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ORIGINAL RESEARCH

Intra- and Inter-Observer Agreement of a Portable A-Scan Ultrasound Biometer in Sitting and Supine Positions and Validity Against an Optical Biometer

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Purpose: The purposes of this study were to test the validity of a portable ultrasound biometer (6000 Scanmate-A, DGH Technology) against an optical biometer and to establish its repeatability and reproducibility on patients in sitting and supine positions.

Patients and Methods: Healthy adults (N = 51) were recruited prospectively. At two study visits, Observer 1 made five measurements of AL and ACD in the right eye using an optical biometer (IOLMaster, Zeiss). Then two sets of three measurements of AL and ACD were made using the Scanmate-A, one while participants were sitting and another while they were supine. Observer 2 made the same measurements at one visit on a subset of participants (n = 42). Averages of the measurements were prepared for analysis (significance threshold set to $\alpha = 0.01$) according to Bland and Altman, repeated-measures analyses of variance, linear correlations, and intraclass correlation coefficients (ICC).

Results: AL and ACD were significantly shorter when measured by the Scanmate-A (median [interquartile range] = 23.4 [22.5, 24.7] mm and mean ± standard deviation = 3.22 ± 0.45 mm, respectively) than when measured by IOLMaster (23.8 [23.1, 25.2] mm and 3.51 ± 0.33 mm, respectively). For both body positions, there were no differences in ACD and AL between visit 1 and visit 2. Correlations were strong between the visits, but the limits of agreement varied. Similarly, there were no significant differences between Observer 1 and Observer 2. Correlations and ICC were strong-to-moderate between the observers, and the limits of agreement varied.

Conclusion: Consistent with reports on other a-scan devices, the Scanmate-A measured shorter AL and shallower ACD than the IOLMaster. Although, mean or median AL and ACD did not differ across study visits, observers, and body positions, large limits of agreement on Bland-Altman analyses must be accounted for by users of the Scanmate-A.

Keywords: biometry, axial length, anterior chamber depth

Introduction

Ocular biometry, particularly the measurement of axial length (AL) and anterior chamber depth (ACD), has critical applications in ophthalmology, optometry, and vision science. Accurate AL and ACD measurements are necessary to calculate intraocular lens (IOL) power before cataract surgery and directly influence postoperative visual outcomes.[1,2] As an often-cited example, a measurement error of 100 microns in axial length results in a residual refractive error of 0.28 D.[3] Beyond cataract surgery, AL plays an increasingly important role in assessing myopia management therapies,[4] as myopia progression is linked closely to axial elongation.[5] Furthermore, AL is a key variable in the estimation of pulsatile ocular blood volume,[6] a parameter relevant to ocular hemodynamics. AL also must be considered during high-resolution retinal imaging to control for magnification error.[7,8]

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Optical biometers are regarded as the gold standard for measuring preoperative AL and ACD due to their excellent precision and resolution.[9–11] However, their high cost and limited portability, compared to ultrasound biometers, and their inability to measure patients with unstable fixation or dense media opacities restrict their use under certain circumstances.[12,13] These limitations pose substantial challenges to using optical biometers in global-health and resource-limited settings, where an ultrasound biometer may offer a more economical, portable, and versatile alternative. Additionally, there is a growing interest in making ocular biometric measurements while patients are in various body positions, including lying supine or head-down Trendelenburg.[14–18] Optical biometers in standard configuration cannot make these measurements without substantial modifications, as patients must be seated upright in front of the devices. Ultrasound biometers can fill this gap because their handheld transducers can be positioned in any orientation to make measurements easily.

Despite the continued utility of ultrasound biometers, the specific validity, repeatability, and reproducibility of the 6000 Scanmate-A device (DGH Technology, Exon, PA, USA) have not been reported. Unlike early generation ultrasound biometers, this device has a grading algorithm to guide alignment of the probe on the cornea and has a compression detection system to regulate contact pressure. Additionally, the repeatability and reproducibility of AL and ACD measurements made using a-scan ultrasonography on patients lying supine have not been studied. These gaps in the literature impair confidence in biometric measurements made with the Scanmate-A device, especially when patients are not in standard sitting position. Thus, the purpose of this study is to evaluate the validity and intra- and inter-observer agreement of the Scanmate-A device for the measurement of AL and ACD in sitting and supine positions in a healthy population.

Material and Methods

This prospective cross-sectional study was reviewed and approved by the Biomedical Sciences Institutional Review Board at The Ohio State University, and it conformed to the Declaration of Helsinki. All participants provided written informed consent before enrollment.

Subject Recruitment and Eligibility

Healthy adult participants (age ≥18 years with no upper limit) were recruited from a university setting between May and September 2024. Inclusion criteria included having the ability to lie supine, vision correctable to at least 20/30 through habitual glasses or contact lenses, and a clear and regular cornea. Exclusion criteria included a history of ocular surgery, retinal disease, clinically significant cataracts, use of rigid gas-permeable contact lenses or orthokeratology contact lenses, glaucoma or ocular hypertension, pregnancy, and an allergy to proparacaine or to benzalkonium chloride. Inclusion and exclusion criteria relating to vision or ocular health were applied to the right eye. A sample size of >50 participants was targeted for consistency with prior biometry studies.[19–22]

Devices

The 6000 Scanmate-A is a portable ultrasound device that received approval from the United States Food and Drug Administration in 2010. In contact configuration, which was used in this study, a handheld transducer (nominal damped frequency = 10 MHz) with a red fixation light is attached to a small base, which communicates with proprietary software on a laptop computer via a universal serial bus. Automatic measurements begin upon gentle flush contact with the anesthetized central cornea and continue until the standard deviation of eight banked measurements falls within a factory-preset limit. The eight measures then are averaged to generate standard outcome metrics of AL, ACD, lens thickness, and vitreous chamber depth. Default acoustic velocities for the device are 1641 m/s for the cornea and lens and 1532 m/s for the aqueous and vitreous humors.

The IOLMaster 500 (Zeiss, Jena, Germany) is a well-established optical biometer that has been described in detail elsewhere.[23] Briefly, the device uses partial coherence interferometry with a semiconductor diode laser (λ = 780 nm) to measure axial length. Anterior chamber depth is calculated using a measurement of corneal radius and the distance between reflections off the cornea and lens generated by a slit-illuminated optic section of the anterior segment (offset angle = 30° temporal). White-to-white corneal diameter also can be measured.

Data Collection

Data collection occurred during standard clinical hours at two study visits separated by at least 24 hours, with the maximum separation being 15 days. The visits were scheduled during similar parts of the day (average ± standard deviation start time = 12:20 PM ± 1.75 hours for visit 1 and 12:04 PM ± 1.80 hours for visit 2) to minimize the effects of diurnal fluctuations in ocular parameters.[24,25] Demographic information, including self-reported age, race and ethnicity, and sex, were collected at the first visit. High-contrast visual acuity was measured at distance in the right eye using a standard Bailey-Lovie eye chart at both visits to ensure adherence to the inclusion criteria. Then, measurements of AL and ACD were made in the right eye using standard factory settings on the two devices described above: the ultrasound biometer and the optical biometer. First, five separate measurements were made using the optical biometer with the participant in sitting position. Then proparacaine hydrochloride (0.5%; Sandoz, Princeton, NJ) was applied to the right eye before measurements were made with the ultrasound biometer: three separate measurements while the participant was sitting and three separate measurements while the participant was in supine position. To avoid a possible order effect, initial measurements with the ultrasound biometer alternated between sitting and supine with each participant.

Observer 1 measured AL and ACD on all participants at both study visits to assess intra-observer repeatability, and Observer 2 performed measurements at one of the study visits on a subset of participants to assess inter-observer reproducibility. Both observers had prior experience making ocular measurements in a clinical setting – Observer 1 as an optometric technician and Observer 2 as an optometrist – and both were trained on the use of both biometers before enrollment began.

Data Management and Analysis

AL and ACD were the primary outcome metrics, and statistical analyses were performed on SigmaPlot software (Grafiti, Palo Alto, CA), unless stated otherwise. First, the normality of all data was assessed using the Shapiro–Wilk test. Intra-observer repeatability within a given visit was assessed using Friedman repeated-measures analyses of variance (RM ANOVA) on ranks and by calculating the coefficient of variation (C_V) for the three measurements made by Observer 1 with the ultrasound biometer in both body positions. For all other comparisons, the three measurements from the ultrasound biometer and the five measurements from the optical biometer were averaged in each position, when applicable, for analysis. Inter-device validity, intra-observer repeatability over two visits, and differences in body positioning were tested using Friedman RM ANOVA on ranks, with post-hoc pairwise comparisons made with the Tukey's test. Data collected by Observer 1 at the first study visit were used to test inter-device validity, with measurements from the optical biometer serving as the reference standard. Intra-observer repeatability over two visits was assessed on data collected by Observer 1 at both study visits. Differences in AL and ACD between sitting and supine positions were tested on data collected by Observer 1 at visit 1. Inter-observer reproducibility was tested using RM ANOVA, with post-hoc pairwise comparisons made with the Tukey's test. Inter-observer agreement was assessed further by calculating single-measure intra-class correlation coefficients (ICC; two-way model, absolute agreement) using MedCalc software (Ostend, Belgium). Linear-regression models with accompanying Bland-Altman analyses were completed for intra-observer comparisons made over two visits and for inter-observer comparisons.[26] A strong linear correlation was defined as $R \geq 0.80$, and a moderate correlation as $0.80 > R \geq 0.60$. The Bonferroni correction for multiple comparisons was used to set the significance threshold at $\alpha = 0.01$.

Results

Fifty-one subjects (N = 51; 67% female; mean [range] = 26 [18 to 65] years) were enrolled. Forty-three percent of participants self-identified as White, 43% as Asian, 6% as Black, 4% as Indigenous, and 4% as mixed-race. Ten percent of participants self-identified as ethnically Hispanic. Data were collected by Observer 1 for all subjects ($n_1 = 51$), and by Observer 2 for 42 subjects ($n_2 = 42$).

Inter-Device Validity

The optical biometer measured a significantly longer AL ($p < 0.001$, Figure 1A) and deeper ACD ($p < 0.001$, Figure 1B) compared to the ultrasound biometer. Although there was a strong linear correlation between the devices for AL (R =

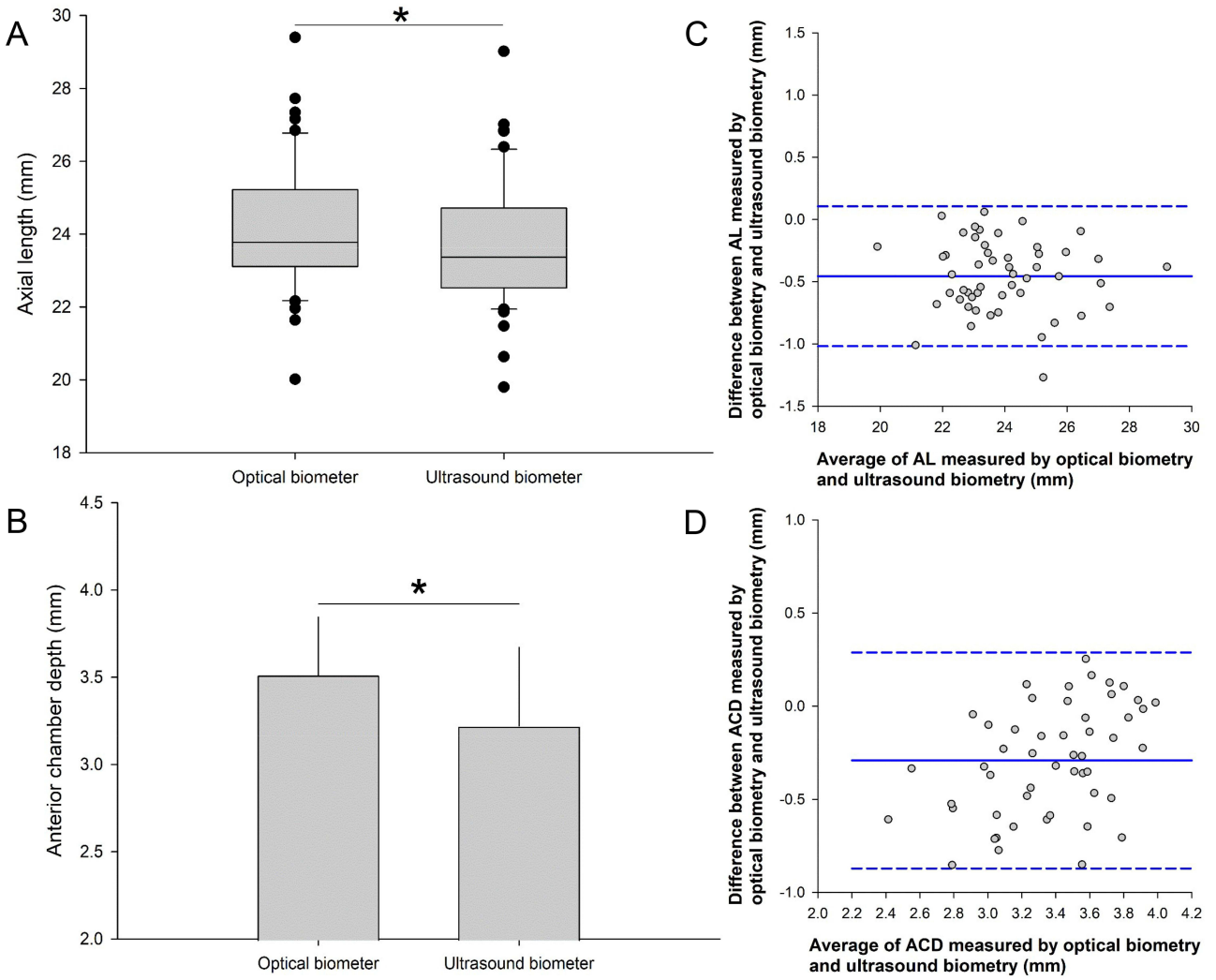

Figure 1 Inter-device validity. Axial length (**A**) was measured by the optical biometer and by the ultrasound biometer. Each box represents the interquartile range, and the internal line is the median. The whiskers represent the 90th and 10th percentiles, and closed circles are outlying values. *p < 0.01, Friedman repeated-measures analyses of variance (RM ANOVA) on ranks with pairwise comparisons made with the Tukey's test. Anterior chamber depth (**B**) also was measured by the optical biometer and by the ultrasound biometer. Bars are means, and error bars are one standard deviation. *p < 0.01, RM ANOVA with the Tukey's test. Bland-Altman plots substantiate a bias in the average difference (solid blue line) toward longer AL (**C**) and deeper ACD (**D**) in the optical biometer than in the ultrasound biometer, and the limits of agreement (dashed blue lines, from 1.96 to −1.96 standard deviations) were wide. n = 51.

0.99, p < 0.001) and a moderate correlation between the devices for ACD (R = 0.75, p < 0.001), Bland-Altman analyses demonstrated biases toward longer AL (limits of agreement [LOA]: −1.02 mm to 0.11 mm; Figure 1C) and deeper ACD (LOA: −0.87 mm to 0.29 mm; Figure 1D) measurements with the optical biometer than with the ultrasound biometer.

Intra-Observer Repeatability

There were no statistically significant differences among the three measurements of AL made within either visit using the ultrasound biometer on participants in sitting and supine positions (Table 1). C_V was 0.07 for measurements made in both positions at both visits. Similarly, there were no statistically significant differences among the three measurements of ACD made within either visit using the ultrasound biometer on participants in sitting and supine positions (Table 2). C_V was 0.15 for measurements made on sitting participants at visit one, 0.14 for measurements made on sitting participants at visit two, and 0.13 for supine participants at both visits.

There were no statistically significant differences in AL between visit one and visit two in both body positions (Figure 2A), and there were strong linear correlations between visit one and visit two, both in sitting (R = 0.99, p <

Table 1 Intra-Visit Measurements of Axial Length (AL)

	AL Sitting Position (mm)	AL Supine Position (mm)
Visit 1		
Measurement 1	23.3 (22.6, 24.8)	23.4 (22.7, 24.7)
Measurement 2	23.5 (22.5, 24.8)	23.5 (22.5, 24.9)
Measurement 3	23.3 (22.5, 24.8)	23.3 (22.7, 24.8)
Visit 2		
Measurement 1	23.5 (22.5, 24.9)	23.4 (22.6, 24.9)
Measurement 2	23.6 (22.6, 24.7)	23.4 (22.7, 25.0)
Measurement 3	23.4 (22.5, 24.9)	23.4 (22.8, 25.0)

Notes: N = 51 right eyes. Values are medians (interquartile range). There were no statistically significant differences between the measurements (p = 0.11, Friedman Repeated Measures Analysis of Variance on Ranks).

Table 2 Intra-Visit Measurements of Anterior Chamber Depth (ACD)

	ACD Sitting Position (mm)	ACD Supine Position (mm)
Visit 1		
Measurement 1	3.30 (2.91, 3.57)	3.18 (2.86, 3.53)
Measurement 2	3.32 (2.91, 3.61)	3.26 (3.03, 3.55)
Measurement 3	3.25 (2.86, 3.50)	3.19 (2.87, 3.45)
Visit 2		
Measurement 1	3.32 (2.96, 3.55)	3.20 (2.86, 3.53)
Measurement 2	3.32 (2.94, 3.63)	3.21 (3.01, 3.46)
Measurement 3	3.21 (2.90, 3.59)	3.29 (2.91, 3.58)

Notes: N = 51 right eyes. Values are medians (interquartile range). There were no statistically significant differences between the measurements (p = 0.60, Friedman Repeated Measures Analysis of Variance on Ranks).

0.001) and supine (R = 0.98, p < 0.001) positions. Bland-Altman analyses demonstrated limits of agreement that spanned between −0.53 mm and 0.60 mm in the sitting position (Figure 2B) and between −0.62 mm and 0.66 mm in the supine position (Figure 2C). There were no statistically significant differences in AL between sitting and supine positions (p = 0.83).

ACD did not differ significantly between visit one and visit two in both body positions (Figure 3A). There was a strong correlation between the visits in sitting position (R = 0.91, p < 0.001), which weakened somewhat in supine position (R = 0.80, p < 0.001). Bland-Altman analyses revealed limits of agreement that spanned between −0.35 mm and 0.41 mm while sitting (Figure 3B) and between −0.45 mm and 0.49 mm while in supine position (Figure 3C). There were no statistically significant differences in ACD between sitting and supine positions (p = 0.996).

Inter-Observer Reproducibility

There was strong agreement between observers for AL measurements using ultrasound both in sitting and supine positions, with an ICC of 0.96 and 0.97, respectively. There were no statistically significant differences in AL between

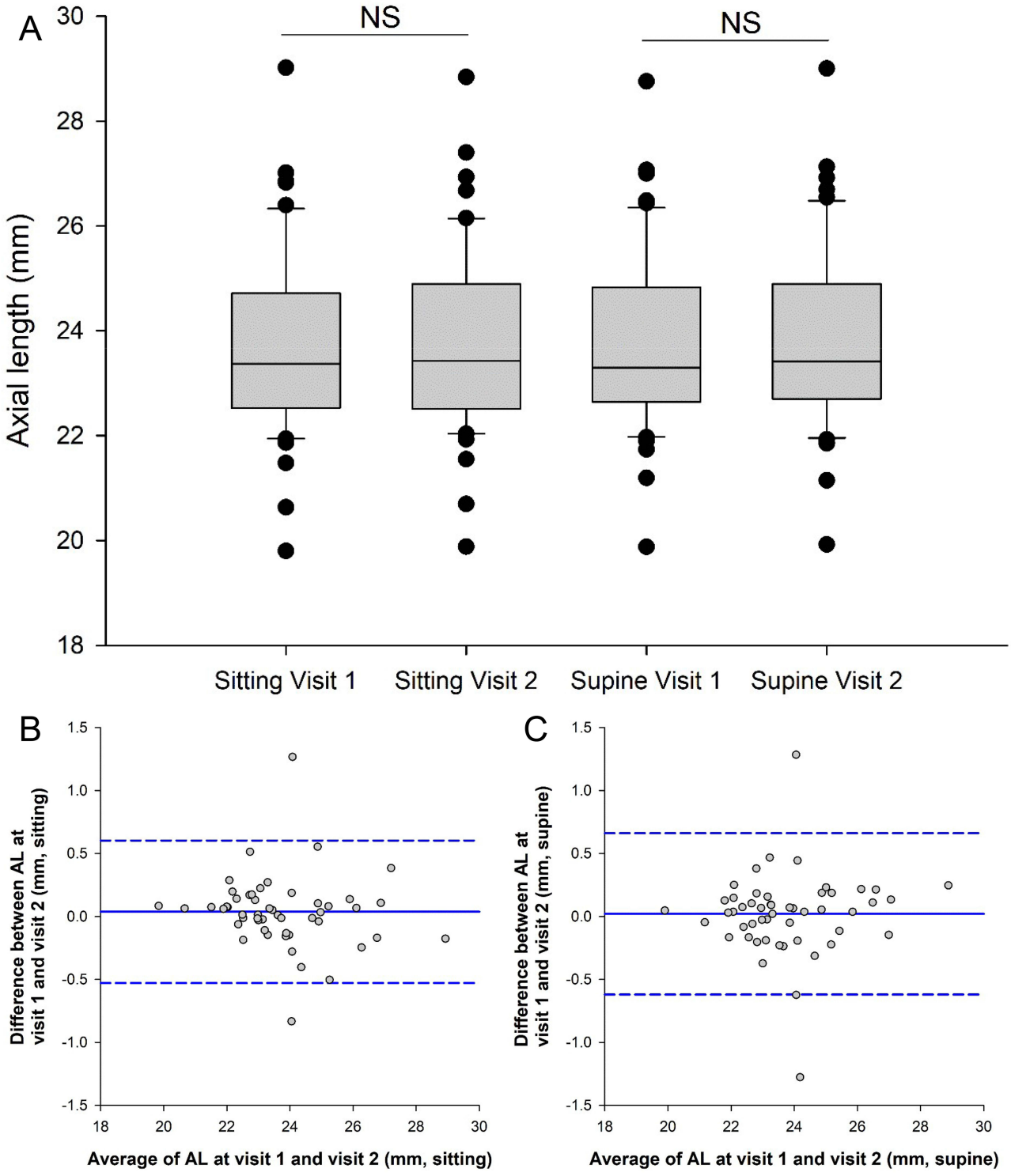

Figure 2 Intra-observer repeatability for axial length (AL) using a-scan ultrasonography. AL was measured in sitting and supine positions by Observer 1 at two separate study visits using the ultrasound biometer (**A**). Bland-Altman plots substantiate little bias in average difference toward one visit over the other both in sitting (**B**) and in supine (**C**) positions, but limits of agreement were wide. n = 51. NS is no statistical significance, Friedman repeated-measures analyses of variance on ranks.

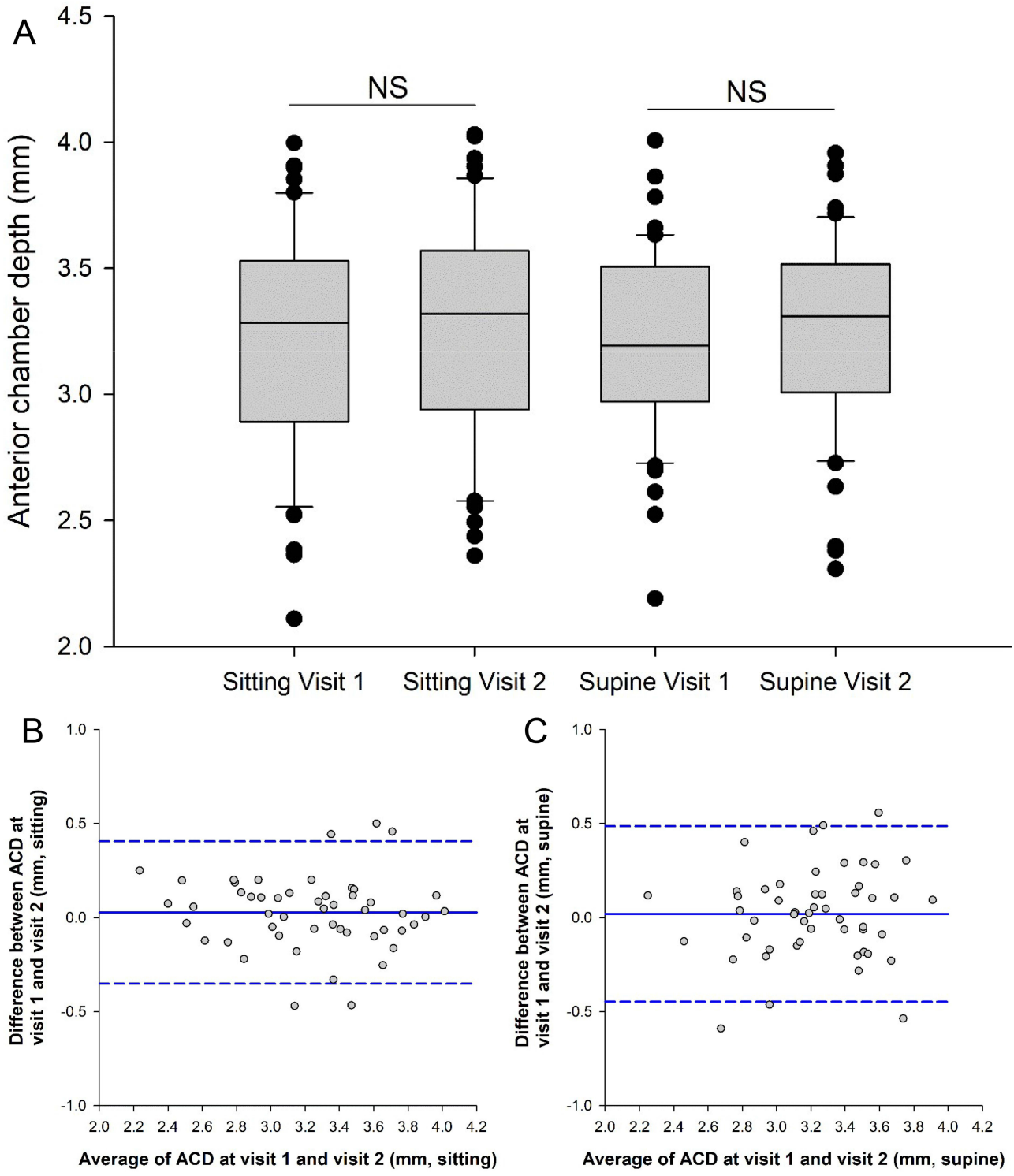

Figure 3 Intra-observer repeatability for anterior chamber depth (ACD) using a-scan ultrasonography. ACD was measured in sitting and supine positions by Observer 1 at two separate study visits using the ultrasound biometer (**A**). Bland-Altman plots substantiate little bias in average difference toward one visit over the other both in sitting (**B**) and in supine (**C**) positions, but the limits of agreement were wide. n = 51. NS is no statistical significance, Friedman repeated-measures analyses of variance on ranks.

the observers both in sitting and supine positions (Figure 4A). There were strong correlations between the observers in sitting ($R = 0.96$, $p < 0.001$) and supine ($R = 0.97$, $p < 0.001$) positions. Bland-Altman analyses found LOAs that spanned between −0.77 mm and 0.67 mm in sitting position (Figure 4B) and between −0.58 mm and 0.69 mm in the supine position (Figure 4C).

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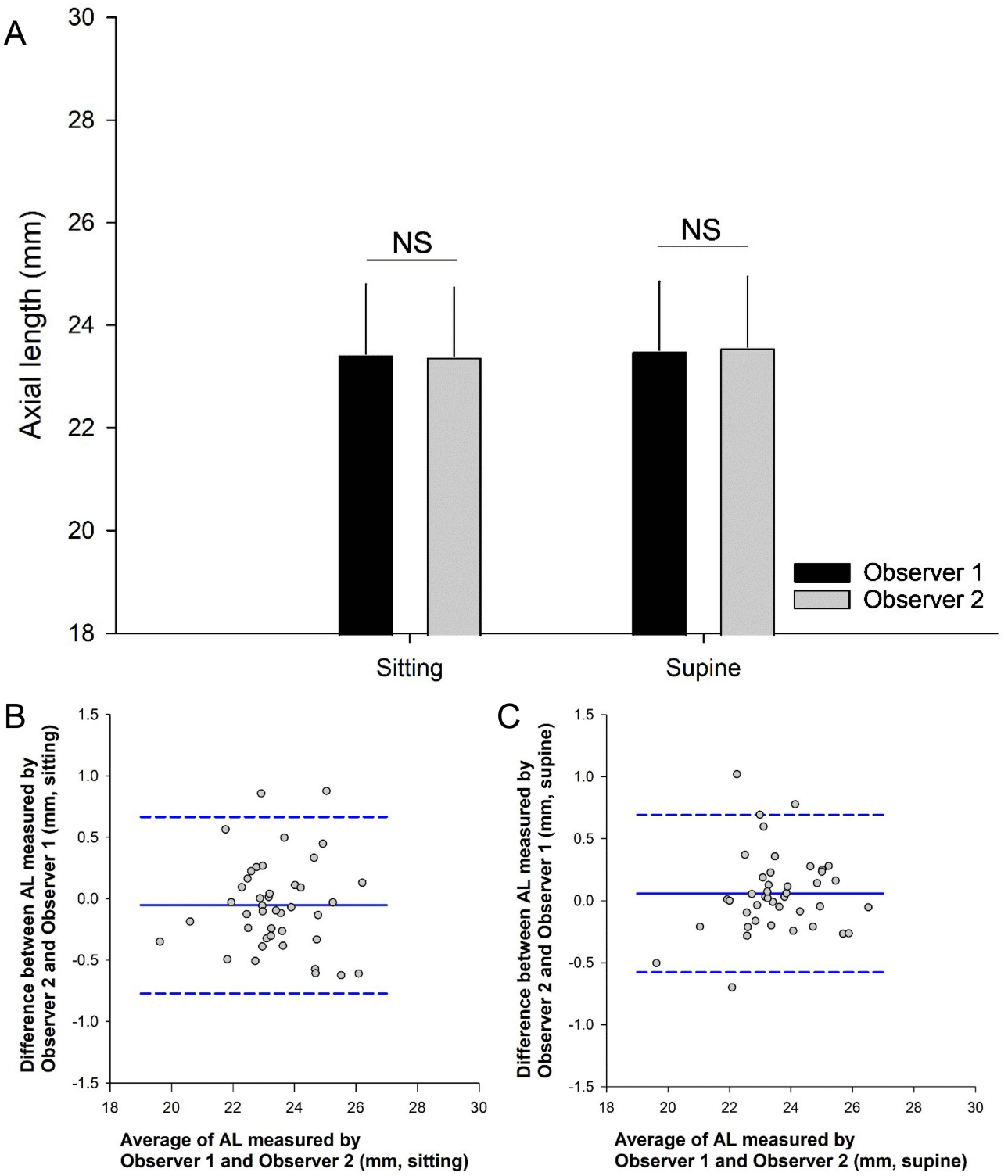

Figure 4 Inter-observer agreement for axial length (AL) using a-scan ultrasonography. Mean AL was measured in sitting and supine positions by both observers at a single study visit using the ultrasound biometer (**A**). Error bars are one standard deviation. Bland-Altman plots substantiate little bias toward one observer over the other both in sitting (**B**) and in supine (**C**) positions, but the limits of agreement were wide. n = 42. NS is no statistical significance, repeated-measures analyses of variance.

In contrast to the AL measurements, the ACD measurements demonstrated moderate agreement between observers both in sitting and supine positions, with an ICC of 0.65 and 0.67, respectively. There were no statistically significant differences between the observers for ACD both in sitting and supine positions (Figure 5A), and there were moderate

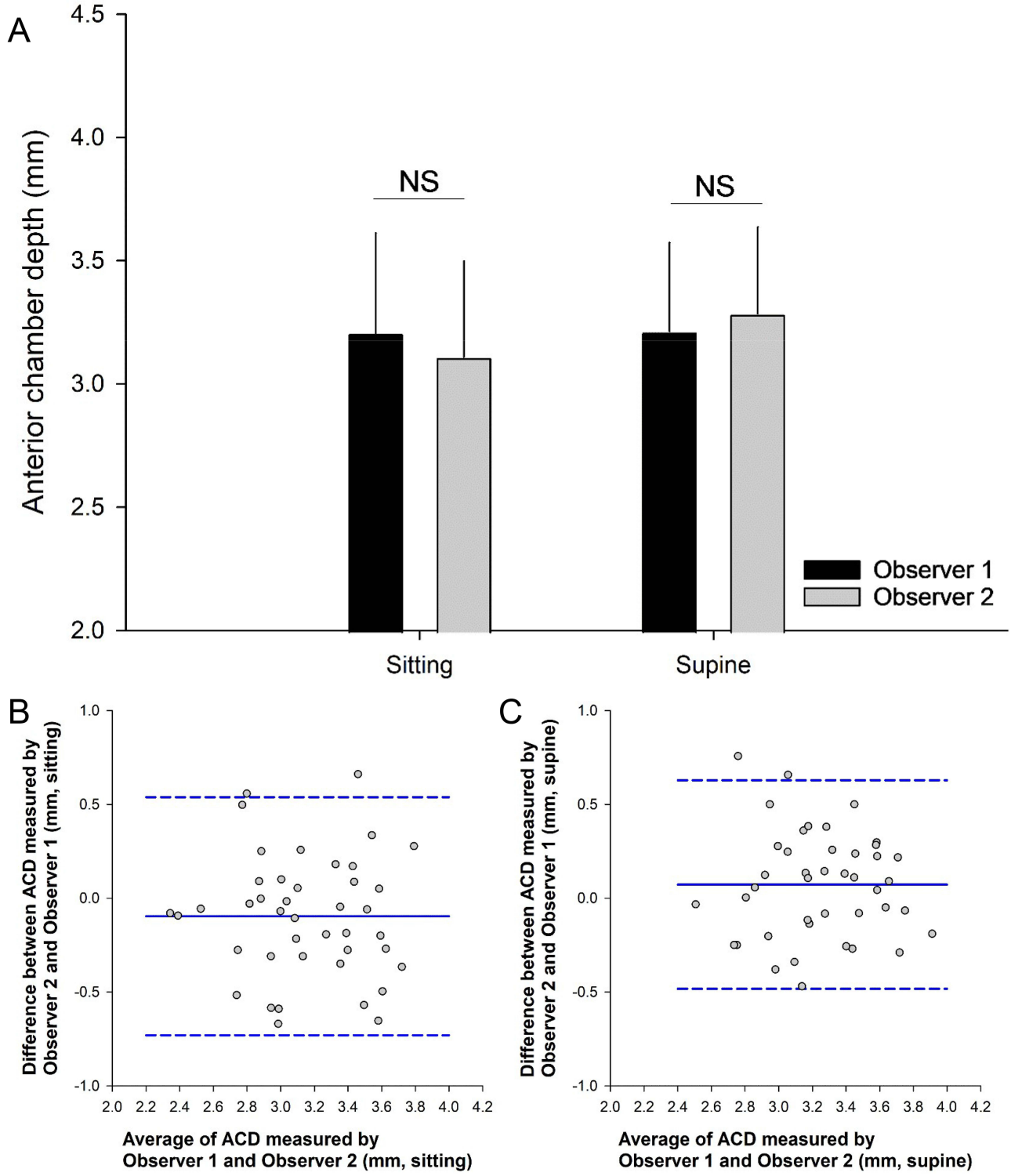

Figure 5 Inter-observer agreement for anterior chamber depth (ACD) using a-scan ultrasonography. Mean ACD was measured in sitting and supine positions by both observers at a single study visit using the ultrasound biometer. (**A**) Bland-Altman plots substantiate little bias toward one observer over the other both in sitting (**B**) and in supine (**C**) positions, but the limits of agreement were wide. n = 42. NS is no statistical significance, repeated-measures analyses of variance.

correlations between the observers in sitting ($R = 0.67$, $p < 0.001$) and supine ($R = 0.68$, $p < 0.001$) positions. Bland-Altman analyses found LOAs that ranged between −0.73 mm and 0.54 mm in sitting position (Figure 5B) and between −0.48 mm and 0.63 mm in supine position (Figure 5C).

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Discussion

This study evaluated the validity, intra-observer repeatability, and inter-observer reproducibility of measurements of AL and ACD made with a portable 6000 Scanmate-A ultrasound biometer on participants in sitting and supine positions.

Compared to the ocular biometer, the validity of the ultrasound biometer used in this study aligned with reports of other applanation ultrasound biometers in the literature. Specifically, although there was a strong correlation between devices, the ultrasound biometer measured significantly shorter AL than the optical biometer, an IOLMaster, and the limits of agreement between the two devices spanned over 1.1 mm. These results are consistent with studies from several other groups that compared the performance of applanation ultrasound biometry against optical biometry.[27–32] Similarly, there was a significant bias toward shallower ACD measurements made by the ultrasound biometer than made by the optical biometer, despite moderate correlation between the two devices. The limits of agreement between the two devices were separated by more than 1.15 mm. These results agree with previous work comparing optical biometry to applanation ultrasound biometry for ACD assessment.[27,28,30,33]

Several variables may contribute to shorter measurements made by the ultrasound biometer, relative to the optical biometer. Previous authors have suggested that the primary contributor is ocular compression caused by contact between the a-scan transducer probe and the cornea.[10,27,28,33] This position is supported by the fact that immersion ultrasound biometers, whose transducers do not have direct contact with the cornea, produce longer readings than applanation ultrasound biometers.[19,34,35] In our data, however, the difference between devices trended toward being larger for AL than for ACD, indicating that other factors also contributed to shorter measurements made with the ultrasound biometer than with the optical biometer. For example, whereas ultrasound biometry measures axial length along the optical axis of the eye, optical biometry measures along the visual axis. The difference between the two axes may account for 0.1 mm of the difference in AL[36] and may be exacerbated by off-axis measurements.[27] Additionally, ultrasound biometry measures AL from the corneal apex to the internal limiting membrane of the inner retina, but optical biometry measures AL from the second principal plane of the cornea to the retinal pigment epithelium of the outer retina, a potential overall difference of approximately 0.3 mm.[31] The IOLMaster takes this difference into account by using post-measurement processing to produce a final value that is calibrated to match AL measured by immersion ultrasonography.[10] Finally, although corneal anesthesia does not affect central corneal thickness one hour after drop instillation, central corneal thickness thins in some patients five minutes after instillation,[37] which aligns with the timing of our ultrasonography measurements. It is possible that drug-induced thinning contributed to shorter measurements made with the ultrasound biometer than with the optical biometer.

Assessment of intra-observer repeatability for ultrasound produced mixed results. For intra-observer agreement within a single given visit, there was no statistically significant difference among the first, second, and third measurements of AL or ACD made with the optical biometer in sitting and supine positions. Moreover, C_V values were low and did not vary among measurements of AL. Although C_V values for ACD were approximately double those of AL, they were within a 0.02 range among themselves. For measurements of AL and ACD made in both body positions across study visits, there were no statistically significant differences between the two study visits, and the correlations between the visits were of strong-to-moderate strengths. Limits of agreement ranged just over 1.1 mm for AL measurements made in the sitting position and widened slightly when participants were supine. Intra-observer repeatability has not been reported previously for measurements of AL made in a supine body position, but variability of the measurements made in a sitting position align with the literature.[27,31,36,38,39] Limits of agreement expanded for the measurements of ACD while sitting, compared to comparable measurements of AL, which was as expected.[27,29,30,36,38,39] There are no other reports of intra-observer repeatability for ACD measurements made on subjects lying supine. In all, although the measures of central tendency aligned well, the substantial limits of agreement between visits must be considered when making and analyzing measurements made with the Scanmate-A device. Note that we attempted to minimize the confounding effect of diurnal fluctuations, but physiological non-diurnal fluctuations in central corneal thickness and choroidal thickness likely contributed to the variability.[40,41]

Assessment of inter-observer reproducibility for the ultrasound biometer generated similar results. There were no significant differences between the observers for measurements of AL and ACD, and the correlations between the two observers were strong for AL and moderate for ACD. The ICC values followed the same pattern: strong for AL and

moderate for ACD, which might be more sensitive to compression artifact due to its relatively small magnitude compared to AL. These results concur with reports of inter-observer agreement on other ultrasound biometers.[42–45] Limits of agreement for the inter-observer measurements of AL were similarly wide for the two body positions, with both ranging under 1.5 mm. Note that these values were driven by a few notable outlying measurements, especially in the supine position. For ACD, the limits of agreement between the two observers also were comparable between two body positions. Interestingly, there were fewer outliers in the ACD measurements than in the AL measurements. To our knowledge, this is the first report of inter-observer agreement for AL and ACD measurements made in different body positions. Much like its intra-observer performance between visits, measures of central tendency did not differ statistically between the two observers, but large limits of agreement between observers must be considered when making and analyzing measurements made with the Scanmate-A device.

We did not find differences in AL or in ACD between the sitting and supine body positions. Note, however, that our study was designed as a validity, repeatability, and reproducibility study, not as an investigation into the effect that body positioning has on ocular biometry, per se. Other groups have designed studies to test this effect, specifically. For example, Andersen et al used optical low-coherence reflectometry to demonstrate significantly shorter AL in supine position than in prone position, starting at 5 minutes after a position shift and lasting until at least 60 minutes.[16] Van Akin et al used the same technology to find an acute increase in axial length when changing from a seated position to a prone position, and this change correlated with an increase in intraocular pressure.[17] Similar to our results, there was no acute change in axial length when transitioning from a seated position to lying supine.

Our results have several implications for the clinic and for the laboratory. First, because the 6000 Scanmate-A measures a shorter AL and shallower ACD, which we show for the first time here, the Scanmate-A and IOLMaster cannot be interchanged freely. Clinicians and researchers should consider these differences when comparing measurements made using both biometers. This recommendation may be especially important when calculating AL and ACD for cataract surgery, where even a small error can result in substantial post-surgical refractive error.[3] Although optical biometry is the gold standard for cataract surgery in the United States, Europe, and the rest of the Global North,[13,46] ultrasound biometry remains relevant in countries in the Global South, where portability, a small physical footprint, and low cost are critical. Moreover, optical biometry struggles to acquire measurements on patients with dense media opacities, with a failure rate of up to 18%.[27,28] Patients in countries in the Global South with low socio-economic status are more likely to have disability from such opacities than those in the Global North.[47] Second, although both intra-observe variability over two visits and inter-observer variability demonstrated no statistically significant differences of central tendencies and strong-to-moderate correlations for measurements of AL and ACD, the large limits of agreement for the measurements are likely clinically meaningful. These errors also have the potential to influence clinical decision-making in cases of calculation of IOL power and of myopia management, and they can undermine the estimation of pulsatile ocular blood volume and correction for axial length during retinal imaging. Finally, this study offers the novel finding that measurements of AL and ACD made with a-scan ultrasonography in the supine position have inter- and intra-observer agreements comparable with those made in the sitting position. This information may be particularly important for studies that seek to define the effect of microgravity on the globe and orbit,[48] where Trendelenburg positioning is a leading terrestrial analogue.[49]

This study has several limitations. First, the study population comprised young, healthy adults. Thus, our results may not be generalizable to individuals with cataract or to children. Subsequent work is needed to address this issue. Moreover, the modest size of the cohort limited the ability of paired tests to detect statistically significant differences between testing conditions for measurements made with the ultrasound biometer ($1 - \beta \leq 0.32$ for all conditions). It was outside of the resources available to this study to enroll the hundreds of participants that would have been necessary to achieve a power of 0.80. Thus, the linear regression and Bland-Altmann analyses were critical to capture the variation within the results of each testing condition. Second, the ultrasound biometry measurements were taken using standard factory settings. The 6000 Scanmate-A has the option to adjust measurements for the detection of corneal compression, but it was not manipulated in this study to limit confounding factors. Future studies should explore the impact that adjusting the compression sensitivity settings has on the measurement. Third, refractive error was not measured or accounted for as a confounding factor. Previous works have suggested that validity and repeatability of ocular biometry

with a-scan ultrasonography varies based on refractive error, particularly in very hyperopic or very myopic eyes.[20,32] Fourth, there were several opportunities for bias in the study. Observer 1 was not blinded to the results of optical biometry when performing ultrasound biometry. Thus, it is possible that the results of the former biased the results of the latter. Any bias likely was small, however, as the differences in AL and ACD between the optical biometer and ultrasound biometer were statistically significant and were similar to those reported previously in the literature, as discussed above. It is also possible that always performing optical biometry before ultrasound biometry introduced bias into the results. Any effect would likely be exceedingly small, however, as optical biometry is a non-contact measurement. Making five measurements with the optical biometer and only three measurements with the ultrasound biometer may have introduced comparative precision bias. Finally, measurements were performed without cycloplegia. There is evidence that the repeatability of biometric measurements made with a-scan ultrasonography increases with cycloplegia, with more narrow limits of agreement.[36] It is possible that both intra- and inter-observer agreement would have improved in this study had cycloplegia been used.

Conclusion

In conclusion, this study found that the validity of the 6000 Scanmate-A, as compared to the IOLMaster, is in line with reports on other a-scan ultrasound devices. That is, a-scan ultrasonography measures a significantly shorter AL and shallower ACD than optical biometry. Inter- and intra-observer agreement were also in alignment with previous studies, but this study is the first to report on agreement both in sitting and supine positions. There were no significant differences in AL and ACD between sitting and supine positions. Although there were no significant differences in AL and ACD between study visits and between observers in both positions, meaningful limits of agreement between them must be accounted for in the clinic and in the laboratory. The limitations that this study was conducted on a small cohort of young and healthy patients, that the primary observer was not masked to the results of optical biometry during ultrasound biometry, that a-scan measurements were made using factory settings, and that measurements were made without cycloplegia sound be considered when interpreting the results of this study. Nevertheless, the 6000 Scanmate-A has the potential for clinical utility that can be deployed even in challenging clinical settings on patients in various body positions.

Abbreviations

ACD, anterior chamber depth; AL, axial length; C_V, coefficient of variation; ICC, intra-class correlation coefficient; IOL, intraocular lens; LOA, limits of agreement; RM ANOVA, repeated-measures analysis of variance.

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