Heavy Silicone Oil as an Endotamponade in Recurrent or Complicated Retinal Detachment and Macular Hole

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Abstract

Objectives: To evaluate the efficacy and safety of heavy silicone oil as an endotamponade in patients with recurrent or complicated retinal detachment and macular hole.

Materials and Methods: Nineteen eyes of 19 patients who underwent heavy silicone oil endotamponade for different indications were included in the study and evaluated by retrospective chart review. At each visit, patients underwent detailed ophthalmological examination and anatomical and functional outcomes, silicone oil emulsification, intraocular inflammation, presence of proliferative vitreoretinopathy, preoperative and postoperative visual acuity, and postoperative complications were recorded.

Results: The study included 19 eyes of 19 consecutive patients: 13 women (68.4%) and 6 men (31.6%). The patients’ median age was 60 years (interquartile range [IQR]: 44-70 years) and the median follow-up time was 19 months (IQR: 9-31 months). Indications for heavy silicone oil endotamponade were recurrent retinal detachment in 11 eyes (57.8%), inferior retinal detachment in 5 eyes (26.3%), inferior rhegmatogenous retinal detachment, recurrent macular hole in 2 patients (10.5%), and macular hole in 1 patient (5.2%). Median best corrected visual acuity was 2 logMAR (IQR: 1-2.6) preoperatively and 0.99 logMAR (IQR: 0.4-2) postoperatively (p<0.001). Postoperative anatomical success was achieved in all patients. Densiron 68 was used for endotamponade in 14 patients (73.7%), Densiron XTRA in 3 patients (15.8%), and AlalHeavy 1.07 in 2 patients. Heavy silicone oil emulsification was observed in only 3 patients (15.8%).

Conclusion: Although heavy silicone oil has limitations as an endotamponade, such as intraocular pressure increase, emulsification, intraocular inflammation, and the risk of complications during removal, it is a safe and effective alternative in eyes requiring inferior retinal tamponade for indications like proliferative vitreoretinopathy and recurrent macular holes.

Keywords: Heavy silicone oil, complicated retinal detachment, macular hole, proliferative vitreoretinopathy
**Introduction**

Traditional endotamponades used during vitreoretinal surgery are air, sulfur hexafluoride (SF₆), octafluoropropane (C₈F₈), hexafluoroethane (C₆F₁₃), and silicone oils.¹ Silicone oil was first used as endotamponade in non-vitrectomized eyes in the 1960s, but results were not very satisfying; in the 1980s, it was combined with pars plana vitrectomy and its clinical use increased.²³⁴ Silicone consists of linear siloxane polymers, which are made of alternating silicon and oxygen molecules.¹ Due to its chemical structure, silicone can bind with organic and inorganic components and form polymers with different properties.¹² For example, silicone oils consist of polydimethylsiloxane (i.e., silicone with two methyl side chains) and are divided into two groups, those lighter than water and those heavier than water.¹ There are two different types of light silicone oil, 1,000 centistokes and 5,000 centistokes. This group is lighter than water, with a specific gravity of 0.97. Therefore, when administered intraocularly, they are buoyant and provide more effective tamponade for the superior retina.¹ Because of this characteristic, they are not an ideal option in conditions such as proliferative vitreoretinopathy (PVR), inferior retinal tears, or macular surgery in which the patient cannot maintain a position. For these indications, heavy silicone oils may be more suitable endotamponade alternatives because they are heavier than water, with a specific gravity greater than 1.¹ Densiron 68 (Fluoron, NeUlm, Germany), Densiron XTRA (Fluoron, NeUlm, Germany), Oxane HD (Bausch & Lomb, Toulouse, France), and 11% silica solution are heavy silicone products used today.⁵ AlaHeavy 1.07 (AlaMedics GmbH & Co. KG, Dornstadt, Germany), which was used in two of the eyes in our study, is no longer produced since the company’s closure due to a problem with another product.⁴⁵ The chemical properties of these endotamponades are presented in Table 1. This study aimed to examine eyes that received heavy silicone oil in terms of anatomical and functional success, silicone emulsification, intraocular inflammation, presence of PVR, postoperative visual acuity, and postoperative complications and evaluate the safety of using heavy silicone oil.

**Materials and Methods**

This retrospective study was approved by the Başkent University Medical and Health Sciences Research Council (decision number: KA20/412) and was conducted in accordance with the principles of the Declaration of Helsinki. The study included 19 eyes of 19 patients who underwent pars plana vitrectomy due to recurrent retinal detachment, inferior rhegmatogenous retinal detachment, or macular hole between August 2015 and February 2020 and received heavy silicone as endotamponade. At each visit, the patients underwent detailed ophthalmological examination and anatomical and functional success, silicone emulsification, intraocular inflammation, presence of PVR, preoperative and postoperative visual acuity, and postoperative complications were recorded.

**Statistical Analysis**

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS version 11.0, SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean ± standard deviation or median and interquartile range (IQR). Normal distribution was tested using skewness and kurtosis and histogram plots. Statistical comparisons between repeated measures of visual acuity were performed with the Wilcoxon signed-rank test and p<0.05 was considered significant for all analyses.

**Results**

Nineteen eyes of a total of 19 consecutive patients, 13 women (68.4%) and 6 men (31.6%), were included in the study. The patients’ median age was 60 years (IQR: 44-70 years) and the median follow-up time was 19 months (IQR: 9-31 months). Indications for heavy silicone oil endotamponade were recurrent retinal detachment in 11 patients (57.8%), inferior rhegmatogenous retinal detachment in 5 patients (26.3%), recurrent macular hole in 2 patients (10.5%), and macular hole in 1 patient (5.2%). The median best corrected visual acuity (BCVA) was 2.0 logMAR (IQR: 1.2-2.6) preoperatively and 0.99 logMAR (IQR: 0.4-2.0) postoperatively (p<0.001). Postoperative anatomical success was achieved in all patients. The demographic characteristics of the patients are shown in Table 2.

Before heavy silicone oil endotamponade, standard silicone endotamponade was administered to 63.2% of the patients once, to 26.3% of the patients twice, and to 10.5% of the patients three times. Densiron 68 was used for endotamponade in 14 patients (73.7%), Densiron XTRA in 3 patients (15.8%), and AlaHeavy 1.07 in 2 patients (10.5%). Heavy silicone oil emulsification

| Table 1. Heavy silicone oils and their properties |
|-----------------------------------------------|
| Heavy silicone oil | Viscosity (mPas) | Specific gravity (g/cm³) | Composition |
|-------------------|-----------------|-------------------------|-------------|
| Densiron 68       | 1400            | 1.06                    | 69.5% 5000 centistoke silicone oil + 30.5% F₃H₆₂⁴ |
| Densiron XTRA     | 1350            | 1.06                    | 69.5% heavy silicone oil with 10% high molecular weight additive + 30.5% F₃H₆₂⁵ |
| Oxane HD          | 3300            | 1.02                    | 80.1% silicone oil + 11.9% RMN3 |
| AlaHeavy          | 1100            | 1.07                    | Homogenized fluorosilicone oil |
| Silica solution   | 2000            | 1.11                    | 11% silica + 89% silicone oil |
was observed in only 3 patients (15.8%). Two patients with emulsification received AlaHeavy 1.07 and the other patient received Densiron 68 for endotamponade. Emulsification was observed on postoperative day 21 and 47 in the 2 patients with AlaHeavy 1.07 and on day 30 in the patient with Densiron 68. The median intraocular residence time of the heavy silicone oil was 80 days (IQR: 30-120 days). The silicone endotamponade could not be removed in 2 patients (10.5%).

PVR was present at diagnosis in 5 of 19 patients (26.3%). In the postoperative period, 6 patients (31.6%) had increased intraocular pressure and 4 patients (21.1%) had hypotony. No intraoperative complications were observed during heavy silicone oil removal. Inflammation was not observed in any eye while the heavy silicone oil was present as an endotamponade.

Table 2. Demographic and clinical characteristics of the patients

| Patient no. | Diagnosis | Sex | Age (years) | Preop BCVA (logMAR) | Postop BCVA (logMAR) | No. of silicone injections | Silicone type | Silicone residence time (days) | Silicone emulsification | PVR | IOP increase | Hypotony | Follow-up time (months) |
|-------------|-----------|-----|-------------|---------------------|---------------------|--------------------------|--------------|-------------------------------|------------------------|-----|--------------|-----------|--------------------------|
| 1           | RRD       | M   | 70          | 2.6                 | 2.0                 | 2                       | Densiron 68  | 120                           | -                      | +  | -            | -         | 6                        |
| 2           | RMH       | M   | 87          | 1.0                 | 2.3                 | 1                       | Densiron 68  | 105                           | -                      | -  | +           | -         | 31                       |
| 3           | MH        | F   | 65          | 1.33                | 0.2                 | 1                       | Densiron 68  | 90                            | -                      | -  | -            | +         | 9                        |
| 4           | RRD       | M   | 33          | 2.6                 | 0.8                 | 3                       | Densiron 68  | 120                           | -                      | -  | +           | -         | 54                       |
| 5           | RRD       | F   | 63          | 2.6                 | 0.3                 | 1                       | Densiron 68  | 90                            | -                      | +  | -            | -         | 10                       |
| 6           | RRD       | M   | 38          | 0.8                 | 0.8                 | 2                       | Densiron 68  | 900                           | -                      | -  | +           | +         | 25                       |
| 7           | RRD       | M   | 58          | 2.6                 | 0.8                 | 1                       | Densiron 68  | 180                           | -                      | -  | +           | -         | 20                       |
| 8           | RRD       | M   | 44          | 2.0                 | 1.33                | 3                       | Densiron 68  | 30                            | -                      | -  | -            | -         | 15                       |
| 9           | RRD       | M   | 60          | 1.33                | 0.8                 | 2                       | Densiron 68  | 60                            | -                      | +  | -            | -         | 19                       |
| 10          | RD        | M   | 54          | 0.8                 | 0                   | 1                       | Densiron 68  | 30                            | +                      | -  | -            | -         | 49                       |
| 11          | RD        | F   | 39          | 2.6                 | 2.0                 | 2                       | Densiron 68  | 60                            | -                      | +  | -            | -         | 40                       |
| 12          | RRD       | M   | 72          | 2.6                 | 1.0                 | 1                       | Densiron 68  | 180                           | -                      | +  | -            | -         | 21                       |
| 13          | RRD       | F   | 41          | 2.0                 | 0                   | 1                       | Densiron 68  | 45                            | +                      | -  | -            | -         | 39                       |
| 14          | RRD       | M   | 60          | 2.6                 | 2.3                 | 2                       | AlaHeavy 1.07 | 21                            | -                      | +  | -            | -         | 22                       |
| 15          | RRD       | M   | 46          | 2.0                 | 0.48                | 1                       | AlaHeavy 1.0  | 47                            | -                      | +  | -            | -         | 10                       |
| 16          | RMH       | F   | 73          | 0.7                 | 0.4                 | 1                       | Densiron 68  | 30                            | +                      | -  | -            | -         | 4                        |
| 17          | RD        | M   | 80          | 1.33                | 1.0                 | 1                       | Densiron Xtra | 80                            | -                      | +  | -            | -         | 3                        |
| 18          | RD        | F   | 49          | 1.0                 | 0.48                | 1                       | Densiron Xtra | 10                            | -                      | +  | -            | -         | 12                       |
| 19          | RD        | M   | 62          | 2.6                 | 2.0                 | 1                       | Densiron Xtra | 300                           | -                      | +  | -            | -         | 1                        |

No: Number, RRD: Recurrent retinal detachment, RD: Retinal detachment, RMH: Recurrent macular hole, MH: Macular hole, M: Male, F: Female, BCVA: Best corrected visual acuity, PVR: Proliferative vitreoretinopathy, IOP: Intraocular pressure.
Discussion

Vitreoretinal surgery outcomes are more satisfactory due to advances in instrumentation and intraocular tamponades over the last three decades. Despite these developments, cases with inferior retinal tears, PVR, recurrent retinal detachments, and macular holes are still difficult to treat.

As standard endotamponades could not meet the need for a more effective and long-lasting tamponade, especially for the inferior retina, the search began for heavier-than-water endotamponades in vitreoretinal surgery. Perfluorocarbon fluids, which were first used for this purpose by Chang et al., facilitated intraoperative retinal manipulation due to their heavier-than-water formulations. Although their toxic structures do not allow them to remain in the eye for a long time, some authors have reported that liquid perfluorocarbon can be left in the eye for up to 2 weeks. Fluorinated silicone oil, which is used for the same purpose, was also an effective endotamponade but is not widely used due to adverse effects such as early emulsification and intense intraocular inflammation. These developments were followed by the use of semi-fluorinated alkanes as endotamponades. However, although they were shown to be well tolerated in animal studies, they were discontinued due to adverse effects in human eyes such as inflammation and retrolental and epiretinal membrane formation. Therefore, as vitreous equivalents that are heavier than water but are well tolerated by the eye, heavy silicone oils have assumed an important place as endotamponades in certain cases.

PVR is known to be mediated by growth factors and cytokines originating from inflammatory cells, retinal pigment epithelial cells, fibroblasts, glial cells, and the aqueous humor. When lighter-than-water tamponades are used and the inferior retina is not adequately stabilized, the shift of aqueous humor to this region results in potential development of PVR. Although it is theorized that heavy silicone oil prevents PVR formation by exerting a barrier function between the aqueous humor and retinal PVR precursor cells, it has been shown that this is not the case in practice. The Heavy Silicone Oil study, the first multicenter, randomized, controlled prospective study comparing PVR inhibition by heavy silicone oil and standard silicone oil demonstrated no difference between the two endotamponades. In our series, PVR was detected at diagnosis in 5 of 19 patients (26.3%), but no patient developed PVR under the heavy silicone endotamponade or after removal.

Heavy silicone oils have been shown to be well tolerated in the eye for periods of 3–4 months, but the risk of causing intraocular inflammation increases when left for more than 6 months. In their series of 75 patients, Dooley et al. compared complications in 39 eyes with temporary heavy silicone oil endotamponade and 36 eyes with permanent heavy silicone oil endotamponade. Complications such as recurrent detachment, corneal pathology, secondary glaucoma, and emulsification were significantly more frequent in the 36 eyes from which endotamponade could not be removed for various reasons when compared with the 39 eyes with early tamponade removal. In our series, heavy silicone oil could not be removed in two cases due to hypotony, but no serious adverse effects were observed in these cases. One of these patients underwent pars plana vitrectomy with standard silicone oil tamponade twice due to giant tear retinal detachment secondary to degenerative myopia, and reattachment was observed after each silicone removal. As retinal reattachment could only be achieved with Densiron 68 and intraocular pressure is below 8 mmHg, this patient has been monitored for 30 months without removing the silicone (Figure 1). Similarly, in our other patient, Densiron 68 was not removed for 10 months due to hypotony.

Increased intraocular pressure after pars plana vitrectomy with silicone oil endotamponade may occur for different reasons, such as silicone oil emulsification and obstruction of the trabecular network, surgery-induced intraocular inflammation, or long-term corticosteroid use. The prevalence of intraocular pressure increase after heavy silicone endotamponade was 31.6% in our series, while this rate ranges from 0.3% to 33% in different series in the literature. Wong et al. compared the effects of light and heavy silicone oil on intraocular pressure and determined that patients who received heavy silicone oil had higher intraocular pressures in the first two weeks postoperatively, but there was no significant difference between the groups at 4 weeks. Ocular hypotony occurred in 4 (21.1%) of 19 patients in our series. In two studies using Densiron 68, Sandner and Engelmann and Li et al. reported hypotony at rates of 2% and 11%, respectively, while Wickham et al. reported a rate of 17% in their study using Oxane HD. In our series, three patients who developed ocular hypotension showed spontaneous improvement, but one required viscoelastic injection into the anterior chamber.

Silicone oil emulsification was observed in 3 (15.8%) of 19 patients in our series, 2 of whom received AlaHeavy 1.07 for endotamponade and 1 of whom received Densiron 68. In the literature, emulsification rates between 1% and 24% have been reported in studies conducted with Densiron 68 and between 11% and 33% in studies conducted with Oxane HD. Sandner and Engelmann showed that heavy silicone oil is more...
prone to emulsification than standard silicone oil. Similarly, Caramoy et al.\textsuperscript{34} found in their in vitro study that semi-fluorinated fluorocarbon made silicone more hydrophilic, and that Densiron is more prone to emulsification for this reason. Caramoy et al.\textsuperscript{35} and Lu et al.\textsuperscript{34} both determined that Densiron XTRA was more resistant to emulsification due to a 10\% high molecular weight silicone additive to the chemical structure.

Kocijank et al.\textsuperscript{35} showed that emulsified silicone oil particles induce inflammatory cell chemotaxis and phagocytosis. Based on this finding, we believe that the absence of intraocular inflammation in any of the patients in our study during follow-up is related to the low prevalence of emulsification. Semeraro et al.\textsuperscript{36} compared the intraocular inflammation inducing effects of heavy silicone oil and conventional silicone oil by measuring prostaglandin E2 and interleukin-1\(\alpha\) levels in the aqueous humor and reported that heavy silicone oil had higher inflammatory potential than standard silicone oil.

In a prospective study by Avitabile et al.,\textsuperscript{37} the anatomical success rate in degenerative myopic eyes with posterior staphyloma was found to be higher in the group using heavy silicone oil than in the group using standard silicone oil. In our series, one patient received heavy silicone oil due to giant tear retinal detachment secondary to degenerative myopia, and the heavy silicone oil could not be removed in this case because the retina only remained attached with permanent silicone endotamponade (Figure 1).

Another advantage of heavy silicone oils is elimination of the need for postoperative positioning in patients with mental retardation, orthopedic problems, or comorbidities and in pediatric cases.\textsuperscript{17} In our series, heavy silicone oil endotamponade was used in 3 patients with macular hole, two of which were recurrent, as the patients were unable to maintain positions due to preexisting orthopedic problems and low compliance.

In the literature, reports vary widely regarding anatomical success rates with pars plana vitrectomy and heavy silicone oil endotamponade. In our series, the anatomical success was 100\%, with significant visual improvement from a median preoperative BCVA of 2 logMAR (IQR: 1-2.6) to a median postoperative BCVA of 0.99 logMAR (IQR: 0.4-2) (p<0.001). In a study by Ozdek et al.,\textsuperscript{38} using Oxane or Densiron in 41 patients, the anatomical success rate was 88\%. In another study of 49 eyes, Caporossi et al.,\textsuperscript{39} using Densiron and reported a success rate of 61.2\% after the first surgery and 81.6\% after the second surgery, with reattachment occurring under intraocular heavy silicone in 19 eyes. Berker et al.,\textsuperscript{40} reported anatomical success in 85.7\% and visual improvement in 71.4\% at a mean follow-up of 5 months in a series of 21 patients that received Oxane HD. In another study from Turkey using Densiron, Aslankurt et al.\textsuperscript{41} reported an anatomical success rate of 88\%. Considering all of these different rates, it should be kept in mind when interpreting the success of heavy silicone endotamponade that most patients are complicated cases that have undergone one or more vitreoretinal surgeries. In addition, the most important disadvantage of heavy silicone oil, especially for developing economies, is its high price.

### Study Limitations

The small number of patients, retrospective study design, and absence of a standard silicone oil control group are limitations of our study.

### Conclusion

Heavy silicone oil is an effective and reliable endotamponade in patients with recurrent retinal detachment and macular hole, in the presence of PVR, and in patients who require inferior retinal support.

### Ethics

#### Ethics Committee Approval
Ba\˘skent University Medical and Health Sciences Research Council (decision number: KA20/412).

#### Informed Consent
Obtained.

#### Peer-review
Externally peer reviewed.

#### Authorship Contributions

Surgical and Medical Practices: Z.K., Concept: Z.K., Design: Z.K., R.A.K., Data Collection or Processing: R.A.K., Analysis or Interpretation: Z.K., R.A.K., Literature Search: Z.K., R.A.K., Writing: R.A.K.

#### Conflict of Interest
No conflict of interest was declared by the authors.

#### Financial Disclosure
The authors declared that this study received no financial support.

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