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The Effects of Surgical Factors on Postoperative Astigmatism in Patients Enrolled in the Infant Aphakia Treatment Study (IATS)

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Abstract

Purpose—To evaluate the impact of surgical factors such as incision type, number of sutures, and technique of closure on postoperative astigmatism in infants undergoing cataract extraction with or without intraocular lens implantation.

Methods—The IATS is a multicenter (n=12) clinical trial in which 114 infants with unilateral congenital cataracts were randomized to undergo cataract extraction with intraocular lens (IOL) placement or contact lens aphakic correction. Surgical videos were reviewed with regard to incision type and location, whether the incision was extended, the number of sutures placed, and technique of closure. Corneal astigmatism was measured using a handheld keratometer prior to surgery and at 1 year of age.

Results—Corneal astigmatism decreased from a mean of 1.92 D at baseline to 1.62 D at age 1 year in the CL group, but remained almost unchanged from 2.00 D to 2.09 D in the IOL group (p=0.023). There was no statistical difference between the amount of corneal astigmatism irrespective of incision type (p=0.214) and no increase in astigmatism with extension of the incision to facilitate IOL placement (p=0.849) at 1 year. The number of sutures and technique of closure did not influence the amount of astigmatism at 1 year.

Conclusions—At the age of one year following cataract extraction in infants, contact lens correction and the lack of IOL placement are associated with a significant decrease in postoperative corneal astigmatism compared to intraocular lens placement. No other surgical factors considered in this study had a statistically significant impact on corneal astigmatism.

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Introduction

Congenital cataracts, especially when unilateral, can lead to significant amblyopia in the affected eye due to deprivation and anisometropia.[1] Minimizing postoperative astigmatism could potentially have a positive impact on amblyopia treatment. There has been extensive research about the effect of various surgical factors on astigmatism in adult cataract surgery.[2–5] Postoperative astigmatism has been studied in pediatric age groups in a few studies using retinoscopy.[6–11]. However, retinoscopy carries with it a degree of subjectivity.[12,13]

The Infant Aphakia Treatment Study (IATS) is a randomized multicenter clinical trial that compares visual outcomes and adverse effects in infants with unilateral cataracts operated between 1 and 6 months of age whose aphakia was corrected with either a contact lens or an intraocular lens (IOL). In contrast to previous studies, the present study utilized handheld keratometry measurements to assess the amount of corneal astigmatism prior to cataract surgery and at one year of age. The aim of this study is to assess the amount of resultant corneal astigmatism with regard to modality of aphakia treatment, age at the time of surgery, enlargement of incision, incision type, number of sutures, and technique of wound closure.

Methods

The IATS included 12 clinical sites. The study design, surgical technique, follow-up schedule, patching and optical correction regimens, evaluation methods, and patient characteristics at baseline have been previously reported and only the elements relevant to the results presented in this paper are briefly summarized.[14] The study was approved by the institutional review board at all participating institutions and was in compliance with the Health Insurance Portability and Accountability Act. The off-label research use of the Acrysof SN60AT and MA60AC IOLs (Alcon Laboratories, Fort Worth, Texas) was covered by US Food and Drug Administration investigational device exemption # G020021.

Study Design

Inclusion criteria included a visually significant congenital cataract (≥3mm central lens opacity) in only 1 eye and age 28 days to <7 months at the time of surgery. Patients with a unilateral cataract due to persistent fetal vasculature (PFV) were allowed in the study as long as the PFV was not associated with visible stretching of the ciliary processes or involvement of the retina or optic nerve as determined by the treating IATS investigator. An examination under anesthesia (EUA) was performed prior to surgery to assess the eligibility criteria and a handheld keratometer was used to obtain keratometry measurements at that time. An average was taken of two readings within 1.0 D of each other. Eligible patients were then randomized to have either an IOL placed at the time of the initial surgery (with spectacle correction) or be left aphakic (with contact lens correction). An IATS certified investigator examined patients at 1 day, 1 week, 1 month, 3 months, and then at 3-month intervals. All patients underwent an EUA at 1 year of age. At that time, keratometry measurements were repeated in the same manner.

Surgical Technique

In the contact lens group, a vitreous cutting instrument was inserted through a stab limbal incision to aspirate lens material and a primary posterior capsulectomy and anterior vitrectomy were performed. Aphakic patients were fitted with either a silicone elastomer (SE) or rigid gas permeable (RGP) contact lens at the discretion of the contact lens professional.

In the IOL group, a 3 mm superior scleral tunnel or clear corneal incision was made and a vitreous cutting instrument was inserted to aspirate lens material. An Alcon SA60AT IOL was placed in the capsular bag if possible. If not, an Alcon MA60AC IOL was placed in the ciliary sulcus. The Holladay 1 formula was used to calculate IOL power with a target refraction of +8.00 spherical equivalent for infants aged 4 to 6 weeks and +6.00 for over 6 weeks. Following IOL placement, the incisions were closed and a vitreous cutting instrument was introduced through a stab incision at the pars plana/plicata. An anterior vitrectomy and posterior capsulectomy were then performed. Incisions for both groups were closed with 9-0 or 10-0 synthetic absorbable suture, except the pars plana/plicata incisions which were closed with 7-0 or 8-0 synthetic absorbable suture. The main incision in the IOL group was closed in either a continuous or interrupted fashion. Some surgeons preferred an X-shaped closure, and this was considered to be continuous. Because absorbable sutures were used, removal was not necessary. The surgeries were recorded and the videos from the IOL group were reviewed by one of the authors to determine the following surgical factors: incision type (scleral tunnel or clear cornea); whether the incision was extended; the number of sutures utilized (1–2 or 3–4); and the technique of wound closure (running or interrupted).

Statistical Methods

The magnitude of the keratometric astigmatism at baseline and at 1 year of age was calculated as the steeper minus the flatter curvature measurements. The change in astigmatism was determined by subtracting the baseline measurement from the 1 year of age measurement so that positive values indicate an increase in astigmatism. The mean astigmatism at baseline and at 1 year of age and the mean change in astigmatism from baseline to 1 year of age were all compared between the two categories of each of the surgical factors using an independent groups t-test. The same analyses were done to relate astigmatism to treatment (CL vs IOL) and age. Age was categorized as < 49 days versus ≥ 49 days since the randomization to treatment was stratified by these categories.

Results

Subjects

Between December 2004 and January 2009, 114 patients were enrolled with 57 patients in each treatment group. The age range was 4 weeks to 6.7 months with a median age of 1.8 months. The patients were 53% female and 85% white with a racial distribution similar to the general population. Of the 57 patients in the IOL group, for 9 patients surgery was performed before videos were required, for 4 patients the surgery was not recorded, for 2 patients the video was not of adequate quality to review and for 1 patient there was a technical problem with the DVD. Therefore, surgical factor data was collected for the 41 remaining IOL patients. In a few patients some of the surgical factor data are missing since their value could not be determined from the recording. Nine patients (5 in the CL group and 4 in the IOL group) did not have keratometry measured at the EUA at 1 year of age.

Surgical Factors for the IOL Group

Among those 41 patients, 20 (49%) received scleral tunnel incisions and 20 (49%) underwent clear corneal incisions. For one patient both types of incisions were used, a clear corneal incision for lens removal and a scleral tunnel incision for the IOL insertion. The keratome incision was extended in 6 (15.4%) of 39 patients. The paracentesis was closed in all 40 IOL patients in whom wound closure was observed. Among 40 of the IOL patients, the number of sutures used for incision closure was as follows: 1 suture (3 patients, 7.5%), 2 sutures (9 patients, 22.5%), 3 sutures (25 patients, 62.5%), 4 sutures (3 patients, 7.5%). Among the 37 patients in whom more than 1 suture used, interrupted sutures were used in 32 (86.5%).

For all the surgical factors, there was no statistical difference between the groups for the mean astigmatism at baseline or at 1 year of age or for the mean change in astigmatism during that interval. (Table 1)

Astigmatism Variation with Respect to Treatment Modality and Age at Surgery

There was no statistical difference between the contact lens and IOL groups for the mean corneal astigmatism at baseline or for the mean change in corneal astigmatism between baseline and 1 year of age. There was a statistically significant difference in astigmatism at 1 year of age ($p=0.023$), with a reduction in the amount of corneal astigmatism in the contact lens group but no significant change in the IOL group. In addition, there was no difference in the amount of corneal astigmatism pre- or postoperatively based on the age at the time of surgery (Table 2).

Discussion

We found significantly less corneal astigmatism at the age 1 year examination in the eyes of infants who underwent cataract surgery between the ages of 1 to 6 months who were left aphakic and treated with contact lenses compared to eyes that underwent primary IOL implantation. The difference was largely due to a reduction in corneal astigmatism between the baseline and the age 1 year examination in the aphakic eyes compared to a largely unchanged astigmatic refractive error in the pseudophakic eyes. The mean astigmatism at 1 year in the contact lens group was 0.37D less than the IOL group. Although this difference was statistically significant, the clinical significance is small. Other factors in the IOL group such as the type of incision, the number of sutures used to close the surgical wound or enlarging the wound were not statistically significant.

The present study differed from previous studies in that astigmatism was measured using keratometry rather than retinoscopy. Retinoscopy is difficult to accurately assess in infants due to their unstable fixation whereas keratometry obtained during an EUA is a more objective measure of corneal astigmatism. Retinoscopy measures both lenticular and corneal astigmatism, whereas keratometry only measures corneal astigmatism. Isolating corneal astigmatism would be preferable to properly assess the impact of factors such as incision type and corneal sutures on astigmatism as they should not have an effect on lenticular astigmatism. Retinoscopy also would not be possible to perform with accuracy in this population at baseline due to the presence of cataract impacting the quality of the red reflex. We documented surgical details by reviewing surgical videos, which has not been mentioned in previous studies. Although there are several studies that address the type of incision and change in astigmatism, we were unable to find studies that compared postoperative astigmatism in patients who had IOL placement versus patients who were aphakic with contact lens correction.

We did not find a difference in the amount of corneal astigmatism between the clear cornea and scleral tunnel groups at 1 year of age. With regard to incision type in congenital cataracts with IOL placement, Spierer et al found a high level of astigmatism at 1 week after surgery, which dissipated over the first 5 months in patients who had either scleral tunnel incisions.[9] Bar-Sela et al also noted a spontaneous reduction in astigmatism over time in patients who had scleral tunnel incisions. In addition, they saw similar results in the clear corneal group but did not compare the two groups to each other.[10] We do not have multiple data points within the first year after surgery. It is likely that, based on previous studies, the magnitude of postoperative astigmatism had already decreased at the one year measurement point. Another study by Gupta et al of children with IOL placement showed a similar level of astigmatism at 1 month after surgery, but statistically significantly lower astigmatism at 3 and 6 months in those who had clear corneal incisions compared to those with scleral tunnel incisions. The difference was clinically insignificant. The incisions were closed using non-absorbable sutures, so this decrease in astigmatism was probably not the result of suture absorption.[11]

We found no difference in corneal astigmatism based on number of sutures placed, whether the wound was extended, or how the wound was closed. We were unable to identify other studies that addressed these parameters in congenital or pediatric cataract surgery; however some of these parameters have been studied with regard to adult cataract surgery. Sood et al looked at continuous versus interrupted sutures in adult extracapsular cataract surgery and found interrupted sutures to cause significantly less astigmatism than continuous sutures.[4] The ability of the present study to identify potentially significant factors was limited by the small sample size, particularly in some of the subgroups. For example, in the case of suture type, only five patients had a running suture.

The difference in the size of the incisions in the aphakic group versus the IOL group could account for a difference in the amount of astigmatism between the two groups at 1 year of age. If this explanation were true, this would imply that the smaller incision causes a decrease in astigmatism in the first year and the larger incision in the IOL group causes it to stay stable because the level of astigmatism stayed stable between baseline and 1 year in the IOL group. Another possible explanation is that the contact lens used in the aphakic group led to a decrease in astigmatism. The contact lens was not removed at a standardized time interval prior to the EUA done at 1 year of age. Contact lenses can cause corneal warpage, and in a study by Wang et al looking at contact lens induced warpage prior to refractive surgery, 12% of patients who were evaluated for keratorefractive surgery had some degree of warpage. They noted up to 2.5D of keratometric shifts as well as changes in topography, and it took an average of 7.8 weeks to stabilize. The longest recovery was in the patients who wore soft extended-wear followed by rigid gas permeable lenses.[15] As was previously published by the IATS group, 74% of aphakic patients were in silicone elastomer (SE) lenses, 21% were in rigid gas permeable (RGP) lenses, and 5% wore both types.[16] The mean decrease in astigmatism was less in the RGP group (0.10 D/mo) than the SE group (0.22 D/mo), but this difference was not statistically significant.

In conclusion, we found a decrease in corneal astigmatism at one year of age in patients who were corrected with a contact lens compared to those who received an IOL. One possible explanation for this decrease could be a change in the shape of the cornea induced by the contact lens. More long term follow up would help to determine whether this difference in astigmatism persists or changes over time.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Astigmatism According to Surgical Factors for IOL Patients

Surgical Factor		Baseline		Age 1 Year		Change	
		n	Astigmatism Mean (SD)	n	Astigmatism Mean (SD)	n	Astigmatism Mean (95% CI)
# Sutures	**1–2**	12	1.77 (1.10)	11	1.88 (1.13)	11	−0.05 (−0.84, 0.74)
	3–4	28	2.16 (1.27)	25	2.31 (1.16)	25	0.03 (−0.67, 0.72)
	Difference: Mean, p (95% CI)		−0.39, 0.364 (−1.24, 0.47)		−0.43, 0.307 (−1.28, 0.41)		−0.08, 0.895 (−1.22, 1.07)
Keratome Extension	**Yes**	6	1.88 (1.79)	5	2.27 (0.77)	5	0.02 (−2.51, 2.56)
	No	33	1.97 (1.06)	30	2.17 (1.23)	30	0.11 (−0.42, 0.64)
	Difference: Mean, p (95% CI)		−0.09, 0.860 (−1.16, 0.97)		0.11, 0.850 (−1.05, 1.27)		−0.08, 0.909 (−1.57, 1.40)
Incision Type	**Clear Cornea**	20	1.78 (1.31)	17	1.89 (0.99)	17	−0.19 (−0.92, 0.55)
	Scleral Tunnel	20	2.32 (1.10)	19	2.37 (1.25)	19	0.09 (−0.69, 0.87)
	Difference: Mean, p (95% CI)		−0.54, 0.169 (−1.31, 0.24)		−0.48, 0.214 (−1.25, 0.29)		−0.28, 0.590 (−1.32, 0.76)
Suture Type	**Interrupted**	32	1.91 (1.20)	28	2.33 (1.22)	28	0.26 (−0.33, 0.85)
	Running	5	2.25 (1.56)	5	1.57 (0.54)	5	−0.68 (−2.54, 1.19)
	Difference: Mean, p (95% CI)		−0.34, 0.576 (−1.55, 0.88)		0.76, 0.186 (−0.39, 1.90)		0.94, 0.215 (−0.57, 2.45)

Table 2

Astigmatism According to Treatment and Age at Surgery for All Patients

Factor		Baseline		Age 1 Year		Change	
		n	Astigmatism Mean (SD)	n	Astigmatism Mean (SD)	n	Astigmatism Mean (95% CI)
Treatment	CL	57	1.98 (1.37)	52	1.62 (0.98)	52	−0.29 (−0.76, 0.17)
	IOL	57	2.00 (1.25)	53	2.09 (1.09)	53	0.01 (−0.42, 0.42)
	Difference: Mean, p (95% CI)		−0.02, 0.944 (−0.50, 0.47)		−0.47, 0.023 (−0.87, −0.07)		−0.30, 0.343 (−0.92, 0.32)
Age at Surgery	< 49 Days	52	1.77 (1.24)	47	1.68 (1.16)	47	−0.14 (−0.58, 0.30)
	≥ 49 Days	62	2.17 (1.35)	58	2.01 (0.96)	58	−0.15 (−0.59, 0.30)
	Difference: Mean, p (95% CI)		−0.40, 0.104 (−0.88, 0.08)		−0.33, 0.110 (−0.74, 0.08)		0.005, 0.988 (−0.62, 0.63)