

INTRODUCTION

- Orthokeratology (OK) is a corneal reshaping technique involving overnight wear of rigid contact lenses with reverse geometry design for correction of mild to moderate degrees of ametropia, most commonly myopia.¹
- During lens wear, OK lenses induce central corneal flattening, correcting myopia temporarily after lens removal, and para-central corneal steepening which alters peripheral refraction, potentially controlling myopia progression.²
- OK lenses are increasingly used for myopia control in recent years following numerous studies showing reduced myopia progression with OK compared to conventional single vision spectacles or contact lenses.³⁻⁵
- Studies that investigated myopia progression have utilized different OK lenses which vary in their lens design.³⁻⁵ It is currently not known whether differences in OK lens design induce differential changes in the cornea and therefore in peripheral defocus.

PURPOSE

To compare corneal refractive power (CRP) changes in the horizontal and vertical meridians of the para-central cornea induced by three OK lens designs worn overnight for 2 weeks.

METHODS

SUBJECTS

- 19 myopic subjects (6M, 13F, age 28 ± 7 years, range 21-41 years)
- Study inclusion criteria:
 - Myopia between 1.00 and 4.00 D with astigmatism ≤ 1.50 DC
 - No prior rigid contact lens wear
 - Good ocular health and general health
 - For soft contact lens users, lens wear was ceased for 24 hours prior to study measurements

STUDY DESIGN

- Phase 1: BE OK lenses (Capricornia Contact Lens, Australia) were fitted in both eyes and lenses were worn overnight for 2 weeks.
- Phase 2: After a minimum 2 weeks of no lens wear, one eye was randomly refit with a Contex OK lens (Contex, USA) and the other eye with a Paragon CRT lens (Paragon Vision Sciences, USA).
- This study design allowed us to compare the effects of the BE lens design in Phase 1 to the effects of other lens designs used in Phase 2.

Contact lens design details:

- BE OK lenses:** 5 curve design, back optic zone diameter (BOZD) 6 mm, total lens diameter 11 mm, fabricated in Boston XO (fluorosilicone acrylate, Dk: 100).
- Paragon CRT:** 3 curve design, BOZD 6 mm, total lens diameter 10.5 mm, fabricated in tisilfocon A (fluoro-methacrylate and siloxanylstyrene, Dk: 163).
- Contex OK:** 3 or more curves, BOZD 6 mm, total lens diameter 10.6 mm, fabricated in Boston XO (fluorosilicone acrylate, Dk: 100).

STUDY MEASUREMENTS (Baseline and after 14 days of OK lens wear)

- Objective refraction: Five measurements taken using Shin-Nippon NVision-K5001 autorefractor. Average central refraction converted into power vectors as described by Thibos et al.⁶
- Corneal topography: Medmont E300 corneal topographer (Melbourne, Australia). Four maps were captured at each study visit.
 - A Custom written MATLAB program (The Mathwork Inc, Version 7.10) was used to determine CRP along horizontal and vertical meridians in 0.5 mm increments from vertex normal up to 8 mm corneal chord.

STATISTICAL ANALYSIS

- Shapiro-Wilk test was used to test parametric distribution of data sets.
- Linear Mixed Model analysis, Repeated measures Analysis of Variance and post hoc t-tests with Bonferroni correction were used to detect differences in CRP change in the para-central zone (from 2.5 to 3.5 mm) between lens designs and to compare effects between visits and lens designs.

RESULTS

BASELINE VARIABLES

- There were no statistically significant differences in mean baseline central refraction between eyes wearing BE and Contex lens designs. No significant differences were also found between eyes wearing BE and Paragon CRT lenses except for refractive J₄₅, which showed a statistically significant but clinically insignificant difference (Table 1).

CHANGES IN CORNEAL REFRACTIVE POWER

- The average CRP change over all designs centrally (3 mm diameter) was -1.75 ± 0.35 D and para-centrally (2.5 to 3.5 mm annular radius) was +0.13 ± 0.46 D. The Student t-test showed a statistically significant difference in these two zones.

BE vs Contex OK lenses:

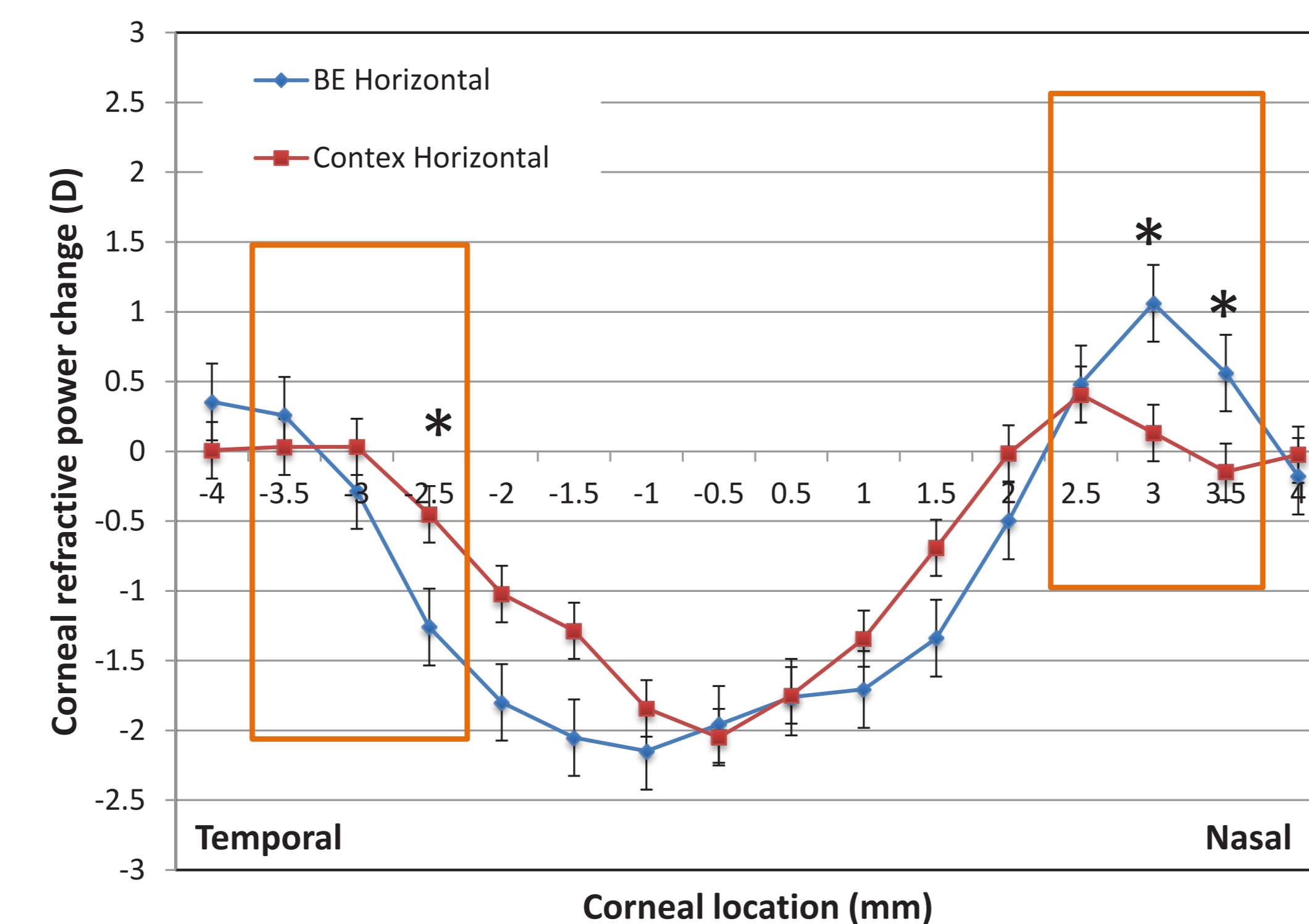


Figure 1. Along the horizontal meridian, a significant difference in overall para-central CRP change was found between BE and Contex lenses ($F = 5.515$, $p < 0.001$).

Analysis of individual locations showed a significant reduction ($p = 0.002$) in CRP at 2.50 mm temporally and an increase in CRP at 3.00 mm and 3.50 mm nasally (both $p < 0.005$) with BE lenses compared to Contex lenses.

BE vs Paragon CRT lenses:

- There was no significant difference in CRP change in the para-central zone between the two lens designs either along the horizontal meridian ($F = 0.958$, $p = 0.329$) or the vertical meridian ($F = 0.104$, $p = 0.748$). However, there was a significant difference in the CRP change between different para-central locations along the horizontal ($F = 8.522$, $p < 0.001$) and vertical ($F = 5.801$, $p < 0.001$) meridians.

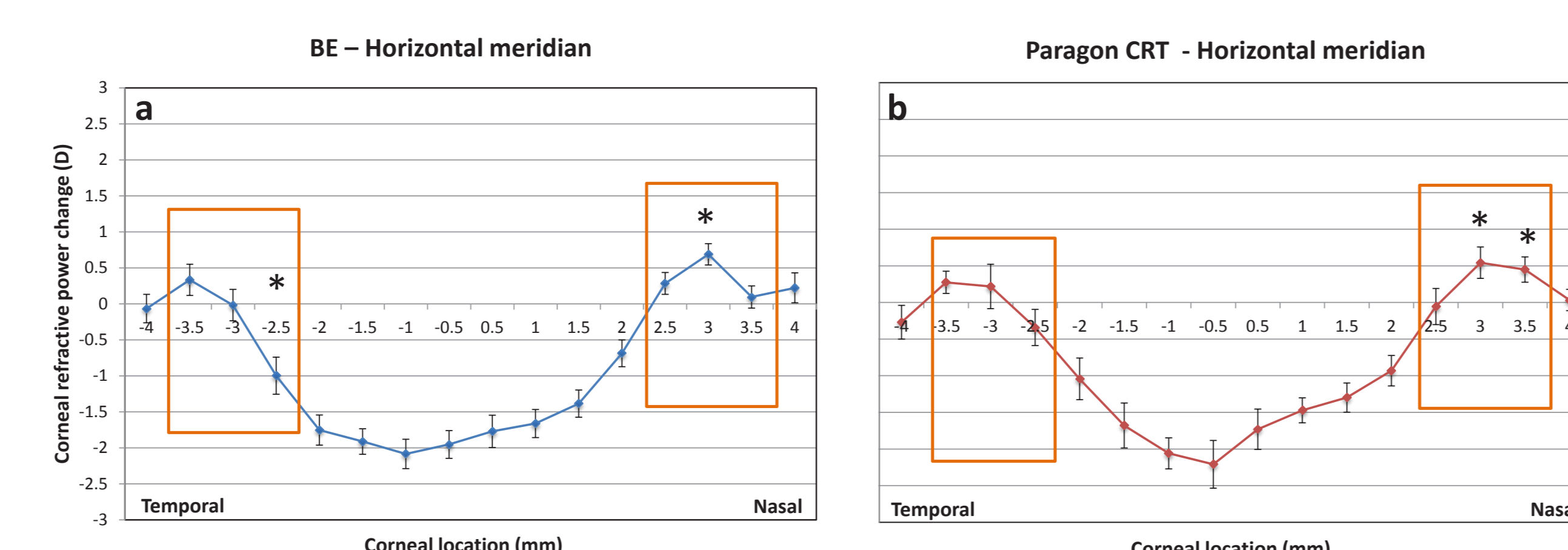


Figure 3. Along the horizontal meridian, in eyes wearing BE lenses, a significant reduction ($p = 0.001$) in CRP from baseline was found at 2.50 mm temporally and an increase ($p < 0.001$) in CRP was found at 3.00 mm nasally (Fig 3a). In eyes wearing Paragon CRT lenses, a significant increase in CRP was found nasally at 3 mm and 3.5 mm (both $p < 0.05$) (Fig 3b).

	BE	Contex	p-value	BE	Paragon CRT	p-value
Refractive M (D)	-1.43 ± 0.70	-1.49 ± 0.67	0.072	-1.59 ± 0.93	-1.56 ± 0.81	0.631
Refractive J ₁₈₀ (D)	-0.06 ± 0.18	-0.02 ± 0.19	0.178	-0.07 ± 0.19	-0.02 ± 0.18	0.027*
Refractive J ₄₅ (D)	0.03 ± 0.12	-0.06 ± 0.12	0.184	0.03 ± 0.12	0.01 ± 0.12	0.420
R _c (mm)	7.80 ± 0.22	7.79 ± 0.21	0.167	7.78 ± 0.21	7.79 ± 0.20	0.402
Flat K (D)	43.12 ± 1.21	43.12 ± 1.19	0.739	43.13 ± 1.13	43.11 ± 1.07	0.649
Steep K (D)	43.82 ± 1.22	43.89 ± 1.21	0.129	43.86 ± 1.17	43.91 ± 1.12	0.369

Table 1. Comparison of baseline central objective refraction and corneal topography parameters between eyes wearing BE and Contex lenses, and BE and Paragon CRT lenses. * indicates statistically significant difference.

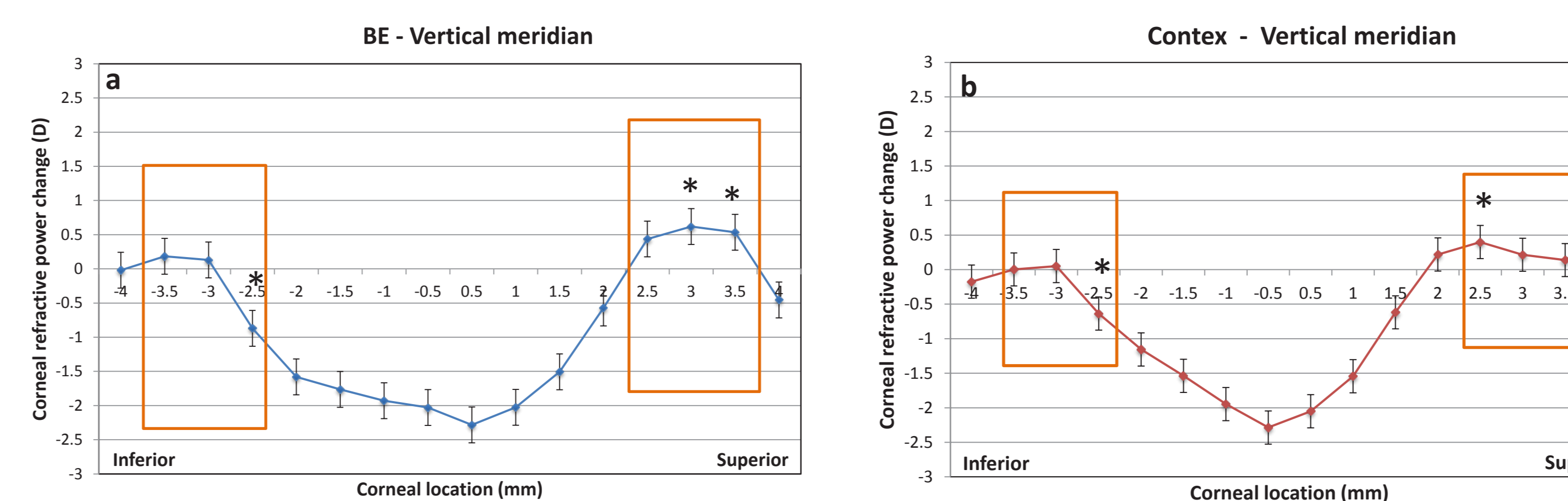


Figure 2. Along the vertical meridian, no difference was found in overall CRP change in the para-central region between the two lens designs ($F = 0.913$, $p = 0.542$). In eyes wearing BE lenses, the change in CRP from baseline was significantly different between locations along the vertical meridian ($F = 11.553$, $p < 0.001$). There was a significant reduction ($p = 0.003$) in CRP 2.50 mm inferior to vertex normal and increase in CRP 3.00 mm and 3.50 mm superiorly (both $p < 0.005$) (Fig 2a). In eyes wearing Contex lenses, there was a significant reduction ($p = 0.003$) in CRP 2.50 mm inferior and increase ($p = 0.040$) at 2.50 mm superior to vertex normal (Fig 2b).

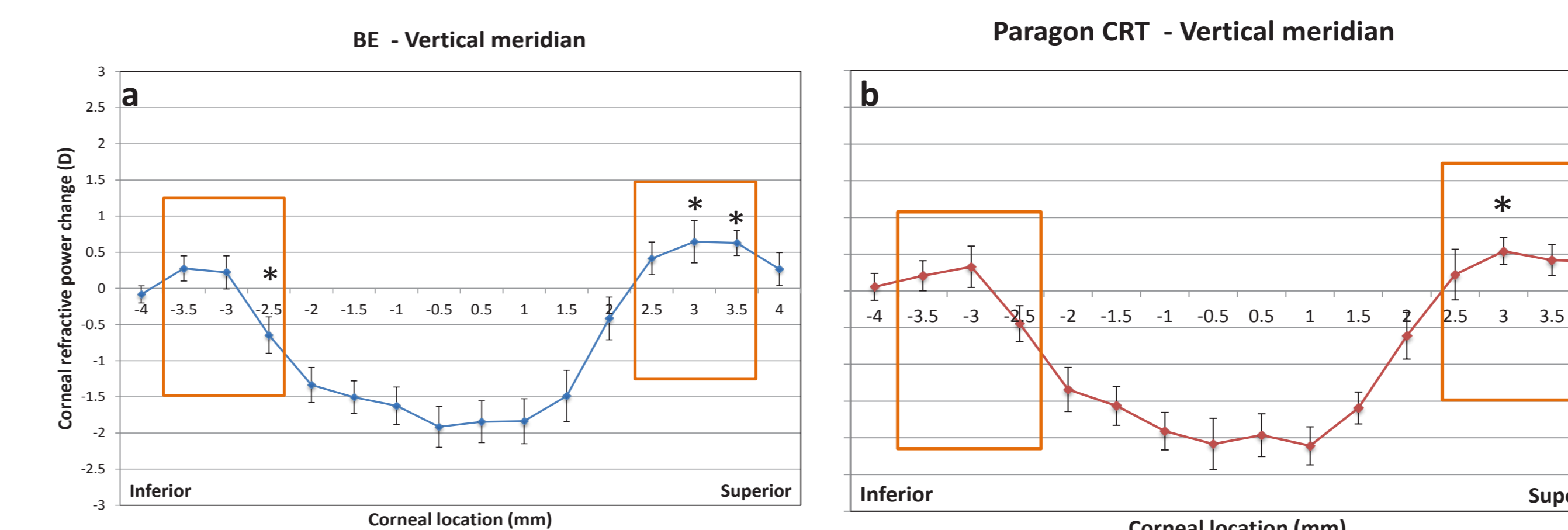


Figure 4. Along the vertical meridian, in eyes wearing BE lenses, a significant reduction ($p = 0.020$) in CRP was found at 2.5 mm inferiorly and an increase at 3 mm and 3.5 mm superiorly ($p < 0.05$) (Fig 4a). In eyes wearing CRT lenses, a significant increase in CRP change was found at 3 mm superiorly ($p = 0.009$) (Fig 4b).

DISCUSSION

- The amount of central corneal flattening and para-central steepening found in our study is consistent with a previous study.⁷
- This study showed significant differences in CRP change between BE and Contex OK lenses at three locations along the horizontal meridian. However, these differences were not clinically significant.
- No significant differences in CRP change were found between BE and Paragon CRT lenses in either meridian.
- Typically all three types of lenses showed an increase in CRP in one or more locations nasally or superiorly. This may be related to OK lens decentration.
- Contrary to other anecdotal reports, we did not find a 1:1 relationship between central CRP reduction and para-central increase in CRP.

CONCLUSIONS

- The three OK lens designs used in this study induce similar corneal refractive effects. If the effect of CRP correlates to refraction changes, this implies that myopia control effects induced by different lens designs are likely to be similar.
- For the same reason, OK practitioners may interchangeably use these lens designs to obtain similar corneal effects or researchers may compare the outcomes derived from different lens designs used in this study.
- Further research is needed to correlate CRP changes with refraction in relation to OK lens decentration.

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