

# LONG-TERM SAFETY AND VISUAL OUTCOMES OF TRANSSCLERAL SUTURED POSTERIOR CHAMBER IOLS AND PENETRATING KERATOPLASTY COMBINED WITH TRANSSCLERAL SUTURED POSTERIOR CHAMBER IOLS

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## ABSTRACT

*Purpose:* To evaluate the outcomes of consecutive patients who underwent transscleral sutured posterior chamber intraocular lens (TS PCIOL) implantation as well as patients who had combined penetrating keratoplasty (PK) and TS PCIOL.

*Methods:* Data from all patients who had sutured PCIOL insertion performed by the same surgeon (V.S.N.) between January 2003 and June 2007 were compiled and analyzed.

*Results:* Group 1 consisted of 69 eyes of 67 patients who had TS PCIOL only. Mean age was 65.1 years, and mean follow-up was 14.25 months. Mean best spectacle-corrected visual acuity (BSCVA) was 20/80 preoperatively and 20/40 postoperatively. Group 2 consisted of 38 eyes of 37 patients who had combined PK and TS PCIOL. Mean age was 70.21 years, and mean follow-up was 14.29 months. Mean BSCVA was <20/250 preoperatively and between 20/70 and 20/80 postoperatively. In both groups, there were no reported cases of choroidal hemorrhage or hyphema. There was one case (0.9%) of suture erosion (group 1). There were no redislocations, lens tilting, suture breakage, or graft rejections. Postoperative complications included uveitis in 1 eye (0.9%), glaucoma in 5 (4.7%), cystoid macular edema in 6 (5.6%), and retinal detachment in 2 (1.9%).

*Conclusions:* The TS PCIOL procedure, as done by the ab externo method, is safe and effective. It has few intraoperative or postoperative complications, and it improves visual acuity in patients requiring either TS PCIOL alone or combined PK and TS PCIOL. Ultimately, in considering TS PCIOL, patient selection, surgical method, and the surgeon's comfort with the technique must be weighed.

*Trans Am Ophthalmol Soc 2009;107:242-253*

## INTRODUCTION

Intraocular lens (IOL) implantation is the standard of care for treatment of aphakia in most scenarios. There are many techniques for IOL implantation. The two main procedures are insertion of an anterior chamber IOL (ACIOL) and insertion of a posterior chamber IOL (PCIOL). The ACIOLs can be inserted via angle-supported ACIOL or iris-fixated ACIOL techniques. Insertion of PCIOLs can be accomplished by capsular-supported PCIOL, iris-supported PCIOL, or transsclerally sutured PCIOL. For cases in which there is little or no capsular support, iris-sutured PCIOL and transscleral sutured PCIOL (TS PCIOL) are preferred. Techniques for TS PCIOL vary and include the ab externo (outside-in) approach and the ab interno (inside-out or open-sky) approach.

The PCIOL is hypothesized to be superior to the ACIOL in patients with glaucoma, diabetes, corneal guttata or low endothelial cell count, peripheral anterior synechiae, and cystoid macular edema (CME) because of the lens's anatomical location. In addition, in the mid-1980s, evidence began to emerge that rigid closed-loop ACIOLs were associated with various complications, such as endothelial cell loss, pseudophakic bullous keratopathy, uveitis, CME, angle structure damage, formation of peripheral anterior synechiae, fibrosis of haptics into the angle, pupillary block, and hyphema.<sup>1</sup> These complications led to the development of open-loop ACIOL and iris-fixated claw IOL designs. Current studies show a decrease in the complications that were associated with rigid closed-loop ACIOLs. All types of ACIOLs cause more damage to the corneal endothelium than the PCIOL.<sup>2</sup> Furthermore, PCIOLs may be preferred to ACIOLs because the IOL is placed closer to the focal point of the eye, thus minimizing magnification effects, anisocoria, and pseudophakodonesis.

Currently, the iris-sutured PCIOL is favored over the TS PCIOL because of a shorter surgical time and a more straightforward technique. However, it is also associated with a higher risk of inflammation-related problems, such as uveitis and CME.<sup>1</sup>

Recent research on the TS PCIOL shows that overall it is a creditable procedure, but not without complications. A recent study by Vote and colleagues,<sup>3</sup> which looked at the long-term outcome of combined pars plana vitrectomy and scleral-fixated sutured PCIOL implantation with a mean follow-up of 6 years, found that suture breakage occurred at a rate of 27.9%. Another recent study of scleral-fixated PCIOLs in nonvitrectomized eyes<sup>4</sup> found that 37% of the eyes had preoperative and postoperative adverse events and that scleral-fixated PCIOLs have a significant risk of intraoperative and postoperative complications. In a study by Djalilian and coworkers,<sup>5</sup> the long-term results of TS PCIOLs combined with penetrating keratoplasty (PK) were evaluated. Exposure of the haptic suture through the conjunctiva occurred in 11% of the patients at an average of 12 months after surgery. There was no suture erosion when the suture was rotated into the eye, but there was a somewhat high incidence of new-onset glaucoma and CME. Finally, an older study, which looked at the incidence and management of complications of TS PCIOLs,<sup>6</sup> found a high rate of suture erosion through the scleral flaps (73%) at a mean follow-up of 9.4 months, and a lower but still substantial rate of suture erosion through the conjunctiva (17%) at a mean follow-up of 12 months.

The current study seeks to evaluate the surgical outcomes of patients who had a TS PCIOL placed, as well as those patients who had a combination of PK and TS PCIOL. The results with 107 consecutive eyes are reviewed and the risks of intraoperative and postoperative complications associated with the ab externo TS PCIOL technique are assessed.

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**Bold** type indicates AOS member.

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## PATIENTS AND METHODS

A list of all patients who had undergone TS PCIOL implantation with or without PK between February 2003 and June 2007 at a single referral-based institution was compiled. Union Memorial Hospital's Institutional Review Board determined that IRB approval was not required before the initiation of this study. Medical records from 155 eyes were analyzed retrospectively. While every attempt was made to include all 155 eyes, 48 eyes were excluded because of insufficient data for analysis, leaving a total of 107 eyes from 104 patients for analysis. All of the procedures were performed by a single surgeon (V.S.N.), who has performed this procedure for 20 years. The medical records of each patient were reviewed for general demographics, baseline preoperative best spectacle-corrected visual acuity (BSCVA), postoperative BSCVA, date of and indication for surgery, surgical technique, intraoperative or postoperative complications, any subsequent surgical procedures required, and date of last follow-up. The patients were split into 2 groups—those who underwent TS PCIOL implantation only (group 1) and those who underwent PK simultaneously with TS PCIOL (group 2). Indications for surgery included aphakia and subluxed or dislocated crystalline lens or IOL. These indications were attributed to complicated cataract surgery, previous trauma, complex retinal detachment surgery, or ectopia lentis. Additional procedures, such as vitrectomy, synechialysis, sphincterotomy, and removal of IOL, may have been performed at the time of the sutured PCIOL procedure.

Visual acuity was measured using the Snellen chart. For the purpose of calculation, visual acuity was further analyzed by using decimal visual acuity. Counting fingers (CF) was assigned a value of 0.01, hand motions (HM) and light perception (LP) were assigned a value of 0.001, and no light perception (NLP) was assigned a value of 0. This was similar to the method used by Akpek and associates.<sup>7</sup> However, in the current study, CF was assigned a consistent value of 0.01 because the distance at which a patient could count fingers was not always noted in the chart. In almost every case in which it was noted, the patient counted fingers at approximately, or less than, 1 meter. The rate of intraoperative and postoperative complications was then assessed and compared to studies that analyzed the TS PCIOL as well as studies that analyzed the iris-sutured PCIOL.

Intraocular pressure (IOP) was measured by pneumotometry; whenever a lower or higher than normal pressure was obtained, the measurement was repeated and the mean was recorded. New-onset glaucoma was defined as an increased IOP requiring treatment in a patient with no history of preoperative glaucoma. An allograft rejection was diagnosed if corneal clouding was noted in association with an epithelial or endothelial rejection line, keratic precipitates, and/or anterior chamber cells. Fluorescein angiography was performed to confirm CME when suspected. Preoperative and postoperative endothelial cell counts were measured using Tomey 1010 endothelial camera (group 1 only).

Detailed outcome analyses were conducted for all 107 eyes of 104 patients with a mean follow-up of 14 months.

## SURGICAL TECHNIQUES

All procedures were performed by a single surgeon (V.S.N.) in a uniform manner. First, the central visual axis was marked, then 2 triangular scleral flaps at 70% to 80% depth and 180° apart were dissected with the base at the limbus. In group 2, the donor corneas were trephined 8 mm with a Hessburg trephine. After trephining the host cornea with a 7.5-mm Hessburg trephine, the lens was removed from the eye. Anterior vitrectomy was performed whenever vitreous remained in the anterior chamber. Goniosynechialysis and sphincterotomies were carried out under direct visualization, when necessary. A secondary IOL was sutured into place using the ab externo technique. The double-armed 10-0 polypropylene suture on long needles (Alcon, Fort Worth, Texas) was passed 1 mm behind the limbus at the base of the scleral flaps and brought out through the superior corneal-scleral incision (group 1) or through the corneal opening (group 2). The long needles were cut off, and the Prolene sutures were tied to the ends of the haptic of the PCIOL (MC30BA and MC20BA; Alcon). The ends of the haptic were gently cauterized to create a small burr at the tip. The IOL was then placed behind the pupil and centered in the ciliary sulcus. The short curved needles at the other end of the sutures were placed through the scleral beds. The 10-0 Prolene sutures were tied, and the knots were buried into the sclera. The scleral flaps were closed with 10-0 nylon suture.

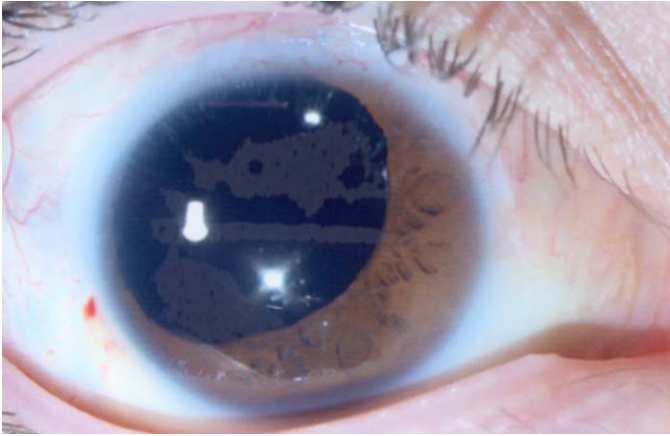
## TWO CASE DESCRIPTIONS

### Group 1

An 84-year-old man, who had an iris-supported IOL placed 28 years earlier, presented with a history of 1 to 2 years of blurry vision and photophobia in the right eye. On examination, he was noted to have uveitis-glaucoma-hyphema (UGH) syndrome with 3+ cell and flare, elevated IOP, and CME. Preoperative BCVA was 20/200. The patient underwent removal of iris-supported IOL, synechialysis, sphincterotomy, vitrectomy, and insertion of TS PCIOL. There were no intraoperative or postoperative complications. Postoperatively, the patient had a clear cornea, deep anterior chamber with no reaction, centrally placed TC PCIOL, and no CME. Postoperative BCVA was 20/40, 18 months after surgery (Figures 1 and 2).

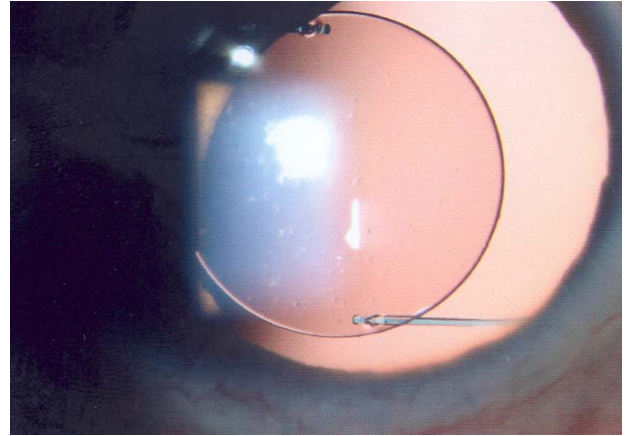
### Group 2

An 84-year-old woman presented with progressive worsening of visual acuity 1 year after cataract extraction and ACIOL insertion in the right eye. On examination, she had marked bullous keratopathy with corneal edema, trace anterior chamber reaction, and limited view of the posterior pole secondary to corneal changes. Preoperative BCVA was 20/200. Preoperative ocular comorbidities included a history of narrow-angle glaucoma treated previously with peripheral iridotomy. The patient underwent removal of the ACIOL, anterior vitrectomy, and combined corneal transplant with sutured PCIOL insertion. There were no intraoperative or postoperative complications. Postoperatively, the patient had a clear corneal transplant, deep anterior chamber, well-centered TS PCIOL, and no CME. Postoperative BCVA was 20/70, 14 months after surgery (Figures 3, 4, and 5).



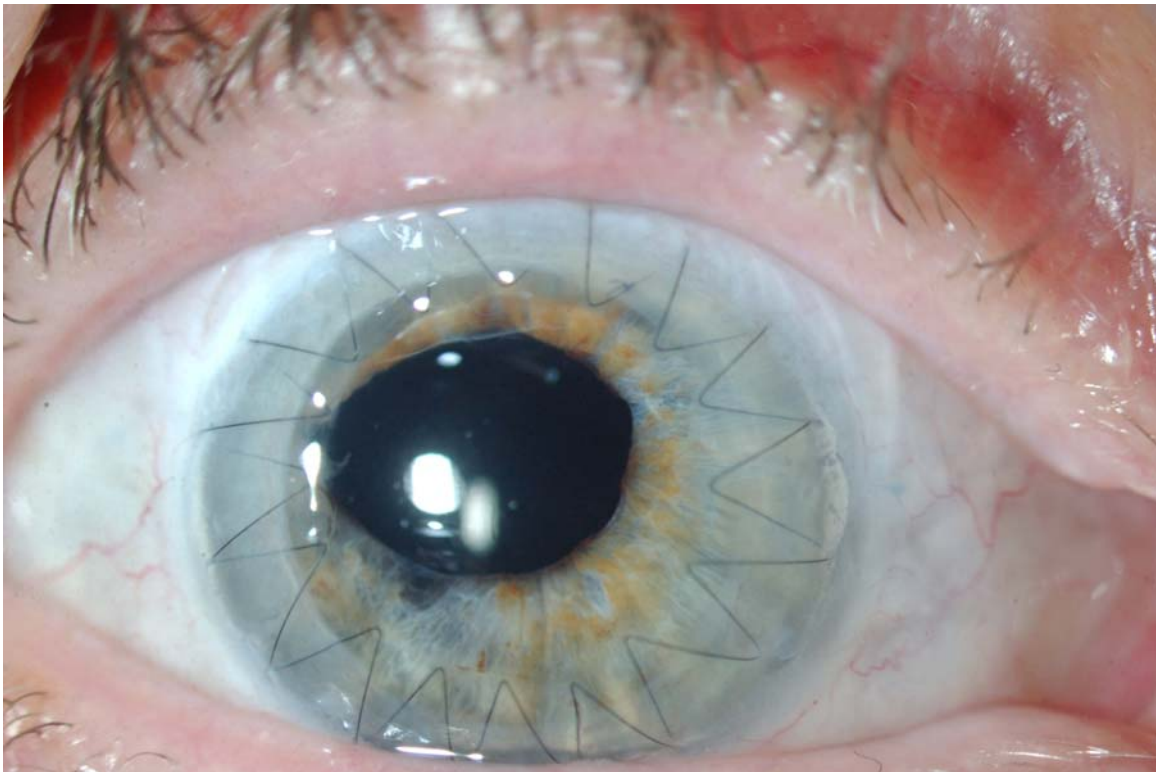
**FIGURE 1**

Patient from group 1, 18 months postoperatively. Well-centered TS PCIOL is seen.



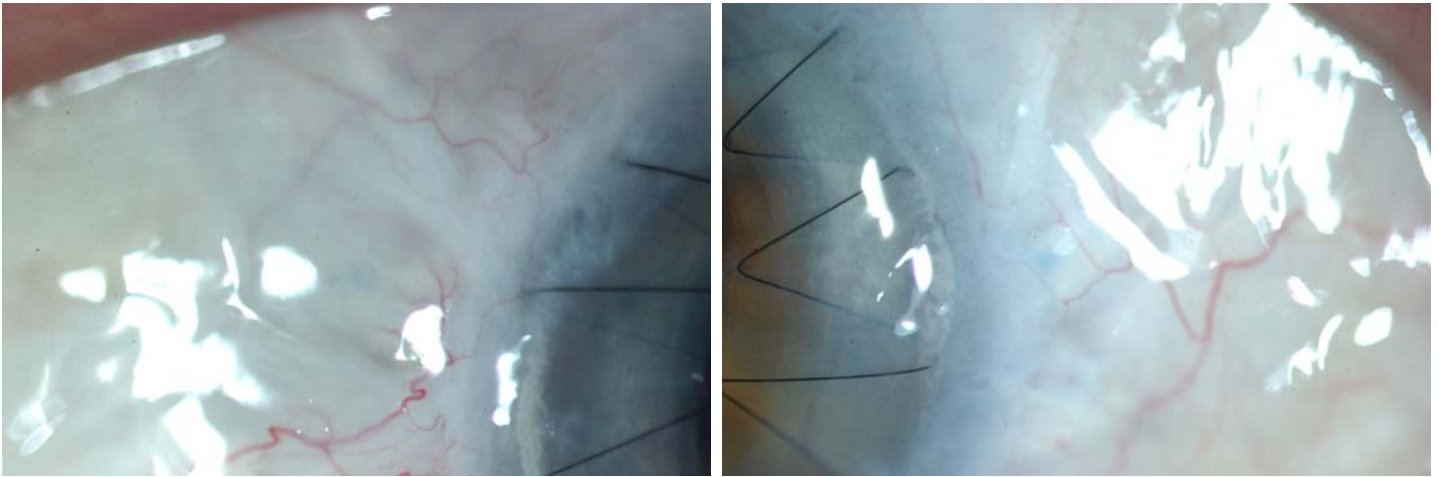
**FIGURE 2**

Patient from group 1, 18 months postoperatively. Well-positioned and centered TS PCIOL is seen by retroillumination.



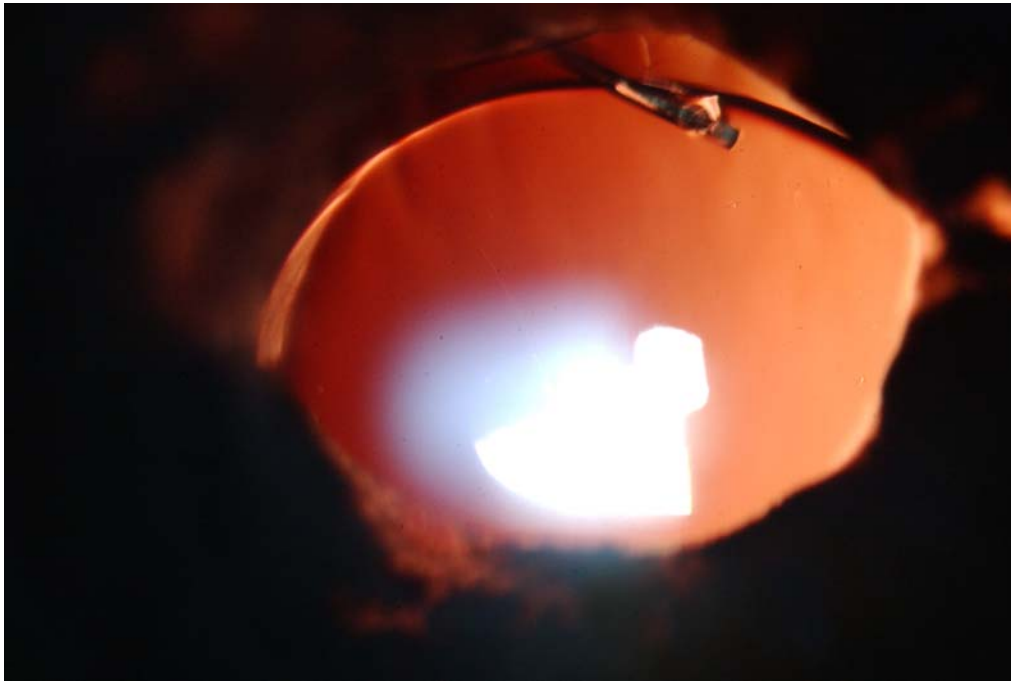
**FIGURE 3**

Patient from group 2, 14 months postoperatively. Clear corneal graft and a centrally placed TS PCIOL are seen.



**FIGURE 4**

Patient from group 2, 14 months postoperatively. Prolene sutures are buried under scleral flap at 3 o'clock and 9 o'clock positions.



**FIGURE 5**

Patient from group 2, 14 months postoperatively. Well-positioned and centered TS PCIOL is seen by retroillumination.

## **RESULTS**

### **GROUP 1: PATIENTS WHO UNDERWENT SUTURED PCIOL IMPLANTATION**

Sixty-nine eyes of 67 patients underwent TS PCIOL implantation. Mean patient age was 65.1 years (SD 18.2 years, range 13-90). There were 30 female (31 eyes) and 37 male (38 eyes) patients. Mean follow-up time was 14.25 months. Preoperative comorbidities included glaucoma in 13 eyes (18.8%), CME in 10 (14.5%), a history of treated retinal detachment in 2 (2.9%), uveitis in 9 (13.0%), trauma in 1 (1.4%), diabetic retinopathy in 1 (1.4%), and age-related macular degeneration (ARMD) in 1 (1.4%).

Preoperative visual acuity was 20/40 or better in 13 eyes (18.8%), between 20/40 and 20/100 in 20 (29.0%), and worse than 20/100 in 36 (52.2%). Preoperative visual acuity ranged from 20/20 to LP. Mean preoperative visual acuity was 20/80. In the same group, 39 eyes (56.5%) had a best postoperative visual acuity of 20/40 or better, 19 (27.5%) had a best postoperative visual acuity that ranged from 20/40 to 20/100, and 11 (15.9%) had a best postoperative visual acuity that was worse than 20/100. The best postoperative visual acuity ranged from 20/25 to NLP, and the mean was 20/40. Postoperative visual acuity was improved in 50 of 69

eyes (72.5%). Eleven of 69 eyes had a postoperative BSCVA of worse than 20/100 (Figure 6). Eight of these 11 eyes either maintained or improved their vision from preoperative to postoperative BSCVA. The 11 eyes with BSCVA worse than 20/100 had other significant ocular comorbidities preoperatively, including uveitis, glaucoma, CME, trauma, diabetic retinopathy, vitreoretinal syndrome, and ARMD.

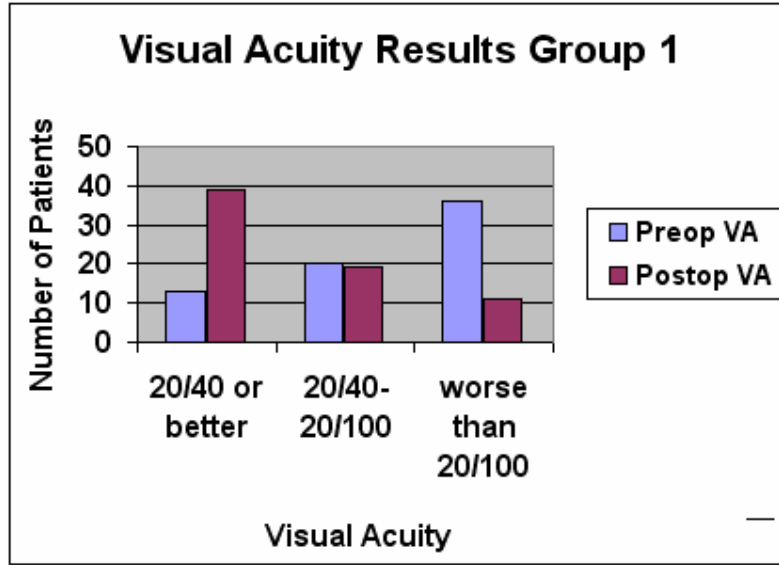


FIGURE 6

Preoperative and postoperative visual acuity in group 1.

Postoperatively, patients in group 1 presented with the following newly diagnosed conditions: bullous keratopathy in 3 eyes (4.3%), glaucoma in 4 (5.8%), CME in 4 (5.8%), and uveitis, retinal detachment, Fuchs dystrophy, hemorrhage (first developing in the posterior pole with spontaneous resolution followed by development of a peripheral choroidal hemorrhage), and herpes simplex virus (HSV) keratitis each in 1 eye (1.4%) (Table 1). The postoperative retinal detachment did not occur at the site of needle insertion.

TABLE 1. POSTOPERATIVE CONDITIONS IN GROUP 1 (TS PCIOL)

| CONDITION                | ALL EYES (N=69) | PERCENTAGE |
|--------------------------|-----------------|------------|
| Glaucoma                 | 4               | 5.8%       |
| CME                      | 4               | 5.8%       |
| Bullous keratopathy      | 3               | 4.3%       |
| Uveitis                  | 1               | 1.4%       |
| Retinal detachment       | 1               | 1.4%       |
| Endothelial dystrophy    | 1               | 1.4%       |
| Hemorrhage*              | 1               | 1.4%       |
| Herpes simplex keratitis | 1               | 1.4%       |
| Suture erosion           | 1               | 1.4%       |

CME, cystoid macular edema; TS PCIOL, transscleral sutured posterior chamber intraocular lens.

\*Retinal hemorrhages, peripheral choroidal hemorrhage.

One eye (1.4%) subsequently developed a suture erosion 2 years after the TS PCIOL surgery. This was treated with a scleral patch graft.

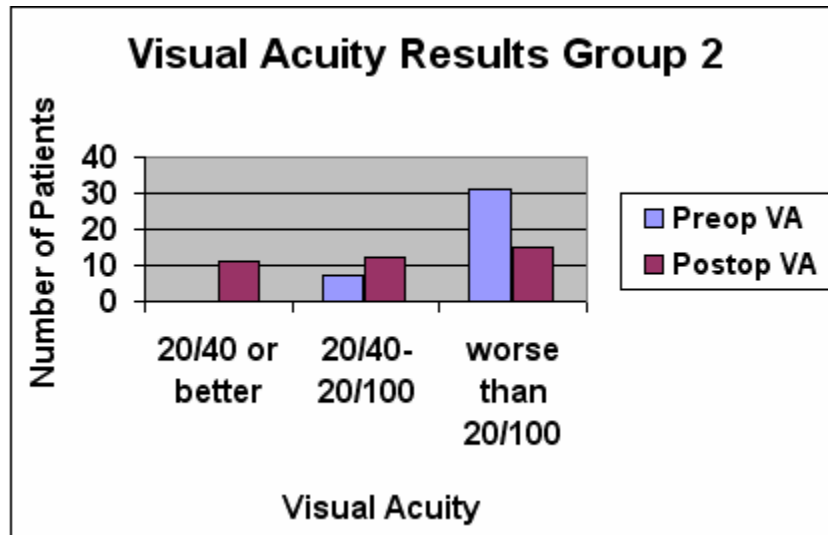
Endothelial cell counts were collected on 34 eyes of 32 patients. Preoperative average cell counts were 2064 cells/mm<sup>2</sup> (range, 955-3302). The postoperative average was 1954 cells/mm<sup>2</sup> (range, 818-2919) at a mean of 32 months postoperatively (range, 6-38). The average endothelial cell loss was 5%.



**GROUP 2: PATIENTS WHO UNDERWENT COMBINED CORNEAL TRANSPLANT AND SUTURED PCIOL IMPLANTATION**

Thirty-eight eyes of 37 patients underwent combined corneal transplant and sutured PCIOL. Mean age of patients in this group was 70.21 years (range, 32 to 91). There were 23 female (23 eyes) and 14 male (15 eyes) patients. Mean follow-up time was 14.29 months. Cumulative survival of corneal grafts was 100% at 14.29 months. Preoperative comorbidities included glaucoma in 5 eyes (13.2%), CME in 3 (7.9%), a history of treated retinal detachment in 5 (13.2%), and uveitis in 2 (5.3%).

No eyes in this group had a preoperative visual acuity of 20/40 or better. Preoperative visual acuity was between 20/40 and 20/100 in 7 eyes (18.4%), and worse than 20/100 in 31 eyes (81.6%). Preoperative visual acuity ranged from 20/50 to LP, and mean preoperative visual acuity was less than 20/250. Best postoperative visual acuity was 20/40 or better in 11 eyes (28.9%), 20/40 to 20/100 in 12 eyes (31.6%), and 20/100 or worse in 15 (39.5%). The mean best postoperative visual acuity was between 20/70 and 20/80 (range, 20/30 to HM). Postoperative visual acuity was improved in 24 of 38 eyes (63.1%). Seventeen of 38 eyes had a postoperative BSCVA of worse than 20/100 (Figure 7). Twelve of these 17 eyes either maintained or improved their vision from preoperative to postoperative BSCVA. Other significant preoperative ocular comorbidities in these 17 eyes included glaucoma, retinal detachment, trauma, vitreous hemorrhage, and ARMD.



**FIGURE 7**

Preoperative and postoperative visual acuity in group 2

Postoperatively, patients in group 2 presented with the following new diagnoses: CME in 2 eyes (5.3%) and bullous keratopathy, glaucoma, retinal detachment, and retinal scarring each in 1 eye (2.6%) (Table 2). The postoperative retinal detachment did not occur at the site of needle insertion.

Endothelial cell counts were not measured for group 2 because preoperative numbers could not be obtained.

**TABLE 2. POSTOPERATIVE CONDITIONS IN GROUP 2 (PK WITH TS PCIOL)**

| CONDITION           | NO. OF EYES (N=38) | PERCENTAGE |
|---------------------|--------------------|------------|
| CME                 | 2                  | 5.3%       |
| Glaucoma            | 1                  | 2.6%       |
| Bullous keratopathy | 1                  | 2.6%       |
| Retinal detachment  | 1                  | 2.6%       |
| Retinal scarring    | 1                  | 2.6%       |

CME, cystoid macular edema; PK, penetrating keratoplasty; TS PCIOL, transscleral sutured posterior chamber intraocular lens.

**GROUPS 1 AND 2 COMBINED: POSTOPERATIVE OUTCOMES**

A total of 22 postoperative complications occurred in groups 1 and 2 combined. These included CME, glaucoma, bullous keratopathy, retinal detachment, uveitis, endothelial dystrophy, hemorrhages (retinal and choroidal), HSV keratitis, and retinal scarring (Table 3). Overall, there were no reported surgical complications associated with the sutured IOL in either group. There was only one reported case of suture erosion in group 1. No subsequent problems, such as IOL dislocation or decentration, suture breakage, or endophthalmitis, occurred. In addition, no patients required repeated surgery. Postoperative visual acuity (groups 1 and 2 combined) was improved in 73 of 107 eyes (68.2%).

**TABLE 3. POSTOPERATIVE CONDITIONS OF ALL TS PCIOL PATIENTS (GROUP 1 AND 2 COMBINED)**

| CONDITION             | NO. OF EYES |            |
|-----------------------|-------------|------------|
|                       | (N=107)     | PERCENTAGE |
| CME                   | 6           | 5.6%       |
| Glaucoma              | 5           | 4.7%       |
| Bullous keratopathy   | 4           | 3.7%       |
| Retinal detachment    | 2           | 1.9%       |
| Uveitis               | 1           | 0.9%       |
| Endothelial dystrophy | 1           | 0.9%       |
| Hemorrhage*           | 1           | 0.9%       |
| HSV keratitis         | 1           | 0.9%       |
| Retinal scarring      | 1           | 0.9%       |

CME, cystoid macular edema; HSV, herpes simplex virus; TS PCIOL, transscleral sutured posterior chamber intraocular lens.

\*Retinal hemorrhages, peripheral choroidal hemorrhage.

**DISCUSSION**

ACIOLs, iris-sutured PCIOLs, and TS PCIOLs are common methods of lens implantation for patients with little or no capsular support. Studies have reported various benefits and complications for each procedure. However, the decision of which IOL to place for each patient may introduce selection bias that could have affected study outcomes. For example, angle abnormalities and anterior synechia may have precluded ACIOL placement in some patients, and patients with limited iris tissue may not get an iris-sutured lens. Schein and colleagues<sup>8</sup> compared all 3 lenses and found similar visual acuity outcome with all 3 types and a slight increase of CME with TS PCIOLs.

In the study described in this report, mean visual acuity improved in both groups. In group 1, mean BSCVA improved from 20/80 to 20/40 postoperatively. Visual acuity was followed for an average of 14.2 months and remained stable for the patients in group 1. In group 2, the mean visual acuity improved from worse than 20/250 to BSCVA of 20/70 to 20/80. Postoperative visual acuity (groups 1 and 2 combined) was improved in 73 of 103 eyes (68.2%). The percentage of patients with stable or improved postoperative visual acuity is comparable to both iris-sutured lenses (72%)<sup>7</sup> and ACIOL (71.4%-76%).<sup>9-11</sup> Visual acuity results likely underestimate the true visual potential of the patients studied, especially in group 2, because the results are based on spectacle-corrected rather than rigid contact lens-corrected visual acuity.

Studies of the TS PCIOL, in particular, have shown that it is a safe procedure that can improve visual acuity, but it can present various complications. The published complications include glaucoma, CME, retinal detachments, endophthalmitis, lens tilt or redislocation, and suture exposure or breakage. All of these complications have been reported at variable frequencies following placement of iris-sutured IOLs, and all except suture exposure or breakage have been documented with ACIOLs.

The mechanism of induced postoperative glaucoma following placement of TS PCIOLs is unknown. Many of the patients who are considered for TS PCIOLs, instead of ACIOL or iris-fixated IOL, have preexisting angle abnormalities that can make them more susceptible to developing glaucoma independent of the sutured IOL. Other compounding factors for interpreting the actual cause of the glaucoma include falsely low IOP measurements before PK from corneal edema and an increased occurrence of glaucoma in patients with PK. The incidence of postoperative glaucoma or elevated IOP after TS PCIOL placement is extremely variable among

all of the current studies and ranges from 4.9% to 40%.<sup>1,3,6,7,12,13</sup> In the current study, the incidence of postoperative glaucoma was 4%, slightly lower than the reported ranges. This value is lower than the reported incidence of postoperative glaucoma following iris-sutured PCIOLs (6.3%)<sup>5</sup> and ACIOLs (39%).<sup>13</sup>

The risk of inflammation (uveitis or CME) with TS PCIOL is likely to be less than that seen with ACIOL or iris-fixated IOLs. Incidence with ACIOL is 15%.<sup>13</sup> Recent studies report an incidence of CME after TS PCIOL ranging from 1.5% to 22.6%.<sup>2,3,6,8,9</sup> The case series reported here had 4.3% incidence of CME in group 1 and 5.3% in group 2, with a combined incidence of 4.7%. In patients with bullous keratopathy or other corneal opacities, preoperative analysis of CME is not possible, and it may be present before the surgery, therefore artificially increasing the postoperative incidence of CME, and should be considered when evaluating these data. Thus it is important to differentiate newly diagnosed CME from new-onset CME. There was only 1 eye (1.4%) from group 1 with postoperative newly diagnosed uveitis in the current study.

Postoperative retinal detachments occur following TS PCIOL insertion at an incidence of 3.1% to 9.5% according to current literature.<sup>1-3,13-16</sup> The case series reported here had a total of 2 (1.9%) postoperative retinal detachments, one in each study group. The retinal detachments were not located at the site of needle insertion for the TS PCIOL. The frequency of retinal detachments in this study is comparable to that in studies of iris-sutured PCIOL (0.5%-2.5%)<sup>5,17-19</sup> and ACIOL (0-1%).<sup>10,13</sup>

A primary contraindication to TS PCIOL implantation is an inherently high risk of hemorrhage. Risk factors for hemorrhage include older age, history of hypertension, peripheral vascular disease, aortic stenosis, emphysema, prior eye surgery, and need for excessive intraoperative manipulation. In uncontrolled and controlled studies, the risk of choroidal hemorrhage ranged from 0 to 22%.<sup>6,8,20,21</sup> In the current study, only 1 eye in group 1 developed hemorrhage, which started in the posterior pole with spontaneous resolution, followed by development of a peripheral choroidal hemorrhage in the postoperative period. The patient had several risk factors for hemorrhage formation, including previous ocular trauma with hypema, older age, and prior ocular surgery.

The study reported here did not have any cases of lens tilt or redislocation. Previously published data report a lens tilt rate of 11% and dislocation rate between 0 and 10%.<sup>5,6,13,15</sup> The incidence of lens dislocation is 9.9%<sup>7</sup> after an iris-sutured lens and 3% after ACIOL implantation.<sup>13</sup>

The incidence of suture erosion with TS PCIOL varies according to surgical technique. When sutures were covered by conjunctiva alone, the rate of long-term suture exposure ranged from 5% to 50%.<sup>4,20,22,23</sup> The technique was improved by covering the suture with a scleral flap, which decreased the occurrence to 11% to 17.9%.<sup>3,6,20,24</sup> With the addition of knot rotation into the sclera, the incidence of suture exposure dropped to 0 to 6.7%.<sup>21,25</sup> The incidence of suture breakage was reported by Vote and associates<sup>3</sup> to be as high as 57% with earlier techniques. With revised techniques, the rate of suture breakage decreased to 0 to 2.2%.<sup>21,25</sup> The total incidence of suture erosion was 0.9% in the current study, and there was no case of suture breakage, which again was lower than in the previous TS PCIOL studies. On the basis of these results, the use of a scleral flap with knot rotation method seems to provide the lowest incidence of suture exposure or breakage in TS PCIOL. Furthermore, preventing suture erosion may decrease the risk of endophthalmitis by limiting open communication and the ability of bacteria to track through the suture path into the eye.

Cases of endophthalmitis are more commonly reported with suture exposure and occurred more frequently with earlier techniques.<sup>23,26,27</sup> No cases of endophthalmitis occurred in the study reported here. Prompt surgical intervention should be performed for cases of exposed sutures to prevent endophthalmitis.

Specifically for group 1, we evaluated preoperative and postoperative endothelial cell counts for 34 eyes of 32 patients and found only a 5% loss of endothelial cells at a mean of 32 months. This indicates that there was not statistically significant cell loss with the TS PCIOL. The amount of endothelial cell loss is significantly better than with iris-sutured PCIOLs, which average a mean loss of 8% to 13% in the first 3 years and 4% to 6% loss in the subsequent years.<sup>19</sup> It is also better than previous reports of endothelial cell loss with TS PCIOLs, which has been reported at 19% cell loss at 1 year.<sup>17</sup>

Specifically for group 2, it is difficult to separate complications (ie, CME and elevated IOP) of lens implantation from those of PK alone. Previously published data report an incidence of 10.7% to 30% graft failure after combined PK and TS PCIOL.<sup>4,9,15</sup> No cases of graft rejection or failure were noted throughout the course of the current study. There was only one case of bullous keratopathy (2.6%).

Although limited by its noncomparative retrospective design, this case series provides evidence that TS PCIOL insertion with or without PK can be performed with minimal postoperative complications. This technique appears to be a satisfactory method of visual rehabilitation. TS PCIOL does not appear to adversely affect overall graft survival. Visual acuity potential, rates of CME, uveitis, glaucoma, retinal detachments, endophthalmitis, and suture erosion or breakage in this study are all comparable to or better than the rates in the current literature on TS PCIOL, iris-fixated IOLs, and ACIOLs. The technique of transscleral PCIOL insertion via the ab externo method with a thick scleral flap and knot rotation offers a low complication profile and should be considered as a viable option for secondary IOL. Ultimately, individual patient factors and surgeon preference and expertise should guide the decision as to which secondary IOL is most appropriate for each patient.

## **ACKNOWLEDGMENTS**

Funding/Support: None.

Financial Disclosures: None.

Author Contributions: *Design of the study* (V.B., V.S.N.); *Conduct of the study* (J.M.N., V.B., V.S.N.); *Management, analysis, and interpretation of data* (J.M.N., V.B.); *Preparation, review, or approval of the manuscript* (J.M.N., V.B., V.S.N.).



Conformity With Author Information: Union Memorial Hospital's Institutional Review Board determined that IRB approval was not required before the initiation of this study.

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## PEER DISCUSSION

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DR. JAY C. ERIE: Dr Nottage and colleagues present a retrospective consecutive case series of the safety and visual outcomes of transscleral sutured posterior chamber (PC) IOLs performed by a single surgeon over a 4 year period. They studied 2 groups. The first group consisted of 69 eyes that underwent secondary scleral-sutured PC IOL insertion after complicated cataract surgery, trauma, or ectopia lentis. The second group consisted of 38 eyes that underwent secondary scleral-sutured PC IOL insertion at the time of penetrating keratoplasty. In all cases, the haptics were secured to the scleral wall under a scleral flap by using 10-0 polypropylene suture tied directly to the haptic. The mean follow-up in both groups was limited to approximately 14 months.

In group 1, the achievement of a best corrected visual acuity (BCVA) of 20/40 or better in 57% of patients is certainly acceptable in the setting of prior complicated cataract surgery or trauma. Complications of corneal edema (3 eyes), glaucoma escalation (4 eyes), and cystoid macular edema (4 eyes) were relatively minor. In group 2, BCVA of 20/40 or better in 29% of patients is consistent with the guarded prognosis that is present after penetrating keratoplasty. Complications were also relatively minor.

The findings of the author should not be unexpected. As recently as 2003, an American Academy of Ophthalmology sponsored report by Wagoner and colleagues<sup>1</sup> reviewed 13 published articles and found similar visual acuity results and complication rates as reported today by Dr. Nottage. Wagoner concluded that, in the absence of capsular support, scleral-sutured PC IOLs are safe and effective in adults. They also concluded that there was insufficient evidence to demonstrate the superiority of scleral-sutured PC IOLs over open loop anterior chamber IOLs.

Although the authors conclude the safety of scleral-sutured PC IOLs, a new concern has been raised about the long-term safety of using 10-0 polypropylene as the suture material to fixate the IOL haptic to the scleral wall. Recent reports have indicated that prolene suture can undergo hydrolysis and degrade, leading to spontaneous subluxation of the scleral-sutured IOL in 10-27% of cases.<sup>2</sup>

The key point in these articles is that 1) IOL subluxation typically occurs 4-5 years after surgery and would not be detected by the mean 14 month follow-up in this study or by the mean 17 months follow-up in those studies reviewed by Wagoner and colleagues; and 2) there is typically no associated trauma or “cheese-wiring” of the suture through the sclera. The suture just degrades and fails.

The fact that 10-0 polypropylene suture might degrade enough to break over time is not completely unexpected. AOS member, Dr. Robert Drews, in his Binkhorst Medal Lecture in 1982,<sup>3</sup> predicted that polypropylene sutures may fail after a period of time in the eye. His scanning electron micrographs of 10-0 polypropylene suture removed from iris-fixated IOLs showed surface cracking and flaking.

Ed Holland and coworkers<sup>4</sup> showed that when haptics are sewn in the ciliary sulcus, a fibrous membrane will form around the haptic and that this scar tissue could fixate the IOL even if the suture fails. It is unknown how long this scar tissue can fixate an IOL without suture support. It is known, however, that a haptic sewn to the sclera, outside of the ciliary sulcus, will not form a fibrous membrane and that as many as 50% of scleral-sutured haptics are unintentionally sewn outside the ciliary sulcus.

The rationale for selecting 10-0 polypropylene suture for this task cannot be found in the literature. Recently Marianne Price and Ed Buckley, among others, have recommended that 9-0 polypropylene suture be used as an alternative to 10-0 because it has a 60% greater tensile strength, a 50% greater diameter, and a 125% greater cross sectional area; all of which may cause it to better resist degradation over time.

But is 9-0 polypropylene just a longer fuse than 10-0? I do not know. Recently, I have tried Gore-Tex suture to scleral-fixate IOLs. Gore-Tex is a sturdy, non-absorbable monofilament suture made of polytetrafluoroethylene (ePTFE). As a suture material, it is used in cardiac and vascular surgery and in the eye it has been used in strabismus surgery. Although the suture is not approved for use in ophthalmic surgery, in the few cases I have used it, it seems to work well. However, before you begin cutting your Gore-Tex rain coats into thin strips, the currently available Gore-Tex suture is larger than we are used to (equivalent in size to 8-0 polypropylene), the current vascular needles are acceptable, but not ideal. The main disadvantage is the larger size of the knot which requires a concerted effort to rotate it into the sclera.

I thank the authors for their nice study and wonder if they would consider removing the word “long-term” from the title of their manuscript and if they are still using 10-0 polypropylene (Prolene) as their suture material of choice.

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## ACKNOWLEDGMENTS

Funding/Support: None

Financial Disclosures: None

DR. RICHARD K. FORSTER: I have no financial interest. It is interesting that we have emphasized throughout this meeting the importance of long-term follow-up, but in this case I would like to just point out my concerns about short-term follow-up. I have been doing secondary sutured posterior chamber lenses either as an IOL exchange at the time of keratoplasty and in the early 1900s in patients who were aphakic and who might have been wearing spectacles or who reached an age or dementia when they could no longer handle contact lenses. I have been concerned about short-term visual rehabilitation and microscopic hemorrhages that are associated with sutured posterior chamber lenses. I have observed delayed visual improvement, although I have not looked at it statistically. Publications on the subject tend not to report short-term visual acuity and whether there might be a higher incidence of cystoid macular edema (CME) or a higher incidence of microscopic hemorrhaging into the vitreous at the time of the procedure. I question what your experience might be in this regard.

Further, in 1994 we had a fellow from Wake Forest University, Dr. Jerry Ford, who had adopted the technique that John Reed popularized of not using scleral flaps. I initially started using the technique of burying the polypropylene (Prolene) sutures under scleral flaps and noted that over time the scleral flap tends to thin, disappear, or erode with a tendency towards exposure of the knot. The technique that John Reed recommended, and that I have adopted, is to pass the Prolene suture about 1½ to 2mm posterior to the limbus, to then do a double tie about 4 to 5mm back in the sclera, to leave the ends long, and then to close the conjunctiva over the suture. I think the exposure and erosion rate is less, but I would appreciate your comments on this technique and on the short-term visual rehabilitation.

DR. ALLAN J. FLACH: I want to start off by saying thank you very much for the incredible bibliography you are going to give me related to your paper. All those cases that you reviewed will be a perfect starting point for another study. Now this is a retrospective comparison study and the controls are difficult to design. In pharmacology we are faced with this problem all the time. When it comes to cataract surgery our techniques change, our equipment changes, the drugs used in the eyes and the body changes, and the indication for surgery changes. We are operating on a much younger and healthier population that takes fewer medications. Retrospective comparisons are by their very nature fraught with hazards. I wonder if you have any clues as to why your retrospective comparisons might be better than those to which we are accustomed.

DR. VERINDER S. NIRANKARI: No conflict. Just to comment on some of the surgical techniques and some of the concerns that has been raised. First, we chose the time frame because we had one of the medical students go back and look at our available results. I have been doing this surgical technique for about 25 years and we have moved several times. It was just a problem of being able to get all patient records or to get back those patients who probably were lost to follow-up. When we looked at the total number it was nearly 1,000 and it just seemed to be a nightmare in trying to assemble all the information.

Secondly, my technique has been fairly consistent and we still follow patients. Our patients who still come back once a year had the same technique done over 25 years ago. I have not observed among my patients any of the concerns about 10-0 Prolene, I know that these problems have been reported before and we always look out for that possibility. We tell the patients that it is possible that the 10-0 Prolene might fail and we may have to go back and re-suture it. Nothing lasts forever, but surprisingly in the last 25 years we have not had a single patient with this problem, except for one who was in an auto accident and had the airbag blowup in his face. He actually noticed loss of vision a week later and one of the sutures had broken. We sutured it, but that this was the only one that I can remember over so many years. Initially we used 10-0 Prolene when we were trying to determine the right suture to use for corneal transplants. Surgeons started with 10-0 nylon and then went to double 10-0 nylon, then 10-0 nylon, then 11-0 nylon, and then and 10 Prolene. I still have at least 10 patients with 10-0 Prolene sutures. I chose to use this material primarily in patients who were mentally challenged because it was difficult to remove their sutures. I still follow them and some have been followed for 18-19 years after surgery. The 10-0 Prolene looks as good today as it did 18 years ago.

DR. MARIAN S. MACSAI: I have two questions. Did you ever consider using Mersilene as opposed to Prolene? When the procedure was done open sky why did you not chose to use the CZ70bd (Alcon Laboratories, Inc.) one piece PMMA (polymethylmethacrylate) intraocular lens with the holes in the haptics? Was it used in some of the patients and not in others and were the results compared?

DR. JAMES L. KINYOUN: No financial disclosures. I consider these to be some of the most technically difficult cases to repair when the lenses become dislocated. Based on my experience, I believe that we should seriously consider why these patients developed cataracts in the first place. If there is any history of possible eye trauma, I would advise using a technique other than sutured posterior chamber IOLs. Some patients with traumatic cataracts tend to have recurrent trauma and trauma has been one of the most frequent causes for dislocation of sutured posterior chamber IOLs. Another cause of IOL dislocation in this setting is abnormal sclera, such as in patients with Marfan syndrome. They are also are not good candidates for this technique. Thank you.

DR. JENNIFER M. NOTTAGE: First, I would like to thank Dr. Nirankari and Dr. Erie. I know Dr. Nirankari answered many of the questions. In summary, the decision for using this set of patients was based on the availability of their medical records. We believed that we had the best ability to evaluate all the different data points from this subset of patients from 2004 through 2007. The arbitrarily picked dates translated into an average follow-up of 14 months.

We believe that scleral flaps are still necessary to protect the polypropylene (Prolene) suture and to prevent endophthalmitis. We are still using 10-0 Prolene sutures because Dr. Nirankari has not had any complications with breaks or erosion of the material. The 9-0 Prolene results in a slightly larger knot that could cause more erosion underneath the scleral flap. This is a consideration when selecting what type of suture to use. I am interested to determine what happens with the long-term results and complications of the Gor-Tex suture if that becomes a more frequently used technique

Just like any other retrospective study, ours has a lower rate of validity. Our study was based on one surgical technique that did

not change during the entire duration of the study. We cannot guarantee that other variables did not sway the data one way or the other. About 50 patients were excluded from the study due to insufficient data. These patients could have altered the final outcome of the study. We did evaluate the short-term follow-up for the visual acuity and determined that it was not significantly different from the final postoperative visual acuity, which I presented in the data of the study. We did not believe that it was important or meaningful to include because it was so similar to the postoperative data

None of the patients developed microscopic hemorrhages after sutured PCIOLs. We observed such a low rate of CME in both groups that we did not evaluate whether the short-term visual acuity was affected by the CME. We did not use CZ7obd (Alcon Laboratories, Inc.) one piece PMMA lens with the holes in the haptics. I just wanted to thank again Dr. Erie for his great summary and Dr. Nirankari for his help on this research project. Thank you very much.