The Effect of Two Different Treatment Methods on the Outcome of Corneal Reshaping

by

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ABSTRACT

Introduction: With corneal reshaping gaining popularity, we are exploring two different fitting techniques to establish the most efficient approach for treating moderate to high myopia. *Methods:* We will fit four patients according to manufacturer's guidelines with corneal reshaping lenses. Of each patient, one eye will be fully corrected at the initial visit. The other eye will require a two-step approach where the initial lens will correct half of the refractive error and the two-week follow-up visit will correct the remainder of the refractive error. The patients presented for six scheduled visits over one month's time. *Results:* On the two week follow-up, the overall spherical equivalent of refractive correction in the fully corrected eye was 3.17 (60.03% of full correction). The overall spherical equivalent of refractive correction in the half corrected eye was 3.00 (54.23% of full correction). On the one month follow-up, the overall spherical equivalent of refractive correction in the initially fully corrected eye was 3.13 (59.70% of full correction). The overall spherical equivalent of refractive correction in the initially half corrected eye was 2.87 (50.00% of full correction). *Discussion:* Treatment zone size, corneal dioptric change and number of lens adjustments showed an overall advantage using the two-step half correction technique, however there was 9.7% less overall refractive correction compared to the fully corrected technique. Our results showed no clinical advantage to the two step half correction technique.

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Introduction

Corneal reshaping, was introduced by George Jessen O.D. in 1962. The innovative technique lay dormant for almost 30 years due to poor technology and little understanding of how to predict a successful correction of myopia. In 1979 the rigid gas permeable (RGP) lens was introduced. Due to advances in technology, in 1989 corneal reshaping re-emerged. New lathes used to cut the corneal reshaping lenses allowed for very accurate control of the lens curvature which is essential for the reverse geometry lens design. With this new lens design it was found that the cornea could result in a transient correction of 2 diopters of myopia after only 1 hour of lens wear. Corneal topographers were able to accurately record the progression of corneal change over time as well as measure an area greater than the central 3mm. Also, new lens materials enabled the overnight wear of RGPs much safer for the patient.

Corneal reshaping lenses are shaped similarly to a regular rigid gas permeable lens, but with a different intention. Rather than to place the lens on the cornea to correct ametropia, the lenses are placed on the cornea while the patient sleeps overnight, then removed for the day so that no visual aid device is needed throughout the day. The lenses are shaped with a "reverse geometry" design which allows the center of the lens to bear down on the central cornea causing the cornea to flatten reducing myopia in the eye. Benefits may include transient myopia and mild astigmatic correction, improved cosmesis, and visual freedom.

Methods

Four subjects were enrolled in the study and followed over a one-month period.

Eligibility requirements included healthy corneas with no previous corneal reshaping or refractive surgery. Manifest refraction was required to fall between -5.00 to -8.00 diopters sphere with no more than 1.00 diopter difference between the two eyes and less than or equal to -1.75 diopters cylinder with-the-rule or -1.00 diopters cylinder against-the-rule. Subjects will have read and signed the informed consent form. Study protocol is outlined below and will take place over a total of six visits. Subjects who maintain study protocol and complete the one month study will be allowed to continue lens wear beyond study completion. Follow-up care will be available through the Michigan College of Optometry via standard patient care protocol.

1) Initial Visit / Evaluation and Fitting
    a) Prefitting evaluation
        i) baseline manifest refraction
        ii) corneal biomicroscopic examination
        iii) keratometry
        iv) computerized corneal topography assessment
    b) Fitting
        i) corneal reshaping lenses will be fit according to manufacturing guidelines and dispensed

2) Planned Follow-up Visits
    a) Intervals:
        i) 1 day – post first night of wear

ii) 1 week

iii) 2 week – including dispensing of fully corrected lens for half corrected eye

iv) 2 week + 1day – post first night wear of full correction in previously half corrected eye

v) 1 month

b) Subjective data

i) visual acuities – unaided at distance

ii) visual acuities – aided with Paragon CRT lenses at distance

iii) over-refraction

iv) manifest refraction

c) Objective data

i) evaluate lens fit at 1 day visit and at dispensing visits

ii) corneal assessment with topography

iii) keratometry

iv) biomicroscopic corneal evaluation

v) if needed, the parameters of the lens will be changed to improve the fit, centration, treatment zone, and refractive correction

vi) if the patient is undercorrected, they will be temporarily fit with soft contact lenses to improve visual acuity until full correction is obtained utilizing corneal reshaping

Results

The initial Paragon CRT lenses were selected according to manufacturer's guidelines and then adjusted as needed to attain the best possible fit based on lens position, movement and fluorescein pattern.

Data collection was initiated for four patients. On the initial visit for evaluation and fitting three patients had met our eligibility requirements and one patient was excluded from the study due to corneal irregularities evident on corneal topography.

Upon the two week follow-up, average corneal dioptric change yielded an overall mean in the fully corrected eye of -2.07, with an average treatment zone of 4.58mm. In the half corrected eye an average corneal dioptric change yielded an overall mean of -1.97, with an average treatment zone of 4.58mm. The overall spherical equivalent of refractive correction in the fully corrected eye was 3.17 (60.03% of full correction). The overall spherical equivalent of refractive correction in the half corrected eye was 3.00 (54.23% of full correction).

On the one month follow-up, the average corneal dioptric change yielded an overall mean in the initially fully corrected eye of -1.95, with an average treatment zone of 4.32mm and a average of 2 lens adjustments needed. In the initially half corrected eye an average corneal dioptric change yielded an overall mean of -2.70, with an average treatment zone of 4.57 mm and an average of 1.3 lens adjustments needed. The overall spherical equivalent of refractive correction in the initially fully corrected eye was 3.13 (59.70% of full correction). The overall spherical equivalent of refractive correction in the initially half corrected eye was 2.87 (50.00% of full correction).

Discussion

Corneal reshaping is rarely done on moderate to high myopes due to difficulty obtaining satisfactory results. Attempting two different treatment methods will help determine if there is a more efficient technique of successfully fitting corneal reshaping lenses on these more complex patients. Our particular study analyzed any possible advantages to these two different approaches at a two week and a one month treatment interval.

At the two week interval, the half correction approach yielded 4.8% less corneal dioptric change, equivalent treatment zone size and 5.8% less overall spherical equivalent of refractive correction compared to the fully corrected eye. The results indicate that there was no advantage in using a two-step half correction approach at the two week interval.

At the one month interval, the half correction approach yielded 27.78% more corneal dioptric change, 5.47% larger treatment zone size and 9.7% less overall spherical equivalent of refractive correction and 35% fewer lens adjustments needed compared to the fully corrected eye.

This shows that even though treatment zone size, corneal dioptric change and number of lens adjustments showed an overall advantage using the two-step half correction technique, there was still 9.7% less overall refractive correction compared to the fully corrected technique.

It should be noted that one subject discontinued the study after 3 weeks and was excluded from the one month results. Also there was a compliance issue of consistent lens wear with another subject which skewed our final results for corneal dioptric and

refractive change.

Even though our results showed no clinical advantage to the two step half correction technique, a study with a larger sample size and better compliance would be needed in order to confirm these results.

REFERENCES

1. Bellis, M. (2006). *The History of Eyeglasses or Spectacles.* Retrieved Nov. 4/2006 from http://inventors.about.com/od/gstartinventions/a/glass_3.htm

2. Endo, A. (2004). *The Birth of Contact Lenses.* Retrieved Nov.3/2006 from http://www.eyetopics.com/articles/18/1/The-History-of-Contact-Lenses.html

3. Orthokeratology Society of Australia (2006). *History*. Retrieved Nov. 4/2005 from http://www.osa.net.au/faq.htm