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Anatomical and Functional Results of Endotamponade with Heavy Silicone Oil – Densiron® 68 – in Complicated Retinal Detachment

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Key Words

Retinal detachment · Endotamponade, heavy silicone oil · Densiron® 68

Abstract

Background: High-density silicone oils are newly developed long-term tamponade agents for the treatment of complicated retinal detachment in the inferior retina. Previous studies describe satisfying anatomical and functional results. In this study we examined the largest cohort so far for a 9-month follow-up and performed a comparison to conventional silicone oil. **Methods:** Our study documents results and adverse effects after vitreoretinal surgery and endotamponade with Densiron® 68 in 99 cases of complicated retinal detachment. A 9-month follow-up was performed. Data of 21 patients with intraocular conventional silicone oil tamponade in complicated retinal detachment were retrospectively analyzed and served as control. **Results:** Anatomical success was achieved in 78 of 89 eyes (87.6%) with completed follow-up; visual acuity did not change significantly (from mean preoperative logMAR 1.88 to postoperative logMAR 1.96 ($p = 0.9$)). Compared to control a higher ana-

tomical success but a similar number of adverse effects were observed with heavy silicone oil in vitreous. Nevertheless, patients who received Densiron 68 twice due to redetachment showed a significantly higher rate of intraocular inflammation with the tamponade agent in situ. **Conclusion:** Our results support the hypothesis of Densiron 68 as potent tamponade agent for complicated retinal detachment in the inferior retinal segments especially in eyes where a previous operation failed.

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Introduction

The well-established tamponade agents such as silicone oil or gas provide good support in cases of complicated retinal detachment. Nevertheless, the results in eyes where pathology is located inferiorly, especially in the presence of proliferative vitreoretinopathy (PVR) that has a propensity to occur in the inferior retina, are still dissatisfactory [1–4]. Other substances, for example perfluorocarbon liquids, that are able to sink due to their high specific gravity can only be used intraoperatively or for short-term application because of their retinotoxicity, increased postoperative inflammation reactions and dispersion [5–10]. The search for a biocompatible heavy

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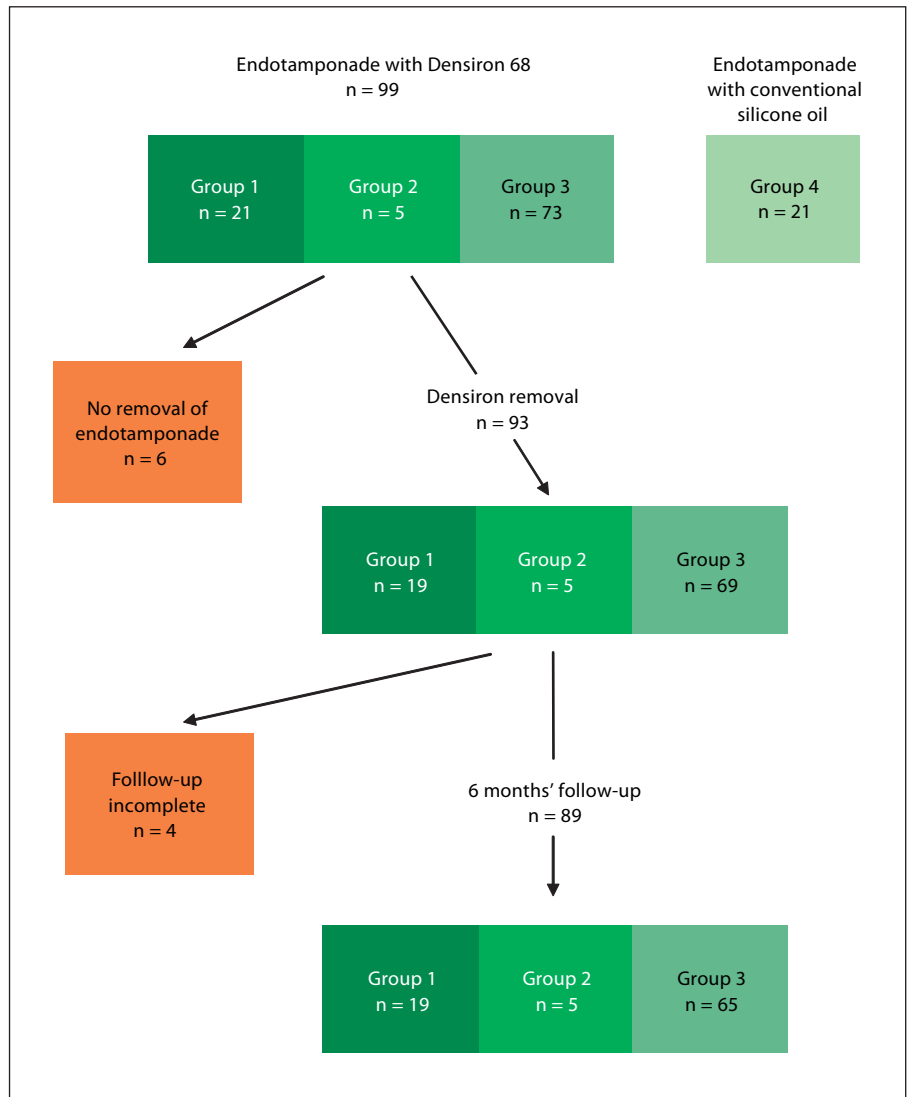


Fig. 1. Overall view of patient numbers and groups.

long-term tamponade led to the development of mixtures of semifluorinated alkanes and silicone oil, so-called heavy silicone oils [11, 12]. Densiron® 68 (Geuder AG, Neu-Ulm, Germany), a mixture of perfluorohexyloctane (F_6H_8) and polydimethylsiloxane with a specific density of 1.06 g/cm^3 fulfills this profile and is available for the treatment of inferior or posterior retinal detachment in cases of PVR, proliferative diabetic retinopathy or giant retinal tears. Wong et al. [13] described 42 patients with Densiron 68 treatment. They achieved an anatomical success rate of 93% including all necessary reoperations. Clinically significant dispersion or inflammatory reactions were not observed [13]. Recently we reported our experiences with Densiron 68 as intraocular tamponade in 48 eyes. That report focused on results of a 3-month

follow-up in patients with previously unsuccessful retinal detachment surgery [14]. The initial anatomical success rate was 45.8% and increased to 91.7% (44/48 eyes) with further interventions. Now we describe the so far largest study population (99 cases) with complicated inferior retinal detachment and heavy silicone oil treatment. To examine whether the short-term results that had been published recently by us show a stable course and whether late adverse effects may occur, we included these data in the here presented study but prolonged the observation period up to 9 months. In addition, eyes without any preceding operation on the posterior eye, cases with a second heavy oil tamponade and a historical control group with conventional silicone oil (polydimethylsiloxane, 5000cs) treatment were included as well.

Table 1. Preoperative characterization of the study population

	Group 1 (n = 21)	Group 2 (n = 5)	Group 3 (n = 73)	All (n = 99)
Age, years	60 (13–85)	73 (63–84)	65 (17–82)	64 (13–85)
Diagnosis				
Retinal detachment	21			21
Retinal redetachment		3	33	36
Persisting detachment/redetachment with intraocular tamponade		2	39	41
Retinal detachment and AMD			1	1
Primary pseudophakic retinal detachment	3	1	16	20
Primary traumatic retinal detachment			7	7
Localization of retinal detachment				
Inferior	4	2	34	40
Inferior to superior	9	1	21	31
Total	7		14	21
Central	1	2	1	4
Inferior and central			3	3
PVR grading				
None	3	1	15	19
B			1	1
<CA3/<CP3	1/5	1/2	4/23	6/30
CA3–CA5/CP3–CP5	1/6	0/1	3/18	4/25
>CA5/>CP5	3/2	0/0	3/6	6/8
High myopia (>–7 dpt)	4	1	7	12
PDR	5	0	8	13
Glaucoma	2	0	10	12

Figures in parentheses indicate ranges. AMD = Age-dependent macular degeneration; PDR = proliferative diabetic retinopathy. Group 1: patients without previous retinal surgery; group 2: patients with repeated Densiron 68 tamponade; group 3: patients with previous retinal detachment surgery.

Methods

Study Design and Subjects

This prospective interventional case study includes all 99 eyes that had an indication for the treatment with high-density silicone oil and received intraocular Densiron 68 tamponade between October 2003 and December 2004 in our department (fig. 1). Additionally data of 21 patients with inferior or posterior complicated retinal detachment that had been operated for the first time on the posterior eye and had got conventional silicone oil (5000cs) as intraocular tamponade recently before Densiron 68 tamponade was established in our department (between April and October 2003) were retrospectively analyzed. All series were performed by the same surgeon (K.E.). The patients were informed about the new character of Densiron 68.

Intervention

The surgical procedures of the vitrectomy, Densiron 68 injection and its removal 3 months later were carried out as recently described by us [14]. A standard 3-port pars plana vitrectomy was performed; membrane peeling, retinotomies or relaxing retinectomies were added if necessary. Thereafter, Densiron 68 was in-

stilled as endotamponade. The removal was planned 3 months after instillation.

Postoperative Procedure/Follow-up

All patients were controlled on day 1 and 6 weeks, 3 months and 6 months after the Densiron 68 removal. At each control the patients underwent the examination of visual acuity, Goldmann applanation tonometry and slit lamp biomicroscopy with indirect ophthalmoscopy. All unscheduled appointments, complications or additional interventions were documented.

Group Formation

To enable an interpretation of the data depending on the case history we separated the cases in three main groups: group 1 includes 21 patients with retinal detachment in the inferior circumference without surgical retinal interventions before heavy silicone oil tamponade; group 2 consists of 5 patients who received heavy silicone oil twice because of retinal redetachment in the inferior or central parts of the retina; group 3 contains patients with retinal redetachment who received heavy silicone oil after previous retinal surgery had failed (n = 73). The 21 patients with primary conventional silicone oil treatment are summarized in

Table 2. Summarized preoperative surgical interventions of the entire study population

	Group 1 (n = 21)	Group 2 (n = 5)	Group 3 (n = 73)	All (n = 99)
Preoperative lens situation				
Phakic	10	0	8	18
Aphakic	1	0	5	6
Pseudophakic	10	5	60	75
Previous surgical interventions in the posterior segment	0	2.0	2.0	1.6
Previous scleral buckling surgery	0	2	46	48
Previous standard silicone oil tamponade	0	3	51	54

Group 1: patients without previous retinal surgery; group 2: patients with repeated Densiron 68 tamponade; group 3: patients with previous retinal detachment surgery.

Table 3. Anatomical results and incidence of complications during Densiron 68 endotamponade

	Group 1 (n = 21)	Group 2 (n = 5)	Group 3 (n = 73)	All (n = 99)
Reattachment rate	15 (71)	3 (60)	54 (74)	72 (73)
Retinal redetachment	6	2	19	27
Inferior	2		10	
Superior	1	1	6	
Central	2	1	2	
Total	1		1	
Complications				
None	2 (9.5)	0	23 (31.5)	25
Emulsified oil, corneal and lenticular bloom	8 (38.1)	2 (40)	21 (28.8)	31
Raised IOP	5 (23.8)	0	15 (20.5)	20
Inflammation	5 (23.8)	4 (80)	8 (11)	17
New membrane formation	3 (14.3)	0	7 (9.6)	10
Keratopathy	2 (9.5)	1 (20)	1 (1.4)	4
Hypotony	1 (4.7)	0	0	1

Figures in parentheses indicate percentages. Raised IOP (>21 mm Hg) = temporary or chronic elevated IOP; new membrane formation = new sub- and epiretinal membrane formation; keratopathy = temporary or chronic corneal affection; hypotony = temporary or chronic hypotony. Group 1: patients without previous retinal surgery; group 2: patients with repeated Densiron 68 tamponade; group 3: patients with previous retinal detachment surgery.

group 4 and served as control to group 1. Both, group 1 and group 4, are comparable in age, localization of retinal detachment and preexisting ophthalmological diseases such as PVR, proliferative diabetic retinopathy, high myopia and glaucoma. For description of PVR the modified classification of Machemer et al. [15] was used. High myopia was defined as myopia more than -7 dpt.

The preoperative data of the study population are given in tables 1 and 2.

Definition of Anatomical Success and Complications

Anatomical success was achieved when the retina was reattached completely or only a stable peripheral redetachment

(posterior to the encircling band, if extant) occurred. Elevated intraocular pressure (IOP) was defined as pressure >21 mm Hg, hypotony as an IOP <5 mm Hg. Keratopathy includes bullous or band keratopathy, stromal edema or circumscribed opacities.

Statistical Analysis

Data were analyzed using SPSS 11.0 for Windows. Comparisons of binomial proportions were calculated using Fisher's exact test. Group differences were calculated by ANOVA. Variables were checked for normal distribution using the Kolmogorov-Smirnov test. Comparing differences in mean value and standard

deviation of variables during follow-up, a two-tailed paired t test was performed. Statistical significance was considered to be present at the 5% level.

Results

The Densiron endotamponade was removed in 93 cases after a mean time of 96 days (range 8–351). Eighty-nine patients completed the 6-month follow-up after oil removal. Two patients rejected the oil removal for personal reasons, 1 patient with a visual acuity of no light perception rejected the oil removal because of the bad prognosis, 3 patients died before removal of non-tamponade-associated reasons. The dropout of 4 other patients after oil removal was due to personal reasons.

Anatomical Results during Intraocular Oil Tamponade

At surgery complete reattachment was achieved in 97 of 99 cases. In 1 eye with severe traumatic destruction of the eye and in another with PVR grade CA12 and multiple preoperation, the trial of intraoperative reattachment failed. During Densiron 68 tamponade, a retinal redetachment occurred in 27 eyes.

The results and adverse effects subdivided into the three groups are shown in table 3 and figure 2.

Comparison of Eyes with Primary Heavy Silicone Oil Tamponade to Control

Anatomical success was achieved in 15 of 21 eyes (71%) with heavy silicone oil in situ and in 9 of 21 eyes (53%) with conventional silicone oil treatment. This difference is not significant. The distribution of the localization of retinal redetachment shows a high rate of renewed inferior detachment in eyes with conventional silicone oil in vitreous (8 of 12 eyes). As it is shown in table 4, the complication rate does not differ significantly between group 1 and group 4.

Anatomical Results after Removal of Densiron 68

The following analysis includes the 89 of initially 99 cases that completed the 6-month follow-up after the Densiron 68 had been removed.

Retinal Reattachment

Immediately after Densiron removal the retina was attached in 82 of the 89 eyes that completed the follow-up (92%). During the follow-up the retina stayed attached in 57/89 eyes (64%). Single redetachment occurred in 28/89

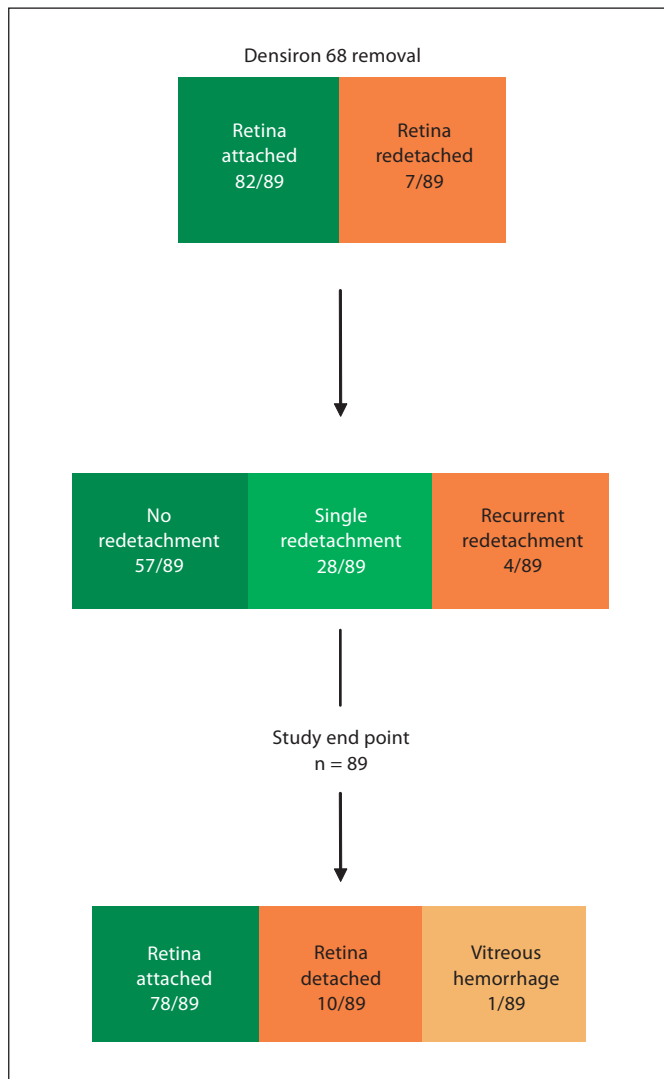


Fig. 2. Anatomical results (89 of 99 patients with completed follow-up).

eyes, 4/89 eyes showed recurrent retinal detachment. An average of 1.62 reoperations on the posterior eye was performed. This number includes heavy silicone oil removal because additional retinal manipulations were performed simultaneously in some cases to achieve or to stabilize retinal reattachment. Further surgeries involved conventional silicone oil, second heavy oil or gas tamponade. Nine months after initial surgery, anatomical success was achieved in 78 eyes (87.6%), of which 50 (56.2%) showed a completely attached retina without any tamponade agent in situ. In 1 eye the retinal situation could not be estimated due to recurrent vitreous hemorrhage. In 45 of 89 eyes, no recurrent retinal detachment after initial sur-

Table 4. Comparison of group 1 with group 4 during 3 months of intraocular heavy or standard silicone oil tamponade

	Group 1 (heavy silicone oil tamponade, n = 21)	Group 4 (control, n = 21)	Difference between groups
Preoperative state			
Age	60 (range 13–85)	62 (range 14–90)	
PVR	18	17	
PDR	5	6	
Myopia	4	2	
Glaucoma	2	3	
Localization of retinal detachment			
Inferior	4	3	
Inferior and superior	9	8	
Total	7	6	
Central	1	2	
Inferior and central	0	2	
Preoperative visual acuity	2.77 ± 1.32	2.86 ± 1.29	p = 0.82
Postoperative visual acuity	2.36 ± 1.23	1.84 ± 1.04	p = 0.15
Significance of changes	p = 0.125	p < 0.0001	
Persisting detachment/ retinal redetachment			
Central	6 (29%)	12 (57%)	p = 0.059
Inferior	2	3	
Superior	2	8	
Superior	1	0	
Total	1	1	
Complications			
Raised IOP	5	5	
Emulsified oil	8	5	p = 0.235
Inflammation	4 ¹	1 ¹	p = 0.092
	1 ²	1 ³	
New membrane formation	3	3	
Keratopathy	2	2	
Hypotony	1	0	

PDR = Proliferative diabetic retinopathy. Raised IOP (>21 mm Hg) = temporary or chronic elevated IOP; new membrane formation = new sub- and epiretinal membrane formation; keratopathy = temporary or chronic corneal affection; hypotony = temporary or chronic hypotony.

¹ Temporary moderate postoperative inflammation.

² Preexisting chronic intermedial uveitis.

³ Epidemic keratoconjunctivitis.

ger occurred, in 24 of them previous treatment with conventional oil tamponade had failed. In all eyes with a second heavy oil tamponade (group 2) the retina was completely reattached. These results are summarized in table 5.

In 19 cases new retinal breaks developed during the observation period. In these eyes the proportion of retinal redetachment was highest (p = 0.001). At study end point, anatomical failure was due to re proliferation processes with sub- and intraretinal fibrosis in 7 eyes, formation of new retinal breaks (2 eyes) or both (1 eye).

New Membrane Formation

New sub- and epiretinal membrane formation occurred in 10 eyes (9 with preexisting PVR) during intraocular oil tamponade and in 33 eyes (29 with preexisting PVR) after oil removal. The rate of new membrane development was significantly elevated in eyes with preexisting PVR (p < 0.05) and proliferative diabetic retinopathy (p < 0.01).

Emulsified Oil

After heavy oil injection the oil was found in the anterior chamber in 29 eyes; 14 of them showed emulsification droplets or pseudohypopyon. At the final control 12

Table 5. Results and complications after removal of Densiron 68

	Group 1 (n = 19)	Group 2 (n = 5)	Group 3 (n = 65)	All (n = 89)
Duration of heavy tamponade, days	85 (33–126)	70 (29–108)	104 (8–400)	95 (8–351)
Number of reoperations on the posterior eye	1.53 (1–3)	1.8 (1–3)	1.63 (1–4)	1.62 (1–4)
Number of repeated intraocular tamponade	0.74 (0–2)	0.8 (0–2)	0.71 (0–2)	0.71 (0–2)
Anatomical situation 6 months after removal of heavy oil:				
reattachment				
Without intraocular tamponade	8	3	39	50
Standard silicone oil in vitreous	5	2	20	27
With heavy silicone oil in vitreous	0	0	1	1
Number of anatomically successful cases	13 (68.4%)	5 (100%)	60 (92.3%)	78 (87.6%)
Retinal redetachment	5 (26%)	0	5 (7.7%)	10 (11.2%)
Superior	1			1
Central	3		3	6
Total	1		2	3
Visual acuity				
Preoperative mean logMAR	2.64 ± 1.32	1.68 ± 1.02	1.68 ± 1.03	1.88 ± 1.15
Postoperative mean logMAR	2.20 ± 1.45	1.57 ± 0.81	1.92 ± 1.21	1.96 ± 1.24
Significance of changes	p = 0.17	p = 0.78	p = 0.13	p = 0.9
Complications				
None	4	0	9	13
Emulsified oil, corneal and lenticular bloom	9	5	44	58
New membrane formation	6	4	23	33
Redetachment during follow-up	8	1	23	32
Raised IOP	5	1	18	24
Inflammation	7	1	11	19
Keratopathy	6	1	10	17
Hypotony	3	1	10	14

Figures in parentheses are ranges, or percentages where indicated. Raised IOP (>21 mm Hg) = temporary or chronic elevated IOP; new membrane formation = new sub- and epiretinal membrane formation; keratopathy = temporary or chronic corneal affection; hypotony = temporary or chronic hypotony. Group 1: patients without previous retinal surgery; group 2: patients with repeated Densiron 68 tamponade; group 3: patients with previous retinal detachment surgery.

out of 50 eyes without any tamponade agent in vitro showed remaining tiny oil droplets in the anterior chamber. Significant emulsification on the epiretinal surface could not be found.

Functional Results after Removal of Densiron 68

Visual acuity did not change significantly from preoperative mean logMAR 1.88 ± 1.15 to 1.96 ± 1.24 nine months later ($p = 0.9$). Ambulatory vision of 1/50 (20/1,000) or better could be preserved in 55 eyes (61%). In anatomically successful cases without tamponade agent in vitreous at study end point, visual acuity was significantly higher (mean logMAR 1.53) than in eyes with retinal reattachment but silicone oil left in situ (mean logMAR 2.21) or in eyes that showed retinal redetachment (mean logMAR = 3.20; $p < 0.0001$). In 33 of 89 eyes (37%) an improvement of 2 Snellen lines could be achieved.

Complications

Raised IOP

With heavy silicone oil in vitreous 20 eyes developed raised IOP, 4 of them with preexisting glaucoma. The rate of temporarily raised IOP in patients with silicone oil in the anterior chamber was significantly higher than in those without ($p = 0.04$). After removal of heavy oil IOP normalized in 9 eyes; 13 further patients developed temporarily raised IOP. Secondary glaucoma occurred in 7 eyes with multiple preoperation (group 3). Mean IOP after oil removal was 13.1 ± 5.8 mm Hg. It remained constant throughout the observation period without significant differences between the three groups.

Intraocular Inflammation

A mild to moderate inflammatory activity of the anterior segment during Densiron 68 tamponade was observed in 13/99 eyes. Four eyes developed a severe intra-

ocular inflammatory reaction with fast regression after removal of Densiron 68 and anti-inflammatory therapy (topical steroid application). In 1 eye (group 1) postoperative moderate inflammation occurred after traumatic retinal detachment and a simultaneous tuberculous infection of the eye; in another eye (group 3), recurrent chronic uveitis intermedia was described preoperatively. Four of the 5 eyes (80%) that received Densiron 68 twice showed moderate (2 eyes) to severe (2 eyes) inflammation with the tamponade agent in the vitreous. Compared to groups 1 and 3 this proportion of inflammation is significantly higher ($p < 0.005$). After removal of Densiron 68 the inflammatory process completely resolved in these eyes.

Keratopathy, Hypotony and Cataract Formation

With heavy silicone oil in situ, 1 eye developed a total corneal decompensation that made a keratoplasty necessary. In this eye a decompensation of IOP during the conventional silicone oil tamponade immediately before heavy endotamponade and a preexisting primary open-angle glaucoma had been described. After removal of heavy oil, band keratopathy occurred in 2 cases. In 1 of these eyes a keratoplasty had previously been performed. In 2 further eyes a total stromal edema coincided with phthisis bulbi. Mild to moderate stromal edema occurred postoperatively in 12 eyes but resolved within a few weeks. Neither silicone oil in the anterior chamber nor the lens situation influenced the incidence of keratopathy in our study population significantly. Phthisis bulbi was observed solely in group 3 (eyes with former unsuccessful retinal surgery) in 7 cases. Six months after Densiron 68 removal, hypotony was present in 3 eyes.

In all phakic eyes cataract formation could be observed and phacoemulsification was performed if useful.

The number and distribution of adverse effects among the different groups are shown in tables 3 and 5.

Discussion

Complicated retinal detachment is successfully treated with conventional silicone oil combined with advanced vitreous surgical techniques. In cases of PVR, the anatomic success rate varies between 30 and almost 83% [16]. Nevertheless, the postoperative success is often complicated by persisting or newly developing inferior detachment that often acquires a long-term internal tamponade with silicone oil. The higher specific density of Densiron 68 and other heavy silicone oils theoretically

permits a more effective tamponade of the inferior and posterior retinal areas.

In our examination retinal reattachment could be achieved in 98% after initial surgery. Six months after removal of Densiron 68, an anatomical success rate of 87.6% was obtained. Fifty eyes (64%) without any tamponade agent in situ showed reattached retinas at the study end point. Compared to our recent publication with a reattachment rate of 91.7% (44/48 eyes) 3 months after Densiron 68 removal the percentage of reattached retina remains stable [14]. The ratio of successfully treated eyes without persisting endotamponade was even improved. Anatomical success was not as high as recently described by Wong et al. [13]. Nevertheless, considering the more complicated preoperative conditions of most of our cases, the results in this study are satisfying. Wolf et al. [17] reported similar results in 33 eyes with a comparable retinal status at baseline. They used Oxane HD (specific density 1.03 g/cm³), a solution of polydimethylsiloxane and a mixed fluorinated and hydrocarbonated olefin (RMN3) as heavy tamponade agent. Twelve months after initial surgery the retina was attached in 18 eyes (54%) without intraocular tamponade. In 13 further eyes the retina was reattached completely with conventional silicone oil in situ. In our study most failures were due to reproliferation and formation of new retinal breaks. The anatomical results in eyes with multiple unsuccessful previous operations (group 3) and in eyes that received Densiron 68 twice (group 2) are encouraging.

In addition, a higher percentage of completely attached retinas in eyes with heavy versus conventional silicone oil in situ was observed. The better support on the inferior retinal areas can be deduced from the location of retinal redetachment. Inferior areas are affected in 2 out of 6 (group 1: 33%) and 8 out of 12 eyes (group 4: 66%), respectively, as shown in table 4.

In contrast to the results reported by Wong et al. [13], mean visual acuity did not improve in the entire study population. It solely showed a slight increase in groups 1 and 2. Nonetheless, the higher preoperative mean logMAR that reflects the worse starting position in our study should be considered. After all an improvement of 2 or more Snellen lines was obtained in 33 eyes (37%). The preservation of ambulatory vision could be achieved in 40 eyes that underwent previously unsuccessful retinal surgery. The better visual outcome shortly after surgical intervention in patients with standard silicone oil in situ (although the difference in median postoperative logMAR is insignificant) should be regarded attentively for a longer follow-up time. Possibly the persisting retinal

distances lead to further retinal redetachment and resultant visual decrease in eyes with standard silicone oil treatment.

Most adverse effects such as hypotony, raised IOP and bullous or band keratopathy are well-known complications of standard silicone oil and do not differ clinically significantly in number and severity [1, 16, 18, 19]. Despite the fact that the good intraocular tolerance of Densiron 68 recently described by Wong et al. [13] could be confirmed in this study by the comparison of the number of adverse effects with standard versus heavy silicone oil in vitreous in most cases, the tendency towards a more frequent moderate intraocular inflammation with Densiron 68 in situ should be carefully observed in future studies. Because the inflammation rate was extremely high in group 2, a second intraocular tamponade with Densiron 68 in the same eye should be considered critically. During and after Densiron endotamponade, a high percentage of emulsified oil in the anterior chamber was observed as well. One should consider that the largest

proportion of our study population had been operated previously and a high percentage of eyes got its second or third endotamponade and had therefore been damaged before. This may explain the higher percentage of complications compared to the clinical experiences with standard silicone oil. Comparing eyes with first endotamponade (groups 1 and 4), a significant difference between standard and heavy silicone oil could not be observed (table 4). These results must be considered carefully because of the small study population and the retrospective character of our control group.

Clinically significant adverse effects after oil removal that seemed to be specific for heavy silicone oil could not be ascertained.

In summary, these results support the hypothesis of Densiron 68 as potent tamponade agent for complicated retinal detachment in the inferior retinal segments especially in eyes where a previous operation failed. The clinical relevance of adverse effects has to be evaluated in further prospective controlled trials.

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