

# Ocular tolerance and efficacy of short-term tamponade with double filling of polydimethylsiloxane and perfluoro-n-octane

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**Objective:** The aim of the study was to evaluate the ocular tolerance and efficacy of double filling with perfluoro-n-octane (n-C8F18) (PFO) and polydimethylsiloxane (PDMS) as a temporary vitreous substitute in patients with retinal detachment complicated by proliferative vitreoretinopathy (PVR).

**Material and methods:** Tamponade was performed in 30 eyes of 30 patients by double filling with 30% PFO and 70% PDMS for an average of 23 (standard deviation 2.2) days. The follow-up visits were scheduled 1 week, 1 month, and 3 months after surgery. The main outcome measures were visual acuity, intraocular pressure (IOP), PVR re-proliferation, and electrophysiological parameters.

**Results:** The primary success rate was 80% (24/30). Fourteen patients (46.7%) had a postoperative improvement in visual acuity, 12 patients (40.0%) maintained their preoperative visual acuity, and four patients (13.3%) experienced a reduction in visual acuity. The mean postoperative IOP was 19.7 mm Hg (11–32 mm Hg); nine cases (30.0%) developed an IOP increase that was treated with topical drops and/or systemic carbonic anhydrase inhibitors. The electroretinogram (ERG) and the bright flash electroretinogram (bf ERG) parameters showed a statistically significant difference of means between 4- and 8-week follow-up visits.

**Conclusion:** Our experience with double filling in selected cases of retinal detachment has been positive. No electroretinographic signs of retinal toxicity and a low incidence of PVR re-proliferation were observed.

**Keywords:** double filling, proliferative vitreo-retinopathy, perfluoro-n-octane, polydimethylsiloxane, retinal detachment, retinal detachment electrophysiology

## Introduction

Double filling endotamponade with silicone oil and perfluorocarbon liquids can be used as short-term intraocular tamponade after pars plana vitrectomy (PPV) for the treatment of complicated rhegmatogenous retinal detachment (RRD).<sup>1</sup>

The presence of perfluorocarbon liquids reduces empty space in the inferior retina, where the concentration of serum components and the migrated pigmented retinal epithelium (RPE) cells are localized in the presence of “light tamponades” (gas or oil), thereby minimizing the risk of developing proliferative vitreoretinopathy (PVR) in the lower retina.<sup>1,2</sup>

The retinal tolerance of perfluorocarbon liquids is still controversial because their highly specific gravity or excitotoxicity due to aqueous exclusion can potentially cause mechanical damage to the retina when used as a short-term vitreous substitute.<sup>3</sup> We evaluated double filling with perfluoro-n-octane (PFO) 70% (n-C8F18, Fluoron GmbH,

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Ulm, Germany) and polydimethylsiloxane (PDMS) 30% (RS OIL 1000 centistokes, AL.CHI.MI.A. srl) as a short-term intraocular tamponade after PPV for the treatment of complicated RRD. PFO was chosen due to its purity, its chemical and physical inertness, and its lack of toxicity.<sup>4</sup> Safe ocular use of PFO has already been described.<sup>5</sup> Only 30% ocular volume was filled in order to avoid the formation of meniscus in the macular area and to minimize the weight of the PFO bubble on the retina.

The aim of the present study was to evaluate the ocular tolerance and efficacy of this double filling on human eyes. The main outcome measures were electrophysiological parameters, visual acuity, intraocular pressure (IOP), and PVR incidence after removal of tamponade.

## Material and methods

Approval for this study was obtained from the central office of the Research and Ethics Committee of the hospital according to the tenets of the Declaration of Helsinki. Fully informed consent was obtained before surgery in all cases.

This study was a prospective, interventional case series of 30 eyes of 30 patients (15 males and 15 females) affected by complicated retinal detachment with PVR (D1–D2)<sup>6</sup> who underwent PPV with an endotamponade of 30% PFO and 70% PDMS.

In all patients, a best-corrected Snellen visual acuity (BCVA) converted into logarithm of the minimum angle of resolution (logMAR), IOP, anterior segment evaluation with slit lamp, and fundus oculi examination were performed. The same surgeon operated on all the patients.

The follow-up visits were scheduled 1 week, 1 month, and 3 months after surgery. We also performed electroretinographic evaluations (electroretinogram [ERG] and bright flash electroretinogram [bfERG]) in 20 of the 30 eyes 2 weeks and 8 weeks after removal of the double fill tamponade.

## Surgical technique

After conjunctival peritomy, a standard three-port PPV with a 20-gauge system was performed. Posterior vitreous detachment was induced when not already present, using aspiration with the vitrectomy handpiece, and the posterior hyaloid was removed. The vitreous cavity was expanded with injection of the perfluorocarbon liquid (PFCL) perfluorodecalin (HPF10, AL.CHI.MI.A. srl, Ponte S.Nicolò, Italy) over the posterior pole to obtain retinal flattening. The vitreous base was carefully shaved over 360° and all the membranes were dissected. Epiretinal membrane peeling was performed in all cases, whereas peripheral retinectomies were performed in 21 out

of 30 cases in order to mobilize the retina and relieve the traction. Argon laser endophotocoagulation was performed with a 20-gauge illuminated probe in order to obtain a barrage around the retinal breaks and rhegmatogenous retinal degenerations. PFCL was then removed and the vitreous cavity was expanded with air. At this time, PFO 30% and PDMS 70% were injected one after the other under air infusion. The 30%–70% filling was estimated intraoperatively and was not preoperatively calculated. No scleral buckle was used in those cases.

After an average of 23.4 (standard deviation [SD] 2.2) days (range 19–27 days), the double fill tamponade was removed and the cataract surgery was performed at the same time in 17/22 phakic patients.

## Electroretinographic examination

ERGs were recorded using standard electrophysiological methods. Pupils were dilated with tropicamide 1% drops 30 minutes before recording. The electrical activity of the retina was evoked with a stroboscopic full-field illumination.

Electrofunctional evaluations were carried out with the following technique. After corneal anesthesia with benoxinate drops, the ERG-Jet contact electrode was positioned in the eye that previously underwent vitreoretinal surgery. The ground electrode was a skin silver chloride fixed at the front. The ERG was recorded using International Society for Clinical Electrophysiology of Vision methodology with white flashes at a frequency of 0.5 Hertz.<sup>7</sup> White flashes of 1.7 Cd/sm/sec were applied every 5 seconds in the Gauzfeld dome after photopic adaptation. Five readings amplified 2000 times and with a 0.1–500 Hz frequency band were averaged with a signal analyzer.

The bf ERG evaluation was carried out using the above methodology at 53.8 cd/sm/sec after 20 minutes of dark adaptation (ie, scotopic adaptation).

Statistical comparisons (Systat statistical packages, Evanston, IL, USA) were made using Spearman's rank correlation (iris fluorescein angiography stage) and paired *t*-test. A random probability of <0.05 was considered statistically significant.

## Results

### Preoperative data

A total of 30 eyes in 30 patients (15/15 male/female) underwent vitrectomy with double filling (with 70% PDMS and 30% PFO) over a 12-month period in a single institution. The descriptive statistics for the patients' preoperative status are summarized in Table 1. The mean age was 54.79 years (range 24–83 years).

**Table 1** Demographics data of patients

Patient	Age	Gender	Preoperative visual acuity (LogMAR)	Preoperative IOP	Lens	Other	High myopia
G/A	24	M	3,0	16	Clear	Posterior break	x
S/M	83	M	3,0	14	Cortical opacities	Post-traumatic RD	
T/T	30	M	2,0	4	Pseudophakia	Posterior break	x
CM/D	77	F	2,0	13	Initial nuclear sclerosis	Post-traumatic RD	
G/B	67	F	3,0	16	Pseudophakia	Posterior break	
A/P	50	F	1,0	17	Nuclear sclerosis	Post-traumatic RD	
V/V	57	F	2,0	14	Nuclear sclerosis	Posterior break	x
F/T	59	M	3,0	12	Pseudophakia		
T/F	25	F	3,0	18	Clear	Posterior break	x
E/G	82	M	2,0	15	Post-traumatic lens dislocation	Post-traumatic RD	
L/L	72	M	3,0	14	Clear	Post-traumatic RD	
G/M	65	M	3,0	4	Cortical opacities		
A/B	42	M	2,0	13	Pseudophakia	Posterior break	x
G/C	60	M	2,0	16	Clear		
G/P	47	M	3,0	17	Pseudophakia	Post-traumatic RD	
G/V	43	M	3,0	18	Nuclear sclerosis	Posterior break	x
S/P	64	M	1,0	18	Nuclear sclerosis	Post-traumatic RD	
D/B	70	M	3,0	14	Pseudophakia	Post-traumatic RD	
C/A	41	M	3,0	12	Clear	Posterior break	x
N/C	37	M	3,0	10	Initial nuclear sclerosis	Posterior break	x
B/T	67	F	3,0	18	Clear	Posterior break	
S/E	49	F	2,0	10	Clear	Post-traumatic RD	
G/P	57	F	3,0	23	Pseudophakia	Post-traumatic RD	
A/A	50	F	3,0	17	Clear		
L/M	70	F	1,0	17	Nuclear sclerosis	Post-traumatic RD	
G/V	37	F	2,0	16	Nuclear sclerosis	Posterior break	x
N/S	24	F	3,0	15	Clear		x
G/S	83	F	3,0	16	Pseudophakia		
M/D	55	F	3,0	18	Clear	Post-traumatic RD	
F/F	52	F	2,0	15	Nuclear sclerosis	Posterior break	

**Abbreviations:** IOP, intraocular pressure; RD, retinal detachment.

The median visual acuity was 2.50 logMar and the median preoperative IOP was 14.7 mm Hg (range 4–23 mm Hg). Eight patients were pseudophakic (26.7%) and 11 patients had mild lens opacity (36.7%). One patient had a post-traumatic dislocation of the lens (3.3%) and therefore underwent phacoemulsification with intraocular lens implantation at the time of vitrectomy. A total of 12 patients had a posterior break (40.0%) and 10 subjects had high myopia (33.3%). Twelve patients had post-traumatic retinal detachment (40.0%).

### Before removal of double fill tamponade

The mean IOP was 21.7 mm Hg (range 10–40 mm Hg). In 16 cases, IOP increased and was treated with topical or systemic therapy (53.3%). In two patients, we observed small droplet emulsification in the inferior chamber or on the surface of the double filling bubble in the vitreous chamber (6.7%). Eleven patients (36.7%) developed cataract. These complications are reported in Table 2.

### After removal of double fill tamponade

Double filling was exchanged with balanced salt solution (BSS) in 20 eyes (67%), with PDMS in six eyes (20%), and with air in four eyes (13%). The primary success rate, without further procedures, was 80% (24 out of 30). Six cases developed epiretinal membrane (20.0%) in the superior retinal quadrants. These eyes underwent peeling of epiretinal membranes at the time of double filling removal, after which time a tamponade of 1000 cSt silicon oil was added.

### Functional outcome

Two months after removal of the tamponade double filling (Table 3), the mean visual acuity was 1.94 LogMar ( $P = 0.41$  *t*-test). Fourteen of 30 patients had an improvement in visual acuity postoperatively (46.7%), 12/30 patients maintained their preoperative visual acuity (40.0%), and 4/30 patients experienced a reduction in visual acuity (13.3%). The mean postoperative IOP was 19.7 mm Hg (SD 5.5 mm

**Table 2** Pre-double filling removal data

Patient	Age	Gender	Preoperative IOP	Lens	Double filling removal (days)	Complications (Pre-double filling removal)			
						PVR	IOP increase	Emulsion	Cataract
G/A	24	M	18	Clear	19	x	x		
S/M	83	M	19	Cortical opacities	27		x		x
T/T	30	M	10	Pseudophakia	23				
CM/D	77	F	15	Initial nuclear sclerosis	24	x	x		x
G/B	67	F	18	Pseudophakia	20				
A/P	50	F	27	Nuclear sclerosis	26		x	x	x
V/V	57	F	20	Nuclear sclerosis	23		x		x
F/T	59	M	32	Pseudophakia	21				
T/F	25	F	40	Clear	25		x		
E/G	82	M	17	Post-traumatic lens dislocation	26		x		
L/L	72	M	29	Clear	23	x	x		
G/M	65	M	11	Cortical opacities	23				x
A/B	42	M	25	Pseudophakia	21			x	
G/C	60	M	25	Clear	26				
G/P	47	M	24	Pseudophakia	27	x	x		
G/V	43	M	28	Nuclear sclerosis	23				x
S/P	64	M	24	Nuclear sclerosis	22	x	x		x
D/B	70	M	14	Pseudophakia	25				
C/A	41	M	30	Clear	21	x	x		
N/C	37	M	27	Initial nuclear sclerosis	23		x		x
B/T	67	F	18	Clear	27				
S/E	49	F	10	Clear	23				
G/P	57	F	32	Pseudophakia	24		x		
A/A	50	F	17	Clear	22				
L/M	70	F	17	Nuclear sclerosis	23				x
G/V	37	F	16	Nuclear sclerosis	23				x
N/S	24	F	25	Clear	25		x		
G/S	83	F	18	Pseudophakia	21				
M/D	55	F	15	Clear	20		x		
F/F	52	F	30	Nuclear sclerosis	26		x		x

**Abbreviations:** IOP, intraocular pressure; PVR, proliferative vitreoretinopathy.

Hg) (range 11–32 mm Hg); nine cases developed an increase in IOP that was treated with topical drops and/or systemic carbonic anhydrase inhibitors (30.0%). In three cases (10.0%), cystoid macular edema confirmed by ocular coherence tomography was observed.

### Electrophysiological outcome

Electrofunctional evaluations (ERG and bf ERG) were carried out in the 20/30 eyes (67%) in which the double tamponade was substituted for BSS (Tables 4, 5 and 6).

Mean ERG amplitudes 2 and 8 weeks after removal of the tamponade were 55.6 (SD 24.7) and 61.6 (SD 26.0), respectively. Mean amplitudes of bfERG 2 and 8 weeks after removal of double filling were 107.2 (SD 49.7) and 128.9 (SD 65.8), respectively. With both techniques, the difference of means was statistically significant (Tables 4, 5 and 6).

### Discussion

PVR can be defined as the growth and contraction of cellular membranes within the vitreous cavity and both retinal surfaces after RRD. This process, a frequent cause of failure after surgical therapy for RRD, may result in recurrent detachment by reopening otherwise successfully treated retinal breaks or creating new retinal breaks.<sup>8</sup> PVR is a dynamic biologic phenomenon with no currently available effective pharmacologic therapy.<sup>9</sup> Vitreal substitutes used as stabilizing substances that close the communication between the pre- and subretinal space minimize this proliferative phenomenon. PDMS is the first-choice vitreous substitute currently used for the treatment of retinal detachment complicated by PVR, multiple retinal tears, or giant retinal tears.

Chemically, silicone oil is generated by polymerization of dimethylsiloxane units or a low-molecular-weight cyclic

**Table 3** Postoperative data (3 months)

Patient	Age	Gender	Post-operative visual acuity (LogMAR)	Post-operative IOP	Complications		
					CME	IOP increase (medical therapy)	PVR
G/A	24	M	1,3	18			
S/M	83	M	3,0	16			
T/T	30	M	3,0	11			x
CM/D	77	F	3,0	27		x	
G/B	67	F	2,0	19			
A/P	50	F	1,0	18			
V/V	57	F	1,3	20		x	
F/T	59	M	3,0	16			
T/F	25	F	1,0	32		x	
E/G	82	M	2,0	18			
L/L	72	M	3,0	16			x
G/M	65	M	3,0	11	x		
A/B	42	M	3,0	27		x	
G/C	60	M	0,7	18			
G/P	47	M	2,0	19			x
G/V	43	M	1,0	18			
S/P	64	M	1,0	20		x	
D/B	70	M	3,0	16			
C/A	41	M	1,0	32		x	
N/C	37	M	2,0	18			
B/T	67	F	3,0	16	x		
S/E	49	F	3,0	27		x	
G/P	57	F	0,7	18			
A/A	50	F	2,0	19			
L/M	70	F	1,0	18			
G/V	37	F	1,0	20		x	
N/S	24	F	1,3	16			
G/S	83	F	3,0	16	x		
M/D	55	F	1,0	32		x	
F/F	52	F	2,0	18			

**Abbreviations:** CME, cystoid macular edema; IOP, intraocular pressure; PVR, proliferative vitreoretinopathy.

**Table 4** Electroretinogram evaluation data at 2 weeks and 8 weeks after surgery

ERG B				bERG B			
Patient	1st exam	2nd exam	Absolute delta	Patient	1st exam	2nd exam	Absolute delta
G/A	65,8	62,9	-2,9	G/A	142,9	115,4	-27,5
S/M	76,9	59,8	-17,1	S/M	160,5	200,5	40
L/M	90,9	88,7	-2,2	L/M	157,1	138,2	-18,9
CM/D	10,4	17,3	6,9	CM/D	36,2	46,1	9,9
G/B	53,9	80,2	26,3	G/B	156,2	162,7	6,5
A/P	83,1	96,1	13	A/P	135,4	191,9	56,5
V/V	57	55,4	-1,6	V/V	98,6	127,8	29,2
T/F	56,4	73,1	16,7	T/F	109,6	213,9	104,3
L/L	43,8	53,7	9,9	L/L	76,9	107,2	30,3
G/M	19,8	13,9	-5,9	G/M	14,2	8,3	-5,9
G/C	64,2	77,9	13,7	G/C	43,1	18,8	-24,3
G/V	75,1	71,8	-3,3	G/V	120,9	161,1	40,2
N/C	88,5	90	1,5	N/C	147,9	119,2	-28,7
C/A	12,2	24,6	12,4	C/A	57,8	77,9	20,1
A/A	52,4	68,9	16,5	A/A	179,4	186,1	6,7
N/S	82,8	95,7	12,9	N/S	151,8	188,5	36,7
M/D	56	55,2	-0,8	M/D	114,6	142,5	27,9
F/F	58,6	75,2	16,6	F/F	125,2	219,7	94,5
S/E	44,4	54,3	9,9	S/E	87,1	131,6	44,5
D/B	20,4	16,7	-3,7	D/B	29	21,1	-7,9

**Table 5** Electroretinogram (full-field) results<sup>a</sup>

Mean at 2 weeks after double filling removal (standard deviation)	55.6 (24.7)
Mean at 8 weeks after double filling removal (standard deviation)	61.6 (26.0)
95% confidence interval for means difference of a correlated sample with paired data ( $\alpha/2$ at 19 degrees of freedom is equal to 2.093)	1.02;10.86

**Note:** <sup>a</sup>The interval excludes the 0 so that the difference of means is statistically significant.

siloxane and constituted of polymer chains of different length. It is an optically clear hydrophobic and lipophilic fluid with different viscosity (1000–5700 cSt) and is slightly lighter than water (specific gravity 0.97 g/cm<sup>3</sup>). It is permeable to oxygen, does not mix with water, and has a high surface tension toward water (35 mN/m).<sup>10</sup>

PFCLs consist of a hydrocarbon molecule in which hydrogen atoms are replaced by fluorine atoms. PFO is a saturated PFCL with highly stable carbon–fluorine bonds that make it virtually inert. It has a highly specific gravity (1.70 g/cm<sup>3</sup>), low viscosity (0.8 cSt), and an interface tension toward water 55 mNm.<sup>11</sup>

Both silicon oil and PFCL are hydrophobic, and surface energy is lowest when the two liquids are in contact. The two liquids prefer to be in contact and exclude aqueous from the interface that is displaced laterally. The double bubble effectively gives good contact only to the inferior retina, whereas the tamponade effect in the superior retina is less effective.

Inferior compartmentalization is an important cause of PVR development. In order to reduce this phenomenon and fill the inferior part of the retina at the same time, other kinds of tamponades have been tested, such as heavy silicone oils, double filling with PDMS, fluorosilicone, semifluorinated alkanes, heavy silicone oils, and perfluorocarbon liquids.<sup>1,12,13</sup>

Perfluorocarbon liquids are currently used as intraoperative tools in the management of retinal detachment due to their ability to displace subretinal fluid and to stabilize the retina during surgical procedures.

**Table 6** Bright flash electroretinogram results<sup>a</sup>

Mean at 2 weeks after double filling removal (standard deviation)	107.2 mV (49.7)
Mean at 8 weeks after double filling removal (standard deviation)	128.9 mV (65.8)
95% confidence interval for means difference of a correlated sample with paired data ( $\alpha/2$ at 19 degrees of freedom is equal to 2.093)	4.43;38.98

**Note:** <sup>a</sup>The interval excludes the 0 so that the difference of means is statistically significant.

In order to avoid potential retinal damage caused by their highly specific gravity (1.94–1.76 g/cm<sup>3</sup>) and low viscosity (2.7–0.8 cSt),<sup>14</sup> the perfluorocarbon liquids are usually exchanged with silicone oil before the end of the procedure. Their retinal tolerance is still controversial, and studies evaluating prolonged tamponade with these liquids are discordant. Some studies in rabbit eyes demonstrated retinal damage to photoreceptors and retinal pigment epithelium with areas of atrophy and necrosis, mainly of mechanical origin.<sup>15–18</sup> Other histologic and electroretinographic studies performed on rabbit and pig eyes demonstrated their tolerance and safety profile.<sup>19–21</sup>

We investigated the ocular tolerance and efficacy of a double filling left in place in the vitreous chamber for an average of 3 weeks in order to allow the formation of a chorioretinal scar. When proliferation of immature membranes occurred, they were peeled at the same time as the double filling exchange. The choice of 30% PFO was made to avoid the formation of meniscus in the macular area and to minimize the weight of the PFO bubble on the retina.

Improvements of ERG and bf ERG after removal of the double fill tamponade supported its retinal tolerability and demonstrated recovery of the retinal tissues from the surgical procedure. Because ERG is an expression of electrical function of the entire retinal tissue and not only of the macula, it is not possible to statistically correlate visual acuity and ERG parameters.

Even if double filling is potentially toxic, when removed within 3 weeks, any retinal surface toxicity is temporary, as indicated by the improvement of electrophysiological parameters after its removal. Postoperative IOP increased in 30% of our patients and in every case was successfully treated with topical therapy. Further proliferation had a low incidence (10%) and electroretinography did not demonstrate retinal damage.

Regarding the anatomic results, the Silicon Study Report 11<sup>22</sup> showed at 36 months an anatomic success in 86% of cases treated with silicon oil for retina detachment complicated by severe PVR with BCVA  $\geq$  10/50 in 24% of cases.

A recent retrospective study on 33 eyes treated with heavy silicon oil for complicated retinal detachment reported an anatomic success rate of 87.9% with first surgery with BCVA.<sup>23</sup> In our series, the primary success rate, without further procedures, was 80% with an improvement of BCVA in 46.7% of the cases.

This study indicates that short-term double filling with 30% PFO and 70% PDMS can be considered effective

with no permanent functional retinal toxicity. The main limitations of our study were the low number of patients and the inherent limitations of ERG in detecting other types of retinal damages. Further studies are necessary to compare the ocular tolerance and advantages of temporary endotamponade double filling with other tamponades in the treatment of complicated RRD.

## Disclosure

The authors report no conflicts of interest in this work.

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