White Paper

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Pupil Size Independence with Multifocal Contact Lenses: Fact or Fiction?

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Key Points:

- Multifocal (MF) contact lenses are designed to provide functional vision to presbyopic patients of different ages, refractive errors and pupil sizes
- Pupil size decreases slightly with age; however, the correlation is weak and there is substantial variation among individuals
- There is no clinically significant relationship between pupil size and refractive error
- Neither age nor refractive error are relevant with respect to multifocal optic zone designs
- A recent study showed that Alcon multifocal contact lenses are pupil size independent and demonstrated that pupil size did not affect the number of lenses required for a proper lens fitting or visual performance

Pupil size

Pupil size may play a role in the efficacy of simultaneous vision multifocal contact lens optics, particularly on the extreme ends of the physiological range of pupil diameter in the human eye. It is well known that pupil size changes dramatically in response to luminance levels in order to control the amount of light entering the eye: bright light constricts the pupil, while dim light allows it to dilate. The pupil also naturally constricts when looking at near, as part of the near triad response (convergence, accommodation, pupil constriction) but is likely also due to some proximal cues rather than convergence and accommodation alone.[1-4] Additional factors such as age and refractive error have been suggested as significantly influencing pupil size and the success of multifocal (MF) contact lenses.[4,5]

Manufacturers design their simultaneous vision MF contact lenses to provide functional vision to presbyopic patients of different ages, refractive errors and pupil sizes. They do this by adjusting the power profile and optic zone size. One manufacturer purports to uniquely optimize their multifocal lens optic zones based on hypothetical changes in the pupil size based on age and refractive error.[6,7] But how relevant is the effect of age or distance refractive error on pupil size and ultimately in the design of a multifocal contact lens optic zone for a presbyopic contact lens wearing population?

Pupil size vs age

Literature has shown that pupil size does decrease with increasing age, although both factors are weakly correlated.[3,5,8] Additionally, there is substantial variation in pupil size among individuals within the same age range[2,8] which makes age a poor predictor of pupil size (or vice versa). Furthermore, the pupil size differences in different age groups is generally small (<2.0mm) and within the typical contact lens wearing presbyopic age range (40-60) even smaller <1.0mm (Figure 1) particularly at higher luminance levels.[2,4,8] Thus, age seems to be a poor design variable for multifocal optic zone design.

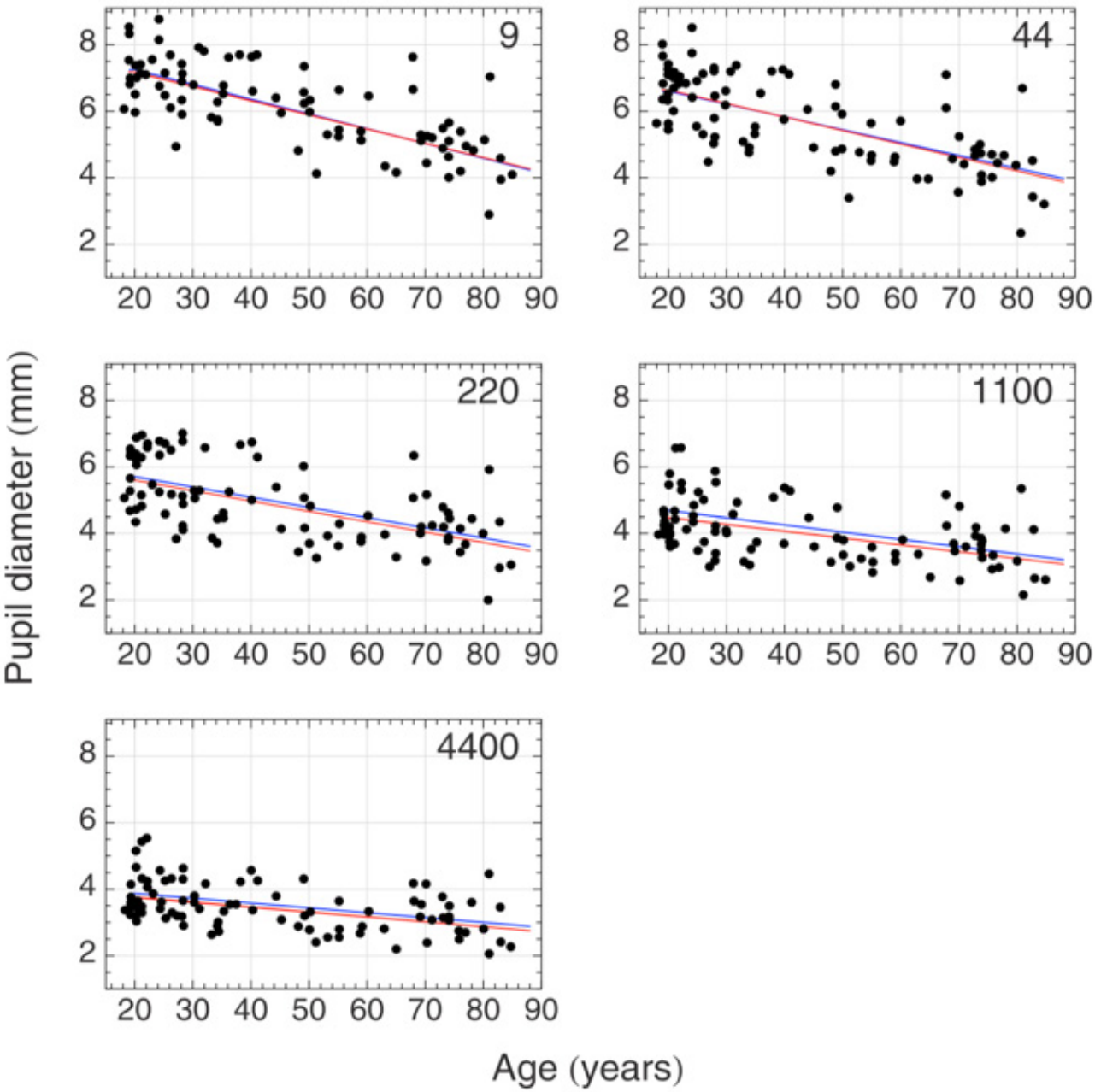


Figure 1: Effect of age on pupil diameter (Watson and Yellot, 2012). Pupil diameter is plotted as a function of age for each luminance condition (Data are fitted by linear regression). Although pupil size decreases with age, there is significant variability across the entire age range as demonstrated by the degree of scatter.

Pupil size vs refractive error

There is similarly no clinically significant relationship between pupil size and refractive error, although some report statistically significant relationships depending on the luminance levels tested.[3-5,8] Figure 2 shows that pupil diameter is not significantly influenced by refractive error (p=0.91). It further shows that pupil diameter is also not influenced by target vergence (0.00D vs 3.00D) or refractive correction status. However, it does show that pupil size is directly correlated to luminance level which is, in fact, the main driving factor of pupil size.[3]

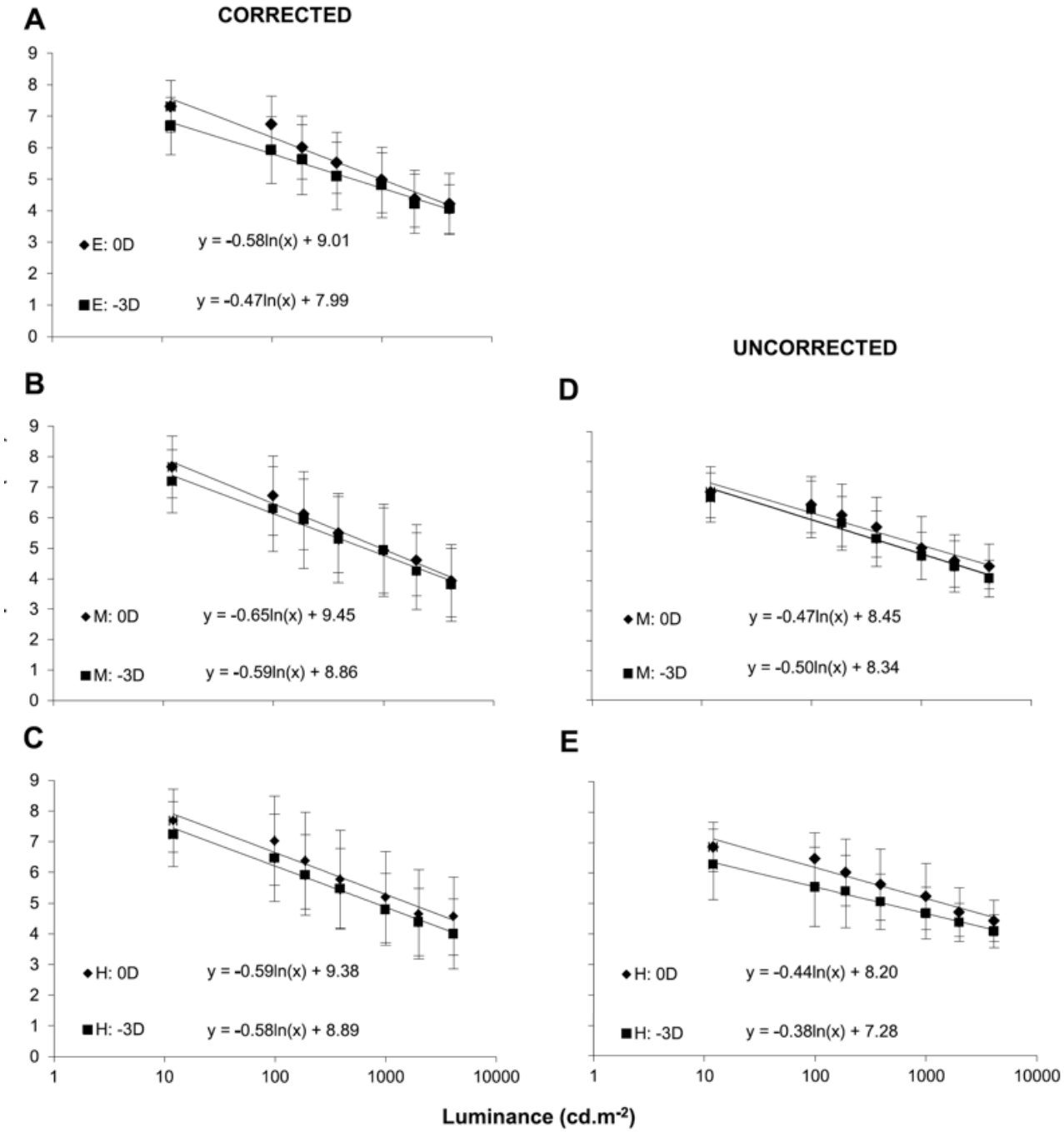


Figure 2: Pupil diameter and target luminance in the emmetropic (E), myopic (M), and the hyperopic (H) groups, at 0 D and -3 D target vergence when refractive error was corrected and not corrected. Error bars are SDs (from Orr et al., OVS, 2015)

Summary

Literature does not support that pupil diameter changes based on refractive error and age. Therefore, these factors must be considered as clinically insignificant within the typical presbyopic contact lens wearing population. Consequently, neither factor should be considered as relevant with respect to optic zone designs, making so-called pupil optimization of optic zones an unrealistic approach in mass-marketed soft MF contact lenses. Instead, pupil size is most significantly affected by luminance levels, which may impact success when fitting simultaneous vision MF lenses.

Alcon Multifocal Contact Lenses Demonstrate Pupil Size Independence

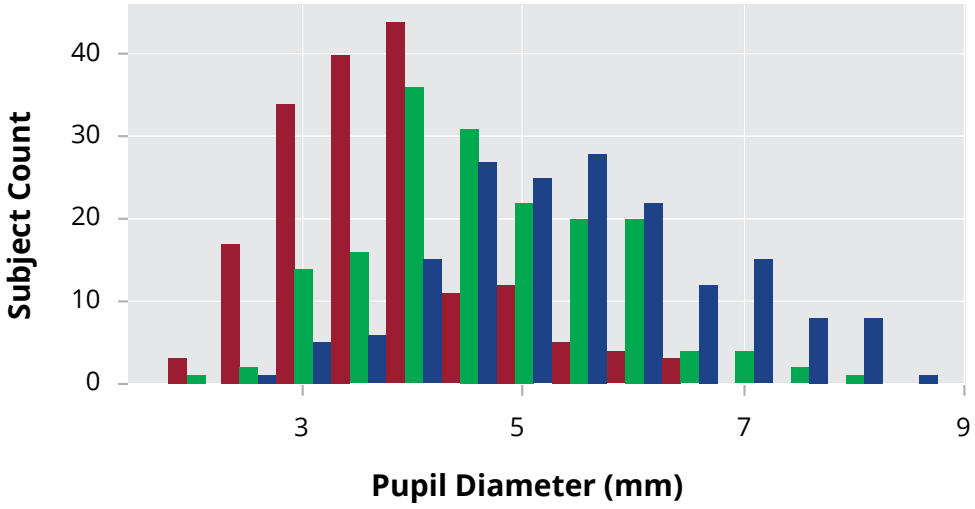
While pupil size is often suggested to be an important variable when designing MF contact lenses, literature shows that accounting for it based on age and refractive error in MF lens designs is not necessary for most patients.[2-5,8]

Alcon MF contact lenses (DAILIES® Total1® MF, DAILIES® AquaComfort® Plus MF and AIR OPTIX® plus HydraGlyde® MF) all feature the same center-near aspheric design called PRECISION PROFILE® Design. This center-near design does inherently favor the natural function of the pupil, which constricts at near and dilates at distance; however, specific design features being applied to account for changes in pupil size based on age or refractive error are unnecessary. In fact, a recent study shows that Alcon MF contact lenses are pupil size independent and work effectively across a wide range of pupil sizes and luminance levels.[9,10] Furthermore, Alcon MF contact lenses can be successfully fit on 98% of patients using two lenses or less per eye (at the initial visit) and 83% can be fit using one lens per eye (at initial visit).[11] This is important because the fewer lenses needed to fit the patient, means less time the doctor is spending switching out trial lenses, allowing them to be more efficient and to be successful faster.

Multifocal Fitting Success Clinical Study[9,10]

The purpose of this analysis was to evaluate if pupil size is associated with 1) the number of lenses required for fitting and 2) visual performance. The clinical study included 84 presbyopes who were successfully wearing a variety of soft MF lens designs and were then randomly refitted with Alcon MF contact lenses: either DAILIES® Total1® MF, DAILIES® AquaComfort® Plus MF and AIR OPTIX® plus HydraGlyde® MF. Prior to lens fitting, pupil size was measured at distance under photopic, intermediate, and mesopic lighting conditions (ORC Eye-Dentify pupil card). The number of lenses per eye required for the fitting at the initial visit were recorded. Following a successful MF CL fitting, subjective visual quality (analog scale from 1–10) and binocular visual acuity (logMAR) were measured at near (40 cm), intermediate (80 cm), and distance (4m) in photopic light. Linear correlation analyses were used to determine whether there was a significant relationship between pupil size (right eye only) and each clinical measure.

The distribution of pupil sizes measured at the different luminance levels are shown in Figure 3 with an overall range in pupil size of 2.0–8.0mm. There was no difference in visual acuity across the pupil diameters at near, intermediate or distance (Figure 4). Tables 1 & 2 show there was no significant correlation of objective or subjective visual performance versus pupil sizes ranging from 2 to 8mm. Lastly, in the photopic pupil size range, there was no significant difference in the number of lenses required during the initial fitting visit (mean=1.36 lenses, p>0.05).



Baseline photopic (red), intermediate (green), and mesopic (blue) pupil diameter were measured prior to MF CL fitting.

Figure 3: Pupil Size Diameter Distribution

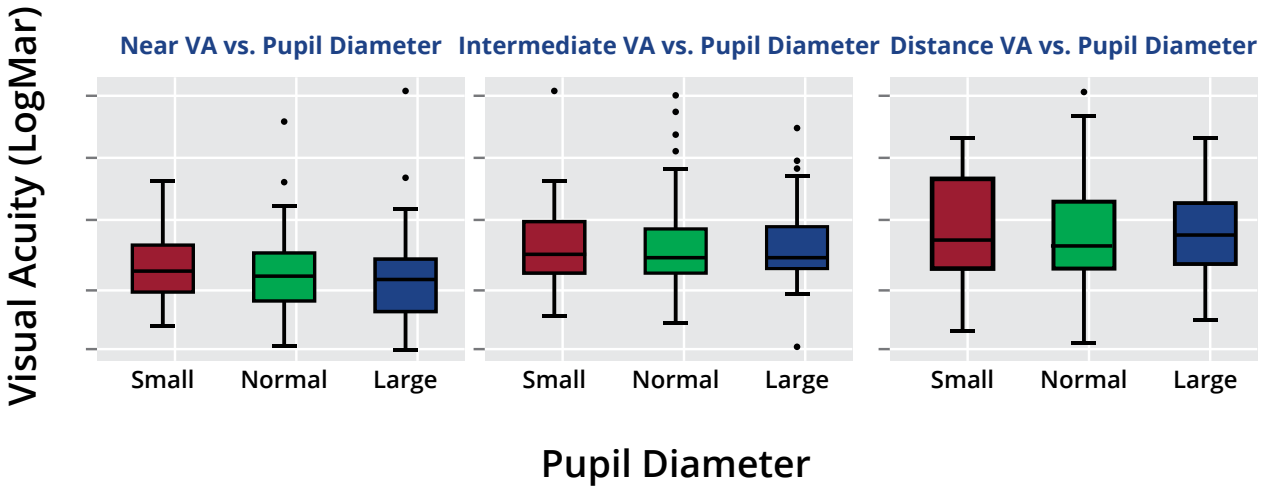


Figure 4: Near, intermediate and distance visual acuity for different pupil diameter sizes

	Near	Intermediate	Distance
BCVA (logMAR)	r = 0.20; p = 0.08	r = 0.046; p = 0.69	r = 0.048; p = 0.67
Subjective Vision Quality	r = -0.004; p = 0.97	r = -0.069; p = 0.53	r = 0.002; p = 0.98

Table 1: Photopic pupil diameter linear correlation coefficient and statistical significance (p-value) with different vision performance measures at three different distance ranges

	Near	Intermediate	Distance
BCVA (logMAR)	r = 0.14; p = 0.23	r = 0.03; p = 0.79	r = 0.048; p = 0.67
Subjective Vision Quality	r = -0.098; p = 0.38	r = -0.18; p = 0.10	r = -0.14; p = 0.22

Table 2: Mesopic pupil diameter linear correlation coefficient and statistical significance (p-value) with different vision performance measures at three different distance ranges

Summary

Alcon MF contact lenses use a center-near aspheric MF design (PRECISION PROFILE® Design) and work successfully across a wide range of pupil sizes, regardless of age, refractive error or luminance level. In this study, pupil diameter was not related to the number of lenses required for a successful fit and was not associated with subjective and objective visual outcomes with Alcon MF contact lenses. The PRECISION PROFILE® Design contact lenses provided good near, intermediate and distance vision across all pupil sizes and demonstrated pupil size independence in patients successfully refitted from other MF contact lenses.

Disclosures: Jessica Mathew, Mo Merchea and Kevin Baker are Alcon employees.

Important information for AIR OPTIX® plus HydraGlyde® Multifocal (lotrafilcon B) contact lenses: For daily wear or extended wear up to 6 nights for near/far-sightedness. Risk of serious eye problems (i.e., corneal ulcer) is greater for extended wear. In rare cases, loss of vision may result. Side effects like discomfort, mild burning or stinging may occur.

See product instructions for complete wear, care and safety information. Rx only

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