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Pre-market monocentric clinical investigation of MAIA on healthy subjects and patients with retinal pathology: agreement with MAIA 2013 EDITION microperimeter and repeatability evaluation

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BACKGROUND

The use of microperimetry (MP) in the diagnosis and follow-up of retinal disorders is continuously growing. MP often detects subtle defects in retinal sensitivity that precede visual acuity loss. This examination provides precise clinical diagnostic insights together with a quantification of the visual impact of commercial therapies of retinal disorders (phase II or III clinical trials). For this reason, MP is increasingly popular as a clinical trial outcome assessment to investigate new treatments for geographic atrophy, as well as a reliable functional outcome measure for other macular degenerative diseases. To ensure the availability on the market of the MAIA technology, a new MAIA device (MAIA3) has been developed and validated through a clinical investigation vs MAIA 2013 EDITION (MAIA2). The two MP devices are reported in Figure 1.

AIMS

The aim of this study was to evaluate the clinical usefulness of the MAIA3 device through an agreement evaluation with MAIA2. Since repeatability is at the basis for the applicability of any instrument as a diagnostic tool in clinical practice, MAIA3 test-retest (TRT) repeatability in comparison with MAIA2 was also evaluated in this study.

Figure1. MP devices: new MAIA device (left) and MAIA 2013 EDITION (right)

STUDY POPULATIONS AND METHODS

A total of 34 healthy subjects (age range [23-50] yrs) and 34 patients with retinal pathology (age range [27-83] yrs) were completed between October 2023 and July 2024. One eye per patient was tested using both devices in a single visit, with a 10-2 stimuli pattern including the Fovea and 4-2 strategy. A total of 4 MP examinations were collected in two separate sessions: two exams in the Agreement session and two exams in the TRT session. Mean sensitivity (MS) average values and ranges for the two study populations were evaluated:

- healthy subjects: 27.15 [24.97 - 29.76] dB for MAIA2, 27.60 [24.38 - 29.28] dB for MAIA3
- patients: 19.55 [0.96 - 27.88] dB for MAIA2, 20.36 [1.50 - 29.15] dB for MAIA3.

The study aims were evaluated through a comparison of threshold sensitivity values data between MAIA3 and MAIA2 as follows:

- [Aim1 – Agreement] assess that the Limits of Agreement (LoA) between MAIA3 and MAIA2 for threshold sensitivity values, both at MS and pointwise (PWS) level, are within MAIA2 repeatability limits.
- [Aim2 – Repeatability] assess that the Limits of Repeatability (LoR) of retinal threshold sensitivity values obtained with MAIA3, both at MS and PWS level, are at least as narrow as MAIA2 repeatability limits.

Bland-Altman plots with 95% Confidence Interval (CI) for Mean Difference, LoA and LoR were derived.

RESULTS

Agreement and TRT repeatability results are reported in Figure 2 for healthy subjects and in Figure 3 for patients. In terms of agreement, the Mean Difference between MAIA3 and MAIA2 was +0.44 dB for healthy subjects and +0.81 dB for patients. Thus, on average, MAIA3 slightly overestimated MAIA2 by a non-clinically significant amount (<1 dB)[*]. For patients the principal aim was globally verified: for MS values, the amplitude of CI of LoA was within MAIA2 repeatability limits by 1.18 dB. The principal aim was not verified for healthy subjects. However, by looking at the amplitude of CI of LoA, this is outside MAIA2 repeatability limits by only 0.34 dB for MS, which can be judged as non-significant amounts from a clinical point of view.

[*] ISO 12866:1999

Concerning the intra-device TRT repeatability, the Mean Difference was close to 0 dB for both devices:

- MAIA2: -0.34 dB for healthy subjects and -0.24 dB for patients with retinal pathology
- MAIA3: -0.23 dB for healthy subjects and -0.14 dB for patients with retinal pathology

The secondary aim was verified for both healthy subjects and patients, at MS and PWS level: the amplitude of CI of MAIA3 LoR was narrower than the amplitude of CI of MAIA2 LoR by 0.79 dB for MS and by 0.26 dB for PWS (healthy subjects) and by 1.39 dB for MS and by 0.73 dB for PWS (patients). This result might be due to the improved technology of MAIA3, which incorporates an automatic alignment feature and a more robust retinal tracking system with respect to MAIA2.

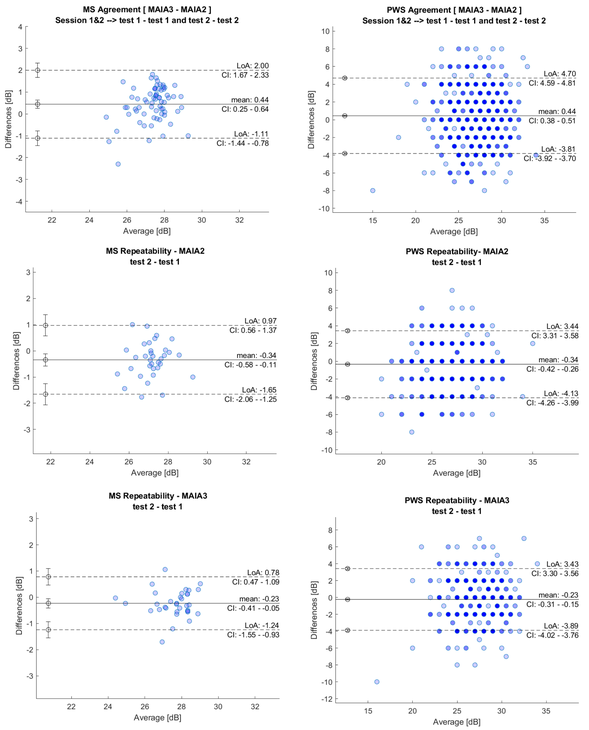

Figure2. Bland-Altman of MAIA3 and MAIA2 for Agreement and Repeatability, MS (left) and PWS (right) for healthy subjects

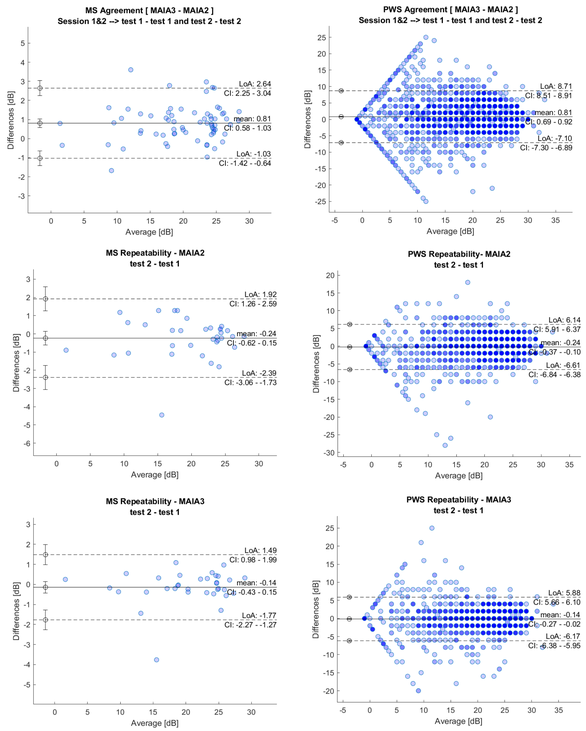

Figure3. Bland-Altman of MAIA3 and MAIA2 for Agreement and Repeatability, MS (left) and PWS (right) for patients with retinal pathology

CONCLUSION

MAIA3 is in good agreement with MAIA2 and more repeatable than MAIA2 in terms of test-retest variability, showing narrower repeatability limits in both study populations vs MAIA2. These results indicate that MAIA3 and MAIA2 can be used interchangeably in clinical practice (ClinicalTrials.gov: ID NCT06071546). Advantages such as the automated alignment to the eye before and during the exam may provide additional benefits in more diverse real-world settings.