Removal of Silicone Oil From Intraocular Lens Using Novel Surgical Materials

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Purpose: To design, fabricate, and evaluate novel materials to remove silicone oil (SiO) droplets from intraocular lenses (IOL) during vitreoretinal surgery.

Methods: Three different designs were fabricated using soft lithography of polydimethylsiloxane (PDMS), three-dimensional (3D) inverse PDMS fabrication using water dissolvable particles, and atomic layer deposition (ALD) of alumina (Al_2O_3) on surgical cellulose fibers. Laboratory tests included static and dynamic contact angle (CA) measurements with water and SiO, nondestructive x-ray microcomputer tomography (micro-CT), and microscopy. SiO removal was performed in vitro and ex vivo using implantable IOLs and explanted porcine eyes.

Results: All designs exhibited enhanced hydrophobicity and oleophilicity. Static CA measurements with water ranged from 131° to 160° and with SiO CA approximately 0° in 120 seconds following exposure. Nondestructive x-ray analysis of the 3D PDMS showed presence of interconnected polydispersed porosity of 100 to 300 μm in diameter. SiO removal from IOLs was achieved in vitro and ex vivo using standard 20-G vitrectomy instrumentation.

Conclusion: Removal of SiO from IOLs can be achieved using materials with lower surface energy than that of the IOLs. This can be achieved using appropriate surface chemistry and surface topography. Three designs, with enhanced hydrophobic properties, were fabricated and tested in vitro and ex vivo. All materials remove SiO within an aqueous environment. Preliminary ex vivo results were very promising, opening new possibilities for SiO removal in vitreoretinal surgeries.

Translational Relevance: This is the first report of an instrument that can lead to successful removal of SiO from the surface of IOL. In addition to the use of this instrument/material in medicine it can also be used in the industry, for example, retrieval of oil spills from bodies of water.

Introduction

Silicone oil (SiO) adherence on intraocular lenses (IOL) is a well-known complication of vitreoretinal surgery.¹ Remnants of SiO in the eye can form droplets, strongly adherent to the surface of the IOL, that cause visual acuity reduction and induction of high order refractive aberrations, monocular diplopia, glare, and halos.¹ Removal of such droplets is technically challenging due to the strong hydrophobic interaction

between the oil and the lens. This complication is more frequent with hydrophobic IOLs, including silicone and polymethylmethacrylate IOLs.²

Over the past years, several methods have been advocated to remove SiO from IOLs using solvents or viscoelastics. However, solvents may cause tissue toxicity, and viscoelastic compounds often result in inadequate removal.^{1,2} Currently, the surgical explanation and replacement of the IOL is the mainstay of treatment,^{3,4} but it is associated with increase in surgical time, complication rate, and cost.

Figure 1. Hydrophobic materials created. (A) Macroscopic appearance of the micropatterned PDMS material with pillar dimensions $10 \times 10 \times 25 \mu\text{m}$ (width $\times$ length $\times$ height) and pillar spacing of $10 \mu\text{m}$. (B) Top-view graphical representation of the surface of a micropatterned PDMS with nano roughness. The surface roughness is constructed by $600 \times 600 \text{ nm}$ features on the surface of each micro pillar (graphical representation not to scale). Projection view of the pillars (C) and graphical representation of a water droplet, at Cassie-Baxter state, resting on the surface of the micropatterned PDMS (D). (E) Macroscopic appearance of 3D porous PDMS material. (F) Graphical representation of water-soluble particles arranged on a substrate prior to PDMS filling. PDMS is cured (G) and particles are removed using water. Removal of the particles results to a 3D interconnected porous PDMS block, as shown by the x-ray microCT (H). 3D porosity diameter between 100 and $300 \mu\text{m}$. The 3D surface roughness provides further surface energy reduction (hydrophobicity) and increase oleophilicity. The 3D structure facilitates SiO absorption within the material. (I) Macroscopic appearance of modified ALD Weck-Cel. Photos of Non-modified (J) and ALD modified Weck-Cel (K) submerged in water. Note the significant hydration of the nonmodified Weck-Cel following 3 second of water exposure, compared with ALD modified Weck-Cel (L).

The purpose of this paper is to delineate the physical mechanisms underlying this complication and to develop novel materials that can safely and effectively remove SiO from the surface of IOLs.

Materials and Methods

Hydrophobic/Oleophilic Materials Created

Three different materials were designed and fabricated, exhibiting low surface energies and adequate critical surface tension. The first two materials were fabricated using biocompatible polydimethylsiloxane (PDMS), modified by either soft lithography or inverse three-dimensional (3D) fabrication, while the third material was fabricated using the United States Food and Drug Administration (FDA)–approved surgical Weck-Cel, precisely modified using

atomic layer deposition (ALD) of alumina (Al_2O_3). All materials exhibited enhanced hydrophobic properties.

1. PDMS surface patterning was performed using standard soft lithography techniques (supplemental methods). The objective was to create a PDMS surface with high-aspect ratio (AR) micropillars with nanoroughness on their surface with minimum surface energy (Fig. 1A–D);
2. 3D porous PDMS block was fabricated using water dissolvable sucrose microparticles as a negative template (supplemental methods). The size of the particles determined the diameter of the cavitation within the block (Fig. 1E–G). Sucrose was chosen due to its excellent biocompatibility, water solubility, and low cost. The resulting microporous PDMS was sectioned to smaller segments ($3 \times 0.5 \times 3 \text{ mm}$; length $\times$ width $\times$ height) for surgical use. Structural analysis was performed using nondestructive 3D x-ray micro-computed tomography (microCT; X-Tek HMXST225; Nikon Metrology Inc., Brighton, MI). X-rays were generated using a molybdenum target exposed to 70 KV and $140 \mu\text{A}$ and x-ray scans were radial. 3D image rendering was used for image reconstruction (VGStudio Max 2.2, Heidelberg, Germany). Using nondestructive x-ray micro-CT imaging, we were able to visualize the porosity of the 3D PDMS (Fig. 1H). The analysis showed presence of polydispersed porosity, from 100 to $300 \mu\text{m}$ in diameter. Due to the rough surface of the 3D porous PDMS, its hydrophobicity and oleophilicity were further enhanced; and
3. Surgical cellulose Weck-Cel was purchased from BVI (Beaver Visitec International, Waltham, MA). Hydrophilic Weck-Cel was converted to hydrophobic using atomic layer deposition (ALD) of Al_2O_3 (supplemental methods). This modification provided hydrophobic/oleophilic properties to Weck-Cel (Fig. 1I–L).

Hydrophobicity/Oleophilicity Assessment

Hydrophobicity/oleophilicity was determined by using static contact angle (CA) measurements with $10 \mu\text{L}$ deionized (DI) water or SiO in room temperature. Hydrophobicity describes the ability of a surface to repel water and oleophilicity the ability to bind hydrocarbons or SiO. Experimentally, this is assessed by placing a water or SiO droplet on the surface of the

Figure 2. Water contact angles of materials. Static CA measurements using a 10- μ L water droplet resting on the surface of: nonpatterned PDMS (CA = 101° [A]) and 10 μ m² micropatterned PDMS (CA = 164° [B]) performed at room temperature. Likewise, CA measurements on 3D porous PDMS (CA = 155° [C]), and ALD-modified Weck-Cel (CA = 131° [D]). The Cassie-Baxter state was evaluated by the degree of droplet elongation (increase in AR) following vertically pulling off the surface. The 10- μ m patterned PDMS resulted in minimal AR change (1:1), suggestive of minimal water adsorption by the surface (E). However, the 40-, 80-, and 120- μ m patterned PDMS exhibited increase in the AR of the droplet (from 1.1–1.3), suggesting increased in water adsorption by the surface (F–H).

materials and measuring the contact angle between the solid–liquid interface. Small contact angles (much less than 90°) correspond to high wettability (oleophilicity or hydrophilicity), while large contact angles (>90°) correspond to low wettability (hydrophobicity or oleophobicity). Contact Angles more than 160° are suggestive of super low wettability (super hydrophobicity or super oleophobicity), while CA of approximately 0° responds to super wettability (super hydrophilicity or super oleophilicity).

A computer-controlled (CCD) camera (Sony XCD-V50, Park Ridge, NJ) with green light-emitting diode (LED) background illumination was used to capture images of nonpatterned PDMS (Fig. 2A), surface micropatterned PDMS (Fig. 2B), 3D porous PDMS (Fig. 2C), and ALD modified Weck-Cel (Fig. 2D). Static water CA was calculated using drop shape Laplacian analysis (Image J; National Institute of Health, Bethesda, MD). Dynamic CA was employed to assess the Cassie-Baxter state of the micropatterned PDMS. Different pillar sizes were tested (10, 40, 80, and 120 μ m) to determine the optimal pillar dimension. Dynamic CA measurements were performed by measuring the elongation of a water droplet subject to vertical pull from the surface of the micropatterned PDMS (Fig. 2E–H). The following formula was employed to calculate the change in droplet's AR (elongation) before becoming detached

from the PDMS surface:

$$AR = (L_{II'} + L_{II''}/2)/L_{ww'} \quad (1)$$

In Vitro Assessment

SiO removal from IOLs was performed in vitro as follows: five IOLs (two silicone and three acrylic) were submerged in medical grade SiO (SILIKON1000; Alcon Laboratories, Fort Worth, TX) for 3 days. They were then removed, and excess oil was removed by balanced salt solution (BSS) irrigation. The IOLs were then placed in a glass beaker (100 mL BSS) for 30 minutes until SiO droplet formation occurred on the IOL surface. SiO removal was then performed using the fabricated materials. SiO removal was assessed based on previously described methods.⁶

Ex Vivo Assessment

Pars plana lensectomy and vitrectomy in explanted porcine eyes was performed using the 23-G transconjunctival Accurus vitreotome from Alcon. An acrylic IOL (AcrySof IQ Aspheric; Alcon) was implanted in the anterior chamber (AC) of the eye, and the posterior segment was filled with SiO 1000 centistoke (Silicon 1000; Alcon). The oil was left for several minutes and was subsequently removed and exchanged for BSS (Alcon). Triple irrigation/aspiration cycles were performed to thoroughly remove the SiO. Droplets of SiO remnants formed on the posterior surface of the IOL and the AC, which were removed using a 2-mm wide 3D porous PDMS material.

Results

In Vitro Assessment of Hydrophobicity/Oleophilicity

Static CA measurements of water or oil were used to determine the hydrophobicity or oleophilicity of surface.

Provided that SiO and IOL interaction is a highly hydrophobic phenomenon, introducing a more hydrophobic material than the IOL itself can challenge this interaction and preferentially remove the SiO from the surface of the IOL.

Three hydrophobic materials (3D porous PDMS, ALD modified Weck-Cel, and micropatterned PDMS) were created as described in methods and supplemental data and shown in Figure 1. Static CA measurements of the three materials were performed using 10 μ L of water. The 3D porous PDMS and

Figure 3. SiO absorption by materials. Spreading of a 10- μ L droplet of SiO on the surface of the micropatterned PDMS in air (A). The micropatterned PDMS resulted in a 358% increase in spreading area as compared with SiO deposited on the surface of nonpatterned PDMS (B). Complete spreading was achieved within 120 seconds following SiO exposure and resulted to a contact angle of 12° (oleophilic) (C–F). The 3D porous PDMS (G–J) and the ALD-modified Weck-Cel (K–N) resulted to complete SiO absorption.

ALD modified Weck-Cel exhibited CA of 155° and 131°, respectively (Fig. 2B–D). Increased hydrophobicity/oleophilicity of PDMS was achieved by generating a pillar structure on its surface (Fig. 2A, 2B), while reducing the pillar size of the pillar structure resulted to increase hydrophobicity. Pillar sizes between 10 and 40 μ m provided superhydrophobic properties, with static water CAs greater than 160°, whereas the 80- and 120- μ m pillar size exhibited water CA of 145° and 136°, respectively. Dynamic CA measurements using vertical pulling showed a significant 7% reduction in water elongation for each step of pillar size reduction (120, 80, 40, 20, 10 μ m) demonstrating reduction in water adsorption. The AR of a vertically pulled water droplet was 1:1 for the 10- μ m, 1:12 for the 40- μ m, 1:35 for the 80- μ m, and 1:33 for the 120- μ m pillar size (Fig. 2E–H), with the 10- μ m pillar size exhibiting the lowest water adsorption.

Table. Contact Angle Measurements in Air With 10 ml of PDMS Si Oil Droplets Resting the Surface of Micro-Patterned PDMS, 3D Porous PDMS, and ALD-Modified Weck-Cel

CA Measurements Using 10 L of Si Oil	Micropatterned PDMS (Spreading)	3-D Porous PDMS (Absorption)	ALD Modified Weck-Cel (Absorption)
t = 0 sec	52°	51°	56°
t = 30 sec	49°	45°	46°
t = 60 sec	29°	39°	12°
t = 120 sec	12°	0°	0°

Both the 3D porous PDMS and the ALD modified Weck-Cel achieve complete oil absorption within 2 minutes from the exposure to Si oil, while the micropatterned PDMS continued the spreading of the Si oil thereafter.

Figure 4. SiO and water interaction with modified Weck-Cel. ALD-modified Weck-Cel (A) absorbed SiO at the same rate as the standard nonmodified commercial Weck-Cel (B). However, water was absorbed with the ALD modified Weck-Cel was inhibited (C) as compared with the nonmodified Weck-Cel (D).

SiO (10- μ L droplet) spreading on the micropatterned PDMS covered 358% more area than the nonpatterned PDMS (Fig. 3A–F). SiO CA measurements on 3D porous PDMS and ALD modified Weck-Cel was approximately 0 due to oil absorption (Fig. 3G–N). The absorption and spreading rates are presented in Table 1.

Comparing SiO absorption rate between standard and ALD-modified Weck-Cel, similar rates were recorded (Fig. 4A, 4B). However, the ALD modified Weck-Cel remained dry when submerged in water compared with standard Weck-Cel that rapidly absorbed water and expanded its volume (Figs. 1J–L, 4C, 4D).

SiO Removal In Vitro

SiO removal from acrylic and silicone IOLs was performed in vitro (Fig. 5I:5A, 5II:5A). The 3D porous PDMS and ALD modified Weck-Cel were employed first to remove the bulk of the SiO (Fig. 5I:5C, 5D, and 5II:5C, 5D). Small remnants of SiO on the IOL were removed using the micropatterned

Figure 5. SiO removal from IOL in vitro by oleophilic materials. Serial images of SiO removal from IOL in aqueous environment using (I) ALD modified Weck-Cel, (II) 3D porous PDMS, and (III) micropatterned PDMS. Bulk SiO removal was achieved using either the 3D porous PDMS or the ALD modified Weck-Cel, and final polishing was accomplished using the micropatterned PDMS. Contact angle measurements with silicone oil. Series of CA measurements of SiO (10 μ L) while spreading on the surface of the micropatterned PDMS. (A) Droplet placement on the surface (CA = 52°), (B) 30 seconds later (CA = 49°), (C) 60 seconds later (CA = 29°), and (D) 120 seconds later (CA = 12°).

PDMS, which is more effective due to its super hydrophobicity (Fig. 5III:5A–D). SiO removal and polishing of the IOL was accomplished in approximately 2 minutes (Supplemental Video V1). Technical difficulty of performing maneuvers shown in the video within a real eye would require experienced surgeons.

SiO Removal Ex Vivo

SiO removal was performed ex vivo using a porcine eye. A 23-G transconjunctival pars plana vitrectomy, pars plana lensectomy, and acrylic IOL implantation (in AC) were performed. SiO infusion was performed after fluid-air exchange. The oil was left for several minutes, then was subsequently removed and exchanged for BSS. Three irrigation/aspiration cycles were performed to thoroughly remove the oil. Nevertheless, remnants of SiO droplets formed on the posterior surface of the IOL and several droplets remained in the AC. The 3D porous PDMS material (3-mm wide stick) was used to remove SiO droplets from the surface of an acrylic IOL implanted in the anterior chamber of the eye (Fig. 6). SiO removal was accomplished in approximately 30 seconds. Floating oil droplets in the anterior chamber and on the posterior surface of the cornea were easily removed without complications.

Figure 6. SiO removal ex vivo. Series of photographs taken during simulated vitrectomy surgery in an explanted porcine eye (I-A). Anterior vitreous removal was performed and an acrylic IOL was implanted in the AC (I-B) through scleral incision. The eye was filled with SiO followed by BSS exchange. Copious irrigation/aspiration was performed to remove residues of SiO from the surface of the IOL and the AC. Small SiO droplets formed on the surface of the IOL (I-C: arrow 1) and the posterior surface of the cornea (I-C & II-A: arrows 2). Complete removal of SiO droplets was accomplished using the 3D porous PDMS material that resulted in instantaneous SiO absorption from the surface of the IOL (II-A, II-B: arrow 1). Further surgical manipulations resulted in removal of additional SiO droplets, attached to the posterior surface of the cornea (II-C: arrows 1, 2), (III-A: arrows 1, 2), and (III-B: arrows 1, 2). The procedure was performed in approximately 30 seconds and resulted to complete removal of visible SiO from the surface of the IOL and the endothelium (III-C).

Discussion

Previous attempts to remove SiO from IOLs have been very difficult due to the strong hydrophobic interaction between the SiO and the IOLs. The use of fluorinated solvents⁷ to remove SiO can have toxic effects intraocularly, since they do not remove SiO, but rather form a solution that is dispersed in the eye. Viscoelastic substances on the other hand, such as Healon, are nontoxic intraocularly, but have limited success in previous attempts.^{1,6}

Achieving SiO removal from IOLs requires good understanding of the physical interactions that take place between SiO and IOL material as described by thermodynamics. In general, the degree of mixing of two fluids is favored by entropy, but also depends on

the enthalpies of mixing. Thus, two nonpolar substances may not mix when the enthalpic disadvantage outweighs the entropic advantage of mixing, as described in the following formula:

$$\Delta G_{\text{mixing}} = \Delta H_{\text{mixing}} - T\Delta S_{\text{mixing}} \quad (2)$$

Where $\Delta H_{\text{mixing}} = 2\Delta H_{\text{a-b}} - \Delta H_{\text{a-a}} - \Delta H_{\text{b-b}}$, and a and b are the two fluids.

However, the inability of hydrophobic compounds to mix with water cannot be explained by the low enthalpic and high entropic behavior of such systems. In hydrophobic interactions, entropy favors demixing instead of mixing, which is a consequence of the conformational entropy of water molecules. Hydrogen molecules have the freedom to make bonds with their nearest neighbors. Replacing one water molecule with a molecule of a hydrophobic solvent reduces the conformational entropy from six possible bonds to three. Thus, this 50% reduction in the conformational entropy of the system results in energy penalty that favors demixing. Therefore, clustering of SiO in water is not due to molecular attraction, but rather an attempt to minimize the conformational entropy loss by surface minimization.

Based on this physical analysis, we fabricated new surgical materials to remove SiO in aqueous environments. Several micro engineering techniques were employed to accomplish this task, including soft lithography and ALD, resulting to the fabrication of three different materials characterized by enhanced hydrophobicity and oleophilicity. By measuring the liquid/vapor interface that meets the solid surface, we determined the hydrophobic/hydrophilic behavior of each material. Likewise, the Cassie-Baxter state was assessed using CA and AR measurements. The Cassie-Baxter state describes the ability of a surface to prohibit water molecules from penetrating into the grooves. This allows effortless spreading of SiO in aqueous environments. The dynamic CA and AR measurements showed that the micropatterned PDMS possess such properties.

In this work, PDMS and Weck-Cel were modified to exhibit oleophilic and hydrophobic properties. Both materials are biocompatible and FDA approved for surgical use.¹⁴ In particular, PDMS is used for the packaging of implantable biomedical microdevices and sensors,^{8,9} for fabrication of implantable glaucoma valves,¹⁰ for designing drug-eluting scaffolds^{11,12} and epiretinal implantable electrodes, and in the synthesis of new composite injectable cement.¹³ Similarly, atomic layer deposition of Al₂O₃ is used as a coating technique in bio-micro-electromechanical

sensors (MEMS) and other devices that come into contact with biological media,¹⁵ scaffold for osteointegration,^{16,17} and bone prosthesis.¹⁸ It is reported to be as biocompatible as glass,¹⁵ with good bone tissue compatibility.¹⁸ Weck-Cel sponges are the standard in eye surgical fluid control, made of highly absorbent, natural cellulose material, and are biocompatible and safe for use in delicate surgical areas. All these properties led us to consider these materials and techniques suitable for surgical use. However, appropriate sterilization is required to ensure the safety of the procedure. Ideally, PDMS should be sterilized by heat (dry or steam) and ALD modified Weck-Cel by gamma-irradiation. Further work is necessary to assess these possibilities.

All materials demonstrated the ability to absorb SiO. The ALD modified Weck-Cel absorbed SiO faster than the 3D porous PDMS, however the 3D porous PDMS has logistical advantages: it is an FDA-approved material, currently used for retinal tamponade, its fabrication is simple and inexpensive, and it can be fabricated in large scale. These properties led us to consider that the 3D porous PDMS material may be a more feasible, not only for clinical use, but also for industrial applications, such as oil retrieval from the sea. Both the 3D porous PDMS and the ALD modified Weck-Cel showed increased capacity to remove bulk quantities of SiO, however the superhydrophobic properties of the micropatterned PDMS provided detailed removal of even strongly adherent SiO remnants. This suggests that these materials should be used synergistically to obtain optimal surgical results.

Our preliminary results suggest that in situ surgical removal of SiO from IOLs is feasible using the described materials. Even though our procedure requires enlargement of the pars plana incision, it is still significantly less invasive compared with the alternative surgical exchange of the IOL. Future developments in our designs include the optimization of the materials for use through a 20- or 23-G vitrectomy port. Since PDMS polymer is already approved for intraocular use, toxicity is not an important concern for this design. However, the use of ALD to modify Weck-Cel is a new technique which requires full toxicological investigation prior to human application.

Conclusion

In conclusion, this work suggests that SiO attachment on the surface of IOLs is a highly hydrophobic

phenomenon that can be addressed by fabricating materials that provide more favorable interactions to SiO₂. Preliminary in vitro and ex vivo results are promising and currently more thorough clinical investigation of these materials is underway.

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