Parenting Stress in the Infant Aphakia Treatment Study

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Objective To evaluate parenting stress following infants' cataract extraction surgery, and to determine if levels of stress differ between 2 treatments for unilateral congenital cataract in a randomized clinical trial. **Methods** At surgery, an intraocular lens (IOL) was implanted or children were left aphakic, treated with contact lens (CL). Stress measures were administered 3 months after surgery and at the first visit after the visual acuity (VA) assessment done at 12 months of age. **Results** Caregivers in the IOL group reported higher levels of stress than those in the CL group 3 months after surgery, but there were no group differences in stress scores at the post-VA assessment. Stress scores did not change differentially for participants assigned to IOL versus CL treatments. **Conclusions** Treatment assignment did not have a significant impact on caregiver stress during infancy or on the change in stress during the child's first 2 years of life.

Key words infancy; parent stress; randomized controlled trial.

Introduction

Congenital cataracts are a rare condition, with prevalence estimated at 2.5 per 10,000 live births (Rahi & Dezateux, 1999). Infants with unilateral congenital cataracts undergo surgery as early as 4 weeks of age, demanding treatment, and repeated follow-up visits for a long period, with significant uncertainty about visual prognosis. The standard of care includes daily occlusion of the ''fellow eye'' for substantial time throughout early childhood and continuous optical correction of the affected eye using a contact lens (CL) and/or spectacles (Lambert et al., 2003). Even with optical correction of the affected eye, the infant may not see well when the fellow eye is patched, potentially causing stress and frustration for parents and infants alike. Without excellent adherence to the treatment regimen of patching and optical correction, the prognosis for good vision in the affected eye is poor (Assaf, Wiggins, Engel, & Senft, 1994; Cheng, Hiles, Biglan, & Pettapiece, 1991). Poor vision in the affected eye poses an increased risk for injury to the fellow eye throughout the individual's life, due to reduced peripheral vision (Tommila & Tarkkanen, 1981), and often results in strabismus requiring surgical correction (BenEzra, Cohen, & Rose, 1997).

As children with cataracts undergo surgery and accompanying treatments during the first years of life, when they are most vulnerable, their caregivers may experience high levels of parenting stress, similar to caregivers of infants with other congenital conditions (Goldberg, Morris, Simmons, Fowler, & Levison, 1990; Innocenti, Huh, & Boyce, 1992; Pelchat, Ricard, & Bouchard, 1999). Parenting stress, defined as generic stress associated with the parenting role, is a well-developed and researched

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construct with important developmental implications for the child and for the parent–child relationship (Deater-Deckard, 2006). Excessive parenting stress can lead to dysfunctional parenting (Belsky, Woodworth, & Crnic, 1996), which in turn increases the risk for later behavioral and emotional problems (Rothbaum & Weisz, 1994). Increased parenting stress during the first year of the infant's life has been empirically linked with infants' insecure attachment to the mother (Hadadian & Merbler, 1996), maternal depression (Frankel & Harmon, 1996), and parent-reported behavioral problems (Goldberg et al., 1997). Given its potential impact on familial and child emotional health, parenting stress has been used as an outcome in clinical trials examining the impact of early intervention programs (Kaaresen, Rønning, Ulvund, & Dahl, 2006) on the caregiver.

However, condition-specific stress measures are more sensitive to changes in symptoms or treatment than generic ones (Müller Godeffroy, Treichel, & Wagner, 2009). Therefore, parenting stress instruments designed to capture the particular burdens associated with taking care of an infant with a unilateral cataract are more likely to clarify the impact of this congenital condition on the child's development and the caregiver–child relationship. Drews and colleagues (Drews, Celano, Plager, & Lambert, 2003) developed a parent-completed questionnaire, the Ocular Treatment Index (OTI), to measure parenting stress associated with caring for a child with congenital cataracts. Using items adapted from the OTI, The Pediatric Eye Disease Investigator Group developed and validated a parent-completed questionnaire to assess the impact of amblyopia treatment on the child and family (Cole et al., 2001; Holmes et al., 2008). This scale has been used in several randomized clinical trials to assess the balance between treatment efficacy and family stress outcomes for pre–school-aged children with amblyopia (Beck et al., 2010; Holmes et al., 2003). Birch and colleagues reported that children with aphakic CLs for monocular cataracts had more difficulty with treatment compared with those treated with intraocular lenses (IOLs) even though visual acuities were similar (Birch, Cheng, & Felius, 2007). These data suggest that condition-specific stress measures may be sensitive to the impact of alternative treatments for the same ophthalmic disorder. To date, however, stress measures relevant to pediatric visual impairment have not been administered to parents of infants with unilateral congenital cataracts during the first few months after cataract surgery.

The Infant Aphakia Treatment Study (IATS) is a multi-center, randomized, controlled clinical trial sponsored by the National Eye Institute. The objective of the study is to compare IOL implantation at the time of cataract extraction with the more usual treatment involving cataract extraction and correction of the resultant aphakia with a CL in infants with a unilateral congenital cataract removed between 28 days and 7 months of age. The primary endpoint for the trial is children's visual acuity (VA) as assessed by a travelling tester masked to treatment group; the secondary endpoint is parenting stress. Earlier reports from this study suggest that there is wide variation in the grating VA of children enrolled in this study at 12 months of age, but that the visual outcome was not significantly different between the two treatments (Lambert et al., 2010b). The purpose of the present article is to evaluate both generic and condition-specific parenting stress 3 months after surgery and after 12 months of age among caregivers with a child with a unilateral congenital cataract, and to determine if such stress differs between the two treatments. To date, there are insufficient data to justify hypothesizing which treatment would produce greater stress. Although the burden of patching is the same for both treatments, the burden associated with visual correction is not. Children undergoing the conventional treatment required regular insertion and removal of a CL, which may produce a greater degree of parenting stress for this group. In contrast, children with an IOL wore spectacles during the first year, as the power of the IOL is intentionally calculated to optically under-correct the eye, thereby compensating for predicted ocular growth. However, implantation of an IOL at the time of cataract extraction was associated with more complications and a greater number of additional surgeries in the first few months after the initial surgery (Lambert et al., 2010b), which could in turn lead to greater parenting stress for the IOL group.

Methods

Screening and Enrollment

The study was approved by the Institutional Review Boards of all participating institutions and is in compliance with the Health Insurance Portability and Accountability Act. The inclusion criteria were as follows: (1) the presence of a visually significant congenital cataract ($\geq$3 mm central opacity) in only one eye, (2) surgical removal of the cataract at 28 to $<$210 days at time of cataract surgery, (3) at least 41 postconceptional weeks at time of cataract surgery, and (4) written informed consent by caregiver agreeing that patient could be randomized in operating room if the examination under anesthesia confirmed that s/he was eligible for the study. Exclusion criteria included the following: (1) cataract was known to be due to trauma or acquired as

adverse effect of treatment administered postnatally, (2) corneal diameter <9 mm, (3) intraocular pressure ≥25 mm Hg, (4) persistent fetal vasculature (PFV) causing stretching of the ciliary processes or tractional detachment of retina, (5) active uveitis or signs suggestive of previous episode of uveitis, (6) child who was delivered preterm (<36 weeks gestational age), (7) retinal disease that might limit visual potential of eye, (8) previous intraocular surgery, (9) optic nerve disease that might limit visual potential of eye, (10) ocular disease in fellow eye that might reduce its visual potential, (11) medical condition in child that might interfere with VA testing at age 12 months or 4½ years, or (12) child was not able to return to IATS clinical center for regular follow-up examinations. Additional information about the design and clinical measures have been previously published (Lambert et al., 2010a).

Children were randomly assigned to receive either an IOL at the time of cataract extraction or to remain aphakic. Randomization was stratified for clinical center (three groups based on the surgeon's experience in implanting IOLs in infants) and patient age (28–48 vs. 49–209 days). Children were examined at 1 day, 1 week, 1 month, and every 3 months after surgery. Children with an IOL were prescribed spectacles for residual refractive errors of >1 diopter (D) hyperopia, >3 D myopia, or >1.5 D astigmatism. Aphakic children were prescribed a CL to be worn at all times after surgery. Patching was prescribed for all patients throughout the first year of life, starting the second week after cataract surgery. Parents were instructed to have the child wear an adhesive occlusive patch over the phakic eye 1 hr/day per month of age until the child was 8 months old. Thereafter, patching of the phakic eye was prescribed for 50% of a child's waking hours.

The stress measures were administered to caregivers by the clinic coordinators 3 months after surgery ± 2 weeks (''3-month assessment''), at the first scheduled follow-up visit after the VA assessment done at 12 months of age ± 2 weeks (''Post-VA assessment''), and at 4.25 years of age. Data collection for the 4.25-year visit is not yet complete; therefore, only the data from the first two assessments are included here. Although clinic coordinators and caregivers were not masked to patients' group assignment (CL vs. IOL), caregivers independently completed the stress measures, which were subsequently mailed directly to the data coordinating center for scoring and review by staff masked to treatment group assignment.

Stress Measures

Parenting Stress Index

The Parenting Stress Index (PSI; Abidin, 1983) is a 120-item self-report measure of parenting stress. Respondents rate their agreement with each statement (e.g., ''My child is much more active than I expected,'' ''I feel trapped by my responsibilities as a parent'') on a 5-point scale. The scale yields two factor-based scores, a Child Domain score (with subscales Distractibility/Hyperactivity, Adaptability, Reinforces Parent, Demandingness, Mood, Acceptability) and a Parent Domain score (with subscales Competence, Isolation, Attachment, Health, Role Restriction, Depression, Spouse), as well as a Total Stress score. A Life Stress score, derived from 19 items not included in the Total Stress score assesses respondents' exposure to stressful life events (e.g., death of a relative, loss of a job) outside the parent–child relationship. The PSI is interpreted via age-based percentile scores derived from the frequency distribution of the normative sample (1-month- to 12-year-olds), with higher scores indicating higher levels of stress. Many studies confirm the reliability and validity of the Total Stress Score (Abidin, 1995).

Ocular Treatment Index

The OTI (Drews et al., 2003) assesses caregiver stress specific to caring for a child with congenital cataracts. Respondents rate the degree to which they agree with each of 36 statements (e.g., ''I have trouble keeping the patch on my child,'' ''I worry that my child's CL will fall out or glasses will fall off during the day'') on a 5-point scale. Items are summed to yield a total score, with higher scores indicating greater levels of stress. The scale's reliability and validity was tested for a sample of 22 parents of preschool-aged children with unilateral or bilateral cataracts (Drews et al., 2003), yielding an internal consistency reliability coefficient (Cronbach's alpha) of 0.94 for a 28-item version of the scale. The scale's validity was supported by significant and positive correlations with PSI Child Domain, Parent Domain, and Total Stress scores, and by the absence of a significant correlation with child age or the PSI Life Stress score (Drews et al., 2003).

Analytic Methods

All analyses were conducted using the SPSS 17.0 and 19.0 statistical packages. Nine OTIs at the 3-month assessment and seven OTIs at the post-VA assessment had missing data for one or two items. Multiple imputation was used to handle missing data, and all analyses involving the OTI were conducted with the pooled data. For analyses in which pooled summary statistics are not available, the F value and/or p value presented is based on the analyses in which mean item substitution was used rather than multiple imputation, as the results are similar. Only one OTI was missing data for more than two items; this case

was not included in the analyses. Cronbach's alpha was used to assess internal consistency reliabilities for the stress measures. *T*-tests and one-way analysis of variances (ANOVAs) (for comparing means) and chi-square tests of independence (for comparing percents) were used to examine relationships between stress measures at 3 months after surgery, demographic variables, and the occurrence of adverse events or additional surgery within 3 months after surgery. Associations between stress measures and caregiver age were assessed by correlation. Comparisons of mean stress measure scores by treatment group (CL vs. IOL) were examined separately for the 3 months and post-VA assessments using independent group *t*-tests and analysis of covariance. For the subsample with the same informant at both the 3-month and post-VA assessment, repeated measures ANOVAs were conducted with the 3-month and post-VA stress scores as within subjects factors and treatment (CL vs. IOL) as the between subjects factor. For all analyses, statistical significance was defined at the alpha = 0.05 level. With 108 participants and an alpha of 0.05, there is sufficient power (0.80) to detect differences of at least 20 on the PSI, and a difference of ≥8.2 on the OTI. At the post-VA assessment, with 93 participants and an alpha of 0.05, there is sufficient power (0.80) to detect differences of at least 22 on the PSI, and a difference of ≥9.0 on the OTI.

Results

Study Population

There were 114 patients enrolled in the study with 57 randomized to each treatment group (see Figure 1). As noted

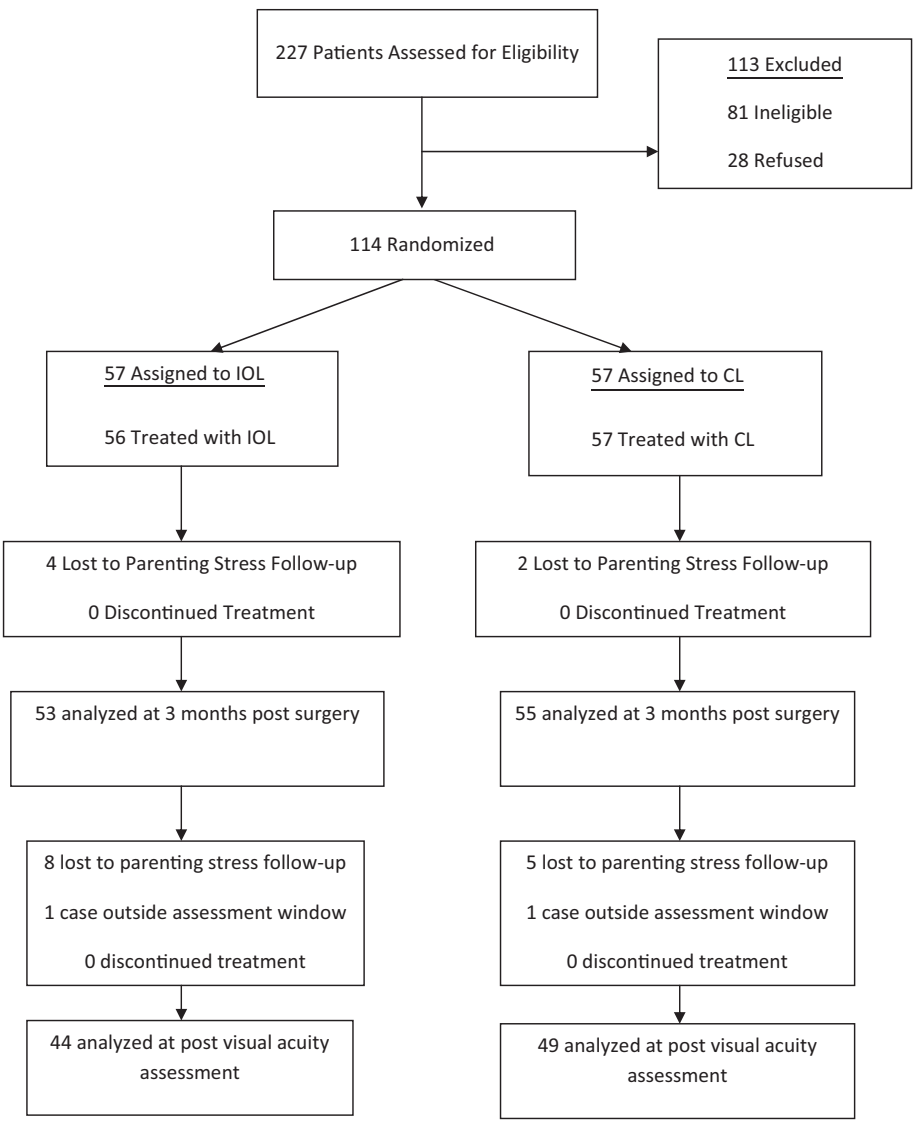

Figure 1. Flowchart of participants in clinical trial.

in previous publications, 1 of the 57 patients randomized to receive an IOL was left aphakic because of clinical concerns about implanting an IOL. However, following the intent-to-treat principle, this patient was analyzed as part of the IOL arm of the analysis (Lambert et al., 2010b). The baseline clinical characteristics of the patients in total and by treatment group have been previously published (Lambert et al., 2010a). None of the patients were lost to follow-up before the post-VA assessment, and all patients had their vision measured by a traveling tester at 1 year of age.

Of the 114 caregivers enrolled in the trial, 108 (95%) completed the stress measures 3 months after surgery; 55 were randomized to the CL group, and 53 were randomized to the IOL group. Five caregivers did not complete parenting stress measures at the 3-month assessment because they missed the follow-up visit, the measures were not given to them, or the child was accompanied by a someone other than the primary caregiver. A sixth caregiver did not answer enough items on the PSI to yield a valid summary score. Caregivers ranged in age from 17 to 42 years (mean = 28.9, standard deviation [*SD*] = 5.7) at the time of cataract surgery, and most were White (84%) and mothers (88%) of the target child. Children ranged in age from 3 to 10 months (mean = 5.0, *SD* = 1.7) at the 3-month assessment. Comparisons between the two treatment groups on demographic and medical variables yielded only two significant differences (see Table I); caregivers of children in the IOL group were significantly younger than caregivers of children in the CL group ($t = 2.90$, $df = 104$, $p = .005$), and patients in the IOL group were significantly more likely to experience adverse events before the 3-month assessment ($\chi^2 = 18.36$, $df = 1$, $p = .000$). As caregiver age is potentially related to parenting stress, it was subsequently treated as covariates in analyses of group differences in PSI and OTI scores. The variable of adverse events was not treated as a covariate in subsequent analyses because it is one of the pathways through which treatment can be associated with stress.

Parenting stress data are not available for 13 caregivers at the post-VA assessment, primarily because the caregivers missed a follow-up visit, the measures were not given to them, or the child was accompanied by someone other than the primary caregiver ($n = 11$). In two cases, the caregiver completed the stress measures but the data were not available at the time of analysis. Two additional cases had assessments conducted well outside of the window (child age, >27 months) and were subsequently dropped from these analyses. The remaining 93 children (49 in CL group, 44 in IOL group) ranged from 11 months to 20.5 months (mean = 13.6, *SD* = 1.5) at the post-VA assessment, with 91% <16 months of age. However, 12 of the caregivers completing stress measures at the post-VA assessment were not the same caregivers who had completed the same measures 3 months after surgery, leaving a sample of 81 for longitudinal analyses.

Overall Summary Statistics for Stress Measures

Internal consistency reliability measured by Cronbach's alpha for the PSI Total Stress Score was 0.94 at both 3 months post cataract surgery ($n = 108$) and at the post-VA assessment ($n = 93$). Scores at 3 months ranged from 128 to 317, with a mean of 205.1 (*SD* = 37.0). Based on national norms, 8.1% of scores would be considered significantly elevated (i.e., >85th percentile). Scores at the post-VA assessment ranged from 141 to

Table I. *Demographic and Medical Characteristics by Treatment Group*

	CL $n = 55$	IOL $n = 53$	Difference	
Characteristic	*n* (%)	*n* (%)	χ^2 or *t*	*p*
Child age at surgery in months	2.39 ± 1.63	2.50 ± 1.60	−0.36	.717
Caregiver age at surgery[a]	30.42 ± 5.40	27.30 ± 5.67	2.90	.005
Female gender	31 (56)	26 (49)	0.58	.447
Caucasian race	47 (85)	44 (83)	0.12	.728
Hispanic	8 (15)	9 (17)	0.12	.728
Private insurance	35 (64)	31 (58)	0.30	.583
Mother education[b]: college degree or higher	18 (33)	12 (23)	1.44	.695
Father education[b]: college degree or higher	18 (33)	17 (32)	1.36	.714
Adverse event(s) before 3 months	11 (20)	32 (60)	18.36	.000
Additional surgery before 3 months	5 (9)	10 (19)	2.16	.142

Note. CL = contact lens; IOL = intraocular lens.

[a]Two caregivers, one in each group, did not provide information for calculating age.

[b]Education was coded into four categories (see Table II) used in the Chi Square analyses; only one category is presented here for ease of presentation.

276 (mean = 201.4, $SD = 34.2$), with 6.4% significantly elevated.

Internal consistency reliability of the 36-item OTI for the current sample was 0.84 ($n = 108$) at 3 months post cataract surgery and 0.89 ($n = 92$, as one case was dropped due to missing data for 10 items) at the post-VA assessment. OTI total scores at 3 months ranged from 44 to 115, with a mean of 86.7 ($SD = 15.0$). At the post-VA assessment, OTI scores ranged from 52 to 131, with a mean of 91.4 ($SD = 18.5$).

The stress measures were moderately to highly correlated with each other. The association between the OTI and the PSI total stress score was .62 ($n = 108$, $p < .01$) at 3 months and 0.57 ($n = 92$, $p < .01$) at the post-VA assessment.

Relationships Between 3-Month Stress Measures and Demographic/Medical Variables

Table II shows the relationships between the stress measures at 3 months and the demographic and medical variables. Three months after surgery, PSI and OTI scores were not significantly associated with relationship of caregiver to child (mother vs. father), child age at surgery, gender of child, race of child, ethnicity (Hispanic vs. non Hispanic), maternal education, or adverse events or surgeries at or before the 3-month assessment. However, higher OTI total scores were associated with older caregiver age at surgery ($r = .20$, $n = 107$, $p = .04$) and with being White ($t = -2.13$, $p = .03$). In addition, Total Stress scores on the PSI were associated with not having private insurance ($t = 2.06$, $df = 106$, $p = .04$). When these relationships

Table II. *Relationship Between Demographic/Medical Characteristics and Stress Measures 3 Months After Cataract Extraction*

		PSI–total		OTI total	
Variable	*N*	Mean ± *SD*	*p*	Mean ± *SD*	*p*
Caregiver					
Mother	95	205.8 ± 37.7	.682	86.8 ± 14.9	.686
Father	12	201.2 ± 32.2		84.9 ± 16.9	
Age at surgery					
28 to 48 days	49	204.6 ± 37.1	.992	86.2 ± 14.2	.626
49 days to 3 months	30	206.7 ± 40.9		87.2 ± 14.9	
3.1 to 5.0 months	16	203.3 ± 30.4		83.8 ± 17.0	
5.1 to <7 months	13	205.3 ± 38.1		91.0 ± 16.9	
Gender					
Male	51	206.4 ± 37.2	.733	86.9 ± 14.8	.884
Female	57	203.9 ± 37.0		86.5 ± 15.5	
Race					
White	91	207.4 ± 37.6	.141	88.0 ± 14.8	.033
Other	17	192.9 ± 31.9		79.7 ± 14.6	
Hispanic					
Yes	17	209.0 ± 44.1	.636	82.4 ± 20.2	.197
No	91	204.4 ± 35.7		87.5 ± 13.9	
Insurance					
Private	66	199.3 ± 34.2	.042	87.8 ± 14.9	.313
Other (no)	42	214.1 ± 39.7		84.9 ± 15.4	
Mother education					
<High school	11	213.0 ± 35.0	.750	86.7 ± 11.9	.727
High school graduate	24	202.1 ± 36.1		84.0 ± 14.4	
Some college	43	207.6 ± 37.6		86.9 ± 16.7	
College graduate	30	201.0 ± 38.5		88.6 ± 14.5	
Adverse events ≤3 months					
Yes	43	206.1 ± 40.2	.819	88.8 ± 15.2	.225
No	65	204.4 ± 35.0		85.3 ± 14.9	
More surgery <3 months					
Yes	15	210.6 ± 37.4	.536	89.9 ± 14.9	.373
No	93	204.2 ± 37.0		86.2 ± 15.1	

Note. OTI = Ocular Treatment Index; PSI = Parenting Stress Index.

were examined for the sample of caregivers with longitudinal data ($n = 81$), only private insurance was significantly associated with stress; caregivers with private insurance reported lower Total Stress scores ($t = 2.15$, $df = 79$, $p = .04$) than caregivers without private insurance.

Treatment Group Differences

There were significant differences between the treatment groups for the PSI total stress score and the OTI Total Score at 3 months (see Table III). Caregivers of children randomized to the IOL group reported higher levels of stress compared with those assigned to the CL group, representing a moderate effect size (Cohen's $d = 0.42$ for PSI, 0.56 for OTI). The group differences in PSI and OTI total scores remained significant even after controlling for caregiver age at surgery (for PSI, $F = 7.72$, $df = 1$, $p = .006$; for OTI, $F = 17.17$, $df = 1$, $p = .000$). To better understand the source of the stress, we examined group differences for the constituent subscales of the PSI; both Child Domain and Parent Domain scores were higher for caregivers of children in the IOL group than for caregivers of children in the CL group, but only the Child Domain test yielded a statistically significant result. Among the six subscales in the Child Domain, only the means for *Adaptability* ($t = -3.07$, $df = 106$, $p = .003$) and *Demandingness* ($t = -2.24$, $df = 106$, $p = .027$) were significantly different between the treatment groups. At the post-VA assessment ($n = 93$), there were no significant differences in PSI or OTI scores between the two treatment groups.

Table III. *Means and Standard Deviations for Stress Measures by Treatment Group at 3 Months*

Instrument	CL $n = 55$	IOL $n = 53$	Total $n = 108$	*p*-value
PSI total stress	197.4 ± 35.7	213.1 ± 36.8	205.1 ± 37.0	.027
Ocular Treatment Index	82.6 ± 15.7[a]	90.8 ± 13.1[a]	86.7 ± 15.0[a]	.003

Note. CL = contact lens; IOL = intraocular lens; PSI = Parenting Stress Index.
[a]Mean standard deviation across the five imputation results.

Despite significant group differences on the PSI total stress, the distribution of percentile scores suggested similar proportions of caregivers with significantly elevated scores across the two groups. Nine percent of caregivers in the IOL group obtained significantly elevated (above the 85th percentile) total stress scores compared with 7% of caregivers in the CL group.

To determine the similarity of our longitudinal sample to the total sample, we compared the 81 cases with the same caregiver completing stress measures at both assessments to the 25 cases with PSI/OTI data from different caregivers (or data for only one assessment) on demographic and medical variables (the two cases with age outliers at post-VA were excluded from this analysis). There were no significant differences between these two groups in treatment group (CL vs. IOL) allocation, caregiver age, or any of the variables in Table I except for caregiver relationship to the child; there were proportionately fewer fathers and others (as compared with mothers) completing the 3-month assessment among the group with the same respondent across both visits ($\chi^2 = 17.7$, $df = 2$, $p < .01$). In addition, the children in the group with the same respondent across visits were significantly younger at surgery ($t = 2.37$, $df = 104$, $p = .02$) than those with PSI/OTI data from different caregivers (or data for only one assessment).

The means and SDs for the stress measures across both assessment points and treatment groups are shown in Table IV. The effect of time was only statistically significant for the OTI, $F\ (1,78) = 12.09$, $p < .01$, with stress scores increasing over the two assessment points. There were no significant treatments by time interactions for any of the stress measures, suggesting that stress scores did not change differentially for participants assigned to IOL versus CL. These results were similar even when private insurance was included as a covariate in the repeated measures analyses of variance. Confirmatory ANOVAs conducted for the developmentally more homogeneous sample of infants 28–48 days old at surgery ($n = 40$) yielded similar results.

Table IV. *Means and Standard Deviations for Stress Measures Across Assessments and Treatment Groups for Caregivers With Data at Both Assessment Points*

	3 months after surgery		Post-VA assessment	
Instrument	CL ($n = 43$)	IOL ($n = 38$)	CL ($n = 43$)	IOL ($n = 38$)
PSI total stress	200.4 ± 37.8	208.0 ± 34.1	202.6 ± 34.4	208.3 ± 30.8
Ocular Treatment Index	82.9 ± 15.7[a]	91.0 ± 12.5[a,b]	91.8 ± 19.1[a]	93.6 ± 14.9[a,b]

Note. CL = contact lens; IOL = intraocular lens.
[a]Mean standard deviation across the five imputation results.
[b]$n = 37$, one Ocular Treatment Index completed at the post visual acuity assessment could not be scored due to too much missing data (10 items, or 28% missing).

Discussion

Parenting stress is an important endpoint in clinical trials because it is associated with a multitude of adverse outcomes, including increased child behavior problems and negative parenting (Crnic & Low, 2002). For caregivers of children with congenital unilateral cataracts, high levels of stress related to parenting or cataract treatment may also interfere in compliance with patching and visual correction regimens. We sought to determine whether, in the context of a randomized clinical trial, caregivers of children treated with an IOL and spectacles experienced more or less stress, compared with those left aphakic who wore a CL.

Our data yielded different results depending on the time of assessment. Approximately three months after surgery, caregivers of children assigned to the IOL group evidenced higher levels of general parenting stress and cataract treatment–specific stress than those assigned to the CL group. These findings are broadly consistent with those of Birch et al. (Birch et al., 2007) for an older sample of children with unilateral congenital cataracts. In our study, parents of children in the IOL group perceived their infants to have difficulty adjusting to changes in their physical or social environment, and to place many demands on them, as compared with parents of children in the CL group. High levels of cataract treatment-specific stress among caregivers in the IOL group at the 3-month assessment may be attributed in part to the greater number of adverse events and additional intraocular surgeries experienced by this group, as compared with the CL group (Lambert et al., 2010b). Although the *t*-tests comparing OTI scores for caregivers with and without adverse events or additional surgeries were not statistically significant, there was a tendency for caregivers with adverse events and additional surgeries to report higher levels of stress than those without these experiences. The primary sources of parenting stress expected for the CL group at this assessment, when the children were 3–10 months of age, consisted of insertion and removal of CL; however, many children were wearing extended wear lenses, minimizing the treatment burden of optical correction for this group.

Group differences in optical correction may have been more pronounced at the post-VA assessment, when the children were 11–20.5 months of age. At this time, all of the children in the CL group continued to wear CLs, but some of the children in the IOL group no longer needed spectacles. Thus, parenting stress may have been diminished in the latter group, leading to attenuation of group differences in stress scores observed at the 3-month assessment. However, at the first post-VA assessment, the differences between the two groups were no longer significant for either of the stress measures. For the subset of caregivers with data for both assessment visits, we found no significant group differences in the change in stress scores from 3 months after surgery to the post-VA assessment. These data suggest that treatment assignment did not have a significant impact on caregiver stress early in the second year of the child's life or on the change in caregiver stress over the measured interval, despite the higher rates of additional surgeries and complications among the IOL group.

Caregiver stress scores may have been influenced by several unmeasured variables, including (a) caregiver perception of their child's progress in attaining optimal VA, (b) family support, (c) family cohesion, (d) maternal depression, and (e) child temperament. Previous literature supports associations between these variables and parenting stress among caregivers of infants (Gelfand, Teti, & Fox, 1992). Treatment group differences in parenting stress are unlikely to be due to stress outside the parent–child relationship, as there were no significant differences between the IOL group and the CL group in PSI Life Stress scores.

The OTI evidenced more change from the 3 months to the Post-VA assessment than the PSI, which has been shown to be fairly stable over 3–12-month intervals among caregivers of typically developing children (Abidin, 1995). The pattern of results suggests that our cataract-specific measure of stress may be more sensitive than the generic PSI. However, an alternative explanation might be that the OTI is more valid for children 11–20 months of age than it is for infants. For example, some OTI items (e.g., ''I worry that my child will take his patch off when I am not around'') may not have been endorsed for infants because they lack the developmental capacity to exhibit these behaviors.

To our knowledge, ours is the first study to assess caregiver stress among caregivers of young children with unilateral congenital cataract, a relatively rare condition with a guarded prognosis for optimal VA. The strengths of the study include the use of both generic and cataract-specific measures of parenting stress and the multiple assessment points. The primary limitation is our limited power to detect significant differences may have resulted in a lack of observed treatment differences at the post-VA assessment. Further, the small sample of caregivers with complete data at both assessment points limited our ability to identify treatment differences in the changes in parenting stress. Although we observed a moderate effect of treatment on parenting stress at the 3-month

assessment, we cannot exclude the possibility of a small effect at the post-VA assessment. However, inspection of the means suggests that any significant difference in stress scores at the post-VA assessment would be small.

Our pattern of findings suggests that caregivers of children treated for unilateral congenital cataract with an IOL may experience greater stress during the child's first few months than caregivers of children treated with a CL, but that these differences may not be apparent early in the child's second year. These data offer limited empirical evidence to justify consideration of caregiver stress in making a decision about whether to treat an infant with an IOL versus CL. However, the two treatments may yield differences in caregiver stress during the child's preschool years, when differential treatment burden or VA may result in social and functional impairments. Data collection in the IATS study is currently underway to assess caregiver stress again when the children are 4.5 years of age.

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