·Clinical Research·

Comparison of Densiron 68 and 1 000 cSt silicone oil in the management of rhegmatogenous retinal detachment with inferior breaks

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Abstract

• AIM: To compare success rates and complications of Densiron 68 and 1000cSt silicone oil (SO) in the management of rhegmatogenous retinal detachment (RRD) with inferior breaks (IBs).

• METHODS: Totally 61 eyes of 61 consecutive patients with RRD with IBs were assigned to pars plana vitrectomy (PPV) with Densiron (*n*=31) or PPV with SO (*n*=30) in order of presentation. SO and Densiron removal was performed 3 months after initial surgery. Follow up visits were terminated 6 months after SO removal.

• RESULTS: With a single operation, the Densiron group showed 84% and SO 74% reattachment. With further surgery, both groups showed 90% reattachment. Complications such as cataract, raised intraocular pressure (IOP), inflammatory reaction, macular epiretinal membranes, and emulsification of SO were seen in both groups.

• CONCLUSION: Densiron and SO are found to have similar success rates and complications.

• KEYWORDS: retinal detachment; silicone oil; Densiron; heavy silicone oil; inferior break
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INTRODUCTION

Since its first use for desperate tractional retinal detachment cases, silicone oil (SO) has been used in vitreoretinal surgery for decades [1]. At present, it is widely used in the treatment of retinal detachment as an intraocular tamponade. However, management of retinal detachment with inferior breaks (IBs) still remains controversial. Owing to the nearly spherical shape of the eye and the tendency of SO to take up the form of a spherical shape, any insufficient amount of injection will lead to unsupported areas of the inferior quadrant [2]. Besides, SO is of lower density than that of water, so it has no ability to support the inferior retina. For this reason, recurrence of retinal detachment with IBs is an issue which vitreoretinal surgeons have to deal with. To overcome this issue, some authors suggest additional scleral buckles (SB), while others prefer pars plana vitrectomy (PPV) and gas injection with extensive laser application and rigorous postoperative posturing [3-6]. Theoretically, it could be possible to solve this problem with the use of tamponades that are heavier than water, such as heavy silicon oil (HSO). Densiron 68 is one of the HSO types which has a density of 1.06g/cm^3, and a viscosity of 1400mPas. It consists of 5000 cSt SO (70%) and perfluorohexyloctane (F6H8) (30%). These heavy tamponades are used in the treatment of various retinal diseases, such as complicated retinal detachment, persistent macular holes, and retinal detachment due to macular hole in myopic patients [7-10]. They have also been used in retinal detachment with IBs [11,12]. The purpose of present study is to compare the safety and efficacy of Densiron 68 and SO in the treatment of RRD with IBs.

SUBJECTS AND METHODS

Subjects Sixty-one eyes of 61 consecutive patients with RRD due to IBs were included in this prospective, randomized, comparative study. The inclusion criterion was RRD with breaks located between 4 and 8 o'clock inferiorly. Eyes with breaks in the superior quadrants and those that had previously vitreoretinal surgery were excluded. Informed consent according to the tenets of the Declaration of Helsinki was obtained from each patient. Patients were alternatively assigned to the Densiron (*n*=31) or 1000cSt SO (*n*=30) group in order of presentation.

Methods Standard 3-port PPV was performed under local anaesthesia with Sub-Tenon's injection on all patients. Biom III, Oculus was used as a viewing system. After vitreous removal, perfluorocarbon liquid (PFCL) injection, peeling of epiretinal membranes or retinectomy in the presence of PVR, PFCL-air exchange, endolaser photocoagulation around

Table 1 Comparison of preoperative outcome data $\bar{x} \pm s$

Parameter	Densiron 68 (*n*=31)	Silicone oil (*n*=30)	P^1
Age (years)	57.9±14.6	56±15.6	0.697
Gender (male/female)	19/12	19/11	1.00 Fisher's exact
Involved quadrants	2.93±0.84	3.07±0.81	0.564
PVR	No PVR:5	No PVR:5	0.634 Chi-square
	PVR A:9	PVR A:10	
	PVR B:9	PVR B:6	
	PVR C:8	PVR C:9	
Number of breaks	2.90±0.97	2.30±1.24	0.060
Macular involment (Maculaoff)	23/31(74%)	21/30(70%)	1.00 Fisher's exact
Lens status	Phakic:15(49%)	Phakic:13(43%)	0.363 Chi-square
	Pseudophakic:11(35%)	Pseudophakic:15(50%)	
	Aphakic:5(16%)	Aphakic:2(7%)	
Preoperative VA(logMAR)	2.54±0.82	2.25±1.01	0.344

[1] *t* -test used for data with normal distribution, Wilcoxon test used for data without normal distribution.

retinal breaks, air silicone exchange, and closure of sclerotomies were performed respectively. SB was not used in either group except for re-operations to treat PVR in the SO group. Three days postoperatively, after a period of 3 hours with supine posturing, prone posturing with the head downwards in the SO group, and the head in an upright position in the Densiron group, was provided in order to achieve the intended adhesive effect of laser photocoagulation [13]. Densiron and SO removal were accomplished by active aspiration through a pars plana approach 3 months after the PPV. In the phakic eyes of the SO group, SO was removed via corneal incision after phacoemulsification and posterior capsulorhexis. If necessary for phakic patients, cataract surgery was combined with the pars plana approach Densiron removal.

Best corrected visual acuity (BCVA) was assessed with decimal charts at preoperative and postoperative follow up visits. BCVA assessed in the sixth month of SO removal was regarded as the final visual acuity (VA). LogMAR VA was obtained for statistical analysis.

Counting fingers VA was assigned a logMAR value of 2.0 and hand movement was assigned 3.0 logMAR. The eyes at the level of light perception VA were excluded from statistical analysis [14].

The primary endpoint of the study was anatomical re-attachment of the retina in the absence of any tampanode. The secondary endpoint was to determine VA changes and complications arising from surgery in the two groups.

Statistical Analysis Statistical analyses were performed with StatPlus software (Analysoft, USA). Comparisons were made by Student *t*-test for normal distribution, and Mann Whitney U test for vice versa. VA changes before and after surgery were compared by Wilcoxon matched pairs test. Two tailed distribution outcomes were accepted for *P* values.

RESULTS

There were no statistical differences in the demographic and clinical characteristics of the two groups (Table 1).

Four eyes in the Densiron group and 5 eyes in SO group had simultaneous cataract surgery with PPV. Retinectomy was performed in 1 eye of the SO group. Subretinal band removal was performed in 1 eye in the Densiron group. Three eyes in the Densiron group and 2 eyes in the SO group had iatrogenic retinal breaks during the surgery. No other intraoperative complications were observed. Retinal re-attachment was achieved at the end of the surgery in all of the patients.

In the Densiron group, 26 of 31 eyes (84%) had retinal re-attachment after SO removal. The same was achieved in 22 of 30 eyes (74%) in the SO group. There was no difference between the two groups (P=0.245, Fisher's exact test). Five eyes in the Densiron group developed PVR, causing apparent traction of the retina. We therefore had to perform PPV with peeling epiretinal membranes, retinectomy and Densiron re-injection. Of these, 2 eyes' retinas remained re-attached after SO removal, whereas 3 developed further PVR, and were then assigned as unsuccessful cases of the Densiron group. In the SO group, 6 eyes showed PVR after PPV. They were re-operated on, in the same manner of the initial PPV, except with the use of SB to relieve traction which would be caused by probable further PVR. Of these, 3 eyes' retinas remained re-attached in the absence of SO. Another 3 eyes developed further PVR and one, which was operated for traumatic retinal detachment, resulted in severe anterior PVR and finally phthisis bulbi. In the SO group, two eyes without PVR showed recurrence after SO removal and were treated successfully by the same manner of initial PPV. With additional surgeries, the Densiron group revealed a 90% (28/31 eyes) success rate, with the SO group's outcome also 90% (27/30 eyes). There was no statistical difference

Table 2 Comparison of anatomical and functional success rates outcome data

	Densiron 68 (*n*=31)	Silicone oil (*n*=30)	*P*
Reattachment with single PPV	26 (84%)	22 (74%)	0.245 Fisher's exact
Reattachment with multiple PPV	28 (90%)	27 (90%)	1.000 Fisher's exact
BCVA (LogMAR&decimal)			
Preoperative	2.54±0.82 (0.003)	2.25±1.01 (0.006)	
Final	0.67±0.37 (0.2)	0.62±0.42 (0.2)	
Pre *vs* postoperative difference *P* value	0.00003 (Wilcoxon matched pairs)	0.0002 (Wilcoxon matched pairs)	
Mean decrease of logMAR	1.85±0.82	1.63±0.86	0.419 *t* -test
Postoperative BCVA			
Improved	28	28	
No change	2	1	
Worse	1	1	
Final BCVA≥0.5	7	6	0.710 Fisher's exact
Final BCVA≤0.05	5	8	0.245 Fisher's exact

between the two groups (*P*=1.000, Fisher's exact test). In both groups, mean BCVA improved after SO removal, with regards to initial BCVA. VA changes and anatomical success rates are shown in Table 2.

In the Densiron group, IOP rise (IOP ≥22mmHg) was observed in 7 eyes in the early postoperative period, in 4 eyes by the first month, and in 2 eyes after SO removal. In the SO group, 7 eyes revealed an IOP rise in the early postoperative period and 1 eye by the first month. IOP rise was controlled through topical antiglaucomatous therapy in all eyes. Cataract formation was observed in 13 of 15 phakic eyes in Densiron 68 group, and 9 of 13 phakic eyes in the SO group. Significant inflammatory reaction with fibrinoid exudation developed in 1 eye of the Densiron group, and in 4 eyes of the SO group. All of them showed complete resolution with steroid therapy. In the Densiron group, 2 eyes showed macular epiretinal membran (ERM) formation. In the SO group, 1 eye developed macular ERM and 1 eye a macular hole with ERM. These membranes were peeled at the time of SO removal. Emulsification of SO was observed in 3 eyes of Densiron 68, and in 2 eyes of the SO group.

DISCUSSION

In this study, we aimed to investigate if Densiron has an advantage in the treatment of inferior retinal breaks. We didn't find a statistically significant difference between two groups in terms of anatomical success rates with single or multiple PPV. Re-detachment rate after first SO removal was lower in the Densiron group (16%), than the SO group (26%). This can be attributed to better support of Densiron to inferior retina, but the difference is not statistically significant (*P*=0.245). As for functional success rates, both groups gained statistically significant VA improvement. There was no significant difference between two groups regarding mean LogMAR decrease. According to these anatomical and functional outcomes, we can say that either of these methods is efficient in the treatment of inferior detachments, and there is no advantage of one over the other. Previous studies with Densiron 68 brought out a success rate of 81%-96% with single PPV, and 90.5%-100% with further Surgery [12,15,16,17]. In this study, single PPV with Densiron use had a success rate of 84%, and with further surgery, the success rate was 90%. These results show similarities to previous studies.

Other than operations to treat recurrences in the SO group, we didn't use additional SBs in either group. In the Densiron group we didn't use SB even if to treat recurrences, because of its ability to support inferior retina. PPV without SB can be used when the risk of PVR is low [5,6]. Wickham reported that PPV with gas alone was more efficient and safer than PPV, gas and SB for the treatment of IB retinal detachments [18]. By virtue of these previous reports, we didn't use SBs in initial PPVs. We preferred SBs in re-operations and only in cases likely to develop further PVR in the SO group. In this way, we achieved a final success rate of 90%, which was equal to that of the HSO group. So being wary of using additional SB to conventional SO in primary IB retinal detachment, seems to be reasonable unless there is an obvious risk of PVR.

Both groups showed similar complications, such as IOP rise, cataract, inflammatory reaction, macular ERM, and emulsification of SO with similar rates. There wasn't a significant difference regarding complication rates. Similar complications have been observed by previous studies with Densiron use [12,15,19,20]. A complication which we didn't observe, such as iridolenticular block due to Densiron, was reported in a study of 23 cases [21]. In this study, a young patient with traumatic retinal detachment had postoperative anterior PVR in the SO group. Although we re-operated on this patient with PPV combined with SB, the patient contracted phthisis bulbi. In comparing the complications of the two groups, the most remarkable difference is this phthisis case. But it should be emphasized that phthisis is due to individual characteristics such as trauma and young age and is independent from SO type. Postoperative posturing may be troublesome for patients with orthopaedic disability, mental retardation and for patients in childhood. In such situations, Densiron can be more useful because it supports the inferior retina whilst in an upright position, which is a natural position. Also, when postoperative posturing is more important as in the case of inferior retinectomies, Densiron seems one step ahead of SO.

In conclusion, it seems that Densiron 68 and conventional SO have similar efficiency in RRD with IBs, as there is a lack of a statistically significant difference between them. Also, Densiron does not have higher complication rates than conventional SO, so there is no need to be wary of using Densiron in these cases. Moreover, in cases likely to develop PVR, Densiron might be useful in avoiding repeated surgeries with SB usage. The number of the cases included in this study is limited, further studies with large series are needed to make consistent conclusions.

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