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## Corneal changes in children after unilateral cataract surgery in the Infant Aphakia Treatment Study

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### Abstract

**Purpose**—We report endothelial cell (EC) characteristics and central corneal thickness (CCT) from Infant Aphakia treatment Study (IATS) patients at the 5-year exam.

**Design**—Randomized, controlled trial of the treatment of unilateral cataract with aphakic contact lens (CL) versus primary intraocular lens implant (IOL).

**Subjects**—114 infants with unilateral cataract.

**Methods**—EC density, coefficient of variation (CV), and percent hexagonal cells were measured by non-contact specular microscopy. Central corneal thickness (CCT) was measured using contact pachymetry. Fellow eyes served as controls.

**Main outcome measures**—Mean differences between treated and fellow eyes of CL and IOL groups were compared with a paired t test. A one-way analysis of variance model and the Tukey-Kramer multiple comparison procedure were used to assess the effect of a diagnosis of glaucoma or glaucoma suspect.

**Results**—105 (52 CL, 53 IOL) had either specular microscopy or corneal thickness data recorded. Mean EC densities were higher in the aphakic eyes compared to fellow eyes (3921 and 3495 cells/mm<sup>2</sup>,  $p < 0.0001$ ). Mean CV was higher in aphakic eyes (27 vs 24,  $p = 0.0002$ ), and mean percent hexagonal cells was lower (72% vs 76%,  $p = 0.002$ ). Mean CCT of aphakic eyes was

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\*A list of the members of the study group appears in the Appendix.

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higher than controls (637 vs 563  $\mu\text{m}$ ,  $p < 0.0001$ ). There was no difference in EC density in eyes treated with IOL compared to fellow eyes (3445 and 3487 cells/ $\text{mm}^2$ ,  $p=0.68$ ). Means for CV (25 vs 24,  $p=0.07$ ) and percent hexagonal cells (74 vs 76%,  $p=0.27$ ) were also not significantly different. Mean CCT was higher in eyes with IOL (605 vs 571  $\mu\text{m}$ ,  $p < 0.0001$ ) compared to fellow eyes. Compared to treated eyes without glaucoma or glaucoma suspect, treated eyes with glaucoma had lower EC density (3289 vs 3783 cells/ $\text{mm}^2$ ,  $p = 0.03$ ) and treated eyes with glaucoma suspect had greater mean corneal thickness (660 vs 612  $\mu\text{m}$ ,  $p = 0.0036$ ).

**Conclusion**—Cataract extraction during infancy with IOL implantation was not associated with a reduced EC count in treated compared to fellow eyes, although CCT was increased. Extended wear aphakic CL may cause corneal polymegathism with increased EC density and CCT. Glaucoma diagnosis was associated with reduced EC counts and increased CCT.

## INTRODUCTION

Cataract surgery is the most commonly performed intraocular surgery in the pediatric population. Although there has been great improvement in the instrumentation, microsurgical techniques and handling of the pediatric eyes, this procedure still appears to be stressful to the intraocular tissues. The corneal monolayer of endothelial cells lack the ability to regenerate,<sup>1</sup> and can be reduced by outside stressors such as physical trauma caused by surgery,<sup>2</sup> intraocular lens contact,<sup>3,4</sup> and toxicity of surgical solutions and drugs.<sup>5,6</sup> An increased propensity for postoperative inflammation<sup>7</sup> and glaucoma<sup>8,9</sup> also exists in pediatric eyes. These complications can be deleterious to the corneal endothelium as well. Changes in the endothelial cells are believed to affect the corneal thickness. Even if the vision is not altered, increased thickness may cause alteration in the accurate intra-ocular pressure assessment.<sup>10,11</sup>

The Infant Aphakia Treatment Study (IATS) is a multicenter, randomized clinical trial comparing the use of primary IOL implantation to the correction of aphakia with a contact lens after cataract surgery performed in infants with a unilateral congenital cataract between 1 and 6 months of age.<sup>12,13</sup> The IATS provides the unique opportunity to objectively examine the endothelial cell integrity after pediatric cataract surgery with modern techniques. The purpose of this work is to report the non-contact specular microscopy and corneal thickness results of treated and untreated eyes from the age 5 year follow-up visit.

## METHODS

### Study Design

The study design, surgical technique, follow-up schedules, optical correction and patching regimens, and examination methods have been reported in detail previously.<sup>12</sup> The main inclusion criteria were a visually significant congenital cataract ( $> 3$  mm central opacity) in one eye, a normal fellow eye and an age of 28 days to  $< 210$  days at the time of cataract surgery. Infants were randomly assigned to either contact lens (CL) treatment or implantation of an IOL and spectacle overcorrection. Randomization was centrally determined using stratification between two age groups (28-48 days and 49-210 days) as

well as study centers, which were grouped into 3 categories based on experience of the surgeon.

The study followed the tenets of the Declaration of Helsinki, was approved by the institutional review boards of the 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.

### **Specular Microscopy and Endothelial Cell Assessment**

The IATS protocol specified that non-contact specular microscopy should be performed on both eyes of each patient at the age 5 follow-up visit. The Konan specular microscope model SP4000 was the preferred instrument. Three images of the corneal endothelium of both the treated and fellow eyes were to be taken and captured as bitmap files and saved to a CD. If bitmap files could not be saved then the images were printed. The CD or pictures were sent to the Data Coordinating Center (DCC) in the Department of Biostatistics and Bioinformatics at Emory University and delivered to the Specular Microscopy Reading Center in the Department of Ophthalmology at Emory University. Non-bitmap files and paper prints were converted to a bitmap format prior to analysis. The images were analyzed using all contiguous cells in the image field with discernible cell borders with a center-to-center algorithm in the Konan KSS 300 software (V2.20) which produced the corneal endothelial cell density (cells/mm<sup>2</sup>), coefficient of variation (CV) of cell area, and hexagonality (% of cells with 6 sides). On an ongoing basis, as batches of images were processed, excel spreadsheets containing for each image the patient ID, eye indicator, image number, number of cells counted, the corneal endothelial cell density, CV of cell area, and hexagonality were emailed to the DCC. At the DCC the spreadsheets were compiled into a single SAS dataset. For each eye, the data for the three measures were combined across the images by calculating a weighted average with the number of cells counted in an image as the weights, creating a single value for corneal endothelia cell density, coefficient of variation of cell area, and hexagonality for each eye.

### **Corneal Thickness**

Corneal thickness of the treated and fellow eye was measured only at the age 5 examination using the Pachmate (DHG Technology). The pachymeter was calibrated before taking measurements using the Calibration Verification Box (Calbox) provided with the instrument. The operational mode was to set for "Continuous Average", with the Standard Deviation and Bilateral Modes enabled and the Number of Measurements set at 25. The Pachmate does not have an activation switch, but automatically takes and averages 25 measurements when the probe tip is properly applanated onto the cornea. After the instillation of topical anesthetic drops, a measurement was made by touching the probe tip to the center of the cornea. Three separate measurements were recorded on the case report form and were averaged to produce a single value for analysis.

## Statistical Methods

Specular microscopy and corneal thickness measurement were done only at the age 5 year examinations and were not done prior to cataract surgery. The means of the outcome factors evaluated in this paper (endothelial cell measures (cell density, CV of cell area, and hexagonality) and corneal thickness at age 5) were compared between the treated and fellow eyes using a paired t test separately for the treatment groups. The means for the outcome factors of the treated eyes were compared between the two treatment groups using an independent groups t test. The same method was used to evaluate the effect of the type of contact lens worn. The relationships of age at surgery and the outcome factors for the treated eyes were evaluated using an independent groups t test to compare the means between the age strata and using the correlation coefficient to assess the association with age at surgery in continuous form. The effect of additional intraocular surgery during follow-up was evaluated along with treatment using a two-way analysis of variance model with interaction. The p-values were based on the Type III sums of squares calculated in SAS Proc GLM and the least squares mean and 95% confidence interval were determined for each treatment/surgery group. The means for the outcome factors in the treated eyes combining the CL and IOL patients were compared among the three glaucoma diagnosis groups (glaucoma, glaucoma suspect, neither) using a one-way analysis of variance model and the Tukey-Kramer multiple comparison procedure. All reported p-values are two-sided. A p-value < 0.05 was considered statistically significant. All analyses were done with SAS 9.3.

## RESULTS

### Patients

There were 114 patients enrolled in IATS with 57 randomized to each treatment group. One IOL patient was lost to follow-up and the remaining 113 patients had an age 5 exam. Of the 113 patients, 80 (71%) had digitizable specular microscopy images of both eyes, 8 (7%) had images of only the treated eye, 8 (7%) had images of only the fellow eye and 17 (15%) had no images of either eye. Of the 17 patients without images for either eye, 9 were in the CL group and 8 were in the IOL group. Although the protocol called for 3 images to be taken of each eye, the lack of patient cooperation and other factors often resulted in fewer images per eye: of the 88 treated eyes, 49 (56%) had one image, 8 (9%) had 2 images, 30 (34%) had 3 images and 1 (1%) had 4 images. Of the 113 patients examined at age 5, 94 (83%) had corneal thickness measured in both eye, 3 (3%) had only the treated eye measured, 3 (3%) had only the fellow eye measured, and for 13 (12%) neither eye was measured. Of the 13 eyes without corneal thickness measurements, 8 were in the CL group and 5 were in the IOL group. Of the 113 patients examined at age 5, 105 had either specular microscopy or corneal thickness data for the treated or the fellow eye. Of the 8 patients examined at age 5 without any specular microscopy or corneal thickness measurements, 5 were in the CL group and 3 were in the IOL group.

For the 105 patients with specular microscopy or corneal thickness data (CL = 52, IOL = 53), the median age at cataract surgery was 1.8 months (interquartile range (IQR) = 1.2 – 3.1 months, range = 0.9 – 6.8 months). The mean age at the time of the age 5 exam was 5.0 ±

0.1 years (range = 4.7 – 5.4 years), which was an average of  $4.8 \pm 0.1$  years (range = 4.4 – 5.3 years) after cataract surgery.

### Endothelial Cell Measures and Corneal Thickness

The median number of cells digitized was 149 cells (IQR = 137 – 328 cells, range = 17 – 449 cells) for 88 treated eyes and 149 cells (IQR = 132 – 405 cells, range = 6 – 450 cells) for 88 fellow eyes. There were 4 treated eyes and 3 fellow eyes with less than 50 cells digitized.

**Treated vs Fellow Eyes**—In both treatment groups, corneas of treated eyes were thicker than fellow eyes by an average of 74 and 34  $\mu\text{m}$  for the CL and IOL groups, respectively ( $p < 0.0001$ , Table 1). In the CL group, treated eyes had greater EC density than fellow eyes by 427 cells/ $\text{mm}^2$  on average ( $p < 0.0001$ ); however, there was no difference between treated and fellow eyes in the IOL group (Table 1, Figure 1). In the CL group, treated eyes had greater CV of cell area (27 vs 24,  $p = 0.0002$ ) and a smaller percent of hexagonal cells (72 vs 76,  $p = 0.002$ ); in the IOL group these factors showed differences in the same direction between treated and fellow eyes but were smaller and not statistically significant (Table 1).

**Treatment**—Mean EC density of the treated eyes was greater in the CL group than the IOL group (3893 vs 3470 cells/ $\text{mm}^2$ ,  $p = 0.0012$ ) (Table 2). The mean CV of cell area for the treated eyes was also greater for the CL group (27 vs 25,  $p = 0.0053$ ), as was CCT (638 vs 605  $\mu\text{m}$ ,  $p = 0.002$ ). Percentage of hexagonal cells for the treated eyes was not significantly different between the treatment groups. For the fellow eyes, there were no differences between the means of the treatment groups for any of the endothelial cell measures or corneal thickness (data not shown).

**Age at Surgery**—For the treated eyes there were no statistically significant differences between the means of the younger and older age stratum for any of the endothelial cell measures or corneal thickness. Cell densities were  $3660 \pm 751$  for infants with age at surgery 28-48 days versus  $3690 \pm 505$  for infants' age at surgery 49-210 days,  $p = 0.82$ . Corneal thickness was  $624 \pm 50$  versus  $619 \pm 57$  for the two groups, respectively ( $p = 0.60$ ). In continuous form, age was not significantly correlated with coefficient of variation or percent hexagonal cells (all correlations were  $< 0.15$  in absolute value).

**Additional Intraocular Surgery**—We evaluated the impact of additional intraocular surgery, including glaucoma surgery, during follow-up after the initial cataract procedure. There was a large difference between the treatments groups in terms of how many patients underwent additional intraocular surgery.<sup>14,15</sup> Among the 105 patients with specular microscopy or corneal thickness data, in the CL group 10 of 52 patients (19%) had additional surgery, whereas in the IOL group 39 of 53 patients (74%) had additional surgery. As the results in Table 3 show, the effect of additional intraocular surgery was lower cell density, greater CV of cell area, lower percent hexagonal cells, and greater corneal thickness in both groups. However, the effect was only statistically significant for percent hexagonal cells. The analysis of corneal thickness shows that, on average, there was little impact of additional intraocular surgery for CL patients (638  $\mu\text{m}$  with or without surgery), while for

IOL patients there was a greater increase with additional surgery (614 vs 571  $\mu\text{m}$ ) – although this interaction effect was not statistically significant ( $p = 0.096$ ).

**Glaucoma**—The patients were classified according to whether by age 5 they had been diagnosed with glaucoma, glaucoma suspect, or neither condition.<sup>15</sup> The means for CV of cell area and percent hexagonal cells did not differ among the three groups (Table 4). Eyes diagnosed with glaucoma had lower mean cell density compared with those not diagnosed with either condition (3289 vs 3783 cells/ $\text{mm}^2$ ,  $p = 0.025$ , Table 4). Patients with glaucoma suspect had greater mean corneal thickness than patients who had not been diagnosed with either condition (660 vs 612  $\mu\text{m}$ ,  $p = 0.0054$ , Table 4).

**Type of Contact Lens Worn**—Among the 57 patients randomized to the CL group, 45 (79%) predominantly wore a Silsoft (Bausch and Lomb, Rochester, NY) contact lens (with 31 patients wearing only Silsoft) and 12 (21%) predominantly wore a rigid, gas permeable (RGP) contact lens (with 9 wearing only RGP, Table 5). There was no difference between the means of these two groups for CV of cell area and percent hexagonal cells. There was a suggestion that, among patients predominantly wearing an RGP lens, the means were greater for cell density (4180 vs 3806 cells/ $\text{mm}^2$ ,  $p = 0.075$ ) and corneal thickness (663 vs 629  $\mu\text{m}$ ) but these differences did not reach statistical significance (Table 5).

## DISCUSSION

In our cohort of children, EC densities were equivalent to controls for children treated with IOLs. Those infants with surgical aphakia had higher EC densities on average when compared to children treated with IOLs or to control eyes. Coefficient of cell size variation was also higher in this group. Finally, CCT was higher in aphakic children when compared to control eyes. These data have several implications.

Previous studies have reported EC loss following pediatric cataract surgery, with cell loss rates ranging from 0-9.2% with lens removal by anterior approach.<sup>2, 16-20</sup> However, surgical techniques (phacoemulsification versus vitrector), length of follow-up, and the use of IOLs varied in these studies. Our study has the advantage of randomized design, and a standardized surgical procedure for both treatment groups. The absence of EC density changes in the IOL group could be a result of our surgical technique. IATS investigators used the vitrector rather than ultrasonic power associated with phacoemulsification to remove lens material, and this may be less damaging to endothelial cells. We did not find significant EC loss in the first five years following unilateral infantile cataract surgery.

However, EC densities are higher in eyes of children that were left aphakic compared to those receiving an IOL, and higher than in fellow unoperated eyes. These results may seem counterintuitive since it is likely that there is some damage to the endothelium when the IOL is implanted. We hypothesize that the difference may arise from the increased corneal polymegathism associated with contact lens wear. The significantly higher coefficient of variation, which is a measure of cell size variation, in the aphakic group supports polymegathism as an explanation for the higher EC densities in the aphakic group. Polymegathism is a condition where unhealthy corneal endothelium form rosettes of smaller



cells. Therefore, more cells are counted in a given area. Polymegathism has been reported with aphakic extended wear contact lenses when compared to aphakic controls.<sup>21</sup> Additionally, extended wear contact lenses and rigid gas permeable lenses have been reported to contribute to polymegathism in phakic patients. Several hypotheses exist as to the cause of these corneal changes. Corneal endothelial hypoxia caused by decreased external oxygen absorption is commonly suggested.<sup>22</sup>

Percentage of hexagonal cells was not significantly different from fellow eyes in either of our treatment groups. In two previous studies that demonstrated no EC density change after surgery, an increase in CV and percent hexagonal cells was reported in one<sup>16</sup> and not in the other.<sup>17</sup> Each study included data sets that contained both aphakic and pseudophakic patients. The relevance of this finding is unclear.

As the corneal endothelium functions to maintain corneal clarity by decreasing corneal water content, EC loss or dysfunction has been associated with corneal edema and increased central corneal thickness.<sup>23</sup> CCT was higher in the CL versus IOL groups, while both groups had measurements that were thicker than fellow eyes. It is possible that abnormalities in anterior segment anatomy in eyes with congenital cataract is the cause of the thicker cornea when compared to control eyes. As CCT was not measured prior to surgery, we cannot evaluate this possibility with this cohort of patients. However, as the study was randomized, it is unlikely that differences in the treated groups would result from innate corneal differences. Thus, it is likely that endothelial function is suboptimal in CL eyes, resulting in the increased CCT. Previous studies have demonstrated that increased CCT is acquired after cataract surgery in infants, and is not a congenital anomaly.<sup>24</sup> Differences between CL type (Silsoft versus RGP) were not significant, although only 19% of patients predominantly wore RGP lenses, making statistical evaluation challenging to interpret. The IATS study protocol did not specify that a “waiting period” occur after contact lens removal before CCT was measured at study visits, an omission that could theoretically confound CCT measures in the CL group.

The EC density was different among the study eyes with glaucoma, glaucoma suspect, and neither diagnosis (Table 4), with lower EC density in eyes with glaucoma vs. those with neither diagnosis. This finding is in keeping with the theory that elevated intraocular pressure stresses and damages the corneal endothelium in pediatric glaucoma,<sup>25</sup> and further provides direct evidence to support glaucomatous EC damage in pediatric eyes after cataract removal. Given that all study eyes with glaucoma or glaucoma suspect also had cataract removal, it is possible that the reduction in EC density in these eyes is multifactorial. Further, mean CCT was different among study eyes with glaucoma, glaucoma suspect, and neither diagnosis (Table 4), with higher CCT in eyes with glaucoma suspect vs. those with neither diagnosis. The abnormally high CCT in pediatric eyes with glaucoma after cataract surgery has been well documented in the literature,<sup>24,26</sup> but this study provides direct evidence to link the CCT increase with EC loss in the setting of glaucoma or glaucoma suspect amongst these eyes. The small numbers in each category, and the mixture of treated eyes with CL with IOL exposure within the glaucoma and suspect groups, further limit the study's ability to make further comparisons by treatment group.

In conclusion, cataract extraction during infancy was not associated with a reduced EC densities in treated compared to fellow eyes. However, increased EC, CV and CCT were present in aphakic eyes treated with extended wear CL. As no visual differences were reported between treatment groups in the IATS at the age 5 year exam,<sup>13</sup> the clinical relevance of these findings remains unclear. However, the long term impact of CL use in aphakic eyes deserves continued study.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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**Précis**

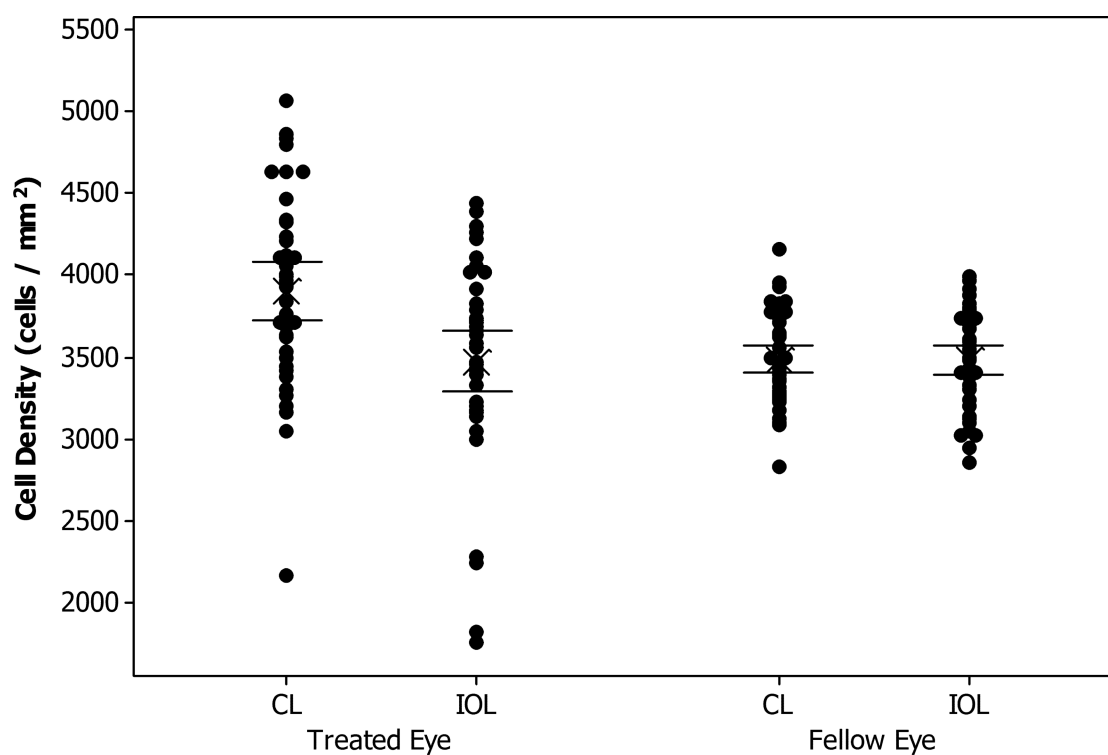
In the Infant Aphakia Treatment Study, endothelial cell densities and central corneal thickness were less favorable for infants treated with aphakic contact lenses compared to those treated with intraocular lenses at the 5-year outcome examination.

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**Figure 1.** Individual value plot of the endothelial cell density for treated and fellow eyes according to treatment assignment. The X indicates the mean and the bars indicate the 95% confidence limits for the mean.

**Table 1**

Comparison of Treated and Fellow Eyes for Endothelial Cell Measures and Corneal Thickness

Measure	# Patients	Eye		p-value*	Difference between Means* (95% CI)
		Treated	Fellow		
		Mean ± SD	Mean ± SD		
CL Patients					
Cell Density (cells/mm <sup>2</sup> )	38	3921 ± 572	3495 ± 284	< 0.0001	427 (248 – 605)
CV of Cell Area	38	27 ± 3	24 ± 3	0.0002	3.4 (1.7 – 5.1)
% Hexagonal Cells	38	72 ± 6	76 ± 5	0.002	–5 (–8 – –2)
Corneal Thickness (µm)	46	637 ± 54	563 ± 41	< 0.0001	74 (63 – 85)
IOL Patients					
Cell Density (cells/mm <sup>2</sup> )	42	3445 ± 613	3487 ± 287	0.68	–42 (–248 – 163)
CV of Cell Area	42	25 ± 4	24 ± 3	0.07	1.3 (–0.1 – 2.8)
% Hexagonal Cells	41	74 ± 7	76 ± 6	0.27	–1 (–4 – 1)
Corneal Thickness (µm)	48	605 ± 49	571 ± 41	< 0.0001	34 (21 – 48)

CV = coefficient of variation, SD = standard deviation

\* The p-value for the paired t test comparing the means of the treated and fellow eyes and the 95% confidence interval for the difference between the means treated and fellow eyes with the difference calculated as Treated – Fellow.

**Table 2**

Endothelial Cell Measures and Corneal Thickness According to Treatment for Treated Eyes

Measure	Treatment				p-value *	Difference between Means * (95% CI)
	CL		IOL			
	n	Mean ± SD	n	Mean ± SD		
Cell Density (cells/mm <sup>2</sup> )	43	3893 ± 582	45	3470 ± 601	0.0012	423 (173 – 674)
CV of Cell Area	43	27 ± 4	45	25 ± 4	0.0053	2 (0.7 – 4)
% Hexagonal Cells	43	72 ± 7	44	74 ± 7	0.056	–3 (–6 – 0.1)
Corneal Thickness (µm)	48	638 ± 53	49	605 ± 49	0.0020	33 (12 – 54)

CV = coefficient of variation, SD = standard deviation

\* The p-value for the independent groups t test comparing the means of the CL and IOL group and the 95% confidence interval for the difference between the means of the two treatment groups with the difference calculated as CL – IOL.

**Table 3**  
Endothelial Cell Measures and Corneal Thickness According to Treatment and Additional Intraocular Surgery for Treated Eyes

Measure	CL				IOL				p-values <sup>‡</sup>		
	No Additional Surgeries <sup>*</sup>		Additional Surgeries <sup>*</sup>		No Additional Surgeries <sup>*</sup>		Additional Surgeries <sup>*</sup>		Trt	Surg	Int
	n	Mean (95% CI) <sup>‡</sup>	n	Mean (95% CI) <sup>‡</sup>	n	Mean (95% CI) <sup>‡</sup>	n	Mean (95% CI) <sup>‡</sup>			
Cell Density (cells/mm <sup>2</sup> )	35	3957 (3759 - 4155)	8	3612 (3198 - 4026)	11	3577 (3223 - 3930)	34	3435 (3233 - 3636)	0.074	0.12	0.51
CV of Cell Area	35	27 (26 - 28)	8	28 (26 - 31)	11	24 (22 - 26)	34	25 (24 - 26)	0.0033	0.23	0.80
% Hexagonal Cells	35	72 (70 - 75)	8	69 (64 - 73)	11	77 (73 - 81)	33	73 (71 - 76)	0.0062	0.037	0.98
Corneal Thickness (µm)	39	638 (622 - 654)	9	638 (605 - 671)	11	571 (541 - 601)	37	614 (598 - 630)	0.0006	0.088	0.096

**Trt** - the p-value for the effect of treatment.

**Surg** - the p-value for the effect of additional intraocular surgery

**Int** - the p-value for the interaction of treatment and additional intraocular surgery

<sup>\*</sup> Indicates whether or not patients had additional intraocular surgery during follow-up after the initial cataract surgery.

<sup>‡</sup> The p-values from a two-way analysis of variance model with interaction:

<sup>‡</sup> The least squares means and 95% confidence intervals estimated from the analysis of variance model.



**Table 4**

Endothelial Cell Measures and Corneal Thickness for Treated Eyes According to Glaucoma Status at Age 5

Measure	Glaucoma Status at Age 5						p-value <sup>*</sup>
	Glaucoma		Glaucoma Suspect		Neither		
	n	Mean (95% CI) <sup>†</sup>	n	Mean (95% CI) <sup>†</sup>	n	Mean (95% CI) <sup>†</sup>	
Cell Density (cells/mm <sup>2</sup> )	12	3289 (2941 – 3636)	13	3519 (3185 – 3852)	63	3783 (3631 – 3934)	0.025 <sup>‡</sup>
CV of Cell Area	12	26 (24 – 28)	13	26 (24 – 28)	63	26 (25 – 27)	0.95
% Hexagonal Cells	12	71 (67 – 75)	13	73 (69 – 76)	62	73 (72 – 75)	0.66
Corneal Thickness (μm)	17	623 (598 – 647)	15	660 (634 – 686)	65	612 (599 – 624)	0.0054 <sup>§</sup>

\* The p-value from a one-way analysis of variance model comparing the means of the three groups.

† The means and 95% confidence intervals estimated from a one-way analysis of variance model.

‡ The means of the patients with glaucoma and the patients with neither are significantly different (Tukey-Kramer multiple comparison procedure,  $p = 0.03$ ).

§ The means of the patients with glaucoma suspect and the patients with neither are significantly different (Tukey-Kramer multiple comparison procedure,  $p = 0.0036$ ).

**Table 5**

Endothelial Cell Measures and Corneal Thickness for Treated Eyes According to the Type of Contact Lens Worn

Measure	Type of Contact Lens Worn				p-value *	Difference between Means * (95% CI)
	RGP		Silsoft			
	n	Mean ± SD	n	Mean ± SD		
Cell Density (cells/mm <sup>2</sup> )	10	4180 ± 631	33	3806 ± 546	0.075	373 (−39 – 786)
CV of Cell Area	10	26 ± 3	33	27 ± 4	0.54	−0.8 (−3 – 2)
% Hexagonal Cells	10	73 ± 7	33	71 ± 7	0.30	2 (−2 – 7)
Corneal Thickness (μm)	12	663 ± 47	36	629 ± 53	0.055	34 (−0.8 – 68)

CV = coefficient of variation, SD = standard deviation

\* The p-value for the independent groups t test comparing the means of the two age strata and the 95% confidence interval for the difference between the means of the two type of contact lens worn with the difference calculated as RGP – Silsoft.