# Evaluation of waiting periods prior to laser refractive surgery after discontinuing wear of rigid and soft contact lenses 

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# Evaluation of waiting periods prior to laser refractive surgery after discontinuing wear of rigid and soft contact lenses 

Abstract<br>PURPOSE: This study evaluated how contact lens induced corneal warpage stabilizes upon discontinuation of lens wear and further evaluated whether the waiting periods for laser refractive surgery now in use can be safely shortened.<br>METHODS: Using corneal topography, both retrospective and prospective analyses were conducted for 16 soft lens eyes and 8 rigid lens eyes. Corneal maps were taken prior to discontinuation of lens wear, serial maps taken during the waiting period (if an RGP wearer), and again on the date of surgery. Using the Humphrey PathFinder Analysis software, comparisons were made of the CIM, Shape Factor, and TKM to evaluate the changes over time.<br>RESULTS: There is very little corneal reshaping once soft lens wear is discontinued. However, statistically significant changes in SF (Shape Factor) and TKM (Mean Toric Keratometry) before and after the waiting period were found for subjects wearing RGP (rigid gas permeable) lenses.<br>CONCLUSION: Careful topographic analysis should allow many long-term RGP wearers without signs of corneal warpage to forego the long waiting period dictated by current standards in refractive surgery. Short waiting periods for soft lens wearers may be a prudent precaution, but is not a necessity.<br>\section*{Degree Type}<br>Thesis<br>\section*{Degree Name}<br>Master of Science in Vision Science<br>Committee Chair<br>Patrick J. Caroline<br>\section*{Keywords}<br>corneal warpage, corneal distortion, contact lenses, computerized topography, LASIK, refractice surgery, waiting period<br>\section*{Subject Categories}<br>Optometry

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# EVALUATION OF WAITING PERIODS PRIOR TO LASER REFRACTIVE SURGERY AFTER DISCONTINUING WEAR OF RIGID AND SOFT CONTACT LENSES 

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A thesis submitted to the faculty of the<br>College of Optometry<br>Pacific University<br>Forest Grove, Oregon<br>For the degree of<br>Doctor of Optometry<br>May 2000

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#### Abstract

\section*{PURPOSE}

This study evaluated how contact lens induced corneal warpage stabilizes upon discontinuation of lens wear and further evaluated whether the waiting periods for laser refractive surgery now in use can be safely shortened.

\section*{METHODS}

Using corneal topography, both retrospective and prospective analyses were conducted for 16 soft lens eyes and 8 rigid lens eyes. Corneal maps were taken prior to discontinuation of lens wear, serial maps taken during the waiting period (if an RGP wearer), and again on the date of surgery. Using the Humphrey PathFinder Analysis software, comparisons were made of the CIM, Shape Factor, and TKM to evaluate the changes over time.

\section*{RESULTS}

There is very little corneal reshaping once soft lens wear is discontinued. However, statistically significant changes in SF (Shape Factor) and TKM (Mean Toric Keratometry) before and after the waiting period were found for subjects wearing RGP (rigid gas permeable) lenses.

\section*{CONCLUSION}

Careful topographic analysis should allow many long-term RGP wearers without signs of corneal warpage to forego the long waiting period dictated by current standards in refractive surgery. Short waiting periods for soft lens wearers may be a prudent precaution, but is not a necessity.


## KEY WORDS

Corneal warpage, corneal distortion, contact lenses, computerized topography, LASIK, refractive surgery, waiting period

## EVALUATION OF WAITING PERIODS PRIOR TO LASER REFRACTIVE SURGERY AFTER DISCONTINUING WEAR OF RIGID AND SOFT CONTACT LENSES

## I. INTRODUCTION

Millions of people have chosen contact lenses, both rigid gas permeable and soft lenses, as their primary if not only means of refractive error compensation. While a reasonably safe and effective method for managing ametropia, contact lens wear has the potential for significant corneal distortion. Many variables affect the amount and severity of corneal curvature change including duration of lens wear, precontact lens refraction, keratometry, age of the patient when fit, lens design, tightness of fit, and compliance with lens care. The changes in corneal curvature may be slow to resolve or even permanent.

With the advent of laser refractive surgery, many patients who are candidates wear rigid or soft contact lenses. A significant proportion of these patients are likely to have lens-induced corneal topographic changes. Current protocol varies among refractive surgeons but suggests a waiting period free of contact lens wear ranging from a few days up to a month or more depending upon the type of lens modality worn by the patient prior to refractive surgery.

The purpose of this study is to evaluate how quickly corneal warpage associated with contact lens wear stabilizes upon discontinuation of lens wear and further evaluates whether the waiting periods now in use can be safely shortened without compromising the desired outcome of laser refractive surgery. By the use of computer-assisted corneal topography analysis, we will attempt to develop a quantitative methodology for assessing corneal stability in an effort to provide prospective refractive surgery candidates with more favorable expected outcomes.

The contact lens-induced changes in corneal curvature were first mentioned in the literature by Hartstein in 1965 and labeled corneal warpage. ${ }^{1}$ The characteristics included were:

1) The corneal change develops during long-term PMMA contact lens wear;
2) It is not rapidly reversible;
3) There is corneal flattening that affects the horizontal meridian more than the vertical meridian;
4) A change in refractive status results and consists of an increase in with-the-rule astigmatism; and
5) The astigmatism has an irregular component that may cause the patient to have poor spectacle vision and be dependent on contact lenses for good vision. ${ }^{2}$

Since that time, there has been increased awareness of the potential for significant corneal distortion with the use of contact lenses. In 1968, Miller noted an increase in corneal curvature of one or both principal meridians of greater than 0.5 diopters in $53 \%$ in a study involving 31 eyes. ${ }^{3}$ His study further established a significant correlation between this increased corneal curvature and an increase in central corneal thickness associated with epithelial edema. He also demonstrated an increase in central corneal thickness was strongly linked to the presence of epithelial edema. He postulated the mechanism of warpage was due corneal hypoxia leading to stromal thickening which in turn produces a change in the corneal curvature.

Levenson states that corneal curvature changes with rigid lens wear is likely causally related to: 1) Disturbance of corneal metabolism; 2) Mechanical forces produced by the lids and exerted on the cornea by the contact lens; and 3) Inherent characteristics of the individual cornea. ${ }^{1}$ Corneal metabolism is disrupted due to hypoxia caused by the reduction of oxygen supply due to the presence of the contact lens. This, in turn, results in a disturbance of corneal water regulation leading to epithelial and stromal edema. This swollen tissue is thought to be more malleable and thus more easily damaged. The force applied by the contact lens onto the
edematous cornea is thought to set the stage for warpage. He goes on to mention that spherical corneas may be somewhat more at risk due to tightness of fit and central touch which is somewhat difficult to avoid in an alignment fit. A small percentage of the patients in Levenson's study developed a clinical picture similar in nature to keratoconus. He determined that these patients were usually satisfactorily refit with gas-permeable rigid lenses. ${ }^{1}$

In 1974, Hill and Rengstorff sought to determine if there was a relationship between corneal curvature changes and the base curve of the contact lens. ${ }^{4}$ They specifically sought to determine whether steep fitting lenses caused the corneal curvature to become steeper. The lens/cornea relationship was considered steep when the base curve was steeper than the flattest curvature of the cornea such that the lens vaulted. The corneas of 40 asymptomatic eyes were measured with a keratometer before wearing contact lenses and immediately after contact lens removal, one to six years later. The results were inconclusive since only slightly more than half the corneas became steeper. There was no obvious trend that could be attributed to the number of years the lenses were worn.

In 1983, Levenson and Berry sought to determine if the corneal warpage seen in PMMA lens wearers would resolve after a period of discontinuing lens wear or refitting into rigid gas permeable lenses. ${ }^{2}$ Twenty cases were studied all of whom had developed one diopter or more of cylinder after a period of PMMA lens wear. Eleven of the patients were refit into rigid gas permeable lenses and wore them from 7 to 30 months following discovery and evaluation of corneal warpage. The cylindrical change that had occurred during PMMA lens wear had resolved in five of the 22 eyes and in four eyes it had decreased. In 11 eyes, the cylinder did not appreciably change while in rigid gas permeable lenses and in two eyes it actually increased a small but significant amount. Thus, there were 13 eyes that developed significant cylindrical
change during PMMA lens wear with no resolution or decrease during subsequent gas-permeable lens wear. The results of this small study indicate that corneal warpage is less likely to progress and more apt to resolve if gas-permeable lens materials is used for refitting.

Levenson and Berry further concluded that corneal warpage appears to have two components: an irregular distortion and a regular cylindrical change that is more like the astigmatism found in routine refractions. The data from this small study suggests that the irregular component of corneal warpage tends to resolve after a period of time but the fate of the regular astigmatic component seems more variable and, may even be permanent. ${ }^{2}$

The early studies determined contact lens induced corneal warpage using keratometic or keratoscopic measures to monitor corneal topographic changes. The keratometer evaluates the corneal curvature from only four paracentral points, approximately 3 mm apart. Thus, the alterations of the corneal surface central and peripheral to these points of measurement are not detectable. The keratoscope provides information from a larger portion of the corneal surface but the data are qualitative rather than quantitative. In 1990, Wilson, et al., used computerassisted analysis of videokeratoscope images to study the warpage induced by contact lens wear. ${ }^{5}$ Statistical analysis of the videokeratoscope data using computerized algorithms provided them with quantitative information regarding corneal surface changes.

In their relatively small study, only those patients with keratometric changes of at least 1 diopter (D) in total cylinder or mean corneal power compared with prefitting values were eligible. Of the 21 eyes meeting the criteria, there were 13 eyes wearing rigid PMMA lenses, three eyes wearing rigid cellulose acetate butyrate (gas-permeable) lenses, and five eyes wearing soft contact lenses. Patients were instructed to discontinue all contact lens wear in both eyes at the time of diagnosis of corneal warpage. Refractive and keratometic measurements were
repeated at 3 to 6 week intervals until a normal topographic pattern was obtained. If the topography remained abnormal, measurements were repeated until the topography remained stable but changed from prefitting values.

There was considerable variability between patients and marked fluctuations in the measurements in individual patients before a return of normal or stable, abnormal topography. Most corneas with warpage caused by rigid contact lenses had a net increase in mean corneal power after discontinuing lens wear. The mean change in the rigid PMMA contact lens group was $+0.71 \pm 0.21$, which was statistically significant. In addition, most corneas had an increase in total cylinder after discontinuation of contact lens wear. The mean change in the PMMA group was $+0.59 \pm 0.22 \mathrm{D}$, which was also significant. The changes in total cylinder tended to be smaller in the soft contact lens group with no significance in the mean change.

Shifts in the major cylindrical axis greater than $20^{\circ}$ were observed in four PMMA wearers. The mean change in Surface Asymmetry Index (SAI) for the rigid PMMA group ( -0.89 $\pm 0.33 \mathrm{D}$ ) was statistically significant. The SAI is a centrally weighted summation of power differences between points $180^{\circ}$ apart on the same videokeratoscope ring. For example, if on ring 1 the calculated dioptric power at $0^{\circ}$ was 47D and on ring 1 at $180^{\circ}$ the calculated surface power was 44D, a value of 3 was entered into the summation for the whole corneal surface average.

The time required for the return of a normal or stable abnormal topographic pattern after removal of contact lenses was: 14.7 weeks $\pm 1.7$ weeks for the rigid PMMA group; 10.1 weeks $\pm 5.8$ weeks for the rigid gas-permeable lens group; and $5.2 \pm 0.8$ weeks for the soft contact lens group. No correlation was detected among the base curve of the contact lenses but a correlation did exist between the initial topography and the resting position of the contact lens on the cornea
for nine of the eyes. All nine eyes wore rigid lenses, which decentered with respect to the anatomic center of the corneal. The initial topography for each showed relative flattening of the corneal contour underlying the resting position of the contact lens.

Wilson, et al. further noted that the topographic pattern in some warpage patients with high riding rigid contact lenses was similar to that noted in patients with early keratoconus who had never worn contact lenses. ${ }^{6}$

This study and others demonstrated in most cases that the greatest change occurred in the first 1 to 2 months, although significant changes were noted for many corneas for up to 5 months. ${ }^{5,6}$

In 1993, Ruiz-Montenegro, et al. reported a study designed to investigate the corneal topography of visually normal asymptomatic eyes that wore rigid and soft contact lenses compared with visually normal eyes that had never worn contact lenses. ${ }^{7}$ Thirty-seven normal corneas which had never worn contact lenses were assessed against 74 corneas in asymptomatic eyes that wore rigid ( 12 PMMA and 23 gas-permeable) and soft ( 26 daily wear and 13 extended wear) contact lenses for refractive compensation.

Corneas with warpage were noted to have central irregular astigmatism, loss of radial asymmetry, and/or frequent reversal of the normal topographic pattern. The majority of corneas that wore a rigid contact lens and had warpage were noted to have a correlation between the topography and the resting position of the contact lenses. As mentioned in previous studies, those corneas with a superior riding contact lens frequently induced reversible, inferior steepening of the corneal contour that simulated early keratoconus. ${ }^{6,7}$ A high degree of central radial symmetry is characteristic of normal corneas.

The results of this study demonstrated that the normal, asymptomatic wearing of contact lenses was frequently associated with alterations of corneal topography including central irregular astigmatism, lack of radial symmetry, and a reversal of the normal topographic pattern. Alterations tended to be more common and more severe in those patients who wore rigid contact lenses, but also were detected in a proportion of soft contact lens wearers. In some instances, 5 to 8 months, and in rare cases even longer, may be needed for severe alterations to resolve in corneas that wear rigid contact lenses.

The topographic alterations that are detected by computer-assisted analysis are frequently not appreciated by visual inspection of keratometer or photokeratoscope mires due to the inherent limitations of the equipment. Clearly, computer-assisted topographic analysis is an important method for detecting subtle, but clinically significant, changes in corneal topography caused by contact lenses, disease, and surgical manipulations. ${ }^{7}$

Ruiz-Montenegro, et al., go on to suggest that the corneas of contact lens wearing patients should be carefully examined by computer-assisted topographic analysis before any refractive surgical procedure. Contact lens wear should be discontinued and the return of a normal and stable topographic pattern should be documented prior to surgery. They postulate that lens-induced alterations are likely to continue to change after the surgical procedure and may do so over an extended period of time. Failure to detect these preoperative abnormalities could be an important source of poor predictability and less than optimal results after refractive surgical procedures. ${ }^{7}$

In 1994, Wilson and Klyce conducted a prospective study to evaluate the corneal topography of patients who sought an opinion regarding refractive surgery for the correction of myopia. ${ }^{8}$ Both eyes of 53 patients were evaluated with topography ( 42 patients wore rigid or
soft lenses, 10 patients wore glasses alone, and one patient wore neither glasses or contact lenses). Topographic maps were judged to be abnormal if they had irregular astigmatism, loss of radial symmetry, or absence of the normal progressive flattening from the center to the periphery of the cornea.

Contact lenses were worn in nearly $80 \%$ of the eyes in this study. Thirty-eight percent of the latter group had contact lens-induced corneal topographic abnormalities. Contact lensinduced warpage may emerge shortly after removal of the lenses but may be most severe in many rigid lens wearers at 2 to 4 weeks after removal of the lenses. Wilson and Klyce believe that the changes observed in soft lens wearers usually resolve faster with a mean time of approximately 5 weeks. They feel that it is not possible to predict how long the contact lenses will need to be discontinued in any individual patient and suggest that the topography return to a normal stable pattern prior to undergoing refractive surgery. They further suggest that a normal pattern can be considered achieved when the topography is unchanged on two examinations at least 1 month apart. ${ }^{8}$

## II. PATIENT SELECTION AND METHODOLOGY

The primary objective of this project was to assess the time required for the corneas of contact lens-wearing patients--both hard (RGP) and soft lens wearers--to stabilize after discontinuing lens wear before undergoing refractive surgery. Because computerized corneal topography offers an excellent means to evaluate changes in the curvature of the corneal surface, it was selected as the principal means of data collection. However, a number of technical and logistical issues regarding patient selection and compatibility of topography systems had to be resolved prior to initiating the study.

To minimize the number of uncontrolled variables in our study, we chose to collect data from a single surgery center and with a single refractive surgeon, Dr. Stanley Teplick at the Teplick Laser Center. Because refractive surgery has become an increasingly popular option, we felt an adequate number of contact lens-wearing subjects could be solicited from among those electing to undergo LASIK or PRK during our study period with Dr. Teplick. (Because we were looking only at corneal reshaping prior to surgery, the type of surgical procedure or the amount of correction actually attempted was not a factor in our study.) All patients whose records were used in this study underwent refractive surgery at the Beaverton, Oregon, office of the Teplick Laser Center, or in its satellite office in Albany, Oregon, using the VISX Star S2 laser.

Compatibility of corneal topography systems placed additional constraints on enrollment of participants in this study. Since Dr. Teplick typically co-managed refractive surgery patients with the patient's optometrist, some patients' pre-surgery corneal topography was available only at the optometrist's office. Similarly, some patients who were screened in Teplick's Beaverton office had their day-of-surgery topography performed at Albany Eye Care, which co-owns the building used by Dr. Teplick for surgery in Albany, Oregon. All patients had topography taken on the day of surgery at the Teplick Laser Center. The Albany office, the Teplick Laser Center, and Pacific University's Beaverton Clinic all possessed compatible Humphrey Corneal Topography systems. However, this equipment restriction limited our selection of other referring doctors to a single location, Murrayhill Eyecare in Beaverton, Oregon, which also possessed a Humphrey Corneal Topography system.

To maximize the number of patient records that could be included in the study, we planned both a prospective and a retrospective assessment. In general, inclusion criteria for our
study mirrored those used to evaluate candidates for refractive surgery in 1998: myopia less than 15 diopters; astigmatism less than 4 diopters; and no ocular pathology that would contraindicate LASIK or PRK.

For the retrospective assessment, patient records from Murrayhill Eyecare were screened for those who had recently undergone refractive surgery at the Teplick Laser Center and thus met the inclusion requirements. These records were then reviewed to find those who had worn either RGP or soft contact lenses prior to surgery. Of this group, only those having a documented date when lens wear was discontinued, as well as corneal topography prior to discontinuing lens wear, were selected. If these patients also had corneal topography performed on the day of surgery at the Teplick center, they were then included in the database.

For the prospective portion of the study, patients who were planning to have refractive surgery and were still wearing their contacts at their initial screening with Dr. Teplick were approached about participating in the study. In addition to meeting the criteria listed above, these patients were further screened for full-time lens wear: at least 10 hours a day, for at least 5 days a week. Patients who had a history of both hard and soft lens wear were classified by their current modality if they had been wearing that type for more than 3 months. (This applied only to former hard lens wearers who had switched to soft lens wear at some point; no patients were encountered who had switched from soft to RGP lenses.) If they expressed interest in participating, they were given an informed consent to review and sign, and were asked to remove their lenses so corneal topography could be taken at that time. This procedure ensured that corneal maps both before and after discontinuing lens wear were available at the Teplick center, which minimized topography compatibility issues for these patients.

Our general methodology of data collection varied somewhat depending on mode of lens wear. In all cases, we required corneal topography taken sometime shortly before discontinuing lens wear, and again on the day of surgery. This would allow us to perform a qualitative and quantitative assessment of corneal changes over the waiting period for both the RGP and the soft lens groups.

Under the protocol recommended by the Teplick Laser Center at the beginning of the recruitment period, soft lens wearers were required to be out of their lenses for one week prior to surgery. Because this waiting period was relatively short, we chose to perform topography only twice for these patients, once before discontinuing lens wear, and then once on the day of surgery approximately one week later. Our analysis of these patients would consist of a comparison of several corneal parameters taken from the topography before and after lens wear. Individual changes would be assessed for each patient, and mean values for the soft lens wear group would be compared before and after to identify significant changes in the population as a whole over the waiting period.

For RGP patients, the Teplick Laser Center followed a protocol that required one month of wait for each decade of hard lens wear. This meant those who had worn RGP lenses up to 10 years waited one month; those who had worn them 11-20 years waited two months; and those with 21-30 years of wear waited three months prior to surgery. Our plan was to perform serial topography on these patients to track corneal changes over time, and thus identify when their corneas appeared to stabilize to determine the adequacy of these waiting period guidelines. For the 10-year group, topography was planned before discontinuing lens wear, and then weekly until surgery. This would provide approximately 5-6 corneal maps for each patient, which we felt would be adequate to identify whether the corneas had stabilized prior to surgery. For the
$20-$ and 30 -year groups, topography was planned every two weeks during the waiting period, which would provide 5-8 corneal maps on each eye. Again, we felt this would be adequate to assess corneal stability prior to surgery.

All corneal topography was performed with the Humphrey ATLAS corneal topography system. One topographer was located at the Teplick Laser Center in Beaverton, one at the adjacent Pacific University College of Optometry clinic, one at the Murrayhill Eyecare office, and one at the Albany Eye Care offices next to the Teplick Laser Center location. Corneal maps for all study patients were archived on a ZIP disk using a portable ZIP drive for downloading. The data was processed and displayed using the Humphrey Atlas corneal topography software located at Pacific University College of Optometry in Forest Grove, Oregon, and on the personal computer of one of the researchers.

The Humphrey Corneal Topography System has a number of capabilities that make it especially useful for analysis of corneal reshaping. It provides the standard axial map of the cornea, which describes the corneal surface curvature (expressed in diopters). Axial maps provide an estimate of central corneal astigmatism, and can be used to assess changes in corneal shape over time. Axial maps, however, are of limited accuracy in reading peripheral curvature or sharply changing local curvatures because of smoothing and their inability to take into account spherical aberration. To overcome this, the Humphrey system provides an Advanced Refractive Diagnostics software module with several additional analysis capabilities. The first is the refractive power map, which calculates curvature based on a tangent to the local normal, and provides a truer estimate of the actual refractive power of the cornea. Refractive power maps are smoothed less and are much more sensitive to small changes on the corneal surface. The second tool in this package is the "irregularity" map. This tool determines a best fit toric reference
surface for each cornea, and then calculates the elevation differences above or below this surface. Irregularity is expressed as "wavefront error," which is a measure of imperfect refraction of light through that portion of the cornea. In addition to axial maps, both refractive power and irregularity maps were used to qualitatively evaluate the changes taking place over the waiting period in our subject's corneas.

The Humphrey system also includes another optional software package, PathFinder Corneal Analysis, which offers several statistical measures to quantify changes to the cornea over time. While aimed primarily at detecting corneal pathologies such as keratoconus, PathFinder offers an excellent means to assess subtle changes and evaluate the "normalcy"of the cornea. Each of the three indices used is compared with a database of population mean values to assess whether the parameter is normal, borderline, or abnormal.

The first parameter is "Shape Factor," or SF, which is a measure of corneal asphericity. It can be used to assess whether corneas are more elliptical or oval in shape. Shape factors may range from negative, or oblate, values to positive, or prolate, values. Population normals are from 0.13 to 0.35 ; borderline values are from 0.02 to 0.12 and 0.36 to 0.46 ; abnormal values are 1.0 to 0.01 and 0.47 to 1.0 .

The second parameter is "Corneal Irregularity Measurement," or CIM. The CIM is determined by calculating the elevation difference between an ideal toric surface and the actual cornea at thousands of points within the central 10 rings of the topographic map. The CIM is the standard deviation of the difference between actual and ideal surfaces, expressed in microns. Higher CIM values indicate a greater amount of corneal irregularity. Population normals fall within a range of 0.03 to 0.68 microns, with a population mean of 0.63 microns; the borderline range is from 0.69 to 1.0 microns; and the abnormal range is from 1.1 to 5.0 microns.

The third parameter is known as "Mean Toric Keratometry," or TKM. TKM is again derived from elevation data--the difference between the actual cornea and an ideal toric model. Two values taken at the apex of the flattest meridian are averaged, and this value is called the mean value of apical curvature. Normal values for the human population range from 43.1 to 45.9 diopters; borderline values are from 41.8 to 43.0 and 46.0 to 47.2 diopters; abnormal values are below 41.7 diopters and above 47.3 diopters. ${ }^{9}$

The PathFinder analysis program allowed us to compare each corneal topography against the population mean, but more importantly, it gave us quantifiable measures of corneal irregularity that could be tracked over time to assess corneal stability. These parameters were used in two ways.

First, to address the hypothesis that there were significant corneal changes over the waiting period after discontinuing contact lens wear, sample mean values of SF, CIM, and TKM for our soft lens group and our RGP group were calculated prior to discontinuing lens wear. These were then compared to the sample mean values of SF, CIM, and TKM taken from the day-of-surgery topography for the respective groups. A Student's $t$-test was used to compare sample means for significance. ${ }^{10}$ Changes in SF, CIM, and TKM were also calculated for each individual cornea over the waiting period, and these values were averaged to determine a mean change in SF, CIM, and TKM for the soft and hard lens groups. These calculations were performed both manually and using the Excel spreadsheet statistical analysis package available with Microsoft Office software. ${ }^{10}$

The second method intended to assess when corneal reshaping had stabilized, was to plot each of the factors for each RGP eye for which serial topography was available. Graphs were created using the Excel program, and regression analysis was performed on each data series.

The statistical analysis package within the Excel spreadsheet program also calculates an $\mathrm{R}^{2}$, or goodness-of-fit, value for each trend line to provide an indication of the amount of variability in the data series that is accounted for by the best-fit curve.

## III. RESULTS

For the soft contact lens portion of the study, a total of 8 patients ( 16 eyes) met the acceptance criteria and participated in the study. Three patient records (6 eyes) came from a retrospective assessment of Murrayhill Eye Care patients, and 5 patients (10 eyes) were recruited into the prospective portion of the study during their initial consultation with Dr. Teplick. For the RGP study, a total of 5 patients met the acceptance criteria: 4 patients ( 8 eyes) were initially recruited into the prospective study, and 3 (6 eyes) had serial topography performed during their waiting period. One patient record ( 2 eyes) from Murrayhill Eye Care met the inclusion criteria, and was used for the pre- and post-waiting period comparison of corneal parameters.

Recruiting patients into the study was straightforward, since by scheduling surgery they were already agreeing to discontinue lens wear and would have corneal topography performed on one or more occasions as part of their normal pre-operative care. However, the number of contact lens wearing patients presenting for surgery during the recruiting period turned out to be much lower than anticipated. Many RGP wearers in particular had discontinued lens wear based on their optometrist's advice prior to seeing Dr. Teplick for their initial consultation, and thus were not eligible for participation in the study. Most of the RGP patients enrolled fell into the 21-30 year group, further limiting the applicability of our results to the general RGP-wearing population. We elected to pursue a case study approach with these patients to evaluate corneal changes on an individual basis. One RGP study participant was refit by his optometrist into soft contact lenses at the beginning of his waiting period and dropped out of the study. One
complication also arose with the soft lens group as well. Because the pre-operative cycloplegic exam results were used by Dr. Teplick to calculate the amount of laser ablation to perform, the recommended protocol was modified somewhat during the study period to have patients out of their lenses for one week prior to the pre-op exam. The pre-op exam was generally $1-2$ weeks prior to surgery, so some patients were allowed restart soft lens wear after the cycloplegic exam. Since their day-of-surgery topography would not be a true reflection of post-lens wear cornea, these patients had to be excluded from the study. One participant was identified and disqualified for this reason.

## Soft Contact Lens Data and Results

A comparison of the CIM, Shape Factor, and TKM values before and after the one-week waiting period was made. A summary of the PathFinder Analysis Software data for all 16 soft lens cases is shown in Table 1, along with means, standard deviations, difference means, and ttest values. Changes in mean values are summarized in Figure 1 below. In all cases, the change in mean values did not achieve a high level of statistical significance. For comparison purposes, central corneal astigmatism and corneal power data from the standard axial map are shown in Table 2.

For the Corneal Irregularity Measurement (CIM), soft lens cases showed a mean difference of -0.008 . The mean absolute value of the differences was 0.076 , and the range was from -0.29 to +0.14 . This means that while most corneas showed a change in CIM, there was no general trend up or down in this shift. In addition, the $t$-test failed to show a statistically significant difference in means at the $\mathrm{p}=0.05$ level. The $\mathrm{p}=0.3346$ value implies a $33.46 \%$ probability that the data come from the same population and therefore have the same mean.

Figure 1: Changes in Corneal Parameters for Soft Lens Wearers


Table 1: PathFinder Analysis Data for Soft Lens Wearers

|  | PathFinder Data for SCL Cases |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Corneal Irregularity |  |  | Shape Factor |  |  | Mean Toric Keratom. |  |  |
| Eye | Before | After |  | Before | After |  | Before | After |  |
| 1 | 0.51 | 0.56 |  | 0.29 | 0.31 |  | 43.6 | 43.5 |  |
| 2 | 0.7 | 0.67 |  | 0.3 | 0.35 |  | 43.1 | 43.4 |  |
| 3 | 0.46 | 0.45 |  | 0.26 | 0.33 |  | 45.2 | 45.2 |  |
| 4 | 0.4 | 0.4 |  | 0.28 | 0.35 |  | 45.7 | 45.8 |  |
| 5 | 1.09 | 1.23 |  | 0.15 | 0.11 |  | 43.6 | 43.9 |  |
| 6 | 0.65 | 72 |  | 0.14 | 0.2 |  | 43.9 | 44.1 |  |
| 7 | 0.51 | 0.63 |  | 0.14 | 0.05 |  | 46.5 | 46.1 |  |
| 8 | 0.63 | 0.63 |  | 0.11 | 0.05 |  | 46.6 | 46.2 |  |
| 9 | 0.46 | 0.55 |  | 0.21 | 0.19 |  | 42.9 | 42.7 |  |
| 10 | 0.71 | 0.58 |  | 0.17 | 0.2 |  | 43.5 | 43.4 |  |
| 11 | 0.45 | 0.4 |  | 0.22 | 0.17 |  | 44.4 | 44.4 |  |
| 12 | 0.57 | 0.45 |  | 0.22 | 0.19 |  | 44.5 | 44.4 |  |
| 13 | 0.59 | 0.6 |  | 0.13 | 0.2 |  | 45.1 | 45.7 |  |
| 14 | 0.64 | 0.7 |  | 0.22 | 0.28 |  | 45.7 | 46.4 |  |
| 15 | 0.82 | 0.53 |  | 0.4 | 0.42 |  | 41.8 | 41.9 |  |
| 16 | 0.69 | 0.65 |  | 0.34 | 0.4 |  | 41.9 | 42.2 |  |
| Mean Value | 0.617 | 0.609 |  | 0.224 | 0.237 |  | 44.25 | 44.33 |  |
| Std Dev: | 0.171 | 0.194 |  | 0.083 | 0.116 |  | 1.48 | 1.45 |  |
| Mean of Di |  |  | -0.008 |  |  | 0.0144 |  |  | 0.08125 |
| Mean of Abs. Value of Differences: |  |  | 0.076 |  |  | 0.049 |  |  | 0.244 |
| T Test (Probability of Same Mean): |  |  | 0.33458 |  |  | 0.324766 |  |  | 0.314739 |

Shape factor (SF) and mean toric keratometry (TKM) also showed small differences
between before and after values, but no general trends. The mean absolute value of the change in shape factor was small (approximately 0.05 ) with a range of -0.09 to +0.07 . The mean absolute value of change in TKM (measured in diopters) was approximately 0.25 D , with a range of -0.2 D to +0.7 D . With the $t$-test, neither change in mean value was significant with a high
level of confidence. For $\mathrm{SF}, \mathrm{p}=0.3248$, and for $\mathrm{TKM}, \mathrm{p}=0.3147$; this implies a greater than $30 \%$ probability that the means were not different.

Table 2: Axial Topography Data for Soft Lens Wearers

|  | Axial Topography Data for SCL Cases |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Corneal Cylinder |  |  | Central Corneal Power |  |  |
| Eye | Before | After | Change | Before | After | Change |
| 1 | 0.75 | 0.88 | 0.13 | 43.2 | 43.3 | 0.1 |
| 2 | 0.88 | 0.88 | 0 | 42.6 | 43.1 | 0.5 |
| 3 | 1 | 0.87 | 0.13 | 44.7 | 45 | 0.3 |
| 4 | 0.88 | 0.5 | 0.38 | 45.3 | 45.6 | 0.3 |
| 5 | 0.25 | 0.5 | 0.25 | 43.3 | 43 | 0.3 |
| 6 | 0.25 | 0.37 | 0.12 | 43.2 | 43.8 | 0.6 |
| 7 | 1 | 1 | 0 | 46.4 | 46.2 | 0.2 |
| 8 | 1.37 | 1.25 | 0.12 | 45.7 | 45.6 | 0.1 |
| 9 | 0.88 | 0.87 | 0 | 42.5 | 42.5 | 0 |
| 10 | 1.75 | 1.62 | 0.13 | 43.1 | 43.3 | 0.2 |
| 11 | 1.13 | 1.5 | 0.37 | 44.2 | 44.1 | 0.1 |
| 12 | 1.25 | 1.5 | 0.25 | 44.2 | 44.3 | 0.1 |
| 13 | 0.62 | 0.62 | 0 | 44.6 | 45.3 | 0.7 |
| 14 | 0.75 | 0.75 | 0 | 45 | 45.8 | 0.8 |
| 15 | 0.5 | 0.37 | 0.13 | 41.1 | 41.5 | 0.4 |
| 16 | 0.5 | 1 | 0.5 | 41.4 | 41.7 | 0.3 |
| Average Change: |  |  | 0.156875 |  |  | 0.3125 |

It is difficult to assess how changes in CIM, SF, or TKM might relate to changes in manifest refraction as the cornea reshapes, since they are averaged values derived from hypothetical reference surfaces. However, changes in corneal curvature noted on axial or refractive power maps should show a more direct correlation, since corneal power and cylinder contribute significantly to the overall refractive power of the eye. From Table 2, it can be seen that changes in corneal shape were small for soft lens wearers. The mean change in corneal cylinder (absolute value) was slightly greater than one-eighth diopter, with only four eyes changing by 0.25 D or more. The mean change in corneal power was less than one-third diopter, with only four of 16 eyes showing a change of 0.50 diopters or more. From a clinical perspective, these are certainly not highly significant changes, and thus correlate to the lack of
significant change noted in the PathFinder analysis. (See Appendix A for topography.)

## Rigid Gas Permeable Lens Data and Results

As with the soft lens cases, a comparison of the corneal irregularity (CIM), shape factor (SF), and mean toric keratometry (TKM) values before and after the waiting period was made for hard lens (RGP) wearers. A summary of the PathFinder Analysis results for all 8 RGP cases is shown in Table 3. Mean values of CIM, SF, and TKM are included, along with standard deviations, difference means, and t-test values. Changes in mean values are summarized in Figure 2 below, which in several instances did achieve a high level of statistical significance. Changes in corneal cylinder and power from the standard axial maps are shown in Table 4 for comparison.

Figure 2: Change in Corneal Parameters For RGP Wearers


Somewhat surprisingly, the mean corneal irregularity values did not show a significant shift. Although CIM varied in each eye during the waiting period, the mean values before and after the waiting period were very close. The mean change in absolute value of CIM was 0.196 , which indicates a fairly substantial change in irregularity for each individual eye. However, when sign is taken into account, the mean value of the difference was very close to zero. The t-
test showed a high confidence that the two sample means were not different but came from the same population ( $\mathrm{p}=0.9897$, or $98.97 \%$ probability).

Table 3: PathFinder Analysis Data for RGP Wearers

|  | PathFinder Data for RGP Cases |  |  |  |  |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Corneal Irr | larity |  | Shape Fac |  |  | Mean Toric | ratom. |  |
| Eye | Before | After |  | Before | After |  | Before | After |  |
| 1 | 0.99 | 0.52 |  | 0.18 | 0.22 |  | 45.4 | 45.1 |  |
| 2 | 0.91 | 0.79 |  | 0.12 | 0.24 |  | 45.3 | 45.9 |  |
| 3 | 0.99 | 1.41 |  | 0.19 | 0.5 |  | 42.2 | 43.6 |  |
| 4 | 1.05 | 1.27 |  | 0.26 | 0.42 |  | 43.3 | 43.9 |  |
| 5 | 0.54 | 0.5 |  | 0.12 | 0.23 |  | 42.7 | 43.1 |  |
| 6 | 0.7 | 0.55 |  | 0.08 | 0.18 |  | 42.7 | 43.3 |  |
| 7 | 0.74 | 0.8 |  | 0.1 | 0.21 |  | 45.9 | 46.9 |  |
| 8 | 0.93 | 1.02 |  | 0.07 | 0.21 |  | 44.9 | 45.8 |  |
| Mean Valu | 0.856 | 0.857 |  | 0.14 | 0.276 |  | 44.05 | 44.7 |  |
| Std Dev: | 0.177 | 0.348 |  | 0.065 | 0.117 |  | 1.471 | 1.415 |  |
| Mean of Di |  |  | 0.00125 |  |  | 0.136 |  |  | 0.6375 |
| Mean of Ab | f Differenc |  | 0.196 |  |  | 0.136 |  |  | 0.74 |
| T Test (Pro | S Same Mea |  | 0.989772 |  |  | 0.001718 |  |  | 0.007566 |

The other two measures, however, did show statistically significant shifts in their mean values. The shape factor changed from a mean of 0.14 to a mean of 0.276 . All eyes experienced an increase in shape factor over the waiting period, and thus absolute and actual mean differences were the same (0.136). The range for individual differences was from 0.04 to 0.31 . This means that all eyes assumed a more prolate shape as they returned to "normal" after discontinuing RGP lens wear. The $t$-test results showed this shift was highly significant ( $p=0.00172$ ), even with this small sample size.

Mean toric keratometry (TKM) also showed a significant change over the waiting period. One cornea's TKM value decreased, but all others increased. The mean difference was an increase of 0.6375 D , with a range of -0.4 D to 1.4 D . While not as dramatic as the shift in SF , the $t$-test showed that this change was still highly significant $(\mathrm{p}=0.00756)$.

Table 4: Axial Topography Data for RGP Wearers


The axial and refractive power topography data in Table 4 shows changes in many cases that could be deemed clinically significant. The mean change in absolute value of corneal cylinder was greater than one-half diopter, and four of eight eyes showed a change of 0.75 D or more. Similarly, mean change in central corneal power was almost one-half diopter, with four of eight eyes changing by 0.50 D or more. This appears to correspond well with the significant changes noted above in TKM and SF from the PathFinder Analysis software.

In order to address our primary goal of assessing when corneal changes have stabilized after discontinuing contact lens wear, we evaluated topographic changes to the six eyes for which serial topography was available. Values of CIM, SF, and TKM for each eye from the PathFinder analysis were plotted as a function of days after discontinuing RGP lens wear. These charts are shown on the following pages.

Several observations are immediately apparent from these plots. First, both eyes of a patient, while showing individual variations in parameters, did tend to respond in a similar fashion over the waiting period. Second, major changes in these measurements did tend to occur in the first 30 days after discontinuing lens wear, however, in some eyes, significant changes (often opposite in direction to the initial change) occurred beyond this time. Third, when
comparing changes in the same parameter, different eyes responded in a significantly different fashion over the waiting period. And fourth, the shape of the curve was not always easily described with a simple logarithmic or exponential best-fit curve.

Figure 3: Change In Corneal Irregularity Measurement (CIM) Over Time For RGP Wearers


The plots of corneal irregularity (Figure 3) show two distinct groupings that make it difficult to make generalizations about this sample. One group of four eyes began with CIM values in the normal to borderline high range and generally decreased slowly over the waiting period. Three of these eyes ended the waiting period in the normal range, and one was still borderline high, although less so than initially. There were small fluctuations from week to week, but no major change in irregularity. The other group (two eyes) began in the abnormal range (slightly above 1.0 ) and showed a marked increase in irregularity over the first 20-45 days. These CIM values then dropped to lower but still abnormal value. These eyes remained more irregular after the end of the waiting period than at the beginning. This unusual response seems
to be consistent with the findings in the 1994 Wilson and Klyce study on eyes diagnosed with significant corneal warpage. This study showed that corneal warpage increased after discontinuing lens wear and became most severe two to four weeks after removing hard lenses.

Figure 4: Change In Shape Factor (SF) Over Time For RGP Wearers


The second parameter, Shape Factor, (see Figure 4) also showed two distinct groupings among the six eyes. Four eyes began in the low normal to borderline range and moved slowly and consistently up to the middle of the normal range over the waiting period. Three of these four were fairly stable after the first 20 days; one eye showed an initial increase followed by fairly stable behavior until day 60, when it increased again (in the normal direction). The other two eyes began in the normal range but immediately increased over the first 20 days to an abnormal shape. Their shape factor then reduced slowly over the subsequent 80 days to lower but still borderline or abnormal values, which were relatively stable after 40-60 days. These were the same two eyes that had the abnormal CIM values.

Figure 5: Change In Mean Toric Keratometry (TKM) Over Time For RGP Wearers


The third parameter, mean toric keratometry, showed a more consistent response over the six eyes (Figure 5). All eyes showed an initial increase in TKM over the first 15-20 days. The four eyes with the lower TKM values did not fluctuate significantly and remained relatively stable for the remainder of the waiting period. The two eyes with the higher initial TKM values continued to gradually increase until day 50 , and then showed a decline back toward their initial values. For all eyes, the maximum fluctuation over the waiting period ranged from 0.6 D to 1.2 D above their initial value.

In an attempt to understand the behavior of these data plots, curve-fitting was undertaken using the trend line analysis routine available in the Excel spreadsheet program. Simple trend lines (logarithmic and exponential) were tried first, since they are monotonically increasing or decreasing functions which "level off" relatively quickly. A point can be found on this type of trend line where the slope of the curve approaches an arbitrarily small value and thus the
function can be considered to be stable. However, for this to be so, the trend line must be a good fit to the data. The goodness of fit is described by the $\mathrm{R}^{2}$ value, which is also calculated by the Excel routine. $\mathrm{R}^{2}$ is a measure of the amount of variability in the data that can be explained by the trend line, and a high value $\left(\mathrm{R}^{2}>0.50\right)$ implies a good fit.

If the simple functions did not produce an acceptable $R^{2}$ value, low-power polynomial functions were tried next in an effort to improve the goodness of fit. However, curve-fitting with polynomials--while it may produce better $\mathrm{R}^{2}$ values--does not allow prediction of stability, since all polynomial functions eventually increase or decrease towards infinity. Further, $\mathrm{R}^{2}$ can be made arbitrarily good (equal to 1 ) by choosing a sufficiently high polynomial order; this yields a trend line that intersects all the data points, but is otherwise of little use. When polynomial trend lines were used in the graphs below, no higher than a third order polynomial (an equation in the form $\mathrm{y}=a \mathrm{ax}^{3}+b \mathrm{x}^{2}+\mathrm{cx}+\mathrm{d}$ ) was used. If the polynomial didn't improve the $\mathrm{R}^{2}$ value significantly, the exponential or logarithmic trend line was retained.

Once an appropriate trend line was selected, an estimate was made of the point where the curve became stable. This was done in a subjective fashion by identifying where the slope of the trend line reached a relatively low value, and then verifying that the actual data points were closely grouped around the trend line from this point on.

Figure 6: Change In Corneal Irregularity Measurement (CIM) With Trend Lines


For the CIM data (see Figure 6), Eyes 1 and 2 were fit with simple exponential trend lines. Although $\mathrm{R}^{2}$ was less than 0.25 in both cases, the trend lines are relatively flat, slowly changing lines that show a general downward trend. Eyes 5 and 6 were fit with second order polynomials, and showed good to high $\mathrm{R}^{2}$ values. These curves were also relatively flat over the period of interest. Eyes 3 and 4 required a third order polynomial to describe their shape with an acceptable $R^{2}$ value. Unlike the other four eyes, which were well-behaved after day 30 , these eyes showed a large variability, which made it difficult to assess their stability at the end of the waiting period.

The trend lines for the Shape Factor (Figure 7) showed more consistent results overall. All eyes were plotted with logarithmic trend lines that appeared to be reasonably well matched to the data. Three eyes showed high $\mathrm{R}^{2}$ values, while Eyes 1,4 , and 6 had $\mathrm{R}^{2}$ values less than 0.50 . These plots appear generally well behaved after day 30 for Eyes 1, 2, 5, and 6, while Eyes 3 and 4 appear fairly stable after day 75 .

Figure 7: Change In Shape Factor (SF) With Trend Lines


Figure 8: Change In Mean Toric Keratometry (TKM) With Trend Lines


Changes in TKM appear to be well described with either logarithmic or polynomial trend
lines (see Figure 8). Eyes 1 and 2 required a second order polynomial for an acceptable $\mathrm{R}^{2}$ value, but Eyes 3-6 were fit with logarithmic trend lines. All but Eye 4 showed acceptable $R^{2}$ values. While the stability of Eyes 1 and 2 is uncertain, the remaining four appeared stable beyond day 45. (See Appendix B for topography.)

## IV. DISCUSSION

Corneal topography has shown itself to be an excellent means of assessing corneal reshaping after discontinuing contact lens wear. Despite the limited number of patient records used in this study, we feel a useful methodology can be proposed that will result in reduced waiting times for many contact lens wearers. Before addressing these recommendations, however, a brief assessment of the utility of the Humphrey topographer is in order.

The Humphrey ATLAS topography system used in this study offered many qualitative and quantitative means for evaluating corneal stability in pre-surgical patients. However, not all of the capabilities available proved to be necessary or useful in making this determination. The optional Advanced Refractive Diagnostics software module, developed to assist in managing refractive surgery patients, offered refractive power, elevation, and irregularity maps in addition to the standard axial map. The irregularity map did not prove useful because the reference toric surface is recalculated for each map, and thus the baseline for evaluating reshaping changed from map to map. The refractive power map, while providing a more accurate estimate of corneal power, did not offer a significant improvement over the axial map. Changes in corneal astigmatism and central corneal power were the same, and the astigmatic patterns and irregularities could be seen equally well on both maps.

The PathFinder Corneal Analysis module did, however, prove useful in assessing corneal distortion. The linear plots of CIM, SF, and TKM against population norms allowed a rapid
assessment of the normality of the cornea's shape. Furthermore, the software can also distinguish between contact lens-induced corneal distortion and pathology such as keratoconus, and provide an alert to the operator. While much of the necessary information is available from the standard axial plot, this module provides a very convenient and rapid means to assess the corneas of contact lens wearers. Because it can also detect subclinical keratoconus and other pathologies, it would seem to be a wise investment for any optometrist who co-manages refractive surgery patients.

Returning to the soft contact lens results, this study showed that there is very little corneal reshaping once lens wear is discontinued. The slight changes in CIM, SF, and TKM were not statistically significant, and even if they had been, they may not have been clinically significant in terms of change in refractive error. This is borne out by the fact that the mean values of change in corneal astigmatism and central power taken from the axial topographic map (which should correlate more directly to refractive error changes) were small: 0.15 D and 0.3 D , respectively. This implies that a short waiting period, while a good idea to ensure any corneal irregularity is resolved, can perhaps be dispensed with without introducing even a moderate amount of uncertainly in the final outcome of the refractive surgery. However, if a waiting period is recommended, it should be prior to the patient's cycloplegic exam, because these findings will be used by the surgeon to plan the laser correction.

Our proposed protocol for soft lens wearers would thus incorporate corneal topography primarily to rule out pathology. The suggested timeline is as follows:

1) Initial screening with topography (PathFinder Analysis) to rule out corneal distortion and pathology;
2) If no pathology or distortion, discontinue lens wear 3-7 days prior to cycloplegic examination;
3) Cycloplegic examination 3-7 days prior to surgery (lens wear after this exam optional until day of surgery).

Detection of pathology should contraindicate surgery until is has been resolved. In the event that significant corneal distortion is found, the patient should discontinue lens wear and be evaluated weekly with topography until the cornea has stabilized.

The need for a waiting period for RGP wearers is much more apparent, as our study results confirm. Statistically significant changes in SF and TKM mean values before and after the waiting period were found. Although the before and after mean CIM values were not statistically different, individual eyes showed a substantial change in CIM over the waiting period. Corneal astigmatism and central power showed much larger changes in mean value than the soft lens group--0.50D and 0.60 D , respectively.

Because there is significant variation in when these corneas become stable, it appears best to divide them into two groups based on initial topography: those eyes that appear relatively "normal," and those that show corneal warpage or distortion. From our RGP data, Eyes 3 and 4 appear to fall into the "warped" category, while Eyes 1, 2, 5, and 6 appear "normal." From the trend line assessment, the point of corneal stability for these two groups is shown in Table 5.

Table 5: Point of Corneal Stability for RGP Wearers

| Shape Parameter | Normal Eyes | Warped Eyes |
| :---: | :---: | :---: |
| CIM | 30 Days | 75-90 Days |
| Shape Factor | 30 Days | 60-75 Days |
| TKM | 30-60 Days | 30-45 Days |

This suggests that a new protocol for determining waiting periods prior to surgery can be developed. Rather than length of RGP wear, the presence of corneal warpage or significant distortion will be the key factor. The proposed protocol would in this case be as follows:

1) Initial screening (before discontinuing RGP lens wear) with PathFinder analysis to rule out pathology and detect corneal distortion if present;
2) A second topography at 3 weeks after discontinuing lens wear to distinguish between "normal" and "warped" eyes:
--Normal eyes will show small changes in CIM (less than 0.5) and in the direction of the population mean of 0.63 ; small changes in SF (less than 0.15 , and generally towards the center of the normal range of 0.13 to 0.35 ); and modest increases in TKM (perhaps up to 075D).
--Warped eyes will show large changes in CIM, and in the borderline or abnormal direction; large changes in SF, again in the borderline to abnormal direction; and moderate increases in TKM (perhaps greater than 0.75D).
3) For "normal" eyes, schedule surgery at least 30 days after discontinuing lens wear, with cycloplegic exam approximately one week prior;
4) For "warped" eyes, schedule surgery no sooner than 75-90 days after discontinuing lens wear. (Additional serial topography may be advisable to verify that the eyes have stabilized prior to conducting the cycloplegic exam.)

## V. CONCLUSION

Heeding the call of earlier researchers such as Ruiz-Montenegro, we have taken advantage of modern computerized corneal topography technology to propose a new protocol for managing contact lens patients prior to laser refractive surgery. Careful topographic analysis should allow many long term RGP wearers who do not show signs of corneal warpage to
undergo laser surgery significantly sooner than the 2-3 month wait dictated by current rules of thumb. Our results also indicate that short waiting periods for soft lens wearers may be a prudent precaution, but not a necessity.

As with any study, we feel many more questions were raised than were answered with our research. The small number of eyes assessed is an obvious limitation on the statistical significance or relevance of our results to the general population of contact lens wearers. Because our data showed that both eyes of a patient generally responded alike, they cannot in reality be treated as independent samples for statistical purposes. No data from hyperopes was collected, since the procedure had not been approved when the study was initiated. While we attempted to control as many variables as possible, many uncertainties still remained: the accuracy and repeatability of the topographic maps; whether any diurnal variation in topography exists; whether any particular RGP material, fitting philosophy, or wear schedule would correlate to our "warped" findings; and so on.

Furthermore, we did not attempt to assess how significant an influence on final outcome corneal warpage actually is, compared to other sources of variability in the laser surgery procedure (such as the accuracy of cycloplegic refraction used, the accuracy of the nomograms used to calibrate the laser, the accuracy and smoothness of the ablation, the healing of the LASIK flap, etc). These are all areas ripe for further research in an effort to reduce variability and improve the ultimate outcome and accuracy of the refractive surgery process.

We trust that this initial effort has contributed meaningfully to this end and will stimulate further research to make refractive surgery a safer and more convenient option for those who choose it.

## APPENDIX A

Advanced Refractive Diagnostics


Advanced Refractive Diagnostics


Advanced Refractive Diagnostics



Advanced Refractive Diagnostics



# Advanced Refractive Diagnostics 



Advanced Refractive Diagnostics



## Advanced Refractive Diagnostics




Advanced Refractive Diagnostics



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## Advanced Refractive Diagnostics




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