

# **A Study of the Effectiveness of CK One-Step Lenses for Correcting Myopia**

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## **ABSTRACT**

Myopia (nearsightedness) may be corrected by using non-surgical and surgical techniques. Orthokeratology, the practice of wearing rigid contact lenses during waking hours, has been used to reduce myopia with minimal success. Recent advances in corneal mapping and contact lens technology have greatly improved lens fitting techniques. In the present study Precision Ocular Technology's CK "One-Step" lenses were used to mold the corneas of 17 myopic patients. The subjects wore the lenses while sleeping in an effort to decrease their need for corrective lenses during waking hours. Each subject's eyes were checked on days 1, 7, 30, and 60 after lens fitting for visual acuity, refractive error, corneal topography, and intraocular pressure (glaucoma test). Post-fit measurements were compared to initial values. Patients were surveyed after 60 days to assess comfort and satisfaction with the procedure. Fourteen patients completed the study through day 30 and had significant corneal flattening and significantly decreased myopia and increased visual acuity. The patients that dropped out of the study were all adults and were advised that the procedure may be less effective for correction of myopia in adults. The remaining patients expressed only mild discomfort in wearing the lenses and reported satisfaction with the procedure.

## **INTRODUCTION**

For years efforts have been made to control or reduce myopia. Precision Corneal Molding (PCM) is a non-surgical approach to sight correction that is available for both adults and children. Sight correction is accomplished by reshaping the cornea with a special contact lens. Reshaping a person's cornea is not a new idea. The early Chinese pressed bags full of sand against their eyes to temporarily improve their sight. In 1962, a man by the name of Jessen tried to improve sight by having people wear flat contact lenses that did not have a prescription in hopes of flattening their corneas. This resulted in great discomfort and corneal irritation (Ruston et. al., 1997).

Even though Jessen's study was not successful, the idea was born and several attempts were made to improve sight using contact lenses. Then, in 1976, Kerns conducted the first major research project to study the effects of orthokeratology (Ruston, et. al., 1997). Orthokeratology has been defined as a "reduction, modification, or elimination of refractive anomalies by the programmed application of contact lenses or other related procedures" (Edrinton et. al., 1996). At the time, this was a huge step, but since improvements in sight were neither consistent nor great, orthokeratology never advanced.

There are three main causes of myopia. First, myopia can be the result of environmental conditions. The more close-up work a person does, the more likely that person is to become nearsighted. Myopia can also be congenital; some people are born nearsighted. There is also evidence that suggests that myopia may have genetic foundations. Whatever the cause, myopia is progressive and results from a lengthened eyeball or over-curved cornea.

Recent advances in corneal mapping and contact lens technology have greatly improved contact lens fitting techniques and optometrists' understanding of the shape of the cornea. These great advances have led to a new nonsurgical approach called PCM (Tieg, 1997). An optometrist begins by evaluating the base curve of the patient's eye lens by using a topographer. A special contact lens is then made for the patient to wear, usually at night while sleeping. Over time, and even sometimes overnight, the cornea is flattened and the person's sight is greatly improved or, ideally, totally corrected. Little research has been done to show the effectiveness of PCM. Therefore, the purpose of this study was to determine the effectiveness of PCM on patients that were deemed good candidates for the procedure.

## **METHODS**

### **Subject Selection**

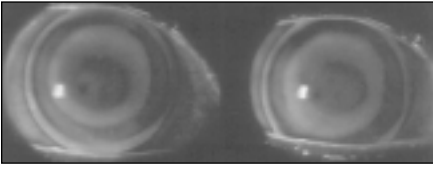
Richard Foss, O.D. of the Family Vision Center in La Crosse, Wisconsin agreed to be the expert advisor of the study. The subjects were seventeen myopic patients from Dr. Foss's clinic. Subjects were recruited by sending out postcards to 750 nearsighted patients. The files of patients interested in being PCM subjects were thoroughly reviewed to determine if the procedure would be appropriate and beneficial for them. This review also determined if the patient's degree of myopia fell within the guidelines of this research study.

### **Lens Fitting**

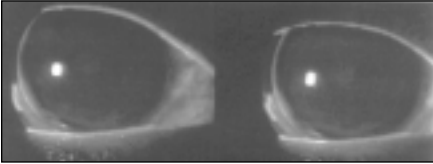
Before the CK One-Step lenses (Precision Ocular Technologies Corporation, Elkhorn, NE) could be ordered, subjects had a comprehensive eye exam and signed a consent form. The exam included K-reading in which a measurement of the flattest and steepest regions of the central three millimeters of the cornea was taken. Dr. Foss used a slit lamp to assess the health of the cornea, and performed a glaucoma test on each subject.

The lenses were ordered according to the individual subject's K-readings. Initial measurements of the subjects were taken during the evening of the first night the subject was to wear the lenses while sleeping. The measurements included visual acuity (how well the subject could see compared to a person with perfect sight at 20 feet), K-reading, prescription, and topography. The subject was then taught how to insert, remove, and care for the lenses.

Fluorescein patterns were checked as well to ensure that that lenses were fitting properly. On day 0, when the lenses were first worn, the tears were stained with fluorescein. Using a slit lamp with a special light that made the fluorescein glow, the fit of the lens could be seen. Where it was black, there were no tears indicating that the lens was touching the cornea. An initial good fitting lens (Figure 1) should appear like a bull's eye when viewed under fluorescence microscopy. The middle should appear black since the goal is to flatten the central part of the cornea. Surrounding the black region should be a ring that glows, followed by a region of slight touch, and finally edge lift which will glow. If the lenses are too tight (Figure 2) no fluorescein can get under the lenses and the eyes would be viewed as all black with no glowing areas. In this situation, the subject would not be allowed to wear the lenses, and a new pair with a looser fit would be ordered. Once the corneas were completely reshaped, the fluorescein pattern appeared evenly with a faint bull's eye pattern.



**Figure 1: Fluorescein pattern of good fitting "One Step" Lenses. Photos reprinted with permission from Dr. Phil Gildersleeve, O.D.**



**Figure 2: Fluorescein pattern of bad fitting "One Step" Lenses. Photos reprinted with permission from Dr. Phil Gildersleeve, O.D.**

### Monitoring Outcomes

The same measurements as above were then taken on day one in the morning (right after sleeping in the lenses for the first time), and on days 7, 30, and 60. At the end of the study, subjects filled out a survey regarding the comfort and their overall opinion of the procedure.

Corneal topography was one of the methods used to monitor the progress of reshaping the cornea. The topographer (Humphrey Instruments, Dublin, CA) utilizes placido disk technology with computer analysis interface. The placido disk contains many rings of light that shine onto the subject's eye. As light reflects off of the cornea, thousands of data points are analyzed and used to reconstruct the corneal surface with a high degree of precision into a tangential map which can then be printed to study.

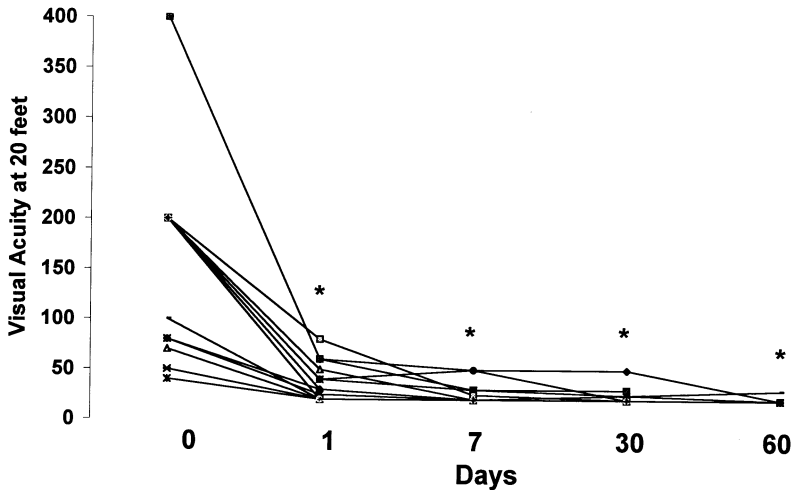
## RESULTS

All data from days 0, 1, 7, 30, and 60 were analyzed using paired t-tests. Several different measurements were analyzed using this method.

A perfect prescription is plano or zero diopters. As a person gets more nearsighted, the prescription gets more negative by quarters of a diopter. The prescriptions of both the right and left eyes were significantly different on days 1, 7, 30, and 60 from day 0 (no intervention) with p-values of  $p < 0.009$  and  $p < 0.01$  for the right and left eyes respectively. The data shows that the subjects' prescriptions advanced towards plano in both the right and the left eye.

Visual acuity is a measurement of how clear a person can see. Normal vision is 20/20. If person "X" has 20/400 vision, this means that a person with normal vision can see clearly at 400 feet, person "X" can see clearly at 20 feet. On the Snellen chart, or eye chart, the big "E" at the top represents 20/400 vision. Figure 3 shows the data points obtained for the visual acuity from the 17 subjects.

The flattest region of the right cornea was significantly flatter from day 0 with a p-value  $< 0.02$  at days 1, 7, 30, and 60. The goal of the CK One-Step lenses was to flatten the central portion of the cornea. The steepest region of the right cornea was significantly different from day 0 with a p-value  $< 0.007$  on days 1, 7, and 30. Day 60 was not significantly different because one subject decided to try to skip a night wearing the lenses, and the cornea became steeper again. The shapes of the left corneas in the flattest region on all post-fit days were



**Figure 3: Visual acuity of subjects wearing the "One Step" lenses for correction of myopia. The asterisk (\*) indicates a significant difference from Time 0 (no intervention),  $p < 0.0001$  as determined by paired t-test.**

significantly different from day 0 with a  $p$ -value  $< 0.008$ . The steepest regions of the left corneas were significantly different from day 0 as well, with a  $p$ -value  $< 0.01$ .

The goal for the shape of the cornea was different from that of the prescription and visual acuity. In the latter two, the goal was to achieve 20/20 and plano, respectively. The corneal shape should become flatter (decreased diopters) than the original. It was individualized for each subject; there was no common goal.

## DISCUSSION

CK One-Step lenses significantly flattened the central region of the corneas of most patients. There was an increase in visual acuity or a decrease in myopia, which means the subjects became less nearsighted. The subjects' visual acuity improved and 14 out of the 17 improved their visual acuity to 20/20.

There were a few limitations that were encountered during the study. The most significant was that the Corneal Topography Clinical Guide was not published until the study was completed. Dr. Foss purchased the corneal topographer to be used to help determine what lenses needed to be ordered for each subject. Without the guide with instructions for use of all of the features of the topographer, it could only be used to monitor the progress of reshaping the cornea.

When working with human subjects, it is hard to control and monitor them at all times. There were a few instances when subjects could not come into the office on the exact day especially if, for instance, day 60 was on a Sunday and the subject was out of town. If a subject decided to skip a night wearing the lenses, the data would reflect improper use of the lenses.

Of the four subjects that dropped out of the study, two wore hard contact lenses. Dr. Foss advised these two subjects that the chance for success was not optimal, however, they wanted to participate. It is known in optometry that people who wear hard lenses do not have success with reshaping the cornea using contact lenses. The exact reason why this is true is not known. However, it has been found that the use of hard lenses in general often stabilizes a person's vision. Two remaining limitations were the number of participants in the study and the length of the study. No long-term results could be determined, and with only 13 subjects completing the study, it is hard to make generalizations for the entire myopic population.

PCM with the use of CK One-Step lenses effectively corrected myopia in most patients. Overall, patients properly using these lenses exhibited a decrease in prescription, better visual acuity, and flattening of the central cornea. PCM would be a more desirable procedure if the results were more predictable. However, the guide has now been published for use of the corneal topographer and evaluation can be made as to what kind of correction a patient is likely to obtain.

The future of PCM looks bright. New technological advances for the fitting and design of the lenses are being made continually. This will increase the accuracy of how well the lenses fit as well as the ability of lenses to reshape the cornea.

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