series were included, with a sample of more than 50 eyes, in patients with a previous diagnosis of TRD due to PDR, GT or trauma, and patients with PVR regardless of the cause, with a minimum follow-up of 6 weeks. Duplicate studies and those with incomplete data were excluded. Regarding language, studies in Spanish and English were searched, without limitation by publication date. The evaluation of the quality of the studies was carried out according to the classification of the Oxford Centre for Evidence-Based Medicine (OCEBM). Study selection was made independently by two investigators (AD and DV) and differences were resolved by a third investigator (AA).

Data extraction and analysis

The studies were exported to the EndNote X9 software to eliminate duplicate articles and subsequently imported to Number v6.1 6369 for tabulation. The data

Figure 1. Flow chart for inclusion of studies in the systematic review according to PRISMA recommendations.

extracted from the studies were the main author, the year of publication, the country of origin, the methodology, the number of patients, age, sex, the type of SO, the most frequent indications, the time elapsed for SO removal and complications.

The data were independently reviewed by three investigators (AD, DV and AA). If there were any observations about one of the studies, it was further evaluated by another investigator (JR). The review was then again evaluated again by experts in the subject (VM and JR) before creating the final manuscript.

Data were grouped in descriptive tables using Numbers v6.1 6369 software (Apple Inc.). Categorical variables were expressed as percentages, and numerical results as mean and standard deviation or as median and interquartile range (IQR). Given the heterogeneity of the studies, no meta-analysis was performed.

Results

The search strategy identified 343 studies, of which 75 were eliminated due to duplication. During the title

and abstract review, we found 50 potential studies. Finally, after the full texts, 13 articles were included for review (Fig. 1). Most of the articles corresponded to reports from the United States of America and Germany; in all cases, 1,000- or 5,000-centistoke SO was used. Only one randomized clinical trial was identified; most of the studies were retrospective, with a level of evidence 2b according to the OCEBM classification. The characteristics of the studies included in the analysis are summarized in Table 1.

The complications after the use of SO reported are described in Table 2, and the most frequent were cataracts with a median of 90 (IQR: 80 -100%), anterior chamber oil emulsification with a median of 64.5 (IQR: 46.5-82.25%), OHT with a median of 23.3 (IQR: 22.15-35.1%) and reRD with a median of 22 (IQR: 18.5-30%). On the other hand, among the less frequent were pupillary block with a median of 4.3 (IQR: 3.8-4.8%), subconjunctival deposits of SO with a median of 4.15 (IQR: 3.75 -4.57%) and finally expulsive hemorrhage with a median of 1 (IQR: 0.95-1.05%).

Table 1. Main characteristics of the included studies and levels of evidence according to the Oxford Center for Evidence-Based Medicine (OCEBM) (n = 13)

Studies	Country	Design:	Population	Age	Sex	SO type	Indications for surgery	Follow-up time	SO removal interval	OCEBM grading
Casswell, et al. ¹⁰ (1987)	England	Retrospective (cohort)	85 eyes (85 patients)	NS	NS	NS	GT: 59 (69.4%) PVR: 26 (30.58%)	18 months	G1: $\bar{X}$ = 9.1 (3-20 weeks) G2 glaucoma: $\bar{X}$ = 20.2 (3-60 weeks) G2 keratopathy: $\bar{X}$ = 76 (16-160 weeks)	2b
Lucke, et al. ³⁶ (1987)	Germany	Retrospective (cohort)	500 eyes (486 patients)	46 (1.5-85)	M: 311 (62%) W: 189 (38%)	5000 cSt	PVR: 55% GT: 15% Posterior ruptures: 14.6% PDR + TRD: 18% Trauma: 7.9%	15.7 months	6-18 months	2b
Federman and Schubert ¹⁵ (1988)	United States	Retrospective (cohort)	150 eyes (170 patients)	40-60 years	NS	NS	PVR C3 or worse: 68.66% PDR + TRD: 21.33% GT: 5.3 %	$\bar{X}$ = 31.6 months (6 months-5 years)	3-6 months	2b
Riedel, et al. ³¹ (1990)	Germany	Retrospective (cohort)	415 eyes (415 patients)	NS	NS	5000 cSt	PVR due to RD: 49% PVR due to trauma: 13% PDR + TRD: 38%	30 months	6 -30 months	2b
Franks and Leaver ¹¹ (1991)	Germany	Retrospective (cohort)	120 eyes (116 patients)	41.5 (12-81)	NS	1000 cSt	GT: 47.5 % Posterior tears: 13.3% PVR: 38.33 %	5 years	$\bar{X}$ = 30 (3 weeks-5 years)	2b
Silicon Study Group ¹⁶ (1992-1994)	United States	RCT	101 eyes (101 patients)	66.2 (24-84)	M: 17 (33%) W: 30 (67%)	1000 cSt	RRD + PVR (100%)	36 months	8 weeks-6 months	1b
Scholda, et al. ¹⁷ (2000)	Austria	Prospective (cohort)	112 eyes (106 patients)	RD group: 44.2 ± 21.4 No RD group: 50.9 ± 19.5	NS	1000 cSt (n = 26) 5000 cSt (n = 86)	PVR (n = 59), PDR (n = 34) Macular hole, IFB, CRVO, uveitis, retinal hemangioma (n = 19)	7 days-6.9 years	RD group: 185 ± 94.5 days No RD group: 319 ± 235 days	1b
Falkner, et al. ¹² (2001)	Austria	Retrospective (cohort)	115 eyes (115 patients)	54.9 (13-83)	NS	5000 cSt	RRD + PVR: 89.2% TRD: 5.4%; trauma 5.4%	6 months-3.5 years	13.3 months	2b
Moya, et al. ²⁰ (2015)	England	Retrospective (cohort)	421 eyes (421 patients)	53.1 (40-74)	UVL (14) M: 12 (86%) W: 2 (24%)	1300 cSt	Giant tear: 71.4% PVR: 28.5%	2 years	141 days (76-218)	2b

(Continues)

Table 1. Main characteristics of the included studies and levels of evidence according to the Oxford Center for Evidence-Based Medicine (OCEBM) (n = 13) (*continued*)

Studies	Country	Design:	Population	Age	Sex	SO type	Indications for surgery	Follow-up time	SO removal interval	OCEBM grading
Anaya-Pava, et al. ⁷ (2017)	Mexico	Retrospective (cohort)	269 eyes (235 patients)	M: 58.6(26-86) W: 59.7 (24-88)	M: 139 (51.7%) W: 130 (48.3%)	5000 cSt	TRD: 65% RRD + PVR: 32% Trauma: 3%	5 years	11 months (1-58) Trauma: $\bar{X}$ = 11 (3-24 weeks) PDR: $\bar{X}$ = 10 (5-16 weeks) RRD + PVR $\bar{X}$ = 11 (8-19 weeks)	2b
Roca, et al. ¹⁸ (2017)	Argentina Brazil Costa Rica Colombia United States Spain Mexico Puerto Rico Venezuela	Retrospective, multicentric (cohort)	324 eyes (324 patients)	UVL: 49.2 ± 16.4 (16-73)	UVL (19) M: 8 (42%) W: 11 (68%)	1000 cSt (42.1%) 5000 cSt (57.9%)	DTRD: 47.4% Giant tear: 10.5% PVR: 31.6% RD macula off: 63.2%	14.8 months	14.8 ± 4.4 months	2b
Jabbour, et al. ¹³ (2018)	Lebanon	Prospective (cohort)	254 eyes (254 patients)	55.33 ± 16.29 (8-86)	M: 175 (68.9%)	1000 cSt (n = 152) 5000 cSt (n = 102)	TRD: 61.1% PVR: 38.9%	22.4 ± 18.1 (6-76 months)	6 months	1b
Abdalkader, et al. ³² (2019)	United States	Retrospective (cohort)	57 eyes (57 patients)	Migration 56.1 ± 16.6 No migration 57.5 ± 18.6	M: 31 (54.4%) W: 26 (45.6%)	1000/ 5000 cSt	TRD: 59,6% Trauma: 7% CMV retinitis: 5.2% Glaucoma: 3.5% Postoperative bleeding: 1.75% Congenital infection: 1.75% Unknown: 21%	1 month to 4 years after SO injection	NA	2b

SO: silicone oil; IFB: intraocular foreign body; CMV: cytomegalovirus; cSt: centistokes; DTRD: diabetic tractional retinal detachment; RD: retinal detachment; GT: giant retinal tear; RRD: rhegmatogenous retinal detachment; TRD: tractional retinal detachment; RCT: randomized clinical trial; G1: removal as prevention of complications; G2: removal as a treatment for complications; W: men; W: women; NA: not applicable; NS: not specified; CRVO, central retinal vein occlusion; UVL: unexplained visual loss; PVR: proliferative vitreoretinopathy; PDR: proliferative diabetic retinopathy.

Table 2. Frequency of complications after silicone oil use

Complication	Median (IQR)
Ocular hypertension	23.3 (22.15-35.1%)
Secondary glaucoma	6 (4.5-9.1%)
Pupillary block	4.3 (3.8-4.8%)
Cataracts	90 (80-100%)
Keratopathy	6.3 (4.55-13.9%)
Re-detachment	22 (18.5-30%)
Hypotonia	13.5 (9.55-17.65%)
Expulsive hemorrhage	1 (0.95-1.05%)
Unexplained visual loss	4.6 (3.95-5.25%)
Submacular migration	8.95 (7.42-10.47%)
Rebleeding	6.1 (5.25-6.85%)
Subconjunctival oil deposits	4.15 (3.75-4.57%)
Emulsification in the anterior chamber	64.5 (46.75-82.25%)

IQR: interquartile range.

Discussion

It is known that most of the indications for the use of SO are complex retinal detachments, such as PVR, GT, PDR, TRD or due to trauma or viral infection¹⁻²⁵. In these cases, OS is very useful to maintain adhesion between the retina and the retinal pigment epithelium and reduce the risk of reRD; however, it is known that its use as tamponade can be associated with several complications that must be considered in the follow-up of these patients¹⁰⁻¹⁷.

One of the most common complications is cataract formation, which may occur de novo or from an existing opacity¹⁸. Cataract formation is observed in 100% in some series at 5 years of follow-up⁸, and the incidence is related to the duration of intraocular SO. Ultrastructural studies have shown alterations in lens epithelial cells⁷⁻⁹. Cataracts are also a cause of low vision and its removal should be scheduled at the same time of SO removal, considering the corneal endothelial cell count, which could be altered by the effect of SO²³⁻³⁴. In our review we found that this is the main complication reported. Its dispersion is wide and is directly related to the time the SO remained in the cavity, as there are studies that follow-up during 5 years and others monitor a shorter interval¹⁸.

Secondary glaucoma and OHT have also been reported as frequent complications, with rates of 3-7.8%

for glaucoma⁷⁻¹⁰ and 11-46.6% for OHT¹⁰⁻²². Associated risk factors are pseudophakia, aphakia, high myopia, previous OHT, and the use of low-viscosity SO¹². Cases of pupillary block have also been described, which should be managed with an inferior peripheral iridotomy with Nd-YAG laser or by reopening a pre-existing occluded iridotomy. Many of these patients improve when the SO is removed, but 6.8% will need filtering surgery to control intraocular pressure¹². It is important before surgery with SO injection to tell patients about the possibility of developing OHT and, therefore, the need for prolonged topical treatment, or even surgical procedures if this complication continues postoperatively¹². Our study shows the high frequency of this complication, and its wide dispersion correlates in part with the methodology used to define OHT in the different studies and with the treatment that the patients received.

reRD rates vary widely, between 14%¹⁴ and 50%¹⁵; this variation depends on the characteristics of the retinal detachment and the underlying pathology. Most studies, almost all retrospective in nature, describe that the highest rate of reRD occurs in the first postoperative days. The factor most frequently associated with reRD is PVR; the larger and more anterior the PVR, the greater the risk of reRD. Other causes of reRD are PDR with TRD, GT and those associated with trauma¹⁶⁻¹⁹. When analyzing the values found in the literature, we observed a great dispersion regarding this complication (IQR: 18.5-30%). It should be mentioned that reRD has been studied more than other complications, considering the surgical indication of these patients (complex detachments), which also contributes to its numerical expression as one of the primary associated complications.

Hypotonia after SO removal was described in 5.2-22.5% of cases²¹. Studies show that it occurs more frequently in patients with postoperative retinal detachment with macular involvement, and the mechanism would not only depend on the indication for surgery, but would also be associated with an alteration of the ciliary body and anterior chamber inflammation²¹.

Unexplained visual loss is a clinical challenge, as many patients may have lower-than-expected best-corrected visual acuity after SO removal without a demonstrable anatomic cause. More and more cases have been described and their cause is not fully understood²⁵⁻²⁹. The pathogenic mechanisms suggested are direct macular dysfunction caused by contact with SO, alterations in growth factors and foveal phototoxicity^{4-25,28}. Many authors believe that OHT could be associated, but there are no studies with a robust methodology

to confirm any of these theories. Rates range from 3.3% to 5.9% of cases¹⁵⁻³².

Considering all the available information on the possible complications after SO injection and its association with the duration of intraocular SO, the question arises about the appropriate timing for SO removal; however, there is no established consensus to date, since many of these patients have complex pathologies with an unpredictable course. Although SO is an excellent long-term retinal tamponade, its use should be temporary due to the complications observed after prolonged use. An important event is the emulsification of SO; the longer the intraocular duration, the greater the probability of emulsification¹⁵⁻³⁵. One study found that the average time for SO emulsification to occur after surgery is 13 months³³. The available evidence does not allow us to answer the question about the optimal time for SO removal, so it is suggested that it should be individualized in each patient; however, most authors agree on a minimum of 3 to 6 months of tamponade¹²⁻³³.

Regarding the limitations of the study, due to the heterogeneity of the articles included, it was not possible to perform a meta-analysis to consolidate the available information. As a result of our inclusion criteria and study methodology, other relevant publications may have been omitted; to minimize this, we performed the evaluation by three authors separately and then together.

In conclusion, the most frequent complications reported were, in decreasing order, cataracts, anterior chamber oil emulsification, OHT, reRD, keratopathy, hypotonia, subretinal SO migration, rebleeding, secondary glaucoma, unexplained visual loss, pupillary blockage, conjunctival deposits of SO and expulsive hemorrhage.

Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their Institution on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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