

HANGING BY A THREAD: THE LONG-TERM EFFICACY AND SAFETY OF TRANSSCLERAL SUTURED INTRAOCULAR LENSES IN CHILDREN (AN AMERICAN OPHTHALMOLOGICAL SOCIETY THESIS)

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ABSTRACT

Purpose: To evaluate the long-term efficacy, safety, and advisability of using transscleral sutured posterior chamber intraocular lenses (IOLs) in pediatric patients with no capsular support and to determine whether 10-0 polypropylene suture should be used for this purpose.

Methods: A long-term retrospective interventional case series review of 33 eyes of 26 patients who had a sutured IOL at Duke University Eye Center were evaluated for the intraoperative surgical risks, postoperative visual and refractive outcomes, and the number, type, and severity of the postoperative complications. In addition, a survey of pediatric ophthalmologists' experience with suture breakage was performed.

Results: Postoperative visual acuity was significantly improved after surgery ($P < .001$). Predicted vs actual refraction was not significantly different ($P = .10$) and was within 1.50 diopters of predicted in 66% of patients. A refractive myopic shift occurred over time and was age-dependent. Intraoperative and immediate postoperative complications were minimal and not sight-threatening. Three patients developed subluxation of the IOL secondary to spontaneous 10-0 polypropylene suture breakage at 3.5, 8, and 9 years after surgery. A survey of pediatric ophthalmologists revealed 10 similar cases (mean, 5 years after surgery).

Conclusion: Transscleral fixation of an IOL in a child appears to be a safe and effective procedure provided that the suture material used is stable enough to resist significant degradation over time. Caution should be exercised in the use of 10-0 polypropylene suture to fixate an IOL to the sclera in children, and an alternative material or size should be considered.

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INTRODUCTION

Optical rehabilitation of the aphakic child who becomes intolerant of glasses and/or contact lens presents a therapeutic challenge. It is even more problematic if there is no capsular remnant to support the placement of an intraocular lens (IOL) in the sulcus. Options for unilateral aphakia include a unilateral aphakic spectacle (with or without contralateral patching), epikeratophakia, an anterior chamber IOL implant, an iris fixated IOL implant, or a scleral fixated (sutured) posterior chamber IOL implant.¹⁻⁶ Each of these approaches has problems. In patients who are bilaterally aphakic and contact lens intolerant, the only options are aphakic spectacles or IOLs. Aphakic spectacles are rarely found acceptable by older children and teenagers.

In patients with unilateral aphakia, wearing aphakic spectacles is the safest approach but the least physiologic method of optical correction and can only be pursued for a short time before patient acceptance and feasibility become issues. Use of this method is reasonable in the young amblyopic child who is undergoing extensive patching and is monocular most of the time. Older children who are not patching do not find this approach acceptable and refuse to wear the glasses. An alternative is epikeratophakia, but unfortunately there is often prolonged optical distortion postoperatively, frequent undercorrections, and a high complication rate, and the tissue is no longer readily available.^{7,8}

In the absence of capsular support, a secondary IOL implant could be placed in the anterior chamber, attached to the iris, or sewn into the posterior chamber sulcus. Pediatric patients who have undergone anterior chamber lens implants have had significant long-term complications such as corneal endothelial loss, corneal decompensation, iris sphincter erosion, pupillary ectopia, and glaucoma, making this procedure undesirable.^{2,6,9} Iris-claw lenses are also placed in the anterior chamber, but instead of being supported in the angle, they are attached to the iris with small polymethylmethacrylate (PMMA) clips that are part of the implant. They have been used in Europe successfully for over 20 years and have been reported as effective as other treatment modalities in children.¹⁰ Unfortunately, these lenses are not routinely available in the United States. Previous reports have shown that secondary sulcus fixated IOL implants are well tolerated in the pediatric population^{3,6,11,12}; however, the only practical way to place a lens in the sulcus of an eye without capsular support is to suture it to the scleral wall. Because of the problems associated with anterior chamber IOLs and the lack of availability of iris-supported IOLs, sutured posterior chamber IOLs are preferred for secondary implantation in the pediatric population.^{3,11,13,14}

Suturing an IOL to the sclera is a relatively new procedure. It was first described by Girard in 1981¹⁵ and then later refined by Malbran and colleagues in 1986.¹⁶ In subsequent years many investigators have described a wide variety of approaches to securing a lens in the ciliary sulcus in the absence of capsular support. The techniques evolved over time, but the basic principle has remained the same. Using 10-0 polypropylene suture, the haptics of an IOL that was meant to be placed into the lens capsular bag or the ciliary sulcus is sutured to the sclera behind the iris. The rationale for selecting 10-0 polypropylene suture for this task cannot be found in the literature, though it is assumed that it evolved from the techniques used to suture IOLs to the iris where a fine nonreactive material was desirable. The other assumption was that the polypropylene was nonabsorbable and would not degrade, thereby providing additional security that the lens would remain in place.

As recently as 2003, an American Academy of Ophthalmology sponsored report by Wagoner and colleagues⁵ on IOL implantation

in the absence of capsular support concluded after a through literature assessment that scleral sutured posterior chamber IOLs were safe and effective in adults. They included 5 clinical case series involving primary insertion after complicated cataract surgery, 4 involving secondary implantation, and 9 reporting on the results of secondary sutured IOL combined with penetrating keratoplasty. None of these studies reported any incidence of lens subluxation due to suture breakage.^{5,17-21} The average follow-up was only 17 months (range, 5.8-29 months). In September 2006, an American Academy publication *Focal Points* published an article entitled "Sutured Posterior Chamber Intraocular Lenses."⁵ The author recommends using either 9-0 or 10-0 polypropylene suture for this surgery. There is no mention of potential long-term failure of the 10-0 suture.

The initial issues with suturing an IOL in the sulcus in adults centered on problems with the suture knot. One of the significant complications was the eventual erosion and exposure of the fixation suture knot through the conjunctiva.²³ To eliminate this problem several techniques were developed that allowed burial of the suture knot into the sclera either partially or fully in a manner similar to that used for nylon sutures in standard cataract wound closure.²⁴

Transscleral fixation of IOLs in the pediatric population did not begin in earnest until the early 1990s. These were first limited to a few select cases that could not be managed with glasses or contact lenses.^{2,25} As the adult experience became more extensive and as the early problems with suture exposure were resolved by newer surgical techniques, the number and types of pediatric patients undergoing this procedure expanded.^{4,26-28} In children this procedure is typically reserved for 3 types of problems: patients who have had severe enough trauma to disrupt zonular support sufficiently to make sulcus or capsular bag fixation risky; those who have had a complete lensectomy either as part of congenital cataract removal or some other ocular procedure; and patients who have subluxed lenses that are idiopathic or due to Marfan syndrome or familial ectopic lentis. Numerous reports have claimed that this approach was safe and effective and causes few complications in the pediatric age-group, but the follow-up has been relatively short, with the longest averaging only 3 years (Table 1).^{4,6,26,28}

Recently, a new concern has been raised in adults having to do with the long-term safety of using 10-0 polypropylene (Prolene) suture to fixate the IOL to the scleral wall. Polypropylene is a monofilament polymer composed of propene ($\text{CH}_2 = \text{CHCH}_3$) configured as an isotactic crystalline polypropylene stereoisomer. As a suture material, it is strong, durable, and nonabsorbent. In addition to use in the eye, the suture is used in a variety of medical applications, including vascular anastomosis, nerve grafts, coarctation repair, and intestinal anastomosis.²⁹⁻³¹

Several recent reports³²⁻³⁴ have indicated that over time the 10-0 polypropylene suture can degrade, resulting in spontaneous subluxation of the intraocular lens. The key point emphasized in these articles is that this happens *years after implantation*, typically 4 to 5 years or later. The investigators raise concern that past reports, which have indicated good results in patients, both adults and children, who have had this procedure using 10-0 polypropylene suture, have not been followed long enough for this complication to occur. The issue of long-term viability of 10-0 polypropylene suture presents a particularly important concern for pediatric patients, because life expectancy is measured in decades.

A review of the current literature would indicate that suture breakage has not been a problem in the pediatric population because there are no reports of suture breakage with lens subluxation (Table 1). However, the use of sutured IOLs in children has lagged behind the use in adults, and the current reported pediatric cases have inadequate follow-up to detect this complication if, as others have indicated, it is a problem that typically occurs only after many years. Because the vast majority of surgeons who are suturing lenses in children are using 10-0 polypropylene suture,^{4,26,28} the issue of subluxation from suture breakage may become an increasing problem over time. Children are much more active than older adults, the typical recipient of a sutured IOL. The constant stress that this active lifestyle exerts may accelerate the breakage of the suture material, especially if it is predisposed to fail. If this suture is inappropriate for this task, then a widespread effort needs to be made to convince surgeons who are operating on children to switch to a more stable suture.

Since the issue with the polypropylene suture safety appears to have surfaced only after long-term follow-up, are there other problems lurking in children and teenagers that have not been detected because follow-up has been too short? Do sutured IOLs provide adequate predictable optical correction? Is there a similar myopic shift over time, as seen in children who have IOLs placed in the capsular bag, or does suturing to the sclera alter this response? Are the current techniques to prevent suture erosion through the conjunctiva adequate over many years? Are there other significant issues, such as glaucoma or retinal detachments, which have begun to surface over time? If so, it may be that transscleral fixation of IOLs should not be used at all in the pediatric population. If not, and the technique really is reliable and safe except for the potential of suture problems, then maybe the current suture material needs to be changed for the pediatric age-group to decrease the likelihood of long-term failure.

This study addressed the following questions:

1. Are transscleral fixated intraocular lenses an *efficacious* way to rehabilitate an aphakic eye with no capsular support in a child?
 - a. Criteria evaluated: the intraoperative surgical risks, postoperative visual and refractive outcomes, and the number, type, and severity of the postoperative complications
2. Is 10-0 polypropylene suture *stable* enough to provide adequate long-term fixation of IOLs to the sclera in children?
 - a. Criteria evaluated
 - i. The long-term efficacy and safety of 10-0 polypropylene sutured IOLs in children at Duke University
 - ii. A survey of the pediatric ophthalmologists' experience with broken 10-0 polypropylene sutures used to fixate IOLs in children

- iii. An assessment of the current published reports in adults who have experienced problems with lenses attached to the sclera with 10-0 polypropylene suture
- iv. A review of the current literature on the use of sutured IOLs in children

PATIENTS AND METHODS

A retrospective study on the use of secondary IOLs in the pediatric population at Duke University Eye Center from 1988 to 2005 was performed under a Duke University Institutional Review Board approved protocol. Selected from this group of patients were all patients who underwent secondary scleral fixated posterior chamber IOL implants (sutured IOLs) in one or both eyes. Patients who previously failed contact lens and/or glasses wear and who had an insufficient remnant of posterior capsular tissue for sulcus fixation (less than 180 degrees of support) were candidates for transscleral suture fixation. The final decision was made at the time of surgery after scleral depression and gonioscopy.

The indications for suturing an IOL in the sulcus of a child were unilateral or bilateral aphakic with absent or insufficient capsular support for a safe sulcus placed capsular supported IOL and who:

- a. were unable to use, or intolerant of, contact lenses
- b. were unwilling or unable to wear aphakic spectacles
- c. had controlled glaucoma and no active uveitis
- d. had no severe anterior segment structural abnormalities

Thirty-three consecutive eyes of 26 aphakic children were included in this study. Nine patients had been previously reported in another publication by this author.⁴ Seven patients had bilaterally sutured IOLs. There were 14 females and 12 males. The mean age at surgery was 9.7 ± 5.1 years (range, 1 to 17 years). Eleven patients (42%) were 5 years old or less at the time of surgery, and 15 patients (57%) were 10 years or less.

Twelve eyes (36%) had congenital cataracts that were previously removed leaving insufficient capsular remnants to support a sulcus-supported IOL or that had subsequent extensive membrane removal with the same result. Nine eyes (28%) were aphakic because of trauma severe enough to either dislocate the lens necessitating complete lensectomy or cause extensive zonular dehiscence leaving no capsular support. Ten eyes of 5 patients (30%) had subluxed lenses due to familial ectopic lentis. Two eyes of one patient had subluxed lens from presumed Marfan syndrome. All patients had their cataracts or subluxed lens removed previously and were attempting to wear contact lens or glasses at the time of surgery. Four patients had both eyes done separated by 2 to 3 months. In one patient the surgery for the second eye was delayed for 1 year. The summary characteristics are shown in Tables 2 and 3.

Preoperatively a complete eye examination was performed, including visual acuity by Snellen, HOTV chart, Allen card, or preferential looking, according to age and cooperation. For analysis the Snellen visual acuity was converted to logMAR using the formula $\log\text{MAR} = -\log(\text{decimal acuity})$, where decimal acuity equals the calculation of the Snellen value (ie, $20/200 = 0.1$, $20/20 = 1.0$). Intraocular pressures were measured using a Tonopen. Gonioscopy, scleral depression, funduscopy, keratometry, and axial lengths were performed prior to surgery under anesthesia. Lens powers were calculated using the SRK II formula (Innovative Imaging Inc, Sacramento, California). Lens power selections were made based on age and refractive status of the fellow eye by previously published criteria but generally undercorrecting those children who were less than 6 years of age in anticipation of a subsequent myopic shift in their refractive status.³⁵ Since the lens was implanted in the sulcus, one diopter was subtracted from the final calculation.

For statistical analyses, sample *t* tests were performed. A *P* value of .05 or less was considered to be statistically significant.

SURGICAL PROCEDURE

The surgical approach has been described in detail in previous publications.^{4,26} Briefly, a superior conjunctival limbal incision was made extending for approximately 120 degrees. An additional small limbal conjunctival incision was made inferior temporally. A double-armed 10-0 polypropylene suture (Prolene) with a straight needle (STC6 needle; Ethicon, Somerville, New Jersey) was used. Using the technique described by Lewis,²⁴ the suture needle was passed through the sclera approximately 2 mm posterior to the limbus and directed across the eye toward a 27-gauge needle, which was also inserted through the sclera 2 mm posterior to the limbus 180 degrees opposite the suture needle (usually at the 2- and 8-o'clock positions). The suture needle was threaded into the 27-gauge needle barrel, and both were withdrawn out the 27-gauge needle entrance site. This process was repeated after switching sides, separating the sites by 2 mm. A groove incision was made superiorly for 7mm at the limbus. A small central opening was created, and viscoelastic was injected into the anterior segment. The 2 Prolene sutures transversing the anterior chamber were hooked and withdrawn through the central limbal opening. The sutures were cut, and the appropriate ends were passed through the haptic eyelet of a CZ70BD 7-mm all PMMA IOL (Alcon Laboratories, Fort Worth, Texas) and tied to each other, not the lens. The knot was rotated out of the eye at each site. The groove incision was opened to 7mm to accommodate the IOL optic. The Prolene sutures were tightened and the lens placed into the sulcus. The sutures were temporarily tied and the lens position was inspected. If the lens was adequately secured and in good position, the sutures were tied permanently. The knots were rotated into the sclera in a manner similar to that used to bury the nylon sutures in standard cataract wound closure. The groove incision was closed using interrupted 10-0 nylon sutures. The viscoelastic was removed and a miotic agent instilled. The conjunctiva was closed using buried 9-0 polyglactin (Vicryl) sutures (Ethicon, Somerville, New Jersey). Subconjunctival injections of 0.25 mL of dexamethasone, 4 mg/mL, and gentamycin, 20mg/mL, were given at separate sites. Antibiotic ointment was instilled, and the eye was patched and shielded.

Postoperative evaluations were performed on days 1, 4, and 10 and then at weeks 3 and 6, and then every 3 to 6 months thereafter,

depending on the status of the eye and amblyopia treatment required. Visual acuity, refraction, slit-lamp examination, motility assessment, intraocular pressure measurement, and funduscopic examination were performed at each visit. Postoperative medications included topical antibiotic drops, alternating with topical prednisolone acetate 1%, given 4 times a day. An antibiotic/steroid ointment was instilled at night. This regimen was tapered slowly over 4 weeks. Cyclopentolate 1% twice daily was also used for the first 2 to 3 weeks. Patients who developed transient elevated intraocular pressure as a result of retained viscoelastic material were treated with oral acetazolamide and topical timolol maleate 0.5% twice a day for 24 to 48 hours. Final refraction was given at week 4 and changed as needed. Amblyopia therapy was instituted when appropriate.

RESULTS

The average follow-up for the 33 eyes in this series was just over 5 years (61 ± 42 months; range, 9-200 months). Twenty-one eyes (64%) had follow-up greater than 3 years, and 14 eyes (46%) had follow-up more than 5 years. Seven children (27%) had bilateral surgery with the surgical procedures separated by 2 to 3 months. The remaining 19 children (73%) had unilateral surgery.

TABLE 1. PUBLISHED REPORTS OF SUTURED INTRAOCULAR LENSES (IOLS) IN PEDIATRIC PATIENTS

FINDINGS	SHARPE ²	LAM ³⁸	KUMAR ²⁵	ZETTERSTROM ³⁹	JACOBI ²⁸	OZMEN ⁴⁷	SEWELAM ²⁷	BARDORF ²⁶	CURRENT STUDY
Year of support	1996	1998	1999	1999	2002	2002	2003	2004	2006
Total No. of eyes	7	6	11	21	26	21	20	43	33
Mean follow-up (mo)	32	17	10	20	13.4	22.5	19	37	61
Congenital (%)			27		53	47		33	36
Trauma			73	10	47	33	100	23	28
Subluxation				90		19		44	36
Mean age at IOL implantation (yr)	32		6.4	5.8	6.6	4.2	7.7	10	10
Suture fixation material	10-0 Prolene	10-0 Prolene	10-0 Mersilene	10-0 Prolene	10-0 Prolene	10-0 Prolene	10-0 Prolene	10-0 Prolene	10-0 Prolene
IOL tilt/decentration	2 (28%)	-	1 (9%)	-	5 (19%)	2 (10%)	-	-	1 (3%)
Iris capture	-	3 (50%)	-	2 (9%)	-	1 (5%)	-	2 (5%)	2 (6%)
Dyscoria	1 (14%)	-	-	-	2 (7.7%)	-	-	-	1 (3%)
Glaucoma	-	-	1 (9%)	-	1 (3%)	-	-	-	2 (6%)
Intraocular hemorrhage	-	-	-	-	-	-	2 (10%)	6 (14%)	1 (3%)
Choroidal effusion	-	-	-	-	-	-	-	1 (2%)	-
Retinal detachment	-	-	-	-	-	1 (5%)	-	-	-
Endophthalmitis	-	-	-	-	-	2 (10%)	-	-	-
Suture breakage	-	-	-	-	-	-	-	-	3 (9%)
Suture erosion	1 (14%)	-	-	-	2 (7.7%)	-	-	-	-
Reoperations	-	-	-	-	1(4%)	-	-	2 (5%)	5 (15%)

VISUAL ACUITY

Visual acuity results are shown in Table 2. The preoperative visions were measured with either aphakic spectacles or contact lenses. Postoperative visual acuities were best corrected at the patient's last follow-up examination. Visual acuity improved postoperatively in 27 of 33(81%) of the eyes. The mean improvement was 0.25 ± 0.23 logMAR units (ie, 20/150 to 20/80 or 20/50 to 20/30) ($P < .001$). Five eyes showed no change. Three of the 5 were 20/20, one was 20/40, and one was 3/200. Twenty-six eyes (79%) had visual acuities of 20/40 or better, and 15 eyes (45%) had acuities of 20/25 or better. The improved visual function was *sustained* in all but one patient (Figure 1). Patient 23 had significant anterior segment trauma with a large corneal laceration and iris cyst formation prior to lens implantation. Contact lenses were not tolerated because of significant corneal disruption. It was felt that deprivation amblyopia was a major threat to vision in this 3-year-old, and a sutured IOL was performed. Postoperatively, the eye had the appearance of epithelial ingrowth, and over time the eye became blind with severe band keratopathy.

Seven patients in this study were young enough to be at risk for amblyopia and required treatment (patients 2, 4, 8, 12, 18, 19, 24). Four responded and 3 failed treatment. Two of the 3 failures had significant other ocular abnormalities. One had a scleral buckle for ROP (patient 19), and one had multiple glaucoma procedures after congenital cataract surgery (patient 2). All 3 children had better visual function postoperatively than preoperatively, but their postoperative vision was quite poor. A summary of the visual acuity results for all patients is shown in Table 2 and Figure 1.

REFRACTIVE STATUS

Refractive results are shown in Table 4. Three months after surgery all the spherical equivalent refractions were within 3.5 diopters of the preoperative goal, and 66% were within 1.50 diopters (Figure 2). The mean difference of the actual vs predictive refraction was 1.07 ± 0.76 diopters (range, 0-3.38 diopters), which was not significant (paired Student's *t* test, $P = .10$). The actual postoperative

spherical equivalent values ranged from +4.00 to -4.38, and, as evidenced by the scatter plot shown in Figure 2, there was considerable variation in the postoperative refraction vs target values. There did not appear to be any factor, such as age, axial length, previous trauma, or IOL power, which was associated with this variability. This is similar to other studies, which have shown a poor to moderate agreement between the predicted and actual postoperative refractive result in children with sutured IOLs.^{36,37}

TABLE 2. TRANSSCLERAL SUTURED INTRAOCULAR LENSES IN CHILDREN: PATIENT CHARACTERISTICS

PATIENT	EYE	SEX	AGE (YR)	ETIOLOGY	PREOP VA	POSTOP VA	FOLLOW-UP (MO)
1	1	F	10	Congenital	20/60	20/25	136
2	2	F	1	Congenital	F/F	3/200	71
3	3	M	16	Trauma	20/50	20/30	117
4	4	M	5	Congenital	CF	20/400	26
5	5	M	12	Trauma	20/100	20/50	107
6	6	F	6	Trauma	20/40	20/25	43
7	7	M	5	Trauma	20/80	20/30	200
8	8	F	2	Congenital	HM	20/400	15
9	9	F	5	Subluxation	20/50	20/40	19
	10		5	Subluxation	20/40	20/40	18
10	11	M	14	Subluxation	20/40	20/25	71
1	12		14	Subluxation	20/60	20/50	72
11	13	M	8	Congenital	20/30	20/25	96
12	14	M	3	Trauma	20/200	20/60	82
13	15	F	15	Congenital	20/60	20/50	113
14	16	F	11	Subluxation	20/20	20/20	38
	17		12	Subluxation	20/20	20/20	35
15	18	F	16	Subluxation	20/100	20/25	32
	19		16	Subluxation	20/20	20/20	26
16	20	M	11	Subluxation	20/25	20/20	38
	21		11	Subluxation	20/25	20/20	52
17	22	F	14	Congenital	20/25	20/20	55
18	23	M	5	Trauma	20/200	20/60	68
19	24	M	3	Congenital	20/400	20/50	41
20	25	F	7	Trauma	20/70	20/60	55
21	26	F	14	Subluxation	20/50	20/20	29
	27		15	Subluxation	20/30	20/20	27
22	28	M	17	Congenital	20/25	20/20	9
	29		17	Congenital	20/25	20/20	11
23	30	M	3	Trauma	20/400	NLP	135
24	31	F	5	Trauma	20/200	20/50	78
25	32	F	13	Congenital	20/160	20/80	32
26	33	F	15	Congenital	20/100	20/25	136

CF, counting fingers; F/F, fix and follow; HM, hand motions; NLP, no light perception.

The CZ70BD lens, which was used for all patients in this study, has a 7.0-mm optic, which requires a 7.5-mm opening for insertion. Since this wound has to be sutured, significant postoperative astigmatism can result. The mean cylinder amount preoperatively was 2.15 ± 1.20 (range, 0-4.25). Three months after surgery the mean cylinder amount actually *decreased* from preoperative amounts to 1.50 ± 1.25 diopters (range, 0-4.25), which was significant (paired Student's *t* test, $P = .03$). The mean change preoperative minus postoperative was $.66 \pm 1.61$ diopters (range, +4.25 to -2.75). The absolute change averaged 1.39 ± 1.03 diopters (range, 0-4.25). The final refraction cylinder (mean, 1.32 ± 1.10 diopters, range 0-3.25) was not significantly different from the 3-month value ($P = .35$).

Over time, there was an average yearly refractive change of -0.34 ± 0.48 diopters (range, 0.17 to -1.52). There was a myopic shift in 24 eyes, a hyperopic shift in 8 eyes, and no shift in one eye. The myopic shift averaged -0.50 diopters a year (maximum, -1.50) and the hyperopic shift was +.08 diopters per year (maximum, 0.17). A summary is shown in Figure 3.

TABLE 3. TRANSSCLERAL SUTURED INTRAOCULAR LENSES (IOLS) IN CHILDREN: ETIOLOGY, PREVIOUS SURGERY, AND COMPLICATIONS

PATIENT	EYE	ETIOLOGY OF APHAKIA	LENS SURGERY	OTHER PREVIOUS SURGERY	COMPLICATIONS
1	1	Congenital	CE		None
2	2	Congenital	CE	Glaucoma, seton implant twice	Recurrent membranes x3
3	3	Trauma	Lensectomy	Cornea repair	None
4	4	Congenital	CE		None
5	5	Trauma	CE		Suture break, inferior
6	6	Trauma	CE	Ruptured globe repair	None
7	7	Trauma	CE	Cornea repair	None
8	8	Congenital	CE	Scleral buckle ROP	None
9	9	Subluxation	Lensectomy		None
	10	Subluxation	Lensectomy		None
10	11	Subluxation	Lensectomy		None, suture exposure
	12	Subluxation	Lensectomy		None
11	13	Congenital	Lensectomy		Suture break, superior
12	14	Trauma	CE	Repair ruptured globe	None, strabismus surgery 2002
13	15	Congenital	CE	Nystagmus surgery	Glaucoma s/p cryotherapy on meds
14	16	Subluxation	Lensectomy		Iris flops around optic
	17	Subluxation	Lensectomy		Iris flops around optic
15	18	Subluxation	Lensectomy		None
	19	Subluxation	Lensectomy		None
16	20	Subluxation	Lensectomy		Vitreous hemorrhage at surgery. Suture break, inferior
	21	Subluxation	Lensectomy		None
17	22	Congenital	Lensectomy		None
18	23	Trauma	Lensectomy	Pupillary membrane removal	Membrane formation requiring removal
19	24	Congenital	CE	ROP laser	None
20	25	Trauma	CE		None
21	26	Subluxation	Lensectomy		Tilted IOL
	27	Subluxation	Lensectomy		None
22	28	Congenital	CE		None
	29	Congenital	CE		None
23	30	Trauma	CE	Iris cyst removal	Cornea decompensation, band keratoplasty pain, NLP
24	31	Trauma	CE	Cornea repair	None
25	32	Congenital	CE		None
26	33	Congenital	CE	Cornea repair	None

CE, cataract extraction; ROP, retinopathy of prematurity; NLP, no light perception.

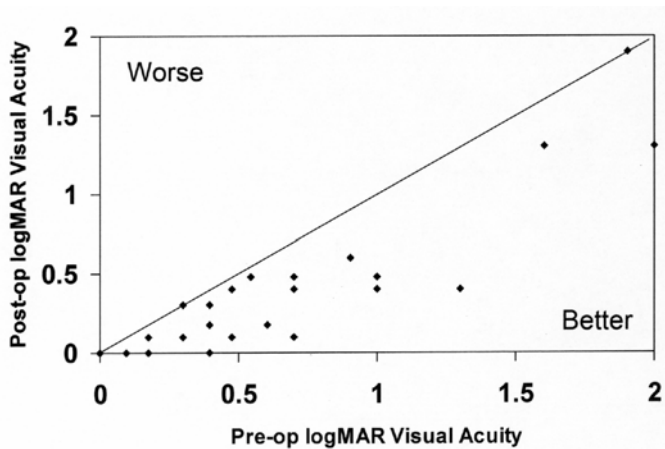


FIGURE 1

Preoperative vs postoperative visual acuities in patients who have had transscleral fixated intraocular lenses. Values are in logMAR units. One patient not shown became blind.

TABLE 4. TRANSSCLERAL SUTURED INTRAOCULAR LENSES IN CHILDREN: REFRACTIVE RESULTS*

CASE	TARGET REFRACTION	POSTOP 3 MO SPHERICAL EQUIVALENT	LAST VISIT SPHERICAL EQUIVALENT	POSTOP REFRACTION (3 MO)	POSTOP REFRACTION LAST VISIT	CHANGE PER YEAR
1	-0.50	-1.00	-1.50	-1.00	-1.50	-0.04
2	4.50	3.25	-5.00	+3.25	-5.00	-1.39
3	-1.50	-0.75	-0.25	-1.50 + 1.50X149	-1.00 + 1.50X90	0.05
4	-0.50	-0.50	-3.50	-1.00 + 1.00X90	-4.50 + 2.00X90	-1.38
5	-0.50	1.00	0.00	- .75 + 3.50X100	-1.50 + 3.00 X 110	-0.11
6	0.65	-1.00	-1.13	-1.25 + .50X100	-1.50 + .75X100	-0.03
7	2.50	3.50	-0.75	+3.00 + 1.00X100	-1.25 + 1.00 X 95	-0.26
8	4.25	4.00	3.00	+4.00	+3.00	-0.80
9	0.50	-1.88	-3.00	-2.25 + .75X175	-3.00	-0.71
10	0.25	-0.75	-1.25	- .75	-1.25	-0.33
11	0.00	1.50	2.50	+ .50 + 2.00X130	+1.00 + 3.00X115	0.17
12	-2.00	-0.50	0.50	-1.50 + 2.00 X32	-1.00 + 3.00X35	0.17
13	-0.20	0.25	-1.00	- .50 + 1.50X153	-1.25 + .50 X180	-0.16
14	2.00	3.00	-1.50	+2.50 + 1.00X90	-3.00 + 3.00 X90	-0.66
15	-1.00	-4.38	-4.88	-5.00 + 1.25 X77	-5.25 + .75 X 83	-0.05
16	0.00	0.25	0.13	- .25 + 1.00X85	- .50 + 1.25 X 75	-0.04
17	-0.20	-1.00	-0.88	-1.25 + .50X90	-1.25 + .75 X90	0.04
18	0.00	-1.00	-0.88	-2.50 + 3.00X100	-1.75 + 1.75 X120	0.05
19	0.50	1.25	1.38	.25 + 2.00X90	+ .25 + 2.25 X 110	0.06
20	0.11	-0.25	-1.50	-1.00 1.50X115	-2.25 + 1.50X135	-0.39
21	-0.68	-1.13	-2.00	-1.50 + .75X90	-2.00	-0.20
22	0.00	1.13	1.38	+ .75 + .75X100	+1.00 + .75X 100	0.05
23	-1.25	0.50	-2.75	-1.00 + 3.00X52	- 4.00 + 2.50X 45	-0.57
24	3.00	1.00	-4.00	+1.00	- 4.00	-1.46
25	0.00	0.63	1.13	Plano + 1.25X81	plano + 2.25X 85	0.11
26	0.10	-1.50	-2.63	-3.25 + 3.50X106	-4.25 + 3.25X 107	-0.47
27	0.80	0.50	-0.13	-1.00 + 3.00X90	-1.25 + 2.25X94	-0.28
28	-0.22	-1.13	-1.25	-2.00 + 1.75 X60	-2.00 + 1.50 X60	-0.17
29	0.32	-0.25	-0.25	- .75 + 1.00 X 55	- .75 + 1.00 X 55	0.00
30	3.00	3.00	-1.25	+2.0 + 2.00 70	-2.50 + 2.50 X 85	-0.38
31	0.50	-1.63	-11.50	- 3.75 4.25X100	-11.5	-1.52
32	0.10	-2.00	-2.50	- 4.00 + 4.00X100	-3.25 + 1.50X90	-0.19
33	-0.50	-1.00	-1.50	-1.00	-1.50	-0.04

*All numbers are in diopters.

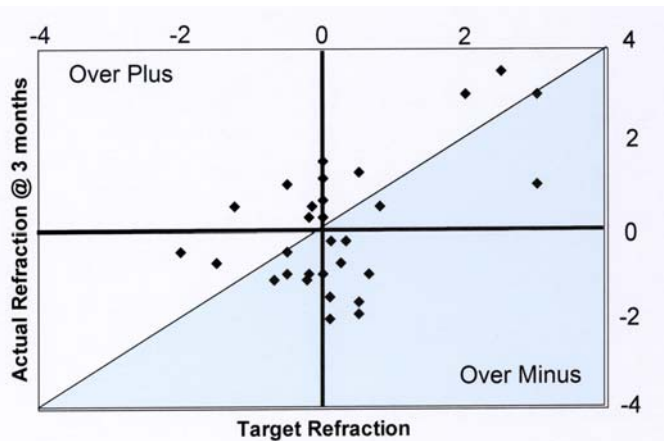


FIGURE 2

Target refraction vs actual refraction 3 months after placement of a transscleral fixated intraocular lens. Note marked variability of the postoperative refraction with both overcorrections and undercorrections from the predicted target value.

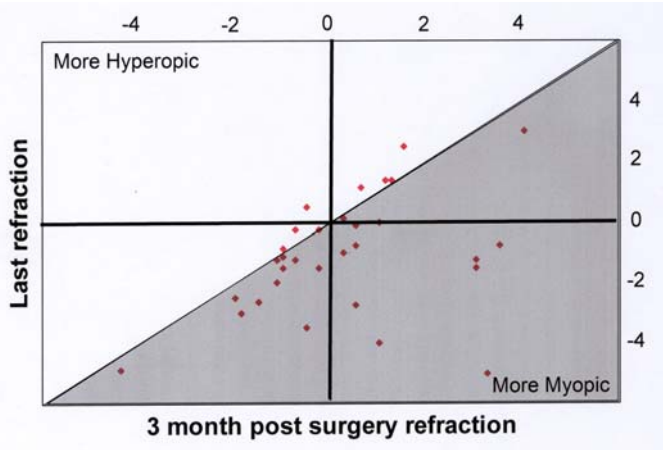


FIGURE 3

Last refraction vs the immediate postoperative refraction in children with transscleral sutured intraocular lenses. Most patients became more myopic with time.

COMPLICATIONS

Intraoperative

One patient had a vitreous hemorrhage associated with passing the 10-0 polypropylene suture through the sclera 2 mm posterior to the limbus. The hemorrhage appeared to come from the ciliary body and tracked back to the macular area. The surgery proceeded and the vitreous hemorrhage cleared by 2 weeks after surgery. The final visual acuity was 20/20.

Postoperative

Early postoperative complications included a persistent anterior chamber inflammation that required steroid eye drops for 6 weeks (patient 7) and mild (approximately 1 mm) IOL decentration (patient 5). The decentration was in an eye that was damaged by severe trauma and had a previous IOL placed elsewhere, which subluxed due to lack of support. Significant peripheral membranes were present, making precise centration determinations difficult. The large optical area of the lens provided sufficient viewing area. One IOL is slightly tilted (patient 21), but it does not appear to be inducing astigmatic change that was not present preoperatively. Preoperative cylinder was +2.50, and postoperative cylinder is +3.35 diopters at 100 degrees. Seven eyes (21%) experienced a rise in intraocular pressure for the first 24 to 48 hours after surgery. This was felt to be due to retained viscoelastic material and was successfully treated with oral and topical antiglaucoma medications.

Two patients (patients 9 and 13) developed persistent increased intraocular pressure postoperatively, which has required a beta blocker and a prostaglandin antagonist to control. Timolol 0.5% twice a day was prescribed for patient 9, who has maintained normal pressures. Patient 13 has been poorly compliant with medications, and the pressures range between the high teens and low 20s. This patient had two previous operations, one to remove the cataract, and a second to remove dense membranes that were causing a secluded pupil. There have been no angle, optic disc, or visual field changes in either patient.

One patient has a floppy iris, which will become partially displaced behind the optic on a daily basis. She has been treated with weak pilocarpine to avoid this but prefers not to use the drug because of brow ache. She experiences no pain but is aware when it occurs. She has not been diagnosed with Marfan syndrome, though she has some of the features of the syndrome. This particular iris problem has been noted by others in patients with Marfan syndrome.^{25,26,38,39}

Membrane formation occurred along the anterior IOL surface in one patient (patient 2) and along the posterior IOL surface in another (patient 18). Patient 2 required 3 operations over a 2-year period to control the problem. The eye had previous glaucoma surgery with a seton implant for pressure control. Visual outcome is poor due to the underlying eye condition and failure to execute effective amblyopia treatment. Patient 18 had previous trauma with lensectomy and vitrectomy. Three months after uneventful sutured IOL placement, he developed a membrane along the back surface of the IOL typical of the type seen after standard cataract extractions in young children. This was removed through a pars plana approach without difficulty and has not reoccurred. Final visual acuity is 20/60.

The surgical technique used in this series is designed to minimize suture exposure, which has been a common problem in adult patients undergoing this procedure (Table 5). The technique requires that the final knots on the suture holding the haptics into the sulcus be rotated into the eye. Unfortunately, in two patients, it was not possible to bury these knots. In both patients an end of the polypropylene suture lies just under the conjunctival surface, and although neither has become exposed to date, this is an ongoing concern. A summary of all complications is shown in Table 3.

Suture Breakage

Suture breakage with IOL subluxation, a potentially serious complication, has occurred in 3 patients (Table 6). This occurred spontaneously in all three, with immediate visual impairment. The superior haptic suture broke in one patient and the inferior haptic suture broke in the other two. The mean age at IOL implantation was 10 years, and the time from the original surgery until suture

breakage was 3.5, 8, and 9 years (mean, 80 months). The suture breakage did not appear to be related to the previous reason for sutured IOL surgery, since one patient had a lensectomy, one had trauma, and one had ectopic lentis. The subluxed IOL did not cause any retinal or other intraocular damage. All three did well with repositioning surgery, retained their original IOL and recovered to their previous level of visual acuity.

TABLE 5. PUBLISHED REPORTS ON DISLOCATION OF SUTURED INTRAOCULAR LENSES (IOLS) SECONDARY TO BREAKAGE OF 10-0 POLYPROPYLENE SUTURE

	McCluskey ⁴¹	Sarrafizadeh ⁴²	Assia ⁴³	Kim ³²	Balta ⁴⁰	Price ³⁴	Vote ³³	Current Study
Year	1994	2001	2002	2003	2004	2005	2006	2006
Type of study		I	I	0	I	I	0	I
Total No. of eyes (% of total in study)	1 (3%)	5 (17%)	4	7	2	5	27 (28%)	3 (9%)
Original sutured IOL indication								
Trauma				5	2			1
Previous Lensectomy			4	2		4		1
Subluxed natural lens		5						1
Subluxed IOL						1		
Mean time to suture breakage (mo)		12	84 (36-108)	73 (38-96)	42	122 (84-170)	50 (33-68)	80 (38-107)
Location of suture break								
Superior				4	2	3		1
Inferior			2	3				2
Temporal			1	1				
Nasal			1			2		
Cause								
Spontaneous	1	7	4	4	2	4	17	3
Traumatic				3		1		
Mean age at IOL implantation (yr)		41	21	33	63	45	31	10

TABLE 6. SUMMARY DATA ON TRANSSCLERAL SUTURED INTRAOCULAR LENS (IOL) PATIENTS WHOSE IOL SUBLUXED ON ACCOUNT OF A BROKEN 10-0 POLYPROPYLENE SUTURE

PATIENT	REASON FOR APHAKIA	AGE AT SURGERY (yr)	TIME TO SUTURE BREAK (mo)	CAUSE	DISPOSITION	VISUAL OUTCOME	FOLLOW-UP (mo)
5	Trauma	12	107	Spontaneous	Resutured	20/60	3
13	Congenital	8	96	Trauma	Resutured	20/25	24
20	Subluxation ectopic lentis	11	38	Spontaneous	Resutured	20/20	9
T1*	Subluxation Marfan	7	70	Spontaneous	Resutured	20/20	24
T2*	Subluxation Marfan	11	41	Spontaneous	Resutured	20/20	10
T3*	Subluxation Marfan	14	24	Spontaneous	Anterior chamber IOL	20/25	6
Mean		10.5	62				12.6

*Courtesy of Larry Tychsen, MD, unpublished data, 2006.

A Kaplan-Meier survival curve is shown in Figure 4. The mean time to suture break was 102 months, and the standard error was 4.19. Also plotted is the adult data from the study by Vote and coworkers,³³ where the mean time to breakage was much sooner (4 years). The Vote data are only those patients who had a suture break (17 of 61) as opposed to the current study data, which includes all patients with and without broken sutures.

Case Reports of Broken Sutures From This Series

Case 1. Patient 13 had bilateral congenital cataracts that were removed at the age of 5 months. Postoperatively the patient used contact lenses and glasses. At age 8 secondary IOLs were implanted. The right eye had sufficient capsular support to allow a one-

piece PMMA IOL (model 6741B; IOLAB Corporation, Claremont, California) to be placed in the sulcus. The left eye had no capsular support, and a one-piece PMMA IOL with eyelets (model CZ70BD; Alcon Laboratories, Inc, Fort Worth, Texas) was sutured to the sclera using 10-0 Prolene suture (Ethicon, Somerville, New Jersey). This was performed without difficulty. Postoperative visual acuity was 20/25 OU with minimal refractive error. Eight years later the patient noted a sudden decrease in visual acuity of the left eye, which improved if he leaned forward with his face pointed downward. He was diagnosed with a subluxed left IOL secondary to a broken suture on the superior haptic. The IOL was placed back in the sulcus and resutured with 10-0 Prolene suture without complications. No attempt was made to reinforce the remaining suture. Postoperative visual acuity in the left eye was 20/25. At the last follow-up 9 months later, he continued to do well with stable visual function.

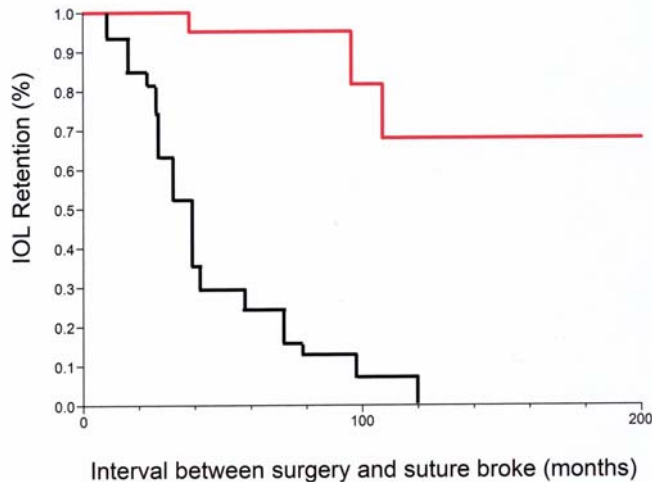


FIGURE 4

Kaplan-Meier survival curve in children with transscleral sutured intraocular lenses (IOLs). The current study includes all patients who had a sutured IOL (33 eyes). Time to suture failure is seen along the x-axis. By 120 months, 30% of the eyes that made it that far had a suture failure.

Case 2. Patient 20 had a history of bilateral familial ectopic lentis, which eventually required lens extraction at the age of 7 years. Because the patient had difficulties wearing contact lenses, a one-piece PMMA IOL with eyelets (model CZ70BD, Alcon Laboratories) was sutured into the sulcus of both eyes when he was 11 years old. The right eye had a vitreous hemorrhage at the time of surgery but subsequently cleared without further complications. Postoperative visual acuity was 20/25 OU. He did well until 3.5 years later, when he noted sudden loss of vision of his right eye. Examination revealed a partially subluxed IOL that was moving freely inferiorly. The IOL was repositioned into the sulcus and resutured using 9-0 Prolene suture. No attempt was made to reinforce the remaining suture. Postoperative visual acuity was 20/20. Twenty-four months later visual function is stable with no further complications.

Case 3. Patient 5 had a penetrating injury to the right eye from a metal object resulting in an inferior corneal laceration and a cataract. His corneal laceration was repaired and his lens was removed. Two months later he had a one-piece PMMA IOL with eyelets (model CZ70BD, Alcon Laboratories) sutured into the sulcus without difficulty. Postoperative visual acuity was 20/50. Nine years later he awoke noting decreased vision that was quite dependent on head position. Examination revealed a subluxed IOL with a freely moving inferior haptic. During surgery to resuture the inferior haptic, the superior fixation suture broke as well. The lens was reattached to the sulcus using 9-0 polypropylene suture. Three months after surgery the patient's visual acuity was 20/60.

SURVEY OF PEDIATRIC OPHTHALMOLOGISTS ABOUT EXPERIENCE WITH SUTURE BREAKAGE IN TRANSSCLERAL FIXATED IOLS

Because of the recent publication of articles raising concerns about the long-term stability of 10-0 polypropylene suture in adults and my own recent experience with the suture failing in children, a survey was conducted to determine whether this was becoming a more widespread problem in children. A simple questionnaire was sent to all members of the ListServ of the American Association for Pediatric Ophthalmology and Strabismus (506 members) in November 2006. The following questions were asked:

- Have you seen or taken care of a child or teenager with a subluxed IOL from a broken 10-0 Prolene suture?
- If so, what was the age at implantation, cause of suture breakage, and how long after the original implant surgery did it occur?
- What was done and how did it turn out?

The survey was sent on two separate occasions. There was an expectation that a reply would be made only if a case was encountered. If a case was reported, further follow-up was made by e-mail. In addition, authors from previous studies using sutured IOLs in children were contacted to ascertain if they have subsequently experienced suture breakage in their previously reported patients.

Results

Ten children were identified as having had a subluxed IOL from a broken 10-0 polypropylene suture. The information is summarized in Table 7. The majority of cases were spontaneous (7 of 10, 70%), occurring years after the original surgery (mean 5.0, range 2-12, median 3.75). Few other conclusions can be reached from these data because recollections were not precise and some records could not be located. No patient appeared to lose vision from the complication.

In response to a direct query to authors of previously published series of transscleral sutured IOLs in children, 3 patients were identified from the previously published study by Bardorf and coworkers.²⁶ All patients had their original sutured IOL for Marfan syndrome with severe ectopic lentis. Since publication, one eye had a suture break due to sports trauma, and in two eyes the sutures spontaneously broke. The sutures broke at 24, 41, and 70 months after surgery (mean, 45 months). Two IOLs were repositioned successfully without loss of vision using 10-0 polypropylene suture. One IOL had the second suture break during the repositioning surgery and an anterior chamber IOL was placed instead. All patients are doing well postoperatively with recovery of preoperative visual function (Table 6). This represents 6% (3 of 51) of their transscleral sutured IOL patients (Larry Tychem, MD, Washington University, St Louis, Missouri, written communication, December 17, 2006).

TABLE 7. TRANSSCLERAL SUTURED INTRAOCULAR LENSES (IOLS) IN CHILDREN: SELF-REPORTED CASES OF SUTURE BREAKAGE BY PEDIATRIC OPHTHALMOLOGISTS IN RESPONSE TO AN E-MAIL SURVEY

CASE	AGE AT ORIGINAL SURGERY (YR)	TIME TO SUTURE BREAK (YR)	CAUSE	OUTCOME	VISUAL ACUITY LOSS?
1	3	2	Spontaneous	Repositioned	No
2	6	4	Trauma	Repositioned	No
3	2	8	Spontaneous	Removed, new lens resutured	No
4	16	2	Spontaneous	Repositioned	No
5	?	3	Trauma (sports)	Repositioned	No
6	10	7	Spontaneous	Repositioned	No
7	5	12	Spontaneous	Repositioned	No
8	7	6	Spontaneous	Repositioned	No
9	11		Trauma	Repositioned	No
10	14	2	Spontaneous	Anterior chamber IOL	No

LITERATURE ASSESSMENT OF SUTURE BREAKAGE IN PATIENTS WITH TRANSSCLERAL FIXATED IOLS

Description of the Evidence

In an attempt to identify how common the problem of 10-0 polypropylene suture failure was becoming, the peer-reviewed literature was analyzed and all possible relevant articles were selected. The literature search was conducted in MEDLINE for 1977 to 2006 and was limited to articles published in English. The MeSH terms used were *lenses, intraocular, or lens implantation*, and the text words were *scleral fix, sutured, transscleral, posterior, chamber, complications, polypropylene, and sutured*. This search yielded 51 citations. Of these, only 8 had clinically relevant information on the issue of 10-0 polypropylene suture breakage.^{32-34,40-44} The above search was repeated with the additional qualifiers of *pediatric and children*. This second search yielded 10 additional reports about the use of sutured IOLs in children.^{2,4,25-28,38,39,45-47} These reports are either case series or case reports, because there are no randomized clinical trials, prospective studies, or case-control studies.

Results

Because there are no reports of 10-0 polypropylene suture breakage in pediatric patients, an assessment of the adult literature looking specifically for such cases was performed. Using the search criteria outlined in the “Methods” section, pertinent articles were identified. There were no prospective studies of adult patients with sutured IOLs in the literature. The studies that are available for review consist of 3 types: retrospective observational case series, retrospective interventional case series, and case reports (Table 5). All of the studies involved the use of 10-0 polypropylene suture to fixate the IOL to the sclera. For many of the reports, the major emphasis of the article was either the observation of what happens in patients with sutured IOLs over time^{33,42} or case reports of patients seen because the suture broke.^{32,34,40,43} Another category that yielded some information was articles that described techniques to reposition subluxed sutured IOLs lens.^{40,44}

There was only one published retrospective observational case series that had an average follow-up of greater than 3 years. This study by Vote and colleagues³³ consisted of all patients undergoing pars plana vitrectomy followed by scleral fixated posterior chamber IOL implantation at Moorfields Eye Hospital from 1993 to 2001. Sixty-one eyes of 48 patients were included in the study. Almost 50% of the patients had the original surgery for subluxed lenses from either Marfan's or ectopic lentis. The remainder consisted of patients who had cataracts removed as a result of trauma. Three patients had a preexisting completely dislocated IOL. In all cases, 10-0 polypropylene suture was used. Postoperatively, 17 eyes (27.9%) had spontaneous suture breakage with several eyes having multiple episodes. Suture breakage occurred on average 50 months (range, 10 to 120 months, SD, 28) after surgery. A subgroup analysis showed that younger patients (mean age, 31 ± 13 years) were more likely than older patients (45 ± 18 years) to have this complication. The multivariate analysis also showed that longer follow-up was associated with increased likelihood of suture breakage ($P = .014$). A Kaplan-Meier survival plot illustrating the time to suture breakage for the group is shown in Figure 4.

The remaining publications are either case observational or case interventional series. Kim and colleagues³² reported on 7 patients who experienced subluxation of sutured IOLs an average of 78 months (± 19) after the original surgery. The subluxation was spontaneous in 4 and associated with trauma in 3. One patient experienced 2 episodes in the same eye associated with a different haptic. They noted that their patients were younger than other reported case series of sutured IOL patients having an average age of 33 years. One patient had the broken suture still adherent to the sclera. Assia and coworkers⁴³ reported 2 patients who had ectopic lentis treated with lens extraction and sutured IOL implants. All 4 sutures broke spontaneously. Three of the 4 broke more than 8 years after the original suture placement. They noted no remnants of the suture tied to any of the haptics.

Price and coworkers³⁴ recently published a retrospective interventional case series of 5 consecutive patients who received treatment for dislocated scleral sutured IOLs that occurred 7 to 14 years after implantation. Four of the dislocations were spontaneous and one was traumatic. All patients had the lens attached to the sclera using 10-0 polypropylene suture at the original surgery. There was no evidence that the suture eroded through the sclera or that the knot came untied. Three patients had the loose haptic resutured without removing the IOL, one patient had the IOL removed and then reinserted, and two patients had the IOL exchanged for a CZ70BD lens. One of the removed IOLs was found to have the sutures still attached to the haptics, and the IOL was examined under high magnification (Figure 5). There was apparent "surface degradation consisting of transverse cracking with clefts between the cracks."³⁴ The investigators concluded that these changes would "reduce the cross-sectional load bearing area" and that the most significant changes were seen where the suture was "embedded in the sclera and ciliary sulcus." All patients had their IOLs resutured to the sclera using 9-0 polypropylene suture without complications.

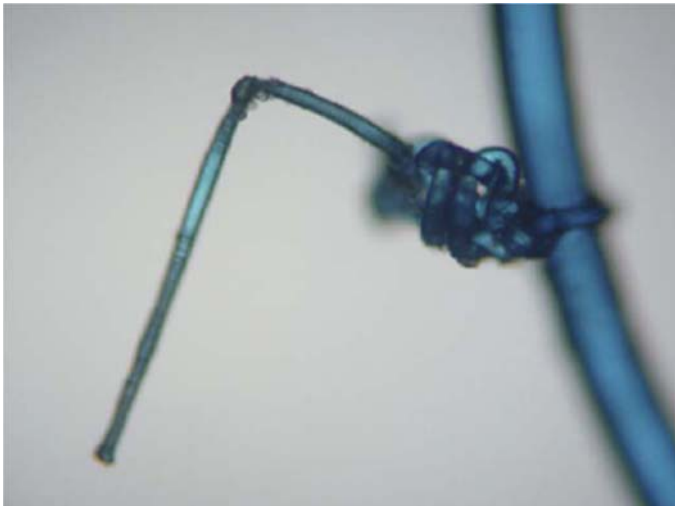


FIGURE 5

High-magnification photograph of a 10-0 polypropylene suture that broke. Note marked irregularity to the suture with obvious fraying. Reprinted from Price et al.³⁴

Sarrafizadeh and colleagues⁴² published a consecutive series of patients treated for dislocation of a previously implanted posterior chamber IOL either "in-the-bag" or in the sulcus. They compared lens repositioning with lens exchange. In the eyes undergoing lens repositioning, 16 were sutured to the sclera using 10-0 polypropylene suture. Of these, 4 (25%) had sutures break with IOL subluxation 6 months to 2 years after surgery. The investigators attributed the high rate of dislocation to the "flexible" haptics of the lenses, which made suture fixation more difficult. Thirty patients had a CZ70BD (Alcon) exchanged lens sutured in the sulcus. One of these patients developed IOL subluxation 1 year later due to suture breakage.

An indirect way to gain insight into the magnitude of the problem of late suture failure is to look for reports in the literature on how to successfully treat the suture breakage problem after it occurs. Only 2 reports specifically directed at treating subluxed previously sutured IOLs were found. Lee and associates⁴⁴ described an approach they used on a patient who had a subluxed lens only 2 weeks after the original surgery. This was undoubtedly a problem from the original surgery. Balta⁴⁰ described a technique that he used on 2 patients. One had a suture break spontaneously 3 years after the original surgery and the other 4 years. Both were treated successfully.

Questions and Answers From Literature Assessment

- a. Are posterior chamber IOLs that are sutured to the sclera with 10-0 polypropylene suture likely to dislocate over time due to suture breakage? Yes, it appears that over time the likelihood of suture breakage increases.
- b. Are there factors that contribute to this breakage, or is it just spontaneous? No causative factors could be identified other than trauma. The majority occurred spontaneously.
- c. Does this complication result in loss of sight? The risk of losing vision from the IOL dislocation by itself was very low. Most of the vision loss was due to a complication of the trauma or the surgical repair due to the trauma. Spontaneous dislocations did not lose vision.

DISCUSSION

This study attempts to address 2 primary issues. Are posterior chamber transscleral sutured IOLs an effective long-term solution to rehabilitate a child's eye that is aphakic without capsular support, and, if so, are the current techniques that use 10-0 polypropylene suture safe over time? If either of these issues is a concern, then adopting an alternate strategy to handle the problem of no capsular support in children needs to be utilized.

The current sentiment reflected in the literature is that use of transscleral fixated posterior chamber IOLs is a reasonable way to treat aphakia in the absence of capsular support in children over the short term. Generally, these patients are difficult to treat and options are limited. The surgical procedure is acknowledged to be more difficult and the intraoperative complications are more numerous than with standard secondary IOL implantation in the sulcus or reformed capsular bag, but this risk is felt to be acceptable when compared to the other alternatives.^{3,6,11} This study supports that claim, and a comparison of the major issues identified in the past reports (Table 1) shows that although some problems occur during or after the surgery, they are generally infrequent and do not tend to have significant vision-threatening implications.

The current study represents the longest follow-up of pediatric sutured IOLs to date. The average follow-up was 5 years with over a third of the patients followed for more than 7 years. The longer follow-up has enabled several important unanswered questions to be addressed. In particular, in children does the postoperative vision remain unchanged after 3 to 6 months, continue to improve, or eventually deteriorate? Did the postoperative refraction become more myopic with time, similar to children with IOLs placed in the capsular bag? Were there new problems that developed over time either with the eye, the IOL, or the sutures that required further treatment, and did they threaten vision?

VISUAL ACUITY

The visual acuity results are summarized in Table 2 and are similar to past studies in the literature,^{26,27,48} which have reported either good visual preservation or improvement after transscleral fixation of IOLs in children. In this study, as well as previous studies, very few children lost vision as a direct result of the surgery. The major factor contributing to visual loss postoperatively has been amblyopia. Seven patients in this study were young enough to be at risk for amblyopia and required treatment. Four responded and 3 failed treatment. Interestingly, the 3 patients who failed treatment have continued to maintain their best visual acuity achieved during amblyopia treatment, even after patching was stopped. This may be attributed to the presence of a continuous focused image as opposed to part-time or not at all. Often patients who are aphakic and using contact lenses stop wearing them if good vision is not obtained by amblyopia treatment. The hassle of wearing optical correction becomes too great for the parents or adolescents, especially if they do not perceive much functional benefit. It appears that in children, amblyopia continues to be a major factor limiting good visual outcome in those with unilateral pseudophakia regardless of where the lens is located, and these visual results are similar to other studies of secondary IOLs in children, including those that were not sutured.^{3,11,12,49,50}

REFRACTIVE CHANGES

Past studies have noted that accurately achieving the target refraction postoperatively when using IOLs is difficult in children.¹² This becomes even more problematic when the IOL is sutured, because the lens position in the posterior chamber can vary, the lens can end up tilted or slightly rotated, and suturing the large opening (7 mm) necessary to insert the IOL may induce some permanent astigmatism. In this study the postoperative refraction (spherical equivalent) was generally within 2 diopters of the target refraction and not statistically different. However, this is misleading because the scatter plot of target vs actual postoperative refraction suggests that there was a fair amount of unpredictability with many overcorrections and undercorrections (Figure 2). There did not appear to be an obvious trend or variable such as age, axial length, or previous trauma to help detect why the actual postoperative refractions were not more accurate. One possible explanation for this in young children is that the axial length measurement may be inaccurate because it was assessed with the child asleep. Because there is no visual fixation to determine the correct visual axis, slight offsets may occur, resulting in an error in the target refraction calculation. In young children this is not so crucial because the appropriate target refraction is just a calculated guess anyway, but in the older child and teenager, significant variance from target can be problematic.

A particular challenge in managing children with IOLs is the determination of what should be the appropriate postoperative refraction. In adults, the target refraction usually is either a "minimal" refractive error (plano) or some degree of myopia to provide reading capability without additional spectacle correction. Unlike adults, the child's eye is going to continue to grow and theoretically any refraction obtained will be subject to change over time. Accurately predicting the change allows the surgeon to make an educated judgment as to what IOL power to implant. Children's eyes that are either aphakic or pseudophakic (lens in the capsular bag) tend to become more myopic with time. This is due to the relative stability of the cornea and the continued elongation of the eye. Numerous

studies have shown that the refractive drift in pediatric pseudophakia is quite variable, but the younger the child the larger the shift over time.^{35,51} Because of this expected myopic shift, most pediatric cataract surgeons tend to undercorrect the postoperative refraction leaving the child hyperopic as opposed to emmetropic. The assumption is that the child will tend toward myopia and thus “grow into the lens.” Based on an analysis of pediatric pseudophakic patients, Enyedi and associates³⁵ recommended a target refraction that is age-appropriate. Table 6 was based on the expectation that children aged 2 to 5 years would change at a monthly rate of -.06 diopters; 6 to 8 years at a rate of -.04 diopters; and children over 8 years at a rate of -.03 diopters.

Do children with sutured IOLs experience the same myopic shift, or does the presence of a lens outside the capsular bag present a different stimulus with either more or less change? Because this study population is quite small, meaningful conclusions are difficult to make. However, the 11 children who were younger than 5 years of age exhibited a mean refractive change of -.07 diopters per month. This is very similar to Enyedi’s pediatric pseudophakic population³⁵ and to Bardorf and coworkers’ pediatric sutured IOL study,²⁶ which found a -.08 diopter per month shift for the same age-group but over a much shorter time frame. There were not enough patients between 6 and 10 years of age in this study to make a reasonable estimation of the refractive change. For those 10 years and older (n = 13), there was a small, -.007 diopter shift per month, or -.08 diopters per year. Although this is less than in the Enyedi study, the patients were at least 2 years older and some were considerably older. Thus it would appear that the myopic shift in the sutured IOL patients is similar to the standard pediatric pseudophakic patient (Table 8).

TABLE 8. RATE OF REFRACTIVE CHANGE AFTER INTRAOCULAR LENS (IOL) IMPLANTATION OVER TIME*

Age (yr)	Enyedi ⁶³	Bardorf ²⁶	Current Study
	Capsular bag	Sutured	Sutured
<5	-.96	-1.00	-.86
5-9	-.50	-.50	-.10
>9	-.36	-.25	-.10

*Values are in diopters/year.

INDUCED ASTIGMATISM

The IOL used in this study was the CZ70BD (Alcon), a one-piece PMMA lens with eyelets on the haptics to facilitate the suturing process. The lens has a very large 7-mm optic requiring an opening larger than 7 mm for insertion. Since this size opening has to be sutured, large amounts of induced astigmatism are a postoperative risk. When the preoperative cylinder, as measured by keratometer (mean, 2.15 diopters), was compared to the postoperative cylinder, as determined by refraction (mean, 1.61 diopters), the average difference was significantly *less* after surgery ($.66 \pm 1.61$, $P = .02$). This effect continued to the “last” refraction (mean, 1.32 diopters, $P = .002$). Why there was less astigmatism after suturing a fairly large cornea/sclera surgical opening is unclear. It has long been observed that a large amount of astigmatism is present in the immediate postoperative period in children whose surgical wounds are sutured after IOL implants. This was especially true when large one-piece PMMA lenses were being used.⁵¹ This astigmatism typically reduced considerably during the first month and usually was only a diopter or less by 3 months.³⁵ It is probable that as the wound heals, a stretching or relaxation occurs, resulting in a flattening of the cornea that reduces the with-the-rule astigmatism that most children have. Regardless of the mechanism, there does not appear to be a significant concern about inducing a large amount of astigmatism in these patients.

DEVELOPMENT OF NEW PROBLEMS OVER TIME

In the study population, there were no additional “eye”-related problems that occurred beyond the initial 3- to 6-month postoperative period that were not already apparent during that time. Specifically, there were no new cases of glaucoma, retinal detachment, or anterior segment issues that subsequently developed (Table 3). Regrowth of membranes was an issue in 2 patients, but they were identified early as a potential problem and were not detected because of the longer follow-up period. The one patient who became blind also was known to be at significant risk early in the course of treatment. Given these findings, it appears that the presence of an IOL sutured to the scleral wall in the posterior chamber is well tolerated even in eyes that were previously disrupted by trauma. This observation is supported by other reports, which have shown that eye-related complications tended to occur immediately after the actual surgery and that once the patients recovered from the surgical-induced trauma, new problems rarely surfaced.²⁶

SUTURE BREAKAGE

The current study does raise real concern about the continued use of 10-0 polypropylene suture for transscleral fixation of an IOL in a child. Three patients (9%) had a 10-0 polypropylene suture spontaneously break. This is a significant number, which raises concern about the safety of our current approach. There appeared to be no associated trauma or ocular predisposition for suture breakage to occur. The suture just failed. Fortunately, none of the patients suffered sustained loss of vision, but the potential is clearly evident. A survey of over 500 pediatric ophthalmologists uncovered 10 more cases of broken sutures (Table 7). Some of these were associated with trauma, mainly sports, but many were spontaneous with no obvious etiology other than suture failure.

The fact that 10-0 polypropylene suture might degrade enough to break over time is not completely unexpected.⁵² Widespread use of 10-0 polypropylene in ophthalmology began in the late 1970s with the advent of iris fixated IOLs. Drews,⁵³ in a report almost 25 years ago, noted that polypropylene may fail after a prolonged period in the eye. He performed scanning electron micrographs on sutures removed from iris fixated lenses and those used for fixation at the limbus. The study showed that the suture material had surface cracks with flaking and that the changes were progressive over time. The deterioration was most marked with sutures buried in actively metabolizing ocular tissue.

Jongbloed⁵⁴ studied a 10-0 polypropylene suture that had served as a fixation suture for an IOL for a period of 6.5 years. The fixation suture showed cracks perpendicular to the longitudinal axis of the suture; part of the surface layer was nearly detached or completely missing; whereas the diameter of the suture was decreased toward both ends by over 50% in comparison with the original diameter. The exposed subsurface layer showed a fibrillar structure. The degradation phenomena are considered to be caused by the enzymatic action of tissue fluids. Virgin material did not show any of the phenomena observed on the fixation suture. Other reports followed indicating that this might be due to the molecular orientation of polypropylene necessary to make sutures, since this did occur with polypropylene lens haptics as well.^{52,55}

PEDIATRIC OPHTHALMOLOGISTS' EXPERIENCE WITH BROKEN SUTURES

Because it appears from a review of the adult literature that there are substantive reasons to be skeptical about the long-term stability of 10-0 polypropylene suture in adults, why are there not more reports of children with broken sutures after transscleral fixation of an IOL? Given all the reasons that the suture might fail, from biodegradation to trauma, it would seem that children would be at a higher risk for this problem from any of these presumed mechanisms. Are sutures just not breaking, or are there not enough in any single practice to raise suspicions? This question prompted an informal survey of pediatric ophthalmologists who may either have such cases in their practice or know of some. Surprisingly, 10 additional cases were uncovered, making this not so uncommon after all. Aside from one high-volume pediatric cataract surgeon who reported 3 patients and the 3 cases in this study (Table 6), the rest were single isolated episodes. Because there were no significant complications associated with the broken suture other than that the IOL had to be reattached, the level of concern among pediatric surgeons that this was a serious problem going forward was minimal. What is not known is how many children are still at risk for the occurrence of this problem. The survey did not yield a denominator, but it is generally believed that the number of children undergoing sutured IOLs is far less than in adults, making the absolute number of children susceptible to suture breakage small. If this is true, then the current known cases could represent a significant percentage of those at risk. More important, when asked about what suture was chosen to reattach the IOL, all responded that 10-0 polypropylene was used, which makes these patients susceptible again to this problem.

FIBROUS MEMBRANE AROUND HAPTICS

Given the above reports in the literature, plus the antidotal cases that are occurring intermittently, it is not clear why 10-0 polypropylene suture is still being used to suture IOLs, especially in children. Are surgeons just unaware of this potential problem, or is there an assumption that there are other factors that make the suture unimportant over time? In adults it has been suggested that if the lens haptics are sewn into the sulcus, a fibrous membrane will form around them, thereby firmly fixing the IOL in position.^{56,57} However, this membrane was not seen if the haptic was positioned either anterior or posterior to the sulcus, and, in one series, this accounted for over 30% of the eyes.⁵⁶ Other reports using ultrasound biomicroscopy have shown that a significant percentage of haptics, up to 50%, are outside the ciliary sulcus.⁵⁸⁻⁶⁰ Does sulcus fixation really result in membrane formation? Lubniewski and associates⁶¹ reported on 3 eyes with sutured IOLs that underwent enucleation. Only 1 of the 6 haptics was in the ciliary sulcus, and none showed a fibrous membrane over the haptic that was substantial enough to hold the lens in place without the suture. It appears that even placing the haptic in the sulcus does not guarantee that a membrane will form around the haptic, and even if it did, our current techniques are not precise enough to ensure sulcus fixation in a substantial number of patients. Clearly, suture integrity is important for long-term fixation of the IOL to the sclera, because membrane formation cannot be assured regardless of where the haptic is attached to the eye.

CONSEQUENCES OF FIXATION SUTURE BREAKAGE

A striking finding in both adults and children who have had a sutured IOL become subluxed is the apparent lack of significant consequences other than the necessity of needing to have it resutured. In this study, 3 children had a suture break that resulted in subluxation of the IOL with no associated problems and, in particular, no retinal damage. It is surprising that the retina is not damaged from this problem, and it would appear to be at more risk depending on which suture broke. Empirically, it would seem that retinal injury would be more likely to occur from a superior broken suture, which would cause the IOL to rotate backward and downward, because it is still attached by the inferior located haptic. Gravity should pull the IOL on to the inferior retina. The superior haptic suture did break in 1 of our patients, and on indirect fundusoscopic examination the IOL was seen to "float" above the retina inferiorly. It appeared to be supported by the vitreous and did not touch the retina. There also appeared to be some "torque" on the IOL, keeping it from freely rotating all the way down. It is possible that the remaining suture or the ciliary body provided some support cantilevering the IOL off of the peripheral retina. The other 2 children had the inferior haptic break, and the IOL was seen to "tangle" from the remaining superior attachment much like a swing. When the patients were placed in the supine position, the IOL "floated" like a superior suture break and did not touch the retina. Fortunately, the IOL is not long enough (13.5 mm) to reach the macular area. Reviews of the reports that include patients who have experienced broken sutures have mirrored our experience, with no patient losing

vision as a result of the IOL damaging the retina or from the resuturing operation. The informal survey of pediatric ophthalmologists had similar results (Table 7).

The first incident of suture breakage in this series was repaired using 10-0 polypropylene suture. It occurred prior to the reports of this problem becoming more prevalent in adults and was felt to be isolated. However, when the second suture spontaneously broke, concern was raised that the suture material may be inadequate for long-term support, and 9-0 polypropylene was used instead. Price and coworkers³⁴ and Stewart and Landers⁶² recommended that 9-0 polypropylene suture be used as an alternative to 10-0 polypropylene because it has a 60% greater tensile strength, 50% greater diameter, and a 125% greater cross-sectional area. The 9-0 polypropylene is available on some of the needles that are currently being used for transscleral fixation (CIF-4, Ethicon Inc) but not others (STC6, Ethicon Inc). As an alternative, other surgeons have fashioned a simple needle-and-hook apparatus to achieve the same effect as the STC6 needle using 9-0 polypropylene suture.⁶² There are no reports in the literature of a sutured IOL dislocation secondary to breakage of a 9-0 polypropylene suture. The only drawback to using this suture is the size of the knot, which is larger and requires an even more concerted effort to adequately protect it from eroding through the conjunctiva. Assia and colleagues⁴³ when dealing with a broken suture in their patients opted for using either an anterior chamber IOL or iris fixation instead of resuturing the IOL to the sclera. Interestingly, none of the investigators who reported on techniques to resuture the IOL recommended another size or type of suture.⁴⁰

CONCLUSION

Two questions were to be addressed by this report. First, Is suturing an IOL in children an effective way to treat aphakia in an eye without capsular support? This was assessed by evaluating the intraoperative surgical risks, postoperative visual and refractive outcomes, and the number, type, and severity of the postoperative complications. In addition, previous reports on the use of sutured IOLs in children were reviewed to identify issues not encountered with the current study that might add concerns. Based on these findings, it seems that using transscleral fixated IOLs to rehabilitate a child with aphakia and no capsular support is a reasonable approach provided that the IOL remains fixated to the sclera. The surgical risks are manageable, the visual acuity and refractive outcomes are satisfactory, and having the IOL in the posterior chamber is generally well tolerated and preferable to placing the IOL in the anterior chamber, which is the only alternative currently available.

Second, Is 10-0 polypropylene suture stable enough to provide long-term secure fixation of an IOL to the sclera in a child? It is apparent from the results of this study, the anecdotal reports of pediatric ophthalmologists elicited through the informal survey, follow-up of previously reported series, and a through review of the adult literature on the use of sutured IOLs, that 10-0 polypropylene suture cannot be relied on to secure a posterior chamber IOL to the sclera over the lifetime of a child. Either the current procedure should be abandoned in children, or some modification to the size or type of suture material needs to be made. The most likely alternative is to use 9-0 polypropylene suture, which has the same characteristics as 10-0 polypropylene but is sturdier and better able to resist degradation over time.

Transscleral fixation of an IOL in a child appears to be a safe and effective procedure provided that the suture material used is stable enough to resist significant degradation over time. Because the long-term reliability of 10-0 polypropylene suture to securely fixate an IOL to the sclera is questionable, using an alternate material or suture size should be strongly considered.

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