

# Improving a Keratoconus Lens Design

Changes to a keratoconus design allow practitioners to offer improved vision with a similar lens fit.

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Dr. Rose is the designer of the Rose K lens. He practices optometry in Hamilton, New Zealand, where he specializes in keratoconus and post-graft contact lens fitting. He has presented papers worldwide on a variety of contact lens topics and is an inaugural fellow and former president of the New Zealand Society of Contact Lens Practitioners

Fitting keratoconus patients remains one of the greatest challenges that GP fitters face today. The unusual profile of the keratoconic cornea doesn't allow use of conventional GP lenses with their large back optic zones because they cause misalignment and subsequent tear pooling and sealing between the back surface of the GP lens and the cornea. Also, the number of fitting curves needed to effectively fit the diverse nature of keratoconic corneas dictates the need for a fitting system that practitioners can easily apply across the whole range of the disease.

The ideal GP contact lens design mimics the shape of the cornea over the main body of the lens, so it causes no distortion to the normal shape of the cornea. But it also must have sufficient edge lift (similar to the principle of a water ski), so that the lens will glide across the surface of the cornea without the edges disrupting the corneal epithelium. Correct edge lift also promotes good tear exchange to prevent the tear layer behind the lens from becoming stagnant, which results in corneal hypoxia and subsequent corneal edema. In keratoconus,

in which the central cornea shows less sensitivity than do normal corneas, failure to fit the cornea correctly and attain adequate tear exchange can result not only in edema and reduced wearing time, but eventually will lead to scar tissue formation and subsequent loss of best vision.

The keratoconic cornea is not like a normal cornea because it has multiple curves that give rise to irregular astigmatism, with the steepest curvature at the cone apex bearing no resemblance to the peripheral cornea. A topographical map shows the huge variety of curves on the keratoconus cornea. Fitters must determine how to align the posterior surface of the lens with this variety of corneal curves to cause the least possible stress to the already weak, insensitive keratoconic cornea.

## Technology Lends a Hand

Over the last 15 years, we've seen major developments in computer lathes that now allow fitters to order lenses manufactured in nearly any shape they can imagine. These advances have led to innovative designs, and one of these was the Rose K lens (Blanchard Contact Lens, Inc.), which

entered the US market in 1995. This design has up to six different curves across the back surface of the lens and a decreasing optic zone as the base curve steepens to try to align the back surface of the lens as accurately as possible with the unusual shape of the keratoconic cornea. The lens design also predicts changes that occur in the corneal shape as the condition progresses, so fitters typically don't need to change to a different design. This design (and its fitting system) has proven successful and today has become, I believe, the most prescribed GP design for keratoconus in the world.

### Design Difficulties

However, patients and fitters were reporting some problems with all GP keratoconus designs that incorporate a small back optic zone and multiple secondary curves. Patients would report ghosting and poorer peripheral vision as compared with conventional-design lenses, which typically have only one curve over the majority of the back surface of the lens. Also, the flatter the fit, more often the better the acuity, which posed a problem for fitters. Patients found these visual effects more noticeable in poor light, where the pupil was dilated, and in more advanced keratoconus. The three main factors that cause these visual problems are as follows:

1. **Spherical Aberration**, which is on-axis aberration that results in a series of focal points along the visual axis (Figure 1). This occurs mainly because the front and back surfaces of the GP lens aren't parallel to each other. Steeper base curves require greater minus power on the front of the lens to compensate, therefore resulting in more dissimilar front and back curves. This is why spherical aberrations are more noticeable in higher-powered lenses that have steep base curves, such as in the design of a typical keratoconus lens. In a normal GP lens in which the two surfaces are more parallel, spherical aberrations aren't nearly as noticeable and often have little effect on the overall acuity.

2. **Small Optic Zone.** To prevent tear pooling within the optic zone of the lens, the back optic zone must be considerably smaller in keratoconus GP designs, often smaller than the average pupil size, particularly in dim lighting conditions. With the Rose K design, the back optic zone becomes smaller as the base curve steepens and may be less than 4mm wide with steeper base curves. As a result, patients view through some of the secondary curves outside of the optic zone, which causes a second "ghost" image for the patient.

3. **Multiple Secondary Curves.** To match the rapid flattening of the keratoconic cornea outside of the cone, secondary curves of keratoconus lenses must flatten much more rapidly than in a conventional GP design. The width of these curves must also be considerably narrower to allow the posterior surface of the lens to remain as parallel as possible to the dramatic curvature changes across the cornea. With the Rose

K design, particularly for steeper base curves in which the optic zone is small, the patient may be looking through at least two secondary curves as well as the optic zone, causing several focus points and subsequent ghost images for the patient.

Up until recently, we've tolerated these visual effects as being one of the unfortunate side effects of the keratoconus GP design. I have worked to resolve them with the new Rose K2 contact lens.

### Improving Vision, Maintaining Fit

We can reduce spherical aberration by slightly changing the curves on the lens surface so that light rays passing through different parts of the lens come closer to focusing at a single point on the retina (Figure 2). We can place these aberration curves on the back, front, or back and front of the lens.

Clinical trials with many patients showed that major visual improvement came from placing a conic curve over the back of the lens over the optic zone area. This not only improved best visual acuity for

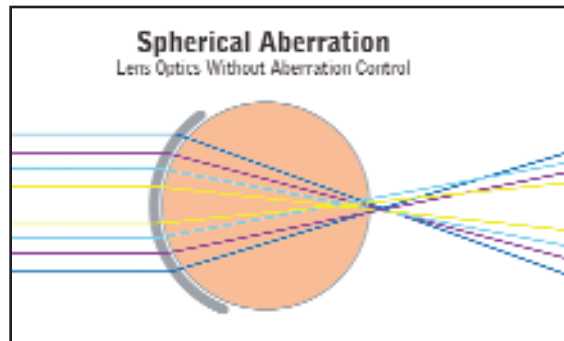


Figure 1. Lens-induced spherical aberrations cause light rays to strike the retina in multiple focal points.

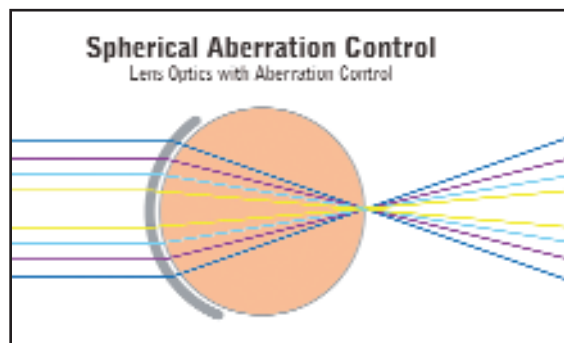


Figure 2. Changing the curves of the lens surface enables light rays to converge to a single point.

patients, but also made it easier for fitters to determine an accurate end refraction point because patients no longer had to choose among multiple images. Keratoconus patients are notoriously difficult to refract, and large power changes of more than +1.00D and -1.00D often seem to have little effect on acuity in the refracting room, particularly in advanced cases. I usually try to end my refraction in lighting conditions that duplicate those that the patient would most likely experience during most of his waking hours. It's not uncommon to find 0.50D to 1.00D differences with the refracting room lights on vs. off.

Placing aberration curves on the front didn't provide the same visual improvement and also resulted in poorer near vision for some presbyopes. It also worsened vision in some patients in which the lens was riding low. However, it offered an advantage in that it didn't change the fit at all.

Placing aberration curves on the back improved vision for the vast majority of patients, didn't affect near vision for presbyopes and, surprisingly, improved the comfort of the lens for a significant number of keratoconus patients already wearing Rose K lenses. However, any changes on the back surface of the lens could potentially affect the fit, and I felt it was imperative that fitters could continue to fit Rose K2 lenses with their original Rose K trial sets.

Therefore, the biggest challenge was how to improve the vision and comfort of the Rose K lens without changing the fit.

The small back optic zone still posed a problem even with the aspheric conic section over the back optic area. However, by stretching the optic zone slightly while making sure it didn't affect the fit clinically, we significantly reduced the ghosting that patients experienced with their previous Rose K lenses.

Choosing eccentricity values for the conic section over the back optic zone is critical to provide an optimum single focal point and depends on the power, base curve, refractive index of the material, edge lift and center thickness of each Rose K lens. We wrote a computer program which considered all of these factors. The program produced an eccentricity value that would optimize focus over the optic zone and the first secondary curve of the lens to bring the fo-

cus as close as possible to a single point. In the UK, we've also added aberration curves to the front of the Rose K lens, but by far the majority of visual benefit comes from changes to the back surface of the lens.

Replacing the central spherical optic zone with an aspherical (conic curve) optic zone that flattens from the center of the lens outward reduced the sagittal

height of the original Rose K lens design of the same base curve, which clinically caused the Rose K2 lens to fit slightly flatter centrally than the original Rose K design. To compensate for this, we needed to make small changes to the base curve to give the Rose K and Rose K2 identical sagittal heights so they would fit identically. For example, for an original Rose K lens with a 5.5mm base curve, 9.0mm overall diameter, -16.50D standard edge lift design in Boston XO (Bausch & Lomb) with an eccentricity value of 0 (a

sphere) and sagittal height of 1.8418, the final cut parameters of the Rose K2 lens would be 5.43mm base curve, eccentricity value of 0.678 and a sagittal height of 1.8418. In this example, we have to steepen the base curve of the Rose K2 lens by 0.07mm to give the lenses the same sagittal height of 1.8418. The computer program has chosen an eccentricity value of 0.678 for Rose K2 to provide the optimum single focal point, taking into consideration the base at 5.5mm, the power of -16.50D, Boston XO's refractive index of 1.415, the standard edge lift and the center thickness of the lens at 0.10mm.

If we now take the same lens, but with a power of -26.50D instead of -16.50D, then the program would now choose an eccentricity value of 0.728 and you would need to make a different adjustment to the Rose K2 base curve.

If we leave the power the same at -16.50D but change the base curve to 6.5mm, then the eccentricity value would change again to 0.653.

So in refitting Rose K patients into Rose K2, nearly every Rose K2 lens will have a slightly different eccentricity value on the back of the lens depending on the original lens' base curve, power, lift value, center thickness and material, and the final base will change slightly compared with the original Rose K design to compensate for the loss in sagittal height that the aspheric surface causes.

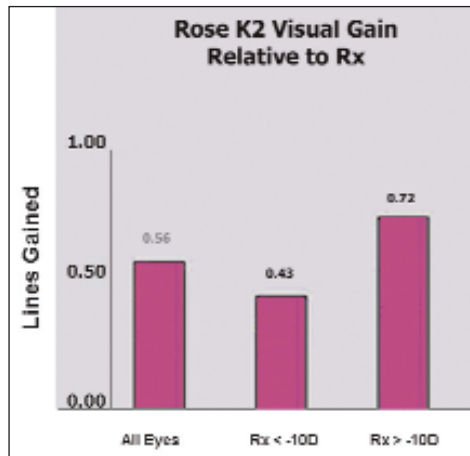


Figure 3. Rose K2 provides greater visual gains for higher prescriptions.

## Rose K2 Patient Trial

Blanchard Contact Lens, which became the master distributor for Rose K for North America in June 2004, wanted to launch Rose K2 in the United States because this design had already been available in the UK for more than one year. However, Blanchard wanted to quantify the benefits that the new design provides before offering it to the US market. The company therefore conducted a trial using several Rose K practitioners and more than 100 eyes.

### Study Protocol:

- The trial involved only existing wearers of Rose K lenses.
- Blanchard provided study patients with new original-design Rose K lenses in their current parameters in Boston XO material to set a baseline so that patients would compare two new sets of lenses (one of each design) rather than comparing old Rose K lenses with new Rose K2 lenses. This also ensured that the same manufacturer (Blanchard) manufactured all of the study lenses in the same material.
- Patients wore their new original Rose K lenses for at least one week to establish a baseline.
- Patients then wore the new set of Rose K2 lenses for a minimum of two weeks. Blanchard asked the dispensing practitioners to make any comments about the fit of the Rose K2 lenses compared with the original Rose K design.
- Following at least two weeks of Rose K2 wear, both patients and practitioners evaluated the lenses. The evaluation form requested:
  - Basic information about the lenses (base curve, power, etc.)
  - High contrast visual acuity with both sets of lenses (The study didn't record low contrast visual acuity.)
  - Fitting characteristics
  - Evaluation of visual performance
  - Evaluation of comfort

## Study Results

**Vision** The study evaluated visual performance for all eyes and broken down into two subgroups: One for lens powers less than  $-10.00D$  and one for lens powers more than  $-10.00D$ , to see if visual gains were more noticeable in one group as compared with the other (Figure 3).

This evaluation showed a monocular gain of 0.56 (over half a line on the Snellen Chart) for all eyes. The gain was 0.43 for patients whose contact lens prescription was less than  $-10.00D$  (Figure 4), whereas the gain was 0.72 for patients whose prescription was more than  $-10.00D$ . This indicates that the higher the prescription, the more monocular visual gain a patient receives with Rose K2.

Although the study didn't measure binocular visual acuity, I believe it's safe to assume that patients would experience a greater overall visual gain binocularly with Rose K2 Aberration Control lenses than the measured monocular vision.

**Fitting** No practitioners reported any clinically significant differences in the fitting characteristics between the original Rose K design and Rose K2.

**Comfort** For all patients, 84 percent said that the comfort of Rose K2 was the same as or better than Rose K and 68 percent reported that comfort was better or much better. No patients reported that Rose K2 was less comfortable than Rose K.

**Patient and Practitioner Preferences** For all eyes, 96 percent of patients and 90 percent of practitioners preferred the Rose K2 Aberration Control Lenses to the original Rose K lenses.

## Summary

The majority of patients and practitioners preferred the Rose K2 Aberration Control design to the original Rose K design. It was gratifying to find that these findings were consistent with trials I had conducted on 50 of my own patients. Blanchard's findings were also consistent with findings in the UK and some European countries where Rose K2 is available. Rose K2 has already replaced Rose K in the UK except for the occasional Rose K replacement lens.

With computer lathes, materials and surgical techniques continuing to advance, it's difficult to predict what the future has in store for keratoconus vision correction. However it's gratifying to see that improved technology and lens design can help enhance vision for thousands of keratoconus GP wearers throughout the world. **CLS**

*My sincere thanks to Blanchard Contact Lens, Inc. and to those US practitioners who participated in the Rose K2 lens trial.*

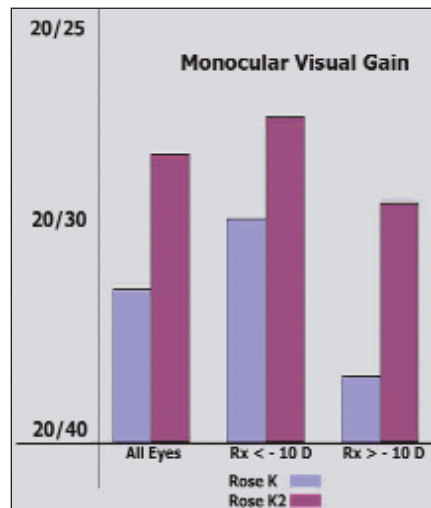


Figure 4. All patients experienced monocular visual gain with Rose K2.