

Irreversible Silicone Oil Adhesion to Silicone Intraocular Lenses

A Clinicopathologic Analysis

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Purpose: To report a newly defined complication of foldable intraocular lenses (IOLs), namely silicone oil–silicone IOL interaction. This is a complication not generally seen by the implanting cataract surgeon but, rather, at a later stage in a patient's postoperative course, by a vitreoretinal surgeon.

Methods: Three clinical case histories, including two explanted silicone IOLs, were submitted for analysis. The submitted silicone lenses were photographed under water, and the nature of the silicone oil coating was documented.

Results: In each instance, the silicone coating was manifest as a thick coating with droplet formation on the lens surface that was tenaciously adherent and could not be dislodged by instruments or injection of viscoelastics.

Conclusion: The use of silicone IOLs in patients with current vitreoretinal disease or those who are at high risk for future vitreoretinal disease that may require silicone oil as part of the therapy should be reconsidered. The authors recommend that information regarding the existence and significance of this complication be printed on all silicone oil and silicone IOL packages and inserts (if not as a warning, at least as an informative comment regarding the existence of this condition). This is a rare but clinically significant complication that will affect the occasional patient treated with both of these modalities. *Ophthalmology* 1996; 103:1555–1562

Although the results of foldable intraocular lenses (IOLs) are generally excellent,¹ there are several complications that may necessitate explantation of the IOL.² These usually are related to surgical technique and IOL design.

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Complications related to the nature of a given biomaterial are unusual but do occur. In this report, three cases have been forwarded to the Center for Intraocular Lens Research in Charleston, South Carolina, for analysis. We provide the first clinicopathologic report of clinically significant adherence of silicone oil (used in vitreoretinal surgery) to silicone IOLs.

This silicone oil–silicone IOL interaction is a complication not generally seen by the implanting cataract surgeon but, rather, at a later stage in a patient's postoperative course, by a vitreoretinal surgeon.

The authors have no proprietary interest in any of the materials used in this study.

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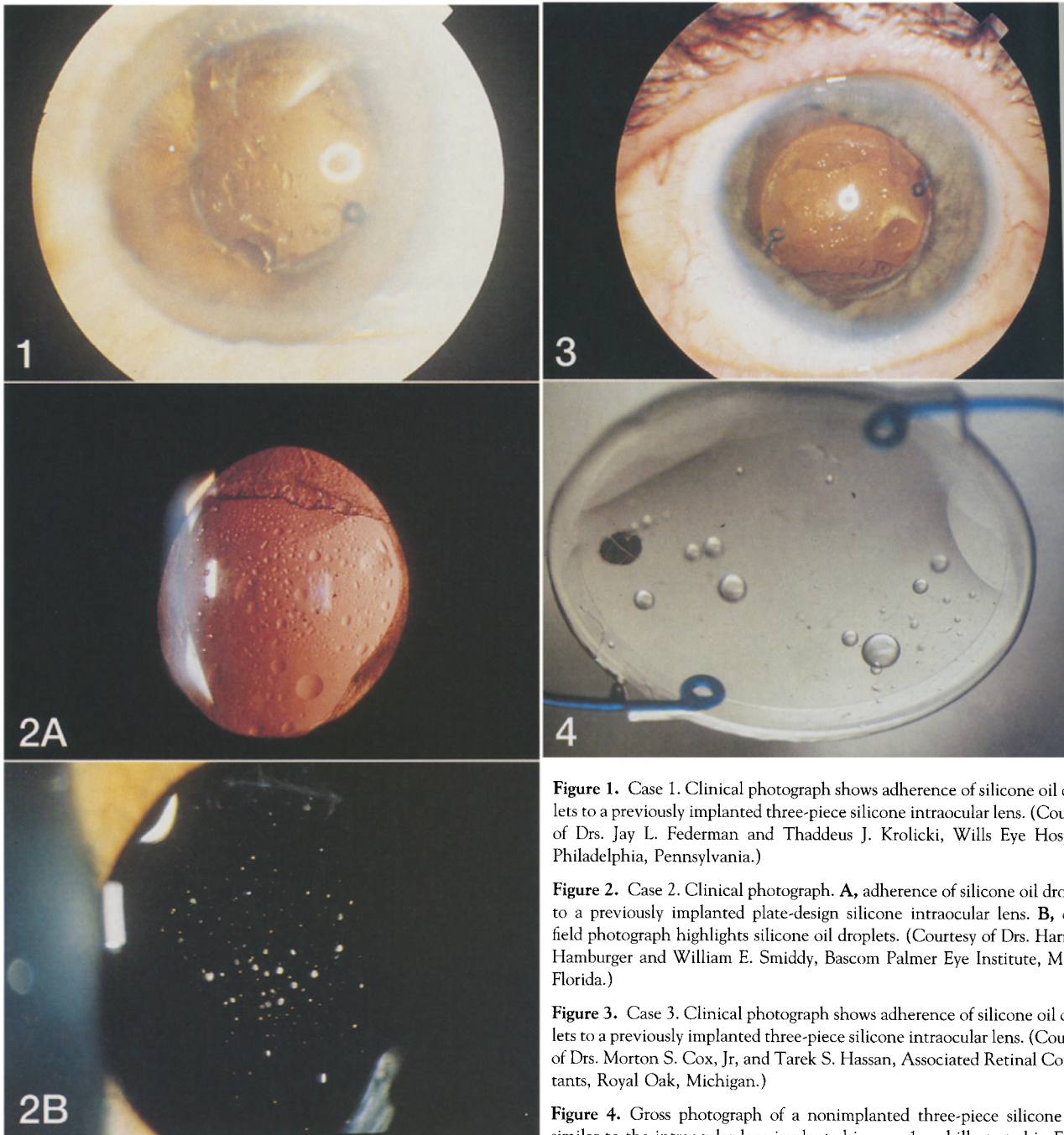


Figure 1. Case 1. Clinical photograph shows adherence of silicone oil droplets to a previously implanted three-piece silicone intraocular lens. (Courtesy of Drs. Jay L. Federman and Thaddeus J. Krolicki, Wills Eye Hospital, Philadelphia, Pennsylvania.)

Figure 2. Case 2. Clinical photograph. **A**, adherence of silicone oil droplets to a previously implanted plate-design silicone intraocular lens. **B**, dark-field photograph highlights silicone oil droplets. (Courtesy of Drs. Harry A. Hamburger and William E. Smiddy, Bascom Palmer Eye Institute, Miami, Florida.)

Figure 3. Case 3. Clinical photograph shows adherence of silicone oil droplets to a previously implanted three-piece silicone intraocular lens. (Courtesy of Drs. Morton S. Cox, Jr, and Tarek S. Hassan, Associated Retinal Consultants, Royal Oak, Michigan.)

Figure 4. Gross photograph of a nonimplanted three-piece silicone lens similar to the intraocular lens implanted in case 1 and illustrated in Figure 1. (Intraocular lens submitted by Drs. Jay L. Federman and Thaddeus J. Krolicki, Wills Eye Hospital, Philadelphia, Pennsylvania.)

1. This lens was incubated in silicone oil for several weeks and then photographed under water. Notice adherence of large droplets to the intraocular lens optic surface. (Intraocular lens submitted by Drs. Jay L. Federman and Thaddeus J. Krolicki, Wills Eye Hospital, Philadelphia, Pennsylvania.)

Case Reports

Case 1. A 75-year-old black man was referred to one of us (JLF) in January 1993. A three-piece silicone IOL (Allergan Medical Optics, Irvine, CA) had been implanted previously in the right eye. He had recurrent pseudophakic retinal detachment and proliferative vitreoretinopathy in this eye. Two retinal procedures were performed. During the course of this treatment, a neodymium:YAG (Nd:YAG) laser secondary posterior capsulotomy was performed. In January 1993, pars plana vitrectomy, relaxing retinotomy, silicone oil–fluid exchange,

and endolaser were performed. The second retinal procedure was performed in May 1993. A bubble of silicone oil from the previous procedure was present in the anterior chamber. As this oil was evacuated, it was noted that some oil was stuck to the IOL (Fig 1). This could be scraped off only incompletely.

This IOL was not explanted. However, after consultation with the senior author (DJA), the surgeon submitted similar silicone IOLs immersed in silicone oil for analysis at the Center for Intraocular Lens Research.

Case 2. A 31-year-old Jamaican woman had had insulin-dependent diabetes since early childhood. In 1991, proliferative

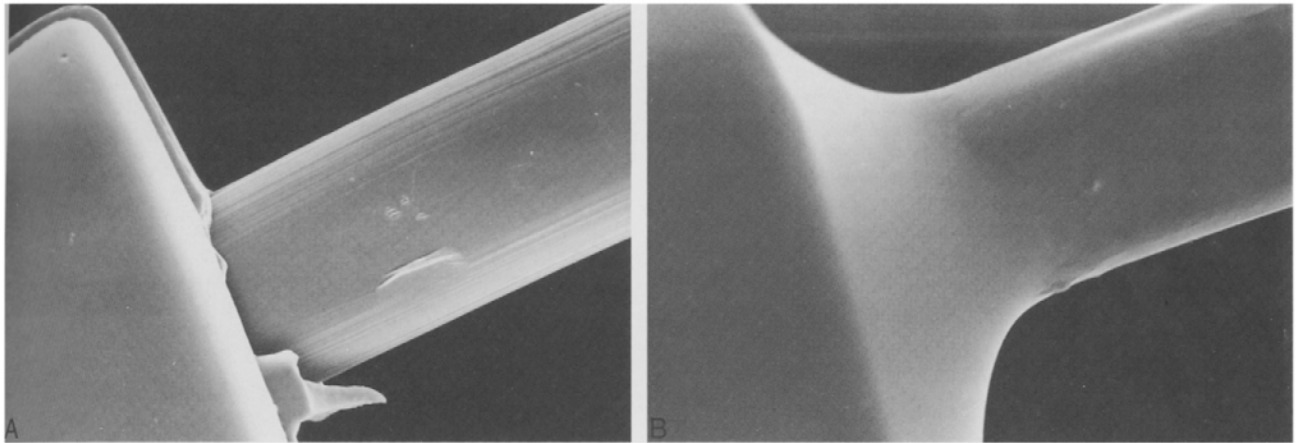


Figure 5. Scanning electron micrographs compare the haptic-optic junction of a control three-piece silicone intraocular lens to the lens shown in Figure 4. **A**, control, nonimplanted lens shows construction markings on the surfaces of the haptic and optic and normal linear striae on the polypropylene haptic. **B**, lens illustrated in Figure 4, immersed in silicone oil. The oil forms a dense diffuse coating over the lens surface so that details of manufacturing and construction are not visible (original magnification, $\times 50$).

diabetic retinopathy developed and the patient received bilateral argon laser panretinal photocoagulation. In 1991, the patient required a pars plana vitrectomy and scleral buckling procedure for a right traction retinal detachment. In 1992, she required a vitrectomy on the left eye with air injection for a similar traction detachment. A cataract developed, and in June 1993 a Chiron foldable silicone plate lens (Chiron, Irvine, CA) was implanted in the right eye. An Nd:YAG laser secondary posterior capsulotomy was performed on the eye in October 1993.

In 1994, the retina in the right eye redetached, requiring membrane peeling and silicone oil injection. The silicone oil was removed because small silicone droplets on the back surface of the implant had caused visual distortion. Four months after oil removal, residual oil droplets (Fig 2) still interfered with the patient's vision. She described the phenomenon, "... like looking through oily water." For this reason, the implant was removed without complications and replaced with an all-polydimethylsiloxane posterior chamber IOL in February 1995. Later in 1995, the patient's retina again detached, but no further surgery could be performed, and the right eye remained at hand motion vision. The left eye currently is stable with 20/40 visual acuity. The silicone IOL that was explanted from the right eye was submitted to the Center for Intraocular Lens Research for pathologic examination.

Case 3. A 56-year-old man was seen on August 5, 1992, with a history of decreased visual acuity in the right eye of 24 hours' duration. He had undergone right cataract extraction on June 9, 1992, and left cataract extraction June 23, 1992. His visual acuity was hand motions in the right eye and 20/50 in

the left. There was a superior retinal detachment in the right eye arising from a large horseshoe tear at the 9:30 clock position. There was cystoid macular edema in the left eye. The patient was being treated with Pred Forte and Ocufen four times daily each for his cystoid macular edema.

A right scleral buckling surgery was performed on August 6, 1992. Results of the patient's first postoperative examination on August 14 demonstrated improved vision in the right eye from hand motions to 20/400. The retina was attached, but there were some folds on the buckle supertemporally. On August 21, his vision had decreased to hand motions due to recurrent inferotemporal detachment. After the fluid-gas exchange, the retina flattened completely, and additional laser surgery was performed. On August 28, his vision again was 20/400. The retina redetached with proliferative vitreoretinopathy on September 16, and the vision again decreased to hand motions. Despite reattachment with vitrectomy with membrane stripping, gas-fluid exchange, and endolaser, the retina redetached totally, with recurrent proliferative vitreoretinopathy documented on October 14, 1992.

On October 22, a repeat vitrectomy with membrane stripping and silicone oil injection were performed. After these procedures, the retina remained attached. On January 18, 1993, a macular pucker was observed, indicating some reepithelialization under the silicone oil. The pucker reduced the vision to an eccentric counting fingers level, so that on June 3, 1993, the silicone oil was removed and the epiretinal membrane causing the macular pucker also was removed. The surgeons encountered considerable difficulty with visualization during this pro-

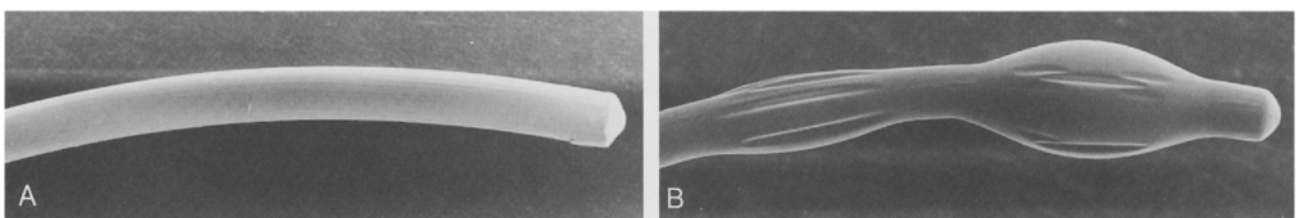


Figure 6. Scanning electron micrographs of polypropylene haptics from a control silicone lens compared with the lens illustrated in Figure 4. **A**, control, nonimplanted lens show normal linear striae on the surface of the polypropylene haptic. **B**, lens from Figure 4 after immersion in silicone oil shows buildup of oil coating on the haptic (original magnification, $\times 45$).

cedure because droplets of silicone oil remained adherent to the previously implanted Allergan Medical Optics, three-piece, haptic-design silicone IOL (Fig 3).

On July 28, recurrent puckering of the central retina was noted and this was followed by a recurrent retinal detachment, which was observed on August 18, 1993. On October 7, 1993, membranes were removed and the IOL was explanted. This greatly improved visual control of the surgery. The retina was reattached and silicone oil was reintroduced. The patient has remained stable after his last surgery. His vision has not improved beyond hand motions. He was last examined on May 5, 1995. No Nd:YAG laser secondary to posterior capsulotomy had been performed. The explanted IOL was submitted to the Center for Intraocular Lens Research for pathologic examination.

Materials and Methods

The nonimplanted silicone lens from Wills Eye Hospital, as well as the explanted lenses from cases 2 and 3 were studied by gross microscopy and scanning electron microscopy. The nonimplanted IOL had been incubated in silicone oil (Adatomad 5000, Adatomad, Munich, Germany). After removal from the oil, this lens and the two explanted IOLs from cases 2 and 3 were photographed in air (dry state) and then immediately placed in water for further examination and gross photography. Each lens was examined by scanning electron microscopy. After sputter-coating the specimen with gold, the examinations were performed using a Leica-Cambridge scanning electron microscope Model 360 (Bausch-Cambridge, Cambridge, UK) at magnifications from $\times 12$ to $\times 140$. The scanning electron microscopies were performed with the assistance of Mr. Richard Campbell and Mr. Thomas Pinness, Robert Bosch Corporation, Charleston, South Carolina.

The percentage of surface area involved and the degree of adherence of the silicone oil to each IOL's optic were estimated. The degree of adherence and the mobility of the oil on the optic were studied qualitatively by injecting viscoelastic (Healon, Pharmacia, Uppsala, Sweden) onto

the immersed IOL. This was done to test the clinical hypothesis that it might be possible to mechanically remove droplets intraoperatively using viscoelastics. A qualitative assessment of silicone oil accumulation, adherence, and mobility on the IOL optic was made, ranging from grade +4 (maximum accumulation, maximum adherence, and minimal mobility, with difficulty in removing the oil from the optic) to grade 0 (no silicone oil-IOL interaction). These comparative studies were made using both still photography and dynamic video analysis. Video analyses were performed with magnification provided by a Leica-Wild Model number M8 stereo microscope.

We performed image analysis on specimen 3 (case 3) using Sigma Scan software (Snappy, Rancho Cordova, CA) and Snappy Video Capture.

Results

In vitro analysis of a nonimplanted Allergan Medical Optics three-piece silicone IOL (submitted by Jay L. Federman, MD) identical to the style of the lens implanted in case 1 was performed. The oil coating the IOL could not be visualized using routine gross photography in the dry state. However, after immersion in water, large bubbles immediately appeared around the IOL optic (Fig 4). Scanning electron microscopy showed the presence of a distinct film or coating of oil on the surface of both the optic and haptic components of the IOL (Figs 5 and 6). They could not be moved with mechanical pressure with injected viscoelastic (Healon); the oily residue remained strongly adherent to the optic surface.

The plate-style IOL from case 2 (Fig 2) was first examined in the dry state, and no obvious changes were readily apparent (Fig 7A). Immediately after immersion of the lens into aqueous solution, prominent droplets appeared on all surfaces of the lens (Fig 7B). The coating was very

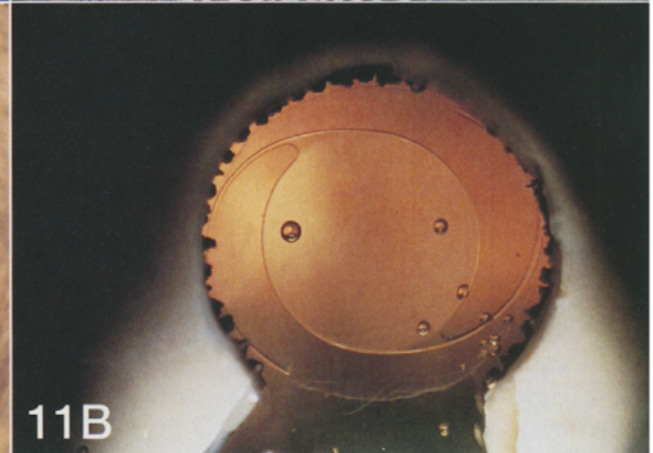
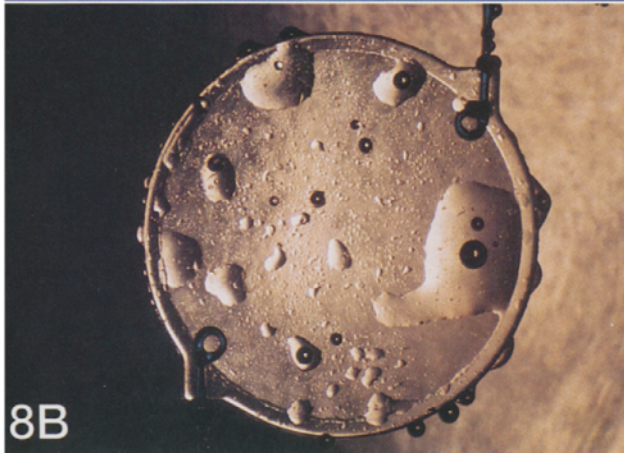
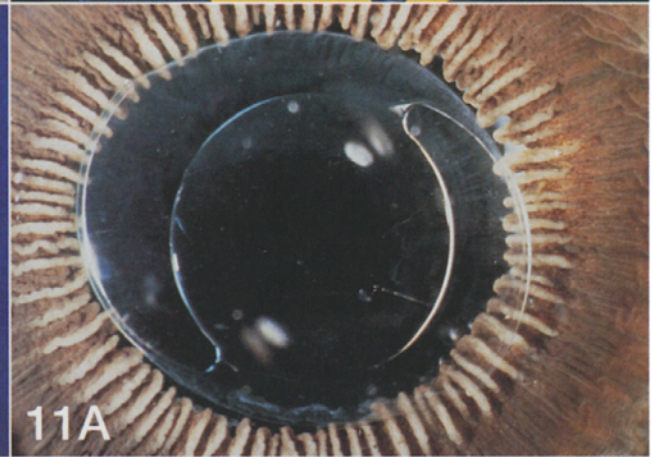
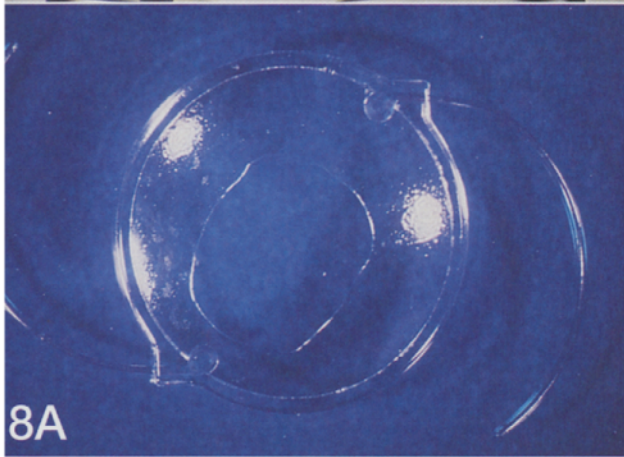
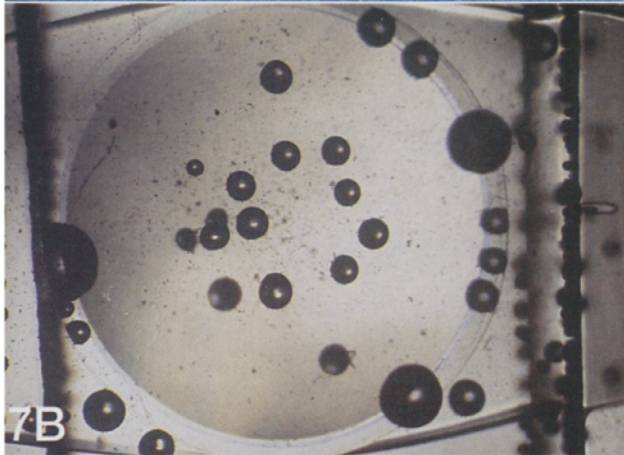
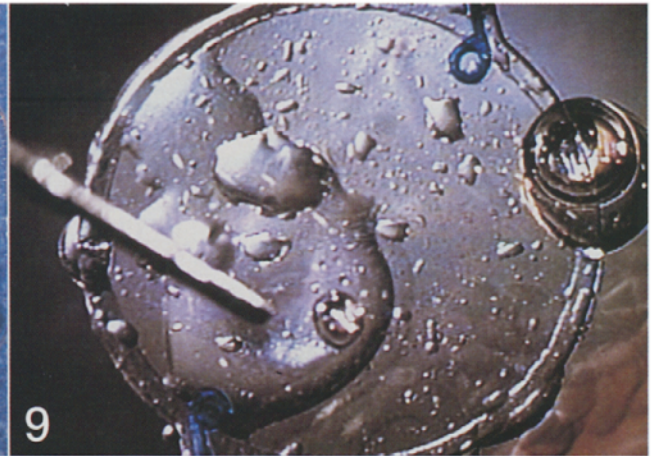
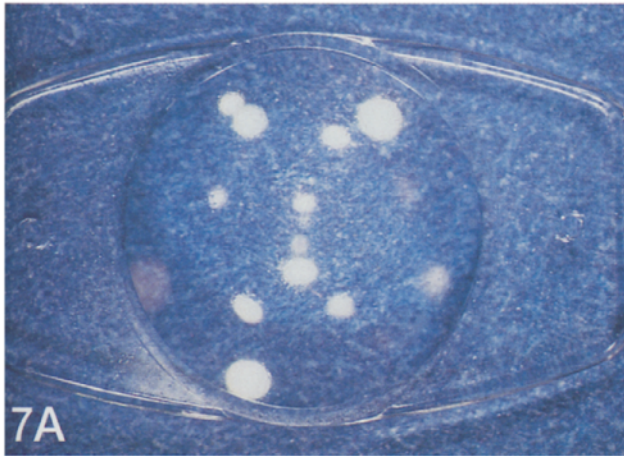
Figure 7. Case 2. Gross photograph of the explanted intraocular lens. **A**, dry state: the silicone oil coating is diffuse and bubbles are not visualized. **B**, after immersion of the silicone intraocular lens in aqueous solution, the bubbles or droplets become visible on the surface of the optic.

Figure 8. Gross photograph of the explanted three-piece intraocular lens from case 3. **A**, dry state: the silicone oil diffusely coats the optic and haptic, and bubbles are not visible. **B**, after immersion of the silicone intraocular lens in aqueous solution, the silicone oil and bubbles become immediately apparent, coating almost the entire optical surface.

Figure 9. Case 3. Gross photograph of an intraocular lens (same lens as shown in Fig 8). It was very difficult to move the oil around over the surface of the intraocular lens optic, either with instruments or with injection of viscoelastic material, as seen in this photograph.

Figure 10. Case 3. Computer-generated image analysis of the explanted silicone lens. The yellow area demonstrates the area of the lens optic that had been coated by silicone material. The blue areas represent intervening areas, showing the optical area not coated by silicone. Almost 80% of the optic is coated. A nonimplanted silicone intraocular lens will always show a 100% coating. In this case, it is probable that the 20% noncoated area was probably occupied by biologic material that rendered this area hydrophilic.

Figure 11. Gross photograph of human eyes obtained postmortem in which one-piece all-polymethylmethacrylate lenses were experimentally implanted in the lens capsular bag. Modern capsular-style intraocular lenses show less adherence to silicone oil and are now known to achieve excellent clinical results.^{4,5} **A**, Miyake view (from behind). Notice excellent centration (preparation technique of Apple and associates¹⁴). **B**, frontal (surgeon's view) shows a lens similar to that shown in Figure 10, again demonstrating excellent centration and the excellent "fit" that can be achieved with modern polymethylmethacrylate posterior chamber lenses (preparation technique of Assia and associates¹⁵).



thick, and it was virtually impossible to move the droplets to any significant degree by viscoelastic injection.

Results of examination of case 3 (Fig 3) in the dry state were not remarkable (Fig 8A). After submersion in water, the thick accumulation of oil was observed, and numerous bubbles were noted (Fig 8B). Again, it was virtually impossible to move the dense accumulation of oil on the surface by injection of viscoelastic (Fig 9).

The score given to all silicone IOLs studied, both the nonimplanted IOL, which was immersed in oil *in vitro* (case 1), and the two explanted lenses (cases 2 and 3), was +4.

Image analysis performed on the IOL from case 3 demonstrated that approximately 79.4% of the IOL surface was covered by silicone oil (Fig 10).

Discussion

The most common reasons for explantation of any IOL, including foldable lenses, are surgical problems.²⁻⁵ Decentration, a major reason for lens removal, may be due to several causes, including asymmetric fixation, loop compression, and asymmetric capsulorhexis contraction. Severe lens subluxation, especially with plate IOLs, after Nd:YAG laser posterior capsulotomy usually requires intervention by a vitreoretinal surgeon.

The complication leading to explantation described in this article is not one that can be ascribed to problems with the surgical technique but, rather, relates directly to the lens optic biomaterial. Silicone oil, a useful adjunct in vitreoretinal surgery,⁶⁻¹² is generally used in severe or "last-resort" cases such as giant retinal tears, severe proliferative vitreoretinopathy, severe diabetic retinopathy, etc.

The clinical reasons for explantation after interaction of silicone IOLs with silicone oil include not only visual acuity decrease, but also visual aberrations such as halos and rainbow patterns. The latter are not surprising because the oil droplets are not soluble in aqueous humor. This interaction occurs on both plate and haptic-type silicone IOLs, and there was no apparent difference in silicone from different IOL manufacturers.

The oil appears as a relatively flat "syrup-like" coating that is difficult to observe in the dry state (Figs 7A and 8A) but becomes manifest as droplets or bubbles when immersed in aqueous fluid. It is difficult to determine whether the droplets are composed of the silicone oil itself, trapped water, or trapped air, or a combination of each. The oil is virtually impossible to move mechanically or to dislodge by agents such as viscoelastics. It has been postulated in anecdotal clinical reports that removal by a mechanical force from instruments or by injected viscoelastics might be a viable alternative, but we could not confirm this.

The use of silicone oil is limited, especially in the United States. However, its use in the United States is increasing, as evidenced by the fact that the product marketed by Chiron (Adatomed Silicone OP5000) has been approved recently by the United States Food and Drug Administration, and multicenter courses on silicone oil

use currently are being presented nationwide in major centers. As the indication for silicone oil increases and as more silicone IOLs are implanted, the chances for this interaction will increase. For example, silicone oil is now increasingly used as a primary rather than a "last resort" tool in some conditions (i.e., infectious retinal disease, human acquired immune deficiency virus-eye disease, etc.). In addition, silicone oil is already used at a much higher incidence in many other countries, for example the United Kingdom. As foldable silicone lenses continue to be introduced into other countries, where silicone oil use is prevalent, the incidence of this complication will increase.

Our findings indicate that the use of silicone IOLs in patients with current vitreoretinal disease or with a high risk for future vitreoretinal disease that may require silicone oil as part of therapy should be reconsidered. There are other options that can be used as intraoperative surgical adjuncts, such as liquid perfluorocarbons, which only minimally adhere to silicone,¹³ that are undergoing clinical studies.

Aaberg, in a discussion of our report at the 1995 American Academy of Ophthalmology Annual Meeting, noted seven conditions that he considered as high-risk factors for pseudophakic retinal detachment. These included (1) previous retinal tears or detachment in the same or fellow eye, (2) rhegmatogenous retinal degeneration, (3) family history of hereditary retinal detachment, (4) high risk of ocular trauma (i.e., athletes susceptible to contusion, work-related categories), (5) high myopia or ocular developmental abnormalities, (6) congenital cataracts, and (7) proliferative diabetic retinopathy.

Although the use of silicone oil in patients with silicone IOLs may be relatively rare, surgeons may want to reconsider using silicone IOLs in patients with these conditions. We recommend that information regarding the existence and significance of this complication at least be pointed out not only on the silicone oil packages (as is currently the case), but also be printed on the IOL inserts—if not as a warning, at least as an informative comment regarding the existence of this complication.

Many surgeons desire to implant a silicone lens (or foldable IOLs in general) into virtually all eyes in all patients with a cataract. This concept of 100% implantation of foldable lenses into all eyes should be reconsidered, especially in patients with various pre-existing conditions such as severe vitreoretinal disease most lenses on the market are not totally immune to this complication. However, standard polymethylmethacrylate lenses show less adherence to silicone and can provide excellent results (Fig 11).^{4,5,14,15} We have performed *in vitro* analyses on other foldable and rigid IOLs to see if this interaction differed among biomaterials used in modern lenses (unpublished). We found that the degree of silicone oil adherence was at least partially related to the interfacial surface change as well as the hydrophilicity of the biomaterial. In general, the more hydrophobic, the greater the adhesion; the more hydrophilic, the less tenacious the adhesion. We would encourage that manufacturers further evaluate the use of various available hydrophilic coatings (such as Pharmacia-Upjohn's heparin surface-modified

IOL) as a possible alternative to be applied to rigid and foldable lenses.

We now realize there are at least three important complications related to foldable IOLs that may be of major concern to the vitreoretinal surgeon:

1. Most vitreoretinal surgeons are already well aware of the complications of severe decentration or subluxation that may require surgical intervention.²
2. A second complication, intraoperative condensation on the posterior surface of silicone IOLs during fluid-air exchange, has been described recently.¹⁶⁻²⁰ Eaton and associates¹⁹ postulated that the intraoperative view into the eye could be facilitated by coating the posterior surface of the IOL with silicone oil. This may improve visualization into the eye for the short term, but according to our study and another recent report²⁰ may actually cause a complication in the long term.
3. The third condition of interest described here (silicone oil-silicone IOL interaction) represents a rare, but clinically significant complication of which anterior segment and vitreoretinal surgeons should be aware.

This report of three patients is the first clinicopathologic demonstration of this condition. Awareness of it should help prevent it.

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Discussion

by

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The authors present a timely article on the vitreoretinal outcomes of three patients with silicone intraocular lenses (IOLs) complicated by irreversible silicone oil adhesions. These three patients illustrate a complication that continues to vex vitreoretinal surgeons—the loss of intraoperative visibility in eyes with silicone IOLs after performing fluid-air or silicone exchange for retinal tamponade.

The overall incidence of pseudophakic rhegmatogenous retinal detachment is low (range, 0.5%–1.0%), and the incidence of proliferative vitreoretinopathy is approximately 5% of eyes

with pseudophakic retinal detachment. Therefore, the overall probability of a pseudophakic eye requiring intraocular vitreoretinal surgery is low, but the probability increases with additional risk factors. Once intraocular surgery for proliferative vitreoretinopathy is necessary, the need is high for some form of nonphysiologic retinal tamponade, such as air, higher retention gases, perfluorohydrocarbons, or silicone oil. When using any of these modalities, adequate surgical visualization is mandatory for optimal outcome. Condensation on the posterior IOL surface, or the anterior surface, if there is a zonular dehiscence, may occur with any type of IOL. Most IOL complications may occur with any type of IOL. With most IOL compositions, condensations can be removed from the surgical visual axis by injection of hyaluronic acid or related compounds and perma-

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nently disappear as the air-gas is absorbed. Such air-gas condensation on silicone lenses may defy intraoperative attempts of surgical elimination,^{1,2} possibly requiring IOL explantation to complete the vitreoretinal surgery.

The current article describes silicone oil droplet adhesion to silicone IOLs, on either anterior or posterior surface, which could not be surgically eliminated and which persisted after the silicone oil removal in all three eyes requiring the IOL to be explanted in two of the eyes. The visual aberration for both the surgeon and patient thus differs from that of air-gas condensation, which disappears as it is absorbed. The authors conclude that the adherence is not a biochemical interaction between the silicone oil and the IOL but a physical phenomenon dependent on the hydrophilic or hydrophobic nature of the lens, which determines the size of the contact angle. Silicone oil adhesion was found to be greatest on silicone lenses and progressively less to polymethylmethacrylate, soft acrylic, hydrogel, and polymethylmethacrylate lenses with a Heparin-modified surface.

The authors recommend that cataract surgeons not insert silicone IOLs in eyes at high risk for retinal detachment. I concur with the authors and believe these high-risk factors include the following:

1. Previous retinal tears or detachment in the same or fellow eye;

2. Rhegmatogenous retinal degeneration;
3. Family history of hereditary retinal detachment;
4. High risk of ocular trauma (i.e., athletes susceptible to contusive injuries, work-related categories);
5. High myopia or ocular developmental abnormalities;
6. Congenital cataracts; and
7. Proliferative diabetic retinopathy.

If intraocular vitreoretinal surgery is necessary, the loss of surgical visualization or postoperative lens clarity may compromise the final visual outcome. Eyes at high risk for retinal detachment thus should have IOLs with the least hydrophobic characteristics. Hopefully, future technology will enhance the hydrophilic characteristics of IOLs, both rigid and foldable, so that cataract surgeons have suitable alternatives for high-risk eyes.

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