

# Optimization of a daily disposable toric soft contact lens to meet the varying needs of patients with low versus moderate/high levels of astigmatism

Ryan Sherrill, MBA<sup>1</sup>, Giovanna Olivares OD FAAO<sup>1</sup>, Ross Franklin BAppScOptom<sup>1</sup>,  
Jessica Cannon-Hill MSc<sup>1</sup>, Pierre Gerligand PhD<sup>1</sup>

<sup>1</sup>Johnson & Johnson MedTech (Vision), Jacksonville, Florida, USA

## Purpose

While the rate of astigmatic lens fitting around the world has been increasing in recent years, toric lenses are still under-prescribed in many markets<sup>1</sup>. Additionally, data on dropout rates among astigmatic patients, clinical results, and willingness to pay highlight two often conflicting opportunity areas: comfort and clear, stable vision. This study was designed to evaluate the impact of alterations in toric lens stability feature geometry on lens rotational performance and initial comfort.

## Background

**Low Cylinder patients** - occasionally fit in spherical soft contact lenses to maximize comfort but at the detriment of their vision<sup>2</sup>.

**High Cylinder patients** - greater sensitivity to lens rotation. Even a few degrees of contact lens movement could lead to noticeable levels of visual blur.

- ▶ Excellent vision clarity and stability are key to success when fitting astigmatic patients. As little as 5° toric lens mis-rotation can induce optical blur (Figure 1).

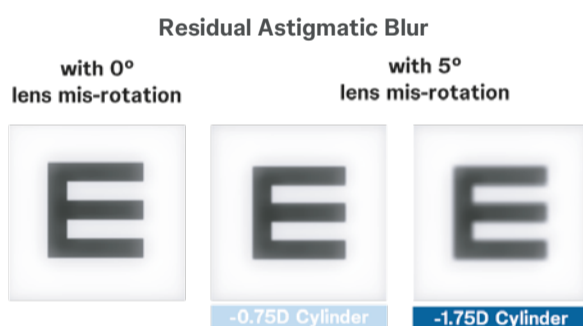
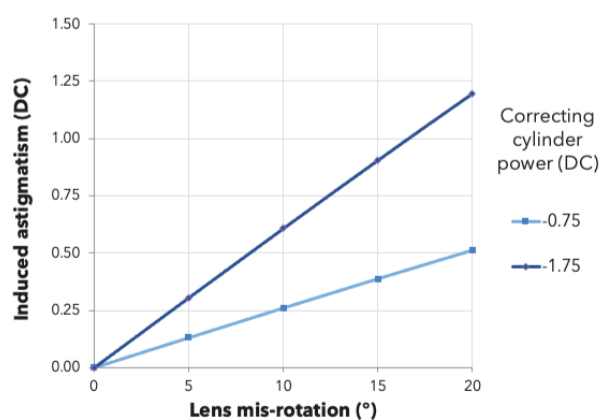


Figure 1

- ▶ The amount of optical blur that is induced depends on the amount of lens mis-rotation and cylinder power (Figure 2).



- ▶ Currently all soft contact lens designs in market offer a one size fits all approach by brand regardless of the level of astigmatic correction.

**Question to be answered: Is there an opportunity to explore the toric stabilization design space for correcting different levels of astigmatism?**

## Method

### Study Design

A total of 43 non-presbyopic myopic astigmatic subjects (0.00 to -6.00 DS), with corneal plane astigmatism  $\leq 3$  diopters were enrolled into a double-masked, non-dispensing 4x4 crossover study.

Subjects wore 4 lens designs in a random order over 2 visits (2 lens designs per visit). For testing, two different test lens designs were worn bilaterally in-office for ~1 hour. A washout period of at least 12 hours up to 10 days between visits was used.

### Test Articles

The study lenses were -3.00D -0.75D x 180° senofilcon A toric soft contact lenses with the BLINK STABILIZED® Design (BSD) method of stabilization. The study lenses were manufactured with four levels of slope differences in the stabilization region (labeled S1, S2, S3 and S4) representing a range from the most gradual slope S1 to the steepest slope S4.

The slope of the BSD concept changes circumferentially from the vertical to the horizontal position. The lens design is symmetrical both vertically and horizontally (Figure 3).

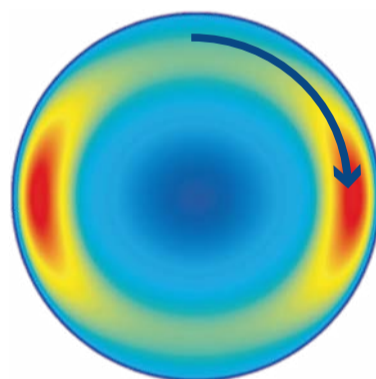


Figure 3

### Measurements

- ▶ Rotation Error and Lens Stability

Rotation error was measured by determining the angular deviation of the inferior toric scribe mark from a vertical reference line (i.e. 6 o'clock) using a slit lamp microscope. For each eye, the stability of post settled lens orientation was assessed from 8 rotation measurements during a wear period. To ensure each measurement was independent, subjects were instructed to walk around the office for at least 2 min between measurements.

- ▶ Initial Comfort

Initial comfort was assessed after approximately 1 hour of wear using CLUE™ (Contact Lens UserExperience<sup>3</sup>), a validated PRO questionnaire used to capture subjective patient feedback.

\*Since the same contact lens power was used for all study participants, without regard for their individual refractive error, the subjective assessment of the lens was limited to initial comfort (lens sensation). The vision quality with the lenses was not measured.

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## Results

Figure 4 shows the relationship between:

- ▶ Rotation error (left y-axis) shows the eye-to-eye variation in lens orientation was highest for the lens with the smallest slope S1 followed in order by S2, S3, and S4 (steepest slope).
- ▶ Initial comfort (right y-axis) shows comfort decreases as the slope increases from S1 to S4. Historical mean shown with dashed line for reference.

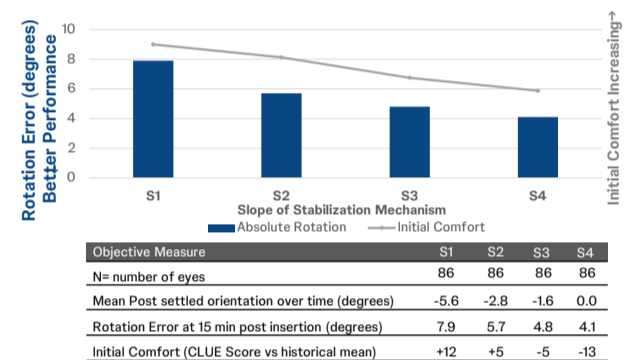


Figure 4

## Conclusion

The data illustrates the relationship between rotational performance, comfort and stabilization design slope differences: contact lens rotational performance improves as the slope increases, while the initial comfort decreased. This data suggests that creating a stabilization design that varies by level of cylinder correction is warranted, perhaps within the range of S2 to S3.

While the BSD has shown to be stable, this would enable a lens designer to implement minor adjustments to the stabilization slope:

1. Maximize comfort for lower levels of refractive astigmatism where larger amounts of axis misalignment may occur while still providing consistent vision.
2. Minimize visual fluctuations for higher levels of cylinder power correction while maintaining comfort.

This early-stage research identified the design space to optimize the stabilization slope for varying levels of cylinder correction. This work was followed by optical/ mechanical modeling as well as clinical validation studies to establish *The First and Only Cylinder Optimized Design*.

## For Additional Information

Visit poster #70 for Eye Care Professionals perspectives on astigmatic needs and the appeal of unique astigmatism correction design for high levels of astigmatism.

Visit posters #66 and #67 to learn about the clinical performance of ACUVUE® OASYS MAX 1-Day for ASTIGMATISM with Cylinder Optimized BSD

## References

1. Efron, N. et al. (2024) International trends in prescribing toric soft contact lenses to correct astigmatism (2000-2023): An update. CLAE, October 2024.
2. Berntsen, D. et al (2019) A Randomized Trial to Evaluate the Effect of Toric Versus Spherical Contact Lenses On Vision and Eyestrain. Eye & Contact Lens January 2019.
3. Wirth R.J, Edwards M.C, Henderson M, Henderson T, Olivares G, Houts C.R. Development of the Contact Lens User Experience: CLUE Scales. Optom Vis Sci. 2016;93(8):801-808.