Corneal reshaping: is it a good alternative to refractive surgery?
Michael J. Lipson and Alan Sugar

Purpose of review
To review current literature on overnight corneal reshaping and present this mode of vision correction in its current state.

Recent findings
Overnight corneal reshaping uses specially designed rigid gas-permeable contact lenses. It is effective in temporarily reducing or eliminating low to moderate myopia. This nonsurgical mode of vision correction allows for good unaided vision during waking hours. There are reports of young patients experiencing serious adverse events, particularly bacterial and *Acanthamoeba* keratitis while using these lenses, although incidence rates are unknown.

Summary
Overnight corneal reshaping is an alternative to refractive surgery and must continue to be studied and monitored to establish its safety.

Keywords
contact lenses, corneal topography, laser in-situ keratomileusis, myopia, overnight corneal reshaping, vision-related quality of life

Introduction
Over the last 3–4 years, contact lens corneal reshaping has become more popular with patients and practitioners. Overnight corneal reshaping (OCR), also called overnight orthokeratology, involves wearing a highly permeable, rigid gas-permeable (RGP) contact lens with multiple posterior curvatures to create a decrease (flattening) of the anterior corneal curvature. These specially designed lenses have a ‘reverse geometry’ configuration which means that the central curvature is flatter or less curved than the peripheral curves. The process generally takes 7–10 nights of wearing to obtain the maximum effect so that after lens removal in the morning, unaided vision remains good for all waking hours. Generally, most patients wear the lenses every night, although some patients find that they can skip nights occasionally and still retain consistently good vision. In June 2002, Paragon CRT (Paragon Vision Sciences, Mesa, Arizona) was approved by the United States Food and Drug Administration (FDA) to be worn overnight for temporary correction of myopia [1]. More recently, vision shaping treatment (VST) (Bausch and Lomb, Rochester, New York) received similar FDA approval for its ‘family’ of four designs of corneal reshaping lenses [2]. The Paragon CRT lens has FDA approval for all ages for up to 6.00D of myopia and less than 1.75D of astigmatism [1]. The VST lenses have FDA approval for up to 5.00D of myopia and 1.50D or less of astigmatism [2]. Estimates from early 2005 as to the number of patients using OCR are over 100 000 outside the US and over 50 000 in the US (J. Jacobson, Director, Polymer Technology, personal communication, January 2005). No estimates are currently available for the number of adults versus children using these lenses.

Corneal reshaping: yesterday and today
Corneal reshaping today is nothing like the form of orthokeratology used in the late 1970s and early 1980s. Orthokeratology used a series of spherical RGP (or PMMA) lenses that were fit progressively flatter to affect a change in corneal curvature. These lenses were worn during waking hours and patients found they had improved unaided acuity for short periods of time. Practitioners found some of these patients to have corneal distortion and irregularity due to the high-riding nature of these fits [3–7].

Today’s corneal reshaping lenses are dramatically different in three major ways. First, lenses are made of high-Dk (highly gas-permeable) RGP materials that are FDA
approved for overnight wear. Second, as mentioned above, the posterior surface of the lens is made with multiple curves with distinct zones such that the central zone (base curve) is flatter than the peripheral curves. The unique curvatures allow carefully controlled centration, myopia reduction and corneal integrity. Third, in most cases, lenses are worn only while sleeping. The only similarity between the original orthokeratology and today’s corneal reshaping is that contact lenses are worn to affect a change.

Although the process has been simplified, there is still a learning curve for practitioners to become proficient with various patients, prescriptions and lens designs.

**Lens designs/techniques**

There are currently five different FDA-approved corneal reshaping lenses (Table 1). Each has its own proprietary design formula to determine the proper fitting relationship. The one common characteristic in each design is that the posterior surface of the lens has peripheral curvatures steeper than the central curvature. Terminology describing these curves varies amongst the brands but can be generalized as follows: base curve – the central curvature that determines the amount of myopia reduction; reverse curve – a curve significantly steeper than the base curve and much steeper than the original flat K reading; alignment curve – a curve that approximately aligns with the peripheral cornea that influences lens position on the eye and ‘floats’ the central portion of the lens on the cornea; peripheral curve – the curve used to give appropriate edge lift to allow tear flow under the lens [1,2].

Different techniques are used to fit each lens. One lens uses a fitting nomogram followed by diagnostic fit evaluation. One is strictly topography based for initial lens selection followed by topographical analysis after wearing the initial lens for one night to determine the final lens ordered. The others are fit empirically based on refraction, K readings, corneal diameter and corneal eccentricity.

**Corneal changes**

Post-treatment topography of corneal reshaping patients shows a central area of flattening surrounded by a steeper mid-peripheral ring somewhat similar to a post-laser in-situ keratomileusis (LASIK) topography (Fig. 1). Proper centration of lenses is critical to give best visual acuity and to minimize the chance of subjective symptoms of glare. Detailed studies of corneal reshaping patients have consistently shown a decrease in central epithelial thickness and an increase in midperipheral epithelial thickness [8–10]. The precise mechanism of these changes has been theorized to be either a compacting of the central epithelial cells or a redistribution of the epithelial cells from corneal center to the midperiphery [11]. A number of studies have been done to evaluate changes in stromal thickness or posterior corneal curvature changes but these have failed to show a consensus.

**Outcomes data**

Results with corneal reshaping have been evaluated from the perspective of both the doctor and the patient.

Efficacy has been evaluated in recent studies. Sorbara et al. [12] followed 23 patients (mean refractive error $\pm 2.72 \pm 1.06 \text{D sph and } -0.55 \pm 0.40 \text{D cyl}$) for 4 weeks and found unaided acuity improving to 0.00 logMAR (20/20 snellen) by day 4 and remaining consistent throughout waking hours by day 10. Unaided acuity and refractive error remained consistent through day 28. Walline et al. [13] followed 29 children aged 8–11 years for 6 months of corneal refractive therapy. Range of myopia was from $-0.75$ to $-5.00 \text{D}$ with less than 1.50D of corneal toricity. At the 6-month afternoon visit, uncorrected acuity was $0.08 \pm 0.15 \text{logMAR (20/24 snellen). The mean spherical equivalent refraction at that visit was } -0.16 \pm 0.66 \text{D.}$

<table>
<thead>
<tr>
<th>Table 1 US Food and Drugs Administration-approved overnight corneal reshaping lenses</th>
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<tr>
<td><strong>Brand name</strong></td>
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<tr>
<td>Paragon CRT</td>
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<tr>
<td>Contex OK4-E Series</td>
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<tr>
<td>BE Retainer</td>
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<tr>
<td>Dream Lens</td>
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<td>Emerald Lens</td>
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*aParagon Vision Sciences, Mesa, Arizona, USA.
*eEuclid, Herndon, Virginia, USA.
A study at Indiana University [14] evaluated long-term safety and effectiveness of overnight orthokeratology. A total of 133 adults and 68 juveniles completed this 12-month study using three different lens designs. The results showed a reduction of more than 90% of original myopia at the 12-month visit. The authors concluded that the procedure is effective, there were fewer symptoms and a general decrease in slit-lamp findings over time, and safe wear of overnight corneal reshaping lenses ‘is predicated on the emphasis of clear patient direction on how to wear and take care of the lenses followed by regular examinations’ by the eye care practitioner.

The return to baseline myopia after discontinuation of corneal reshaping lenses has been studied [15,16]. These two studies showed that the majority of the recovery occurs within 72 h after discontinuation of lens wear. Rates of regression were found to vary based on amount of original myopia with higher myopic corrections regressing more quickly. Uncorrected visual acuity during the immediate 16 h after lens removal remained at a level of 0.10 logMAR (20/25) or better.

Quality of vision has been analyzed in terms of acuity as well as higher-order aberrations. Two separate studies [17,18] came up with similar findings. First, that unaided visual acuity was excellent (−0.07 ± 0.18 logMAR or 20/15) and there was no change in best corrected acuity. Second, there were increases in higher order aberrations (HOAs) and spherical aberration. As with LASIK, increases in HOA affect patients more with larger pupils. The spherical aberration increase was shown to reduce low-contrast unaided visual acuity.

From the perspective of the patient, Lipson et al. [19**] evaluated patients in a crossover study who wore both corneal reshaping lenses and soft disposable lenses for 2 months each. At the end of the study, 67% chose the corneal reshaping lenses as their preferred mode of correction. This study evaluated vision-related quality of life attributes scored on the NEI-RQL42 and showed no significant difference in perceived acuity with soft lenses compared with OCR lenses. For this study’s population as a whole, patients wearing the OCR lenses had a mean unaided logMAR acuity of 0.10 (20/25) at the 2-month visit, while soft lens wearers had acuity of 0.06

Figure 1 Corneal topography

![Corneal topography](image)
Another study [20] using the NEI-RQL42 was done comparing OCR patients to LASIK patients [20]. There were no significant vision-related quality of life differences in the two groups at the end of the study, although interestingly, there were differences noted in the two groups prior to treatment.

Safety
As discussed above, the original form of orthokeratology was considered to be safe, but lacked effectiveness. OCR has been shown to be effective, but there is little quantitative information available to support or deny its long-term safety in large numbers of patients. Prospective studies of effectiveness have known denominators that are not large enough to establish safety. Retrospective studies of effectiveness have known denominators that are not large enough to establish safety. Retrospective data on safety, derived from case reports and series, lack the knowledge of denominators necessary to determine the incidence of adverse events.

The most significant safety issue has been microbial keratitis in eyes treated with OCR. Watt and Swarbrick [21] reviewed the first 50 cases of microbial keratitis reported from 2001 onward following OCR. Most cases were severe and involved the central cornea. The review noted a preponderance of Asian patients (88%). The most significant findings were the culture of *Pseudomonas aeruginosa* in 52% and *Acanthamoeba* species in 30%. The frequency of *Acanthamoeba* has raised an alarm because of the difficult and prolonged course of treatment and often poor outcomes [22]. This group of organisms has been confirmed in more recent reports [23–27]. The most alarming finding, however, was the peak prevalence in children age 9–15, who accounted for 61% of cases [21]. In a series of 28 cases from China seen over an 18-month period, the average age was 16 and all were 21 or less [27]. It is not clear whether the predilection of infectious keratitis for young Asian OCR patients is related to patterns of OCR use in Asia or to other unknown factors. It is clear that further study is indicated, possibly as mandated postmarket surveillance [28]. At least heightened awareness of keratitis risk and prompt reporting are indicated [29].

In uncontrolled studies, OCR has been shown to induce higher-order corneal aberrations after lens removal [17,30]. This is associated with a decrease in low-contrast corrected visual acuity [17] and increases with rising myopic correction [30]. Studies comparing these findings with other forms of contact lens wear are lacking. Although it is likely that these effects are reversible, further study is necessary to document the extent of reversibility.

Candidates for overnight corneal reshaping
Candidates for this treatment include the following.

Low myopes
Low myopes are the best candidates for OCR. They respond quickly and retain very good vision during all waking hours [1,12,13–17]. This group would include those who elect not to have refractive surgery but still want to enjoy good acuity without correction.

Contact lens intolerance
Dryness is the most common complaint in contact lens wearers. They often report dryness as the reason they are seeking LASIK or OCR. Patients with severe dry eyes may not be candidates for either procedure. Also, contact lens wearers bothered by allergy-related itching are ideal candidates for OCR because they wear no contacts during waking hours. Very careful lens hygiene is crucial for these patients to maintain a clean, wettable lens surface.

LASIK noncandidates
Some patients who are fearful of surgery, attracted to the temporary (reversibility) nature of OCR or are under 21 and still showing myopic progression are suitable.

Undercorrected post-LASIK patients
Patients who are still myopic following LASIK and are not candidates for enhancement can do very well with OCR [31]. OCR has its effect on the epithelium and does not alter corneal stroma. It is recommended that only experienced OCR fitters work with post-LASIK patients.

Conclusion
Overnight corneal reshaping is a nonsurgical refractive procedure that has been shown to temporarily reduce myopia and improve unaided visual acuity. Studies have shown it to be effective and patients have found it to be a very attractive option to traditional contact lenses. Safety is an important issue with OCR. As with any procedure, there have been reports of problems. While there are no published studies to evaluate the relative risk or incidence of adverse events while wearing OCR lenses, ophthalmic journals have published case reports of adverse events over the past 7 years. The case reports do not establish the incidence of microbial infections related to corneal reshaping contact lens wear. Risk of severe complications with corneal reshaping contact lenses is present but may be no different than with other overnight wear contact lens modalities [32]. The FDA approved Paragon CRT 4 years ago and is watching the practice of corneal reshaping carefully while evaluating whether a postmarket surveillance study is appropriate. The FDA’s current position is that practitioners must follow careful guidelines regarding patient selection, monitoring compliance with lens care and follow-up exams, informed consent, minors’ agreement to
treatment and reporting of adverse events. ‘The FDA will monitor the situation and take appropriate, evidence-based regulatory action’ [29].

Certainly, patient selection, patient education and careful monitoring of patients are critical for continued success and safety with corneal reshaping. Continued study [33] of corneal reshaping is necessary to reduce or eliminate serious complications.

References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

* of special interest
** of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 419).


This is a well controlled study showing the efficacy of corneal reshaping.


This vision-related quality of life study allowed 81 patients to experience corneal reshaping lenses and soft lenses and choose the modality they preferred.
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29 Saviola JF. The current FDA view on overnight orthokeratology: how we got here and where we are going. Cornea 2005; 24:770–771.