Determination of IOLMaster Number of Measurements for Tracking Axial Length Changes in Myopia (# 2133 - A0267)

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Purpose

The IOLMaster (Carl Zeiss Meditec AG) is often used for tracking changes in axial length (AL) in myopic progression. The number of measurements for AL values reported in the literature varies from 3 to 20. We performed a prospective analysis to determine the fewest number of measurements to obtain a measurement error (ME) of ≤ 0.04mm and 95% Confidence Interval (CI) of ≤ 0.04mm, or approximately 0.125 Diopters (D).

Methods

The study was conducted at 3 sites with the IOLMaster (software 5.0 or later) with 7 subjects (5 female, 2 male) who were enrolled in this study. This sample size provided a power of 0.81 against type 2 errors.

All subjects were age 40 or younger and in good health. ME was determined by using the following formula[1]: $ME=(RE)^2 + (RP)^2)^{½}$, where RE represented the repeatability and RP represented the reproducibility.

For RE, which represented the intraobserver variability, the standard deviation of multiple measurements performed by a single operator was used. For RP, which represented the intersessional variability, the standard deviation between measurements performed at different sessions by the same operator was used. The Standard deviation (SD) of one observer at Site 1 measuring the same subject 10 times with 5,10,15, 20 measurements was used for RE. The SD of the difference between session 1 and 2 for all 7 subjects at all 3 sites was used for RP.

Composite AL values were recorded for each measurement with an index of refraction of 1.335. No individual readings were eliminated or manually adjusted, per the instructions manual.[2]

Two-sample, two-tailed t-tests were used to determine statistical significance ($p \leq 0.05$, with post-hoc Bonferroni correction to 0.008). 95% CIs were calculated for the difference between sessions, and the number of measurements were compared to the pre-determined criteria using a Bland-Altman analysis.[3,4]

To convert AL to refractive error difference in D, 1mm in AL was set equal to 3D.[4]

Results

Intraobserver Number of Measurements	Axial Length Mean ± SD	P value
5	23.14 ± 0.030	v 10: 0.910 v 15: 0.329 v 20: 0.564
10	23.14 ± 0.029	v 15: 0.288 v 20: 0.494
15	23.12 ± 0.022	v 20: 0.632
20	23.13 ± 0.016	

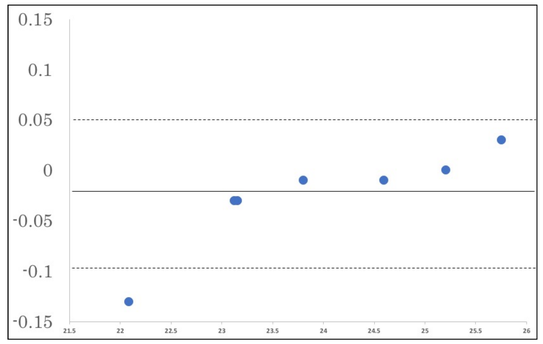
Intersessional Number of Measurements	Difference in Axial Length Between Sessions Mean ± SD	P value
5	-0.028 ± 0.039	v 10: 0.225 v 15: 0.492 v 20: 0.005
10	0.030 ± 0.038	v 15: 0.133 v 20: 0.001
15	0.042 ± 0.051	v 20: 0.0009
20	-0.0007 ± 0.008	

Number of Measurements	Measurement Error (mm)	Measurement Error (D)	95% Confidence Interval Values for Difference Between Sessions	95% Confidence Interval Spread (mm)	95% Confidence Interval Spread (D)
5	0.05	0.149	-0.045, -0.10	0.035	0.103
10	0.048	0.143	0.014, 0.046	0.032	0.095
15	0.056	0.167	-0.063, -0.02	0.043	0.129
20	0.018	0.054	-0.004, 0.005	0.009	0.030

Results (Continued)

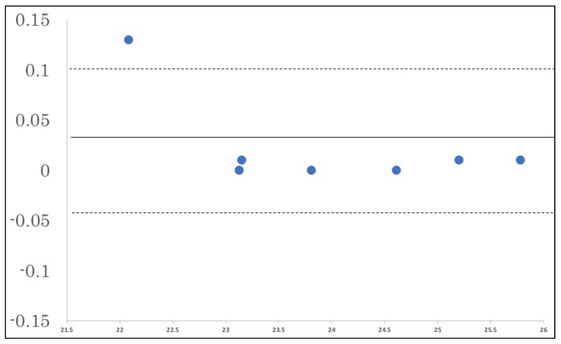
Bland-Altman Plots Based on Number of Measurements per Session
Middle Solid Line Represents the Mean Difference Between the Means of the Sessions
95% Limits of Agreement Enclosed by Dashed Lines (Mean ± 1.96SD)

5 Measurements



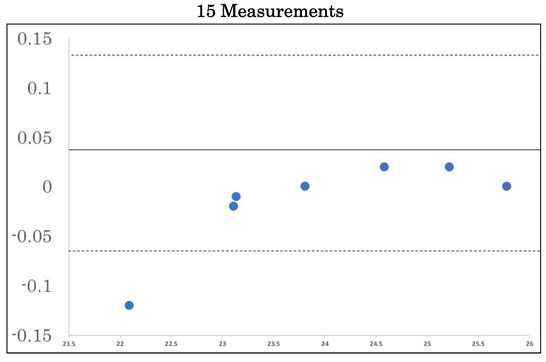
Mean Axial Length (mm)

10 Measurements



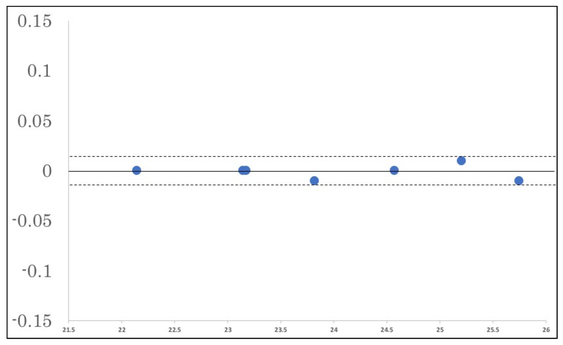
Mean Axial Length (mm)

15 Measurements



Mean Axial Length (mm)

20 Measurements



Mean Axial Length (mm)

Conclusions

Only 20 measurements met the ME criteria to be ≤ 0.04 mm or 0.125D. For the difference in mean values between sessions, 20 measurements was better than 5, 10, and 15 measurements both in terms of being statistically different from the others and having a narrower 95% CI.

Whereas t-tests only compare the mean results, the Bland-Altman plots can better assess the repeatability of the instrument by demonstrating the mean difference and the 95% limits of agreements (LOA).[4] The 95% LOA is calculated from the mean difference ± 1.96SD. The plots demonstrated that the 95% LOA is substantially narrower for 20 measurements as compared to 5, 10, or 15 measurements. Bland-Altman plots showed a 95% LOA of 0.05 to -0.10 (0.15 mm), 0.10 to -0.04 (0.14 mm), 0.14 to -0.06 (0.20mm), and 0.015 to -0.016 (0.031 mm) for 5,10, 15, and 20 measurements. These would correlate to 95% LOA of 0.45, 0.42, 0.60 and 0.093 D respectively. Only 20 measurements met the pre-determined criteria for both for AL in mm and D based on LOA. Shorter axial length measurements showed greater variability between sessions for the 5, 10, and 15 measurements. Only 20 measurements provided a consistently small difference between the means of the two sessions for all axial lengths measured in this study.

When using the IOLMaster with software 5.0 or greater to track changes in AL over time for myopic progression, the most appropriate number of measurements to take is 20 per session to have 95% confidence that the true measurement is within 0.04mm, or 0.125D, and that subsequent measurement sessions would be within a 95% LOA to prior sessions. This level of ME and LOA would provide clinicians with a sensitive method to assess whether observed refractive error changes are likely represented by concurrent axial length changes.

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Commercial Relationship Disclosures: None