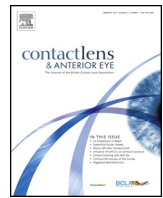




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# Contact lens fitting and training in a child and youth population

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### ABSTRACT

**Purpose:** To determine the ease with which children and youths without previous soft contact lens (SCL) experience were able to handle, care for, adapt and be fitted with SCLs.

**Methods:** 179 children aged 8–16 were recruited. Study visits included: screening and training visits, 1-week and 3-month follow-ups. During the training visit, the time taken to demonstrate proficiency in lens insertion and removal and care was recorded. A second training visit was scheduled if necessary.

**Results:** Nine children did not complete the screening visit and eight discontinued during the study. Of those eight, seven discontinued during the first week and one before the 3-month visit. Of those recruited, 90.5% (162/179) were successfully fitted and completed the study. A majority of children were dispensed with lenses at the first training visit (94.6%, 162/171). The mean training time for all children was 30 min. There were no statistically significant differences in the number of lenses required to fit or instruction time by age group ( $p > 0.05$ ) or gender ( $p > 0.05$ ). Nine participants (5.3%, 9/171) required a second training visit with four still unable to handle lenses (2.3%, 4/171). By the 1-week visit 13.2% (22/167) of participants either lost or tore lenses, no subsequent lost or torn lenses occurred. No serious adverse events occurred during the study.

**Conclusion:** Children and youths with no previous contact lens experience were easily fitted, able to successfully wear and care for lenses. The results of this study should encourage practitioners to recommend SCLs as a vision correction option.

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## 1. Introduction

A study reviewing data from the National Health and Nutrition Examination Survey suggested that the prevalence of myopia in children is increasing in the United States [1]. For children aged 12–17, the prevalence of myopia was 12% in 1971–1972, increasing to 31.2% by 1999–2004 [1]. Children who require vision correction at a young age may benefit from contact lens wear, and all options for correction should be considered and be part of the discussion process with the child and their parent(s). Contact lenses provide advantages of increased magnification for myopes, unobstructed field of view and the absence of prismatic peripheral field distortion, all of which are beneficial regardless of age [2].

However; according to Sindt and Riley [3] practitioners appear reluctant to recommend contact lenses as a refractive correction option to parents for their young children, noting that preference for spectacles compared to contact lenses was highest for younger children and fitting contact lenses as a preference occurred when the child reached 13–14 years of age. Efron et al. [4] reported data from their international fitting survey for children with contact lenses, that minors (under 18 years) represented only 13% of the total fits reported and that a majority were fitted to teenagers, possibly indicating a reluctance to fit younger in age. This reluctance could be due to concerns that younger children may not be mature enough to handle and care for contact lenses, or that the fitting of contact lenses designed for adult eyes will either be unsuccessful or take more chair time.

Practitioners may have the view that risks associated with contact lens wear are too great to consider this as a viable option for children. With respect to safety concerns, a study reviewing National US data indicated that contact lens wear may not be as safe for children as for adults [5]. This study reported that contact lenses accounted for 23% of medical device-associated emergency room visits in a paediatric population. However, most of the adverse

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events reported were self-limiting and described as abrasions, conjunctivitis, or haemorrhage. In contrast, other studies conducted in the United States [6] and Singapore [7] have found no difference between children and teenagers with respect to adverse ocular signs from contact lens wear. There were no serious adverse events reported during the 3-month Contact Lenses in Paediatrics (CLIP) study, which was a study of 8–17-year-old children wearing soft contact lenses [6]. A similar 3-month study of 8–11-year-old children in Singapore also found no serious adverse events reported [7]. The authors of these two studies concluded that contact lenses provided no added health risk to children.

The CLAY study, conducted by Chalmers et al. [8], suggested that the risk of a corneal inflammatory event (CIE) increased in a non-linear fashion up to age 21 and then decreased. The peak years for CIE risk were seen at ages 15–25 years. Compared to teens and young adults, patients aged 8–15 years old actually presented with significantly fewer CIEs [8].

Walline et al. [3] reported that contact lens wear improved how children and teens felt about their appearance and participation in activities, leading to greater satisfaction with their correction by developing and validating a quality of life tool called the Paediatric Refractive Error Profile (PREP).

Walline et al. [6] reported time to fit children and teenagers with contact lenses. They found that the older aged group took less time to fit lenses, this difference being due to the time taken to teach lens insertion and removal. This study selected a lens that offered two base curves and allowed the participating practitioners to select an alternate lens design if the fit was not acceptable.

Recently there has been an increasing interest in the use of contact lenses in the control of myopia [9,10], an interest which if proven successful will likely lead to an increasing interest in fitting children with contact lenses.

## 2. Purpose

This manuscript reports on the success of fitting children and youths (age 8–16 years of age) with no previous contact lens experience with a one base curve design soft contact lenses. The length of time taken to teach and for the child to demonstrate competency in handling, insertion, removal and lens care is also reported.

## 3. Methods

The data reported in this manuscript came from a prospective study in which children were recruited and placed into one of the three study groups; Group 1 (8–10 years), Group 2 (11–13 years) and Group 3 (14–16 years). The purpose of the study was to measure changes in the quality of life for the children (not reported here) using the PREP questionnaire developed by Walline et al. [2]. The target for the original study was to recruit 65 participants into each of the three study groups; this was to ensure 60 participants completed the study in order to provide a statistical power of 90%, assuming a mean effect size for the PREP questionnaire of 10 units, a standard deviation of  $\pm 15$  units and an alpha value of 0.05.

All children had no prior experience with contact lens wear and those eligible for inclusion in the study were invited to be participants. Key inclusion criteria were: aged 8–16 years, have written permission from the parent/legal guardian, have signed assent from the child, have had an ocular examination in the last 2 years, never worn contact lenses, have clear corneas/no active pathology and have 6/7.5 (20/25) or better best corrected visual acuity in each eye. Key exclusion criteria included: any ocular disease, any systemic disease that may affect the study outcome variables, using any systemic or topical medications that may affect ocular health, known sensitivity to the diagnostic pharmaceuticals to be used in

the study, any ocular or systemic allergies that could interfere with contact lens wear, any ocular pathology or condition that would affect the wearing of contact lenses.

The participants were fitted with daily wear, monthly disposable lenses Soft contact lenses (SCLs) according to the manufacturer's guidelines (lotrafilcon B, BC 8.60 mm and diameter 14.20 mm, Alcon Laboratories). The study received approval from the Office of Research Ethics at the University of Waterloo and was conducted according to tenets of the Declaration of Helsinki.

Study visits included: a screening/fitting visit (during which the researcher inserted the lenses) to determine eligibility, a training visit (a second visit was booked if necessary) and 1-week, 1-month and 3-month follow up visits.

The training visit was provided by the research optometrist who taught lens handling, insertion, removal and lens care procedure following a standardised protocol based on the manufacturers guidelines. The time taken for the participant to demonstrate proficiency in lens handling, insertion and removal as well as lens care was recorded. At the end of this visit, participants were required to demonstrate that they could independently insert and remove the lenses. Participants also were required to demonstrate the proper use of the study lens care system (Clear Care Cleaning and Disinfecting Solution, Alcon Laboratories). A second instruction session was scheduled if a participant was unable to demonstrate that they could handle and care for the lenses within the allotted 1-h time limit for the initial training session. If the participant was unable to handle the lenses by the end of the second visit, they were discontinued from the study.

## 4. Statistical analysis

Data were analysed using Statistica 10 (Statsoft Inc., Tulsa, OK). Repeated measures ANOVA and Tukey post hoc Honestly Significant Difference (HSD) tests were used to analyse the training time between groups. Differences between categorical data were analysed using the Chi Square statistic. An alpha level of  $\leq 0.05$  was considered statistically significant; vertical bars in figures denote 0.95 confidence intervals. In addition, descriptive statistics (mean  $\pm$  SD; counts; percentages) and McNemar's test are reported where applicable.

## 5. Results

### 5.1. Recruitment, screening, and discontinuations

A total of 179 myopic children ( $\leq -6.00$  DS with astigmatism  $\leq -1.50$ ) were recruited for screening into this study. Seventeen participants did not complete the study due to either screen failure (nine children) or discontinuation during the study (eight children); three were from Group 1, three from Group 2, and ten from Group 3. Of the discontinuations/screen failures, 12 were male and five were female, the reasons for discontinuation are described in Table 1.

Reviewing the gender balance for the discontinued participants in comparison to the participants who completed the study, it was found not to be of significance for Group 1 (ChiSq 0.7923,  $p > 0.25$ ) or Group 2 (ChiSq 0.0683,  $p > 0.75$ ) however; for Group 3 the proportion of males that discontinued in comparison to those completing was found to be statistically significantly higher (ChiSq 5.5746,  $p < 0.025$ ).

Details for the remaining 162 participants who completed the study are shown in Table 2.

The sample size for the older age groups were successfully recruited with 66 (Group 2) and 63 (Group 3) participants completing the study respectively. Recruitment for the younger age group

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