Short communication

Heavy silicone oil (Densiron® 68) in proliferative vitreoretinopathy: 4 years of experience

B. Macías-Murelaga*, M. Ruiz, L. Bascarán, A. Gibelalde, M. Aldazabal, C. Irigoyen

Servicio de Oftalmología, Hospital Donostia, Donostia-San Sebastián, Spain

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ABSTRACT

Method: Prospective observational study including 10 patients (age range: 27–74 years) with recurrent retinal detachment (RD) and proliferative vitreoretinopathy (PVR) and 2.8 mean unsatisfactory previous surgeries. Densiron® was injected in all patients, with surgical retinectomy being required in 70% of them. Minimum follow-up time was 12 months.

Results: The mean length of time before Densiron® withdrawal was 4 months. Three patients (30%) presented with a new RD. The main complication detected was cataract development. No relationship was found between re-detachments and tamponade time, baseline disease or RD evolution time. Densiron® may be a good option in cases of recurrent RD in which previous treatment with scleral buckle, gas and/or 1000/5000 silicone oils has proven to be unsatisfactory.

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Aceite de silicona pesado (Densiron® 68) en vitreorretinopatía proliferativa: 4 años de experiencia

RESUMEN

Método: Se estudiaron los antecedentes de 10 pacientes (rango de edad: 27–74 años), los cuales, a pesar de una media de 2,8 intervenciones previas, presentaban de nuevo desprendimiento de retina (DR) y vitreorretinopatía proliferativa (VRP). En todos ellos se optó por realizar retinotomía quirúrgica e implantación de Densiron® y valoramos su evolución con un seguimiento de 12 meses.

Resultados: El tiempo medio de Densiron® hasta su retirada fue de 4 meses. Tres pacientes (30%) presentaron nuevo DR. El desarrollo de cataratas fue la complicación principal. No encontramos relación entre los redespimensiones y la duración del tamponamiento, enfermedad de base o tiempo de evolución del DR. Densiron® puede ser una buena opción en casos de DR recidivante en los que el tratamiento previo con cerclaje, gas o aceites de silicona de 1.000/5.000 cts resulte insuficiente.

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* Corresponding author.
E-mail address: beatriz19es@hotmail.com (B. Macías-Murelaga).

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Introduction

Inferior retinal tracional disease continues to be a challenge for retinal surgeons. Gas (SF₆ and C₂F₅) and conventional silicone oil (SO) are the most widely used products to date but involve limitations. In some cases it is necessary to use substances heavier than water for adequately tamponading the inferior retina, avoiding the confinement of substances in this area and enhancing confinement (PRV soup) in the superior area. In addition, said new substances must not be miscible in water and be heavier than water to provide adequate tamponade of the inferior retina (with appropriate occlusion of retinectomy tears and edges). In addition, they must develop high surface tension with water to adequately occlude tears, preventing the passage of water and of vitreoretinal proliferation (VRP). Due to this demand, second generation heavy silicone oils have appeared on the market. The main characteristics of the 3 most important heavy oils are detailed in Table 1.³

Densiron® 68 (Fluoron Gmbh) is a combination of polymethylsiloxane having a density of 5000 centistokes (cts) with perfluorohexyloctane in a proportion of approximately 70/30, providing a density slightly above that of water (1.06 g/cm³) so that the floatation forces are directed downward in order to block lesions in the inferior retina.² This compound is well tolerated and features low emulsification.¹⁻¹⁰ Its main indications are inferior and posterior retinal holes, inferior VRP after placing cerclage or post-vitreectomy, large inferior retinectomies, retina detachments (RD) associated to macular holes in high myopia or with inferior tears, giant inferior tears, traumatic RD, RD in diabetic retinopathy, inflammatory RD, endophthalmitis, RD associated to hypotony and finally patients who exhibit an impossibility of postural repose.²

The objective of this study is to describe the authors’ experience of the past 4 years with the use of heavy SO, Densiron® 68 in patients with relapsing RD and VRP, with assessment of obtained results.

Materials and methods

A review of all patients intervened in the Donostia Hospital since 2009 up to the present time injected with heavy Densiron® 68 SO.

Inclusion criteria

Patients with relapsing RD and VRP grade B or more, in whom previous surgical treatments were not sufficient.

Surgical technique

All the surgeries were performed under retrobulbar anesthesia (mepivacaine 2% and bupivacaine 0.5%, mixed at 50%) and sedation with intravenous midazolam. In all cases, 23 gauge (G) vitrectomy was performed by the same surgeon (M.R.M.), displacing the conjunctiva and placing the trocar at an angle of 30° between 3.5 and 4 mm of the sclerocorneal limbus. After reviewing and completing peripheral vitrectomy, surgical retinectomy was required to release the inferior VRP in 70% of cases. Retinectomy was performed with vitreotome after diathermia of peripheral retinal vessels. Two rows of endolaser were applied at the retinectomy edge and retinal tear areas. In the cases in which perfluorocarbon (PFO) was applied, it was withdrawn completely prior to the introduction of Densiron®. This step is important because PFO can cause the separation of Densiron® in its 2 components (SO and F₂H₆). Superior iridotomy was performed due to the post-surgery displacement toward the inferior region of the tamponade element. The surgery was completed with fluid-air exchange and subsequent introduction of heavy SO, maintaining a continuous pressure of 25 mmHg, in addition to withdrawal of trocars and external washing with iodine solution. In no case the sclerotomies had to be sutured. The post-surgery treatment was 1% atropine eyedrops at a dosage of one drop every 12 h and tobramycin with dexamethasone eyedrops, one drop every 6 h in descending dosage.

Subsequently, assessments were carried out the day after surgery, at month 1 and month 3. In the latter assessment the extraction of SO was evaluated and, if said extraction was considered necessary, the number of visits increased. In the assessments, visual acuity (VA) was taken, together with intraocular pressure (IOP) and biomicroscopy of the anterior and posterior segments.

After months of follow-up, when the extraction of SO was considered to be adequate, an additional 23 G vitrectomy was performed. One sclerotomy was increased introducing a 20 G intravenous Abbocath catheter (Abbocath, Sligo, Republic of Ireland) in bevel tip and sufficient length to access the vicinity of the posterior pole. This was necessary because, as Densiron® is heavier than water it tends to deposit in the posterior pole. SO was withdrawn in the viscous fluid extraction mode (Stellaris®, Bausch&Lomb, Rochester, New York, USA) with a suction force of 600 mmHg. None of the procedures required stitching sclerotomies. After the extraction of SO it was not necessary to use any of the tamponading products.

Table 1 – Physical and chemical properties of the main heavy silicone oils.

<table>
<thead>
<tr>
<th></th>
<th>Densiron 68</th>
<th>Oxane HD</th>
<th>HWS 46–3000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components (weight %)</td>
<td>30.5% F6H8; 69.5% SiO 5000</td>
<td>11.9% RMN3; 88.1% Oxane 5.700</td>
<td>55% F4H5; 45% SiO 100,000</td>
</tr>
<tr>
<td>Specific gravity (g/cm³) (25 °C)</td>
<td>1.06</td>
<td>1.02</td>
<td>1.118</td>
</tr>
<tr>
<td>Refractive index (20°)</td>
<td>1.387</td>
<td>1.4</td>
<td>1.366</td>
</tr>
<tr>
<td>Interfacial tension vs air (mN/m)</td>
<td>19.13</td>
<td></td>
<td>18.8</td>
</tr>
<tr>
<td>Interfacial tension vs water (mN/m)</td>
<td>40.82</td>
<td>&gt;40</td>
<td>41.3</td>
</tr>
<tr>
<td>Viscosity (MPa) (25°)</td>
<td>1.349</td>
<td>3.800</td>
<td>2.903</td>
</tr>
</tbody>
</table>
Results

Overall, 10 patients were included (8 males and 2 females) with a mean age of 59.7 years (range: 27–74). Their baseline diseases are detailed in Fig. 1. At the time of the presurgery ophthalmological exploration they exhibited a mean VA of 1.45 logMAR ± 0.50 SD. The 10 patients had undergone a mean of 2.8 previous unsatisfactory interventions which are detailed in Table 2. When the application of Densiron® was decided, the patients exhibited inferior tears in 80% of cases and in 100% VRP grade B or greater was verified.

Mean time to withdrawal was of 4 months (132 ± 32.24 days). It was not necessary to stitch the sclerotomies due to the adequate angle of the trocars, and Densiron® was completely withdrawn in all cases. After 6 months follow-up, VA was 1.16 logMAR ± 0.40 SD. A reapplication rate of 70% was obtained after >6 months follow-up.

In the 3 patients the latter intervention was not successful, with RD being detected again. In one patient, RD occurred immediately after extracting Densiron® and in the other 2 cases RD occurred after 10 and 11 months respectively. Table 3 illustrates the details. In all these cases a new intervention was decided for administering 5000 cts SO. At present, the retina was applied in 2 cases but RD was observed with new VRP in the third, with expectant attitude being maintained at present. In these cases, no relationship was found with the baseline disease, the number of previous interventions or the period of time during which Densiron® remained in the eye.

No severe complications were observed. However, cataracts were observed in 5 of the 10 patients, corresponding to 100% of phakic patients. IOP increase was observed in only one case which was resolved with anterior chamber (AC) puncture with 25 G needle. In another patient, emulsification of SO in AC was observed and in 2 patients slight corneal decomposition was observed. No intraocular inflammation or re-detachments were observed before SO extraction (Fig. 2).

Discussion

Despite the findings of the Silicone Oil Study, precise indications for using long-lasting gas or conventional SO remain unclear. Complicated RD can be successfully treated combining conventional SO and advanced vitrectomy techniques. However, post-surgery success can be overshadowed by persistent or new inferior RD or VRP in which the anatomic success rate varies from 30% up to almost 83%. The doubt remains whether to treat these cases with inferior retinotomy and subsequent injection of conventional SO or to choose heavy SO. Some studies recommend the sequential use of conventional SO followed by Densiron® 68. In the majority of published papers, indications for the application of Densiron® include complicated or relapsing RD with VRP.

Two techniques have been proposed in relation to the exchange of perfluorocarbon. The most widely used method and the one favored by the authors is to perform exchange first with air and subsequently with heavy SO, although this method involves the risk of posterior retina slippage, the avoidance of which requires an in-depth drying of the edges. Accordingly, in the case of extensive retinotomies the second method becomes relevant as it directly exchanges perfluorocarbon with heavy SO, making visible the interface between both components.1 Carrying out surgical retinectomy prior to the

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**Table 2 – Previous surgical procedures of patients.**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>VPP 20/23 G + laser</td>
<td>100%</td>
</tr>
<tr>
<td>SF6/C3F8</td>
<td>80%</td>
</tr>
<tr>
<td>Cerclage</td>
<td>80%</td>
</tr>
<tr>
<td>Cryotherapy</td>
<td>40%</td>
</tr>
<tr>
<td>Silicone oil 1000/5000 cts</td>
<td>30%</td>
</tr>
</tbody>
</table>

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**Fig. 2 – Complications observed for over 6 months follow-up after withdrawal of Densiron®.**

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**Fig. 1 – Primary disease of patients.**
Table 3 – Main characteristics comparison of the 3 cases with retinal detachment after Densiron® withdrawal.

<table>
<thead>
<tr>
<th>Baseline disease</th>
<th>Sterile endophthalmitis with inferior and temporal tear, with complete RD</th>
<th>Giant RD (6–12 h)</th>
<th>Superior RD with inferior colobomatous lesion and intense dystrophy</th>
</tr>
</thead>
<tbody>
<tr>
<td># Of previous interventions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Densiron® time</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Time from removal up</td>
<td>Following day</td>
<td>6 months</td>
<td>5 months</td>
</tr>
<tr>
<td>Treatment</td>
<td>Silicone oil 5000 cts</td>
<td>Silicone oil 5000 cts</td>
<td>Silicone oil 5000 cts</td>
</tr>
<tr>
<td>Current condition of retina</td>
<td>VRP retinal raising</td>
<td>Applied</td>
<td>Applied</td>
</tr>
</tbody>
</table>

Insertion of Densiron® for removing VRP is very important because it determines the success of the overall surgery.

One of the biggest controversies about the use of heavy SO and in fact of all tamponing treatments in general is the time of withdrawal. The duration of the tamponade should comprise sufficient time for adequate cicatrizations of tears, taking into account the biology of VRP, but in all cases pondering possible toxicity, the formation of perisilicone membranes and the emulsification of oil in the AC. In our case, extraction was considered after observing the retina plane with efficient pexia and neutralized tractions (mean time: 132 ± 32.24 days). According to Heimann et al., the mean time of recommended permanence is between 90 days and 4 months for HWS 46–3000®, between 108 days and 4 months for Densiron® 68 and between 88 days and 3 months for Oxane® HD. The HSO® study guide recommends a minimum period of 2 months and a maximum period of 6 months. In what concerns the 3 patients who suffered retina re-detachment, the time during which Densiron® remained in the eye was not determinant as it was extracted at 120, 150 and 180 days approximately.

The extraction technique is also important and somewhat more complicated than with conventional oils because it has to be found as it deposits in the posterior pole, endangering the retina. For this reason it is necessary to use long extraction tubes. On the other hand, it is true that heavy SO exhibits relative floatability and the maneuver is facilitated by the cannula-SO surface tension. In addition, we are assisted by the suction force over the viscous fluid which produces a tubeless syphon effect. Stapler et al., demonstrated that it is possible to extract heavy SO using a 20 G needle, reducing iatrogenic damage. Subsequently, Romano et al. reported SO extraction with a 7.0 mm long 23 G needle using a suction pressure of 600 mmHg.

The percentage of primary reapplication of our study is similar to that described in other studies (Table 4), in most cases being above 70%.

Visual results improved from a mean presurgery VA of 1.45 logMAR±0.50 SD to 1.16 logMAR±0.40 SD, similar to the improvement described by Auriof et al. (from 1.55 logMAR±0.21 SD to 1.34 logMAR±0.39 SD) or

Table 4 – Comparison of results with the use of Densiron® in other studies.

<table>
<thead>
<tr>
<th>No. eyes</th>
<th>Disease Description</th>
<th>Primary reapplication rate (%)</th>
<th>Main complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Inferior RD (80%) VRP (100%)</td>
<td>70</td>
<td>Cataracts (100%)</td>
</tr>
<tr>
<td>46</td>
<td>Inferior RD/post with VRP</td>
<td>28.3</td>
<td>Cataracts (1/10)</td>
</tr>
<tr>
<td>12</td>
<td>Inferior RD</td>
<td>91</td>
<td>Cataracts (6/12)</td>
</tr>
<tr>
<td>13</td>
<td>RD complicated with VRP</td>
<td>84.6</td>
<td>Cataracts (8/13)</td>
</tr>
<tr>
<td>21</td>
<td>RD complicated with VRP</td>
<td>85.7</td>
<td>Inflammation (23.8%)</td>
</tr>
<tr>
<td>122</td>
<td>RD complicated with VRP inferior or posterior RD</td>
<td>71.3</td>
<td>Emulsification and dispersion (23.8%)</td>
</tr>
<tr>
<td>10</td>
<td>Recurring RD with VRP</td>
<td>70</td>
<td>Cataracts (76.3%)</td>
</tr>
<tr>
<td>27</td>
<td>RD complicated with posterior and anterior VRP</td>
<td>92.5</td>
<td>Inflammation (1/10)</td>
</tr>
<tr>
<td>41</td>
<td>Primary inferior RD</td>
<td>91</td>
<td>Severe inflammation (1/10)</td>
</tr>
<tr>
<td>48</td>
<td>Relapsing RD with VRP, previous trauma, endophthalmitis</td>
<td>46</td>
<td>Hypertension (8%)</td>
</tr>
</tbody>
</table>

Comments:

1. The data are presented as mean ± standard deviation (SD).
2. LogMAR (Logarithm of the Minimum Angle of Resolution) is a logarithmic scale used in visual acuity measurement.
3. IOP (Intraocular Pressure) is the pressure inside the eye and is measured in millimeters of mercury (mmHg).
4. The percentage of success or improvement is calculated from the number of patients who showed a particular result over the total number of patients.
5. Cataracts are a common eye condition that causes cloudy vision and can affect people of any age.
6. Inflammation is a natural response of the body to injury or infection.
7. Hypertension is a condition in which the blood pressure is consistently elevated, leading to an increased risk of heart disease, stroke, and other health problems.
8. Hypotony is a condition where the intraocular pressure is abnormally low.
9. Ischemic optic neuropathy is a type of optic neuropathy characterized by impaired blood flow to the optic nerve.
Stappler et al. 6 (from 1.38 ± 0.87 SD to 1.06 logMAR ± 0.83 SD).

With the use of Densiron®, the authors have observed the appearance of cataracts in 100% of phakic patients. This percentage is similar to those of other studies. In addition, they have observed IOF increases in 10% of patients, in line with the results described by Lim and Franzco 9 or Hernández da Mota et al. 4 but lower than those found by Hussain and Banerjee. 7 Severe complications such as ischemic optic neuropathy, inflammatory reactions with fibrin aggregation in AC or clinically significant emulsification and dispersion have not been observed.

In the experience of the authors, the use of Densiron® has been satisfactory with a reaplication rate of 70%. Complications were very few, mainly the formation of cataracts in 100% of cases. The authors consider the treatment to be a good option in cases of relapsing RD with inferior VRP in which previous treatment with cerclage, gas or 1000/5000 cts silicone oil was insufficient or when it is impossible to maintain post-surgery position. At present, the authors are unable to recommend any period of intraocular permanence of the product and accordingly each case should be considered individually.

Conflict of interests

No conflict of interests has been declared by the authors.

References


