Time constants of corneal molding recovery following ortho-k lens wear

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Introduction

Prevalence estimates from the 1972 National Health and Nutrition Examination Survey indicates that 25 percent of persons in the United States between the ages of 12 and 54 years are myopic.[1] The correction of myopia has been quite successful with conventional spectacles and contact lenses. Patients with myopia have expressed annoyance and discomfort with these appliances. They continue to desire normal and unencumbered vision without dependence on traditional appliances. Therefore, eye care practitioners continue to study the development of myopia and procedures wich may «eliminate or reduce the refractive error.[2]

As early as 1957 there was discussion that myopia ceased to progress following rigid contact lens wear.[3] Patients have also reported seeing better after the removal of their rigid contact lenses.[4-7] Late in the 1960's several definitions of what today is called orthokeratology, the process of flattening the cornea with a series of specially designed lenses for the reduction of myopia, were formed. One such early definition was by Kerns, it stated «a purposeful attempt to modify the corneal curvature to result in a reduction or elimination of refractive anomaly by a programmed apllication of lenses».[8,9].

Kerns, Binder et al, the Berkeley Orthokeratology Study Group, and Coon all performed separate orthokeratology prospective studies in the late 1970's and early 1980's. Binder et al found the greatest mean reduction in myopia of 1.52 D in patients with 2.5 D or greater of myopia, but a mean reduction of only 0.30 D in low myopes with less that 2.5D. The majority of these effects were seen with 9 months.[10] Kerns reported a mean reduction in myopia of 1.25 D after 900 days of treatment.[9] Coon reported a maximun change of slightly less than 1.00 D of myopia over a 5 month period.[11] Polse et al, from the Berkeley Orthokeratology Study Group, reported a mean reduction of 1.01 D in patients whose myopia ranged from 1-4D. This was achieved with a treatment period of 444 days[12-15]

The studies discussed previously all vary in the time course of the orthokeratology treatment, but the «results from the Berkeley Orthokeratology Study Group and Bender et al suggest that the majority of the reduction in myopia will occur in the first six months of lens wear.[2] Conventional lenses were used in these early studies fitting them flatter than the flattest K by a determined amount, or in Coon's study steeper than the flattest K.

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A report of an 0.80 D increase in corneal toricity by Binder et al[10] and a report by Kerns of an average astigmatism increase by 0.42D[14, 15] suggests that orthokeratology induces unwanted astigmatism. Development of newly designed lenses specifically for orthokeratology have helped stabilize the contact lens on the cornea. This eliminates induced astigmatism and results in a more effective reduction of myopia.[2] Such a lens is the OK-3™ produced by Context Inc. This lens is designed with the secondary curve steeper than the base curve allowing for better lens centration and stability.

In our studies of patients wearing the OK-3 ™ lenses, we found a mean reduction of 0.85 D in myopia after wearing the lenses for 4 hours, and reductions in myopia as large as 7.0 D[16] have previously been reported in patients that have worn these lenses for an extended period of time. One question that seems germane to Orthokeratology being considered a reasonable regimen for reducing myopia with the OK-3™ lenses or other designs is: « Does long term wear of these contact lenses produce changes in the cornea that are permanent?» The question of the stability of the corneal changes needs to be investigated. To date we are unaware of any stadies that examine the dynamics of these changes in corneal topograghy following rigid contact lens wear. This study was designed to investigate the time course of corneal changes and the nature of the corneal recovery after lens wear has been discontinued.

Methods

Subjects:

Two groups of patients were served as subjects for this investigation. Group included seven subjects who previously had not worn rigid lenses for the purpose of orthokeratology. Group II consisted of three subjects who had worn the OK-3™ lenses for one year.

The subjects in group II had been wearing the OK-3™ as a retainers as needed for the maintenance of their myopic reduction. The retainer lenses were the last pair of lenses in a series of progressively flatter lenses (usually three) worn to maximize the amount of central flatterning and myopia reduction.

Materials:

The OK-3 ™ lens have an overall diameter of 9.5 mm, an optical zone of 6.0 mm, and a 1.1 mm wide secondary curve that is 3.00 D. steeper than the base curve. This back surface relationship serves to stabilize a flat fitting relationship to the central cornea, and provide a tear reservoir in the initial stages.

Procedures:

Subjects in group I (following consent) were fitted unilaterally by trial lenses and fluorescein pattern evaluation with OK-3™ rigid gas permeable contact lenses. The lenses were fit approximately 1.5 D flat to yield the standard peripheral clarance, mid-peripheral alignment relationship required to manintain normal tear movement under the lenses. Each subject wore their lens for 1, 2, and 4 hour periods with each session separated by at least one week and randomized. Preceding insertion of the lens, baseline video keratoscopy was measured with the Topographic Modeling System (TMS). Following lens removal after the 1, 2 or 4 hour treatment periods, this measure was repeated when the lenses were removed and every 30 minutes for the first hour and every hour thereafter.

The subjects in Group II were instructed to wear their lenses in their standard fashion on the day preceding their appoiment for testing. No subjects slept with their lenses. These subjects were instructed to not wear their lenses the morning of their appointment. Video keratoscopy was performed preceding a 2 hour treatment period of lens wear. After the 2 hour treatment period, video keratoscopic data was colleted at the same intervals with Group I. Data collected after the 2 hour treatment period was then compared to the original baseline of the subjects which was on file from their initial visit one year earlier before the orthokeratology lenses were dispensed. The original baseline was chosen to be used in the analysis because all subjects in Group II showed significant differences in their video keratoscopy between baseline defined a year earlier and the measures made before the 2 hour treatment.

Analysis

At each testing time four video keratoscopic pictures were taken. Since alignment is critical on the TMS instrument, the selection of the processed keratograph (color map) to be used for the longitudinal analysis was made from notes made by the examiner operator and by inspecting all four keratographs simultaneously. The selection of the examiner was checked as being a representative color map for the four color maps produced for each test time. The longitudinal data for the analysis below was then taken from two location on each of the representative color maps. Since calibration data by our lab and others have demostrated that the estimates of curvature in the central 0.5 mm of TMS color maps is requestionable, we selected two locations for comparison outside the central 0.5 mm of the color maps. The selection was made by comparing the appropriate baseline pre-treatment map to the representative color map acquired at the end of the treatment period. We selected one location representing the steepening of the cornea typically found in the more peripheral cornea and one location was selected representing the typically central flattening. The difference maps, a computer generated comparison, was used for the identification of the flattened and steepened position. The specific location was found by manually searching the difference map in the most obvious flattened or steepened area. Once the position was determine it was recorded in terms of meridian and distance from the center of the color maps. The difference map comparison was done on a 80286 clone with our own software. Manual searching is not supported in the TMS difference software so our own software was written to accomplish this task. After these locations were determined from the comparison of the baseline and first post treatment color maps, the locations were then examined in all representative color maps acquired during the course of the longitudinal testing.

The absolute powers (expressing an estimate of the local radius of curvature) found by reading each color map for each subject's specific locations on their representative color map were converted to relative changes in curvature. To quantify the rate of recovery, an exponential curve was fitted (by minimizing chi square) to the data corresponding to the following formula:

$$y = dmax * \exp(ma*M0)$$

where dmax= the maximum change attained,

M0 = the time of each measure, and

M1 = time constant

The percentages of recovery per hour (prph), an expression of the slope of the recovery, were computed for each patient's steep and flat data by first computing the power change still present after one hour:

$$d = dmax * \exp(m1*1)$$

where d= change after one hour of recovery

and then defining the prph by:

$$prph = (dmax-d) / dmax * 100$$

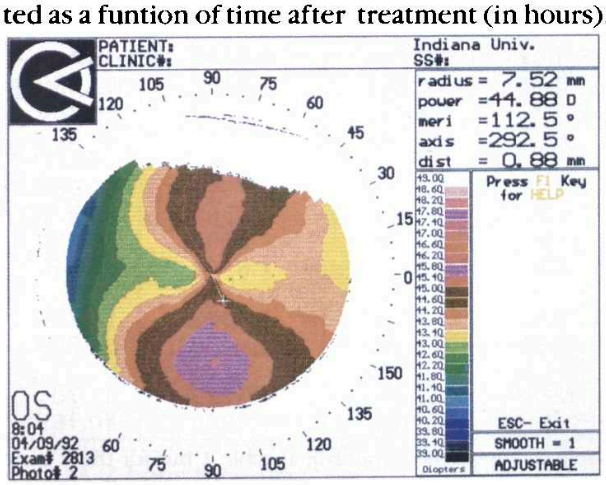
The time to 95% recovery was also computed for the steep and flat data for each subject by the formula:

T95=(1n(1/0.05))/ m1

Results

Corneal flattening was noted in both groups of patients in all of the treatment periods. This was generally confined to central and paracentral regions of the cornea. All subjects also showed a compesating steep area with a characteristic crescent shaped area found inferior specially. Representative color maps of corneal topography for one subject at (a) baseline and post treatment times of (b) 0, (c) 3 and (d) 7 hours are shown in figure 1. Dramatic changes in the corneal topography can be seen inmediately after lens removal when figure 1 a and b are compared. A gradual return toward the baseline topography is seen. The locations that were used to analyze these color maps were at 292 deg., 09 mm from center for the flattened data set and 162 deg, 2.7 mm from center for steepened location. These locations are shown in figures 1 a and b respectively. The position is shown by the location of the plus sign cross hair in each color map (fig. 1A, 1B, 1C, 1D).

Figure 2 shows the dioptric change relative to the baseline data of the steepened position plotted as a funtion of time after treatment (in hours).



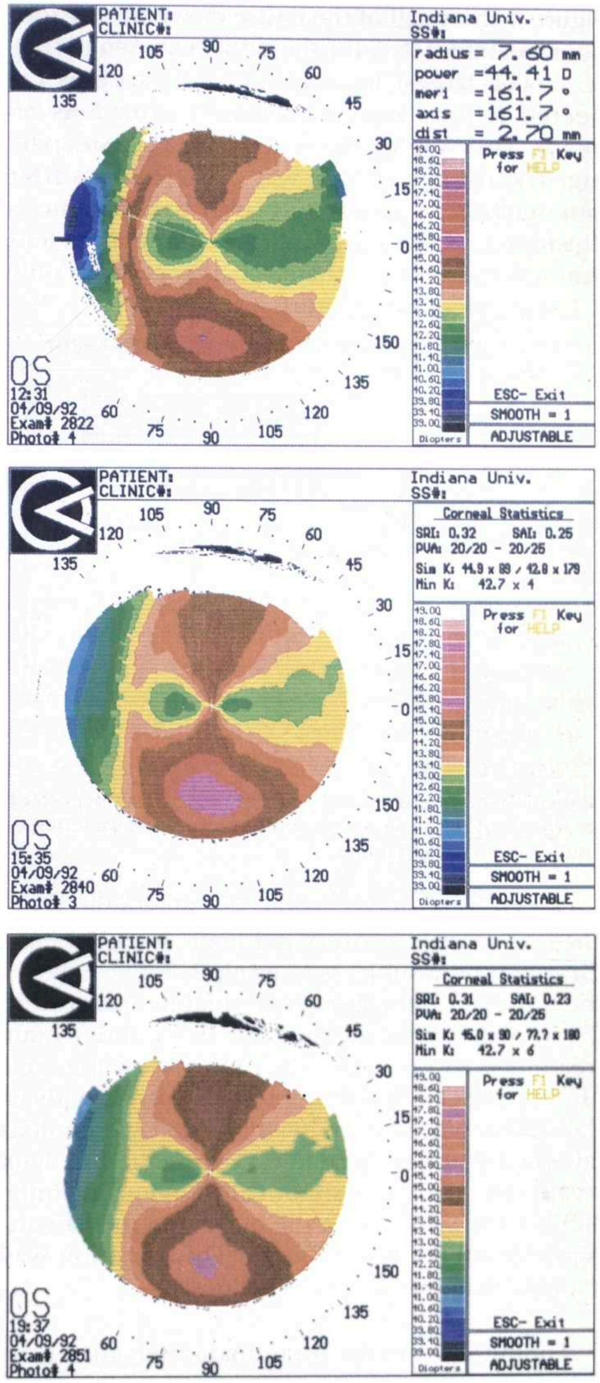


Figure 1A, 1B, 1C, 1D. Repreesntative color maps showing corneal topography at (a) baseline and post treatment of (b) 0, (c) 3 and (d) 7 hours.

Figure 2 shows all of the entire curve for the four hour treatment data for the subject shown in figure 1. The largest local change was seen as expected at time zero, immediately after lens removal. This was approximately 1.6 D of steepening. The relative change was 0.8 D 2 hours after lens removal. A steady return to the baseline is illustrated on this graph. Seven hours after lens removal the relative change had recovered only 0.1 D of steepening (figure 2.)

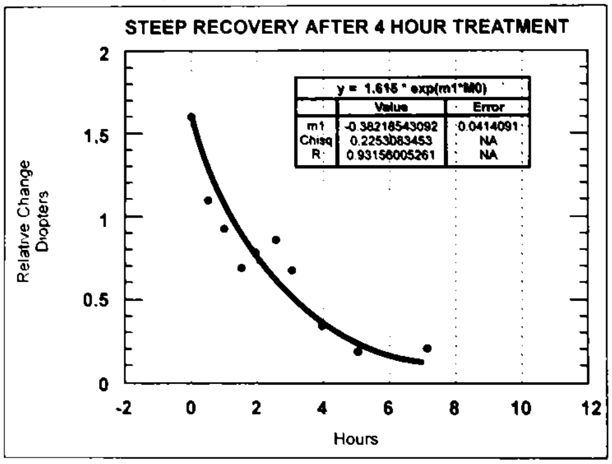


Figure 2. The relative change in diopters of the local steep are for a four hour treatment period plotted as a function of timme for recvery in hours.

(Tables 1, 2, and 3) show the maximum local change, percent recovery per hour, and t95 values for each of the subjects in group I. Table 1 shows these measures for the 1 hour treatment and table 2 and 3 show the measure for the 2 and 4 hour treatments respectively. The f and s following each of the subjects identifying initials corresponds to the data acquired from locations that were initial falttened (f) or steepened (s) by the contact lens treatment. Due to a significant amount of inter subject variability both the mean and median are reported on the tables below. This variation was especially noted on the t95values.

Figure 3 shows the mean maximum change in diopters for the three treatment conditions of Group I and also includes the data from Group II for comparison. It can be seen from this figure

[illegible] 1 HOUR DATA			
SUGJETS	t95	MAX CHANGE	PRPH
BL-S	6.1738	0.9600	38.437
BL-F	1.1704	0.9400	92.261
DP-S	8.8042	0.9400	92.261
DP-F	2.7281	O. 9500	66.641
TH-S	8.8775	0.3500	28.640
TH-F	4.2350	1.2700	50.697
CH-S	3.6880	1.9400	55.607
CH-F	4.2112	1.5950	50.895
CT-S	4.1001	0.8400	51.832
CT-F	4.4021	0.5850	49.356
KW-S	6.7608	0.9100	35.789
KW-F	11-588	2.3750	22.776
KA-S	7.9845	1.1950	31.278
KA-F	0.9766	0.9200	95.343
MEAN	5.4072	1.1086	49.885
MEDIAN	4.3186	0.0945	50.027

Table 1. Shows the individual 1 hour treatment data time to 95% recovery (T95), maximum dioptric change and the percent recovery per hour (prph) for each of the subjects in group I for the steepened (s) and flattened (f) location.

Table 2 2 HOUR DATA			
SUGJETS	t95	MAX CHANGE	PRPH
BL-S	3.160	1.5000	61.200
BL-F	6.570	1.5250	36.610
DP-S	11.750	0.4400	22.490
DP-F	7.420	1.0150	33.200
TH-S	5.210	0.9250	43.700
TH-F	4.600	1.7000	47.830
CH-S	4.750	1.2000	46.760
CH-F	5.030	1.0700	44.820
CT-S	2.780	1.7550	65.960
CT-F	7.650	1.6300	32.370
KW-S	8.200	1.6400	30.600
KW-F	2.830	1.8100	65.340
KA-S	14.450	1.3000	18.700
KA-F	7.140	1.0750	34.240
MEAN	6.539	1.3275	41.701
MEDIAN	5.890	1.4000	40.155

Table 2. Shows the same data as table 1 but for the 2 hour treatment.

Table 3 3 HOUR DATA			
SUGJETS	t95	MAX CHANGE	PRPH
BL-S	6.3712	3.9350	37.505
BL-F	5.4804	2.3450	42.102
DP-S	14.362	0.6450	18.823
DP-F	8.6252	1.4000	29.336
TH-S	108.91	1.5700	2.712
TH-F	12.235	2.0650	21.714
CH-S	7.8365	1.6150	31.763
CH-F	8.2183	1.3400	30.541
CT-S	8.9126	1.3500	28.541
CT-F	21.581	1.7700	12.958
KW-S	3.8690	2.3000	53.888
KW-F	5.9267	2.5600	39.670
KA-S	17.403	1.5600	15.810
KA-F	6.2819	1.5150	37.921
MEAN	16.858	1.8550	28.806
MEDIAN	8.4218	1.5925	29.939

Table 3. Shows the same data as table 1 for the 4 hour treatment

that wearing the OK-3 lens for a 1 hour treatment time produced slightly over 1D of mean local change. By comparing the average maximun change for each of the specific treatment periods it can be seen than the mean local change increased as the wearing time increased. A 2 hour treatment time produced a mean maximum change of approximately 1.4 D, and the 4 hour treatments produced almost 2 D of change. This increase in the mean local change with increase treatment period continues for long term wearers of group II. The maximum change in group II was approximately 1.5 D more than the maximum change of group 1 with the same treatment time. The 1.5 D approximates the difference between the two possible baseline reading for group II (figure 3 .)

In figure 4 the rates of corneal recovery in percentage recovery per hour were plotted as a function of different treatment time and group. After a 1 hour treatment the mean prph was 50% per hour. A 2 hour treatment period revealed a prph

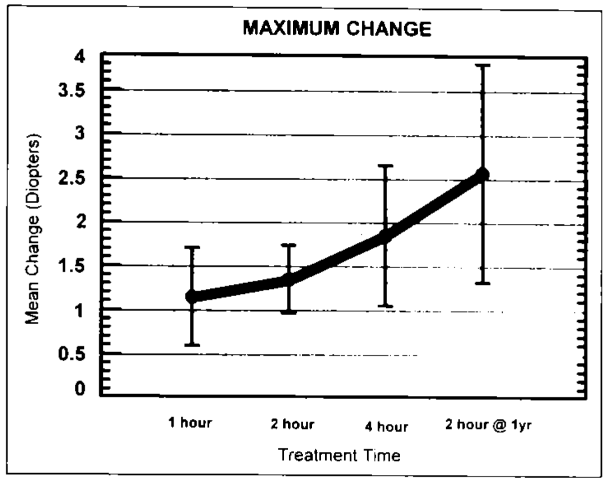


Figure 3. The mean maximun local change in diopters for each of the four treatment conditions in group I and group II plotted as a function of treatment time in hours.

of just over 40% for group I. A steady diminish in the prph as the wearing time increases can be observed by comparing the individual prph for each treatments. A prph of less than 30% is seen with the 4 hour treatment period of group I. Group II, comprised of those that have worn orthokeratology lenses for 1 year previous to this study, showed an even more marked decrease in the prph than was found in group I for the same treatment period of 2 hours (figure 4.)

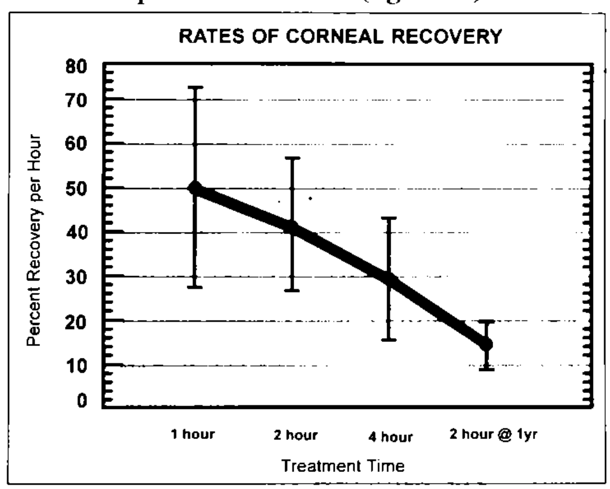
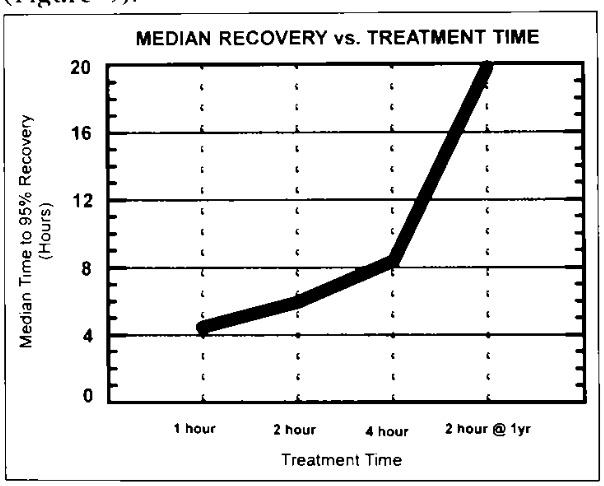


Figure 4. Same as figure 3 but the rates of corneal recovery in percentage recovery per hour (prph). as a function of treatment time.

Figure 5 shows a graph of time to 95% corneal recovery, t95, (combining the steep and flat calculated data) for the various treatment times and groups. The inter subject variability was most evident on the t95 values, therefore the median was reported in this figure (see table 2). The t95 value was just over 4 hours for a 1 hour wearing time. A treatment period of 2 hours showed a t95 of approximately 6 hours, and an even further increase was seen after a 4 hour treatment time where the t95 was approximately 8 hours. It is evident that the t95 value increased as the wearing time increased. Group II showed an even further increase in the t95 than did group I (subjects with no previous orthokeratology) for the 2 hour time period. The t95 for group II was aprroximately 20 hours compared to a group I t95 of 6 hours the same treatment time (Figure 5).



Fgure 5. Same as figure 3 for (combined flat and steep) median times to 95% recovery in hours, t95, plotted as a function of treatment time

We also examined whether the percent recovery per hour could be predicted from the maximun change in local topography. Figure 5 shows the prph plotted as a funtion of the maximum change of each subject for the three acute conditions of group I. The idea that if the maximum local change was known then the duration of the effect could be predicted from that does not hold up statistically. It can be seen than there is very significant scatter in the data and a linear model does not fit the data very well (figure 6).

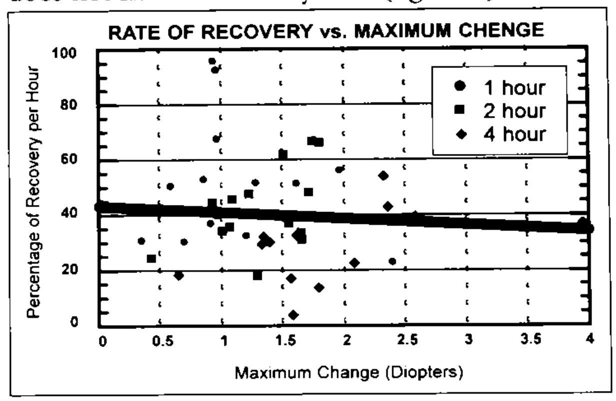


Figure 6. The prph plotted as a function of the maximum change of each subject for the tree acute conditions.

When one compares the maximun local change, percent recovery per hour, and the t 95 values of group I to group II one could conclude that there is a significant difference in the effects of a 2 hours treatment period between two groups. In this data for group I, the baseline used in all comparison was taken the day of the treatment just before lens insertion. Two different baseline references were avaible for group II. If the video keratoscopy measured just before the 2 hour treatment were used, much less diferrence would be demostrated between the 2 hour treatment data between groups. We chose to express the data from the original baseline measured before lenses were worn a year earlier. We chose this reference because it reflects the cornea be for lens wear began and gives an indication that there are long lasting changes occurring due to lens wear. An overnight period of not wearing the lenses was not sufficient time for the cornea to return completely to its original one year earlier shape.

Discussion

As far back as 1957 there has been reports of alterations in refractive error following rigid contact lens wear. This process of corneal flattening with rigid lenses, called orthokeratology, prior to the current novel lens design of the OK TM lenses has been studied on several different occasions with similar modest results. Our results with the OK TM suggest that easily two diopters of flattening can be achieved routinely in a shorter interval of time than previous reports. Our study on the dynamics of the corneal topography following wear of the OK-3TM lenses has revealed several interesting conclusion. Group I, no previous lens wear, showed a significantly faster recovery time back to baseline than did group II. In group II, baseline the morning of treatment still revealed flattening of the cornea compared to original baseline, previous to any lens wear. This indicates that a permanent change in corneal topography is possible with continuation of orthokeratology treatments.

In the early studies discussed previously, induced astigmasm was reported. Theses early studies used conventional rigid lenses. We found no induced astigmatism when subjects were fit with lenses designed for orthokeratology purposes. The mean local change after a 1 hour treatment period was 1.0D. The cornea is capable of rapid alterations in a fairly short time period. Corneal changes of several diopters would be an obtainable goal with increased treatment times and proper lenses to retain the reduction in myopia as needed. These times needed to archieve significant reductions in myopia are reasonable and would not be impractical for the doctor or the motivated patient. When the prph is plotted against the maximum change, no relationship is seen. Therefore, it can be said that the amount of change present after a treatment period can not be used to predict how the effect of corneal flattening will last after lens wear is discontinued.

Orthokeratology offers those with myopia an alternative to the traditional methods of correction. The reduction seen may completely correct the refraction error (in low myopia) or may provide funtional vision witout correction for moderate to high myopia.

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