Published in final edited form as:

J AAPOS. 2013 April ; 17(2): 144–148. doi:10.1016/j.jaapos.2012.11.005.

Intraobserver reliability of contact pachymetry in children

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Abstract

Background—Central corneal thickness (CCT) is an important measurement in the treatment and management of pediatric glaucoma and potentially of refractive error, but data regarding reliability of CCT measurement in children are limited. The purpose of this study was to evaluate the reliability of CCT measurement using handheld contact pachymetry in children.

Methods—We conducted a multicenter intraobserver test–retest reliability study of more than 3,400 healthy eyes in children aged from birth to 17 years using a handheld contact pachymeter (Pachmate DGH55) in two clinical settings—with topical anesthesia in the office and under general anesthesia in a surgical facility.

Results—The overall standard error of measurement, including only measurements with standard deviation $\leq 5 \mu\text{m}$, was $8 \mu\text{m}$; the corresponding coefficient of repeatability, or limits within which 95% of test–retest differences fell, was $\pm 22.3 \mu\text{m}$. However, standard error of measurement increased as CCT increased, from $6.8 \mu\text{m}$ for CCT less than $525 \mu\text{m}$, to $12.9 \mu\text{m}$ for CCT $625 \mu\text{m}$ and higher. The standard error of measurement including measurements with standard deviation $> 5 \mu\text{m}$ was $10.5 \mu\text{m}$. Age, sex, race/ethnicity group, and examination setting did not influence the magnitude of test–retest differences.

Conclusions—CCT measurement reliability in children using the Pachmate DGH55 handheld contact pachymeter is similar to that reported for adults. Because thicker CCT measurements are less reliable than thinner measurements, a second measure may be helpful when the first exceeds $575 \mu\text{m}$. Reliability is also improved by disregarding measurements with instrument-reported standard deviations $> 5 \mu\text{m}$.

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A complete listing of the Pediatric Eye Disease Investigator Group members participating in this study is provided as e-Supplement 1, available at jaapos.org.

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Central corneal thickness (CCT) is a key clinical measure in pediatric glaucoma.¹⁻⁴ Researchers have measured CCT after cataract surgery in children^{4,5} and studied its relationship with refractive error.⁶⁻¹¹ CCT also has been studied in a variety of systemic conditions in children.¹²⁻¹⁷ It is recommended prior to adult refractive surgery^{18,19} and may become increasingly important as refractive surgery is evaluated in children.²⁰ Most studies of CCT reliability have been conducted in adults.²¹⁻²⁴ There are few studies of CCT reliability in children.²⁵⁻²⁷ The purpose of this study is to evaluate the intraobserver reliability of handheld contact measurement of CCT in a large cohort of children aged birth to 17 years with normal eyes.

Methods

The subjects for this report participated in a study of CCT in healthy children conducted by the Pediatric Eye Disease Investigator Group (PEDIG).⁶ The protocol and United States Health Insurance Portability and Accountability Act–compliant informed consent forms were approved by the institutional review boards for participating sites, and a parent or guardian of each study subject gave written informed consent. The protocol is available on the PEDIG website (<http://publicfiles.jaeb.org/pedig/protocol/CCTS%20protocol%20v1.0%204-4-08.pdf>).

CCT was measured either in the office or under general anesthesia during an already-scheduled surgical procedure using the ultrasound-based DGH 55 handheld Pachmate (DGH Technology Inc, Exton, PA), which was calibrated each day prior to the initial subject testing. Three CCT measurements per eye were attempted. Each CCT measurement was an average of up to 25 readings made in a single attempt; the average and standard deviation (SD) as reported by the instrument were recorded (98% of measurements in this study were based on 25 readings). For each measurement, the pachymeter was aimed on the central 3 mm of the cornea. For measurements made in the office, this occurred after instillation of one drop of proparacaine 0.5%.

Statistical Methods

CCT measurements with a standard deviation $>5 \mu\text{m}$ or missing ($N = 2,735$ measurements) were excluded from the primary analysis because the high variability was considered to be due to inaccurate or unsteady placement of the probe against the cornea. A secondary analysis including these measurements was performed to determine the effect of this exclusion on measurement reliability. The difference and relative difference between the test and retest measurements was calculated for each pair, resulting in up to three differences and relative differences per eye (measurement 1 vs 2, measurement 2 vs 3, measurement 1 vs 3). The relative difference was defined as the difference between the initial and repeat measurements (repeat minus initial) divided by the average of all measurements multiplied by 100%. The primary analysis included 1,933 subjects (3,494 eyes), with 400 subjects (21%) measured while under general anesthesia. Three measurements were available for 2,583 eyes (74%), whereas 911 eyes (26%) had two measurements. The secondary analysis including measurements with $\text{SD} > 5 \mu\text{m}$ had 2,150 subjects (4,275 eyes), with 410 subjects measured under anesthesia.

Presence of a testing order effect within eyes was tested using the paired t test with the generalized estimating equation to adjust for correlation between right and left eyes. The standard errors of measurement based on the differences and relative differences were derived using repeated measures analysis of variance.²⁸ The coefficient of repeatability and its 95% confidence interval were calculated using the standard error of measurement. The coefficient of repeatability gives the limits within which 95% of test–retest differences are

expected to fall. Because the variation in differences was related to the average CCT, standard errors of measurement stratifying by average CCT also were calculated.

The effects of age, sex, race/ethnicity group, eye laterality, examination setting (office versus operating room), and mean of the CCT measurements on the magnitude of absolute test–retest differences was examined using a random effects model to account for correlation between eyes.²⁹ A forward selection procedure was used to identify factors associated with absolute test–retest differences while simultaneously adjusting for other associated factors as potential confounders.

Results

The 1,933 subjects (3,494 eyes) included in the primary analysis had a mean age of 7.5 ± 4.5 years (range, birth to 17.97 years). Additional characteristics of the study sample are described in e-Supplement 2 (available at jaapos.org). The average CCT per eye ranged from 438 μm to 790 μm , with a mean of $559 \pm 38 \mu\text{m}$. The mean absolute value of the test–retest differences was $6.1 \pm 9.4 \mu\text{m}$. The distribution of differences is reported in Table 1. The overall coefficient of repeatability was $\pm 22.3 \mu\text{m}$ (95% CI, 21.4–23.1 μm ; Table 2). In the office setting, 24% of measurements had SD $> 5 \mu\text{m}$ versus 9% of measurements taken under anesthesia. When measurements with SD $> 5 \mu\text{m}$ were included in the analysis, the coefficient of repeatability was significantly higher ($\pm 29 \mu\text{m}$; 95% CI, 27.9–30.1 μm , Table 2).

The test–retest difference increased as the CCT increased ($P < 0.001$, Table 3). Consequently, the coefficient of repeatability was lower for thinner CCT measurements and higher for thicker CCT measurements (Figure 1). The magnitude of relative differences and the coefficient of repeatability for the relative differences also increased as the CCT measurement increased ($P < 0.001$; Table 3). Left eyes tended to have smaller test–retest differences compared with right eyes (coefficient of repeatability, $\pm 21.3 \mu\text{m}$ and $\pm 23.2 \mu\text{m}$, respectively; $P = 0.017$). There was no evidence of a testing order effect for the three measurements taken within each eye; (average difference, $-0.18 \mu\text{m}$ for measurement 1 vs 2; $-0.06 \mu\text{m}$ for 1 vs 3; and $0.12 \mu\text{m}$ for 2 vs 3; $P > 0.40$ for test of non-zero difference for all three differences). Age ($P = 0.56$), sex ($P = 0.89$), race/ethnicity group ($P = 0.32$), and examination setting ($P = 0.15$) did not affect the magnitude of test–retest differences after adjusting for laterality and CCT. In particular, the group of children measured under anesthesia was younger than the group measured in the office, and had thinner CCTs, as expected for younger children. After adjustment for the difference in CCT between the two groups and elimination of measurements with SD $> 5 \mu\text{m}$, there was no difference between the two settings in the reliability of the measurements.

Discussion

In children from birth to age 17 years with normal eyes, the reliability of CCT measurement with a handheld contact pachymeter was not influenced by age, race/ethnicity, or examination setting but was related to the measured CCT, with better reliability for thinner CCT measurements. Even when considering reliability as percentage of the CCT measurement, it was still true that thicker CCT measurements were less reliable than thinner measurements. It is likely that off-center measurements contributed to the finding of poorer reliability for thicker measurements. As the cornea is typically thicker off-center than at the center, an average of three measurements that includes off-center measurements will be higher than the true central thickness. Off-center measurements also will tend to have greater variability among the measurements because these are from different locations that include true differences in thicknesses. This occurrence leads to thicker *measured* CCT

values having larger test–retest differences than thinner *measured* CCT values; it does not mean that thin corneas are measured more reliably. The percentage of observations falling outside the calculated coefficient of repeatability lends support to this idea (Table 3). In theory, 5% of observations should fall outside the coefficient of repeatability; in practice, this percentage tended to be lower in this study. This was due to difference and relative difference data that deviated from the expected normal measurement error distribution, with more than the expected number of observations having large test–retest differences. This increases the estimate of the coefficient of reliability.

We previously reported in this cohort that intraocular pressure (IOP) was 1.5 to 1.9 mm Hg higher on average for every 100 μm thicker CCT depending on the tonometer used.^{6,30} In a study that included children, Burdova and colleagues³¹ also reported a 2 mm Hg average difference in IOP using tonopen with a 100 μm difference in CCT. These data suggest that a 1 mm Hg difference in IOP may occur with a difference of 50–70 μm in CCT. Given that the coefficient of repeatability for CCT measurements with SD < 5 μm was less than 50 μm , the effect of measurement error in the CCT on measured IOP would be expected to be less than ± 1 mm Hg on average. The measurement error in CCT is sufficiently small that it should affect neither the assessment of glaucoma risk nor the utility of the glaucoma risk estimate.

There was a clinically small, but statistically significant, difference in reliability between eyes, with testing of the left eye being more reliable than the right. Measurement order was not dictated by the protocol, but likely the right eye was measured first per clinical routine. Therefore, this difference may be due to a testing order effect. Handedness or position of the operator could also have contributed. Given the large sample size of this study, it is unlikely that any clinically important factors affecting reliability were missed from among the factors tested.

The overall coefficient of repeatability in CCT measurement of children in this study, ± 22.3 μm , is similar to that found in intraobserver studies of adult CCT measurement using contact pachymetry showing 95% limits of agreement, ranging from ± 10 to ± 24.5 μm .^{21–24,32,33} Of test–retest differences, 95% are expected to fall within the coefficient of repeatability/limits of agreement. (Coefficient of repeatability and limits of agreement are effectively the same for test–retest data in the absence of a testing order effect). However, because coefficient of repeatability varied with the CCT in this study, a higher percentage of test–retest differences were within the coefficient of repeatability range of ± 22.3 μm for thinner CCTs than for thicker CCTs. To minimize the impact of placement error, CCT measurements with a SD of > 5 μm were excluded from analysis in this study, which contributed to a smaller standard error of measurement than would have been found otherwise.

These data should be useful for management of pediatric glaucoma and for the emerging field of pediatric refractive surgery, and future research regarding CCT and its associations with refractive error and systemic conditions in children. Reliability of CCT measurement is improved by disregarding a measurement when the instrument-reported standard deviation is > 5 μm . Measurement error in CCT is sufficiently small that it should not affect the assessment of glaucoma risk. In addition, thick CCT measurements are less reliable than thin ones, and a second measurement should be taken when the first is > 575 μm .

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Supported by National Eye Institute of National Institutes of Health, Department of Health and Human Services EY011751 and EY018810. The sponsor and funding organization had no role in the design or conduct of this research.

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FIG 1. Bland-Altman plot showing CCT test-retest difference versus average of test-retest measurements with coefficient of repeatability (black lines; measurement 1 vs 2 only).

Table 1Absolute value of test–retest differences^a

Absolute value of test–retest difference, μm	Excluding measurements with SD > 5.0 μm		Including measurements with SD > 5.0 μm	
	N (%)	Cumulative N (%)	N (%)	Cumulative N (%)
0	745 (9)	745 (9)	906 (7)	906 (7)
1-5	4918 (57)	5663 (65)	6142 (48)	7048 (55)
6-10	1802 (21)	7465 (86)	2791 (22)	9839 (77)
11-15	596 (7)	8061 (93)	1215 (10)	11054 (87)
16-20	250 (3)	8311 (96)	597 (5)	11651 (91)
21-40	233 (3)	8544 (99)	796 (6)	12447 (97)
41-60	65 (<1)	8609 (99)	195 (2)	12642 (99)
61-80	21 (<1)	8630 (>99)	63 (<1)	12705 (>99)
81-100	22 (<1)	8652 (>99)	42 (<1)	12747 (>99)
101-120	5 (<1)	8657 (>99)	10 (<1)	12757 (>99)
121-140	1 (<1)	8658 (>99)	8 (<1)	12765 (>99)
141-160	2 (<1)	8660 (100)	2 (<1)	12767 (>99)
161-204	0 (0)	8660 (100)	2 (<1)	12769 (100)
Total	8660 (100)	8660 (100)	12769 (100)	12769 (100)

^aIncludes all differences (ie, for test 1 vs 2, 2 vs 3, and 1 vs 3).

Table 2

Standard error of measurement and coefficient of repeatability for CCT measurement in children by examination setting^a

Examination setting	Excluding measurements with SD > 5.0 μm		Including measurements with SD > 5.0 μm	
	SEM	CR ^c (95% CI)	SEM	CR ^c (95% CI)
Office	8.3 ^b	± 23.1 (± 22.1 , ± 24.1)	11.0	± 30.4 (± 29.2 , ± 31.6)
Under anesthesia	7.0 ^b	± 19.4 (± 17.7 , ± 21.1)	7.9	± 21.8 (± 20.0 , ± 23.6)
Overall	8.0	± 22.3 (± 21.4 , ± 23.1)	10.5	± 29.0 (± 27.9 , ± 30.1)

CR, coefficient of repeatability; SEM, standard error of measurement.

^a All values are in micrometers (μm).

^b After adjustment for the thinner CCTs in the under anesthesia group, the difference in measurement error between the in office and under anesthesia settings was not significant ($p=0.14$).

^c The coefficient of repeatability gives the limits within which 95% of test-retest differences fall.

Table 3

Standard error of measurement and coefficient of repeatability for CCT measurement in children by CCT^a

CCT, μm	Original scale (μm)			Relative difference scale (%)		
	SEM ^b	CR (95% CI)	Percent observations outside $\pm$ CR	SEM ^b	CR (95% CI)	Percent observations outside $\pm$ CR
<525	6.8	± 18.8 ($\pm 17.1, \pm 20.5$)	2.6	1.3%	$\pm 3.8\%$ ($\pm 3.4, \pm 4.2\%$)	2.4
525-574	7.2	± 20.1 ($\pm 19.0, \pm 21.2$)	3.1	1.3%	$\pm 3.6\%$ ($\pm 3.4, \pm 3.8\%$)	3.3
575-624	9.2	± 25.5 ($\pm 23.8, 27.2$)	4.4	1.5%	$\pm 4.2\%$ ($\pm 4.0\%, \pm 4.4\%$)	4.6
625	12.9	± 35.7 ($\pm 29.4, \pm 42.0$)	6.8	2.0%	$\pm 5.4\%$ ($\pm 4.4\%, \pm 6.4\%$)	6.8
Total	8.0	± 22.3 ($\pm 21.4, \pm 23.1$)	3.5	1.4%	$\pm 3.9\%$ ($\pm 3.7\%, \pm 4.1\%$)	3.6

CCT, central corneal thickness; CR, coefficient of repeatability; SEM, standard error of measurement.

^aMeasurements with SD > 5.0 μm are excluded. The coefficient of repeatability gives the limits within which 95% of test-retest differences are expected to fall. For the original scale, SEM and CR are reported in microns. For the relative difference scale, SEM and CR are reported as a percentage of the average CCT measurement.

^b $P < 0.001$ for test for trend with average CCT measurement.