Comparison between the Nidek MP-3 and CenterVueMAIA microperimeters in healthy eyes and eyes with diabetic retinopathy and age-related macular degeneration

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Background

Microperimetry (MP) is a robust tool that assesses retinal sensitivity, which is a useful endpoint in ophthalmic clinical trials. MP devices have considerably evolved over the last two decades. The Macular Integrity Assessment (MAIA) (CebterVue, Padova, Italy) was introduced in 2009[1]. The latest generation of MP technology includes the MP-3 (Nidek, Gamagori, Japan)[2]. As these devices are key instruments in clinical trials and studies, understanding whether results can be inter-related between the two devices is important.

Retinal pathologies, including diabetic retinopathy (DR) and age-related macular degeneration (AMD) and a cohort of healthy subjects can be studied to understand the relationship between the two devices.

Purpose

To compare and correlate the mean sensitivity values obtained with the Nidek MP-3 and CenterVue MAIA microperimeters in healthy eyes and eyes with DR and AMD.

Methods

Design
Prospective comparative cross-sectional study
Subjects
Total of 38 eyes of 35 subjects
12 healthy eyes of 9 subjects, 18 eyes of 18 patients with DR (mild, moderate, and severe NPDR, PDR), and 8 eyes with non-exudative AMD (neAMD) (early, intermediate, advanced)
Inclusion Criteria
Healthy eyes and eyes with DR and neAMD, BCVA 20/20 – 20/40 & mild cataract NS0C0 – NS2C2
**Exclusion Criteria**
Significant media opacity, concurrent vascular conditions (retinal vein occlusion), history of macula involving tractional and/or rhegmatogenous retinal detachment, exudative AMD, advanced glaucoma
MP-3 and MAIA Parameters
10-2 macular grid (68 stimuli), Goldman III stimuli size, 4-2 threshold strategy, circle fixation target, background luminance 4 asb, maximum luminance 1000 asb
Statistical Methods
Mean sensitivity values assessed with MAIA (Panel A) and MP-3 (Panel B) on healthy subjects and subjects wit h DR and AMD were used for Bland-Altman repeatability analysis. Conversion formulae from MP-3 to MAIA were identified using a shift method and a simple regression method, respectively. The coefficient of Repeatability (CoR) between MAIA and converted values from MP-3 were calculated and used to assess the requirement for a clinically significant change that is beyond natural variability.
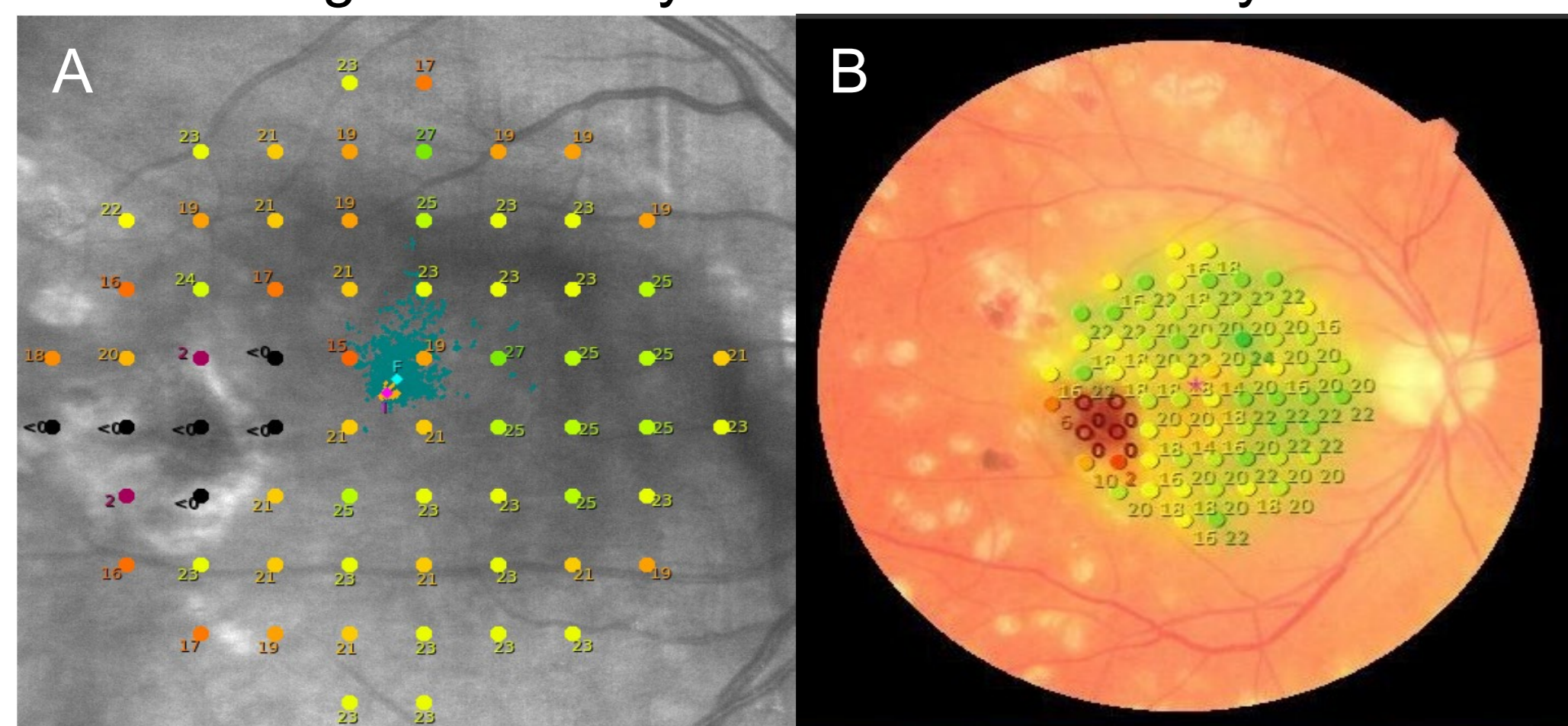

Results

Conversion formula from MP-3 to MAIA using the shift method

MAIA_shift was created from MP-3 measurement by applying shift conversion formula
- MAIA_Shift (dB) = MP-3 + 2.64

Bland-Altman plot of agreement on Mean Sensitivity between MAIA and MP-3

Conversion formula from MP-3 to MAIA using the simple regression method

MAIA_Reg was created from MP-3 measurement by applying regression conversion formula
- MAIA_Reg (dB) = 6.50859 + 0.80649 x MP-3

Regression
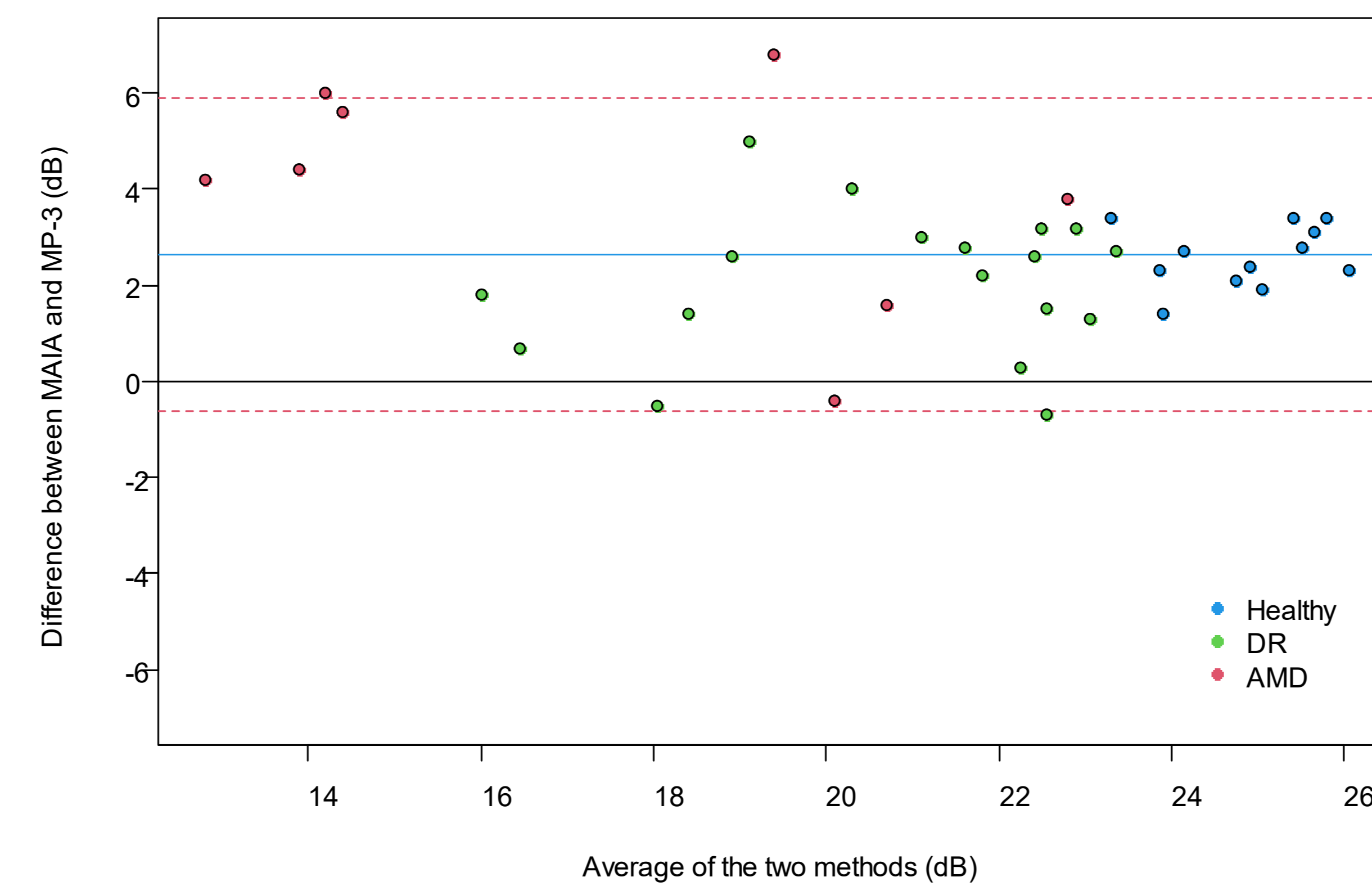
Coefficients of repeatability between MAIA and converted values from MP-3

CoR is a useful index that quantifies absolute reliability. The CoR can be used to define the requirement for a clinically significant change that is beyond natural variability (measurement error).
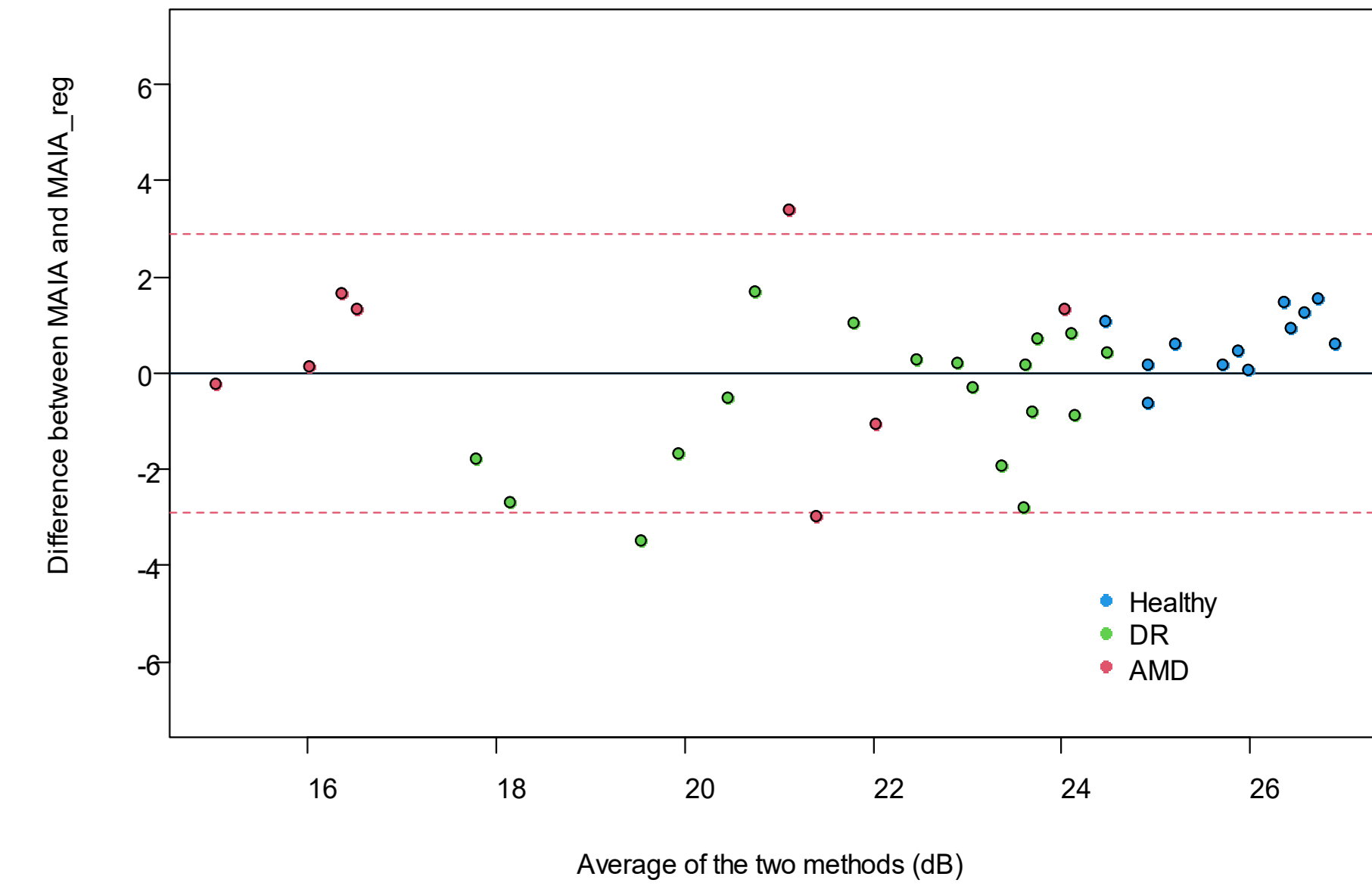- $CoR_{(MAIA\ vs.\ MAIA\_shift)}$ = 3.23
- $CoR_{(MAIA\ vs.\ MAIA\_reg)}$ = 2.87

Bland-Altman plot of agreement on Mean Sensitivity between MAIA and MAIA-shift
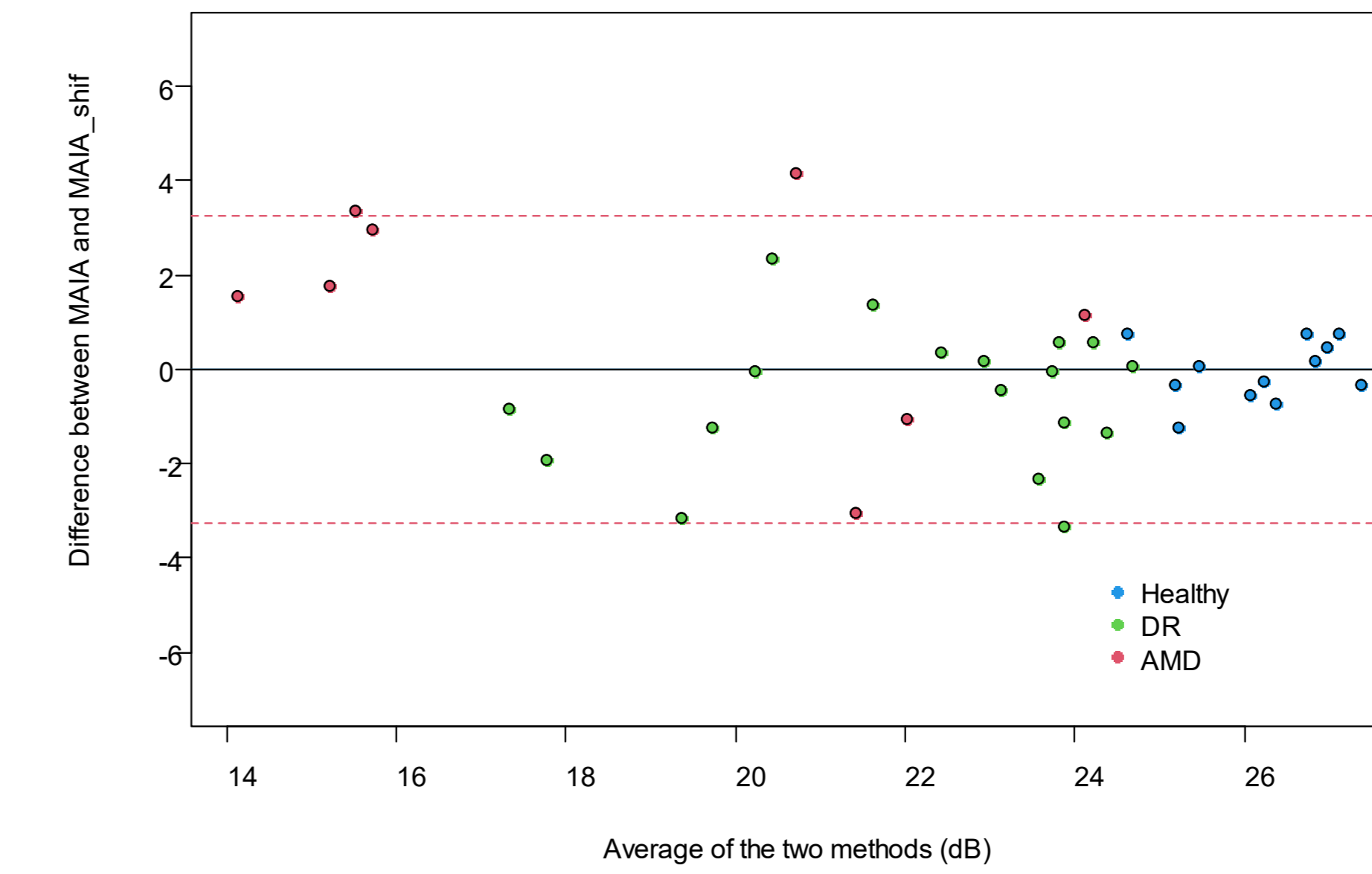
Bland-Altman plot of agreement on Mean Sensitivity between MAIA and MAIA-reg

Mean sensitivity and SD of each subgroup

Group	Mean (SD)			
	MAIA	MAIA_shift	MAIA_reg	MP3
Healthy	26.2 (1.00)	26.2 (0.87)	25.5 (0.70)	23.6 (0.87)
AMD	19.3 (3.49)	17.9 (4.51)	18.8 (3.64)	15.3 (4.51)
DR	21.8 (2.54)	22.3 (2.38)	22.4 (1.92)	19.7 (2.38)

Comparison of each patient group vs. healthy subject group

The following table summarizes the LSMEAN (p-value) comparing each patient group vs. healthy subject group, and the conclusion

Comparison	Difference (LSMean, p-value)			
	MAIA	MAIA_shift	MAIA_reg	MP3
AMD vs. Healthy	-6.9 (p <0.0001)	-8.3 (p <0.0001)	-6.7 (p <0.0001)	-8.3 (p <0.0001)
DR vs. Healthy	-4.4 (p <0.0001)	-3.9 (p =0.0004)	-3.1 (p = 0.0004)	-3.9 (p =0.0004)

Conclusion

Retinal sensitivity measures higher for MAIA- generated values compared with MP-3 and the values were correlated with a consistent relationship between the two devices. Overall conclusions comparing each patient group with healthy subject group remained the same across all parameters (MAIA, MAIA converted from MP-3 using the shift method, MAIA converted from MP-3 using the simple regression method, and MP-3). Limitations of this study include that we did not randomize the sequence of device testing and the inclusion of subjects regardless of fixation losses, false positive and false negative rates.

Commercial Relationship Disclosure

References

1. Maia - The New Frontier of Microperimetry.www.icare-world.com
2. Microperimeter MP-3. Retina & Glaucoma. www.nidek.intl.com