

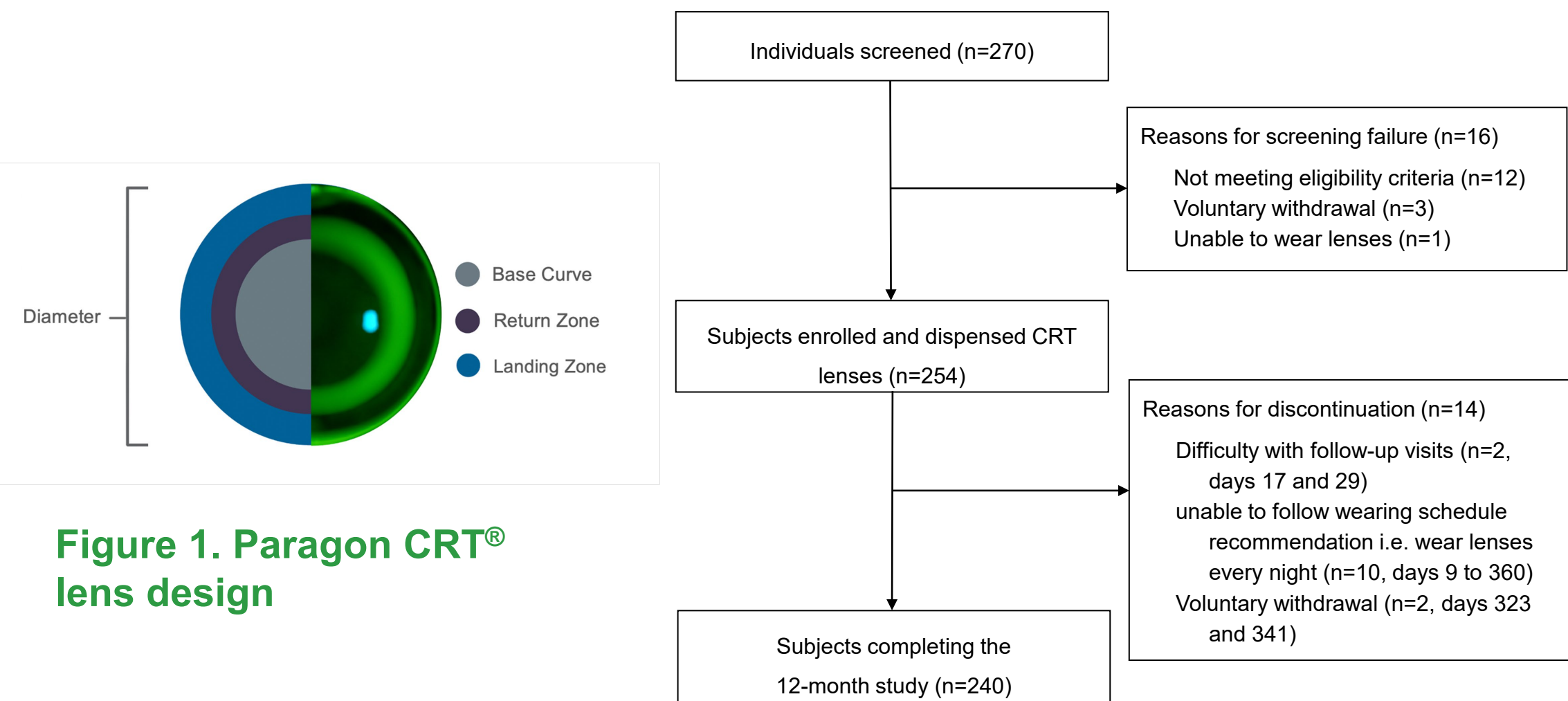
The effect of an overnight corneal refractive therapy lens on vision and corneal curvature in Chinese myopes: a prospective, multi-center study

Background

- Myopia is particularly prevalent in East and Southeast Asia,¹ and many hospitals in major Chinese cities have specialist orthokeratology clinics. Orthokeratology is a non-surgical means of myopia correction that provides patients with the benefit of being lens-free during their waking hours. Orthokeratology temporarily treats mild to moderate myopia by re-shaping the cornea through overnight wear of specially designed rigid gas-permeable contact lenses. Given the mode of action, visual outcomes can be less predictable with orthokeratology than with daytime corrective lenses.
- A new orthokeratology lens, Paragon CRT® 100, CooperVision Specialty EyeCare (CRT 100), was introduced in China in early 2017 and is widely fitted in hospitals and clinics.

Purpose

- To evaluate the effects of CRT 100 lens on vision and corneal curvature in myopic Chinese children and adults in China.



Methods

- This was a 12-month, multi-center, bilateral-dispensing, single-arm clinical trial. This clinical trial conformed with the tenets of the Declaration of Helsinki and ethics committee of each investigational site in China reviewed and approved the clinical trial. This clinical trial was registered at clinicaltrials.gov with identifier NCT04187599.
- Subjects were eligible for enrolment if both eyes had myopic refractive error of -4.00DS or less, astigmatism of 1.50DC or less, and no corneal abnormality. Unaided distance visual acuity (UDVA), manifest refraction spherical equivalent (MRSE), and corneal curvature were assessed at baseline and at follow-up visits after CRT 100 (lens design see Figure 1) lens-wear periods of 1 day and 1 week, 2 weeks, and 1, 3, 6, 9, and 12 months. Investigators also examined the lenses for breakages, protein deposition, and scratches at dispensing and all follow-up visits. Figure 2 shows subjects flow diagram.

Results

Visual acuity

- Four sites in China enrolled a total of 254 subjects aged 8 to 43 years (mean \pm SD: 12.1 \pm 5.6 years). Data were collected from both eyes of all enrolled subjects. UDVA and MRSE significantly improved compared to baseline values at all follow-up visits ($P < 0.05$). Mean UDVA had improved by 0.44 \pm 0.27 logMAR at Day 1 and 0.68 \pm 0.22 logMAR at 1 month compared to baseline (0.65 \pm 0.30 logMAR) (Figure 3). Mean MRSE had improved by 1.66D \pm 0.94 at Day 1 and 2.64D \pm 0.71 at 1 month compared to baseline (-2.66D \pm 0.94) (Figure 4). At 1 month, the proportion of eyes with UDVA of ≤ 0.1 logMAR and MRSE of $< \pm 0.50$ D was 94% (472/502 eyes, 95%CI: 92–96%).

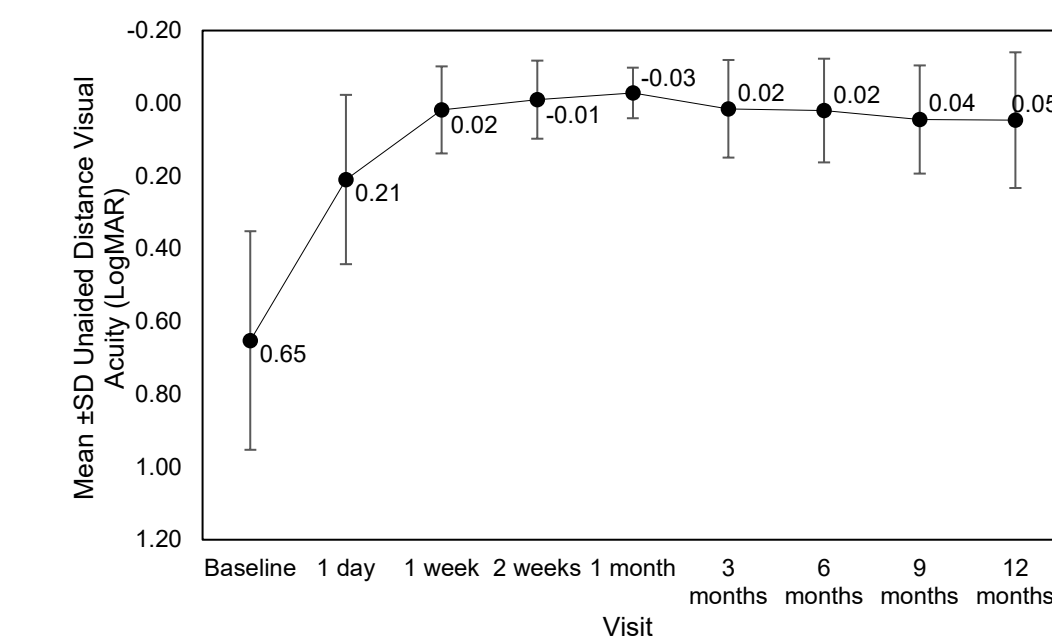


Figure 3. Mean \pm SD UDVA (LogMAR) at baseline (n=254) and follow-up visits

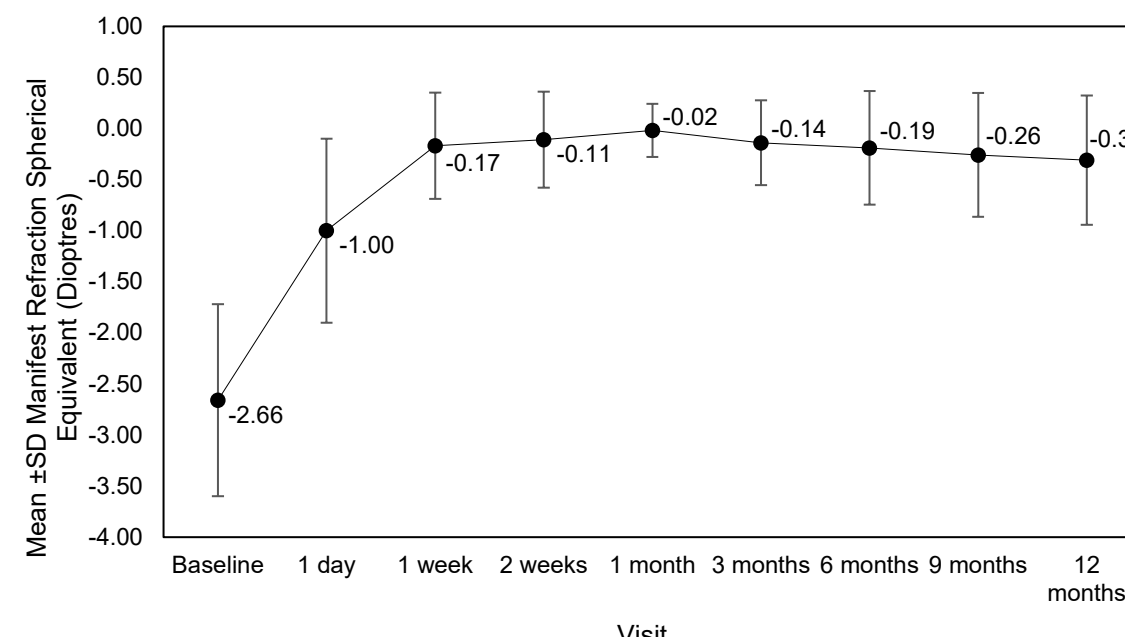


Figure 4. Mean \pm SD MRSE (dioptries) at baseline (n=254) and follow-up visits

Corneal curvature

- Corneal curvatures on both steep and flat meridians were significantly flatter at all follow-up visits than at baseline ($P < 0.001$). The steep meridians had mean (\pm SD) curvatures of 43.73 \pm 1.28 D at baseline and 42.75 \pm 2.26 D to 41.61 \pm 1.25 D at follow-up visits. The flat meridians had mean (\pm SD) curvatures of 42.55 \pm 1.22 D at baseline and 41.59 \pm 2.21 D to 40.67 \pm 2.90 D at follow-up visits.

- Similarly, corneal astigmatism was significantly lower from the 1-week visit onward than at baseline ($P = 0.003$). Mean (\pm SD) corneal astigmatism was 1.20 \pm 0.45 D at baseline and 1.10 \pm 0.56 D to 0.89 \pm 0.53 D from the 1-week visit onward.

Lens damage and deposition

- Investigators conducted 4,748 individual lens assessments for breakages, protein deposition, and scratches. Lens breakage was less than 1% during the study. In total, lenses exhibited protein deposition at 81 assessments (1.7%) in which 29 cases were exhibited on both anterior and posterior surfaces. On anterior surface, lenses exhibited protein deposition at 65 assessments (1.4%); 63 cases and two cases were classified as negligible and mild respectively. On posterior surface, lenses exhibited protein deposition at 45 assessments (0.9%); all cases were classified as negligible. Lenses exhibited scratches at 217 assessments (4.6%); 187 cases, 25 cases and five cases were classified as negligible, mild and moderate respectively.

Discussion

- This study found that orthokeratology lens significantly improved UDVA and MRSE in Chinese patients from Day 1 onwards, visual outcomes improved over time and plateaued by about 1 week, which is mostly consistent with other published data.²
- Moreover, 94% eyes achieved UDVA no worse than 0.1 LogMAR meanwhile MRSE less than -0.50 D at 1 month. The study also found that the lens significantly flattened corneal curvature in both the flattest and steepest meridians and reduced corneal astigmatism, similar findings can be found in other studies.²⁻³
- A couple of findings in this study differ from those in other peer-reviewed papers. For example, some studies observed an increase in astigmatism after orthokeratology⁴⁻⁵ or no change⁶⁻⁷ instead of reduction in astigmatism found in this study. Another difference is the discontinuation rate; this study had a low discontinuation rate of 5.5%, whereas a retrospective case review observed a 1-year discontinuation rate of 17.2% among children and 33.2% among adults.⁸
- This study has several strengths that give credibility to its conclusions; these include a large sample size, long follow-up duration, and stringent criteria for effectiveness.
- A few improvements could be made in future studies, including recording LogMAR to the nearest letter rather than by line, having a control group, controlling the time of day of the follow up visits, and recording lens wear frequency and duration.⁹ Future randomized controlled trials of the CRT 100 lens could also evaluate its effect on axial length elongation.

Conclusion

- The Paragon CRT® 100 orthokeratology lens temporarily reduces myopia effectively in a large majority of Chinese patients as demonstrated by the significant improvements to clinically relevant levels of both uncorrected distance visual acuity and manifest refraction spherical equivalent.

REFERENCES

- Morgan IG, Ohno-Matsui K, Saw S-M. Myopia. Lancet. 2012;379(9827):1739-1748. doi:10.1016/S0140-6736(12)60272-4
- Singh K, Bhattacharya M, Goel A, Arora R, Gotmare N, Aggarwal H. Orthokeratology in Moderate Myopia: A Study of Predictability and Safety. J Ophthalmic Vis Res. 2020 Apr 6;15(2):210-217.
- Lyu T, Wang L, Zhou L, Qin J, Ma H, Shi M. Regimen Study of High Myopia-Partial Reduction Orthokeratology. Eye Contact Lens. 2020 May;46(3):141-146. doi: 10.1097/ICL.0000000000000629. PMID: 31361656.
- Hiraoka T, Furuya A, Matsumoto Y, Okamoto F, Sakata N, Hiratsuka K, Kakita T, Oshika T. Quantitative evaluation of regular and irregular corneal astigmatism in patients having overnight orthokeratology. J Cataract Refract Surg. 2004 Jul;30(7):1425-9.
- Rajabi MT, Hosseini SS, Ghorbani Z, Nobahari F, Bazvand F, Doostdar A, Zarrinbakhsh P, Rajabi MB. Utility of orthokeratology contact lenses; efficacy of myopia correction and level of patient satisfaction in Iranian myopic/myope-astigmatic patients. J Curr Ophthalmol. 2016 Feb 5;27(3-4):99-102.
- Kong QH, Du XY, Li X, Wu ZZ, Lin ZL. Effects of orthokeratology on biological parameters and visual quality of adolescents with low-grade corneal astigmatism myopia. Eur Rev Med Pharmacol Sci. 2020 Dec;24(23):12009-12015.
- Guo HC, Jin WQ, Pan AP, Wang QM, Qu J, Yu AY. Changes and Diurnal Variation of Visual Quality after Orthokeratology in Myopic Children. J Ophthalmol. 2018 Oct 15;2018:3174826.
- Gispets J, Yébanes P, Lupón N, Cardona G, Pérez-Corral J, Pauné J, Cortilla B. Efficacy, predictability and safety of long-term orthokeratology: An 18-year follow-up study. Cont Lens Anterior Eye. 2022 Feb;45(1):101530.
- Santolaria E, Cerviño A, Queirós A, Brautaset R, González-Méjome JM. Subjective satisfaction in long-term orthokeratology patients. Eye Contact Lens. 2013 Nov;39(6):388-93.

CORRESPONDENCE:

CooperVision Specialty EyeCare
2120 W Guadalupe Rd #112
Gilbert, AZ 85233 USA
javega@coopervision.com

ACKNOWLEDGEMENTS:

Support provided by CooperVision Specialty EyeCare.



CooperVision®
Specialty EyeCare

