Central corneal pachymetry in Yemeni patients undergoing refractive surgery

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ABSTRACT

الأهداف: تقييم سماكة القرنية المركزية قبل الجراحة لمرضى قصر النظر و/أو الإستجماتزم الذين حضروا للجراحة الانكسارية في مستشفى باليمن.

الطريقة: أجريت هذه الدراسة المقطعية على 2304 مريض تتراوح أعمارهم من 50–18 عام مصابين بقصر النظر واللا بؤرة (الإستجماتزم) الذين حضروا للجراحة الانكسارية. اشتملت معايير الاختيار على غياب المرض أو الجزء الأمامي للقرنية، والجلوكوما، وأي عملية جراحية في العين. تم قياس سماكة القرنية المركزية باستخدام مقياس الموجات فوق الصوتية. كما تم تحليل البيانات من العين اليمنى.

النتائج: اشتملت الدراسة على مواطنين يمنين وكان أغلب العينة نساء (54.2%؛ 1248) معدل العمر، (±6.1) 26.74 عام، وتراوح المدى من 50–18 عام، كان متوسط سماكة القرنية المركزية (±31.62) 521.7، وتراوح المدى من 643–432 وحدة/مليميتر، لم يظهر هنالك أي تأثير للجنس على سماكة القرنية المركزية (p=0.567) ولم يختلف بين كلا العينين (p=0.371). زادت سماكة القرنية مع العمر، وارتبطت بالرؤية (p=0.027)، قراءات قياس القرنية (K1 ، K2) p<0.001 وارتفعت مع ارتفاع شدة قصر النظر (p=0.026).

خاتمة: كانت سماكة القرنية المركزية أقل لدى المرضى اليمنين بالمقارنة مع الشعوب الأخرى. يجب على جراحي الانكسار الحذر عند اختيار الطريقة المناسبة. حيث أن القرنية المتاحة للاستئصال تحدب القرنية الموضعي بالليزر محدودة. لذا يجب مناقشة العلاجات البديلة مثل (عملية ازالة الخلايا السطحية للقرنية وزراعة عدسات داخل العين لتصحيح الاضطرابات الانكسارية مع المرضى قبل الجراحة.

Objectives: To assess the preoperative central corneal thickness (CCT) of myopic and/or astigmatism patients presenting for refractive surgery in a tertiary hospital in Yemen.

Methods: In this hospital-based cross-sectional study, 2,304 subjects aged 18-50 years with myopia and myopic astigmatism who presented to the refractive surgery unit were recruited. Data for the current study was collected from our electronic pool of patients presenting to the refractive surgery clinics in Yemen Magrabi Hospital, Sana'a, Yemen, between January 2006 and December 2008. The inclusion criteria were absence of corneal or anterior segment disease, glaucoma, and any ocular surgery. Central corneal thickness was assessed by ultrasound pachymetry. Data from the right eye only was analyzed.

Results: All patients were Yemeni citizens, where the majority (1248; 54.2%) were women with a mean (±SD) age of 26.74 (±6.1), range 18-50 years. The mean (±SD) CCT was 521.7 (±31.62), range 432-643 µm. The measured CCT was independent of gender (p=0.567) and did not differ between both eyes (p=0.371). Corneal thickness increased with age, correlated to vision (p=0.027), keratometric readings (K1 , K2) (p<0.001 for both), and increased with the increase in severity of myopia (p=0.026).

Conclusion: Yemeni patients have thinner CCT compared to other populations. Refractive surgeons should be careful in choosing the suitable procedures. The available cornea for ablation in Laser-Assisted in situ Keratomileusis (LASIK) is very limited. Possible alternative treatments; namely photorefractive keratectomy (PRK) and phakic intraocular lens implantation options should be discussed with patients prior to surgery.

Saudi Med J 2014; Vol. 35 (1): 56-62

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Received 18th June 2013. Accepted 18th November 2013.

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Pachymetry to assess the human corneal thickness is an important investigation for patients seeking refractive surgery, and there is a growing interest in the use of different methods of pachymetry. Measurement of corneal thickness is essential prior to Laser-Assisted in situ keratomileusis (LASIK), photorefractive keratectomy (PRK), and phakic intraocular collamer lens implantation (ICL). Accurate measurement of central corneal thickness (CCT) during preoperative evaluation is helpful in the diagnosis of corneal disease, and helps in the determination of the amount of corneal tissue available for a safe and effective refractive surgery, the decision of whether to perform surgery, and rate of postoperative complications.[1,2] Thin CCT is a potential risk factor for ectasia after LASIK.[1,3] It is also a risk factor for glaucomatous optic neuropathy,[4] which is the second most common cause of blindness in Yemen.[5] Recently, there is increasing clinical interest in the potential role of CCT measurements in screening, diagnosis, and management of ocular hypertension and glaucoma patients as an addition to intraocular pressure (IOP) measurement by applanation tonometry.[6] Although we do not clearly understand the nature of thin CCT and its associated risk for glaucomatous diseases, researchers need to identify ethnic groups with thin CCT because these groups may be at a higher risk for developing glaucomas. In the literature, there is a number of recent studies that compare CCT across various races and ethnic groups, including: Caucasians, Asians, Hispanics, Africans, and African-Americans.[7-10] Some studies have also shown differences within subgroups of populations of the same ethnic origin, particularly among Asians and Africans.[7-8]

Interpretation of what is abnormal requires accurate identification of the normal range. Most published studies have evaluated the CCT of Caucasian, African-Americans, American Indians, Latinos, and East Asians. These studies have identified African-American persons as well as Japanese and Mongolian populations as having a thinner CCT compared to that of Caucasians.[7,10] Extensive review of literature using PubMed, Google Scholar, and King Saud University electronic access, revealed that there is limited published findings of CCT in the Yemeni population and there is only one report from the Eastern Mediterranean region.[11] Values based on the CCT, can easily be measured with a pachymeter to help in clinical decision-making for refractive surgery patients. Knowledge of the pattern and distribution of specific corneal thickness in the clinically normal eyes of Yemeni subjects is therefore, important. Refractive surgery such as LASIK is becoming more popular in Yemen in the last few years. When undertaking such surgery to correct myopia, CCT is one of the important findings taken into consideration when planning the procedure in order to prevent the cornea from becoming too thin after treatment and hence, the development of postoperative ectasia.[2,12] Therefore, the purpose of this study is to report the preoperative ultrasonic CCT readings on a relatively large number of Yemeni patients with myopia and myopic astigmatism presenting for refractive surgery. It also situates the specific Yemeni CCT range within the reported ranges from different regions in the literature.

Methods. Data for the current study was collected from our electronic pool of patients presenting to the refractive surgery clinics in Yemen Magrabi Hospital, Sana'a, Yemen, between January 2006 and December 2008. The current study follows a cross-sectional study design, and all data were limited to the results of the preoperative examination. The following demographic and clinical indices were collected from the preoperative examination chart; age, gender, uncorrected visual acuity (UCVA), and best-corrected spectacle visual acuity (BSCVA), manifest and cycloplegic refraction, slit-lamp biomicroscopic examination (Haag Streit, Koeniz, Switzerland) and fundus examination which was carried out through +90 dioptre Volk lens (EyeSupply USA Inc., Tampa, Florida, USA). Meanwhile, computerized corneal topography was taken using the TMS-2 machine (Tomey Co, Phoenix, AZ, USA).

Operators placed a drop of Benoxinate hydrochloride 0.4% (Benox, Eipico, Tenth of Ramadan, Egypt) for local anesthesia, and then acquired 3 sequential measurements of CCT. The CCT of the right eye followed by the left eye was measured with an ultrasound pachymetry using the Nidek US 1000 (Nidek Co,Tokyo, Japan). The thinnest CCT reading was considered the best value taken since the probe direction would be the most perpendicular to the cornea. Data from the right eye only was used in the analysis to avoid both potential selection bias and correlation bias. All the investigations were carried out by 2 ophthalmic technicians trained in these examinations.

Eligibility criteria for inclusion in this study were: adults 18 years of age or older; spherical equivalent myopia between plano and -24 diopters (D); cylinder of 6 D or less; no contact lens use for at least one week before assessment; no previous eye surgery, normal cornea and normal anterior and posterior segments (no ocular co-morbidity). Exclusion criteria included keratoconus or keratoconus suspect, pellucid marginal degeneration, any active ocular disease, patients who had previous refractive or other intraocular surgery, and women who

were pregnant or nursing. Non-Yemeni patients were also excluded from the study. The Research and Ethics Committee of Yemen Magrabi Hospital approved the study. All data were analyzed in a way to ensure patient confidentiality and privacy, and the study adhered to the tenets of the Declaration of Helsinki for research involving humans.

Data was collected, reviewed, and entered into a specifically designed database using Microsoft Access 2007®. Data management and cleaning then took place. Data were then imported, coded, and analyzed using the Statistical Package for Social Sciences version 19.0 (SPSS Inc., Chicago, IL, USA) and MedCalc® 11.6 (MedCalc Software bvba, Mariakerke, Belgium). Descriptive analysis was conducted to describe the major demographic and clinical indices using median and inter-quartile range. Regarding inferential analysis; Mann-Whitney U test was used to compare means, Spearman correlation coefficient was used to detect the correlation between CCT and other clinical indices, while Kruskal Wallis R test was used to compare means across different levels of myopia. A threshold *p*-value was set as 0.05 with a corresponding confidence interval of 95%, whereas a *p*-value of <0.05 was set to indicate statistical significance.

Results. The total number of patients seeking refractive surgery that satisfied our inclusion criteria and hence recruited in the current study was 2,304 patients. All recruited patients were Yemeni citizens with a mean (±SD) age of 26.74 years (±6.09) (range 18-50 years). Among recruited patients, females (1248 [54.2%]) slightly exceeded males (1056 [45.8%]). Our recruited sample was representative of the Yemeni population on a national level in terms of both geographic and literacy distribution. Geographically, it included referred patients from 21 governorates covering a wide range of the country. Most cases were from Amanat Al-Asema (1138; 49.4%), followed by Taiz (167; 7.2%), and then Aden (93; 4%), while both Hadramout and Hodeidah came in fourth place (82; 3.6%). In terms of occupation, most of our patients were students (722; 31.3%), followed by employees (470; 20.4%), and housewives (462; 20.1%), whereas schoolteachers were ranked in fourth place (162; 7%). In both geographic and occupational aspects, the rest of the categories were more or less equally distributed. The mean (±SD) CCT in our group of patients was 521.7 (±31.6) µm in the right eye and 521.9 (±32.1) µm in the left eye. The median (inter-quartile range) was 516.5 (500-544) for the right and 518 (500-545) for the left eyes. Although there was no significant difference between the right and left CCT values (p=0.371), to avoid potential bias, the right eye of each subject was selected for the analysis.

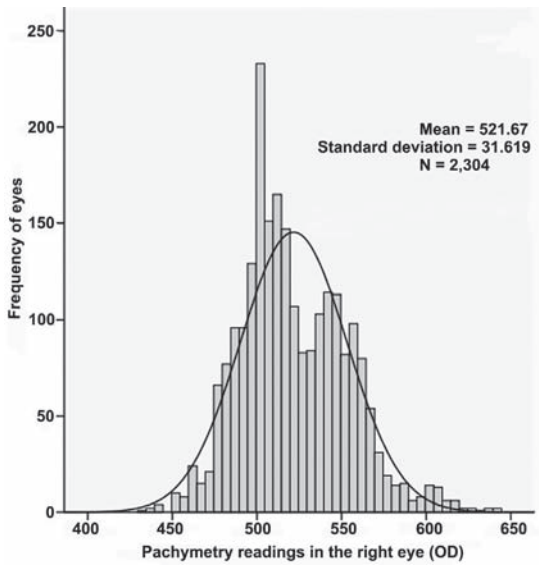

Figure 1 - Pachymetry readings in the right eye by Shapiro Wilk test.

Table 1 - Descriptive analysis of different clinical indices of the right eye.

Variables	Mean ± SD	Range (Min.-Max.)	Median	Interquartile range (25-75%)
CCT (µm)	521.67±31.62	(432 - 643)	516.5	(500-544)
Sphere (D)	-4.15±3.30	(-24 to 0)	-3.25	(-5 to -2)
Cylinder (D)	-1.03±1.04	(-5.5 to 0)	-0.75	(-1.5 to -0.5)
Spherical equivalent	-4.66±3.37	(-24 to 0)	-3.75	(-5.5 to -2.5)
Axis (°)	65.51±66.83	(0 - 180)	35	(5 - 120)
LogMAR	0.12±0.19	(0 - 1.60)	0.41	(0 - 0.18)
K1 (D)	44.91±1.56	(38.88 - 48.3)	44.94	(43.8 - 45.9)
K2 (D)	43.68±1.53	(37.27 - 47.73)	43.71	(42.7 - 44.7)

CCT - central corneal thickness, LogMAR - logarithm of the minimum angle of resolution, K1 - keratometry flat reading, K2 - keratometry steep reading

The mean right eye thickness was 521.7 (±31.6) µm within a range of 432-643 µm. This value was not normally distributed and significantly skewed towards the mode of 503 µm (Shapiro Wilks test for normality, $p<0.001$); therefore, alternative medians and inter-quartile ranges were used to describe and investigate the potential association between CCT and other clinical indices (**Figure 1**).

Both the mean (±SD), and median values of CCT tended to be thicker among older subjects (50 years and above), mean: 538.5 µm (±36.5 µm), median: 540.5 (509.8-560.3); however, this tendency was not statistically significant ($p=0.627$). **Table 1** shows descriptive details of the CCT and other related ophthalmic clinical indices of the total studied patients, while the age-specific distribution of CCT is fully demonstrated in **Table 2**. Gender-wise, the average CCT was almost the same for males (521 [±31.6]) and females (522 [±31.7]), while the median value for males was 516 (500-543.8), and for females was 517 (500-545) µm with no statistically significant difference between them ($p=0.570$). The least CCT measurement for the right eye was 437 µm for females and 432 µm for males. Testing the correlation between the right eye CCT and different clinical indices, there was a significant inverse correlation between CCT and logMAR visual acuity (R; -0.046, $p=0.027$), K1 reading (R; -0.12, $p<0.001$) and K2 reading (R; -0.12, $p<0.001$). Otherwise, CCT was not correlated with age ($p=0.734$), sphere ($p=0.233$), cylinder ($p=0.18$), axis ($p=0.957$), or spherical equivalent ($p=0.330$). Comparing the CCT measurement among different levels of myopia, the mean (±SD) CCT decreased as the power of myopia increased, and such a trend was statistically significant ($p=0.026$) as shown in **Table 2**. Comparing our findings within similar findings from other countries, the mean CCT value seems to be lower among the Yemeni population than other populations. **Table 3** shows pachymetric readings in different countries.

Table 2 - Distribution of central corneal thickness by different age categories.

Variable	Right eye		
	Median	Interquartile range (25-75%)	*P*-value
Age, years			
<20	518	(500-548)	0.627
20-29	516	(500-543)	
30-39	517	(500.8-546.3)	
40-49	514.5	(500-545.5)	
50+	540.5	(509.8-560.3)	
Gender			
Male	516	(500-543.8)	0.570
Female	517	(500-545)	
Level of myopia			
<-5 Diopter (D)	516	(500-543)	0.026
-5<-10 D	520	(501-547)	
≥-10 D	512	(495-543)	

Discussion. This study attempts to determine normal values of CCT pachymetric measurements in Yemeni patients. These measurements are crucial because they document the CCT in a large cohort of patients undergoing refractive surgery for myopia. In our refractive surgery unit, we offer LASIK, PRK, and phakic intraocular lens implantation, namely, ICL (intraocular collamer lens, STAAR Co, STAAR Surgical Company, Monrovia, CA, USA) depending on the refractive error, corneal topography, and CCT. Several methods can be used to obtain reliable measurements of corneal thickness. The most commonly used approach is the ultrasonic method due to its simplicity, reproducibility, low cost, small variability after corneal refractive surgery, and good predictability compared with other available systems.[13] Other alternative instruments used to measure corneal thickness use

Table 3 - Average pachymetric readings in different countries.

References	Year of publication	Sample size (eyes)	Country	Central corneal thickness (µm)	Range (µm)
Price et al[25]	1999	896	USA	550	472 - 651
Ambrosio et al[35]	2003	1392	USA	556	454 - 669
Kunert et al[24]	2003	1214	India	519.9	420 - 640
Fam et al[33]	2006	1428	China	534.5	405 - 684
Ntim-Amponsah et al [17]	2007	169	Ghana	533.3	435 - 611
Mercieca et al[8]	2007	70	Nigeria	532.0	--
Hashemi et al[18]	2009	800	Iran	555.6	--
Al-Mezaine et al[11]	2009	982	Saudi Arabia	543.8	458 - 645
Gros-Otero et al[36]	2011	357	Spain	548.2	487 - 609
Bamashmus et al	Current study	2304	Yemen	521.7	432 - 643

optical methods such as the Orbscan Analyzer (Orbscan Inc, Salt Lake City, UT, USA) and Scheimpflug camera system (Pentacam, Oculus Inc, Lynnwood, Washington, USA).[14] Many disparities exist between instruments; therefore, differences in CCT measurements should be reviewed considering the type of instrument used.[15] There are several limitations to the accuracy of the ultrasonic technique such as the inaccurate positioning of the probe and the difficulty in finding the thinnest area.

Doughty and Zaman[16] published a meta-analysis of the literature pertaining to corneal thickness, based on more than 300 articles. They concluded that the mean CCT of eyes reported as 'normal' was 534 μm. The CCT was found to be significantly thinner in several ethnic groups such as in African-American, Mongolian, Indian, North African, and Israeli populations compared with other populations. Our findings show that the mean (±SD) CCT in our cohort of patients presenting for refractive surgery aged 18-50 years was 521.67 (±31.62) μm within a range of 432-643 μm. There was no difference in CCT values between the right and left eyes. Similar to our findings, Ntim-Amponsah et al[17] reported no difference between the right and left eyes. Meanwhile, our study group has on average relatively thinner CCT than the average CCT reported in the literature. Comparing CCT across different age groups, the central cornea was apparently thicker; however, insignificantly in the fifth decade of life. These findings agree with Ntim-Amponsah et al.[17] However, Aghaian et al,[7] Hashemi et al,[18] and Lekskul et al[19] reported decreased CCT values with increasing age in China, Iran, and Thailand. Additionally, a gradual decrease in corneal thickness was detected with increasing age in the Japanese,[20] while other studies found no change in corneal thickness with increasing age.[21] Among our series, no gender difference was noted, and similar findings were reported in most of the literature.[17,22] Nevertheless, Mercieca et al[8] found that males had significantly thicker CCT than females, while reversely, Torres et al[10] reported that in his series, females had thicker CCT than males.

Racial differences have not been addressed adequately in the literature; however, many studies detected that there is a difference as Caucasian populations have thicker corneas than non-Caucasians. It was noted in different studies from the USA that African American patients have thinner corneas compared with Caucasians.[23] Moreover, Mercieca et al[8] found that the CCT was similar between populations living in sub-Saharan Africa, African Americans, and Afro-Caribbeans. In our facility, visiting refractive surgeons from Egypt and Saudi Arabia have noticed that CCT in Yemeni patients is much thinner compared with the average value in their countries. Our major finding was detecting a lower mean corneal thickness (521.67 μm) in Yemeni patients compared with findings reported in the literature from different populations except for a study conducted in India,[24] which reported thin corneas among the Indian population. Having an adequate corneal thickness is crucial to prevent leaving the corneal bed too thin after LASIK treatment. The residual stromal bed depth is highly dependent on preoperative CCT, the thickness of the flap, and the depth of the laser ablation. We believe that it is very important to calculate residual bed thickness in each case before surgery, particularly when using thicker flaps. It is essential to measure preoperative CCT in patients seeking refractive surgery, and also to perform an intra-operative measurement for those undergoing LASIK before and after cutting the flap. Additionally, it is also necessary, to a lesser extent, to perform intra-operative pachymetry for those undergoing PRK. Earlier in our practice, we used to leave a residual corneal bed of 250 μm as per previous recommendations and studies.[25] The U.S. Food and Drug administration (FDA) have recommended that the residual corneal thickness in the bed should not be less than 250 μm.[26] Recent studies recommended leaving at least 300 μm residual stromal corneal bed and accordingly, we changed our practice towards this recommendation.[12] Ectasia were reported in beds thinner than 250 μm;[12] and the lower limit for stable bed thickness is still unknown.[1,2]

In our practice, we used to utilize Moria 2 microkeratome (Moria Co, Antony, France) reusable heads that give a flap thickness of 130-160 μm. However, in the last 2 years we started using the single use 90 μm Moria 2 head, which produces 90-100 μm flaps.[27-29] It should be noted that variability in resection depths with the Moria 2 and other microkeratomes have been reported.[27] As a result of this variability in resection depth, surgeons should consider leaving a convenient margin of error when calculating the planned resection in LASIK. We suggest, as previously mentioned, that the surgeon should measure the CCT pre- and post-performing the flap. Different lasers remove tissue at different ablation depths per diopter of treatment.[30] Our excimer laser machine (NIDEK EC-5000, Nidek Co, Inglewood, CA, USA) ablates 12-15 μm for each diopter. Eventually, all these factors should be taken into consideration.

With these thin corneas in Yemeni patients, we used a minimum CCT of 480 μm and 250 μm as residual stromal bed for LASIK candidates in the first 2 years.

However, after the newly published recommendations to prevent and decrease the risk of ectasia, we increased the minimum CCT to 510 μm, and the residual stromal corneal bed to 300 μm.[12] This approach helped to significantly increase the safety of patients undergoing LASIK, but in general the number of LASIK cases decreased and there was an associated increase in the number of cases that had PRK and phakic intraocular lens implantation. Many studies have shown the importance of corneal thickness in determining the value of readings with the Goldmann applanation tonometer.[31] The Goldmann applanation tonometer is only accurate theoretically for CCT at 520 μm; a cornea 70 μm thicker results in a 5 mmHg higher reading and a cornea 70 μm thinner results in a 5 mmHg lower reading.[32] With this under- or overestimation of intraocular pressure (IOP) ranging almost 16 mmHg, CCT have important implications in regards to IOP change, diagnosis, and management of glaucoma.[31]

Our findings show that there is a significant association between CCT and visual acuity as measured by LogMAR, K1, and K2 readings. These findings are in parallel with findings of a study by Francis et al,[32] which reported a highly significant correlation between CCT and the K readings. Similarly, Torres et al[10] found that the spherical equivalent is a significant predictor of the corneal thickness among the American population. However, although Fam et al[33] and Channa et al[34] reported no association between CCT and the severity of myopia, we were able to detect a significant difference in CCT across different levels of myopic severities; this may suggest a decreasing trend in CCT with an increase in the severity of myopia.

Although the current study has tried to provide a comprehensive view of the pachymetry pattern in Yemen, it faced several limitations including the fact that: cases with corneal ectasia cannot be easily ruled out only by topography and additional imaging such as Orbscan or pentacam may be necessary to fulfill that. Moreover, although the current study enjoys a relatively convenient sample size, it is still a hospital based study covering a relatively short time duration, which may slightly deviate the findings from the true situation in the community, and suffers from other hospital-based studies' limitations. Future studies should cover a longer period of time, compare different procedures, and be conducted in a multi-center fashion.

In conclusion, this study highlights the fact that Yemeni patients have thinner corneas and that LASIK surgeons should adhere to the international recommendations of using a minimum CCT value of 510 μm and leaving a 300 μm residual stromal bed, and to use other alternative procedures for cases with thin corneas; namely, PRK and phakic intraocular lens implantation. It is important to measure CCT before surgery and intra-operatively, and treatment plans should be chosen accordingly.

Acknowledgment. *The authors gratefully acknowledge the administrators and staff of Yemen Magrabi Hospital for permitting us to conduct this study and for their valuable contribution in patients' care during our study. We also wish to thank Mr. Fahim Al-Horeibi and Mr. Fathi Al-Hamadi for the topography and pachymetry measurements. The authors also value the editing, formatting, and review of this manuscript by Ms. Priscilla Gikandi, Research Assistant, King Saud University, Riyadh, Saudi Arabia. Lastly, we appreciate the efforts and cooperation extended to us by all patients in this study.*

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