

Comparative axial length measurements using optical and acoustic biometry in normal persons and in patients with retinal lesions

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ABSTRACT

Comparative measurements of the the axial length using optical (IOLMaster from Carl Zeiss Meditec AG) and acoustic biometry (Accusonic A-scan Plus from Accutome Inc.) in immersion technique were performed in cataract patients and a group of patients with retinal lesions. Comparing the mean differences between axial lengths measured with the IOLMaster and the A-scan Plus, no statistically significant differences were found between the results of 0.012 ± 0.143 mm for the "normal" cataract group and -0.002 ± 0.237 mm for the "retinal pathology" group. The comparative axial length measurements with both instruments showed very good reproducibilities; the differences in the measured values were neither statistically significant nor clinically relevant.

INTRODUCTION

Since the introduction of optical biometry with the ZEISS IOLMaster in 1999, this method has become established as an alternative to ultrasound biometry for axial length measurements as part of the preoperative workup for intraocular lens (IOL) implantation. With regard to its

measurement results output, the IOLMaster behaves in a way similar to a precision immersion ultrasound system. This is attributable to a special internal system calibration created on the basis of a large number of comparative measurements using the Grieshaber Biometric System in the Biometry Laboratory of the University Eye Hospital in Würzburg, Germany [1]. In the meantime several clinical studies on the correlation between IOLMaster biometry and immersion ultrasound [2], [3], [4], [5] have been published, although the ultrasound devices applied did not fully correspond to the latest generation of instruments. As it is not possible to rule out the possibility that different signal processing modalities in commercial ultrasound biometry systems may lead to differing measurement results – even if measurements are performed in immersion in each case –, a new comparison of optical biometry with a modern ultrasound system of a more recent generation appeared to be advisable.

MATERIAL AND METHODS

Comparative axial length measurements using acoustic and optical biometry were performed within the framework of a monocentric, prospective clinical study in the Laboratory for Biometry in the Dept. of Ophthalmology of the University of Würzburg.



PATIENTS

Over a period of six months 318 eyes of 224 patients were examined; the eyes either suffered from cataract or retinal pathologies, or showed normal, age-related findings. The subjects were recruited from a pool of patients scheduled for regular cataract surgery and presenting for routine axial length measurements who showed no retinal pathology ("normal") or displayed fundus abnormalities requiring retinal surgery ("retinal pathologies"). The "normal" group comprised 158 eyes of 116 patients (male: 45, female: 71), the "retinal pathologies" group 160 eyes of

108 patients (male: 44, female: 64). Further details about the patient population are summarized in Tables 1 and 2. All patients fulfilled the study's inclusion criteria (minimum age: 18 years) and fell under none of its exclusion criteria (infectious diseases, current immunosuppression, known allergies to used medication, pseudophakia). In an attempt to match the general population as exactly as possible, both short eyes (< 22 mm) and long eyes (> 28 mm) were included in the study. The axial length range can be seen from Figs. 4 and 5.

| | "Normal" group | "Retinal pathologies" group |
|-------------|---|---|
| Patients | 116 (male: 45, female: 71) | 108 (male: 44, female: 64) |
| Age (years) | 70.3 ± 12.4 (19.3 ... 89.2; median: 71.1) | 69.2 ± 10.3 (41.1 ... 93.3; median: 69.4) |
| Eyes | 158 (OD: 79, OS: 79) | 160 (OD: 83, OS: 77) |

Table 1: Details about the patients participating in the two groups

| Diagnosis | Number |
|--|--------|
| Epiretinal gliosis | 41 |
| Proliferative diabetic retinopathy | 33 |
| AMD | 22 |
| Macular foramen | 19 |
| Macular edema | 10 |
| Myopic fundus changes | 10 |
| Preceding retinal surgery | 5 |
| Retinal detachment | 2 |
| Other (e.g. fundus hypertonicus, preceding chorioretinitis, ...) | 18 |

Table 2: Diagnoses in the "retinal pathologies"

MEASUREMENT INSTRUMENTS

The following devices were used for axial length measurements:

- IOLMaster with Software Version 5 (manufacturer: Carl Zeiss Meditec AG, Jena, Germany), abbreviated to IOLMaster or 'IOLM'
- Accusonic A-scan Plus biometry system (Accutome Inc., Malvern, PA, USA), abbreviated to Accusonic or 'ACC'

Biometry with the Accusonic system was performed by examiner JM. The measurements with the IOLMaster were conducted by two staff members routinely responsible for this task in the hospital.

MEASUREMENTS

OPTICAL MEASUREMENTS

The measurements were repeated until 5 acceptable single measurements were obtained for each eye (cf. Fig. 1). The average of these measurements was taken as the measured value for the axial length.

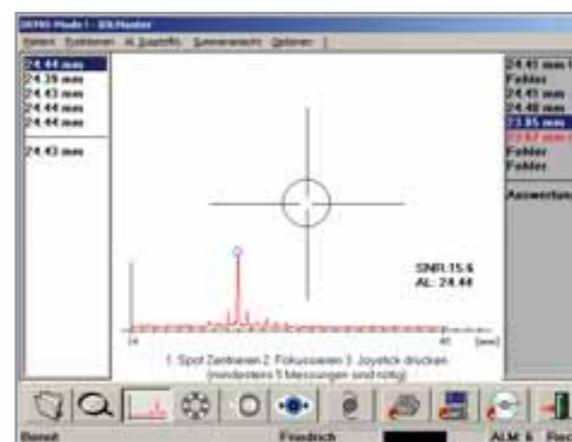


Fig. 1: Typical measurement result with the IOLMaster

as possible. Special care was exercised to assure a steep rise in the retinal echo. The measurements were repeated until 5 acceptable single measurements were obtained for each eye (cf. Fig. 2).

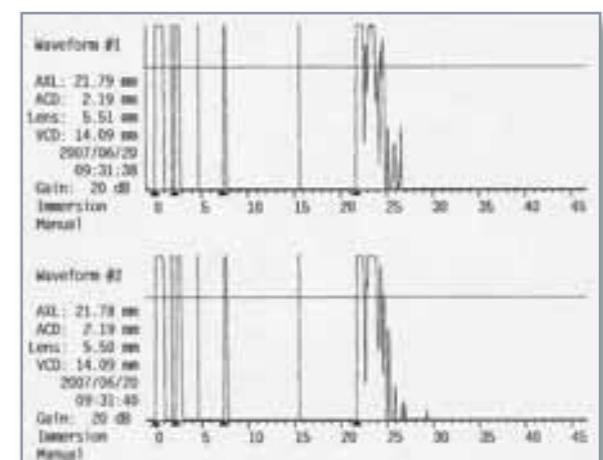


Fig. 2: Typical measurement result with the Accusonic system (ACC)

The mean of these measurements – automatically calculated by the instrument – was taken as the measured value for the axial length. The measurement data was saved manually after completion of measurements.

RESULTS

Typical measurement results obtained with the individual systems are shown in Figs. 1 and 2. Table 3 provides an overview of the number of eyes measured with the two instruments in the two patient groups.

| | "Normal" group | | "Retinal pathologies" group | |
|------------|----------------|-----|-----------------------------|-----|
| | IOLM | ACC | IOLM | ACC |
| Measurable | 156 | 158 | 157 | 160 |
| Total | | 158 | | 160 |

Table 3: Number of measured eyes in the two groups

For the IOLM as well as the ACC, means and standard deviations (sd) for the measured axial lengths were determined. The standard deviation can be used as a quality characteristic for the measurement and should not exceed 0.1 mm in ultrasound biometry. Table 4 gives the number of measured eyes in the respective standard deviation ranges in the two patient groups.

| sd | "Normal" group | | "Retinal pathologies" group | |
|----------|----------------|-----|-----------------------------|-----|
| | IOLM | ACC | IOLM | ACC |
| n | 156 | 158 | 157 | 160 |
| ≤ 0.1 mm | 153 | 153 | 149 | 151 |
| > 0.1 mm | 3 | 5 | 8 | 9 |
| > 0.2 mm | 0 | 2 | 3 | 1 |
| > 0.5 mm | 0 | 0 | 0 | 0 |
| > 1.0 mm | 0 | 0 | 0 | 0 |

Table 4: Number of measured eyes in the two groups, for which a standard deviation sd of the axial length measurement was determined, as well as the number of eyes for which this value was ≤ 0.1 mm and > 0.1, 0.2, 0.5 and 1.0 mm.

In the following, the comparative measurements were evaluated under two conditions: first, for all eyes examined, second, only for those eyes for which the standard deviation of the mean value was ≤ 0.1 mm. Table 5 shows the mean reproducibility of the axial length measurement for all measurements performed and for all measurements with sd ≤ 0.1 mm. A graphic illustration is shown in Fig. 3.

| "Normal" group | | |
|--------------------|----------------------------------|----------------------------------|
| System | IOLM | ACC |
| All n | 156 | 158 |
| sd [mm] | 0.020 ± 0.021 0.004 ... 0.161 | 0.034 ± 0.033 0.007 ... 0.279 |
| n with sd ≤ 0.1 mm | 153 | 153 |
| sd [mm] | 0.018 ± 0.012 0.004 ... 0.095 | 0.030 ± 0.016 0.007 ... 0.084 |

| "Retinal pathologies" group | | |
|-----------------------------|----------------------------------|----------------------------------|
| System | IOLM | ACC |
| All n | 157 | 160 |
| sd [mm] | 0.031 ± 0.044 0.004 ... 0.323 | 0.042 ± 0.034 0.004 ... 0.216 |
| n with sd ≤ 0.1 mm | 149 | 151 |
| sd [mm] | 0.022 ± 0.015 0.004 ... 0.098 | 0.035 ± 0.021 0.004 ... 0.094 |

Table 5: Reproducibility of the axial length measurement (mean standard deviation sd for 5 consecutive single measurements) for all measurements performed and for all measurements with a standard deviation sd ≤ 0.1 mm

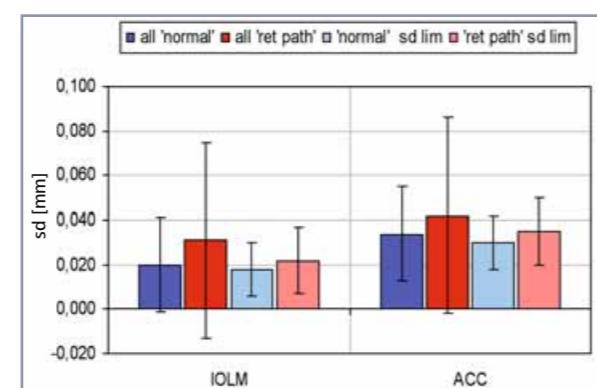


Fig. 3: Mean reproducibility of the axial length measurement in all groups for all measurements performed and for all measurements with sd ≤ 0.1 mm (data from Table 5)

Figs. 4 and 5 show a direct comparison of the measurement results for the two biometry instruments.

The statistical details of the corresponding regression lines in Figs. 4 and 5 are summarized in Tables 6 and 7. Table 6 is based on all data, Table 7 only on measured data with a standard deviation ≤ 0.1 mm.

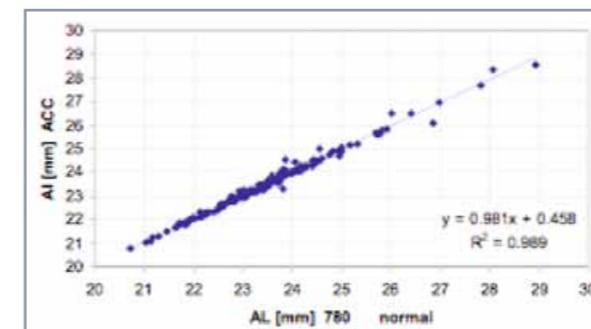


Fig. 4: Comparison of ACC and IOLM, "normal" group on the basis of all data

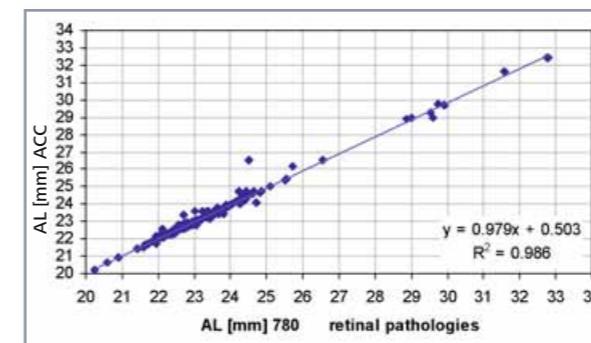


Fig. 5: Comparison of ACC and IOLM, "retinal pathologies" group on the basis of all data

| "Normal" group | | "Retinal pathologies" group |
|----------------|--------------------|-----------------------------|
| y = mx+t | ACC vs IOLM | ACC vs IOLM |
| m | 0.981 | 0.979 |
| t | 0.458 | 0.503 |
| R ² | 0.989 | 0.986 |
| p | < 10 ⁻³ | < 10 ⁻³ |
| n | 156 | 157 |

Table 6: Statistical details of the functional dependencies of the axial lengths obtained with different instruments on the basis of all data

| "Normal" group | | "Retinal pathologies" group |
|----------------|--------------------|-----------------------------|
| y = mx+t | ACC vs IOLM | ACC vs IOLM |
| m | 0.996 | 0.984 |
| t | 0.115 | 0.368 |
| R ² | 0.990 | 0.981 |
| p | < 10 ⁻³ | < 10 ⁻³ |
| n | 112 | 100 |

Table 7: Statistical values of the functional dependencies of the axial lengths obtained with different instruments on the basis of measurement data with a standard deviation sd ≤ 0.1 mm

Finally, the mean values of the measured axial lengths were compared for the two instruments, once again based on all measurement results as well as those with a standard deviation ≤ 0.1 mm. Tab.8 lists for both patient groups the number of eyes in which the absolute value of the difference in measured values was ≤ 0.1 mm or > 0.1 , 0.2 , 0.5 and 1 mm.

| abs. Δ | "Normal" group | "Retinal patholo." group |
|---------------------|----------------|--------------------------|
| System 1 - System 2 | ACC - IOLM | ACC - IOLM |
| n | 156 | 157 |
| ≤ 0.1 mm | 117 | 101 |
| > 0.1 mm | 39 | 56 |
| > 0.2 mm | 14 | 29 |
| > 0.5 mm | 3 | 6 |
| > 1.0 mm | 0 | 1 |

Table 8: Number of eyes in the two groups, for which an absolute value of the axial length difference (abs. Δ)...between the two instruments could be measured, as well as number of eyes for which this value was ≤ 0.1 mm or > 0.1 , 0.2 , 0.5 und 1.0 mm

Fig. 6 illustrates the number of eyes in both patient groups in which this value was > 0.1 mm. Tables 9 and 10 show the arithmetic means of the measured axial length differences together with further statistical data for both patient groups again based on all (Table 9) and on measured data with a standard deviation ≤ 0.1 mm (Table 10). Fig. 7 gives a graphical representation of these results.

| | "Normal" group | "Retinal patholo-gies" group |
|---------------|-------------------|------------------------------|
| | ACC - IOLM | ACC - IOLM |
| mean \pm sd | 0.012 ± 0.143 | -0.002 ± 0.237 |
| p for mean | 0.286 | 0.901 |
| Median | 0.010 | -0.023 |
| Min. / Max. | -0.780/0.680 | -0.625/2.048 |
| n | 156 | 157 |

Table 9: Statistical details of the differences of the measured axial length values on the basis of all data

| | "Normal" group | "Retinal patholo-gies" group |
|---------------|-------------------|------------------------------|
| | ACC - IOLM | ACC - IOLM |
| mean \pm sd | 0.019 ± 0.124 | -0.010 ± 0.182 |
| p for mean | 0.099 | 0.600 |
| Median | 0.010 | -0.030 |
| Min. / Max. | -0.278/0.680 | -0.630/0.700 |
| n | 112 | 100 |

Table 10: Statistical details of the differences of the measured axial length values on the basis of measurement values with standard deviation $sd \leq 0.1$

DISCUSSION

Table 3 shows that it was not possible to measure all patients with the IOLMaster ("normal" group: 99 %, "retinal pathologies" group: 98%). It was, however, possible to use the Accusonic system for all eyes in both groups (100%).

Taking the standard deviation for 5 consecutive single measurements in Table 4 as a measure of their reproducibility, the IOLMaster produced the best results in both patient groups; the percentage of measurements with $sd \leq 0.1$ mm totaled 98.1 % (IOLM) and 96.8% (ACC) for normal patients, and 94.9 % (IOLM) and 94.4 % (ACC) for patients with retinal pathologies. If in Table 5 and Fig. 3 the mean standard deviations for the "good" ($sd \leq 0.1$ mm) are compared to the "worse" ($sd > 0.1$ mm) measurements, no major difference results. As expected, the values for normal patients are slightly lower than for patients with retinal pathologies. Taken as a whole, the following reproducibilities are obtained for all patients: IOLM: 0.018 ... 0.031 mm; ACC: 0.030 ... 0.042 mm. For both patient groups, the comparison of the measurement results in Figs. 4 and 5 shows excellent correlations with coefficients of determination R^2 of 0.989 ... 0.986 corresponding to correlation coefficients of 0.994 ... 0.993 and slopes of the regression lines of 0.996 ... 0.979 (Tables 6 and 7).

The same findings are reflected in Table 8 and Fig. 6 if we consider the number of eyes for which the difference in the measured values is > 0.1 mm.

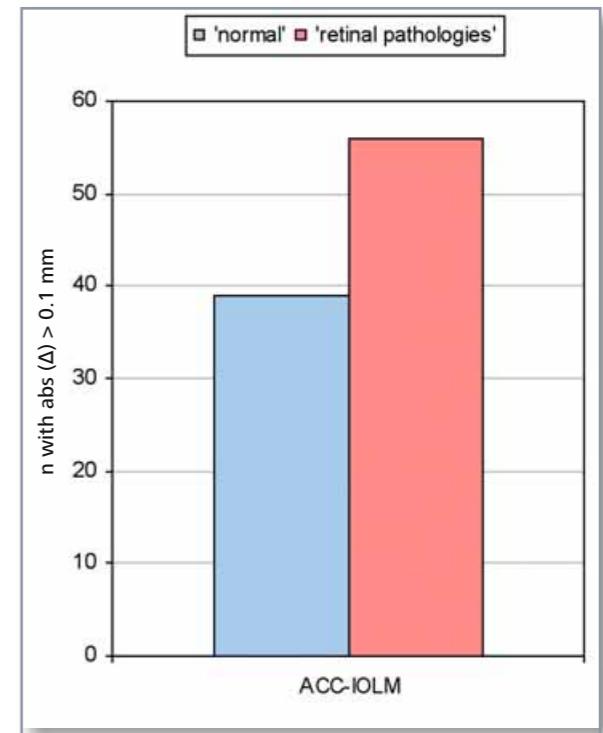


Fig. 6: Number of eyes for which the absolute value of the difference in the measured axial lengths is > 0.1 mm

If we compare the mean arithmetic axial length differences (Tables 9 and 10, Fig. 7) with values from -0.010 ... $+0.019$ mm, no statistically significant differences are found in the patient groups and measurement quality classes (n with $sd \leq 0.1$ mm and all n).

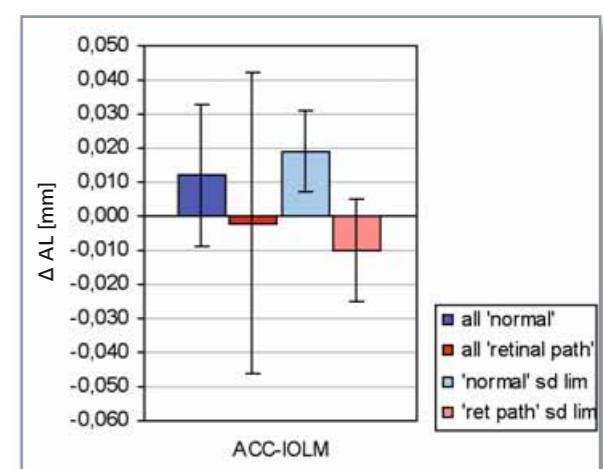


Fig. 7: Arithmetic mean of the difference between the measured axial lengths under different conditions

The differences found are not clinically relevant because 0.02 mm in the axial length of a normal eye approximately corresponds to a difference in refractive power of 0.1 D in an intraocular lens. The literature contains various comparisons between the IOLMaster and ultrasound immersion biometry systems. Packer et al [3] specify a correlation coefficient of 0.996 (i.e. $R^2 = 0.992$). In measurements [4] on 101 patients in our laboratory, a value of 0.988 (i.e. $R^2 = 0.976$) was found.

Taking the measurement results in the "normal" group as a reference, then our results with $R^2 = 0.989$ lie in the same order of magnitude. Values of 0.01 ± 0.13 mm [2], 0.01 mm [3], -0.010 ± 0.019 mm (median: 0.010 mm; range: -0.770 to +0.420 mm, n = 146, IOLMaster-GBS) [5] are reported in the literature as differences between ultrasound and PCI measurements. Again, on the basis of the measured values in the "normal" group (ACC - IOLM: 0.012 ± 0.143 mm), the results with the Accusonic instrument are directly comparable to the literature.

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