·Clinical Research·

Anatomical and functional outcomes after Densiron 68 heavy silicone oil tamponade for complicated retinal detachment in Chinese eyes

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Abstract

• **AIM: To evaluate the safety and efficacy of Densiron 68 heavy silicone oil (HSO) tamponade for complicated retinal detachment (RD) in Chinese eyes.**

• **METHODS: Twenty-one eyes of 21 patients with complicated RD were included in this retrospective study. All patients underwent pars plana vitrectomy with an internal tamponade using Densiron 68 HSO. Anatomical and functional results and complications were evaluated, including retinal status, visual acuity (VA), intraocular pressure (IOP), intraocular inflammation, lens opacity, and HSO emulsification.**

• **RESULTS: All the patients were followed up for 3mo to 1y (5.8±1.16mo). Retinal reattachment was achieved in 19 of 21 patients (90.5%). VA improved in 18 of 21 patients (85.7%), from 1.93 logMAR (±0.48) to 1.52 logMAR (±0.45) (P=0.001). Postoperative complications included early dispersion of HSO in 7 eyes (38.8%), cataract in 10 of 18 phakic eyes (55.5%), moderate postoperative inflammation reaction in 10 eyes (47.6%), and elevated IOP in 5 eyes (23.8%), all of which were controlled by medication or by surgery.**

• **CONCLUSION: High anatomical and functional success rates can be achieved with primary vitrectomy for complicated RD by using Densiron 68 HSO; however, it should not be ignored that Densiron 68 HSO can cause some complications in the eye.**

• **KEYWORDS:** complicated retinal detachment; heavy silicone oil; intraocular tamponade; vitreoretinal surgery

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INTRODUCTION

For decades, the use of silicone oil (SiO) as an intraocular tamponade to treat complicated retinal detachment (RD) has increased the success rate of the operation, and it is currently widely used [1,2]. However, the specific gravity of SiO is less than that of water, and it does not provide good support to the inferior retina, which may result in proliferative vitreoretinopathy (PVR) in the inferior vitreous and recurrence of inferior RD[3,4]. It has long been recognized by vitreoretinal surgeons that a new substance similar to SiO but with a specific gravity greater than that of water would be useful in these particular cases complicated by recurrent inferior RD with PVR. The heavy silicone oil (HSO) Densiron 68 is comprised of a mixture of F6H8 and 5000mPas SiO (density 1.06 g/cm^3), which is heavier than water and may provide good tamponade for the inferior retina [5-8]. Therefore, HSO has most commonly been used for complicated RDs and redetachments. In spite of this, its use is limited because it can cause inflammation, emulsification, and cataract, and it has not been widely used in clinical practice[9-11]. However, studies of HSO application in Chinese eyes in other intraocular inflammation diseases, such as uveitis, have recently been reported [12]. Clinical use of HSO in Chinese eyes has been rarely described, and because Chinese eyes exhibit different clinical patterns and characteristics, the complications of HSO application in these patients are not yet clear. The aim of our study was to evaluate the clinical results and complications associated with the use of Densiron 68 as an internal tamponade in the treatment of complicated RDs in Chinese patients.

SUBJECTS AND METHODS

Subjects A retrospective study enrolled 21 patients (21 eyes) who underwent vitreoretinal surgery with intraocular Densiron 68 tamponade between May 2008 and December 2009 at Shanghai Tenth People's Hospital. The study adhered to the tenets of the Declaration of Helsinki, was approved by the Institutional Review Board of the hospital and informed consent was obtained. Inclusion criteria were RD

Table 1 Preoperative characteristics

Patient	Age	PVR grade[1]	Quadrant of RD	Location of retinal hole	No. previous operations	Lens status	History	Preop. VA
1	50	CP4	4	I, MH	0	Cat	Staph	HM
2	13	CP6	4	IGRT	1 (SB)	Clear	Penetrating trauma	HM
3	17	CP3	3	I	0	Cat	None	CF
4	44	CP3	4	MH	1 (PPV)	IOL	DM	HM
5	36	CP4	4	IT	1 (PPV)	Clear	Trauma	LP
6	34	CP3	4	IGRT	0	Clear	Staph	20/180
7	61	CP3	4	MH	0	Cat	HM	HM
8	38	CA3	4	IT, MH	1 (PPV)	Cat	HM	HM
9	57	CP5	1	I	1 (PPV)	Cat	Trauma	HM
10	47	CP6	4	IGRT	0	Clear	/	20/1000
11	50	CA6	4	IT	0	Clear	Trauma	20/2000
12	58	CP4	4	IGRT	1 (PPV)	Aphakic	Trauma	HM
13	38	CP4	3	I	0	Clear	/	CF
14	35	CP2	4	MH	0	Clear	HM	20/400
15	46	CP2	4	IT	0	Clear	/	20/800
16	52	CP3	4	MH	1 (PPV)	Cat	HM	20/800
17	37	CA4	4	IT	1 (PPV)	Aphakic	/	HM
18	63	CP6	4	IT	1 (PPV)	Cat	Trauma	HM
19	65	CP6	2	IT	1 (PPV)	Cat	Trauma	CF
20	27	CP5	4	MH	0	Clear	DM	20/1000
21	25	CA2	4	MH	0	Clear	DM	20/400

CF: Counting fingers; Cat: Cataract; DM: Diabetes mellitus; HM: Hand movements; I: Inferior; IGRT: Inferior giant retinal break; IOL: Intraocular lens; IT: Inferior temporal; LP: Light perception; MH: Macular hole; PVR: Proliferative vitreoretinopathy; PPV: pars plana vitrectomy; RD: Retinal detachment; SB: Scleral buckling; Staph: Posterior staphyloma; VA: Visual acuity. [1]Includes updated Retina Society PVR classification.

complicated by severe PVR involving the inferior quadrants with a grade greater than CP-2 and CA-2 (updated PVR classification system of the Retina Society) and an inability of maintaining the posture [13]. Exclusion criteria were PVR less than CP-2 and CA-2, lack of informed consent, and unavailability for regular follow-up examinations. All patients were fully informed of all aspects of the procedure, and all signed the informed consent. Approval by the institutional ethics committee was obtained.

Methods Preoperative examination included best-corrected visual acuity (BCVA), measured using a Snellen chart, and measurement of intraocular pressure (IOP). The anterior segment was examined using a slit-lamp, and the fundus was examined using a +20 D indirect ophthalmoscope. RD was classified according to the grade of PVR using the Retina Society Classification (1983)[14]. The same examinations were carried out at all follow-up visits throughout the study.

Seven patients had a history of primary ocular injury, and one patient exhibited congenital amblyopia and nystagmus. In all cases, the RD involved the macula (Table 1).

Statistical Analysis Analysis were carried out using SPSS statistical software (version 13.0, SPSS Inc., Chicago. IL, USA) by a two-tailed paired t-test. Results are expressed as mean±standard deviation (SD). A Pvalue less than 0.05 was considered statistically significant.

RESULTS

Twenty-one eyes of 21 patients were included in this study. The 6 females and 15 males ranged in age from 13 to 65y (42.5±14.6y). All patients were followed up for 3mo to 1y (5.8±1.16mo). The duration of Densiron 68 tamponade ranged from 23 to 105d (72.8±23.4d). Postoperative complications included early HSO dispersion in 7 eyes (38.8%), cataract in 10/18 phakic eyes (55.5%), moderate postoperative inflammation reaction in 10 eyes (47.6%), and elevated IOP in 5 eyes (23.8%). IOP can be controlled either by anti-glaucoma eye drops, an intake of acetazolamide or HSO removal (Table 2).

The surgical procedure was performed as a standard three-port pars plana vitrectomy without additional scleral buckling procedures under local anesthesia by one experienced vitreoretinal surgeon (Wang F). During vitrectomy, epiretinal membrane peeling was performed in most cases (Table 1). In eyes with significant retinal shortening due to long-lasting RD, circumscribed relaxing retinectomies were performed to allow reattachment with intra-operative perfluorocarbon liquid (PFCL) (Table 1). Retinal breaks were treated by cryocoagulation and/or endolaser photocoagulation. PFCL-air exchange was performed, followed by a slow injection of Densiron 68 with a 16-G cannula. In all cases, the tamponade was removed via

Table 2 Postoperative data

Patient	Present postop VA	Retinal status after HSO removal	Densiron 68 removal (d)	Endotamponade after Densiron 68 removal	Present endotamponade	Complication
1	20/600	Attached	99	SiO	/	Sec Cat,
2	20/400	Attached	23	C3F8	/	Sec Cat, HIOP, HSOE
3	20/200	Attached	60	SiO	/	Sec Cat, HSOE
4	HM	Not attached	90	SiO	SiO	/
5	HM	Attached	75	SiO	/	/
6	20/50	Attached	40	C3F8	/	Sec Cat, HSOE
7	CF	Attached	90	C3F8	/	HSOE
8	HM	Attached	89	C3F8	/	Sec Cat, HSOE
9	CF	Attached	92	C3F8	/	Sec Cat, HIOP, HSOE
10	20/500	Attached	84	C3F8	/	PCO
11	20/1000	Attached	101	C3F8	/	/
12	CF	Attached	102	C3F8	/	HIOP, HSOE
13	20/200	Attached	68	C3F8	/	Sec Cat
14	20/200	Attached	74	C3F8	/	/
15	20/400	Attached	71	C3F8	/	/
16	20/600	Attached	57	C3F8	/	Sec Cat
17	HM	Not attached	90	SiO	SiO	/
18	CF	Attached	105	C3F8	/	Sec Cat, HIOP
19	20/200	Attached	56	C3F8	/	Sec Cat
20	20/100	Attached	89	C3F8	/	HIOP, HSOE
21	20/200	Attached	70	C3F8	/	/

CF: Counting fingers; HIOP: High intraocular pressure; HM: Hand motions; HSOE: Heavy silicone oil emulsification; PCO: Posterior capsule opacity; Sec Cat: Secondary cataract; SiO: Silicone oil; VA: Visual acuity.

the pars plana 23 to 105d (72.8 ±23.4d) after surgery by means of active aspiration through a 16-G cannula. Highly emulsified droplets were removed by PFCL injection. Surgical success was defined as complete retinal attachment after HSO removal. The preoperative data are summarized in Table 1.

Retinal reattachment was achieved in 19 of 21 patients (90.5%) (Table 2). Retinas remained detached in two eyes at the last follow-up. In 16 eyes, C3F8 tamponade was performed after HSO removal, and the retina remained attached after the C3F8 was absorbed. However, in the remaining 5/21 eyes, RD recurred after HSO removal. Re-operation was necessary with conventional SiO tamponade. The retina was attached after SiO was removed in three patients, while the retina was not attached in two of them, even with the SiO inside the eyes (patients 4 and 17). One patient suffered from a very severe PVR as a result of diabetic retinopathy. The patient developed an inferior recurrence of RD after HSO removal. Re-operation was necessary, and an inferior retinectomy with standard SiO tamponade was carried out. The second patient was admitted with a recurrence of an RD with a severe anterior PVR after a previous vitrectomy procedure with SiO tamponade. He developed total RD after HSO removal and required further surgery with an extensive peripheral retinectomy and a conventional SiO tamponade. The SiO was not removed due to low IOP (Table 2).

Visual acuity (VA) was improved in 18 of 21 patients (85.7%) (Tables 1, 2), from a mean of 1.93 logMAR (±0.48) to a mean of 1.52 logMAR (±0.45) (P =0.001). In three patients (cases 4, 8, and 17) VA remained unchanged, but did not decrease. In 12 of the 21 patients (57.1%) the final VA was equal to or better than 20/800.

The most common complication in our patients was intraocular inflammation. Mild-to-moderate anterior aqueous flare and cells were observed in 10 patients (47.6%), with fibrin exudations in 2 eyes after 1wk of follow-up. Topical and systemic steroids were used; however, aqueous flare and cells in the anterior chamber persisted until Densiron 68 removal.

Eighteen phakic eyes had clear or mildly opaque lenses; cataract developed in 10 of them (mainly posterior sub-capsular cataract) after HSO tamponade. Cataract surgery was performed in these eyes at the time of Densiron 68 removal.

HSO emulsification was observed in seven eyes 3wk after Densiron 68 tamponade. In three of the seven eyes, significant pseudo-hypopyon (emulsification droplets) were also observed in the anterior chamber in the young patients (cases 3, 6, and 8). One of the three had a giant retinal tear.

Five eyes had an IOP higher than 30 mm Hg at 1wk postoperatively. In two of them, IOP was controlled using topical beta blockers, alpha agonists, and systemic carbonic anhydrase inhibitors. However, three of them were not controlled by antiglaucoma therapy. A large amount of HSO droplet floating occurred in the anterior chamber. IOP was controlled after HSO removal.

DISCUSSION

SiO has been established successfully in the management of complicated RD [15,16]. However, SiO and gas tamponades are lighter than water, and inferior RDs are difficult to tamponade, resulting in higher reproliferation rates in the inferior oil-free space. In addition, postoperative posturing for patients managed with these agents is consequently quite troublesome.

In order to prevent this, a "heavier than water" intraocular tamponade is needed, and the indications for such tamponades have been extensively discussed in the past[16-18]. Densiron 68 is a mixture of 30.5% perfluorohexyloctane (F6H8) with 69.5% polydimethylsiloxane (SiO) (vol/vol). The specific gravity of Densiron 68 (1.06 g/cm^3 at 25℃) is higher than that of water and has been shown to have good anatomical results in patients with inferior RDs with or without the complication of PVR [19-21]. This characteristic allows it to support the inferior retina in the sitting position and to support the posterior pole in the supine position. The viscosity of HSO is 1400 mPa.s at 25℃, so it can be easily injected and removed. Furthermore, HSO is easy to inject and remove due to its low density. A 16-G needle was used to inject and to remove it with auto-aspiration. Multiple air-gas exchange was used when there were only a few droplets, whereas heavy liquid was employed to remove larger droplets.

The primary reattachment success rate after Densiron 68 tamponade differed considerably between the pilot and current series (from 45.8% to 92.3%)[22,23]. Such differences might be attributable to differences in case selection, previous retinal conditions, PVR, follow-up period, the definition of anatomical success, and the vitreous surgical techniques. Sandner and Engelmam [23], for example, applied Densiron 68 exclusively to patients for whom previous retinal surgery had failed. Use of SiO tamponade for complicated RD in several series resulted in anatomical success rates of 45%-87%. When we used Densiron 68 as a tamponade in Chinese eyes with complicated inferior RD, anatomical success was achieved in 19 of 21 eyes (90.5%) at the last check-up, which was satisfactory compared with previous studies[24]. Although the anatomical success rates differed, the complication rates from different series were similar. The evidence suggests that Densiron 68 and SiO have similar complication rates in clinical use[25].

Because of differences in previous retinal conditions, visual function results are not easy to compare. When examining pre- and post-operative VA, most studies report an improvement in VA in the majority of patients. HSO tamponade for complicated RD in several series resulted in reported VAs equal to or better than 20/800 in 45% to 63% of patients[3,26,27]. In our series, mean VA improved in 18 of 21 patients (85.7%), from 1.93 logMAR (±0.48) to 1.52 logMAR (±0.45) (P=0.001). In 12 of 21 patients (57.1%) final VA was equal to or better than 20/800. VA was not improved after surgery in some cases because of the severity of the initial condition of the retina. These results were similar to those described in previous reports[3,4,23].

Complications after HSO tamponade described in other studies include severe inflammation, HSO emulsification/dispersion, new tears in the superior retina, retinal vascular changes, cataract, and ocular hypertension and hypotension[27-29]. Inflammatory reactions, including exudation and membrane formation, are quite common complications; likewise, the most common complication in our patients was intraocular inflammation[21,24]. Ten of 21 eyes (47.6%) showed mild-to-moderate anterior aqueous flare and cells, with fibrin exudations in 2 eyes. Severe inflammatory reactions were observed that resulted from the initial condition of the retina, as well as heavy pigment in Chinese eyes and multiple depigmentation during the surgery.

An increase in IOP is another common complication after pars plana vitrectomy and HSO tamponade. Transient ocular hypertension has been recorded in 13%-33% of cases and can easily be controlled by medication or HSO removal [21-23]. We observed five cases of ocular hypertension after HSO tamponade; three were easily controlled by medication, and two were resolved after HSO removal. No ocular hypertension developed in the late postoperative period of the follow-up.

Cataract is another common complication after surgery. In our study, cataract improved after HSO tamponade in 10 of 18 phakic eyes (55.5%). This rate of cataract formation was lower than the rates reported in other series (77.8%-100%), possibly because of the supine head positioning after HSO tamponade and partly because of the short (3mo) tamponade period [21,24,30,31].

In our study, HSO emulsification was observed in seven eyes (33.3%) 3wk after Densiron 68 tamponade. This result is comparable to other reports of HSO emulsification in 32.5%-42.2% of eyes [21,23,30]. Emulsification may occur as early as 2wk after HSO tamponade, which is much faster than observed with SiO. There seems to be more emulsification after HSO tamponade in young patients and in those with giant retinal tears. This is probably because those involved tend to be more physically active than other patient groups.

In summary, this retrospective study shows that HSO Densiron 68 can be used as an effective tamponade in complicated RD occurring in inferior retinal segments with good anatomical and functional results in Chinese patients.

The most common complications after HSO tamponade are inflammation, cataract, and HSO emulsification, and attention should be paid to these adverse effects.

Although the surgical outcomes in this study are encouraging given the high anatomical and functional success rates, no conclusions can be reached regarding the effectiveness and safety of HSO because of the small number of patients and the relatively short follow-up. However, these results do suggest that a prospective randomized controlled trial to compare the relative effectiveness of HSO and SiO in the management of complicated RD should be considered.

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