SILICONE OIL–RMN3 MIXTURE ("HEAVY SILICONE OIL") AS INTERNAL TAMPONADE FOR COMPLICATED RETINAL DETACHMENT

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Purpose: To evaluate the efficacy and safety of a silicone oil–RMN3 mixture ("heavy silicone oil") as heavier as water internal retinal tamponade after vitrectomy for complicated retinal detachment. The relative density of the heavier-than-water silicone oil was 1.03 g/cm^3, and the viscosity was 3,000 cSt. Heavy silicone oil is designed to tamponade the inferior retina in complicated retinal detachment.

Methods: Patients with a complicated retinal detachment involving the inferior part of the retina requiring internal tamponade with silicone oil were recruited for this prospective study. Inclusion criteria were retinal detachment secondary to proliferative vitreoretinopathy (stage $\geq$C2), inferior or posterior tears, or penetrating trauma. The heavy silicone oil was injected at the end of surgery after peeling of retinal membranes or retinotomy. Follow-up examinations were scheduled at 1, 3, 6 months, and 1 year after the initial surgery.

Results: A total of 33 eyes of 33 patients aged from 20 to 84 years (mean, 56 $\pm$ 18 years) were treated with heavy silicone oil. Follow-up ranged from 12 to 16 months. Rhegmatogenous retinal detachment with significant proliferative vitreoretinopathy accounted for 17 cases, inferior holes for three, and trauma with retinal detachment for three. Initial visual acuity ranged from 20/50 to hand motions. Initial retinal reattachment was achieved in all cases. Complications included increased intraocular pressure in six eyes (18%), intraocular inflammation and synechia formation in one eye (3%), a central retinal artery occlusion after heavy oil removal in one eye, and scattered retinal hemorrhages during follow-up in two eyes (6%). Significant emulsification was not observed during intraocular tamponade with heavy silicone oil. At the last follow-up, all eyes had macular attachment, and 24 eyes had a visual acuity better than or equal to 20/400.

Conclusions: The results of this prospective study show the good intraocular tolerance of heavy silicone oil as tamponade in complicated retinal detachment. Its specific gravity allows for sufficient tamponade of inferior retinal tears for at least 3 months without significant side effects.

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AQ: 1

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The improvement of vitreous microsurgical techniques and the use of silicone oil have increased the rate of successful treatment of complicated retinal detachment, including proliferative vitreoretinopathy (PVR), giant retinal tears, and severe trauma cases.[1–13] Especially for superior breaks and detachments, silicone oil is effective because its specific gravity is less than that of intraocular fluid. The low gravity can result in fluid accumulation in the inferior quadrants underneath the silicone oil bubble and an increased rate of reproliferation in the inferior part of the retina.[7,14–19] Therefore, several attempts have been undertaken to develop a vitreous tamponade with a specific gravity greater than that of intraocular fluid.[20–24] Several heavier-than-water fluorinated silicone oils have been evaluated for intraocular use.[25–27] Despite their ability of sufficient tamponade in the inferior quadrants of the retina, the high rate of complications has prevented the widespread use of these substances.[21,22,24,28,29] However, the need for an intraocular tamponade with a specific gravity greater than that of intraocular fluid has resulted in the development of several new vitreous substitutes.[23,30–32]

In this prospective, controlled study, we investigated the safety and efficacy of a silicone oil with a specific gravity heavier than water for internal tamponade after surgical treatment of complicated retinal detachment.

Materials and Methods

"Heavy silicone oil" (Oxane HD, Bausch & Lomb, Toulouse, France) is a new vitreous substitute with a high specific gravity. It is a mixture of silicone oil (Oxane 5700, Bausch & Lomb) and a mixed fluorinated and hydrocarbonated olefin (RMN3). The mixture is homogeneous and stable in the presence of water, air, or perfluorocarbon.[33] Details of its chemical and physical properties are listed in Table 1. T1

Table 1. Chemical and Physical Properties of "Heavy Silicone Oil"

Density	1.03 g/cm^3
Viscosity	3,500 cSt
Surface tension	>40 mN/m
Refractive index	1.40
Volatility	<0.1%
RMN3 volume	11.9%

RMN3, mixed fluorinated and hydrocarbonated olefin. AQ: t1

All patients who were referred to the University Eye Clinic Leipzig for a complicated retinal detachment between November 1999 and October 2000 were recruited for the study. Inclusion criteria were age of at least 18 years, a complicated retinal detachment involving the inferior part of the retina in the study eye, and visual acuity of 20/40 or better in the fellow eye. A complicated retinal detachment was diagnosed in eyes with PVR grade ≥C2 (updated classification of the Retina Society[34]), retinal detachment by penetrating ocular trauma, giant retinal tear, or posterior or inferior tears, which necessitate internal tamponade with silicone oil. The presence of PVR was not restricted to the inferior quadrants but needed to involve the inferior quadrants. Exclusion criteria were pregnancy, severe arterial hypertension, any uncontrolled ocular disease other than retinal detachment, pseudophakia with a silicone intraocular lens, inability for regular follow-up examinations, or missing informed consent. After the experimental nature of the treatment was explained to the patients, informed consent was obtained. This study was approved by the local review board. Anatomic success was defined as a completely attached retina posterior to the encircling band. AQ: 2

Preoperative evaluation included a detailed history of ophthalmic surgery and of the retinal detachment, a postrefractive ophthalmologic examination to determine the best-corrected Snellen visual acuity, followed by slit-lamp biomicroscopy, Goldmann applanation tonometry, and indirect and direct ophthalmoscopy. The grade of possible PVR was determined using the classification of the Retina Society. Follow-up examinations were scheduled 1, 3, 6 months, and 1 year after initial surgery. Additionally, 5 weeks after removal of the heavy silicone oil, an additional follow-up visit was performed. Measurement techniques and units were the same as in the preoperative examination. The presence of silicone oil emulsification was carefully noted.

Surgery was performed in all patients under general anesthesia. The surgical procedure included a standard three-port pars plana vitrectomy. During vitrectomy, the vitreous base was thoroughly removed. Scleral buckling or revision of existing buckles was performed with an encircling band. Epiretinal membrane dissection and relaxing retinotomies were performed when necessary. After mobilization of the retina, perfluorocarbon liquid was used as an intraoperative tool to reattach the retina. Retinal tears were treated by retinopexy with cryocoagulation or laser photocoagulation. At the end of the surgical procedure, heavy silicone oil was injected slowly by an automatic device. Usually, heavy silicone oil was directly exchanged with perfluorocarbon liquid. In aphakic eyes, we performed a peripheral iridectomy in the 12-o'clock position to prevent a pupillary block by the heavy silicone oil.

Heavy silicone oil removal was planned within 3 months of the initial surgery. Removal was performed under general anesthesia. An infusion cannula was

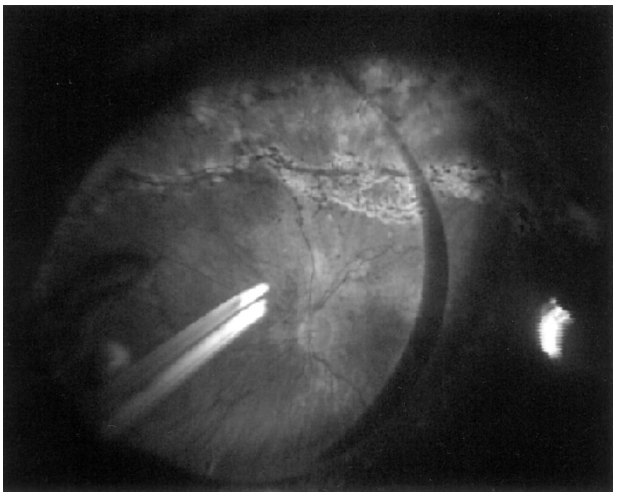

Fig. 1. Removal of heavy silicone oil with an 18-gauge cannula.

placed and sclerotomies were performed as for a standard pars plana vitrectomy. Balanced salt solution was used as an infusion fluid. The heavy silicone oil was AQ: 3 removed using active aspirated with the vitrectomy system (Millennium Microsurgical System, Bausch & Lomb). An 18-gauge cannula was directed by the surgeon using endoillumination and microscopic vi- F1 sualization (Figure 1). The process was carried out until all visible heavy silicone oil was removed.

Results

A total of 35 eyes of 35 patients (13 women and 22 men) were included in the study of heavy silicone oil. Patients' ages ranged from 20 to 84 years (mean, 56 ± 18 years). Follow-up ranged from 12 to 16 months (mean, 12 ± 1 months). Rhegmatogenous retinal detachment with inferior tears accounted for four cases, rhegmatogenous retinal detachment with PVR ≥C2 for 27 cases, and trauma with retinal detachment for four cases. Three eyes had high myopia (more than −7 diopters). Thirty-three eyes had undergone previous surgical attempts to repair the retinal detachment. The previous surgical procedures included scleral buckle in five eyes and vitrectomy in 28 eyes. Primary PVR accounted for two cases. The number of previous operations ranged from one to nine (mean, 2.3 ± 1.3 operations). Twenty eyes had an internal tamponade T2 with silicone oil at study entry (Table 2). At baseline, seven eyes were phakic; 15 eyes were aphakic; and 13 eyes were pseudophakic. Initial visual acuity ranged from 20/50 to hand motions.

During the initial surgery, two patients were excluded from the study. One patient, a 43-year-old man with a retinal detachment after penetrating trauma, had severe anterior PVR in the superior part of the retina. Therefore, normal silicone oil was injected as internal tamponade. The second patient, a 60-year-old man, had an inferior tear and PVR C1 and was successfully treated with a long-acting gas (SF_6) as internal tamponade. After 12 months, the retina was reattached in both patients, with normal silicone oil as internal tamponade in one patient.

In the remaining 33 eyes, heavy silicone oil was injected at the end of surgery without complications. We report functional and anatomic results and adverse events in the 33 eyes treated with heavy silicone oil in more detail. Table 3 summarizes all data on the retinal T3 status of study eyes at the follow-up visit and the presence of silicone oil at the last follow-up visit of all patients.

During surgery in four phakic eyes, the lens was removed. Relaxing retinotomy was required in 22 cases. Perfluorocarbon liquid was used in 32 eyes. The injection of heavy silicone oil was easy in all cases. Especially during direct exchange with perfluorocarbon liquid, the interface was easily visible in all cases. Intraoperative retinal reattachment was achieved in all cases.

One month after the study, the macula was attached in all eyes. The tamponade of the inferior quadrant was very good in 30 eyes (Figure 1). Anatomic success was achieved in 28 eyes. We noted a retinal detachment peripheral to the encircling band in four eyes and a retinal detachment not involving the posterior pole in five eyes. In three of the latter eyes, the inferior quadrants were involved in the retinal detachment. Visual acuity ranged from 20/40 to light perception.

Three months after the initial surgery, the macula was detached in two eyes; one of these had heavy silicone oil removed 2 months after the initial surgery. The indication for silicone oil removal was the presence of scattered retinal hemorrhages as described below. All other eyes had no surgical interventions before the 3-month visit. Anatomic success was achieved in 25 eyes. A limited retinal detachment peripheral to the encircling band was observed in five

Table 2. Baseline Characteristics of Eyes Included in the Study

Rhegmatogenous	31 eyes
Inferior tears	4 eyes
PVR C2	6 eyes
PVR C3–C5	10 eyes
PVR ≥ C6	11 eyes
Trauma with retinal detachment	4 eyes
Previous surgery	33 eyes
Previous silicone oil tamponade	20 eyes

PVR, proliferative vitreoretinopathy.

Table 3. Summary of Patient Data and Retinal Status for Baseline, 3-Month, 6-Month, and 12-Month Visits

No.	Retinal Status at Baseline	Previous Surgery	Initial Silicone Oil	Initial VA	Retinal Status 3 mo	Retinal Status 6 mo	Retinal Status 12 mo	Silicone Oil Present	Final VA
1	PVR C2	4	Yes	20/200	++	++	++	No	20/400
2	PVR C5	2	Yes	20/200	++	±	++	Yes	20/200
3	Inferior hole	0	No	20/800	++	++	++	No	20/300
4	Inferior hole	2	No	20/100	++	++	++	No	20/70
5	PVR C3	1	Yes	20/240	+	++	++	No	NLP
6	PVR C2	3	Yes	20/125	++	++	++	Yes	20/125
7	PVR C6	1	No	HM	++	++	++	Yes	20/300
8	PVR C4	3	Yes	20/400	±	++	++	Yes	20/200
9	PVR C12	2	No	HM	++	++	++	No	20/400
10	PVR C5	4	Yes	20/240	++	++	++	No	20/160
11	PVR C3	1	No	CF	−	++	+	Yes	20/400
12	PVR C4	1	Yes	20/700	+	++	++	Yes	CF
13	PVR C6	1	No	HM	−	++	++	Yes	20/400
14	PVR C6	1	Yes	HM	++	++	++	No	20/500
15	PVR C6	3	Yes	20/200	++	++	++	Yes	20/200
16	Trauma PVR C6	3	Yes	20/500	+	++	++	No	20/400
17	PVR C4	3	Yes	20/300	++	++	++	Yes	20/1000
18	PVR C2	1	Yes	20/300	++	++	++	No	20/200
19	PVR C9	3	Yes	20/400	±	±	±	Yes	20/700
20	PVR C6	5	Yes	20/700	++	++	++	Yes	20/660
21	PVR C6	1	Yes	HM	±	++	++	Yes	HM
22	PVR C2	1	No	20/125	++	++	++	No	20/200
23	PVR C2	2	No	20/70	++	++	++	No	20/63
24	PVR C6	1	No	20/700	++	++	++	Yes	20/200
25	PVR C9	2	Yes	20/170	−	++	++	Yes	20/125
26	PVR C7	0	No	20/300	+	++	++	No	20/500
27	PVR C12	9	Yes	HM	±	±	++	Yes	LP
28	PVR C6	3	Yes	HM	+	++	++	No	20/100
29	PVR C2	3	Yes	20/80	++	++	++	No	20/125
30	Inferior hole	1	No	CF	++	++	++	No	20/400
31	PVR C2	2	No	20/50	++	++	++	No	20/63
32	Trauma PVR C4	2	Yes	20/800	±	++	++	No	20/200
33	Trauma PVR C2	1	No	20/400	++	++	++	No	20/160

AQ: t1 ++, completely attached; +, limited detachment peripheral to the encircling band; ±, detachment central to the encircling band; −, macula detached; VA, visual acuity; PVR, proliferative vitreoretinopathy; NLP, no light perception; HM, hand motions; CF, counting fingers; LP, light perception.

eyes, and a retinal detachment not involving the posterior pole was observed in six eyes. The retina was totally attached in 20 eyes. The inferior quadrant was involved in the retinal detachment in five eyes; four of these had heavy silicone oil as internal tamponade. One of these eyes had a retinal detachment involving the macula; two had a retinal detachment not involving the posterior pole; and one had only a limited retinal detachment peripheral to the encircling band. Visual acuity ranged from 20/40 to light perception (Figure 2).

AQ: 4 F2

As required by the study protocol, heavy silicone oil removal was planned in all eyes with internal tamponade with heavy silicone oil within 1 week of the 3-month visit. Thirty-one eyes underwent removal of heavy silicone oil; one patient had heavy silicone oil removed previously; and one patient refused removal of heavy silicone oil at that time. During silicone oil removal, membrane peeling (three eyes), retinotomy (two eyes), and endolaser (seven eyes) was performed if necessary. Additionally, standard silicone oil was used as endotamponade in 14 eyes. Removal of heavy silicone oil was easier than the removal of standard silicone oil with 5,700 cSt, but more difficult than removal of standard silicone oil with 1,300 cSt.

After 6 months, the macula was attached in 32 eyes, and 25 eyes had a visual acuity better than or equal to 20/400. In two of these eyes, a peripheral detachment not involving the macula was present. Nineteen eyes had an internal tamponade with standard silicone oil, and one patient had heavy silicone oil as endotamponade.

The 12-month follow-up visit was completed in all 33 eyes treated with heavy silicone oil (Figure 3). In 31 eyes, the retina was completely attached. In two

F3

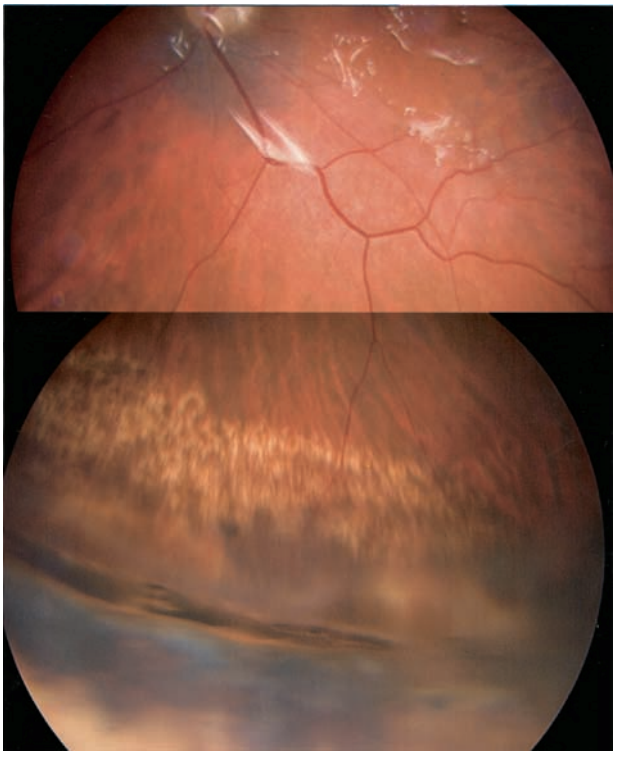

Fig. 2. Inferior retinotomy under heavy silicone oil. Note the good tamponade at the encircling band.

eyes, the macula was attached. In one, we noted a limited retinal detachment peripheral to the encircling band, and the other eye showed a limited detachment in the inferior retina not involving the macula. Visual acuity ranged from 20/63 to no light perception, and 24 eyes had a visual acuity better than or equal to 20/400. Heavy silicone oil was removed in all eyes, but 15 eyes had an internal tamponade with standard silicone oil.

Removal of heavy silicone oil was performed in 32 eyes within the first 3 months of study entry, as required by the study protocol. One patient refused removal of the heavy oil after 3 months, but it was removed after 9 months in this patient. Before removal of heavy silicone, 32 eyes had macular attachment, and 25 eyes had a visual acuity better than or equal to 20/400. In 15 eyes, we injected normal silicone oil at the end of the heavy silicone oil removal. Indications for silicone oil tamponade included peripheral limited retinal detachments and redetachments during heavy oil removal.

At the examination 5 weeks after oil removal, five previously attached maculae were found to be detached. These eyes underwent surgery again and received normal silicone oil as internal tamponade. At the last follow-up visit, 15 eyes had an internal tamponade with silicone oil. Eleven of the 20 eyes that had previous unsuccessful attempts at repair of a retinal detachment with silicone oil tamponade needed a long-lasting silicone tamponade.

In two aphakic eyes, we observed a tamponade of the anterior chamber with increased intraocular pressure (IOP) during the first postoperative days. After removal of 0.1 to 0.2 mL of silicone oil, IOP was normalized in both eyes. An increased IOP during the first 3 months was detected in four eyes and was treated with topical or oral antiglaucoma medications. In the follow-up period after heavy silicone oil removal, two additional eyes had an IOP greater than 25 mmHg and were treated with topical antiglaucoma medications. Marked intraocular inflammation and synechia formation between the iris and lens capsule or intraocular lens was present in one eye. Four weeks after heavy silicone oil removal, one patient had a central retinal artery occlusion in the study eye resulting in no light perception. The central retinal artery occlusion occurred during a phase of severe emotional stress. In two patients, we observed some scattered retinal hemorrhages during follow-up. None of these had an increased IOP or significant emulsification or inflammation. One eye developed the hemorrhages within 4 weeks after the initial surgery. Therefore, we decided to remove the heavy silicone oil 2 months after the initial surgery. At the time of heavy silicone oil removal, most of the hemorrhages had resolved. The other eye developed scattered retinal hemorrhages 6 months after removal of the heavy silicone oil.

Significant emulsification (e.g., tiny droplets of silicone oil in the anterior chamber, in the inferior angle, or on the epiretinal surface) was not observed during the period of intraocular tamponade with heavy silicone oil. Even in the eye with a 9-month period of endotamponade with heavy silicone oil, we observed no significant emulsification. Six months after the exchange of heavy oil with standard silicone oil, however, we observed some degree of emulsification in five eyes.

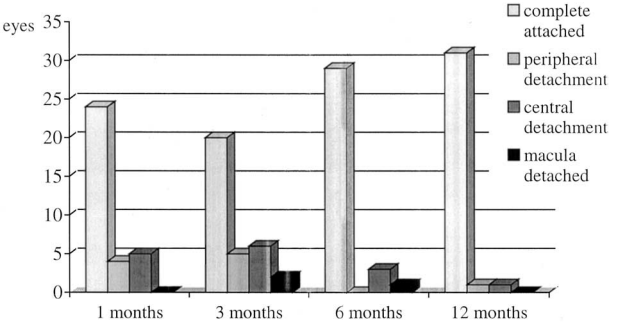

Fig. 3. Graphic representation of the retinal status of the 33 eyes treated with heavy silicone oil at each follow-up visit.

Discussion

The use of silicone oil in conjunction with advanced vitreous surgical techniques permits successful treatment of complicated retina detachment.[4,9,35–37] The anatomic success rate in cases with PVR varies between 30% and 75%.[7,9,18,36–38] However, many eyes with successful macular reattachment have residual inferior detachments[35] and need long-term internal tamponade with silicone oil. This may be the result of the low specific gravity of silicone oil and the accumulation of fluid under the silicone oil bubble. Therefore, various attempts have been undertaken to develop a heavier-than-water vitreous substitute.[21–23,29,31] The theoretical advantages of the higher specific gravity tamponades are retinal postoperative tamponade in the inferior quadrants, postoperative supine positioning, and long-term retinal tamponade. Our study suggests that these objectives can be achieved with heavy silicone oil.

In our series, retinal reattachment was achieved in all eyes at the end of the initial surgery. Postoperative supine positioning was used in all patients, in many cases with the head slightly elevated. Inferior retinal tamponade was nicely maintained postoperatively during the entire period of endotamponade with heavy silicone oil. Retinal reattachment at the posterior pole and in the inferior quadrants was achieved in 91% of cases at the 1-month follow-up visit. However, we observed residual retinal detachments in the superior quadrants in six (18%) eyes. Interestingly, two of the eyes with residual retinal detachments in the superior quadrants showed a complete reattachment after 3 months, but three other eyes developed retinal detachments in the superior quadrants during this period. In all eyes with retinal detachment in the superior quadrants after 3 months, the superior quadrants had PVR at baseline. We think that the development of retinal detachments in the superior quadrants may be caused by insufficient tamponade of the superior retina in these cases. After removal of the heavy silicone oil, these eyes were treated with standard silicone oil (four eyes) or gas (two eyes) leading to complete reattachment in the superior quadrants. During follow-up, one eye developed a peripheral detachment in the inferior quadrants.

Anatomic success at the last follow-up visit was achieved in all cases. This success rate is better than that previously reported in several studies using the same definition of anatomic success.[9,11,39–41] However, this definition may be questioned because a peripheral retinal detachment may need further treatment if silicone oil removal is planned. To achieve anatomic success, silicone oil tamponade was necessary in 51% of the eyes in this study. This rate is similar to that in previous reports.[9,13] Additionally, visual results with 76% of eyes that had a visual acuity better than or equal to 20/400 are encouraging.

In analogy to the inferior iridectomy as suggested by Ando,[42] we performed a peripheral iridectomy in the 12-o'clock position in all aphakic eyes with heavy silicone oil tamponade. This iridectomy sufficiently prevented pupillary block by allowing aqueous to flow from the posterior to anterior chamber.

In our series, no significant emulsification occurred that would have reduced the efficacy of the inferior tamponade as described for fluorosilicone oil.[22] However, the follow-up time with heavy silicone oil tamponade was limited to 3 months in all but one eye. Therefore, emulsification may occur after periods of endotamponade longer than 3 months, as described for standard silicone oil.[28,43]

Removal of the 3,000-cSt heavy silicone oil was performed by creating suction with the vitrectomy system connected by a 20-mL syringe and tubing to an extrusion cannula. Approximately 10 minutes of aspiration time was required. Remaining small bubbles of heavy silicone oil were collected from the retinal surface with a standard fluid needle. Overall, removal of the heavy silicone oil was uncomplicated.

The relatively high rate of intraoperative or postoperative redetachment may be related to the selection of the patients. A high percentage of patients had previous unsuccessful vitreoretinal surgeries with silicone oil tamponade. For these eyes, 3 months of tamponade with heavy silicone oil may be not sufficient. For safety reasons, however, we had to remove the heavy silicone oil after 3 months.

Six (18%) eyes in our series had postoperative IOPs of at least 25 mmHg, occurring as early as the first postoperative day. Two aphakic eyes had an increased IOP as the result of complete silicone oil tamponade of the anterior chamber due to overfilling. Removal of the silicone oil from the anterior chamber normalized the IOP immediately. The other four eyes were receiving antiglaucoma medications for at least 2 to 6 weeks to control the IOP. Two of these eyes had an increased IOP during the period of heavy silicone oil tamponade and two eyes after the exchange of heavy silicone oil with standard silicone oil. In our series, the incidence of IOP increase is in the same range of those previously reported.[3,11,44–46]

Our study had several limitations. One limitation was the lack of a control group. Therefore, no definite conclusions regarding the advantages of heavy silicone oil are possible. However, pilot studies like our prospective study are necessary before planning a prospective, randomized clinical trial. Based on the results of this study, we are planning a prospective

randomized controlled study to compare heavy silicone oil and standard silicone oil. Another limitation is the short follow-up period. The period of tamponade with heavy silicone oil was limited in this study to 3 months because of possible side effects. Further studies are needed to evaluate the safety of heavy silicone oil as tamponade for periods longer than 3 months.

In summary, this prospective study shows that heavy silicone oil (Oxane HD) can be used as an effective endotamponade in complicated retinal detachment and to provide retinal support in the inferior quadrants for at least 3 months. The retinal reattachment rate under heavy silicone oil appeared to be higher than in previous studies. Complications are similar to those reported with conventional silicone oil.[37,45–48] In particular, the incidence of emulsification was not increased as compared with conventional silicone oil with a similar viscosity. Based on our experiences in this study, we are planning a prospective, randomized, controlled clinical trial to compare heavy silicone oil and standard silicone oil in cases of complicated retinal detachment with involvement of the inferior quadrants.

Key words: retinal detachment, retinal tamponade, silicone oil, vitrectomy, vitreous substitute.

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