# Heavy silicone oil tamponade - a multicentre experience.

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**Abstract**

**Objective:** To report multicentred use of the heavy silicone oil Densiron 68 for anatomical reattachment following rhegmatogenous retinal detachment (RRD) repair and its associated complications.

**Methods and Analysis:** Patients from seven vitreoretinal units within the UK that underwent RRD repair with Densiron 68 between January 2015 and December 2019 were identified. Primary outcome measures were primary and final reattachment rate, retained Densiron and failure rate. Secondary outcome measures were duration of tamponade, final visual acuity (VA) and complications of heavy silicone oil.

**Results:** 134 eyes of 134 patients were involved in the study. Primary surgical success was achieved in 48.5%, while a final reattachment rate of 73.4% was observed. The mean duration of Densiron 68 tamponade was 139.5 days. Mean final VA was 1.01 (range 0-2.9). 8 eyes (6.0%) required long-term topical steroids for anterior uveitis, whereas none of the eyes required long-term pressure-lowering treatment. Emulsification rate was 10.7% (6 eyes).

**Conclusion:** This is the largest real-world study on Densiron 68 in the UK. Densiron 68 facilitates tamponade of inferior retinal pathology and may be considered as an option for tamponade of inferior retinal pathologies.

- **What is already known on this topic** - Densiron 68 and other heavy silicone oils have been used as tamponade for inferior RD with varying success rates and complication profiles.
- **What this study adds** – This is the largest real-world data series on Densiron 68 in the UK, showing that Densiron 68 can achieve similar long-term reattachment rates and complications compared to conventional silicone oil.
- **How this study might affect research, practice or policy** – This data will better inform vitreoretinal colleagues about heavy silicone oil tamponade as a management strategy for inferior RD.

## Introduction

Rhegmatogenous retinal detachment (RRD) can cause significant vision loss, particularly if not treated in a timely fashion. For uncomplicated RRD, current surgical techniques carry a high anatomical success rate (>90%).[1,2] Recognized risk factors for failure include choroidal detachment, hypotony, Grade C proliferative vitreoretinopathy (PVR).[3–5] RRD associated with inferior retinal breaks located at a position between 4 to 8 clock hours, particularly with concomitant PVR, remains a surgical challenge. Pars plana vitrectomy (PPV) with intraocular gases and standard silicone oil tamponades are unlikely to provide adequate support for such inferior peripheral retinal pathology.[6,7] Recurrent RRD secondary to PVR is estimated to occur in about 5-10% of all patients with failed primary retinal detachment repair.[8]

Retinal re-detachment after surgery is likely to arise by several mechanisms: continued vitreoretinal traction, passage and propagation of fluid through an untreated retinal break, possibly due to intraocular fluid currents. In tamponade the gas or oil bubble prevents flow of fluid through tears in the retina.[9] This allows retinal reattachment to be temporarily maintained while a permanent chorioretinal adhesion forms in response to retinopexy. Although inferior retinal detachment breaks without adequate tamponade have been reported to reattach,[9] this is not replicated consistently in clinical practice and the search for adequate tamponade in these cases continues.

Endotamponades with a higher specific gravity within the vitreous cavity than aqueous are theorized to be useful for treating inferior retinal pathology.[6,7,10] Examples include heavy oils and perfluorocabon liquids. The former are used for longer periods. First generation heavy silicone oils such as fluorosilicone and perfluorocarbons (introduced in 1990s) were marked with complications such as fibrinous reactions, cataract or even retinal necrosis.[11–13] A number of newer generations of heavy silicone oil of different compositions are available for

use: Densiron 68 [Geuder], Oxane HD [Bausch & Lomb, mixture of Oxane 5700, mixed fluorinated and hydrocarbonated olefin (RMN3)] and Alaheavy [Alamedics].[6,7]

Densiron 68 (Geuder AG, Neu-Ulm, Germany) is a mixture of perfluohexyloctane ($F_6H_8$) and siluron 5000, giving a mid-range viscosity of 1400 mPas and gravity of 1.06 g/cm3.[14] It is licensed for the treatment of inferior or posterior retinal detachment in cases of PVR, proliferative diabetic retinopathy and giant retinal tears.[14] It was chosen as one of the endotamponades in the Heavy Silicone Oil study.[15] Anatomical success rates with Densiron 68 varies from 33.3 % to 81.3%.[7,15,16]

Herein, we present the largest evaluation of patterns of use, clinical outcomes and complications associated with the use of Densiron 68 as an internal tamponade in the treatment of RRDs amongst multiple vitreoretinal units within the UK.

## Materials and Methods

This was a retrospective, nonrandomized study involving seven National Health Service vitreoretinal units within the UK; Bristol Eye Hospital (University Hospitals Bristol and Weston), Dundee eye clinic (Ninewells hospital, Dundee), Queen Elizabeth Hospital (King's Lynn, Norfolk), Leicester Royal Infirmary, St Paul's Eye Hospital (Royal Liverpool and Broadgreen University Hospitals), Norfolk & Norwich University Hospitals and Southend University Hospital. Surgical teams reported their outcomes using a standard anonymized spreadsheet. The tenets of the Declaration of Helsinki were followed in the study.

Inclusion criteria were patients receiving Densiron 68 during primary or recurrent RRD surgery during the period of January 2015 to December 2019 with a minimum follow-up of 3 months post-Densiron 68 removal. Cases receiving other heavy oil such as Densiron Xtra, Alaheavy or Oxane HD were excluded. Cases were collected via a combination of EPR, personal and theatre logs. All surgical procedures were performed by either vitreoretinal fellows or consultants.

Surgeons used their conventional vitreoretinal management to allow intraoperative reattachment of the retina, including use of retinotomies, drainage through breaks, retinectomies or use of perfluoroctane/perfluorodecalin. Patients were not instructed to undertake any particular posture.

Patients who required Densiron 68 tamponade were identified by the vitreoretinal units and their anonymized outcomes were pooled and analysed with Microsoft Excel 2020/GraphPad 2020. The primary outcome measures were primary success, final reattachment, qualified success and failure rates. Primary success was defined as achieving a flat retina at 3 months after one Densiron surgery and no subsequent retinal re-intervention other than Densiron

removal. Final reattachment was defined as achieving a flat retina at 3 months after repeated surgery following the introduction of Densiron. Qualified success referred to the proportion of patients with a flat retina and Densiron retained rather than removed at 3 months. Failure was defined as inability to achieve a flat retina despite all efforts.

The secondary outcome measures were median duration of tamponade, postoperative visual acuity (VA), initial postoperative uveitis, long-term anterior uveitis, ocular hypertension (OHT), and emulsification of oil. Adequate follow-up was defined as at least 3 months after Densiron 68 removal.

Best corrected visual acuity (BCVA) was assessed using LogMAR. If Snellen VA had been used at any of the participating centres, this was converted to a LogMAR equivalent value. Very poor VA groups were assigned the following LogMAR equivalent: counting fingers (1.85), hand movement (2.3), light perception (2.6) and no light perception (2.9).[17]

The outcomes were analysed using Excel for mac 2020 and STATA statistical software version 14. A 5% significance level was used (two-tailed). Continuous data were presented as mean (SD) or median (IQR) depending on the distribution of data and categorical variables were expressed as counts and percentages. Chi-squared test or Fisher's Exact test was used to compare proportions between groups. The independent t-test and paired sample t-test were used to compare means from parametric datasets, and the Mann-Whitney and Wilcoxon tests were used to compare non-parametric data.

No patients nor the public were involved in the design, conduct or reporting of this study.

## Results

134 eyes of 134 patients were included in the study. During the study period, eleven patients (8.0%) had long-term Densiron 68 retention. The median age of patients was 64 years old (range 25-91 years), with 91 males (67.9%) and 43 females (32.1%).

The median (range) number of operations prior to Densiron 68 tamponade was 1 (0-4). All patients had had RRD, with the most common indication being inferior retinal pathology (N=128; 93.4%) as displayed in table 1. 86 cases (64.2%) had had failed previous RD surgery secondary to inferior pathology. The median (range) number of inferior retinal tears (between 4 to 8 o'clock associated with subretinal fluid) was 1 (0-7). Densiron 68 was used in cases presenting with all grades of PVR, including no PVR as shown in table 2. All PVR C cases involved the inferior retina.

**Table 1: Indications for Densiron 68 tamponade.**

| Indications | N |
|---|---|
| Inferior RD | 116 |
| Inferior GRT | 4 |
| Inferior schisis RD | 4 |
| Inferior RD under light silicone oil | 2 |
| Dense VH due to wet AMD and inferior retinal tears | 2 |
| Multiple RD | 1 |
| Primary macular hole RD | 1 |
| PDR and TRD | 2 |
| Total PVR RD | 1 |
| Dropped nucleus with inferior RD | 1 |
| | 134 |

Abbreviations: RD - retinal detachment, GRT - giant retinal tear, VH – vitreous haemorrhage, AMD – age-related macular degeneration, PDR – proliferative diabetic retinopathy, TRD - tractional retinal detachment, PVR - proliferative vitreoretinopathy.

**Table 2: Primary outcomes by grade of proliferative vitreoretinopathy (PVR)**

| PVR | N (%) | Primary success | Final reattachment | Qualified success |
|---|---|---|---|---|
| **0** | 74 (55.2%) | 48 (64.9%) | 60 (81.1%) | 3 (4.1%) |
| **A** | 7 (5.2%) | 4 (57.1%) | 5 (71.4%) | 0 (0.0%) |
| **B** | 14 (10.4%) | 7 (50%) | 10 (71.4%) | 1 (7.1%) |
| **C** | 39 (29.1%) | 18 (46.2%) | 24 (61.5%) | 7 (17.9%) |
| | ***p* value** | **0.259** | **0.162** | **0.088** |
| **Total** | 134 | 65 (48.5%) | 99 (73.9%) | 11 (8.2%) |

72 eyes (53.7%) were phakic, 63 (47.0%) were pseudophakic and 2 (1.5%) were aphakic at time of Densiron 68 insertion.

The median (IQR) duration for Densiron 68 tamponade was 107 days (70-156). Densiron 68 was used most commonly during recurrent RRD repair (87 eyes; 64.7%) with the remainder using it during primary RRD surgery.

***Primary outcomes***

Sixty-five patients (48.5%) achieved a flat retina with Densiron surgery without need for further retinal re-intervention. Final reattachment was observed in 99 patients (73.9%). Eleven patients (8.2%) had long-term Densiron 68 retention, while failure was seen in 24 patients (17.9%) There was a trend for higher final reattachment rate after Densiron 68 removal for recurrent RRD (68 eyes (79.1%)) compared to those who had had primary RRD (31 eyes (64.6%)) although this did not quite reach statistical significance (table 3; p=0.067). Table 4 shows subgroups of the 48 patients that underwent primary RRD surgery with Densiron. There were no significant differences in final reattachment when grouped by age, diabetic status or number of inferior retinal tears. Males (p=0.024) and pseudophakic patients (p-0.007) showed a higher rate of final reattachment with recurrent surgery compared to primary surgery.

Reattachment rates for primary and recurrent RRD surgery showed a general decrease with increasing severity of PVR, however differences between grades did not differ significantly (p=0.162). Patients in our cohort achieving final reattachment following Densiron removal underwent a mean of 2.01 (range 1-5) surgeries.

**Table 3: Primary outcomes by indication for surgery - primary vs recurrent RD**

| | N (%) | Primary success | Final reattachment | Qualified success |
|---|---|---|---|---|
| **Primary** | 48 (35.8%) | 21 (43.8%) | 31 (64.6%) | 3 (6.3%) |
| **Recurrent** | 86 (64.2%) | 45 (52.3%) | 68 (79.1%) | 8 (9.3%) |
| | ***p value*** | **0.341** | **0.067** | **0.537** |
| **Total** | 134 | 65 (48.5%) | 99 (73.9%) | 11 (8.2%) |

**Table 4: Primary outcomes between different subgroups divided by baseline characteristics.**

| **Baseline characteristics** | **Subgroup** | **N** | | **Final reattachment (%)** | | |
|---|---|---|---|---|---|---|
| | | **P** | **R** | **P** | **R** | |
| Age | 10-64<br>65-91 | 25<br>23 | 30<br>56 | 17 (68%)<br>14 (61%) | 24 (80%)<br>44 (79%) | ***p* = 0.309**<br>***p* = 0.106** |
| | | | | ***p* = 0.606** | ***p* = 0.877** | |
| Gender | Female<br>Male | 15<br>33 | 31<br>55 | 12 (80%)<br>19 (58%) | 24 (77%)<br>44 (80%) | ***p* = 0.842**<br>***p* = 0.024*** |
| | | | | ***p* = 0.132** | ***p* = 0.778** | |
| Lens status | Phakic<br>Pseudophakic | 32<br>16 | 38<br>48 | 22 (69%)<br>9 (56%) | 26 (68%)<br>42 (88%) | ***p* = 0.976**<br>***p* = 0.007*** |
| | | | | ***p* = 0.393** | ***p* = 0.031*** | |
| Diabetic status | Diabetic<br>Non-diabetic | 6<br>42 | 9<br>77 | 3 (50%)<br>28 (67%) | 8 (89%)<br>60 (78%) | ***p* = 0.095**<br>***p* = 0.181** |
| | | | | ***p* = 0.425** | ***p* = 0.444** | |
| No. of inferior retinal tears | 0<br>1<br>2<br>3+ or GRT<br>Not documented | 6<br>16<br>14<br>8<br>4 | 16<br>29<br>14<br>11<br>17 | 5 (83%)<br>11 (69%)<br>7 (50%)<br>5 (63%) | 15 (94%)<br>21 (72%)<br>12 (86%)<br>7 (64%) | ***p* = 0.116**<br>***p* = 0.915**<br>***p* = 0.373**<br>***p* = 0.981** |
| | | | | ***p* = 0.509** | ***p* = 0.193** | |

Asterisk (*) denotes a statistical significance between subgroups. Abbreviations: P = Primary surgery; R = recurrent surgery; GRT = giant retinal tear.

***Secondary outcomes***

Complete BCVA data was available for 85 eyes in both baseline and 3 months post-Densiron 68 removal. The mean VA improved slightly from baseline to 3 months (mean [SD]: 1.19 [0.10] at baseline, to 0.97 [0.08] at 3 months; a slight increase of 0.22 (95%CI: 0.001-0.44, t(84)=1.996, p=0.049). Forty-nine eyes (36.6%) developed anterior uveitis during the initial (first 2 weeks) postoperative period, including one patient who developed an inflammatory hypopyon (0.75%). Long-term anterior uveitis which required treatment was present in 8 patients (6.0%), of whom 2 had retained long-term Densiron 68 tamponade. There was no association between inflammation and duration of Densiron 68 tamponade (p=0.779).

Forty-nine eyes (36.6%) required topical intraocular pressure (IOP) control postoperatively. Long-term raised IOP persisted in 24 eyes (17.9%). 8 patients (6.0%) required surgical intervention to lower IOP. Interestingly, none of the patients with long-term Densiron 68 retention required long-term antihypertensive drops, although two required surgical intervention. There was no correlation between long-term IOP issues and duration of tamponade (p=0.358).

6 eyes (4.5%) had evidence of Densiron 68 emulsification. Those patients with long-term tamponade were not recorded to have emulsification. There was no correlation between emulsification rate and duration of tamponade (p=0.984).

10 eyes (7.5%) remained phakic by the 3 months postoperative point. There was no change to pseudophakic or aphakic patients lens status.

## Discussion

The total final reattachment rate of 73.9% from the present study of heavy oil tamponade for RRD compare favourably with previous published reports of 33-92%.[7,15,18,19] This total comprised 64.6% of primary surgeries and 79.1% of surgeries for recurrent RRD. Although this difference did not quite reach statistical significance, it does suggest that those cases having Densiron 68 for primary RRD may have a higher failure rate. This may reflect the challenging nature of the cases with primary RRD that had Densiron 68 chosen as a tamponade. A similar reported primary success rate of 71.4% has previously been published in one large series.[18] Primary surgery success for inferior PVR with light silicone oil has been reported to be as high as 82%,[20] however this rate was detected in a small single-centre retrospective subgroup of 22 patients and larger scale data is lacking. Our study is multi-centred and larger than all previous reports and is therefore encouraging. The major indication was inferior PVR C. Pseudophakic patients achieved better results than phakic patients undergoing recurrent surgery in our cohort, while amongst males, those undergoing recurrent surgery had better outcomes than those undergoing primary surgery. As discussed above, this may reflect the nature of primary RRD cases and Densiron use, or the early use of Densiron 68 in failed cases. No other significant differences were seen between pooled or subgroup data.

Herbrig *et al* provided a large previously published series (99 eyes) on Densiron 68 for the treatment of complicated RRD. 74% of their cases had had previously failed RRD surgery, which is in keeping with our indications and suggestive of the most common approach for use of heavy silicone oil. 78 of 89 eyes (87.6%) that underwent PPV and Densiron 68 endotamponade showed retinal reattachment at 9 months, with 34 eyes (36%) requiring reoperation to achieve reattachment. These further operations included light silicone oil, second heavy oil or gas tamponade. In all eyes with a second Densiron 68 tamponade, the retina

was completely reattached. This series compared 21 prospective patients with no previous history of retinal surgery before receiving Densiron 68, with a retrospective similar control group of 21 patients that had received light silicone oil tamponade. 15 eyes with Densiron 68 (71%) showed reattachment at 3 months while the heavy oil was still in situ, compared to only 9 eyes (43%) with light silicone oil. While it failed to reach statistical significance (p=0.059), this difference may suggest greater efficacy of Densiron 68 in such cases.[18] In contrast the Heavy Silicone Oil (HSO) study, a multicentre randomized masked controlled trial by Joussen *et al,* suggested lower reattachment rates with heavy silicone oil (28.3%) compared to standard silicone oil (1000 or 5000 centistokes; 40.4%) in the treatment of complicated inferior RRD.[15] This trial also failed to show statistical difference between the two different oil tamponades in terms of reattachment rates or VA at 12 months follow-up. However, the trial was stopped early due to slow recruitment and may not have been adequately as powered as initially planned.[15] In our series we had a higher anatomical success rate (61.5%) in inferior PVR C cases with Densiron 68 compared with the HSO study, accepting that our data is retrospective. Furthermore, we do not compare to light oil so any comparisons with historical data must be tentative. Our findings from the largest dataset on this topic (a decade later) provide consideration to perhaps review this subject prospectively. The causes for re-detachments were not investigated as part of this study.

The HSO study did not find any difference in vision comparing heavy silicone oil against standard silicone oil, but there was an improvement from baseline in both groups.[15] Whilst our study showed a VA improvement from baseline to post-oil removal, it failed to show statistical significance, supporting the findings of Kocak and colleagues.[21] This may reflect the complex nature of these eyes in which retinal reattachment may be a primary goal. However, other heavy silicone oil studies did show statistically significant improvement in vision and anatomical reattachment.[18,19,22]

The reported adverse effects of heavy silicone oil tamponade include raised IOP, inflammatory response, cystoid macular edema, oil dispersion/emulsification and cataract formation.[23,24] In our series, 49 patients (36.6%) required topical treatment for IOP control. Of those, long-term raised IOP persisted in 24 eyes (17.9%). In their smaller series, Caporossi *et al* found a rate of 34.7% of patients requiring topical treatment, reducing to 26.5% after Densiron 68 removal.[25] Other published series showed OHT rates of 12-27%.[15,18,23,26] 8 patients in our cohort (6.0 %) required surgical intervention for IOP management, whereas Stappler *et al*'s prospective cohort of 122 patients did not require any surgical IOP-lowering treatment, describing a steady decline in OHT rate over 3 months post-heavy silicone oil removal.[7] Nguyen *et al* found that 42% of patients required removal of oil and/or glaucoma surgery to lower their IOP during the early phase, and 32% required medication for chronic OHT.[27] This study had a much higher reported incidence of OHT (48%) and this could be attributed to having a small cohort of 47 patients. Our rates were lower and may represent a closer reflection of the true rate, considering the size of our cohort. Whether Densiron 68 has a greater effect on IOP than light silicone oil is unclear; but our data suggests similar rates, although we acknowledge we have no direct control group.

Heavy silicone oils are suggested to promote an inflammatory response.[6,28] In our series, 49 patients (35.7%) developed anterior uveitis within the postoperative period. Following Densiron 68 removal, 8% of patients required long-term topical anti-inflammatory treatment. Auriol *et al* reported a 40.7% rate of anterior chamber inflammation with fibrin accumulation and a mean time to removal of Densiron 68 of 14 weeks.[29] However, Kocak *et al* found a much lower rate (3%) of anterior inflammation with fibrin.[21] Russo *et al*'s review of heavy silicone oil concluded that inflammation may depend on tamponade duration.[28] However,

data analysis of our cohort did not reveal any association between inflammation and duration of Densiron 68 tamponade. Our data must be interpreted with caution, as prospective objective analysis of inflammation was not undertaken. Data on long-term inflammation rates with light silicone oil is limited.

Emulsification is also recognized as a complication of heavy and light silicone oil.[6] It has been reported to occur in 8.3-16% of patients with heavy silicone oil.[7,18,19,30] In our series, the emulsification rate was 10.1%, in keeping with reported emulsification rates of Densiron 68. Densiron Xtra (a newer tamponade) is promoted as being more resistant to emulsification due to its higher viscosity and longer silicone oil molecular chain.[31] *In vivo* confirmation is still awaited.[32] Emulsification of light silicone has been reported to occur in up to 40% of cases with long chain silicone oil (5700 cSt)[33] and 63.4% in shorter chain silicone oil (1300 cSt). Other series have reported similar disparities over a mean period of 7.3 months (standard deviation 4.2 months, range 1-17 months).[34] Our rates of emulsification with Densiron 68 are therefore reassuring.

Cataract is a recognized consequence of PPV.[26] Whilst our study did not specifically look at progression of cataract, 85.7% of patients required lens extraction. This could be secondary to multiple factors: pre-existing lens status, previous tamponades, multiple surgeries or use of steroids.[6] Our series has similar lens findings to a series of 122 patients by Stappler *et al*,[7] however Joussen *et al* did not show conclusive evidence of cataract progression in their randomized control trial.[15]

There are several limitations to this study. Its retrospective nature limited more detailed interrogation of the outcomes and complications of Densiron 68. Unlike previous published

case series, our data offers a high proportion of patients receiving Densiron 68 as a primary endotamponade. We did not collect data on superior retinal breaks, therefore whilst it is unlikely that any patient with superior pathology received Densiron as primary endotamponade, we cannot exclude this as a possibility that may have contributed to our relatively high redetachment rate. Therefore, this patient group is significantly different from others in published literature, so we recommend cautious interpretation of our results when compared to other studies. Subgroups for analysis were retrospective and therefore limited in interpretation. It is possible that not all cases of Densiron 68 use were identified across all centres, which may represent a source of bias in the study. However, this process was optimised using a combination of personal logbooks, theatre records and electronic patient records. We were unable to compare Densiron to light silicone oil in this study, nor were we able to investigate causes for retinal redetachment.

However, this is the largest series presenting real-world, long-term, multicentre UK data on the use and outcomes of surgery with Densiron 68. Densiron 68 is perhaps not widely used due to lack of familiarity with injection and removal process. The data presented here should reassure surgeons that Densiron 68 is a useful tamponade alternative for the management of complex inferior RRD, with similar morbidity to standard silicone oil.

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**Ethics statement**

Ethics approval was deemed not to be necessary due to the retrospective nature of the study.

**Contributorship Statement**

SD wrote the initial draft and analysed data.

MD analysed data, made major reworkings to the text and co-ordinated author responses before producing the final manuscript.

TS and JK made invaluable suggestions during the editing process.

JZ provided valuable statistical input.

AC was supervising author.

Remaining authors all helped with data collection.

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