# Comparing 5mm and 6mm Back Optic Zone Diameter (BOZD) in Orthokeratology Lens Design

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## Introduction

**Overnight orthokeratology (OrthoK)** rigid lens design can be altered to achieve a safe fitting lens-to-cornea relationship that is effective in reshaping the corneal topographic profile to correct myopia.

The **back optic zone (BOZ)** of the OrthoK lens is the central area that imparts corneal flattening. The diameter of the BOZ plays a critical role in determining the size of the corneal treatment zone.

## Purpose

This study compares Paragon CRT® lens design with 5mm and 6mm BOZD on the impact of topographical changes, clinical safety efficacy, and visual performance.

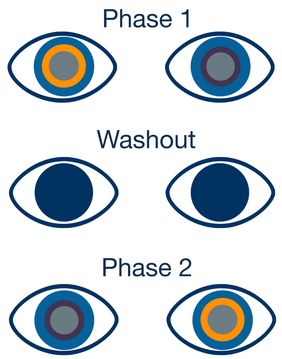
## Methods

A two-stage, self-controlled, randomized crossover study was conducted at the University of California, Berkeley.
**18 subjects** (14 female, 4 male), average age 23.7 (±2.35) years, with -3.08(±1.57)D of myopia and -0.86(±0.59)D of astigmatism.

**Control lenses with 6mm BOZD** were empirically ordered based on auto-refraction, corneal topography, and white-to-white (WTW).

**Test lenses with 5mm BOZD** were designed mathematically to have identical overall diameter and sagittal depth as control lenses.

**Phase 1:** Masked subjects were randomly allocated to wear the **6mm BOZD control lens** in one eye, and **5mm BOZD test lens** in the other eye for 4 weeks. Subjects were evaluated by slit lamp, visual acuity, manifest and autorefraction, and corneal topography at **baseline, 1-day, 1-week and 4 weeks** after initiation of treatment.




**Washout:** Subjects discontinued lens wear for 1-2 weeks to allow corneal shape to return to baseline.

**Phase 2:** Lens allocation was **reversed** and worn for 4 weeks with matched follow-up visits and evaluation.

## Results

### Onset of Correction

- The test lens had **faster onset** of myopic correction
- 1-day: Test lens had 0.42D more myopic correction (p=0.001).
- 1-week: Test lens had 0.31D more myopic correction (p=0.007)
- 4-weeks: No difference

### Visual Performance

- **Similar visual acuity** between the two designs at any f/u visit. Trained subjects were unable to "unmask" the lens design based on visual performance.

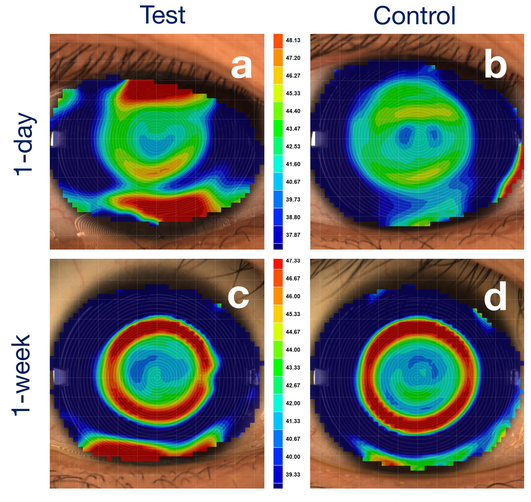



**Figure 1.** Topographical images of (a) test lens at 1-day, (b) control lens at 1-day, (c) test lens at 1-week, (d) control lens at 1-week

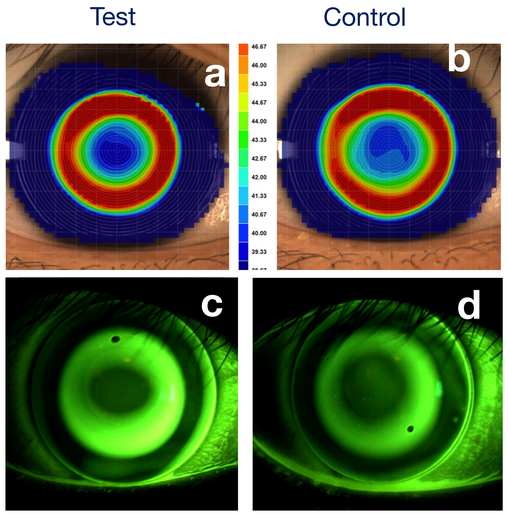



**Figure 2.** Topographical images at 4 weeks of (a) test lens, and (b) control lens. Anterior segment image of fluorescein pattern of (c) test lens, and (d) control lens.

### Corneal Treatment Zone Size

- The test lens had a **smaller horizontal treatment zone size** than the control at 4 weeks
- **Overall smaller** corneal treatment zone than BOZD of both lenses
- **Significant individual variability** on size of treatment zone within the same BOZD group

| | BOZD | Corneal Treatment Size |
|---|---|---|
| Test Lens | 5mm | 3.05±0.11mm (ranged from 2.1 to 4.4mm) |
| Control Lens | 6mm | 3.44±0.13mm (ranged from 2.1 to 4.5mm) |
| | Difference of 0.38±0.18mm (p=0.04) | |

**Table 1.** Comparison of horizontal corneal treatment zone size with test and control lenses.

### Symptoms and Adverse Events

- No significant interocular difference in the comfort of lenses at any visit
- No serious adverse events occurred with either lens

## Discussion

The study confirmed the short-term safety, subjective and objective performance of the Paragon CRT® lens design with 5mm BOZD test lens. An advantage of the test lens was a faster onset of myopic correction at day 1 and 7, with similar magnitude of correction at 4 week.

The corneal treatment zone of the test lens was statistically significantly smaller than the control lens. However, the difference was much smaller than that incorporated on the BOZD. Additionally, there was significant individual variability independent of the baseline level of myopia and lens design, suggesting a general disparity between the profile of the back surface of the lens and achieved corneal molding. Thus, altering the BOZD size may have a less-predictable effect on the corneal treatment size.

## Conclusion

The **5mm BOZD test lens** had:

- **Effective visual performance** and no serious adverse events
- **Faster rate of onset** of myopic correction after first night and first week of wear
- **Smaller diameter of corneal treatment zone**

The test lens with smaller BOZD safely, effectively and efficiently corrected myopia, while creating a smaller corneal treatment zone. Future topographical analysis of the magnitude of paracentral steepening of the cornea achieved by the smaller BOZD lens may be insightful for imposed retinal defocus, aberration, and anti-myopia efficacy.

## References

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