Effect of Orthokeratology in Patients with ≥ -4.00D of Myopia

Stephanie Ramdass, OD, MS, FAAO; Craig W. Norman, FCLSA

FERRIS STATE UNIVERSITY

Michigan College of Optometry
Vision Research Institute

Introduction

Overnight orthokeratology (corneal reshaping) is a refractive correction process that employs the use of specially designed reverse geometry gas permeable (GP) contact lenses that reduce myopia by flattening the central cornea curvature during sleep.

Paragon CRT® Contact Lenses have FDA clearance for treatment up to -6.00D sphere, with or without astigmatism up to -1.75D. Even though products in this category are 15 or so years old, there remains debate on how much

reduction in moderate to high myopia occurs, and over what time frame does this reduction occur.

The Vision Research Institute of the Michigan College of Optometry at Ferris State University (VRI) carried out an analysis of a series of patient records previously fitted with Corneal Refractive Therapy (CRT®) Contact Lenses in patients with ≥ -4.00D of Myopia in attempt to gain insight on these two questions.

Methods

In this Ferris State University's Institutional Review Board approved study protocol, a database inquiry was performed at Paragon Vision Sciences upon request of the VRI, culling orders where the initial amount of myopia was -4.00D or greater. Practices were identified, then asked if interested in participating in a retrospective record analysis of patients in this group. Five practices agreed, supplying data on 37 patient records.

Demographic information was gathered on each patient regarding age, ethnicity and gender. Additionally, pre-treatment ocular information was acquired to include habitual spectacle Rx, manifest refraction at time of initial fit, keratometric measurements and baseline topography. Slit lamp findings were recorded, as well as the initial CRT lenses chosen based on the PVS fitting recommendations and the use of the CRT design calculator.

Trial lens information was noted as well as the initial lens order, additionally noting whether the

trial lens chosen was dispensable to the patient. Analysis was then carried out documenting the patient's response at the 1-day, 1-week, 1-month, and 3-month time frame. Of particular interest was the decrease in myopia at each of these visits and its comparison to the target amount of myopia reduction.
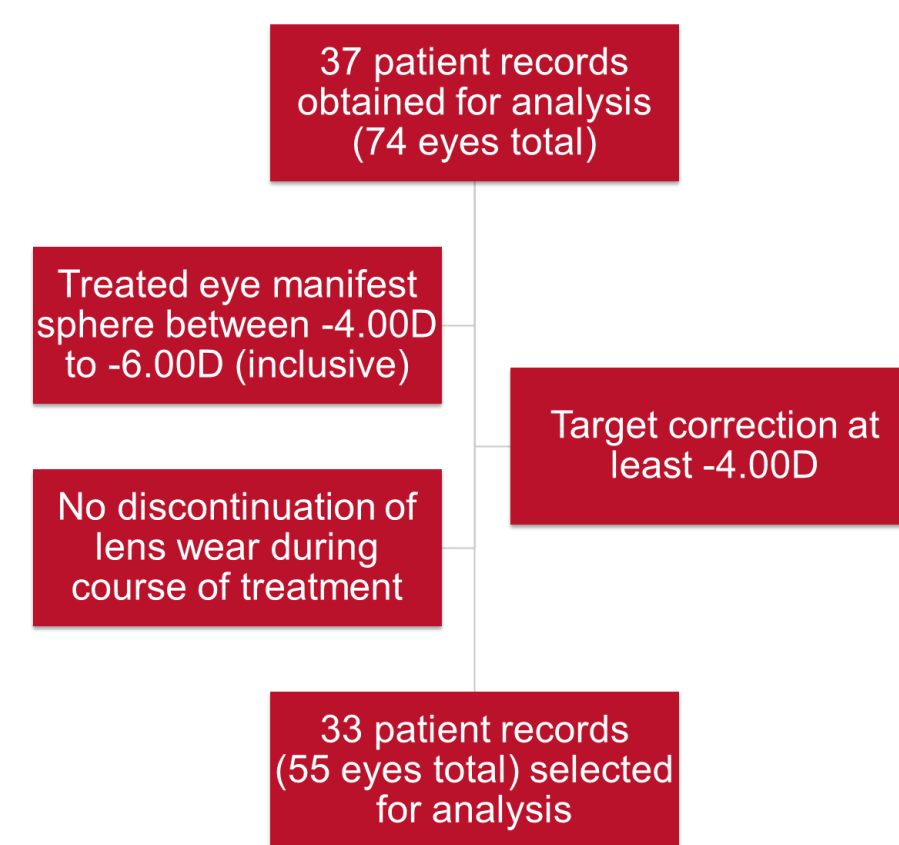
37 patient records obtained for analysis (74 eyes total)

Treated eye manifest sphere between -4.00D to -6.00D (inclusive)

Target correction at least -4.00D

No discontinuation of lens wear during course of treatment

33 patient records (55 eyes total) selected for analysis

Figure 1. Protocol Eligibility Criteria

Results

Based on the protocol eligibility criteria (Figure 1), 33 patient records were selected for analysis. There were 51 qualifying eyes at the 1-day visit and 55 eyes at the 1-week, 1-month and 3-month visits. Average age was 21.2 years, with the youngest 9 and the oldest 69. Twenty-five patients (76%) were of Asian descent, while the remaining 8 (24%) were Caucasian. Nineteen (58%) were female and 14 (42%) male.

Although a significant amount of data was acquired, reported in this poster is primarily the amount of treatment (myopic decrease) at each visit after dispense along with the percentage of the target correction achieved. Tables 1-4 summarize these findings, as well as the average maximum and minimum amounts of myopia corrected throughout the course of lens wear.

Based on the charts reviewed, approximately -4.50D of average target correction was needed at each visit in the 3 month period of CRT use. Chart 1 shows there is an upward trend in achieving these refractive goals over time, with 92% of average target corrected achieved at 3-months. There was also a linear increase in the amount of refractive treatment over time, increasing from an average 2.50D decrease in myopia after the 1-day visit, up to 4.10D of myopic correction at the 3-month mark.
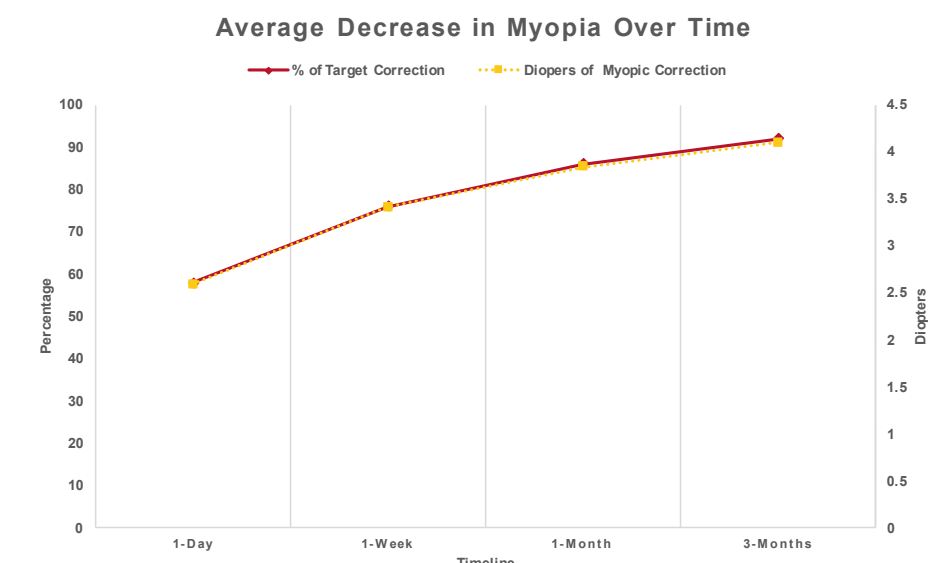
Some eyes were undercorrected while others were overcorrected, however we were unable to discern why this occurred from this analysis.

The topography tangential difference maps below provide a sequential example of the variability in treatment zone development that can be observed in patients with moderate to high amounts of myopia undergoing orthokeratology treatment.
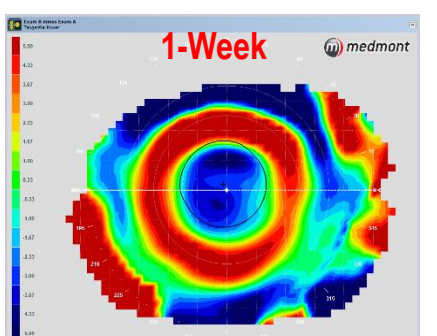
1-Day	Avg	Std Dev	Minimum	Maximum
Target correction – all eyes, n=51	-4.49	0.56	-4.00	-6.00
Manifest refraction 1 day	-1.90	1.02	0.00	-4.00
Amount of refractive treatment 1 day	-2.59	0.94	-1.00	-4.75
% of target correction 1day	**58%**	**0.21**	**25%**	**100%**

Table 1
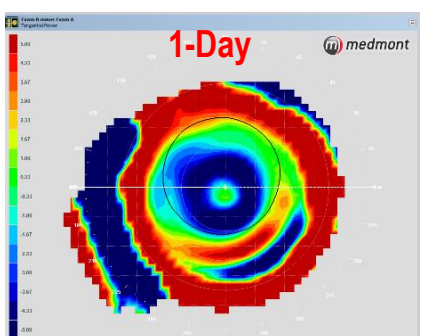
1-Week	Avg	Std Dev	Minimum	Maximum
Target correction – all eyes, n=55	-4.52	0.58	-4.00	-6.00
Manifest refraction 1 week	-1.11	1.11	1.50	-3.75
Amount of refractive treatment 1 week	-3.41	0.95	-0.50	-5.75
% of target correction 1 week	**76%**	**0.24**	**12%**	**135%**

Table 2

1-Month	Avg	Std Dev	Minimum	Maximum
Target correction – all eyes, n=55	-4.52	0.58	-4.00	-6.00
Manifest refraction 1 month	-0.68	0.76	0.50	-2.50
Amount of refractive treatment 1 month	-3.84	0.64	-2.00	-5.25
% of target correction 1 month	**86%**	**0.16**	**47%**	**113%**

Table 3
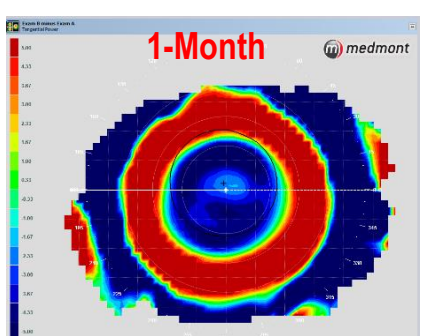
3-Months	Avg	Std Dev	Minimum	Maximum
Target correction – all eyes, n=55	-4.52	0.58	-4.00	-6.00
Manifest refraction 3 months	-0.41	0.59	0.50	-2.00
Amount of refractive treatment 3 months	-4.10	0.51	-2.75	-5.25
% of target correction 3 months	**92%**	**0.12**	**65%**	**113%**

Table 4

Average Decrease in Myopia Over Time

Chart 1. Change in amount of myopia correction over time
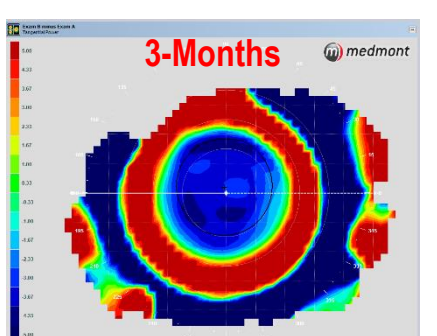
Discussion & Conclusion

This evaluation shows that patients, who present with myopia in the range of -4.00 to -6.00D, can be successfully corrected using Paragon CRT® Contact Lenses. It is a process that takes time and requires the eye care practitioner to communicate to patients the expected time course of treatment and the need to maintain compliance with prescribed nightly lenses wear and follow-up schedule.

Patients can expect by the end of 1 month of wear, over 80% of targeted correction can be achieved, with over 90% of expected correction achieved after 3 months of lens wear in this cohort. Although less than 10% of under-correction of myopia was observed on average by the end of the 3-month period, the patients in the records evaluated remain successful CRT wearers.