A Study of Corneal Sphericalization Obtained With Radial Keratotomy Versus That Following Ortho-keratology

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OBJECTIVE:

The goal of this project was to compare the corneal sphericalization obtained after ortho-keratology with that following radial keratotomy. A total of ten subjects were used in this study. Five of those underwent the ortho-keratology procedure while a second five, with similar refractive errors to the first group, had radial keratotomy. Both of the groups were under the professional care of an optometrist and ophthalmologist, respectively. In both cases, the EyeSys corneal topographical mapping system was used to monitor the corneal changes as they occurred and to allow for any necessary modifications or enhancements of procedures. We attempted to show how these corneal changes could be controlled and how a corneal mapping system could be used to monitor the corneal sphericalization.

INTRODUCTION:

Ortho-keratology (ortho-k) can be defined as the manipulation of the fitting characteristics of a rigid contact lens to flatten the anterior surface of the cornea and decrease the amount of myopia and/or astigmatism. Radial keratotomy (rk) can be defined as the surgical alteration of the anterior surface of the cornea by making radial incisions in a pie-shaped pattern from the central cornea to the periphery. Rk is also utilized to decrease myopia and/or astigmatism. Both ortho-k and rk have benefited from advancements in both the techniques and the materials used. Ortho-keratology now has more normalized data for fitting the contact lenses and for the parameters used to manufacture the lenses. There have also been great improvements in the development of new lens materials which are more comfortable for the patient and allow for a healthier cornea by means of greater oxygen transmissability. Radial keratotomy has improved by utilizing much better and more consistent nomographic datafrom increasing numbers of cases. There have also been technological advances in the materials used to fabricate the diamond blades used in the procedure. Along with these better blades, there have been improvements in the ability to

accurately set the blade depth. Lastly, the use of corneal mapping systems in both ortho-k and rk allow a much more detailed picture of the cornea. The mappings allow the clinician to see corneal changes as they occur and base any procedural changes accordingly. In effect, the initial mappings can be compared to subsequent ones to determine how much and what type of change is occurring. In the case of ortho-k, a change in lens parameter would be necessary to allow for better centration and acceptable fluorescein pattern. In the case of rk, enhancements would be used to achieve the necessary corneal changes.

Our study was designed to investigate how ortho-keratology and readial keratotomy differ in their effects on the cornea as a whole entity. We realized that the goal of both procedures is to minimize the patient's myopic refractive error; our main concern was to ascertain the amount of change that occurred in regard to the overall sphericalization of the cornea at certain points outside the central cornea. We felt the data would be most accurate with the use of a corneal topographical mapping system.

METHODS:

Ten subjects were picked from a clinical population and entered into the study. These subjects had spherical equivalent refractive errors between -2.25 diopters and -4.37 diopters. They ranged in age from 22 to 29 years old. Five of the subjects underwent ortho-keratology with as many lens changes as were necessary to achieve best unaided Snellen acuity. The other five subjects underwent radial keratotomy with as many enhancements as were necessary to achieve best unaided Snellen acuity. All subjects in both groups had initial and post-procedural corneal mappings. The corneal shape was monitored through the course of both procedures to allow for any necessary contact lens changes or enhancements.

Each member of the ortho-k group had a correlate in the rk group with a similar, if not identical, pre-procedural spherical equivalent refractive error. We also chose to limit the amount of allowed corneal astigmatism to no more than one diopter. All patients were screened for the two procedures based on the accepted nomograms for both. The

maximum allowable amount of myopia was six diopters. Rk patients were screened based on age and their refractive error being allowable based on accepted nomograms. All patients had pre-surgical spherical equivalent refractive error of less than six diopters which tends to provide the best resultant visual acuity. Patients in both groups underwent comprehensive eye examinations with emphasis on unaided Snellen visual acuity, keratometry, spectacle refraction, and ocular health. They were to have healthy corneas free of any underlying pathology. All patients signed an appropriate informed consent in which the nature of the procedures being performed was explained. All patients in both groups had corneal mappings using the EyeSys corneal topography system.

Patients in the ortho-keratology group were fit with specially designed contact lenses from Contex, Inc. These lenses were made of a rigid gas permeable material with a relatively high dk value (oxygen permeability), good wettability, and good optical quality. These lenses, which are used specifically for ortho-k, are unique in that they have a secondary curve which is steeper than the base curve. This steeper curve allows the cornea to be gently and safely flattened. The peripheral curve is also of an aspheric design to allow for better fit and comfort.

Patients in the radial keratotomy group had their procedure performed by a licensed ophthalmologist. They underwent an initial procedure based on accepted nomograms. All procedures were done on an out-patient basis with the patient receiving a mild sedative and post-operative anesthetic eye drops. Patients were also given antibiotic eye drops for prophylaxis. Due to the potential hyperopic shift following the surgery, some patients were initially left relatively undercorrected. These patients underwent follow-up and had any enhancements deemed necessary.

RESULTS:

Figure 1 shows the eligibility requirements for the study. Figures 2 and 3 show pre, post, and differential mappings of one of the ortho-k subjects along with the same types of mappings for his correlate in the rk group. The mapping used as post-procedural was taken

after the patient had achieved best visual acuity and undergone all lens changes or enhancements. Figure 4 shows the intial patient spherical equivalent refractive error as found by refraction. Figure 5 shows the final (post-procedural) spherical equivalent refractive errors for both groups as found by refraction. In all cases there was a decrease in the amount of both myopia and astigmatism. Figure 6 shows the total decrease in corneal power at points taken 1.25 and 2.50 mm from the center of the cornea. The orthok group showed a change in corneal power of an average of -1.43 diopters at the corneal center, -.84 diopters circumferentially at 1.25mm from the center, and -.64 diopters circumferentially at 2.50mm from the center. The values were determined by averaging the differential corneal powers at the points selected superiorly, inferiorly, nasally, and temporally at the given distances. The rk group showed a change in corneal power of an average of -1.52 diopters at the corneal center, -1.04 diopters circumferentially at 1.25mm from the center, and -.68 diopters circumferentially at 2.50mm from the center. These values were also found by averaging the circumferential values at the given distances.

DISCUSSION:

The results of the study showed that both ortho-keratology and radial keratotomy were effective procedures for the reduction of myopia and astigmatism. Most patients who undergo these procedures are happy with the final unaided visual acuity and are subject to no deleterious visual effects. In this study, it was found that the corneas of our patients reacted in a very predictable way to both procedures. The ortho-k subjects had a very nice central reduction in corneal power with a gradual flattening as one moved out toward the peripheraly. Although some lenses tended to ride a bit high on the patients' corneas and induce a slight inferior steepening, possibly due to the superior lid-lens interaction, the corneas did tend to sphericalize and a reduction in the overall amount of corneal astigmatism was observed in all cases. The large absolute deviation in corneal power in the

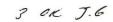
superior cornea. We feel this could be overcome with a prism ballasted lens design which would allow better centration.

The rk group had a very nice reduction in central corneal power with a gradual decrease in reduction as one moved out away from the center. As would be predicted, there is actually a steepening of the far peripheral cornea due to the pushed in nature of the central cornea. The cornea did tend to sphericalize very well centrally and all patients had a reduction in the overall corneal astigmatism. There was a much smaller amplitude in deviation in corneal powers due to the relatively equal removal of power from the central cornea.

It was interesting to find that although the two groups had undergone two completely different procedures, both the ortho-k and rk corneas presented very similarly at follow-up. There was a relatively large reduction in central corneal power with a less marked reduction as one moved out to the periphery. In both cases, the corneas did undergo sphericalization with a decrease in overall corneal astigmatism. We feel that the EyeSys corneal topographical mapping system provided a remarkably accurate and detailed view of corneal curvature. It is a great tool which will allow much better control of future procedures to change anterior corneal curvature.

Ortho-k/ Rk Study Eligibility Criteria

- Spherical equivalent refractive errors less than six diopters
- No more than one diopter of corneal astigmatism
- Must be free of keratoconus or any other corneal pathology



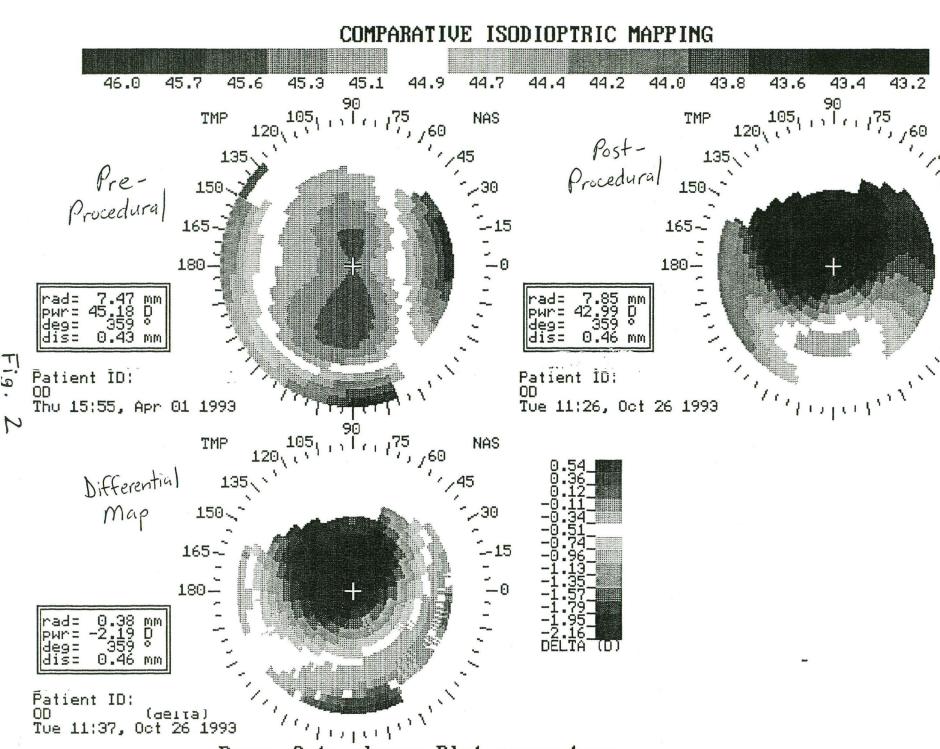
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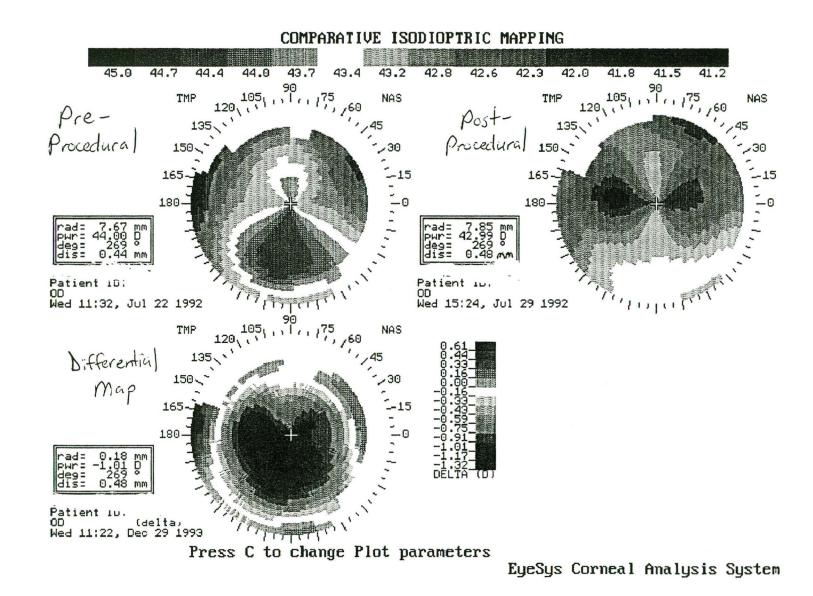
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EyeSys Corneal Analysis S__tem



Initial Spherical Equivalent Refractive Errors

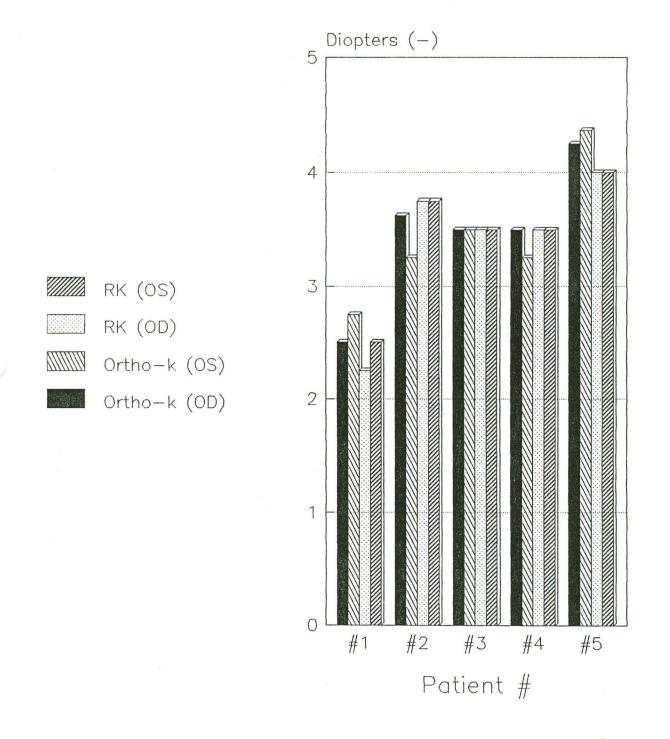


Fig. 4

Final Spherical Equivalent Refractive Errors

