

Does Pupil Size Influence Vision Performance of a New Silicone Hydrogel Daily Disposable Multifocal Contact Lens (Kalifilcon A)?

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INTRODUCTION

Past studies suggests that factors like age, refractive error, and luminance influence pupil size,¹ which may affect the performance of multifocal contact lenses (MFCLs). Traditionally, conventional MFCL designs use refractive error or refractive error and pupil size in optical design development. In contrast, additional factors were also considered in the development of a novel 3-Zone Progressive lens design. In addition to refractive error and pupil diameter, the design accounted for accommodative amplitude, depth of focus, higher-order aberrations, pupil changes as a function of object distance, corneal curvature, axial length, and residual accommodation across nine distances.²

This study was performed to investigate correlation between vision performance and pupil size of a new 3-Zone Progressive daily disposable (DD) silicone hydrogel MFCL (kalifilcon A).³

METHODS

Habitual wearers of MFCL at age ≥ 40 years were enrolled in this 3-week, single arm, bilateral, open-label study to assess near, intermediate, and distance vision performance. Spherocylindrical refraction and pupil size were recorded at the dispensing visit, and binocular high-contrast visual acuity (VA; logMAR) was obtained at dispensing, 1-week, and 3-week follow-up visits; subjects rated vision performance for each eye using a 0–100 scale (100=most favorable) at each visit. For each subject, mean ratings for near, intermediate, and distance vision were calculated by averaging the values for each eye. Responses were categorized as favorable if the score was ≥ 50 , and p-values were calculated from a two-sided binomial test comparing the percentage of favorable responses to 50%. Pearson correlation coefficient was used to determine whether there was a significant relationship between pupil size and vision performance.

RESULTS

292 subjects completed the study. Pupil size ranged from 2.0 to 7.0 mm. Mean logMAR VA at the 1-week and 3-week visits was -0.009, 0.046, and 0.114, and -0.012, 0.046, and 0.115 for distance, intermediate, and near, respectively.

Correlations between pupil size and logMAR VA, and between pupil size and vision performance ratings at each follow-up visit are shown in **Tables 1 and 2**, respectively. Vision performance ratings and the percentage of responses that were favorable after 1 week and 3 weeks of MFCL wear are shown in **Figures 1 and 2**, respectively.

Global Specialty Lens Symposium, Las Vegas, NV, USA. January 17–20, 2024

ABBREVIATIONS: DD, daily disposable; logMAR, Logarithm of the Minimum Angle of Resolution; MFCL, multifocal contact lens; VA, visual acuity.

Table 1. Correlations between logMAR visual acuity and pupil size

Vision	1-week follow-up visit		3-week follow-up visit	
	Correlation	p	correlation	p
Distance	0.05	0.41	0.04	0.47
Intermediate	-0.13	0.02	-0.11	0.06
Near	0.08	0.16	0.01	0.80

Table 2. Correlations between vision performance rating and pupil size

Vision	1-week follow-up visit		3-week follow-up visit	
	Correlation	p	correlation	p
Distance	-0.04	0.49	-0.005	0.93
Intermediate	-0.01	0.82	0.002	0.96
Near	-0.02	0.71	-0.02	0.69

Figure 1. Mean vision performance ratings after 1 week and 3 weeks of MFCL wear

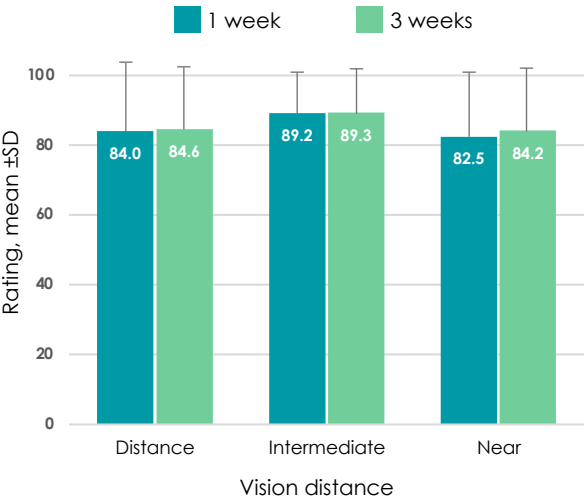
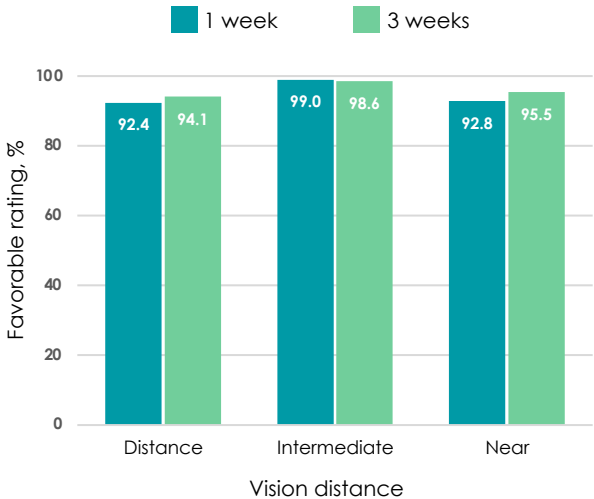


Figure 2. Percent favorable vision performance ratings after 1 week and 3 weeks of MFCL wear



DISCUSSION

Statistical analysis of the distribution of logMAR VA found no significant correlation after 1 week of MFCL wear for distance or near vision (correlation coefficients 0.05 and 0.08, respectively, both $p > 0.05$), and a weak but statistically significant correlation between intermediate VA and pupil size (correlation coefficient = -0.13, $p = 0.02$; **Table 1**). No significant correlation was found after 3 weeks of MFCL wear for any distance, with correlation coefficients ranging from -0.11 to 0.04 (all $p > 0.05$; **Table 1**).

Similarly, no significant correlation between vision performance rating and pupil size was observed at either follow-up visit, with correlation coefficients ranging from -0.04 to 0.002 (all $p > 0.05$; **Table 2**).

Subjects rated the lens 84.0 ± 19.9 , 89.2 ± 11.8 , and 82.5 ± 18.5 for distance, intermediate, and near vision, respectively after 1 week of MFCL wear, and 84.6 ± 18.0 , 89.3 ± 12.6 , and 84.2 ± 17.9 , respectively after 3 weeks (**Figure 1**). Overall, responses were significantly favorable at the three distances: 92.4, 99.0, and 92.8%, respectively after 1 week of MFCL wear and 94.0, 98.6, and 95.7%, respectively after 3 weeks (all $p < 0.05$; **Figure 2**). No significant correlation between pupil size and subject age was observed (correlation coefficient = 0.01, $p = 0.86$).

While the MFCL evaluated in this study was not specifically designed to pupil size based upon range and refractive error, the extensive modeling used in lens development ensured that the lens would perform as intended across a large range of pupil size.

CONCLUSIONS

Overall, there was no correlation between the pupil size and the vision performance at distance, intermediate, or near for the DD MFCL used in the study. The kalifilcon A 3-Zone Progressive design MFCL delivers favorable ratings for distance, intermediate, and near vision for patients with a wide range of pupil sizes.

REFERENCES

- Guillon M, et al. Optom Vis Sci 2016;93:1093-100
- Kingston AC & Cox IG. Optom Vis Sci 2013;90:1111-8
- 510(k) Summary K220613. Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Astigmatism, and Bausch + Lomb (kalifilcon A) Soft (hydrophilic) Contact Lens for Presbyopia A. March 8, 2023. Food and Drug Administration. Accessed November 24, 2023. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220613.pdf

ACKNOWLEDGMENTS

This study was funded by Bausch + Lomb.

