Comparison of central corneal thickness using non-contact tono-pachymeter (Tonopachy) with ultrasound pachymetry in normal children and in children with refractive error

Kiruthikadevi Thiagarajan, Kavitha Srinivasan, Keerthi Gayam, Venkatesh Rengaraj

Purpose: To compare the central corneal thickness (CCT) measured by non-contact tono-pachymeter [Tonopachy (TP)] with the gold standard ultrasound pachymetry (UP) in normal children and in children with refractive error. **Methods:** This cross-sectional study involved 95 normal children (190 eyes) and 123 children with refractive error (246 eyes), a total of 218 children (436 eyes) aged 7-15 years. After refraction and complete ophthalmic evaluation, axial length was measured with IOLMaster 700, CCT was measured with TP followed by UP. The correlation between the CCT measurements obtained with the two methods was analysed by Intraclass correlation coefficient (ICC) and the limits of agreement were assessed with Bland-Altman analysis plot. **Results:** Mean CCT measured with TP was 537.46 ± 36.41 µm and by UP was 537.17 ± 39.80 µm in normal children ($P = 0.79$) and in refractive error group, the mean CCT was 533.50 ± 34.91 µm by TP and 531.60 ± 36.30 µm by UP ($P = 0.04$). The 95% limits of agreement between TP and UP ranged from -19.2 to + 21.6 µm (mean = 1.20) for total children, -20.8 to + 21.4 µm (mean = 0.29) for normal group and -18.0 to + 21.8 µm (mean = 1.90) for refractive error group. ICC for CCT measurement between TP and UP was 0.980 for total children and refractive error group and 0.981 for normal group. **Conclusion:** The CCT measurement obtained by TP showed an excellent agreement with UP. Hence non-contact TP can be used to assess CCT in children above seven years of age.

Key words: Central corneal thickness, tonopachy, ultrasound pachymetry

Central corneal thickness (CCT) is an important parameter in the diagnosis and management of many ophthalmic conditions. The average CCT in general adult population has been reported to be 535 microns.[1] CCT can be obtained by either optical or ultrasound methods. An accurate, reliable measurement of CCT is important in the screening and planning of keratorefractive surgeries,[2] contact lens practice during orthokeratology, monitoring the corneal ectatic conditions like keratoconus, collagen cross linking procedures,[3] and in the management of many corneal diseases.

Additionally CCT influences the intraocular pressure (IOP) measurements, the only modifiable risk factor in the management of glaucoma.[4,5] The variation in the corneal thickness alters the resistance to corneal indentation and thus affects the accuracy of IOP measurements. The gold standard Goldmann applanation tonometry (GAT) overestimates IOP in thick corneas and underestimates IOP in thin corneas.[1] CCT itself is an independent risk factor for developing glaucomatous optic nerve head damage and more importantly a thin CCT has been identified as a predictor of glaucoma progression.[6-9] The ocular hypertension treatment study showed that thinner CCT at baseline is an important risk factor for conversion of ocular hypertension to primary open-angle glaucoma.[7] Hence CCT is an integral component of glaucoma workup.

Literature regarding the CCT in children is sparse as compared to that of the adults. Studies have shown racial and ethnic differences in the CCT in children.[10-13] According to available literature the child's cornea reaches the adult corneal thickness by 3-9 years of age.[13-15] Gender differences have been noted with certain studies reporting a greater CCT in male children.[11,16] Many ocular and systemic conditions in children influence the CCT. Children with congenital diseases such as Down syndrome exhibit a thinner cornea than healthy children, and a decreased CCT might be an early sign of degenerative corneal disease in these children.[12] Children with congenital glaucoma also have significantly lesser CCT than that of healthy children.[17,18]

Refractive error is another factor associated with CCT, not only in adults but also in children, with high myopic refractive errors reported to have reduced CCT as compared to those with greater hyperopic refraction.[19-22] Children might require long term steroid therapy for certain ocular conditions like uveitis, vernal keratoconjunctivitis, where there are chances of steroid induced IOP spikes. Additionally steroid therapy post cataract surgery may tend to rise IOP in some children.

Departments of Glaucoma and Paediatric Services, Aravind Eye Hospital, Pondicherry, India

Correspondence to: Dr. Kavitha Srinivasan, Aravind Eye Hospital, Thavalakuppam, Pondicherry, India. E-mail: skavitha.shree@gmail.com

Hence it is quintessential to measure CCT at baseline, to avoid under-treatment or over-treatment of glaucoma based on IO*P* values. Likewise the thicker cornea of aphakic eyes introduces a potential source of measurement error when using IOP alone as a criterion for diagnosing glaucoma.[23-25] These evidence highlight the importance of obtaining CCT in children.

Ultrasound Pachymetry (UP) is currently the gold standard method employed to measure CCT.[1] However, placement of the probe on the central cornea is subjective and operator dependent errors due to off-centre placement (leading to thicker measurements) are a possibility.[26] Errors can be caused by indentation leading to slightly thinner readings.[27] In addition, it is a contact procedure with some disadvantages like patient discomfort, need of topical anaesthesia, risk of corneal epithelial damage and infection. More importantly patient cooperation might be an issue with such contact procedures especially in children. Hence, it is not surprising that non-contact techniques to measure CCT are gaining popularity.[28-31]

A relatively new non-contact tono-pachymeter (TP), Tonopachy (NT-530p; Nidek Gamagori, Japan) is a unique system that has two simultaneous functions, one is a non-contact applanation tonometer which utilizes an air jet to flatten the cornea and CCT measurement using Scheimpflug camera system.[32] It provides a rapid, convenient, non-invasive, objective measurement of CCT and IOP in a single shot, minimizing the user influence. Being a non-contact procedure it eliminates the need of topical anaesthesia, improves patient cooperation and also reduces the risk of infection. Moreover auto alignment option available with the TP eliminates the operator factor.

A recent study from India comparing TP and GAT showed a moderate agreement between the two instruments, in the corneal corrected IO*P* values, in adults with and without glaucoma. Additionally they found that TP marginally overestimated CCT as compared to UP in both the groups.[28] Few other previous studies comparing the CCT measurements using these two equipment have shown contrasting results with either marginal overestimation[28,29] or underestimation[30] of CCT by TP as compared to UP. However these studies comparing CCT measurements by TP with UP have been conducted only in adults [28-30] and none in children. Hence in this cross-sectional study, we aimed to assess the CCT by using non-contact TP and UP in normal children and in children with refractive error and to find the levels of agreement between the two equipment. To the best of our knowledge this is the first study to compare non-contact TP with the gold standard UP in children.

Methods

The study was approved by the Institutional review board and the Ethical committee (AEH/PDY/EC/THESIS/16/2016) and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from the parents of all study participants.

Study participants

In this cross sectional study, we recruited two groups of children aged 7 to 15 years, from august 2016 to august 2018 from Paediatric ophthalmology services of a tertiary eye care hospital in south India. The normal group consisted of children with healthy cornea without any ocular or systemic condition that influences CCT. The refractive error group consisted of children with refractive error including myopia, hypermetropia or astigmatism of any range without any other ocular or systemic pathology that can influence the CCT. Children with ocular abnormalities like anterior segment dysgenesis, congenital cataract, corneal structural abnormalities, uveitis, micro-ophthalmia/nanophthalmos, glaucoma, history of contact lens use, periocular steroid use within 3 months of enrolment or current systemic steroid use or any intra ocular/ extra ocular surgeries were excluded.

Clinical assessment

Fig. 1 Clinical examination of the study participants

Once the child qualified the study inclusion criteria, informed written consent was obtained from the parents and then a detailed comprehensive ophthalmic evaluation was performed including visual acuity measurement with Snellen's chart, retinoscopy and subjective refraction by trained technicians. One of the study investigators (SK, RV, KG) did the anterior segment evaluation using slit-lamp biomicroscopy, undilated posterior segment evaluation including optic disc and macula using a slit-lamp and +90 diopter lens. Rest of the investigations were done in the following order.

IOLMaster 700 (Carl Zeiss Meditec AG, Jena, Germany) readings: A trained technician (PK) who had more than 5 years of experience in handling the IOLMaster obtained all the A-scan measurements. The device acquires measurements in a single capturing process. The average value of the three scans displayed automatically, was taken as the axial length value.

Tonopachy™ (NT-530P; Nidek co., LTD. Gamagori, Japan) readings: The same technician (PK) who obtained the axial length who was also well experienced in using the tonopachy instrument obtained CCT and IOP. The child was asked to sit with forehead against the forehead rest and to look at the fixation target. Three CCT and three IOP readings were obtained and the instrument automatically averages each of the three CCT and three IOP readings.

Ultrasound pachymetry (300P Pacscan, Sonomed Escalon) readings: Cornea was anaesthetised with the topical 0.5% proparacaine eye drops. The child was asked to fixate on a distant target and then the pachymeter probe was gently aligned as perpendicularly as possible to the central part of the cornea. Five CCT readings were obtained by another experienced ophthalmic assistant who was masked to the readings obtained from TP. The automatically generated average value of 5 readings displayed on the screen was noted. If the standard deviation of CCT was >10 μm, all measurements were repeated.

Cycloplegic refraction for the required children and dilated fundus evaluation with +90 D lens was done. TP was done first as it's a noncontact procedure. Both the ophthalmic technicians performing TP and UP were masked to readings of the other instrument. All the instruments used in the study were calibrated once in 10 days.

Statistical analysis

Group differences in baseline variables were evaluated using Student *t*-test for continuous variables and Chi-square test

for categorical variables. Independent *t*-test was used to find out the significant difference in CCT between two genders. Analysis of variance (ANOVA) test was used to find out the difference in CCT between different age groups and different ranges of refractive error. Pearson correlation co-efficient was used to find out the correlation between CCT and axial length in refractive error group. The correlation between the CCT measurements obtained with the two methods was analysed by Intraclass correlation coefficient (ICC). Bland-Altman analysis was performed to assess the clinical agreement between the two methods of CCT measurement. *P* value of < 0.05 was considered statistically significant.

Sample size: To detect a difference in mean CCT of 20 microns between the two instruments in both groups, standard deviation of 40 and 55 μm in normal and refractive error children respectively with 5% level of significance and 80% power, a sample size of 182 (91 in each arm) patients was chosen.

Statistical analysis was performed using the statistical software STATA 11.0 (StataCorp, College Station, TX).

Results

Ninety five normal children (190 eyes) and 123 children with refractive error (246 eyes), a total of 218 children were recruited. Though we collected data from both eyes, the data from the right eyes were taken for analysis, in both the groups.

Both the groups were comparable with respect to age (*P* = 0.41) and gender distribution (*P* = 0.08), Table 1. The mean CCT in normal children was 537.46 ± 36.41 μm by TP and 537.17 ± 39.80 μm by UP (*P* = 0.79). In children with refractive error, the mean CCT was 533.50 ± 34.91 μm by TP and 531.60 ± 36.30 μm by UP (*P* = 0.04). Though the difference in the refractive error group is statistically significant, this difference may be clinically insignificant. There was no significant difference in CCT between normal and refractive error group of children with both TP (*P* = 0.42) and UP (*P* = 0.28), Table 2.

Male children had significantly higher CCT than the female children in normal group by both TP (545.67 μm vs. 530.08 μm respectively; *P* = 0.04) and UP (546.69 μm vs. 528.60 μm respectively; *P* = 0.03). Also in refractive error group mean CCT was higher in males than the females with both TP (539.20 μm vs. 530.33 μm; *P* = 0.18) and UP (537.36 μm vs. 528.39 μm; *P* = 0.19) though the difference was not statistically significant, Table 3.

In the sub group analysis based on age, between 7-9 years, 10-12 years, 13-15 years there was no significant difference in the mean CCT in normal and refractive error group with both TP (*P* = 0.27, *P* = 0.77 respectively) and UP (*P* = 0.52, *P* = 0.76, in normal and refractive error group respectively), Table 4.

The subgroup analysis between different ranges of refractive error as <3 diopter (D), 3 to 6 D and >6 D showed a mean CCT of 537.33 μm, 534.29 μm and 525.19 μm respectively when measured by TP, 535.08 μm, 533.03 μm and 523.32 μm respectively by UP. There was no significant difference in CCT between different ranges of refractive error by both TP (*P* = 0.29) and UP (*P* = 0.33), Table 5.

Pearson correlation co-efficient showed no correlation between CCT and axial length in refractive error group when measured by both TP (r = -0.06, *P* value = 0.53) and UP (r = -0.02, *P* value = 0.70).

The Bland-Altman plot analysis for CCT measurement by TP and UP showed that the mean CCT difference was 1.20 μm and the 95% limits of agreement ranged from -19.2 to + 21.6 μm for the total children, -20.8 to + 21.4 μm (mean = 0.29) for the normal group and -18.0 to + 21.8 μm (mean = 1.90) for the refractive error group [Figs. 2-4].

The Intraclass correlation coefficient (ICC) for CCT measurement between TP and UP for the total children and in the refractive error group was 0.980 and for the normal group was 0.981 showing an excellent agreement between the two instruments, correlating well with Bland-Altman plot.

Discussion

Our study demonstrates an excellent agreement between the CCT values obtained by TP and UP, in both normal children and in children with refractive error. There was no significant correlation between the CCT and different ranges of refractive error, axial length and age, with both the instruments. Distribution of CCT has been well described in adults in several population-based studies. In contrast, very little information has been reported regarding CCT in children, especially in Indian population. To the best of our knowledge this is the

Table 1: Demographic characteristics of study participants

Group	Mean age (SD)	P	Gender (n %)	P
Normal (*n*=95)	11.05 (2.58)	0.41	Males: 45 (47.4%)	0.08
Refractive error (*n*=123)	11.35 (2.65)		Males: 44 (35.8%)	
Total (*n*=218)	11.22 (2.62)		Males: 89 (40.8%)	

Table 2: Mean CCT by tonopachy and ultrasound pachymetry in the study population

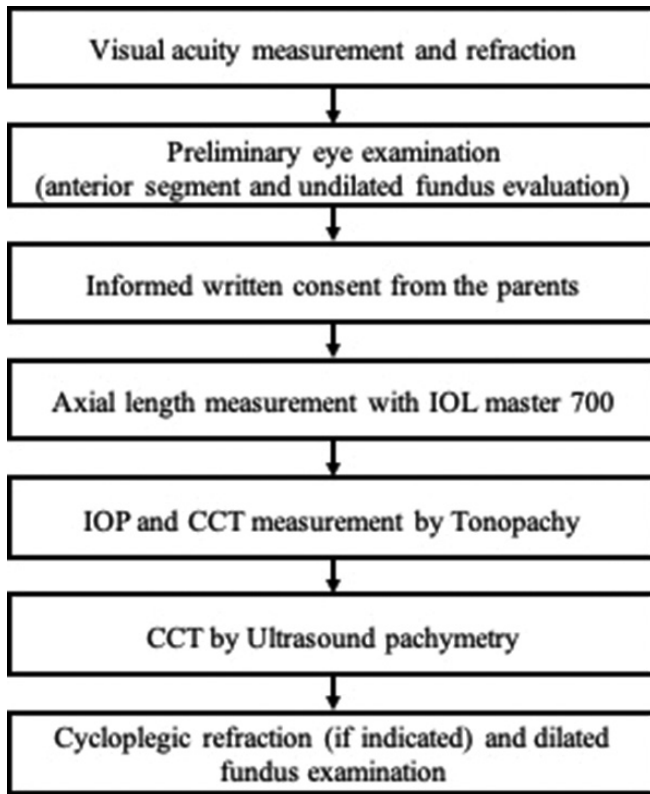| CCT	Normal (*n*=95)	Refractive error (*n*=123)	Total (*n*=218)	P
Tonopachy				
Mean (SD)	537.46 (36.41)	533.50 (34.91)	535.23 (35.54)	0.42
Min-Max	449-673	454-625	449-673	
Ultrasound pachymetry				
Mean (SD)	537.17 (39.80)	531.60 (36.30)	534.03 (37.88)	0.28
Min-Max	452-685	452-632	452-685	
P	0.79	0.04	0.08	

Figure 1: Clinical examination of the study participants. Flow chart depicting the process of clinical examination of the study participants

Figure 2: Bland-Altman plot for CCT by TP and UP for the total children. Bland-Altman plot of CCT measured by TP and UP for total population. The solid line represents mean difference of CCT between TP and UP (1.20 μm) and dotted lines represent upper (+21.6 μm) and lower (-19.2 μm) limits of agreement
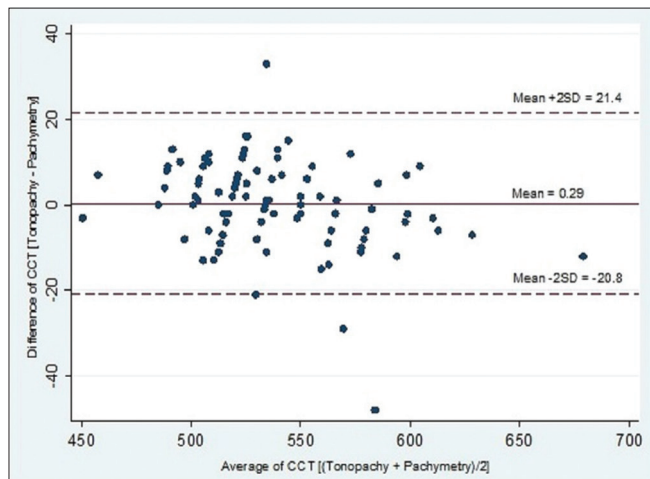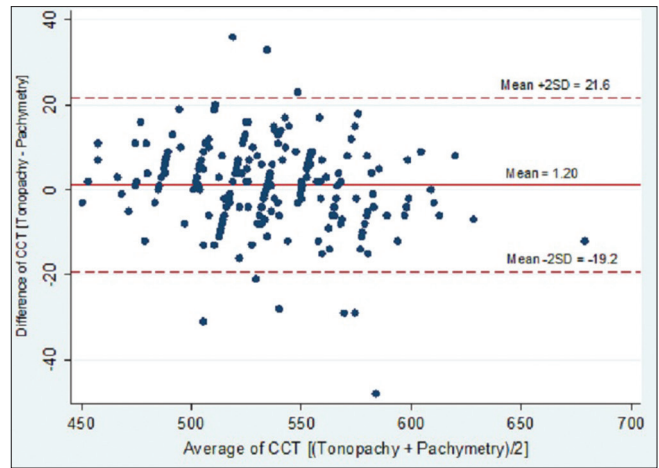

Figure 3: Bland-Altman plot for CCT by TP and UP for the normal group. Bland-Altman plot of CCT measured by TP and UP in normal group. The solid line represents mean difference of CCT between TP and UP (0.29 μm) and dotted lines represent upper (+21.4 μm) and lower (-20.8 μm) limits of agreement
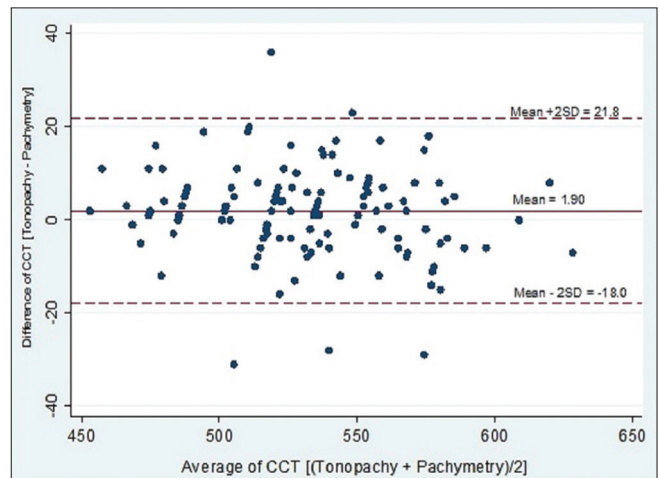

Figure 4: Bland-Altman plot for CCT by TP and UP for the refractive error group. Bland-Altman plot of CCT measured by TP and UP in refractive error group. The solid line represents mean difference of CCT between TP and UP (1.90 μm) and dotted lines represent upper (+21.8 μm) and lower (-18.0 μm) limits of agreement

largest study comparing the non-contact TP with the gold standard UP in children.

The mean CCT of our total study population by TP was 535.23 ± 35.54 μm and by UP was 534.03 ± 37.88 μm which is comparable with the values obtained by Lee *et al*.[29] They studied 614 Chinese children aged 7 to 15 years and found that average CCT was 532.96 ± 28.33 μm using fourier-domain optical coherence tomography. Hussein *et al*.[14] reported a mean CCT

of 549 ± 46 μm in 108 children aged 6 months to 14 years using UP and Wei *et al*.[11] reported the mean CCT of 554.19 ± 35 μm in 514 children aged 7–18 years by TP. Shih *et al*.[33] reported that the mean CCT was 567 ± 39 μm in 25 children from new born to 12 years of age using UP. The differences in the mean CCT in these studies might be due to the influence of the age group, the instruments used and also the ethnicity of study population. We could notice from our study that the mean CCT value in children aged 7 to 15 years are comparable to that of adult CCT values (526 to 545 μm).[34-36]

The relationship between CCT and age remains a controversial issue. We did not find any significant difference in the mean CCT of children based on the various age groups, in both the study groups and with both the instruments. Hussein *et al*.[14] and Shih *et al*.[33] found that mean CCT will increase with age. Hussein *et al*.[14] also reported that CCT reaches adult thickness by 5 to

Table 3: Comparison of CCT between male and female children using tonopachy and ultrasound pachymetry

CCT	Normal			Refractive error		
	Male (*n*=45)	Female (*n*=50)	P	Male (*n*=44)	Female (*n*=79)	P
Tonopachy						
Mean (SD)	545.67 (40.09)	530.08 (31.34)	0.04	539.20 (37.12)	530.33 (33.43)	0.18
Min-Max	461-673	449-610		468-624	454-625	
Ultrasound pachymetry						
Mean (SD)	546.69 (43.99)	528.60 (33.82)	0.03	537.36 (37.91)	528.39 (35.20)	0.19
Min-Max	454-685	452-616		465-616	452-632	

Table 4: Comparison of CCT in normal and refractive error group in different age groups using tonopachy and ultrasound pachymetry

CCT	Age Range			P
	7-9 years	10-12 years	13-15 years	
Tonopachy				
Normal	(*n*=31)	(*n*=32)	(*n*=32)	
Mean (SD)	545.13 (40.69)	537.25 (33.95)	530.25 (33.95)	0.27
Min-Max	461-673	490-625	449-609	
Refractive error	(*n*=37)	(*n*=40)	(*n*=46)	
Mean (SD)	532.00 (31.94)	536.82 (34.05)	531.83 (38.31)	0.77
Min-Max	473-588	463-624	454-625	
Ultrasound pachymetry				
Normal				
Mean (SD)	542.13 (46.01)	538.69 (39.48)	530.84 (33.59)	0.52
Min-Max	454-685	485-632	452-600	
Refractive error				
Mean (SD)	529.05 (34.15)	535.00 (36.08)	530.70 (38.65)	0.76
Min-Max	469-588	452-616	452-632	

Table 5: Comparison of CCT between different ranges of refractive error using tonopachy and ultrasound pachymetry

CCT	Refractive error			P
	<3D (*n*=61)	3-6D (*n*=31)	>6D (*n*=31)	
Tonopachy				
Mean (SD)	537.33 (35.71)	534.29 (32.58)	525.19 (35.24)	0.29
Min-Max	463-625	454-581	468-594	
Ultrasound pachymetry				
Mean (SD)	535.08 (37.59)	533.03 (34.39)	523.32 (35.38)	0.33
Min-Max	452-632	452-585	465-600	
P	0.07	0.48	0.37	

9 years of age. Similarly paediatric eye disease investigator group found that CCT in healthy children changes modestly with age, with most of the change occurring before 11 years of age.[10] Conversely, other investigators have not found any correlation of CCT with age. Our results were comparable with Wei *et al*.[11] and Zheng *et al*.[16] who also reported a non-significant association. The children included in our study were relatively older, with nearly 67-69% were more than 10 years of age and this might be the reason for our observation.

In our study, the mean CCT of males was found to be significantly greater than that of females, in both the study groups, which is in agreement with Zheng *et al*.[16] Wei *et al*.[11] and Lee *et al*.[29] reported no significant correlation with gender. Our results did not show a significant difference in CCT between normal and refractive error group of children. Also no significant change in CCT between different ranges of refractive error was noted. These findings were in agreement with the study by Lee *et al*.,[29] Prasad *et al*.[37] and Ortiz *et al*.[38] Paediatric eye disease investigator group observed a 1 µm thinner cornea on an average for each 1.00D myopic shift in refractive error.[10] Though our study showed no significant change in mean CCT between different ranges of refractive error, our study was not powered to find out these differences

and also the influence of various types of refractive errors. Our results show a non-significant correlation between CCT and axial length, which is in agreement with Lee *et al.*[29]

There are few studies comparing TP and UP in adults. Lee *et al.*,[29] found that TP overestimated the CCT by 13.9 μ when compared with that of UP and they concluded that TP is a reliable instrument for evaluating CCT in adults. Velis *et al.*[28] compared the TP and UP in normal adults and also in patients with glaucoma. They reported a marginal overestimation of CCT by TP in eyes with and without glaucoma. The possible explanation could be the displacement of the tear film by the applanation force of the probe tip of UP and the compression of the corneal surface, leading to lower pachymetry values than those obtained by the Scheimpflug imaging system in TP. Schiano *et al.*[30] found that CCT readings by TP were on average 13 μm thinner than those measured with UP in 62 eyes of normal adult subjects. Unlike these studies conducted in adults, we found an excellent agreement between the non-contact TP and the gold standard UP (95% confidence interval 0.97 to 0.98).

To our knowledge, ours is the first study in children comparing the CCT readings of TP with the gold standard UP. The major advantages of our study include a larger sample size, equal representation of males and females, employing masked technicians with good experience, assessing and comparing the CCT in normal children with those having refractive error. Our study is limited by the fact that we did not include children less than 7 years of age. Though our study showed no significant change in mean CCT between different ranges of refractive error, our study was not properly powered to find out these differences. Additionally we did not evaluate the effect of different types of refractive error on CCT values. The results are also not generalizable to other ethnic groups as our study included only south Indian cohort. We could not comment on the interobserver variation as we employed only one technician for each of the equipment. Additionally we did not evaluate the IOP obtained with TP as our population consisted of either normal children or children with refractive error and we excluded children with or suspicious of glaucoma in whom it might add value.

Conclusion

Tonopachy can be used as a screening tool for obtaining CCT measurements in both normal children and in children with refractive error. As the mean CCT was found to be similar to that of the adults, we can consider applying the same nomograms used in adults, for obtaining the CCT corrected IOP in children older than 7 years. However further validation of tonopachy is warranted to study the CCT in different types and ranges of refractive error and also the CCT in children less than 7 years of age. Further research is warranted to validate the IOP readings of tonopachy in children against the gold standard GAT and other available tonometers.

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