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LABORATORY SCIENCES

# Controlling the Capsular Shape in Lens Refilling

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**Objectives:** To investigate control of the capsular shape by determining the ability of the lens capsule to mold injected silicone and to evaluate the relationship among the volume of silicone injected, refraction, and the amplitude of accommodation.

**Methods:** After endocapsular phacoemulsification following an upper, minicircular capsulorhexis,the lens capsule of a pig eye was refilled with a silicone mixture that polymerizes in vitro in 2 hours. The minicircular capsulorhexis opening was sealed by a small silicone plug to prevent leakage. The anterior capsule curvature and refraction of the lens were measured by a Scheimpflug camera and lensometer, respectively, with and without zonular tension. Zonular tension was created using a ciliary ring sutured to the ciliary bodies and expanded.

**Results:** The mean (±SD) anterior curvature of the lenses without zonular tension was 6.50±0.07 mm after 17 hours and 6.54±0.04 mm after 42 hours; with zonular tension it was 7.01±0.11 mm and 7.23±0.24 mm, respectively. The curvature became flatter when zonular tension was applied or steeper when zonular tension was abolished momentarily during measurements after 17 hours, but after 42 hours the curvature was unaffected by the application or removal of zonular pressure. The mean (±SD) amplitude of accommodation (the difference between refraction without zonular tension and that with it) was 3.2±0.5 diopters (D), 6.1±1.8 D, 4.8±0.8 D, and 2.8±1.3 D, when the lens was refilled with a silicone volume corresponding to 45%, 55%, 75%, and 95%, respectively, of the mean normal lens volume.

**Conclusions:** The lens capsule possesses some ability to mold the injected silicone during its polymerization. When the eye is atropinized, the lens capsule may conform to its nonaccommodated state. Accommodation could be obtained by various degrees of refilling. Moderate refilling yields a greater amplitude of accommodation than does more complete refilling. Using a silicone plug to seal the capsular opening facilitates lens refilling with excellent reproducibility and seems to be useful in research.

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REFILLING THE empty lens capsule following endocapsular phacoemulsification through a minicircular capsulorhexis while preserving capsular integrity offers the potential to restore ocular accommodation.[1-7]

In an earlier study,[6] using our inflatable endocapsular balloon, we were able to confirm a mean (±SD) amplitude of accommodation of 4.6±0.5 diopters (D) in young cynomolgus monkey eyes. From that study, we concluded that during lens refilling, the lens capsule should be restored to its nonaccommodated state to obtain the optimal amplitude of accommodation. Haefliger et al[3] also supported this principle. The next issue to arise is control of the capsular shape, which primarily depends on the ability of the lens capsule to mold the injected silicone and on the volume of silicone injected.

For further study on these subjects, refilling using a balloon is inappropriate, because the balloon itself is a preformed membrane possessing a certain ability to mold the injected silicone and providing a second capsule that, despite its flexibility, always causes a slight discrepancy between its shape and that of the lens capsule; therefore, we developed a new procedure for direct lens refilling that is described herein. Using this procedure, we investigated the physical properties of the capsule and lens involved in control of the capsular shape after refilling.

## RESULTS

### LENS REFILLING PROCEDURE

It was often difficult to insert the lower plate of the plug into the capsular bag, because the capsule was tightly pressed together after the fluid had been removed from the bag. Once the capsular opening (measuring 1.2 to 1.5 mm in diameter) created by minicircular capsulorhexis had undergone phacoemulsification aspiration, there were 5 capsular openings that tore when the disk of the 3-mm-wide anterior capsular plug was inserted into the capsular bag. Minimal leakage occurred at the capsular opening during silicone injection in some cases be-

## MATERIALS AND METHODS

Forty pig eyes were obtained from a slaughterhouse for the study. In preliminary experiments, the mean volume of the pig lenses, the mean diameter of the ciliary bodies, and the mean lens refraction were determined. The mean specific gravity, 1.14 g/mL, of the pig lenses was calculated from the total volume and weight of all lenses. The mean (±SD) lens volume, 0.40±0.02 mL, was calculated from the mean specific gravity and the weight of each lens. Refraction was measured by a lensometer after the lens was carefully removed from the eye and was found to be 64.6±1.5 D in 6 lenses. The mean (±SD) diameter of the ciliary body (between the iris roots) in 10 pig lenses was measured to be 12.0±0.1 mm using calipers.

### LENS REFILLING PROCEDURE IN PIG EYES

#### Anterior Capsular Plug

To prevent the leakage of liquid silicone, a capsular plug was developed to obstruct the capsular opening created by minicircular capsulorhexis. The plug comprised a thin delivery silicone tube (outer diameter, 0.650 mm; inner diameter, 0.305 mm) with an umbrellalike, thin silicone, double plate (0.15 mm in thickness) fixed at the end of the delivery tube. The 2 plates were attached by soft, sticky, silicone gel as a cement. The round upper plate and the silicone gel were 2.5 mm in diameter. The lower plate was 3 mm in diameter and had a small projection as the leading edge for insertion into the capsular bag (**Figure 1**). The inner lumina of the delivery tube was filled with a soft, cured silicone gel to prevent reflux of the injected refilling material.

#### Surgical Technique

Prior to surgery, the cornea and iris were removed. Endocapsular phacoemulsification aspiration was performed following an upper minicircular capsulorhexis of 1.2 to 1.5 mm in diameter. The fluid within the capsular bag was pressed out and absorbed by a sponge. The lower plate of the capsular plug was introduced through the capsulorhexis opening into the capsular bag, so that the silicone gel between the 2 plates blocked the capsular opening. A mixture of 2 liquid silicone compounds, polymethyl siloxane as the main component and polymethyl disiloxane as a cross-linking agent, was injected through the delivery tube into the capsular bag (**Figure 2**) using an odontological syringe with a 27-gauge disposable needle as previously reported.[6] One push of the lever injected exactly 0.05 mL of liquid silicone. After the capsular bag was filled with silicone, the delivery tube was cut at its root. The injected silicone polymerized in 2 hours in vitro.

#### Ciliary Ring for Exerting Tension on Zonules

Because the pig eye has no accommodation ability, a ciliary ring was used to arbitrarily change the capsular shape. The ring was made of steel, 12 mm in diameter, corresponding to the mean diameter of the pig eye. The ring was sutured to the ciliary body at the iris root after the iris was removed entirely. Both ends of the ring were crossed and appropriately bent such that the sutures placed at both bent ends would not slip out. When the ring was maximally widened by bringing the 2 crossed ends together, the diameter increased to 16 mm. When the suture was loosened, the ring conformed to the original diameter due to the high elasticity of the steel. The ring was placed at the ciliary body by a running 9-0 nylon suture using 24 stitches (**Figure 3**).

### CONTROLLING THE CAPSULAR SHAPE

#### Lens Capsule Ability to Mold Injected Silicone

Using this procedure we refilled 10 lenses with 0.4 mL of the silicone and then divided them into 2 groups. In 5 lenses, no tension was exerted on the zonules, but in the other 5, tension was exerted on the zonules by the ciliary ring during polymerization of the injected liquid silicone mixture. Scheimpflug photography was performed before and immediately after surgery, and thereafter at between 15 and 17 hours and at between 40 and 42 hours (48 hours after death) to measure the anterior capsule curvature. The equivalence of 2 K-readings was determined as the anterior capsule curvature. At each measurement in both groups, zonular tension was momentarily exerted or abolished.

#### Relationship Among Volume of Injected Silicone, Refraction, and Amplitude of Accommodation

The lens was refilled with 0.175 mL of the silicone in 5 lenses, with 0.225 mL in 7 lenses, with 0.300 mL in 5 lenses, and with 0.375 mL in 6 lenses.The ciliary ring sutured to the ciliary body was widened to generate zonular tension by bringing the 2 ends of the ring together with 7-0 silk. The lens with the sutured ciliary ring was then placed on a small packing ring 7 mm in diameter, which was glued on the bottom of a Petri cup filled with a saline solution (Figure 3). After 2 hours, the cup with the refilled lens was placed under the lensometer and the refraction was measured before and after cutting the suture that had widened the ciliary ring. The refraction of the normal, nonrefilled lens was also measured in the same manner.

#### Elasticity of the Normal and Refilled Lenses

The elasticity of the normal and refilled lenses was measured by a digital force gauge (DFG-0.2K, Shimpo Co, Kyoto, Japan). The lens was pressed at the equator by a small plate held against the sensor-probe of the gauge until the press-plate moved toward the probe for 1 or 2 mm. Elasticity was expressed as the pressure being exerted on the sensor and was measured before and after removing the lens capsule.

cause of the difficulty in maintaining the stability of the tiny plug connected to the syringe. However, after the lens capsule was refilled with the appropriate volume of silicone mixture and the syringe was withdrawn from the delivery tube, the minicircular capsulorhexis opening was closed effectively by the capsular plug. Reflux through the tube was also prevented, since the tube stump was filled with silicone gel. Any air bubbles that were not removed from the bag or that entered it during surgery (Figure 3) were fully absorbed within 24 hours; no irregularity or indentation was left on the surface of the polymerized silicone.

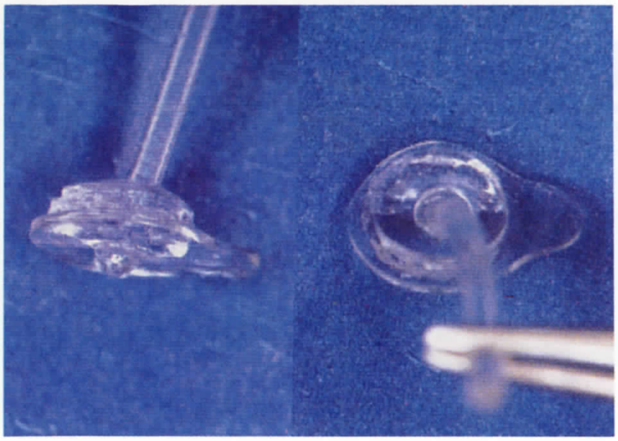

**Figure 1.** *Two views of the anterior capsular plug, consisting of a delivery tube and 2 silicone plates attached by a silicone gel as a cement.*

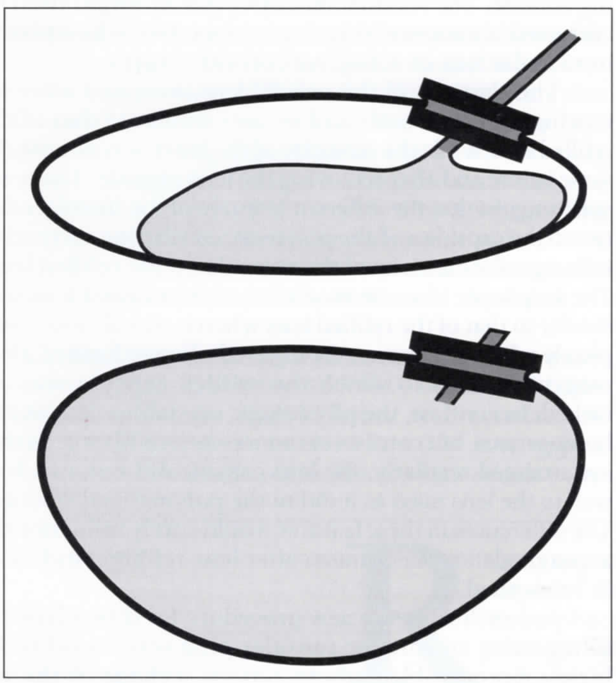

**Figure 2.** *Schematic representation of the direct lens refilling procedure using the anterior capsular plug. Top, The silicone lower plate with a projection was inserted through a minicircular capsulorhexis opening into the capsular bag. Bottom, After silicone was injected into the capsular bag, the delivery tube was cut.*

## ANTERIOR CURVATURE OF THE NORMAL AND REFILLED LENSES

Preoperatively, the mean (±SD) anterior curvature of 10 normal lenses was 6.74±0.26 mm. Immediately after refilling, the anterior curvature was 6.49±0.11 mm. For the 5 normal lenses without zonular tension , the anterior curvature was 6.50±0.07 mm after 15 to 17 hours. After 40 to 42 hours (ie, about 48 hours after death), the mean anterior curvature became almost equal to the initial value, 6.54±0.04 mm.

In the second group with continuous zonular tension during polymerization of the injected silicone, the mean anterior curvature was 7.01±0.11 mm after 15 to 17 hours. After 40 to 42 hours the mean anterior curvature was 7.23±0.24 mm (**Table 1**). In both groups, the anterior curvature became flatter or steeper at 15 hours postoperatively when zonular tension was temporarily exerted or abolished, respectively. However, at the 40- to 42-hour measurement after surgery, anterior curvature remained unchanged in both groups, even after zonular tension was exerted or abolished (Table 1). Forty-eight hours after death, the capsule and zonules appeared to be no longer sufficiently pliable to mold the polymerized silicone to the original capsular shape.

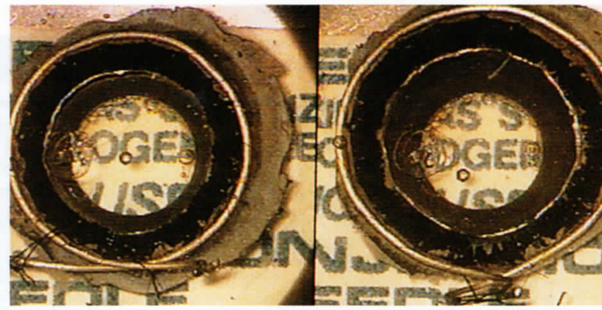

**Figure 3.** *A refilled lens extracted from a pig eye. A ciliary ring was sutured to the ciliary body without (left) and with (right) widening.*

**Table 1. Anterior Capsule Curvatures of Pig Lenses After Refilling the Capsule***

| | Mean±SD Anterior Capsule Curvature, mm | |
|---|---|---|
| **Postoperative Time, h** | **Without Zonular Tension** | **With Zonular Tension** |
| 15-17 | | |
| After temporary application or removal of zonular pressure at 15 h | 6.50±0.07 (7.17±0.26) | 7.01±0.11 (6.39±0.09) |
| 40-42 | | |
| After temporary application or removal of zonular pressure at 40 h | 6.54±0.04 (6.58±0.08) | 7.23±0.24 (7.18±0.21) |

**n equals 5 for each group.*

## RELATIONSHIP AMONG INJECTED SILICONE VOLUME, REFRACTION, AND AMPLITUDE OF ACCOMMODATION

The relationship among the volume of injected silicone, refraction, and the amplitude of accommodation is described in **Table 2**. Refraction increased in mean value as the volume of injected silicone increased. The mean amplitude of accommodation also increased initially. However, it reached the maximal volume at 0.225 mL and, thereafter, decreased with increases in volume (Table 2).

## ELASTICITY OF THE LENSES

In the normal lens, the mean (±SD) value of force required to press the lens for 1 and 2 mm was 1.04±0.19 gram-force (gf) and 3.28±0.68 gf, respectively. These values were 0.5±0.2 gf and 1.28±0.38 gf after removing the capsule. The mean value of force required to press the refilled lenses for 1 mm and 2 mm was 0.46±0.13 gf and 1.63±0.32 gf, respectively, and 0.34±0.05 gf and 1.27±0.18 gf after removing the capsule (**Table 3**). The lens capsule adhered fairly well to the polymerized silicone and did not slide when the capsule was removed with fine forceps.

**Table 2. Relationship Among Volume of Injected Silicone, Refraction, and Amplitude of Accommodation**

| No. of Pig Eyes | Injected Volume, mL, (% of Mean Lens Volume)* | Mean±SD Refraction, D Without Zonular Tension | Mean±SD Refraction, D With Zonular Tension | Amplitude of Accommodation, D | *P* |
|---|---|---|---|---|---|
| 5 | 0.175 (45) | 23.5±0.8 | 20.3±0.4 | 3.2±0.5 | .05 |
| 7 | 0.225 (55) | 26.6±1.1 | 20.6±0.8 | 6.1±1.8 | . . . |
| 5 | 0.3 (75) | 27.0±0.8 | 22.2±0.6 | 4.8±0.8 | .01 |
| 6 | 0.375 (95) | 28.2±1.6 | 25.3±1.6 | 2.8±1.3 | .01 |
| 6† | NA | 64.6±1.5 | 62.6±1.3 | 2.2±0.6 | NA |

*Mean lens volume (n=40) equals 0.40±0.02 mL.
†Row gives values for normal (noninjected) lenses. NA indicates not applicable.

**Table 3. Elasticity of Pig Lens**

| | Mean±SD Force for Pressing the Lens, Gram-force* | | | |
|---|---|---|---|---|
| | Before Capsule Removal | | After Capsule Removal | |
| | To 1 mm | To 2 mm | To 1 mm | To 2 mm |
| Normal lens (n=5) | 1.04±0.19 | 3.28±0.68 | 0.5±0.2 | 1.28±0.38 |
| Refilled lens (n=7) | 0.46±0.13 | 1.63±0.32 | 0.34±0.05 | 1.27±0.18 |

## COMMENT

The anterior capsular plug effectively prevented leakage of the injected silicone except in some cases with minimal leakage. This facilitated lens refilling with excellent reproducibility, although there was some difficulty in inserting the capsular plug.

Investigating control of the capsular shape, our results show that the lens capsule of the pig eye possesses some ability to mold the injected silicone mixture during polymerization, although it should be considered that the cornea and iris were removed from those eyes. This suggests that when the eye is atropinized postoperatively, the lens capsule will conform to its nonaccommodated state, which should yield the optimal amplitude of accommodation according to the lens refilling principle previously described.

Some amplitudes of accommodation could be obtained with any degree of refilling. Moderate refilling yielded a greater amplitude of accommodation than more complete or poor refilling, as shown in the highest amplitude at 55% bag volume. When refilled moderately, the lens is flatter. As a result of flatter anterior curvature of the lens capsule and a lower lens mass, more potential energy may be stored in the anterior curvature of the lens capsule and released by zonular relaxation, which is consistent with Fisher's theory.[8] Refilling approximately 55% bag volume seemed to be most favorable for obtaining the optimal amplitude of accommodation in the pig eyes under these conditions. Although an in vitro observation, the decreasing amplitude of accommodation with the increasing degree of refilling suggests that an increase in lens volume may be a factor in presbyopia.

Mean refraction in the refilled lenses ranged from about 20 to 28 D, compared with 64 D in the normal lenses. This may be due to the lower refractive index of the injected silicone (1.405) and smaller bag volume in the refilled lenses. If a refilling biomaterial with a wide range of refractive indexes were available, postoperative emmetropia could be achieved despite varying the refilling volume. The residual refractive power might then be corrected intraoperatively or postoperatively by a phatic intraocular lens or refractive corneal surgery.

The elasticity of the normal lens increased after removing the lens capsule and became similar to that of the refilled lens, while the elasticity of the latter was almost the same before and after removing the lens capsule. These results suggest that the different features of the interface between the capsule and the polymerized silicone seemed to influence the elasticity of the normal and the refilled lens. The amplitude of accommodation of the normal lens was similar to that of the refilled lens when it was almost completely refilled. However, the injected silicone formed a homogenous mass to which the refilled capsule was attached. In contrast, the physiologic crystalline lens is not homogenous, but consists of numerous lens fiber cells that are arranged regularly; the lens capsule did not attach as well to the lens mass as it did to the polymerized silicone. The differences in these features would surely influence the accommodation mechanism after lens refilling and need to be clarified.

In conclusion, the new procedure for direct lens refilling using an anterior capsular plug was found to be highly reproducible without serious leakage of the injected silicone. The technique described may contribute to further study of experimental lens refilling.

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