

## The Current State of Corneal Reshaping

Jeffrey J. Walline, OD, PhD, Brien A. Holden, BAppSc, PhD,  
 Mark A. Bullimore, MCOptom, PhD, Marjorie J. Rah, OD, PhD,  
 Penny A. Asbell, MD, Joseph T. Barr, OD, MS, Patrick J. Caroline, COT,  
 H. Dwight Cavanagh, MD, Nick Despotidis, OD,  
 Fonn Desmond, MOptom, DipOptom, Bruce H. Koffler, MD, Kevin Reeder, OD,  
 Helen A. Swarbrick, DipOptom, PhD, and Lisa G. Wohl, MD

**Purpose.** The application of contact lenses to alter the shape of the cornea and temporarily reduce or eliminate myopia is known as orthokeratology, corneal refractive therapy, or corneal reshaping. It was first introduced in the 1960s, but high oxygen permeable materials and more sophisticated designs allow patients to wear contact lenses only during sleep, while dramatically improving the predictability and rate of myopia reduction. Many studies have shown that most corneal reshaping patients achieve uncorrected visual acuity of 20/25 or better that lasts all day long in one to two weeks of nighttime wear.<sup>1-3</sup> Treatment is primarily effective through central epithelial thinning and midperipheral epithelial and stromal thickening. Much remains to be learned about corneal reshaping contact lenses and their effects on the cornea. **Methods.** The authors reviewed existing knowledge and determined what needs to be learned in order to provide patients with appropriate informed consent prior to corneal reshaping contact lens wear. **Results.** While corneal reshaping contact lenses are effective at temporarily reducing or eliminating myopia, claims about the progress of myopia being controlled with corneal reshaping contact lenses should not be made until further studies are published in peer-reviewed literature. The incidence and prevalence of microbial keratitis related to corneal reshaping contact lens wear is not known. Any overnight wear of contact lenses increases the risk of infection, but it is not known whether the risks of microbial keratitis are greater for corneal reshaping overnight contact lens wearers than other form of overnight contact lens wear. It is also not known whether the risk of microbial keratitis is greater for children than adults, but we must determine if children are at greater risk than adults because many children are wearing corneal reshaping contact lenses. **Conclusions.** Finally, it is recommended that ongoing education be provided to practitioners and staff

regarding safety, informed consent, and prevention of potential problems, with special emphasis on the critical need to properly and thoroughly disinfect lenses that will be worn overnight.

**Key Words:** Orthokeratology—Corneal reshaping—Children—Myopia—Contact lens—Review—Microbial Keratitis.

Corneal reshaping, also known as corneal refractive therapy or orthokeratology, was initially reported in the early 1960s.<sup>4</sup> The original goal of corneal reshaping was to permanently change the shape of the cornea while wearing contact lenses for several hours early in the day. As shown in Table 1, the early studies reported an incomplete treatment effect and transient, unpredictable refractive error reduction.<sup>5-16</sup> None of the studies reported significant adverse events resulting from corneal reshaping contact lens wear.<sup>9,13,15</sup>

Three studies from the late-1970s to the mid-1980s used spherical design (base curve steeper than secondary curve) contact lenses worn during waking hours only. While treating subjects with a mean spherical equivalent refractive error of about  $-2.50D$ , the time to maximal treatment effect ranged from 132 days<sup>16</sup> to 17.7 months.<sup>13</sup> In all three studies, the achieved myopia reduction was less than 75% (Table 1). All three studies reported a return toward baseline values for corneal curvature, refractive error, and unaided visual acuity after corneal reshaping contact lens wear was discontinued.<sup>10,13,16</sup>

Due to the unpredictable results and minimal benefits of early corneal reshaping (for brevity, we will no longer include the term orthokeratology in this article) procedures, they were not evaluated again until the mid-1990s. Innovative materials and designs allowed for quicker, more predictable treatment effects and nighttime contact lens wear.<sup>1-3,17-20</sup>

After one to six months of reverse or sigmoid geometry corneal reshaping nighttime contact lens wear the average visual acuity was between 20/19 and 20/24.<sup>1-3,20</sup> The average refractive error measured at the same visit as the visual acuity data, ranged from  $+0.27D$  to  $-0.41D$ .<sup>1-3,20</sup> Changes in corneal curvature measured by keratometry or autokeratometry explained only 43% to 78% of the change in refractive error,<sup>1,2,20</sup> so corneal changes were investigated further.

Current research indicates that the central epithelium thins,<sup>21-25</sup> and a midperipheral thickening of the stroma follows within the

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The Ohio State University College of Optometry, The Vision Cooperative Research Centre, The Ohio State University College of Optometry, New England College of Optometry, Mount Sinai School of Medicine, The Ohio State University College of Optometry, Oregon Health Sciences University Casey Eye Institute, UT Southwestern Medical Center, Eye Care Professionals, Centre for Contact Lens Research, Eagle Creek Medical Plaza, Carmel Mountain Vision Care Center, School of Optometry & Vision Science University of New South Wales, New Vista LASIK Center  
 Address correspondence to Jeffrey J. Walline, OD PhD, 338 West Tenth Avenue, Columbus, OH 43210-1240. Phone: (614) 247-6840 Fax: (614) 247-6452; email: walline.1@osu.edu

Accepted July 20, 2005.

Sources of Support: Paragon Vision Sciences and Polymer Technology Corporation.

DOI: 10.1097/01.icl.0000179709.76832.4f

TABLE 1. A Review of Corneal Reshaping Studies.

Author (year)	Contact lens design	Wear schedule	Baseline refractive error (D)	Percent myopia reduction (%)	Time to maximum effect
Kerns (1977)	Spherical	Daily	-2.31 ± 0.80	57.6	300 days
Binder (1980)	Spherical	Daily	-2.50 ± 1.10	71.8	17.7 months
Polse (1983)	Spherical	Daily	-2.66 ± 1.08	62.6	132 days
Mountford (1997)	Reverse geometry	Overnight	-2.19 ± 0.79	100.0	Not available
Swarbrick (1998)	Reverse geometry	Daily	-2.36 ± 0.90	74.2	28 days
Lui (2000)	Reverse geometry	Daily	-2.12 ± 0.51	70.1	40 days
Nichols (2000)	Reverse geometry	Overnight	-1.84 ± 0.81	98.9	7 days
Rah (2002)	Sigmoid geometry	Overnight	-2.37 ± 0.93	102.5	< 1 month
Walline (2004)	Sigmoid geometry	Overnight	-2.44 ± 1.38	93.4	2 weeks
Sorbara (2005)	Sigmoid geometry	Overnight	-3.00 ± 1.03	86.3	10 days

first month. Recovery toward baseline refractive error is very rapid over the first 24 to 72 hours,<sup>2,26,27</sup> but complete recovery may require more than two weeks.<sup>27</sup>

Several side effects of corneal reshaping contact lens wear have been reported. There have been several reports of asymptomatic corneal pigmentation rings associated with corneal reshaping contact lens wear,<sup>28-31</sup> and it has been found that these rings are reversible.<sup>32</sup> Corneal reshaping contact lenses have also been shown to increase higher order aberrations,<sup>33-35</sup> especially spherical aberration.<sup>33,35</sup> Severe complications, such as corneal ulcers, have been reported in patients wearing corneal reshaping contact lenses, but all of these are anecdotal case reports.<sup>36-44</sup>

In summary, new contact lens materials and more sophisticated contact lens designs permit predictable, reversible treatment of refractive error and allow myopic patients to see clearly throughout the day by wearing contact lenses only during sleep.

## RESULTS

The purpose of this review was to:

1. Review the literature on myopia control with corneal reshaping contact lenses and recommend a summary of information that practitioners should share with their patients.
2. Recommend changes in labeling and/or advice to eye care professionals on precautions that should be followed by clinicians in order to minimize risk and make corneal reshaping contact lens wear as safe and efficacious as possible.
3. Assess available information on microbial keratitis events related to corneal reshaping contact lens wear and recommend investigations that could be conducted by scientists to determine the relative incidence of microbial keratitis and the risk factors for microbial keratitis.
4. Evaluate the current system of practitioner education and provide guidelines for improved practitioner education.

### Myopia Control

Many children throughout the world have been fitted with corneal reshaping contact lenses because many contact lens practitioners have claimed that this modality of contact lens wear will slow or stop the progression of myopia. Three reports of myopia control with corneal reshaping contact lenses have been published.<sup>45-47</sup> Two publications provide only anecdotal information and neither include information from control subjects.<sup>46,47</sup> The only investigation that compares the effect of corneal reshaping contact lens wear to spectacle wear suggests that corneal reshaping contact lenses slow the axial growth of the eye 46% over two

years.<sup>45</sup> However, the treatment groups were not randomly assigned, the contact lenses were not fitted according to a standardized protocol, and the study has not been replicated, so definitive conclusions cannot be gleaned from this article.

Due to the preliminary nature of the information available regarding myopia control with corneal reshaping contact lenses, the authors recommend that the following statement be used by doctors for education of patients regarding myopia control with corneal reshaping contact lenses:

*Results of the only scientific report of the effects of corneal reshaping contact lens wear on the progression of nearsightedness in children suggest a potential slowing of myopia progression, but the results rely on historic controls, have not been confirmed, and indicate unpredictable results for individual children. Further studies are thus required to provide you with adequate information to make an informed decision.*

### Product Labeling

The United States Food and Drug Administration (USFDA) requires contact lens manufacturers to obtain approval on product labeling information, such as package inserts, patient information booklets for potential users, instructions for wearers, and the professional fitting and information guide. Much of the information included in these documents is standard language required by the USFDA. In fact, a variety of contact lens modalities shares the exact wording in each of their documents. Because much of the wording of these documents cannot be changed and because few patients or practitioners read the required labeling information, the authors have written the following short summary of key points to emphasize to practitioners and patients regarding the use of corneal reshaping contact lenses. The critical messages that should be given to contact lens wearers include:

1. *Never* rinse or store your contact lenses in tap water.
2. Clean and disinfect your contact lenses according to the manufacturer's directions *every* time you remove them from your eyes.
3. If you experience any unusual redness, pain, or poor vision, especially if it does not improve, call and visit your eye care practitioner immediately.
4. Have your eyes and contact lenses examined at least every six months, even if you are not experiencing problems.

Practitioners should provide this information to their patients in concise, forcefully written instructions with simple graphic illustrations. Patients should also be provided with contact information for the eye care practitioner in case of emergencies. Practitioners should also tell their patients that the refractive change achieved

with corneal reshaping contact lenses disappears when lens wear is discontinued and the lenses have not been proven to slow the progression of myopia in children or adults.

Accurate informed consent is vital for providing patients with the information they need before considering corneal reshaping contact lens wear. A consent form (Appendix A) and a pediatric assent form (Appendix B) for corneal reshaping contact lens wear are available. A companion quiz is available in order to improve compliance and education with reading the consent forms (Appendix C). The quiz should not be used to determine who is able to wear corneal reshaping contact lenses but to further educate parents and patients of the importance of proper contact lens care and to enhance care and safety with corneal reshaping contact lenses. Use of the informed consent and assent forms should not be mandatory, but it should be considered the standard of care.

### Microbial Keratitis and Potential Studies

The most serious complication that has been associated with corneal reshaping contact lens wear is microbial keratitis. Recent case reports of corneal ulcers associated with corneal reshaping contact lens wear,<sup>36-44</sup> particularly in children, have caused concern about the safety of this modality. While these individual cases highlight the importance of continued monitoring of complications associated with corneal reshaping contact lens wear, they do not allow comparison of the risk of severe complications associated with corneal reshaping contact lenses to other contact lens modalities. The case reports also do not allow for an estimation of the incidence of microbial infections related to corneal reshaping contact lens wear. The risk of severe complications has not been proven to be greater with corneal reshaping contact lenses than with other overnight wear contact lens modalities. The recent prominence of reports regarding corneal reshaping contact lenses is likely to be influenced by the novelty of the modality, the severity of a few cases, and the fact that several cases have occurred in children. Therefore, it should not be assumed that corneal reshaping contact lens wear increases the risk of microbial keratitis more than other overnight contact lens modalities.

A review of 50 cases of microbial keratitis reported in the literature indicates that the vast majority of the cases have come from Asia, where the details of lens material and specific modality are often difficult to ascertain.<sup>48</sup> Nearly one-third of the cases cultured have been due to *Acanthamoeba*, which is almost invariably associated with the use of tap water.<sup>48</sup> The relatively high frequency of *Acanthamoeba* infections (33% versus 3% with other contact lens modalities) may be due to use of non-sterile solutions, especially tap water. This finding alone highlights again the need for aggressive education on lens care and disinfection for corneal reshaping contact lens patients.

A study is underway to compare the rate of microbial infections in an animal model wearing corneal reshaping versus alignment fitted gas permeable contact lenses to compare the increase in risk of microbial infection.<sup>49</sup> More studies need to be conducted to examine etiologic factors of microbial infections associated with corneal reshaping contact lens wear, such as pressure effects on epithelial defense systems, thinness and dysfunction; tear stagnation; microbial load; and pressure effects in relation to *Pseudomonas* and *Acanthamoeba* infections.

Although many of the reported cases of microbial keratitis that have been published involve children, it should not be assumed

that children have a greater risk of complications with corneal reshaping contact lens wear than adults. Complications in children may be reported more often than in adults because of the greater potential for adverse effects due to a larger number of cumulative years that a young person may be affected. There may also be more children wearing corneal reshaping contact lenses than adults, due to the perceived potential for myopia control with the contact lenses.<sup>50</sup> The risks of corneal reshaping contact lens wear in children cannot be compared to the risks in adults using only the data currently published in the literature because of the large potential for bias in reporting data from isolated case reports. Large-scale, prospective studies comparing corneal reshaping contact lens wear in children and adults to other forms of contact lens modalities must be conducted in order to truly ascertain the amount of risk associated with corneal reshaping contact lens wear.

It is very difficult to determine the incidence of corneal ulcers in corneal reshaping contact lens wearers with a retrospective survey because of the need to accurately determine both the number of cases of microbial keratitis and the number of patients fitted with corneal reshaping contact lenses. Contact lens practitioners, the best source of the "number of wearers," may not be able to accurately define the number of microbial keratitis patients because patients may be referred to tertiary centers or other practitioners and/or due to inconsistency in diagnosis of infected corneal ulcers. It is also difficult to retrospectively determine the number of patients fitted with corneal reshaping contact lenses because practitioners may dispense contact lenses from their dispensing fitting set without replacing the contact lens, and replacement contact lenses may be ordered due to loss or breakage.

A prospective study to determine the incidence of corneal ulcers would be time-consuming and cost-prohibitive, primarily because the occurrence of corneal ulcers is extremely rare. The sample size necessary for a study of the incidence of corneal ulcers may be prohibitive, given the limited number of patients wearing corneal reshaping lenses.

A voluntary patient registry could be used to ascertain cases of microbial keratitis, but patients are often not well-informed about the conditions that they have, the potential for bias is great,<sup>51,52</sup> and finding similar control subjects becomes very difficult. An alternative approach is to identify cases of microbial keratitis using clearly defined criteria in a prospective investigation. Information could concurrently be collected on a specified group of control patients matched for factors such as location of treatment and time of treatment, which would provide information for a nested case-control study.

Risk factors that may be considered in a case-control study include, but are not limited to, those listed in Table 2.

A random digit dialing survey is being conducted in Australia to collect information about contact lens wear. Valuable information regarding the risks involved in contact lens wear will be found by this study, but the number of corneal reshaping contact lens wearers in this sample may be too low to reach conclusions about this particular modality.

Although they are not the gold standard for collecting information about the risks associated with corneal reshaping contact lens wear, retrospective and small prospective studies can play a valuable role in identifying possible risk factors associated with corneal reshaping contact lens wear.

**TABLE 2.** Candidate Risk Factors for Corneal Ulcers in Corneal Reshaping Contact Lens Wearers

General Hygiene
Smoking
Dry eye status
Compliance with lens care
Storing/rinsing with tap water
Wearing time
Epithelial thickness
Age
Refractive error
Gender
Ethnicity
Socio-economic status
Contact lens material
Age of contact lenses/Replacement cycle

### Practitioner Education

Corneal reshaping contact lens manufacturers currently certify eye care practitioners prior to allowing them to fit corneal reshaping contact lenses, but the certification process typically emphasizes fitting the contact lenses and management of common contact lens fitting problems. Certification of practitioners by manufacturers to fit corneal reshaping contact lenses should continue, but the current certification process may not place sufficient emphasis on safety, informed consent, and prevention of potential adverse events. Standardization of certification procedures is possible for patient compliance and lens care, but it is difficult to standardize fitting and management of specific products due to differences in product designs. Efforts should be made to develop and promote common standards through and with the cooperation of organizations such as the Gas Permeable Lens Institute, the Contact Lens Manufacturers Association, and the academic organizations and/or institutions. Aside from fitting and troubleshooting guidelines, the certification process should also include information on how to educate patients about corneal reshaping contact lens wear and the related risks, live web-based training, immediate feedback when a question is answered incorrectly during the certification process so that practitioners and technicians can learn from their mistakes, and ongoing education for practitioners and office staff.

A formal mentoring system or peer interaction program (having a mentor to show one how to fit contact lenses and educate patients) was discussed by the authors, but it was determined that would not be feasible due to time and cost constraints involved.

### DISCUSSION

Advances in corneal reshaping contact lens designs and materials have greatly enhanced the benefits of the modality. Many people are being successfully fitted with this modality, allowing clear vision throughout the day for myopic patients without the need for surgery or refractive correction. Questions about myopia control, the safety of the modality, and education necessary to optimally prepare patients and practitioners for the most appropriate care of corneal reshaping contact lenses still exist. Guidelines for answering these questions were recommended by experts with clinical and research experience related to corneal reshaping contact lens wear. Following these guidelines will help to maximize the benefits and safety of corneal reshaping contact lens wear, and allow practitioners to provide their patients with appropriate informed consent.

### ACKNOWLEDGMENTS

This article results from a series of discussions about corneal reshaping or orthokeratology contact lens wear. The costs of the meetings were met by grants from Paragon Vision Sciences and Polymer Technology Corporation.

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## APPENDIX A

### INFORMED CONSENT DOCUMENT

You are being fitted with corneal reshaping contact lenses, also known as Corneal Refractive Therapy. Corneal reshaping temporarily reshapes the cornea (the clear layer on the front of the eye), allowing you to see clearly without the use of glasses or contact lenses during waking hours. The Corneal reshaping contact lenses must be worn on a regular basis during sleep in order to reduce the need for glasses or contact lenses during the day.

Corneal reshaping contact lenses carry the same risks as other types of contact lenses, such as swelling of the cornea, scratching of the eye, irritation, infection, unusual eye discharge, excessive tearing, dry eyes, sensitivity to light, pain, redness, and distorted vision. These risks are usually temporary if the contact lenses are removed promptly and if appropriate professional care is received. In some instances permanent corneal scarring, infection, or blood vessel growth on the cornea may occur, which can lead to reduced sight in rare cases. Although uncommon, infection of the cornea can develop rapidly and lead to loss of vision. The risk of infection of the cornea has been shown to be greater among patients who wear their lenses overnight than among those who do not sleep in their lenses.

Corneal reshaping contact lens wear also has risks that are not typically associated with other types of contact lenses, such as blurry or variable vision, especially late in the day. The blurry vision and how long it lasts each day should decrease with time. You may also experience distortions or ghost images, particularly outside at night which may affect night driving. The risk may be increased in patients with a high degree of correction or large pupils. You may also develop a pigmented ring in the cornea. This is not noticeable, it does not change your vision, and it does not require treatment.

All risks are minimized if you follow the correct contact lens wearing schedules and care procedures, remove your contact lenses if problems occur, and report to your primary eye care practitioner as soon as possible. With any procedure, there may be unforeseeable risks. If you experience any of the symptoms listed above, remove your lenses immediately. If the condition continues after lens removal, you should immediately call for an appointment or consultation with your eye care practitioner who will provide the necessary treatment.

Your doctor will recommend a wearing schedule for you to follow. The wearing time necessary for corneal reshaping contact lens wear is typically 7 to 8 hours per night. Your doctor will also recommend a follow-up schedule to check your vision and contact lenses. **It is important that you attend every visit that your eye care practitioner recommends in order to maintain the health of your eyes.**

Alternatives to corneal reshaping contact lens wear include, among others, eyeglasses, traditional contact lenses, and refractive surgical procedures.

Pregnancy could adversely affect my corneal reshaping treatment results. If problems exist during pregnancy, you may need to

temporarily discontinue Corneal Refractive Therapy contact lens wear.

I have read and fully understand the above information. I agree to adhere to the wearing and follow-up schedules as prescribed. If I fail to return for my scheduled follow-up visits, I may forfeit my chance to continue overnight wear of corneal reshaping contact lenses. All of my questions concerning my eyes and contact lenses have been answered to my satisfaction.

Patient Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Attending Doctor/Witness signature: \_\_\_\_\_

Date: \_\_\_\_\_

## APPENDIX B

### CHILD ASSESSMENT DOCUMENT

I am being fitted with corneal reshaping contact lenses. These contact lenses reshape the cornea (the clear layer on the front of the eye) for a short time, which allows me to see clearly without the use of glasses or contact lenses while I am awake. The corneal reshaping contact lenses must be worn on a regular basis during sleep so that I can see clearly during the day without glasses or contact lenses.

It is important that I agree to the following guidelines to keep my eyes healthy and allow me to wear contact lenses. Place a checkmark in each box if you agree.

- I agree to wear my lenses no more than \_\_\_\_\_ hours per night.
- I agree to wash my hands before inserting or removing my contact lenses.
- I agree to clean my lenses according to my doctor's instructions each time I remove them.
- I agree not to rinse my contact lenses in water from the sink. I will only use contact lens solutions to rinse my contact lenses.
- I agree to tell my parents or my doctor immediately if my contact lenses irritate my eyes.
- I agree to tell my parents or my doctor immediately if my eyes appear red or are painful.
- I understand that if I do not do the things listed above, my eyes may get hurt or I may not be able to wear my contact lenses.

Child's Name: \_\_\_\_\_

Child's Age: \_\_\_\_\_

Child's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## APPENDIX C

### INFORMED CONSENT QUIZ

Please choose the single best answer for each question.

- 1.) If I experience red eyes, irritated eyes, excessive tearing, or light sensitivity, I should:
  - A.) go to the emergency room.
  - B.) remove your contact lenses immediately.
  - C.) wait for three days to see if it goes away.
  - D.) put a drop of artificial tears in your eyes.
- 2.) After wearing corneal reshaping contact lenses for approximately three months, the cornea will be permanently reshaped so contact lenses will never need to be worn again.
  - A.) True
  - B.) False
- 3.) To minimize risks associated with corneal reshaping contact lens wear, I should:
  - A.) follow the correct contact lens wearing schedules and procedures.
  - B.) remove all contact lenses if problems occur.
  - C.) report to an eye care practitioner if I have problems with my eyes or contact lenses.
  - D.) all of the above.
- 4.) If I am not experiencing problems with my eyes or contact lenses, I do not need to attend a regularly scheduled appointment with my eye care practitioner.
  - A.) True
  - B.) False
- 5.) The risk of infection is for patients who wear contact lenses overnight than for patients who do not sleep in their contact lenses.
  - A.) greater
  - B.) lower