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ORIGINAL RESEARCH

# Pediatric Scleral Lenses: 21-Year Retrospective Review

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**Purpose:** Retrospective study to review scleral lens outcomes in the pediatric population over a 21-year period, at a single clinical center.

**Results:** A total of 209 pediatric eyes (108 males and 101 females), distributed between 97 right and 112 left eyes, of which 147 eyes had ocular surface disease and 62 eyes had irregular cornea/refractive conditions, were treated with scleral lenses over a 21-year period. The mean age at the time of treatment initiation was  $10.6 \pm 2.6$  years and at the time of the last evaluation recorded was  $14.7 \pm 4.0$  years. One hundred and forty-seven eyes (70%) continued to wear scleral lenses at the time of review, with a mean duration of lens wear of  $8.2 \pm 4.6$  years. Sixteen eyes (8%) discontinued lens wear, and of these, challenges with application and removal were the predominant reason for discontinuation. The lens wearing status of forty-six eyes (22%) was unknown. Mean LogMAR visual acuity at presentation for the entire cohort was  $0.93 \pm 0.74$  and improved to  $0.43 \pm 0.58$ , p < 0.05 with scleral lens wear. LogMAR visual acuity at the last evaluation recorded was  $0.4 \pm 0.6$ , p < 0.05. The mean initial lens diameter of the full study cohort was  $17.7 \pm 1.2$  mm, with a mean increase of 1.3mm (p = 0.0004) over the study period, to end with a mean final diameter of  $18.2 \pm 1.5$  mm, at the time of the last evaluation recorded.

**Conclusion:** Scleral lenses are a viable option for therapeutic and visual rehabilitation applications in the pediatric population for both ocular surface disease and irregular cornea/refractive conditions. Most eyes continued to wear lenses over a 21-year review period. The mean final lens diameter was 18.2mm, suggesting that larger diameters do not appear to be a deterrent or obstacle for successful long-term outcomes in the pediatric population.

Keywords: scleral lenses, pediatrics, ocular surface disease, irregular cornea, PROSE

### Introduction

Scleral lenses are rigid lenses that vault the cornea and rest on the conjunctiva overlying the sclera. They are filled with preservative-free saline and serve as an effective treatment modality for visual rehabilitation (VR) in cases of irregular cornea and as a therapeutic modality in cases of ocular surface disease (OSD).<sup>1–6</sup> While most peer reviewed scleral lens studies report on outcomes in the adult patient population, some studies have reported outcomes in the pediatric patient population.<sup>7–13</sup> These reports validate the benefits of these lenses in mitigating pain, photophobia, and improving vision in conditions across the corneal disease spectrum in the pediatric population, especially when other treatment modalities have failed.<sup>14</sup> Some studies have also reported on the ability of the pediatric cornea to remodel and show clearing of corneal opacities with daily wear of scleral lenses and without the use of adjuvants, showing an additional benefit of these lenses in this patient population.<sup>15,16</sup>

Most literature describing the benefits of scleral lenses in the pediatric population have a narrow scope, limited longterm data, and/or limited patient sampling. This article, to the best of our knowledge, is the largest patient sampling and longest retrospective review analyzing pediatric scleral lens outcomes for both irregular cornea conditions and OSD. In

© 2024 Carrasquillo et al. This work is published and licensed by Dove Medical Press Limited. The full terms of this license are available at https://www.dovepress.com/ the work you hereby accept the Terms. Non-commercial uses of the work are permitted without any further permission from Dove Medical Press Limited, provided the work is properly attributed. For permission for commercial use of this work, please see paragraph 4.2 and 5 of our Terms (https://www.dovepress.com/terms.php). addition, to the best of our knowledge, it's the first to report on indications for treatment, visual acuity outcomes, especially by age sub-groups, duration of lens wear, lens diameter, patient candidacy, amongst others. As practitioners navigate this unique patient population, this study sheds light into these important questions and provides a road map for what is possible with pediatric patients.

# **Materials and Methods**

#### Study Design

This retrospective study was approved by the New England Institutional Review Board, as BFS-KC-Retrospective-01, for research involving the collection or study of existing data, documents, pathological specimens, or diagnostic specimens, if the investigator records the information in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Accordingly, all guidelines were followed to ensure HIPAA compliance. We adhered to the Declaration of Helsinki and applicable federal and state laws. In each case, at the time of scleral lens treatment, informed consent regarding risks and benefits was obtained from the legal guardian.

Retrospective analysis of the medical records of pediatric patients who were fit with scleral lenses at the same clinical site, over a 21-year period (1998–2019) was undertaken. As part of the chart review, external records from co-managing and primary care providers that were already existing in the clinic database were also reviewed.

Patients were referred for prosthetic replacement of the ocular surface ecosystem (PROSE) treatment for the treatment of irregular cornea and/or OSD. PROSE is an integrated and iterative medical treatment to restore visual function, support healing, reduce symptoms and improve quality of life for patients suffering with complex corneal disease.<sup>17</sup> Patients were fitted with FDA-approved highly customized and fabricated scleral lenses (PROSE devices, BostonSight, Needham, MA) to replace or augment impaired ocular surface functions in eyes with distorted corneal surface or ocular surface disorders.<sup>14,18</sup>

Before fitting initiation, all patients had a consultation evaluation to determine candidacy and indication for a scleral lens. In determining candidacy, contraindications to scleral lens wear and feasibility of A/R of a lens by the parent/guardian or patient were assessed. To maximize A/R success, extra time was added to the clinical schedule when working with a pediatric patient, parents were involved in the A/R process, careful attention was paid to proper lid spreads and actual application of a lens was not attempted until both the fitting clinician and parents were confident of obtaining a good lid spread. Lens diameter was chosen based on the patient's condition (ie need for broader ocular surface coverage), presence of any anatomical obstacle (ie symblepharon), and/or lid aperture. The indication for scleral lens fitting included VR, support of the ocular surface, improvement in comfort, or any combination of the three. After the initial scleral lens fitting, each patient was monitored at varying intervals as appropriate, over a six-month period. During this six-month period, the fit of the lens, vision, and ocular physiologic response to wear were assessed. All lenses were designed and fabricated using proprietary CAD/CAM technology to customize the bearing surface of the lens haptic to align with the conjunctiva and a transitional optic portion designed to vault the cornea. Each scleral lens was filled with preservative-free, sterile normal saline solution at the time of application, and removed for nightly cleaning and disinfection. Assessment of physiological function included evaluation of corneal clearance and haptic alignment, corneal status, and subjective tolerance after 1, 3–4, and 6–8 hours of lens wear or as required by the treating clinician. Patients returned for evaluation of medical status and monitoring of lens function as instructed by the fitting clinician, after lenses were dispensed and asked to return yearly thereafter.<sup>15</sup> All patients continued care under their referring or primary eye care providers, for non-scleral lens-related needs.

The primary inclusion criterion was patients who were between the ages of >0 to 17 years at the time of the initial clinical evaluation. Analysis was undertaken in May 2020; patients were excluded if scleral lens fitting was initiated after December 2019, which corresponded to the month prior to the beginning of data collection and study initiation. Date of birth, sex, country, state, underlying condition, eyes treated, indication for lens wear, presence of persistent epithelial defect (PED) at the time of consultation, date of initial fitting conclusion, date of last evaluation recorded during analysis period, age at fitting initiation, age at the time of last evaluation, presenting visual acuity (VA), VA at conclusion of fitting, VA at time of last evaluation, lens diameter at conclusion of fitting, lens diameter at last evaluation, years of lens wear at time of last evaluation, presumed total years of lens wear, discontinuation of wear during analysis period, reason for discontinuation, and reason for non-candidacy (if any), were extracted from the medical records.

## Statistical Analysis

Vision was measured using Snellen acuity but was converted to LogMAR for statistical analysis. For best corrected visual acuity (BCVA) analysis, mean values with their respective standard deviations were calculated at presentation, at conclusion of fitting, and at last evaluation. Statistical analysis and specific testing were based on the Shapiro–Wilk test (normality test). If the p-value for the Shapiro–Wilk test was greater than 0.05, the data was considered to be normal, and the *T*-test was used. Otherwise, the data was considered to be not normal and Wilcoxon rank test was used. Specifically, to compare results between two means, *t*-test or paired *t*-test was performed for the parametric data and Wilcoxon rank sum test or Wilcoxon signed-rank test was performed for the non-parametric data with a common threshold ( $\alpha$  level) of 0.05 based on the structure of the data. Normality for the data was tested using Shapiro–Wilk test with a threshold ( $\alpha$  level) of 0.05. For the subjects with both eyes recorded, one of the two eyes was selected randomly to eliminate bias. The sample size of some cohorts was too small to support the robustness of the hypothesis tests, thus not performed.

# Results

## Demographic Data

The range of pediatric scleral lens fittings spanned twenty-one (21) years, from 1998 to 2019. Out of the 21 years of fittings, 10 of those had  $\geq$ 10 eyes fitted within a year period (2006–2012, 2014, and 2018–2019) and of these, 4 years (2009–2011, and 2018) had  $\geq$ 20 eyes fitted. The rest of the years reviewed had <10 eyes fitted within a year period. A total of 209 eyes, 108 male and 101 female eyes, distributed between 97 right eyes and 112 left eyes, were treated.

The geographic spread of the pediatric patient population was wide and international, however, most of the eyes treated (173 eyes, 82.8%) were from the United States (USA; 76% Northeast, 8% Southeast, 6% West, 5% Southwest and 5% Midwest). Twenty eyes (9.6%) were from Canada, 2 (1%) from Mexico, 2 (1%) from Barbados, 1 (0.5%) from Honduras, 1 (0.5%) from Cayman Islands, 2 (1%) from Colombia, 2 (1%) from Peru, 2 (1%) from England, 1 (0.5%) from Lebanon, 2 (1%) from Israel, and 1 (0.5%) from Hong Kong.

The mean age at the time of fitting initiation was  $10.6 \pm 2.6$  (range 0.6-17) years and at the time of the last evaluation recorded, was  $14.7 \pm 4.0$  (range 2–27) years. The distribution of conditions for which scleral lenses were used was 147 eyes (70%) with OSD and 62 eyes (30%) with irregular cornea (IC), or refractive conditions. The individual breakdown of eyes, mean age at the time of initiation of fitting, sex, and laterality by subcategory (specific conditions) within each major category, can be found in Table 1.

Condition	No of Eyes	Age <sup>a</sup> , yr	Sex	Laterality	
		Mean (SD; Range)	Male/Female	OD/OS	
Ocular Surface Disease	147				
Epidermal Ocular Disorders <sup>b</sup>	8	10.9 (4.3; 2–15)	2/6	3/5	
Dry Eye Syndrome <sup>c</sup>	17	11.4 (4.4; 0.6–17)	8/9	8/9	
Corneal Exposure <sup>d</sup>	18	10.3 (3.6; 0.6–17)	11/7	6/12	
Neurotrophic Keratitis <sup>e</sup>	45	9.1 (5.0; 0.58–17)	20/25	21/24	
Limbal Stem Cell Deficiency <sup>f</sup>	59	11.2 (4.0; 4–17)	22/37	31/28	
Irregular Cornea	62				
Corneal Scarring <sup>g</sup>	4	9.3 (4.1; 5–15)	1/3	0/4	
After surgery <sup>h</sup>	4	5.4 (7.0; 0.58–15)	2/2	2/2	
Degenerations	54				
Keratoglobus	6	11.7 (5.0; 7–17)	4/2	3/3	
Keratoconus	48	15.0 (3.3; 2–17)	38/10	23/25	

Table	I	Demographic	Data	for	the	Study	Population
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**Notes:** <sup>a</sup>Age at initiation of fitting/treatment. <sup>b</sup>Etiologies include Goldenhar syndrome and ectodermal dysplasia. <sup>c</sup>Etiologies include Graft versus Host Disease (GVHD), after radiation, unspecified dry eye syndrome. <sup>d</sup>Etiologies include paralytic lagophthalmos and anatomic lagophthalmos. <sup>e</sup>Etiologies include Familial Dysautonomia, Trigeminal Nerve Dysfunction, status post Herpes Simplex infection, Moebius syndrome. <sup>f</sup>Stevens-Johnson Syndrome. <sup>g</sup>Etiologies include after trauma, after vernal keratoconjunctivitis, and after infection (unspecified). <sup>h</sup>Etiologies include aphakia and open globe injury.

## Indication for Fitting/Treatment

Most of the pediatric eyes treated with scleral lenses were fitted for multiple indications (Figure 1). Most eyes (70, 34%; mix between IC and OSD cases) were fitted with the combined indication to support the ocular surface and provide comfort and visual rehabilitation. For patients with a single indication for scleral lens fitting, the predominant indication (35 eyes, 17%) was for visual rehabilitation, and all were IC cases. Those fitted strictly for comfort (2 eyes, 1%) or strictly to support the ocular surface (16 eyes, 8%), were all OSD cases.

## Presence of Persistent Epithelial Defect at the Time of Consultation

On occasion, pediatric patients were referred for scleral lens consultation due to the presence of recalcitrant PEDs that had not responded to other therapies. Documentation noting either the presence or absence of a PED at the time of consultation was found in 200 out of the 209 eyes in our cohort. Of these 200 eyes, 16 (8%) were reported to have a PED at the time of consultation. The distribution of eyes that presented with a PED at baseline were mainly OSD cases, with neurotrophic keratitis (NK) being the most prevalent (8 eyes, 50%), followed by SJS (6 eyes, 38%) and dry eye syndrome (DES; 1 eye, 6%); with one IC case secondary to corneal scarring from vernal keratoconjunctivitis (VKC) (1 eye, 6%).

## Visual Acuity

Visual acuity statistical analysis was conducted on 113 observations, out of the 209 in our cohort, as randomly, one eye of a two-eye patient encounter was eliminated to preserve data integrity. Of these 113 eyes, VR was the indication for fitting in 92 eyes. The mean VA across the entire cohort at presentation, at the conclusion of initial of lens fitting and at the last evaluation recorded, for both the full cohort and for the subset of eyes that had a VR as indication for fitting are summarized in Figure 2. The VA improvement from the time of initial presentation to the conclusion of initial fitting was statistically significant, p <0.05, with a net change in acuity of  $0.5 \pm 0.6$  LogMar units (5 lines of VA improvement) in the full cohort and  $0.6 \pm 0.6$  LogMAR units in the subset with VR indication (6 lines of VA improvement). Comparison of VA from the conclusion of the initial fitting to the last evaluation recorded (mean length of time of  $5.5 \pm 4.4$  years of  $5.5 \pm 4.4$  years) showed that there was no statistically significant difference in mean VA measurement for the full cohort  $0.4 \pm 0.6$  (range -0.12-2) or the subset with VR indication  $0.4 \pm 0.5$  (range -0.12-2), p >0.05 in both instances (Figure 2). Analysis of the change in VA over scleral lens wear duration showed that there was no visible trend, and that longer wear duration did not necessarily result in improvement in VA. Additionally, we intended to analyze the subset of VA outcomes for those eyes where VR was not an indication for fitting; however, the sample size was too small to proceed with analysis and hypothesis testing.



Figure I Distribution of eyes per indication for treatment/fitting.



Figure 2 Visual acuity analysis for the entire study cohort (ALL) and data subset that included visual rehabilitation (VR) as indication for fitting at time of consultation (presenting), conclusion of initial fitting and the last evaluation recorded. Statistically significant outcomes (p < 0.05) are denoted by one asterisk (\*), whereas non-statistically significant outcomes (p > 0.05) are denoted by two asterisks (\*\*).

Visual acuity analysis divided into OSD and IC cohorts or broken down by sex showed the same trends seen in the full cohort (Figure 3). Each individual cohort followed the same trend of having a statistically significant improvement in VA from presenting at the time of consultation to the conclusion of initial fitting and from presenting to the last evaluation. There was no statistically significant improvement in VA from the conclusion of initial fitting to the last evaluation recorded. Analysis of the same data subset, filtered by selecting those eyes where VR was chosen as an indication for fitting, showed the same trend outcomes for both individual cohorts.

#### Visual Acuity by Age Groups

Three age groups were analyzed to evaluate the effect of age on VA. The age groups (GRP) were GRP 1 = 0-6 years (17 eyes), GRP 2 = 7-12 years (44 eyes), and GRP 3 = 13-17 years (52 eyes). Normality testing showed that the data did not follow a normal distribution. After performing a Significant Rank Test (non-parametrical *T*-test), GRP 1 had to be excluded as the small sample size could lead to bias. Mean presenting VA for GRP 2 was  $0.9 \pm 0.7$  and improved to  $0.4 \pm 0.5$  at the conclusion of initial fitting; p < 0.001. Comparison between VA at the conclusion of the initial fitting and the last evaluation ( $0.4 \pm 0.5$ ) showed that there was not a significant change, p > 0.05. Mean presenting VA for GRP 3 was  $0.8 \pm 0.7$  and improved to  $0.2 \pm 0.4$  at the conclusion of initial fitting, p < 0.001. Comparison between VA at the conclusion between VA at the conclusion of performing the last evaluation ( $0.2 \pm 0.2$ ) showed that there was not a significant change, p > 0.05. Mean presenting VA for GRP 3 was 0.8 ± 0.7 and improved to  $0.2 \pm 0.4$  at the conclusion of initial fitting, p < 0.001. Comparison between VA at the conclusion between VA at the conclusion of initial fitting and the last evaluation ( $0.2 \pm 0.2$ ) showed that there was not a significant change, p > 0.05.

Comparison of presenting mean VA at the time of consultation between GRP 2 and GRP 3 showed that there were no statistical differences (p = 0.525). However, comparison of mean VA at the conclusion of initial fitting (p = 0.002) and at the last evaluation (p = 0.009) between age GRP 2 and GRP 3 showed there was a statistically significant difference; GRP 3 (eyes from older patients) yielding better VA outcomes at the conclusion of initial fitting and at the last evaluation.

Analysis of the same age data subset, filtered by selecting those eyes where VR was chosen as an indication for fitting, showed the same trend outcomes as for the full data cohort. Comparison of presenting mean VA at the time of consultation between age GRP 2 ( $0.92 \pm 0.67$  LogMAR) and GRP 3 ( $0.80 \pm 0.62$  LogMAR), for subset who had VR as



Figure 3 Visual acuity analysis in the ocular surface disease, irregular cornea, female, and male cohorts at time of consultation, conclusion of initial fitting, and last evaluation recorded. Statistically significant outcomes (p < 0.05) are denoted by two asterisks (\*\*).

the indication for fitting, showed that there were no statistical differences (p = 0.29). However, comparison of mean VA outcomes between age GRP 2 ( $0.42 \pm 0.34$  LogMAR) and GRP 3 ( $0.16 \pm 0.22$  LogMAR) at the conclusion of initial fitting (p = 0.0003) and at the last evaluation [GRP 2 ( $0.45 \pm 0.46$  LogMAR) and GRP 3 ( $0.22 \pm 0.22$  LogMAR) (p = 0.003)], showed that there was a statistically significant differences between the two age groups; with GRP 3 (older patients) yielding a better outcome.

#### Lens Diameter

Scleral lens diameters used to fit pediatric patients with IC and OSD conditions over the 21-year study period ranged from 13.5mm to 23mm. The mean initial diameter of the full study cohort was  $17.7 \pm 1.2$  (range: 13.5–21; mode: 18.0; IQR 1.5) mm, with a mean increase of 1.3mm (p = 0.0004) over the study period, to end with a mean final diameter of 18.2 ± 1.5 (range: 13.5–23; mode 18.5; IQR 2.2) mm, at the time of the last evaluation recorded (Figure 4).

The individual mean initial and ending values for diameter, mean age at the last evaluation, mean difference in diameter and mean age difference between initial fitting and last evaluation, broken down by condition, is listed in Table 2. The mean initial diameter and age in OSD cohort were  $17.6 \pm 0.2$  (range 13.5-21; mode 18.5; IQR 1.5) mm and  $10.4 \pm 0.2$  (range 0.58-17; mode 9; IQR 7) years. Through the study period, the mean diameter and age for the OSD cohort increased to  $18.1 \pm 0.3$  (range 13.5-21.5; mode 18.5; IQR 2) mm, p = 0.0001 and  $16 \pm 6$  (range 2-29; mode 20; IQR 8) years, or a net mean increase of +0.5mm, 5.6 years. Within the IC cohort, the mean initial diameter and age were  $17.5 \pm 0.2$  (range 16-19.5; mode 18; IQR 1) mm and  $13.8 \pm 5.0$  (range 0.58-19; mode 16; IQR 4) years and throughout the study period the mean values changed to  $17.9 \pm 0.3$  (range 15-23; mode 18; IQR 1.5) mm, p = 0.0001 and  $18.3 \pm 6.0$  (range 5-27; mode 21, 25; IQR 8) years, for a net mean increase of +0.4mm, 4.5 years.

Comparison between OSD and IC cohorts, respectively, showed that there was not a statistically significant difference between initial diameters  $17.6 \pm 0.2$  (OSD),  $17.6 \pm 0.8$  (IC); p = 0.9, but there was a statistically significant difference between the ending diameters  $18.1 \pm 0.3$  (OSD),  $18.6 \pm 1.5$  (IC); p = 0.02. When comparing the age at initial fitting between the OSD cohort ( $10.4 \pm 4$  years) and IC cohort ( $13.8 \pm 5$  years), there was a statistically significant difference;



Figure 4 Starting and ending scleral lens diameter distribution throughout the study period (21 years).

p = 0.0001, but not a statistically significant difference between the mean ages during the last evaluation  $16.6 \pm 6$  (OSD),  $18.3 \pm 6$  (IC); p = 0.06.

#### Duration of Lens Wear

Throughout the 21-year review, 147 pediatric eyes (70%) had continued to wear scleral lenses, 46 eyes (22%) had an unknown wear status (no documentation noted in the chart and/or no correspondence with the primary eye care provider for >3 years found), and 16 eyes (8%) had discontinued lens wear.

The average number of years from fitting initiation to the time of the last evaluation recorded for the entire cohort was  $5.5 \pm 4.4$  (range of 0.5–19; mode 2.25; IQR 6.67) years. The mean presumed duration of scleral lens wear based on documentation noted in the chart and/or correspondence with the primary eye care provider within last 3 years at the time of review was  $8.2 \pm 4.6$ ; (range 0.5–21.7; mode 11.33; IQR 7) years.

 Table 2 Scleral Lens Diameter at Initiation of Fitting and at the Last Evaluation and Correlation to Age, Broken Down by Condition

Condition	Diameter (I) <sup>a</sup> , mm	Diameter (L) <sup>b</sup> , mm	Age (L) <sup>b</sup>	$\Delta \mathbf{D}, \Delta \mathbf{A} (\mathbf{L-I})^{c}$
	Mean (SD; Range)	Mean (SD; Range)	Mean (SD; Range)	Mean
Ocular Surface Disease				
Epidermal Ocular Disorders <sup>d</sup>	17.9 (1.4; 17-18.5)	18.6 (1.6; 16.0–21)	15.4 (7.6; 2–24)	+0.7, 5
Dry Eye Syndrome <sup>e</sup>	17.3 (1.0; 14.5–19)	18.0 (1.6; 14.5–20.5)	15.0 (5.3; 10-22)	+0.7, 4
Corneal Exposure <sup>f</sup>	17.7 (1.0; 16–19.5)	18.1 (1.0; 16–19.5)	13.3 (3.5; 9–18)	+0.4, 3
Neurotrophic Keratitis <sup>g</sup>	17.6 (1.2; 16–20.5)	17.9 (1.6; 15–21.5)	14.6 (6.7; 3–27)	+0.3, 6
Limbal Stem Cell Deficiency <sup>h</sup>	17.6 (1.5; 13.5-21)	18.0 (1.6; 13.5–21)	19.0 (4.8; 8–29)	+1.4, 8
Irregular Cornea				
Corneal Scarring <sup>i</sup>	17.7 (0.8; 17-18.0)	18.2 (0.6; 17–18)	9.8 (4.6; 5–16)	+0.5, 6
After surgery <sup>i</sup>	17.4 (0.5; 17-18.5)	17.5 (0.4; 17.5–18.5)	9.4 (4.0; 6–15)	+0.1, 2
Degenerations				
Keratoglobus	17.3 (1.4; 16-19.0)	17.8 (1.4; 16–19)	19.5 (1.0; 19–21)	+0.5, 15
Keratoconus	17.7 (0.8; 16-19.5)	18.0 (1.4; 15–23)	19.7 (5.3; 6–15)	+0.3, 16

**Notes**: <sup>*a*</sup>I = Initial Evaluation, <sup>*b*</sup>L = Last Evaluation. <sup>*c*</sup> $\Delta D$  = Change in diameter (mm) between Last evaluation and Fitting initiation;  $\Delta A$  = age change (years) between last evaluation and fitting initiation; Initial age listed in Table I. <sup>*d*</sup>Etiologies include Goldenhar syndrome and ectodermal dysplasia. <sup>*c*</sup>Etiologies include Graft versus Host Disease, after radiation, unspecified dry eye syndrome. <sup>*i*</sup>Etiologies include paralytic lagophthalmos and anatomic lagophthalmos. <sup>*g*</sup>Etiologies include Familial Dysautonomia, Trigeminal Nerve Dysfunction, status post Herpes Simplex infection, Moebius syndrome. <sup>*b*</sup>Stevens-Johnson Syndrome. <sup>*i*</sup>Etiologies include after trauma, after vernal keratoconjunctivitis, and after infection (unspecified). <sup>*j*</sup>Etiologies include aphakia and open globe injury.

Comparison between the OSD and IC cohorts showed that the average number of years from the time of initial fitting to the time of last evaluation was  $6.2 \pm 4.9$  (range 0.3-19.5; mode 2.25; IQR 7.1) years in the OSD cohort and  $6.2 \pm 4.3$  (range 0-14; Mode 0.25; IQR 8.46) years in the IC cohort, p = 1.0. Comparison of mean duration of scleral lens wear between the OSD cohort  $8.9 \pm 5.0$  (range 0.6-21.7) years and IC cohort  $8.5 \pm 4.1$  (range 0.5-13.83) years showed that patients in the OSD cohort wore lenses for a greater duration than the IC cohort by an average of 0.4 years, but this was not a statistically significant difference, p = 0.58.

#### Discontinuation of Lens Wear

Of the 209 eyes in our cohort, 16 eyes (8%) had discontinued scleral lens wear over a 21-year review period. Of these, 9 eyes (56%) discontinued secondary to A/R challenges, 2 eyes (13%) discontinued secondary to patient becoming deceased, 1 eye (6%) discontinued secondary to lens intolerance, 1 eye (6%) no longer required a scleral lens, and 3 eyes (19%) had discontinued for other reasons, which included one case of corneal perforation, one case of worsening of symblepharon and patient not returning to complete the fitting, and one eye for which no reason was given. The mean age of this subset of 16 eyes that had discontinued scleral lens wear was  $10.9 \pm 5$  (range 2–17; mode 16, 12, 9; IQR 6) years and the mean lens diameter value last recorded was  $16.4 \pm 2$  (range 13.5-20.5; mode 16; IQR 1) mm.

Most pediatric eyes that discontinued lens wear, 12 eyes (75%), were from the OSD cohort (5 eyes with SJS, 4 eyes with NK, 2 eyes with corneal exposure (CE), and 1 eye with DES post-radiation). Four eyes (25%) were from the IC cohort (3 eyes with Keratoconus (KCN) and 1 eye with corneal scarring (CS) secondary to VKC). The mean age and diameter for all the SJS eyes that discontinued lens wear was  $12.8 \pm 3.3$  years and  $15.0 \pm 1.2$  mm. For NK eyes,  $5.3 \pm 4.7$  years and  $16.8 \pm 1.0$  mm, CE  $10.5 \pm 2.1$  years and  $16.3 \pm 10.4$  mm, DES  $12.0 \pm 0$  years and  $13.5 \pm 0$  mm, KCN  $14.0 \pm 0$  years and  $15.5 \pm 2.6$  mm, and CS  $9 \pm 0$  years and  $17 \pm 0$  mm.

The mean diameter value for the cases that discontinued secondary to A/R challenges was  $16 \pm 1$  (range 13.5–17mm; mode 16; IQR 0.75) mm, with a mean age of  $9.8 \pm 6$  (range 2–17; mode 16, 2, 9; IQR 12.5) years.

The one eye that discontinued secondary to lens intolerance was a KCN eye (16 years of age at the time of fitting) that was fitted in a 20.5mm lens. The one case that no longer required lens wear was a NK eye (11 years at the time of fitting, 18mm diameter lens) which had a history of recurrent PED and had required a scleral lens to support the ocular surface. After years of scleral lens wear and no further epithelial breakdown, during his college years, the patient self-discontinued lens wear and continued with daily lubrication with artificial tears and use of ointment at night. The patient with DES post-radiation passed away from complications of a brain tumor.

### Non-Candidacy

There were 36 pediatric eyes (13; 36% female, 23; 64% male) which were non-candidates for scleral lenses at the time of consultation. Most eyes were from USA (30; 83%), while 2 eyes (5%) were from Uruguay, 2; 5% from Nigeria, and 2; 5% from Kuwait.

A detailed breakdown of the reasons for non-candidacy and the conditions associated with this data subset is listed in Table 3. Most eyes in this subset were from the OSD cohort (23 eyes; 64%), while the IC cohort represented 36% (13 eyes) of this data subset. The most prevalent conditions were limbal stem cell deficiency (10 eyes; 27%), followed by KCN and aphakia, each with 4 eyes; 11%.

The causes for non-candidacy stemmed from scleral lenses not being indicated at the time, patients being uncooperative, no improvement in vision, no improvement in comfort, and A/R challenges. Of these five categories, the three most prevalent were scleral lenses not being indicated at the time (13 eyes; 36%), followed by A/R challenges (11 eyes; 30%), and patients being uncooperative (6 eyes; 17%). Most eyes within the three most prevalent reasons for non-candidacy were from of the OSD cohort (see Table 3).

Conditions	Eye (s); %	Reason/Cause by Condition	Eye (s); %
Ocular Surface Disease	23; 64	Sclerals Not Indicated	13; 36
Ectodermal Dysplasia	I; 3	Dry Eye Syndrome	
Dry Eye Syndrome		Unspecified	l; 7
Unspecified	I; 3	Neuralgia	2; 14
Neuralgia	2; 6	Corneal Exposure	
Graft vs Host Disease	2; 5	Unspecified	l; 7
Corneal Exposure		Lagophthalmos	2; 15
Unspecified	I; 3	Limbal Stem Cell Deficiency	
Anatomic Table	2; 6	Stevens-Johnson Syndrome	l; 7
Lagophthalmos	3; 8	Aniridia	2; 14
Neurotrophic Keratitis		Corneal Scarring	
Familial Dysautonomia	I; 3	Vernal Keratoconjunctivitis	2; 15
Limbal Stem Cell Deficiency		After surgery	
Stevens-Johnson Syndrome	7; 19	Congenital Cataracts	2; 14
Aniridia	3; 8	Aphakia	l; 7
Irregular Cornea/Refractive	13; 36	A/R Challenges	11; 30
Corneal Scarring		Limbal Stem Cell Deficiency	
Vernal Keratoconjunctivitis	I; 3	Stevens-Johnson Syndrome	5; 46
After surgery		Degenerations	
Congenital Cataracts	2; 6	Keratoconus	3; 27
Open Globe Injury	2; 5	Dry Eye Syndrome	
Aphakia	4; 11	Graft vs Host Disease	۱; 9
Degenerations		After surgery	
Keratoconus	4; 11	Aphakia	۱; 9
		Open Globe Injury	l; 9
		Uncooperative	6; 17
		Dry Eye Syndrome	
		Graft vs Host Disease	1; 15
		Neuralgia	1; 15
		Limbal Stem Cell Deficiency	
		Aniridia	l; l4
		Corneal Exposure	
		Lagophthalmos	l; l4
		Anatomic	1; 15
		Neurotrophic Keratitis	
		Familial Dysautonomia	l; l4
		Ectodermal Dysplasia	l; l4
		No Improvement in Vision	3; 14
		Aphakia	2; 50
		Stevens-Johnson Syndrome	I; 25
		Anatomic Corneal Exposure	I; 25
		No Improvement in Comfort	l; 3
		Anatomic Corneal Exposure	1; 100

#### Table 3 Non-Candidacy Parameters

## Discussion

To our knowledge, our series, with 21 years of data, constitutes the longest retrospective review on pediatric scleral lenses. A previous study from our center had reported on a 10-year retrospective review,<sup>7</sup> a study from India reported on a 4-year review<sup>9</sup> and more recently, Severinsky reported on a 2-year retrospective review.<sup>11</sup> It also constitutes the largest cohort of pediatric eyes, with 209 eyes. Similar to Gungor and Rathi's study, our study showed that scleral lenses were used primarily for therapeutic reasons to treat OSD, with 70% OSD conditions treated versus 30% IC/refractive

conditions.<sup>7,9</sup> Most of the OSD conditions were comprised of limbal stem cell deficiency (most of which were SJS cases) and NK. This finding correlates with the indication for fitting, with the goal to provide ocular surface support for the majority of eyes (148 eyes, 70% - either as a single indication or together with other indications).

Of the 30% of eyes in the IC/refractive cohort, the majority (77%) were KCN eyes, while only 6% were used for refractive purposes (aphakia/after cataract surgery). This is an increase over time versus a previous report from our center,<sup>7</sup> which had only 2 KCN eyes (4%) in the cohort. The increased referral of pediatric KCN eyes over the years may in large part be due to an increased awareness of scleral lenses, the visual rehabilitation potential, and the added benefit of improved comfort compared to traditional corneal gas permeable contact lenses – which can be particularly important for the pediatric population.<sup>19,20</sup>

Sixteen eyes (8%) in our pediatric cohort presented with an existent and recalcitrant PED at baseline. Previous studies from our center have reported on the use of scleral lenses to heal recalcitrant PED.<sup>14,21–23</sup> A standardized off-label protocol was developed over time<sup>23</sup> which involves the use of preservative-free saline and antibiotic in the lens reservoir as prophylaxis, extended wear of scleral lenses with daily disinfection and daily monitoring – including weekend days. Lim et al<sup>23</sup> reported on 20 eyes (one of which was that of a 7-year-old NK patient) for which scleral lenses were used to heal recalcitrant PED. Seventeen eyes out of the 20 eyes (85%) fully healed with scleral lenses, and the pediatric eye in this cohort was one of the eyes that fully healed and responded to treatment. Of note, there was no complication secondary to microbial keratitis (MK). Ciralksi et al<sup>24</sup> later reported on outcomes using this protocol at a different center (there was one pediatric eye in this cohort, 5 years old, out of the total 8 eyes) and showed that all PED eyes healed with scleral lenses and without incidence of MK.

Scleral lenses provide ocular surface support by providing continuous lubrication and protecting the ocular surface from anatomical insults (ie trichiasis, entropion, and lid keratinization) and/or the external environment (ie chronic exposure and desiccation).<sup>25</sup> As it pertains to PED in pediatric eyes, a previous report highlighted the additional potential benefit of clearing chronic corneal opacities when continuing daily wear of scleral lenses for ocular surface support, after healing of recalcitrant PEDs.<sup>15</sup>

It is important to highlight that the overnight use of scleral lenses and using a therapeutic agent in the lens reservoir (preservative-free moxifloxacin) constitutes an off-label use of scleral lenses. As such, informed consent should be obtained before proceeding with this off-label scleral lens therapeutic approach. Risks and benefits for overnight scleral lens wear should be reviewed and discussed with patients and guardians (in the case of pediatric patients), strategies to minimize hypoxia during lens wear should be prioritized (use of high Dk lens materials and minimize lens center thickness) and daily monitoring and evaluation should be carried out until resolution of the PED. In our cohort, no eye discontinued lens wear secondary to complications from microbial keratitis.

The mean improvement in VA for the entire data cohort and for the subset that included VR as an indication for fitting corresponded to 5 lines and 6 lines of acuity improvement, respectively. Considering that our cohort was a mix of 70% OSD and 30% IC/refractive, our data seems to show some improvement compared to Rathi's et al,<sup>9</sup> where only 40% of eyes had  $\geq$ 4 lines of acuity in improvement. One differentiator though is the smaller sample data and the fact that over 80% of Rathi's cohort was OSD. It may be that a larger percentage of OSD cases skewed the data to a lesser impact with respect to VA. Breaking down the full cohort between OSD and IC/refractive conditions showed that the mean improvement in VA after scleral lens fitting corresponded to 7 lines of acuity improvement for both subsets; with a mean VA of 0.3 LogMar at the conclusion of initial fitting and at the last evaluation. This data correlates overall with Severinsky et al<sup>11</sup> with mean VA improvements to 0.3 LogMar units in the OSD cohort and 0.2 LogMar in the IC cohort.

Our data showed that there was no statistically significant difference in mean VA outcomes between females and males; however, there was a statistically significant difference in mean VA outcomes by age. The older age group of 13 to 17-year-olds had a better mean VA outcome compared to the younger, 7- to 12-year-old age group. This difference may be secondary to a higher reliability in testing outcomes with older patients, but also because the 7- to 12-year-old age group had more OSD cases (89%, 62 eyes) compared to IC/refractive eyes (11%, 8 eyes). In contrast, the split in the 13- to 17-year-old age group was more balanced between OSD and IC/refractive eyes; 57% OSD (58 eyes) and 43% IC/ refractive (44 eyes).

The diameter outcomes in our cohort contrasts other retrospective studies on pediatric scleral lenses.<sup>9,11</sup> The range of diameter choices (13.5 to 23mm) was significantly greater in our cohort compared to Severinsky et al (14.9 to 16.6 mm) and Rathi et al (17–18.5 mm). The mean diameter at the conclusion of the initial fitting was larger as well; 17.7 mm versus 15.8 mm and 17.2 mm, respectively.<sup>9,11</sup> The larger sample size in our cohort may have included more severe or advanced presentations, which may have required more coverage of the ocular surface to provide optimal ocular surface support and/or improvement in comfort in OSD cases. Additionally, we may have required larger diameters to spread the weight of the lenses over a larger surface area to prevent/minimize complications of compression and/or suction over time. This notion may be supported by the fact that over the course of scleral lens wear, there was a shift in the mean diameter to larger diameter values, with a mean change of +0.5 mm (18.2  $\pm$  1.5) at the time of the last evaluation recorded. It is worth mentioning that the OSD cohort experienced a 0.5mm diameter increase over time, and the IC/ refractive cohort experienced a 0.4mm diameter increase. This finding may indicate a probable combined mechanism or cause for the diameter increase over time (as mentioned above), but perhaps leading to a greater need to maximize coverage of the ocular surface in more severe cases of OSD.

Interestingly, despite this mean initial diameter of 17.2mm and ending diameter of 18.2mm across the entire pediatric cohort, most pediatric eyes (70%) continued to wear scleral lenses, throughout the 21-year review period. This data correlates with a previous study from our center specifically studying the outcomes of scleral lens fitting in pediatric patients with SJS, where 65% continued to wear lenses at the time of review and the mean diameter was 17.4mm.<sup>12</sup> These findings may challenge the conventional wisdom that pediatric eves may require diameters <17mm for successful long-term outcomes.<sup>9,11</sup> Our data show that if the condition or disease presentation warrants the need for larger diameter lenses, pediatric eves can be successful long term with scleral lenses. Only 8% (16 eyes) had discontinued lens wear at time of data analysis and of these, only 9 eyes had discontinued lens wear secondary to A/R challenges. Interestingly, the mean diameter value for all the cases that discontinued scleral lens wear was  $15.0 \pm 1.2$  mm and those that discontinued secondary to A/R challenges was  $16.0 \pm 1.0$  mm. Based on the average horizontal visible iris diameter (HVID) of 10.8mm for a pediatric cornea<sup>26</sup> and the classification of scleral lens design and lens diameter choice based on HVID.<sup>27</sup> these diameters would fall into the mini-scleral lens category. This highlights that perhaps diameter/lens size was not the cause of discontinuation in the eyes that discontinued secondary to A/R challenges. Most eyes (75%) that discontinued lens wear were from the OSD cohort, and despite the fact that the main cause for discontinuation was due to A/R challenges, it may be that other factors within the disease etiology and presentation played a major role versus the choice of lens diameter. It is important to highlight that proper A/R training, unique techniques and strategies for A/R success,<sup>28,29</sup> and time commitment in working with this unique patient population is also fundamental to maximize patient success and minimize lens drop out.16,17

As mentioned above, 70% of eyes in our cohort continued to wear scleral lenses at the time of review, with a mean duration of lens wear of  $8.2 \pm 4.6$  (range 0.5-21.7) years. Gungor et al reported that 52% of their patient cohort had continued to wear scleral lenses at the time of review, with a mean duration of wear of 2.5 years, while Severinsky reported that 83% continued to wear lenses with a mean of 1.83 years.<sup>7,11</sup> Even though the review periods of these different studies vary, the data shows that more than 50% of the eyes in each cohort continued to wear scleral lenses at the time of review. In our case and in Severinski's report, most eyes were successfully wearing lenses at the time of review.

A small portion of eyes were determined to be non-candidates for scleral lenses. This reality may be more prominent in the pediatric population, as some of these patients may have a harder time with A/R and/or overall be less cooperative than adult patients. In fact, the three most prevalent causes of non-candidacy were: lack of indication, A/R challenges and lack of patient cooperation. Most non-candidate eyes were OSD cases, with limbal stem cell deficiency (specifically the subcategory of SJS) being the most prevalent condition. These patients experience a significant amount of insult or injury to the cornea as a result of the disease process, significant amount of pain and photophobia, and some eyes may be too compromised (ie shortened fornices, symblepharon formation, and corneal perforations) or present with other contra-indications, prior to scleral lens consultation.<sup>30–32</sup> This can all make scleral lens fitting more challenging, and the lack of cooperation may simply not be conducive for a successful outcome. For this reason, it is important to conduct a thorough baseline evaluation and consultation to properly determine if scleral lenses are an appropriate treatment approach,

keeping in mind the patients and caregivers' ability to fully cooperate, ability to master the A/R process, and comply with the treatment and cleaning/disinfection process.

# Conclusion

This large sample size and long-term retrospective study on pediatric scleral lens outcomes supports scleral lenses as an efficacious treatment option for this unique patient population. Despite A/R challenges being the main cause for discontinuation of lens wear in a small subset of eyes, large diameter options do not seem to be a deterrent for successful lens wear in this patient population. Scleral lenses are a therapeutic treatment option in pediatric OSD and provide statistically significant VR in both OSD and IC/refractive conditions. Proper baseline evaluation is key to ensure candidacy and rule out potential contraindications. Our report is limited by the retrospective nature of the study and the predetermined variables and parameters studied; one example of a study limitation in this regard was the inability to properly collect/report on scleral lens complications, if any. A lack of standardization in clinic chart documentation proved difficult to collect and specifically analyze scleral lens-related complications or to be more specific about the complications that may have resulted in unsuccessful cases in this cohort. This limitation is a consequence of the retrospective design. Such information may be better obtained by a prospective future study or registry. More data and further studies are warranted to study the prevalence of microbial keratitis within the pediatric scleral lens population, the effect of age in VA outcomes and better determine whether, as our data suggests, the condition and potential disease state presentation have a greater impact on visual outcomes.

## Disclosure

KGC, BA, DB, and EC are salaried employees of the non-profit 501c3 BostonSight. Neither has proprietary or financial interest in any BostonSight technology/product. KR, JL, YS, and BP have no financial interest in any BostonSight technologies.

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