Silicone Oil in the Repair of Pediatric Complex Retinal Detachments

A Prospective, Observational, Multicenter Study

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Objective: To report anatomic and visual acuity outcomes, as well as complications, after using 1000-centistoke silicone oil as a retinal tamponade for the treatment of complex retinal detachments in a pediatric population.

Design: A prospective, observational, multicenter study.

Participants: The study cohort consisted of 205 patients 16 years of age or younger (211 eyes) treated at community and university-based ophthalmology clinics for complex retinal detachments associated with trauma, proliferative vitreoretinopathy (PVR), giant retinal tear (GRT), or retinopathy of prematurity (ROP).

Intervention: Vitrectomy surgery for complex retinal detachment with 1000-centistoke silicone oil as the retinal tamponade.

Main Outcome Measures: Anatomic outcomes include complete retinal attachment and macular attachment. Visual acuity outcomes include ambulatory vision (≥4/200) and preservation of preoperative visual acuity. Complications include rates of secondary intraocular pressure (IOP) elevation (≥30 mmHg), hypotony (≤5 mmHg), corneal opacification (including band keratopathy, corneal edema, and corneal abrasions), oil emulsification, and cataract. All outcome measures were assessed 6, 12, and 24 months after surgery and at last examination.

Results: At the 6-month examination, the retina was completely attached in 43 (57%) of 76 eyes in the trauma group, 24 (63%) of 38 PVR eyes, 23 (68%) of 34 GRT eyes, and 6 (33%) of 18 ROP eyes. The macula was attached in 60 (79%), 33 (87%), 26 (76%), and 8 (44%) eyes, respectively. Ambulatory vision was achieved in 19 (25%) eyes in the trauma group, 18 (47%) PVR eyes, 19 (56%) GRT eyes, and 4 (22%) ROP eyes. Visual acuity was preserved in 53 (70%), 26 (68%), 28 (82%), and 9 (50%) eyes, respectively. The corresponding rates of complications for traumatic, PVR, GRT, and ROP eyes were: elevated IOP—3 (4%) of 76, 1 (3%) of 38, 1 (3%) of 34, and 0 (0%) of 18; hypotony—9 (12%), 3 (8%), 2 (6%), and 2 (11%); corneal opacity—25 (33%), 8 (21%), 15 (44%), and 5 (28%); emulsification—4 (5%), 1 (3%), 3 (9%), and 1 (6%); and cataract in phakic eyes—1 (33%) of 3, 2 (67%) of 3, 2 (50%) of 4, and 1 (33%) of 3.

Conclusions: Retinal reattachment and preserved visual acuity were achieved in the majority of eyes using vitrectomy and silicone oil retinal tamponade. Complete retinal and macular attachment was achieved less frequently in ROP eyes than in eyes in the other diagnostic groups. Use of 1000-centistoke silicone oil can be considered in the management of pediatric complex retinal detachments associated with multiple etiologies.
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Since the first report of silicone oil for the treatment of retinal detachment in 1962,[1] silicone oil has been used increasingly as a retinal tamponade in the management of complex retinal detachments associated with cytomegalovi-

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Table 1. Preoperative Characteristics of Study Groups

Characteristic	Giant Tear	Trauma	PVR	ROP	Total
No. of patients	37	101	47	20	205
No. of eyes in study	39	102	49	21	211
1 eye	35 (95%)	100 (99%)	45 (96%)	19 (95%)	199 (97%)
2 eyes	2 (5%)	1 (1%)	2 (4%)	1 (5%)	6 (3%)
Age (yrs) [mean (SD)]	10.2 (4.4)	10.5 (4.4)	9.3 (5.2)	9.1 (4.7)	10.0 (4.6)
Gender					
Female	6 (16%)	24 (24%)	10 (22%)	8 (40%)	48 (23%)
Male	31 (84%)	77 (76%)	37 (79%)	12 (60%)	157 (77%)
Visual acuity					
NLP/LP	16 (41%)	43 (42%)	10 (20%)	5 (24%)	74 (35%)
CF/HM	14 (36%)	40 (39%)	24 (49%)	5 (24%)	83 (39%)
3/200–20/400	4 (10%)	8 (8%)	7 (14%)	0 (0%)	19 (9%)
20/300–20/60	4 (10%)	4 (4%)	2 (4%)	3 (14%)	13 (6%)
20/50–20/20	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Ambulatory (≥4/200)	8 (21%)	12 (12%)	9 (18%)	3 (14%)	32 (15%)
IOP (mmHg)					
≤5 (hypotony)	9 (23%)	22 (22%)	9 (18%)	2 (10%)	42 (20%)
≥30 (elevated)	1 (3%)	0 (0%)	1 (2%)	0 (0%)	2 (1%)
Corneal status					
Opacification/abrasion	3 (8%)	37 (36%)	9 (18%)	1 (5%)	50 (24%)
Status of lens					
Phakic	16 (41%)	43 (42%)	21 (43%)	15 (71%)	95 (45%)
With cataract	7 (44%)	26 (60%)	6 (29%)	2 (13%)	41 (43%)
Aphakic	21 (54%)	52 (51%)	24 (49%)	5 (24%)	102 (48%)
Pseudophakic	2 (5%)	4 (4%)	4 (8%)	0 (0%)	10 (5%)

PVR = proliferative vitreoretinopathy; ROP = retinopathy of prematurity; NLP = no light perception; LP = light perception; CF = counting fingers; HM = hand motions; IOP = intraocular pressure.

rus necrotizing retinitis,[2–11] proliferative diabetic retinopathy,[12–18] giant retinal tears (GRT),[19–28] proliferative vitreoretinopathy (PVR),[29–37] and ocular trauma.[38–45] Although several series have reported the anatomic retinal reattachment and visual acuity results using silicone oil for long-term intraocular tamponade in adults,[36,46–54] to our knowledge, there are only four published series reporting results of the use of silicone oil for complex retinal detachments in the pediatric population. The number of eyes included in each of these series ranges from only 10 to 48[55–57] (Rodriguez F, Lewis H. Ophthalmology 1991;98[Suppl]:257).

The current prospective observational multicenter study was designed to investigate the anatomic and visual acuity outcomes, as well as complications, of using 1000-centistoke silicone oil as a retinal tamponade for pediatric complex retinal detachments associated with trauma, PVR, GRT, and retinopathy of prematurity (ROP). The current study represents the largest published series of pediatric patients treated with pars plana vitrectomy and silicone oil retinal tamponade for complex retinal detachments.

Patients and Methods

Study Design

The study protocol was approved by the Institutional Review Board at each of the participating centers. The study population consisted of patients 16 years of age or younger with retinal detachments associated with ocular trauma, PVR, GRT, or ROP in whom surgical repair was indicated to improve or preserve vision. Patients were recruited as part of a multicenter national study and treated at 1 of 36 investigation sites by individual investigator–surgeons who had completed fellowship training in vitreoretinal surgery and who signed an Investigator Agreement, permitting them to purchase Richard–James 1000-centistoke silicone oil (SILIKON 1000) for use in their patients. Included in the current study were major medical centers that had participated in the National Eye Institute Silicone Oil Study, and investigator–surgeons at these centers had training and experience in the use of silicone oil. Other study centers were added after a determination from review of surgeons' credentials and training so that similar outcomes of surgery could be expected. The clinical investigation of SILIKON 1000 was initiated in August 1991 and the database locked in November 1996. Investigator–surgeons had no proprietary interest in the product nor were they compensated for their participation in the study. (After the study was completed, the authors received a small grant for data analysis.)

Operative procedures varied according to the surgeons' preferences, and investigator–surgeons did not have review sessions to discuss indications or techniques for the use of silicone oil. In general, surgical intervention consisted of pars plana vitrectomy, relief of epiretinal traction, retinal reattachment by fluid–air exchange, and simultaneous internal drainage of subretinal fluid. In some cases, fluid–silicone exchange was used to reattach the retina, and perfluorocarbon liquids were also used occasionally. Most eyes underwent some form of retinopexy. After retinal reattachment was accomplished, the vitreous cavity was filled with silicone oil to the iris plane. In patients with aphakia, an iridectomy at the 6-o'clock position was generally performed. In patients with pseudophakia, an inferior iridectomy was performed occasionally but less often than in aphakic eyes. Eyes were often treated with scleral buckling, and most phakic eyes underwent lensectomy.

Surgeons provided brief preoperative data, including demographics, general medical and ocular history, and an ocular eval-

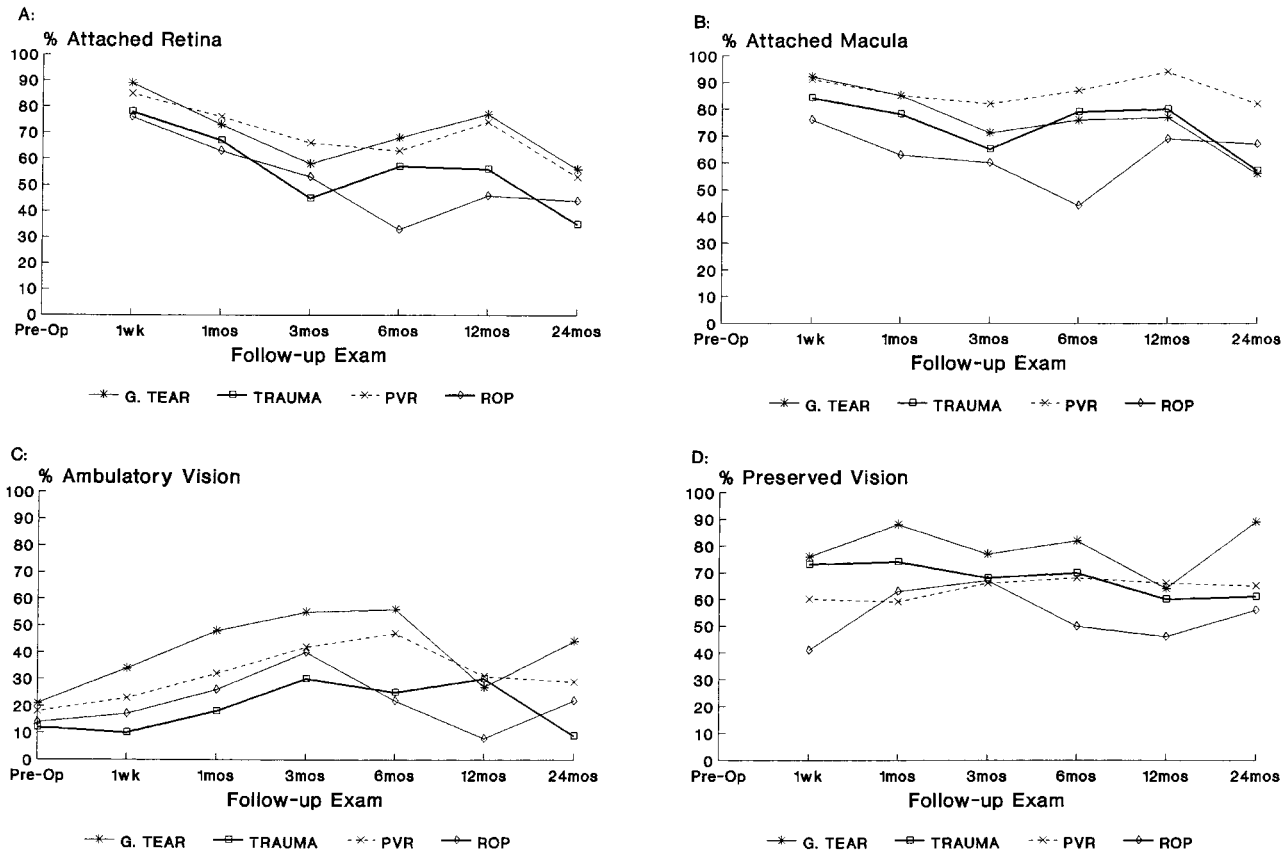

Figure 1. Anatomic and visual acuity outcomes at postoperative examinations for eyes with giant retinal tear (solid line with asterisks), trauma (solid line with boxes), proliferative vitreoretinopathy (dashed line), and retinopathy of prematurity (solid line with diamonds). **A,** percent of eyes with completely attached retinas. **B,** percent of eyes with attached maculas. **C,** percent of eyes with ambulatory visual acuity (≥4/200). **D,** percent of eyes with preserved visual acuity.

uation. Operative procedures were reported by the surgeon and confirmed by review of the operative reports by the study coordinator. Postoperative data collected included visual acuity, status of the retina and macula, and complications. Further details of the study design were published previously.[52]

Outcome Measures

Anatomic and visual acuity outcomes and complication rates were the assessed outcome measures. Anatomic success was defined as complete retinal attachment or macular attachment. Visual acuity outcomes analyzed included ambulatory vision (≥4/200) or preservation of visual acuity. Ambulatory vision was defined as a visual acuity of 4/200 or greater because at the time this study was designed, the U.S. Food and Drug Administration limited the use of silicone oil in the United States, and most of the available reference data on the use of silicone oil in treating complex retinal detachment were in the European literature, which defined ambulatory vision as 4/200 (0.02) or greater.[53] Preservation of visual acuity was defined as a postoperative visual acuity that was the same or better than the preoperative visual acuity. Event rates of secondary glaucoma (intraocular pressure [IOP] ≥ 30 mmHg), hypotony (IOP ≤ 5 mmHg), corneal opacity, emulsification, and cataract (in phakic eyes) were tabulated. In this report, one-time event rates are reported at any given examination, although the event may not have persisted over time and, in fact, may have improved. Emulsification was defined as any oil droplets observed either by direct slit-lamp examination or gonioscopy, but gonioscopy was not required as part of the study protocol.

Statistical Analyses

Outcome measures were reported at both the 6-month examination and the last examination. The reporting of outcomes at 6 months was selected because postoperative retinal reattachment results are generally stable at 6 months. Presenting outcomes at the last examination permitted the inclusion of patients who did not have a 6-month follow-up examination. Outcomes were also evaluated at the 1-week and 1-, 3-, 12-, and 24-month examinations to show stability of outcomes.

Statistical analyses were primarily descriptive in nature; summary statistics (means ± standard deviations, or percentages) were calculated for each variable. Summary statistics were presented for the total number of eyes and also for the subgroups of trauma, PVR, GRT, and ROP. Statistical tests comparing rates between groups were not performed because the aim of this study was descriptive in nature; the nonrandomized nature of this study does not exclude a selection bias and, therefore, potentially confounding factors are uncontrolled.

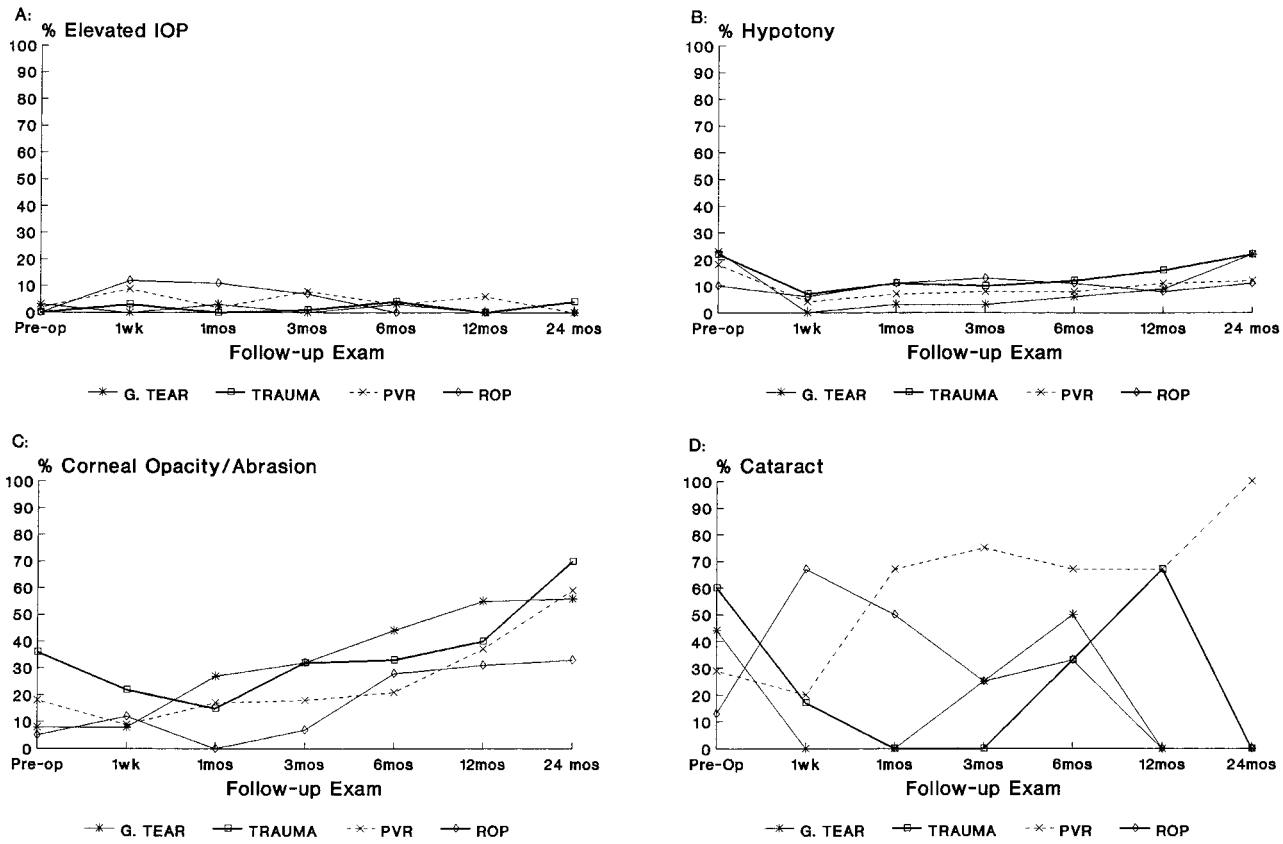

Figure 2. Complications at postoperative examinations for eyes with giant retinal tear (solid line with asterisks), trauma (solid line with boxes), proliferative vitreoretinopathy (dashed line), and retinopathy of prematurity (solid line with diamonds). **A,** percent of eyes with elevated intraocular pressure (≥30 mmHg). **B,** percent of eyes with hypotony (≤5 mmHg). **C,** percent of eyes with corneal opacity. **D,** percent of phakic eyes with cataract.

Results

Characteristics of Study Cohort at Baseline Examination

Table 1 presents the demographic and ocular characteristics for the study groups. The study cohort consisted of 205 patients and 211 eyes. The retinal detachments in the 205 patients were associated with trauma in 101 (49%), PVR in 47 (23%), GRT in 37 (18%), and ROP in 20 (10%). Twenty-nine patients had other diagnoses (including toxoplasmosis, toxocariasis, Peter anomaly, and Marfan syndrome) and, because of the small number of patients in each of these diagnostic groups, were excluded from these analyses.

Table 1 presents the demographic and ocular characteristics for the study groups. The average age was approximately 10 years. The distribution of males varied across etiology of retinal detachment, ranging from 60% in the ROP group to 84% in the GRT group. Ambulatory vision was recorded preoperatively in 32 of 211 (15%) eyes. Hypotony was observed in 42 (20%) eyes, and elevated IOP was present in 2 (1%) eyes. Of the 95 phakic eyes, 50 (53%) had clear lenses, ranging from 40% of trauma eyes to 87% of ROP eyes.

Operative Data

Operative procedures included: endolaser photocoagulation in 164 (78%) eyes, drainage retinotomy in 54 (26%) eyes, and scleral buckling procedures in 76 (36%) eyes. In addition to the primary oil injection, 52 (25%) of the 211 eyes had repeated injections of oil (42 eyes with 1 reinjection, 9 eyes with 2 reinjections, and 1 eye with 3 reinjections), and 56 (35%) eyes had oil removal without reinjection.

Extent of Follow-up

Overall, 210 (99.5%) of 211 treated eyes had at least 1 follow-up examination, including 102 (49%) trauma eyes, 48 (23%) PVR eyes, 39 (19%) GRT eyes, and 21 (10%) ROP eyes. The distribution of the last examination was 4 eyes at 1 week, 13 at 1 month, 16 at 3 months, 43 at 6 months, 67 at 1 year, and 67 at more than 2 years. The average length of follow-up was 361 days for trauma eyes, 537 days for PVR eyes, 380 days for GRT eyes, and 499 days for ROP eyes.

Of the 210 eyes with at least one follow-up examination, 166 (80%) had a 6 month evaluation. Of the 44 eyes without a 6-month examination, 3 (7%) were discontinued (i.e., patient deceased, reinjection with silicone oil other than SILIKON 1000, or enucleated), 29 (66%) were lost to follow-up (i.e., patient exited from study before 6-month examination for reason other than discontinuation), and 12 (27%) were noncohort (i.e., subject missed the 6-month examination but had a later postoperative examination, or subject's 6-month postoperative examination report was not received by the Coordinating Center by study close-out). Additional factors responsible for the patient failing to report for the 6-month scheduled visit include unrelated patient illness, distance from the treatment institution, patient perception of lack of need for follow-up, patient satisfaction with outcome, and relocation.

Table 2. Efficacy and Safety Outcomes at 6 and 24 Months and at the Last Examination

Outcome	Examination	Giant Tear	Trauma	PVR	ROP	Total
Complete attachment	6 mos	23/34 (68%)	43/76 (57%)	24/38 (63%)	6/18 (33%)	96/166 (58%)
	24 mos	5/9 (56%)	8/23 (35%)	9/17 (53%)	4/9 (44%)	26/58 (45%)
	Last visit	26/39 (67%)	49/102 (48%)	34/48 (71%)	8/21 (38%)	117/210 (56%)
Macula attachment	6 mos	26/34 (76%)	60/76 (79%)	33/38 (87%)	8/18 (44%)	127/166 (77%)
	24 mos	5/9 (56%)	13/23 (57%)	14/17 (82%)	6/9 (67%)	38/58 (66%)
	Last visit	27/39 (69%)	71/102 (70%)	42/48 (88%)	11/21 (52%)	151/210 (72%)
Ambulatory vision	6 mos	19/34 (56%)	19/76 (25%)	18/38 (47%)	4/18 (22%)	60/166 (36%)
	24 mos	4/9 (44%)	2/23 (9%)	5/17 (29%)	2/9 (22%)	13/58 (22%)
	Last visit	14/39 (36%)	19/102 (19%)	21/48 (44%)	3/21 (14%)	57/210 (27%)
Preserved vision	6 mos	28/34 (82%)	53/76 (70%)	26/38 (68%)	9/18 (50%)	116/166 (70%)
	24 mos	8/9 (89%)	14/23 (61%)	11/17 (65%)	5/9 (56%)	38/58 (66%)
	Last visit	27/39 (69%)	61/102 (60%)	33/48 (69%)	8/21 (38%)	129/210 (61%)
Visual acuity (≥counting fingers)	6 mos	23/34 (68%)	36/76 (47%)	22/38 (58%)	7/18 (39%)	88/166 (53%)
	24 mos	4/9 (44%)	4/23 (17%)	9/17 (53%)	2/9 (22%)	19/58 (33%)
	Last visit	16/39 (41%)	33/102 (32%)	30/48 (63%)	5/21 (24%)	84/210 (40%)
Visual acuity (≥20/400)	6 mos	17/34 (50%)	17/76 (22%)	16/38 (42%)	2/18 (11%)	52/166 (31%)
	24 mos	4/9 (44%)	1/23 (4%)	5/17 (29%)	1/9 (11%)	11/58 (19%)
	Last visit	14/39 (36%)	15/102 (15%)	18/48 (38%)	2/21 (10%)	49/210 (23%)
Visual acuity (≥20/200)	6 mos	13/34 (38%)	13/76 (17%)	12/38 (32%)	2/18 (11%)	40/166 (24%)
	24 mos	3/9 (33%)	0/23 (0%)	2/17 (12%)	1/9 (11%)	6/58 (10%)
	Last visit	12/39 (31%)	12/102 (12%)	12/48 (25%)	2/21 (10%)	38/210 (18%)
Elevated IOP (≥30 mmHg)	6 mos	1/34 (3%)	3/76 (4%)	1/38 (3%)	0/18 (0%)	5/166 (3%)
	24 mos	0/9 (0%)	1/23 (4%)	0/17 (0%)	0/9 (0%)	1/58 (2%)
	Last visit	1/39 (3%)	1/102 (1%)	3/48 (6%)	0/21 (0%)	5/210 (2%)
Hypotony (≤5 mmHg)	6 mos	2/34 (6%)	9/76 (12%)	3/38 (8%)	2/18 (11%)	16/166 (10%)
	24 mos	2/9 (22%)	5/23 (22%)	2/17 (12%)	1/9 (11%)	10/58 (17%)
	Last visit	7/39 (18%)	16/102 (16%)	3/48 (6%)	3/21 (14%)	29/210 (14%)
Corneal opacity/abrasion	6 mos	15/34 (44%)	25/76 (33%)	8/38 (21%)	5/18 (28%)	53/166 (32%)
	24 mos	5/9 (56%)	16/23 (70%)	10/17 (59%)	3/9 (33%)	34/58 (59%)
	Last visit	18/39 (46%)	47/102 (46%)	21/48 (44%)	6/21 (29%)	92/210 (44%)
Aphakic eyes	6 mos	28/34 (82%)	70/76 (92%)	31/38 (82%)	14/18 (78%)	143/166 (86%)
	24 mos	7/9 (78%)	21/23 (91%)	16/17 (94%)	7/9 (78%)	51/58 (88%)
	Last visit	31/39 (79%)	91/102 (89%)	41/48 (85%)	16/21 (76%)	179/210 (85%)
Cataract in phakic eyes	6 mos	2/4 (50%)	1/3 (33%)	2/3 (67%)	1/3 (33%)	6/13 (46%)
	24 mos	0/0 (0%)	0/0 (0%)	1/1 (100%)	0/1 (0%)	1/2 (50%)
	Last visit	1/3 (33%)	2/6 (33%)	3/3 (100%)	0/2 (0%)	6/14 (43%)
Emulsification	6 mos	3/34 (9%)	4/76 (5%)	1/38 (3%)	1/18 (6%)	9/166 (5%)
	24 mos	0/9 (0%)	1/23 (4%)	0/17 (0%)	1/9 (11%)	2/58 (3%)
	Last visit	0/39 (0%)	6/102 (6%)	4/48 (8%)	1/21 (5%)	11/210 (5%)

PVR = proliferative vitreoretinopathy; ROP = retinopathy of prematurity; IOP = intraocular pressure.

Outcomes at Follow-up Examinations

Figures 1 and 2 present, for each of the diagnostic subgroups, outcome data at each of the follow-up examinations. Table 2 presents outcomes (stratified by etiology) at the 6-month examination and last visit. At the 6-month examination, complete retinal attachment rates were comparable among trauma, PVR, and GRT eyes (57%, 63%, and 68%, respectively) and lower for ROP eyes (33%) (Fig 1A). Similarly, macular attachment rates were comparable among trauma, PVR, and GRT eyes (79%, 87%, and 76%, respectively) and lower for ROP eyes (44%) (Fig 1B). At the 6-month examination, ambulatory vision outcomes were comparable between PVR and GRT eyes (47% and 56%, respectively) and lower for trauma and ROP eyes (25% and 22%, respectively) (Fig 1C). In all subgroups, the percentage of eyes with ambulatory vision before surgery increased after surgery (from 12%–25% in trauma eyes, 18%–47% in PVR eyes, 21%–56% in GRT eyes, and 14%–22% in ROP eyes). These increases in the percentages of eyes with ambulatory vision are also reflected in the percentages of eyes with preservation of vision (ranging from 50% in ROP eyes to 82% in GRT eyes) (Fig 1D). Overall, 70% and 61% of eyes demonstrated preserved vision at the 6-month and last examinations, respectively.

For all subgroups, the percentages of eyes at 6 months with elevated IOP were very small (ranging from 0% of ROP eyes to 4% of trauma eyes) and did not differ across etiologies (Fig 2A). The rates of hypotony at 6 months ranged from 6% of GRT eyes to 12% of trauma eyes (Fig 2B). The percentage of eyes with preoperative and postoperative corneal opacities remained quite stable in the trauma eyes (36% and 33%, respectively) and in the PVR eyes (18% and 21%, respectively) (Tables 1 and 2, Fig 2C). In contrast, in the GRT group, the percentage of eyes with corneal opacities increased from 8% before surgery to 44% after surgery at 6 months; in the ROP group, the percentage of eyes with corneal opacities increased from 5% before surgery to 28% after surgery at 6 months (Tables 1 and 2, Fig 2C). At 6 months, the rates of oil emulsification ranged from 3% of PVR eyes to 9% of GRT eyes (Table 2). Cataract was noted in 41 (43%) of 95 phakic eyes before surgery and in 6 (46%) of 13 phakic eyes 6 months after surgery (Tables 1 and 2, Fig 2D).

Silicone Oil Removal

Silicone oil was removed from 83 eyes. Of these, follow-up data were available for 76 eyes (92%). Table 3 summarizes outcomes

Table 3. Effect of Oil Removal: Changes in Outcome from Examination prior to Oil Removal to Last Follow-up Examination after Oil Removal

Time of Removal (mos)	No. of Eyes/No. of Procedures	No. of Eyes Followed	Retina Redetached	Vision Loss	Hypotony (≤5 mmHg)	Elevated IOP (≥30 mmHg)	Abnormal Cornea
0–3	26/27	24	3 (13%)	2 (8%)	5 (21%)	1 (4%)	3 (13%)
4–6	23/24	23	1 (4%)	4 (17%)	1 (4%)	0 (0%)	5 (22%)
7–12	27/33	24	1 (4%)	3 (13%)	3 (13%)	0 (0%)	2 (8%)
13–24	7/8	5	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (20%)
Total	83/92	76 (92%)	5 (7%)	9 (12%)	9 (12%)	0 (0%)	11 (14%)

Time of removal = time from first injection to last oil removal; Vision loss = loss of visual acuity of 1 or more lines; Retinal redetachment = retina changed from completely or partially attached to completely detached; Abnormal cornea = change from normal cornea to cornea with opacity or abrasion; IOP = intraocular pressure.

for these eyes, stratified by time of oil removal. Retinal redetachment occurred in five eyes (7%) and visual acuity loss of 1 or more lines occurred in nine eyes (12%). Nine eyes (12%) had a change in IOP from normal to hypotony, and 11 eyes (14%) developed corneal abnormalities.

Stratified Analyses

Rates of complications at 6 months were compared between eyes with and without retinal attachment (Table 4). Hypotony and corneal opacities occurred significantly more frequently in eyes without retinal attachment. This is not surprising since decreased IOP is a well-recognized feature of retinal detachment and since corneal decompensation is known to occur in hypotonous eyes.

To investigate the possible impact of amblyopia on visual outcomes, the rates of ambulatory and preserved vision were compared between patients 7 years of age and younger versus patients older than 7 years. There was no significant difference between the two groups.

Long-term Outcomes

Anatomic outcomes were stable from 6 to 24 months (Figs 1A, B). Visual acuity outcomes were also generally stable (Figs 1C, D).

Discussion

Silicone oil has been used increasingly in the 1980s and 1990s for the repair of complex retinal detachments, but published data on outcomes of such surgery are relatively limited. The Silicone Oil Study reported that among eyes with complex retinal detachment associated with advanced PVR, retinal reattachment rates, visual acuity outcomes, and complication rates were superior with silicone oil compared with sulfur hexafluoride gas as a retinal tamponade,[46] and results achieved with silicone oil were similar to those achieved with perfluoropropane gas.[47,48] Unlike long-acting gases, silicone oil does not resorb spontaneously and, therefore, requires a second surgery for oil removal. However, advantages of silicone oil over long-acting gases include earlier visual rehabilitation, no restriction of air travel, and avoidance of the requirement for strict prone positioning after surgery. Lucke and Laqua[53,54] and Azen et al[52] reported results of large series of patients in whom silicone oil tamponade was used in the repair of complex retinal detachments; in both of these series, the majority of retinal detachments were caused by PVR (130 patients treated between October 1984 and January 1989 in the series by Lucke and Laqua; 926 patients treated between August 1991 and November 1996 in the study by Azen et al). At 6 months after surgery in PVR eyes, complete retinal reattachment was achieved in 77% of eyes in the series by Lucke and Laqua and in 76% of eyes in the series reported by Azen et al; ambulatory vision was achieved in 78% and 40% of eyes, respectively, and preoperative vision was preserved in 72% and 86% of eyes, respectively.

To our knowledge, there are only four published studies of the use of silicone oil in the pediatric population, and the results of these studies, as well as those of the current series, are displayed in Tables 5 and 6.[55–57] Among the 12 eyes from which silicone oil was removed in the study by Ferrone et al,[55] retinal redetachment occurred in 5 (42%) (compared to 5 [7%] of 76 eyes in the current study). A potential explanation for the worse anatomic and visual acuity outcomes reported by Ferrone et al as compared with those

Table 4. Safety Outcomes at 6 Months and at Last Examination between Eyes with and without Retinal Attachment

Outcome*	Examination	Attached	Detached	P†
Emulsification‡	6 mos	7/61 (11%)	2/45 (4%)	0.30
	Last visit	8/68 (12%)	3/43 (7%)	0.53
Cataract in phakic eyes	6 mos	5/9 (56%)	1/4 (25%)	0.56
	Last visit	5/10 (50%)	1/3 (33%)	0.99
Hypotony (≤5 mmHg)	6 mos	4/79 (5%)	11/49 (22%)	0.003
	Last visit	5/103 (5%)	18/59 (31%)	<0.001
Elevated IOP (≥30 mmHg)	6 mos	3/79 (4%)	2/49 (4%)	1.0
	Last visit	3/103 (3%)	2/59 (3%)	1.0
Corneal opacity/ abrasion	6 mos	19/93 (20%)	25/54 (46%)	0.001
	Last visit	41/114 (36%)	38/66 (58%)	0.005

IOP = intraocular pressure.

* Eyes with unknown outcomes were excluded from all analyses.

† Chi-square or Fisher exact test was performed for comparisons.

‡ Eyes with oil removal were excluded from analysis of emulsification rates.

Table 5. Anatomic Status in Published Series of the Use of Silicone Oil in the Repair of Pediatric Complex Retinal Detachments

Study	No. of Eyes	Patient Age (yrs)	SO Used	Mean Length of Follow-up (mos)	Complete Retinal Attachment [no. (%) of eyes]
Ferrone et al[55]	48	≤16	1000 or 5000 cs	23	16 (35)
Biedner et al[56]	12	≤16	NR	33.6	7 (58)
Moisseeiev et al[57]	28	≤15	1000 cs	24	9 (32)
Rodriguez et al[58]	10	NA	NR	>6	6 (60)
Current study	211	≤16	1000 cs	13.9	117 (56)

SO = silicone oil; cs = centistoke; NR = data not reported.

observed in the current study may be that 90% of eyes in the former study had hand motion or worse vision before surgery compared with 74% of eyes in the current study. Further, the former study included 16 (33%) eyes with developmental anomalies (e.g., coloboma, high myopia, Coats disease, Sturge–Weber syndrome, Stickler syndrome).

The anatomic and visual acuity outcomes reported by Biedner et al[56] are more comparable to those of the current study. The higher percentage of patients with complete retinal attachment and a visual acuity of counting fingers or better at final follow-up in the current study compared to the report by Moisseiev et al[57] may be due, at least in part, to a longer duration of follow-up in the latter study. Published data concerning the study population reported by Rodriguez and Lewis (Ophthalmology 1991;98[Suppl]:257) are insufficient for comparative analyses.

In all five studies outlined in Tables 5 and 6 (and consistent with reports of the use of silicone oil in adult PVR series[17,46,48,51,58,59]), functional success rates were generally lower than the anatomic success rates.[55–57] A visual acuity of 5/200 or better was achieved in 40% to 60% of adult PVR series[55–57]; the visual acuity outcomes reported in a series of pediatric patients treated for complex retinal detachments with silicone oil as a retinal tamponade are worse than those reported for adult PVR series. A potential explanation for this difference is the higher percentage of pediatric eyes with developmental anomalies and trauma. Further, children may develop more extensive postoperative inflammation, scarring, and PVR than would adults.

There are few reports regarding outcomes of surgical repair of pediatric retinal detachments without silicone oil. Large series of pediatric retinal detachments repaired without vitrectomy techniques were reported decades before the current study and consisted of scleral buckling procedures.[60,61] In the 1968 series reported by Hilton and Norton,[60] 71 patients (39%) 1 to 20 years of age achieved a final visual acuity of 20/200 or better after scleral buckling procedures. In the 1978 series reported by Winslow and Tasman,[61] 179 patients (58%) younger than 16 years of age achieved a final visual acuity of 20/100 or better after scleral buckling procedures. In a more recent (1990) series, Zilis et al[62] reported a final visual acuity of fix and follow or greater in 5 (35%) of 14 eyes with stage-4 ROP and in 12 (12%) of 101 eyes with stage-5 ROP. Other more recent series also focus on specific disease entities (such as ROP, familial exudative vitreoretinopathy, and persistent hyperplastic primary vitreous), are much smaller, often include only infants, and include scleral buckling procedures as well as vitrectomies.[63–66]

The current study reports the outcomes of the largest published series of pediatric patients treated with silicone oil retinal tamponade for complex retinal detachments associated with multiple etiologies. At 6 months after surgery, complete retinal reattachment was achieved in 58% of eyes, and macular attachment was achieved in 77% of eyes. Preoperative vision was preserved in 70% of eyes, and 36% of eyes achieved ambulatory vision. Study limitations include the fact that this is a nonrandomized observational investigation. In addition, data were not collected concerning such potentially confounding variables as the presence of pre-existing macular diseases, glaucoma, and other ocular comorbidities. However, visual deterioration throughout the study period because of progression of ocular comorbid

Table 6. Final Visual Acuity Outcomes in Published Series of the Use of Silicone Oil in the Repair of Pediatric Complex Retinal Detachments

Study	≥20/200	≥20/400	≥5/200	≥4/200	≥CF	NLP
Ferrone et al[55]	2 (4%)	2 (4%)	3 (6%)	NR[1]	8 (17%)	19 (40%)
Biedner et al[56]	NR	NR	NR	NR	6 (50%)	6 (50%)
Moisseeiev et al[57]	5 (18%)	5 (18%)	NR	NR	6 (21%)	3 (11%)
Rodriguez et al[58]	NR	NR	2 (20%)	NR	NR	NR
Current study	38 (18%)	49 (23%)	53 (25%)	57 (27%)	84 (40%)	22 (11%)

NR = data not reported; CF = counting fingers; NLP = no light perception.

conditions would tend to bias our results in the direction of demonstrating poorer outcomes. The current study indicates that in the pediatric population, as in adults, silicone oil should be an option within the standard of care for the treatment of complex retinal detachments.

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Discussion
by
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In 1962, Cibis and coauthors[1] first described the use of liquid silicone in retinal detachment surgery in 30 patients. Four of these patients were 16 years of age or younger, and three of these patients achieved retinal reattachment. Since that report, modern vitreous surgery techniques have developed, and silicone oil injection has been described in case series of complex retinal detachments, including associations with trauma,[2] relaxing retinotomy,[3,4] proliferative vitreoretinopathy,[5,6] and giant retinal tears. Patient age ranges listed in these case series frequently include younger patients. However, specific comments regarding these pediatric patients are rare.

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The Silicone Study was a randomized, multicenter, prospective, controlled clinical trial comparing silicone oil and gas tamponade in the management of adult patients with proliferative vitreoretinopathy.[7,8] Patients in the trial were 18 years of age and older. Cases of trauma and giant retinal tears were excluded. The trial examined anatomic and functional results of silicone oil versus gas use in this adult population with up to 72 months' follow-up.[9] Although this study provided valuable information on the safety and efficacy of silicone oil, it included no pediatric patients.

Four previous case series have focused on the use of vitrectomy and silicone oil injection in complicated retinal detachments in the pediatric population[10–12] (Rodriguez F, Lewis H. Vitreoretinal surgery and silicone oil injection for severe penetrating ocular trauma in children. Ophthalmology 1991;98[Suppl]:257). These reports describe from 10 to 48 cases, yielding a combined total of 98 such published cases. The current study by Scott and coauthors

includes an impressive 211 cases.[13] This report is a nonrandomized, prospective, multicenter study in patients 16 years of age and younger.

Patients with retinal detachments complicated by trauma, proliferative vitreoretinopathy, giant retinal tears, and retinopathy of prematurity were treated with vitrectomy techniques and silicone oil injection. No cases of relaxing retinotomy or retinectomy are described. Cases associated with uveitis and congenital abnormalities were excluded. Visual and anatomic outcomes were measured at 6 to 24 months.

Anatomic results of macular attachment and total retinal attachment at 6 months compare favorably with previous reports in pediatric cases,[10–12] achieving a total 58% at 6 months. Ambulatory vision—here defined as 4/200 or better—was achieved in 36% of cases. Acuity outcomes correspond to anatomic outcomes in subgroup analysis of associated conditions. Twenty percent of patients achieved acuity of 20/200 or better. Again, these results compare favorably with previous reports of pediatric case series,[10–12] and these findings show the efficacy of this surgical adjunct in these difficult cases.

As in adult patients, complications of silicone oil use were observed, and these findings compare favorably regarding hypotony, intraocular pressure elevation, and oil emulsification.[14] Corneal abnormalities are reported as opacity or abrasion; this description alone is not sufficient to evaluate silicone keratopathy, thus making corneal information difficult to interpret.[15] Silicone oil removal was achieved in 83 eyes, with redetachment, hypotony, and corneal abnormalities occurring 7%, 12%, and 14%, respectively. These findings are not unexpected, and again they compare favorably to literature reports of adult patients.[16] These overall results show the relative safety of silicone oil use in pediatric patients.

Some information regarding amblyopia management would be useful. With a study population mean age of 10 $\pm$ 4.6 years, a significant group could be at risk of developing amblyopia. Information on postoperative refraction and optical rehabilitation is not provided. This information would be useful as scleral buckling (36% of cases), silicone oil use (100% of cases), and aphakia (found 48% before surgery and near 90% after surgery) present significant optical challenges to the postoperative eye.[13]

The Silicone Study's long-term follow-up demonstrated that if retinal reattachment and visual success were achieved at 3 years, these outcomes would likely be maintained.[9] Scott and coauthors show relative stability in anatomic and functional results at 6 through 24 months. However, with such a long life expectancy in this patient population, longer follow-up could provide useful information.

As the Silicone Study demonstrated the safety and efficacy of silicone oil use in adults with proliferative vitreoretinopathy, this current study confirms the safety and efficacy of silicone oil use in the pediatric population in cases of complex retinal detachments. We are indebted to Scott and coworkers for providing us with this thoughtful and valuable investigation. These findings will help us better approach the management of pediatric patients with these complex conditions.

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