ORTHOKERATOLOGY

A RETROSPECTIVE LOOK AT CHILDREN FIT WITH ORTHO-K LENSES

Practice data spanning 17 years show that orthokeratology slows myopia progression in a clinical setting.

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The use of “modern-day” reverse geometry overnight orthokeratology (ortho-k) lenses is now more than 25 years old. When first employed, these lenses were a major leap forward from previous attempts at short-term myopia reduction, and they laid the groundwork for future designs. These lenses were primarily used to temporarily (but predictably) mold the cornea in such a manner to decrease a patient’s myopia while asleep, providing freedom from both spectacles and contact lenses as well as clear vision throughout the daytime hours.

Anecdotal reports began surfacing in the late 1990s regarding the potential for ortho-k designs to provide myopia control effects. Today, several controlled studies in Asia, Europe, Australia, and the United States have demonstrated the myopia control benefit of ortho-k, as referenced in a recent meta-analysis (Si et al, 2015). Most studies had relatively small numbers of participants but provided excellent prospective data on what levels of myopia control can be expected.

The mounting evidence is evolving our perspective. We know that, when compared to non-wearers, children who undergo treatment of their myopia utilizing ortho-k lenses progress less in myopic refractive error compared to their counterparts wearing spectacle correction. Among the scholarly community, it is accepted that the use of ortho-k lenses can decrease the progression of myopia from approximately –0.50D per year with spectacle use only (Donovan et al, 2012) to approximately one-half of this value (Lin et al, 2014). However, the U.S. Food and Drug Administration (FDA) has yet to clear any ortho-k lenses for use in myopia control.

Co-author Dr. Despotidis’ multi-professional practice embraced this corrective technology early, fitting more than 1,000 patients in numerous designs over the past two decades. Reflecting back, however—keeping in mind what we know today—many questions remain. Two that we will address here are:

1) Did we slow myopia progression using ortho-k lenses to correct myopia in clinical practice?

2) Did the age of the children at fitting impact myopia progression?

A retrospective chart analysis would be the methodology to partially answer these questions, but this poses inherent issues. First, it is not possible to have a comparable control population; second, instrumentation evolved with changes in topography measurement; third, there was not an accurate method for axial length measurement in the early 1990s; and, finally, there were many different lens designs used over the years in addition to variable wearing periods.
Despite these issues, a wealth of data existed regarding refractive and corneal curvature changes observed during the multiple office visits within this practice. Thus, a database was developed of children who had undergone ortho-k over a 17-year period, which was then selectively filtered. A thorough assessment of all corresponding examination findings was performed.

**METHODS**

In collaboration with the Vision Research Institute at Ferris State University’s Michigan College of Optometry, a chart review study was performed that focused on actual patient findings pre- and post-ortho-k use. With many young patients wearing ortho-k lenses for several years, it appeared that long-term data from their medical records could be analyzed to assess the clinical effects of this modality. This retrospective chart review was performed after receiving Institutional Review Board approval from Ferris State University’s Human Subjects Committee, and it followed the tenets of the Declaration of Helsinki.

Patient selection began with an electronic medical chart database search of approximately 29,000 records (**Figure 1**). The patients desired were those fitted with ortho-k lenses by one of three optometrists between Jan. 1993 and April 2010 using the following criteria:

1) Began wearing ortho-k contact lenses at the age of 18 or younger.

2) Had a baseline manifest refraction of up to –6.00D spherical power and up to a maximum of –1.75D of cylinder power.

3) Wore ortho-k lenses for at least three years (36 months).

4) Stopped lens wear for a minimum of three weeks (21 days) to assess ocular data changes. All pre-fit, during wear, and post-fit measurements were used in our comparison.

![Subject eligibility flow chart.](image)

Initially, an ortho-k fit was deemed ideal when the following clinical findings were obtained:

- consistently central lens position after overnight wear
- post-fit refraction with ±0.50D of residual refractive error
• no corneal staining upon slit lamp examination

• the patient was happy, with good quality of vision during all waking hours.

The Statistical Package for the Social Sciences 21 (SPSS) was used for analysis of the filtered data. For the analysis, a critical p value ($\alpha$) of 0.05 was used to denote statistical significance.

RESULTS

The search criteria yielded 105 patient records (206 eyes) that included age, gender, ethnicity, keratometric readings, manifest refractions, tenure wearing ortho-k lenses, and a period of non-wear. The cohort at the time of initial fitting ranged from as young as age 5 up to 18 years old. The age range for the same group at the time of stopping ortho-k lens wear was 9 to 28 years old.

Of the 105 patients, 64.6% were female and 35.4% were male. The ethnicity of our cohort was 130 (63.11%) and 76 (36.89%) Asian and Caucasian unique eyes, respectively. The minimum wear time for patients was three years, and the maximum was 14.5 years. The median period of ortho-k lens wear discontinuation was approximately five weeks. Table 1 chronologically lists the ortho-k designs used in this study.

<table>
<thead>
<tr>
<th>TABLE 1 ORTHO-K CONTACT LENS DESIGNS USED OVER THE SELECTED TIME FRAME</th>
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<tbody>
<tr>
<td>OK-3 (Contex/Bausch + Lomb Vision Shaping Treatment [VST])</td>
</tr>
<tr>
<td>DreamLens (Various manufacturers/VST)</td>
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<tr>
<td>Vipok (E&amp;E Optics/VST)</td>
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<tr>
<td>CRT (Paragon Vision Sciences)</td>
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<tr>
<td>Emerald (Euclid/VST)</td>
</tr>
<tr>
<td>Delta (Tommy Yee)</td>
</tr>
<tr>
<td>RG-4 (Paragon Vision Sciences/CRT)</td>
</tr>
<tr>
<td>Wave (Wave/Metro Optics/VST)</td>
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We took advantage of the fact that children often discontinue ortho-k lens wear during the course of treatment, although the reason for discontinuation varied. Over the 17-year investigation period, most children were refit to a new FDA-cleared design to improve visual outcome; others transitioned into soft contact lens wear, and some decided to undergo laser vision correction in adulthood.

The reasons for refitting into different ortho-k designs also varied. Some patients were refit when their best-corrected visual acuity achieved with a current design did not fulfill their visual demands. The most common reason for refitting in this subgroup was an improvement in centration of the lens fit. Additionally, if their current design was causing corneal sequelae, such as superficial punctate epitheliopathy, that did not resolve with parameter changes, a new fit was required.

To proceed with a refit, a patient was determined to be adequately washed out when the follow-up topography did not show any residual effect from wearing shaping lenses, such as midperipheral corneal steepening. Figure 2a-c shows topographic examples depicting washout following discontinuation of ortho-k lens wear.
Figure 2a. Difference map (right) of baseline (top left) and initial fit (bottom left) topographies, showing decentered treatment zone.

Figure 2b. Washout topography approximately three weeks post-discontinuation OD with Sim Ks of 43.50D @ 062/43.83D @ 152 (left) compared to baseline OD Sim Ks of 43.62D @ 001/44.34D @ 091 (right), showing near return to baseline.

Figure 2c. Refit difference map (right) of washout baseline (top left) and refit (bottom left) topographies, showing centered treatment zone.
Clinically, a minimum of three weeks was required for the topography to stabilize without midperipheral steepening, although most regression occurred within the first week. If there was any question regarding residual midperipheral steepening, we waited another three weeks before refitting. In this cohort, the average length of time that patients were washed out of their ortho-k lenses was 12.41 weeks, with a median of 4.86 weeks (minimum: three weeks; maximum: 127.71 weeks).

The study investigated the effects of ortho-k on refractive error and corneal shape changes in myopic children before and after discontinuing wear. All pre-fit, during wear, and post-fit measurements were used in our comparison. Thirty-two (15.5%) eyes were from patients aged 8 years or younger; 55 (26.7%) were aged 9 to 10 years; 70 (33.98%) were aged 11 to 12 years; 22 (10.68%) were aged 13 to 14 years; and 27 (13.11%) were aged 15 years and older. At baseline, refractive error ranged from +0.25D to –6.00D (median [M] –3.19D, standard deviation [SD] 1.43), and astigmatism ranged from –0.25D to –1.75D (M –0.80D, SD 0.42). The descriptive statistics revealed the average refractive change in myopia (spherical equivalent) per year of lens wear, per age category (Table 2). Figure 3 shows the graphical breakdown. The mean myopia progression values across all of the age groups undergoing ortho-k was –0.13D (SD 0.20).

### Table 2: Myopia Progression (Spherical Equivalent) Per Year Between Starting Age Groups

<table>
<thead>
<tr>
<th>STARTING AGE GROUP (YEARS)</th>
<th>CHANGE IN REFRACTIVE ERROR (D) MEAN ± SD</th>
</tr>
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<tbody>
<tr>
<td>8 and under</td>
<td>0.31 ± 0.22</td>
</tr>
<tr>
<td>9 to 10</td>
<td>0.16 ± 0.23</td>
</tr>
<tr>
<td>11 to 12</td>
<td>0.07 ± 0.16</td>
</tr>
<tr>
<td>13 to 14</td>
<td>0.10 ± 0.11</td>
</tr>
<tr>
<td>15 to 18</td>
<td>0.05 ± 0.07</td>
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**Figure 3.** Refractive change (diopters) in myopia per year per age category.

Next, the total change in spectacle refraction was analyzed from the time patients began wearing ortho-k lenses until after lens use was discontinued (Table 3). The children in the 8 and under category progressed the most in their myopic refractive error, while the oldest age group (15 to 18 years), progressed the least (Figure 4).

### Table 3: Total Myopia Progression (Spherical Equivalent) Between Starting Age Groups

<table>
<thead>
<tr>
<th>STARTING AGE GROUP (YEARS)</th>
<th>CHANGE IN REFRACTIVE ERROR (D) MEAN ± SD</th>
</tr>
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<tbody>
<tr>
<td>8 and under</td>
<td>1.57 ± 1.05</td>
</tr>
<tr>
<td>Age Category</td>
<td>Refractive Change (Diopters)</td>
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<tr>
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<tr>
<td>9 to 10</td>
<td>$0.83 \pm 1.20$</td>
</tr>
<tr>
<td>11 to 12</td>
<td>$0.46 \pm 0.98$</td>
</tr>
<tr>
<td>13 to 14</td>
<td>$0.72 \pm 0.75$</td>
</tr>
<tr>
<td>15 to 18</td>
<td>$0.32 \pm 0.46$</td>
</tr>
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**Figure 4. Overall refractive change (diopters) in myopia per age category over the course of orthokeratology lens wear.**

The variations in both refractive error and corneal curvature from baseline measurements were analyzed, comparing changes in auto-refraction, auto-keratometry, topography, dry manifest refraction, and manual keratometry when possible. Regarding the plot of keratometric changes observed over the course of ortho-k lens wear (Figure 5), while there were no statistically significant differences found for either the flat K or the steep K, clinically it is worth noting that the youngest starting age group encountered the steepest change in their flat K readings. However, this value was still less than 0.50D of steepening.

**Figure 5. Overall keratometric change (diopters) in myopia per age category over the course of orthokeratology lens wear.**
DISCUSSION

From this retrospective chart review of more than 17 years’ worth of ortho-k fittings and associated examinations of 105 different patients, several key clinical findings should be considered. First, many eyecare providers are often plagued with the question of how long the washout period should be when refitting an established ortho-k wearer. A minimum of three weeks for discontinuation of wear for our chart review was selected, as clinically, a stabilization of the refractive error was noted after this period, similar to the protocol design of Swarbrick et al’s (2015) investigation of ortho-k lens wear. If stabilization of topographic findings was not noted after three weeks of discontinuation, longer periods were prescribed before refitting. In the example in Figure 2a-c, a suboptimal fit led to a washout out of nearly four weeks to allow for regression to near baseline findings, after which a subsequent refit was carried out.

Secondly, recall that the earliest patient in this retrospective analysis began wearing ortho-k lenses in 1993. It was not until 2003 that the first scientific evaluation utilizing posterior A-scan measurements reported an increase in axial length of 0.29mm in an ortho-k treated group and 0.54mm in a spectacle-wearing group over a two-year period (Cho et al, 2005). From that point on, it became standard among the academic community to use changes in axial length as a means of assessing the extent of myopia control, typically in a controlled setting. However, in a clinical setting—and when the children of our cohort began wearing lenses—baseline measurement of posterior chamber depth was not readily available. These results thus shed light on the refractive development of myopia in a non-controlled, practice setting.

For this clinical retrospective chart review of 206 eyes having worn ortho-k lenses, an overall spherical equivalent refractive error progression rate of –0.13D (SD 0.20) per year was found. In addition, recall that a breakdown based on age groups is depicted in Figure 3. In the 8 and under group, there is a statistically significant larger rate of myopic refractive change per year compared to all other age groups. Earlier studies have shown that myopia progression is faster in younger age groups, a consistent finding based on whether treatment was used (Gwiazda et al, 2003) or not (Pärssinen and Lyrya, 1993). For children who began ortho-k lens wear at 8 years of age or younger, they progressed an average of –1.57D (SD 1.05) over the course of their treatment. These findings shed light on the impact of the starting age of ortho-k lens wear; the tendency for younger age groups to progress in their myopia status follows patterns of non-treatment myopia progression, only at slower rates and smaller values.

Although this retrospective analysis has known limitations, one benefit of the clinical nature of this chart review is the ability to evaluate the effects of long-term ortho-k lens wear on corneal curvature in children who had discontinued the treatment modality. In the cohort of patients analyzed in this retrospective review, the mean change in flat K observed was 0.29D steeper compared to baseline keratometric values recorded.

While no statistically significant difference was found between groups, when looking at the mean difference in corneal curvature before and after ortho-k, generally the younger the starting age group, the steeper the flat K readings became. There were no clinically significant differences observed for the mean change in steep K for all 206 eyes from baseline to post-ortho-k wear. In this analysis, corneal measurements, specifically the post-ortho-k status of the flat and steep corneal curvatures that could account for refractive changes, do not support the amount of myopia change observed across this cohort over the time span of treatment. We remain interested as to whether factors such as gender and ethnicity may play a role in the progression of myopia in this population.

CONCLUSION

This retrospective chart review reveals that long-term ortho-k wear can impact the development of myopic refractive error in children within a clinical setting. The magnitude of myopia development in our cohort was dependent on the age at which lens wear was initiated and occurred independent of corneal curvature changes.

Ortho-k successfully reduced the amount of myopic refractive error and impacted how the refractive condition progressed as a child increased in age. From a clinical standpoint, even with lens wear, the youngest age groups progressed the most in their myopic refractive error when comparing their pre- and post-ortho-k examination findings. Had they not undergone any ortho-k treatment, based
on what we know today regarding myopia control, they likely would have progressed much more.

As eyecare providers, it is our duty to address myopia progression with the parents of even our youngest patients to discuss potential treatment plans to minimize the potential ocular risks in their future. CLS

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For references, please visit www.clspectrum.com/references and click on document #251.

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