Special Focus, Glaucoma

Validating the use of U-tool as a novel method for measuring the corneal diameter in infants screened for congenital glaucoma

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Purpose: The Castroviejo caliper is routinely used for measuring the corneal diameter in patients with primary congenital glaucoma, but needs an examination under anesthesia (EUA) or sedation. A simple U-shaped tool was devised to aid in the estimation of the corneal diameters of patients in settings where an ophthalmic caliper is not available or EUA is not feasible. **Methods:** Infants presenting to the congenital glaucoma clinic posted for EUA were recruited. The demographic details of the patients such as age, sex, and diagnosis were noted. A simple U-shaped tool was devised using three Schirmer strips or a printable ruler. Before the patient underwent a EUA, the corneal diameters were measured using the U-tool. During EUA, corneal diameters were measured using the Castroviejo caliper. **Results:** The mean age of infants was 6.7 ± 3.39 months (R = 1–12). The mean corneal diameter measured using the U-tool was 13.29 ± 1.33 mm and with Castroviejo caliper was 13.18 ± 1.39 mm. The difference between the corneal diameters measured using the two techniques was −0.114 mm with the Bland–Altman plot 95% Limits of agreement (LoA) from −0.965 to 0.737 mm. Corneal diameters measured with both instruments had a good correlation (Pearson's correlation coefficient = 0.95, $P < 0.001$). **Conclusion:** U-tool can be used for screening congenital glaucoma by first-contact physicians or optometrists. It can also be used by ophthalmologists when EUA is delayed.

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Assessment of the corneal diameter is important for cataract and refractive surgeries, diagnosis of various congenital anomalies of the cornea, and especially for congenital glaucoma. Congenital glaucoma is the third major cause of treatable childhood blindness in India.[1] The prevalence of congenital glaucoma varies from 1 in 1250 live births in Slovakian gypsies to 1 in 30,200 live births in the Republic of Ireland.[2,3] In India, the prevalence of congenital glaucoma was found to be 1 in 3300 live births.[4] Primary congenital glaucoma is characterized by a large eyeball, increased corneal diameter, corneal haze, and increased intraocular pressure. Corneal diameter is a very sensitive indicator for diagnosis and monitoring the progression of the disease when compared to other parameters such as axial length.[5] In congenital glaucoma, an early diagnosis and intervention can aid in maintaining the vision and prevent progression to blindness. According to Dandona *et al.*,[6] in India, primary congenital glaucoma presents to ophthalmologists only in a very advanced stage with near-total or total cupping of the optic nerve head and severe corneal edema. Apart from measuring the intraocular pressure, the corneal diameter measurement also is an essential part of monitoring the progression of congenital glaucoma.[7] Various methods are available for assessing the corneal diameters, including the use of Castroviejo caliper and digital vernier caliper and anterior segment imaging systems such as orbscan, pentacam, Galilei, eyesys, IOL master, and lenstar.[8-11] These anterior segment imaging devices cannot be used in infants owing to low cooperation, and the use of calipers requires administration of anesthesia to infants. It would be of great benefit if the first-contact health worker such as general physicians at the primary health center, the obstetricians conducting delivery, or the pediatricians were trained to conduct a basic screening for congenital glaucoma in neonates and infants and refer the doubtful cases at the earliest to an ophthalmologist. Herein, we have described the use of a simple U-shaped tool that was devised intending to estimate the corneal diameter in settings where an ophthalmic caliper is not available and EUA is not immediately feasible. The authors have previously described the beneficial role of this U-tool to measure and monitor the size of corneal ulcers during the COVID-19 pandemic via the teleconsultation mode when

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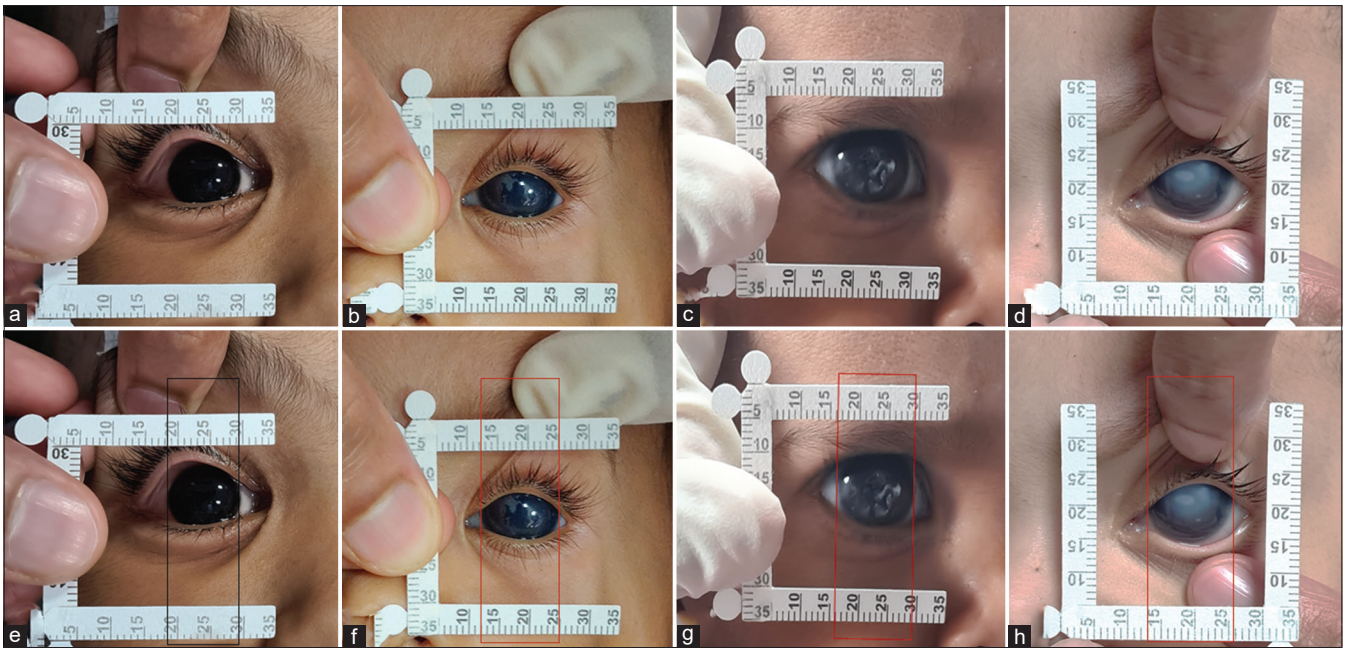

Figure 1: Placement and measurement of corneal diameter using a U-tool in the normal eye (a, e), primary congenital glaucoma (b, c, f, g), and Peter's anomaly (d, h)

physical out-patient visits were limited due to the ongoing restrictions during the pandemic.[12]

Methods

After obtaining ethical clearance, we conducted a cross-sectional observational study in a tertiary eye care center in North India. The study was conducted in adherence to the Declaration of Helsinki. Infants presenting to the congenital glaucoma clinic who were posted for EUA were recruited for the study. Consent was taken from the parents or the legal guardian. Patients' demographic details such as age, sex, and diagnosis were noted. Before undergoing EUA, the corneal diameter was measured using U-tool and later reassessed using the Castroviejo caliper. One eye of each patient was randomly chosen for analysis. Randomization was done by sealed envelope online software (London, United Kingdom).

Measurement of corneal diameter with U-tool

The U-tool was designed using three Schirmer strips (made of Whatman filter paper 41) glued to each other with an adhesive as shown in Fig. 1. Alternatively, one may use a printable ruler (readily available on the Internet). When the child was asleep, the eyelids were retracted gently by the attendant and U-tool was placed at the level of the orbital rim or just above it [Fig. 1a, 1b, 1d]. In a cooperative child, U-tool was placed directly at the level of the orbital rim either resting on it or just above it as shown in Fig. 1c. If the child was uncooperative and not asleep, a sedative was given. Digital photographs were captured with a smartphone. Care was taken to place the smartphone and U-tool parallel to the eye. Using the image editing software in the smartphone, a rectangular frame was drawn along the limbus extending till the U-tool.[12] The first reading was calculated [Fig. 1e–h] by counting the markings on the U-tool. To avoid errors in measurement, it should be ensured that the line in the rectangle is parallel to the markings in U-tool and tangential to the limbus [Fig. 1a–d]. As we do not place the U-tool on the corneal limbus to measure the corneal diameter, a correction factor must be added for the minification caused due to distance. The distance from the corneal limbus to U-tool was measured using a ruler in all the eyes and was approximately 16 mm on average (15–17 mm). To calculate the correction factor for minification caused due to distance (16 mm), an experimental setup was carried out. Two transparent rulers were placed one above another, 16 mm apart and parallel to each other. The lower ruler was considered to be the cornea, and the upper ruler was considered to be a U-tool. A photograph was taken on the smartphone paced above the rulers and care was taken to avoid parallax error. The length of the lower ruler corresponding to the length of the upper ruler at 2.5, 5, 7.5, and 10 cm were calculated (by drawing the rectangle frame in the image editing software of smart phone[12]). The correction factor was calculated by dividing the length of the lower ruler by 2.5, 5, 7.5, and 10, respectively, for 2.5, 5, 7.5, and 10 cm length in the upper ruler. Thus, at 16-mm distance, the correction factor was deduced to be approximately 1.15. The corneal diameter was calculated by multiplying the first reading with the correction factor (1.15).

Statistical analysis

Data were entered in Microsoft excel and either of the two eyes was randomly chosen for analysis. SPSS version 23 was used for statistical analysis. The normal distribution of data was tested by the Kolmogorov–Smirnov test. The horizontal corneal diameter measured with the U-tool and the caliper was compared using paired *t*-test. Pearson correlation coefficient was used to calculate the correlation between the two methods. The Bland–Altman plot was used to statistically calculate the limits of agreement (LoA) between the corneal diameter measured with U-tool and caliper.[13,14] It gives a 95% confidence interval of the limits of agreement and the formula for this has been given by Bland and Altman.[13] $P < 0.05$ was considered to

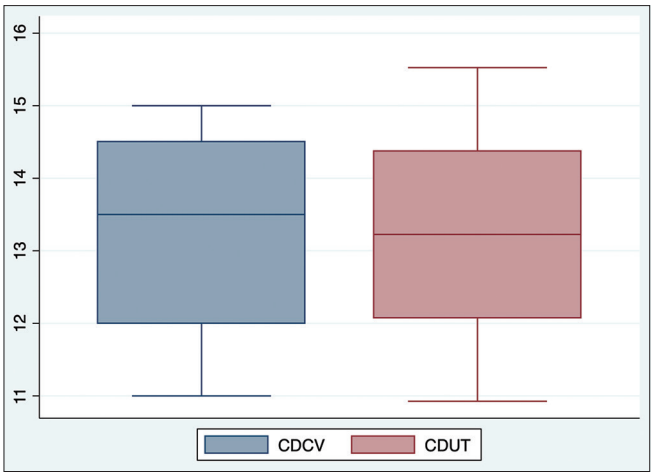

Figure 2: Box and whisker plot showing the distribution of horizontal corneal diameter measurements for the U-tool (CDUT) and Castroviejo caliper (CDCV) in mm

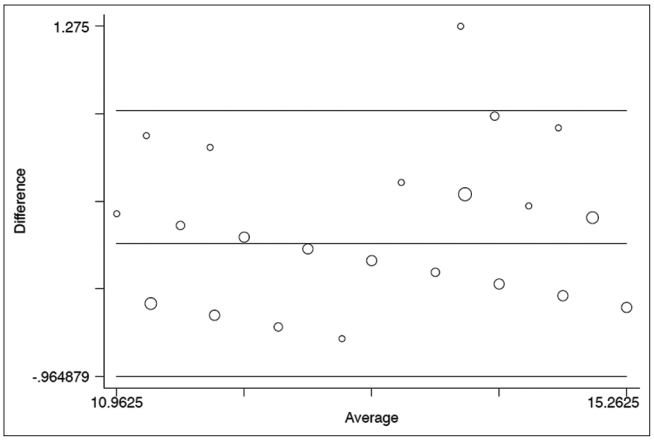

Figure 3: Bland–Altman plot. The differences between the two methods are plotted against the mean values. The upper and lower lines represent the 95% LoAs

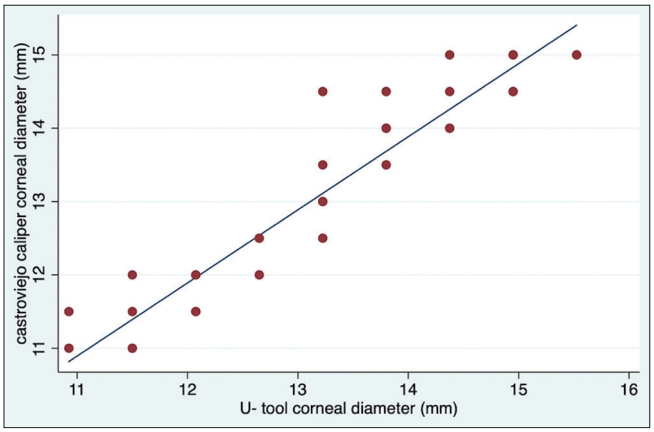

Figure 4: Scatter plot and Pearson correlation analysis for corneal diameter measurements obtained with U-tool and Castroviejo caliper

be statistically significant. A difference of > 0.5 mm between the two methods was considered clinically relevant.

Results

Fifty eyes of 50 patients were analyzed. The mean age of infants was 6.7 ± 3.39 months (R = 1–12 months). Among the cohort, 33 eyes (66%) had primary congenital glaucoma, 11 eyes (22%) had anterior segment dysgenesis, 4 eyes (8%) had post-cataract surgery glaucoma, and 2 eyes (4%) were normal. The mean corneal diameter measured with U-tool was 13.29 ± 1.33 mm and that with Castroviejo caliper was 13.18 ± 1.39 mm [Fig. 2]. The difference between the corneal diameters measured by the two techniques was −0.114 mm with the Bland–Altman plot 95% LoA from −0.965 to 0.737 [Fig. 3]. Corneal diameters measured with both instruments had a good correlation [Pearson's correlation coefficient (r) =0.95, $P < 0.001$, Fig. 4]. Further, 72% (36 eyes) of the eyes had a difference within ± 0.5 mm, 9 eyes (18%) had a difference less than −0.5 mm and 5 eyes (10%) had a difference of more than 0.5 mm. U-tool measurements were taken while sleeping in 36 (72%) infants, using sedatives in 9 (18%) infants, and while awake in 5 (10%) infants.

Discussion

In our study, the corneal diameters measured with U-tool had a good correlation with the values measured with Castroviejo caliper. Measuring corneal diameter is of paramount importance in screening for primary congenital glaucoma. It is usually measured using a Castroviejo caliper (a contact procedure that needs cooperation/EUA) as anterior segment imaging devices cannot be used in infants and early childhood. A major advantage of the U-tool being that EUA is not required. Many other noncontact methods that do not require EUA were tried in the past with limited success.[5,7,15,16]

Kiskis *et al*.[5] used a transparent plastic gauge for rapid measurement of congenital glaucoma. Lagrèze *et al*.[15] described a noncontact method to measure corneal diameter in children with the aid of a ruler, digital camera, and computer. Although their methods were reproducible, the correction factor for minification caused was not taken into consideration. If an object's size is measured by placing a ruler at a certain distance from it, a correction factor must be applied to correct for the minification produced due to the distance between them. Moreover, no comparison and correlation with the most acceptable technique, that is, Caliper method were evaluated to ascertain the reliability. Robinson *et al*.[7] compared the photographic method of measuring corneal diameter with calipers and a plastic ruler. The photographic method had a good correlation with calipers but not with the plastic ruler method as the correction factor for distance was not applied. This highlights the importance of applying the correction factor to improve the precision of readings.

Considering a difference of ± 0.5 mm within the acceptable range, 72% of the readings taken with the U-tool were in the acceptable range. The U-tool readings overestimated corneal diameter in 18% of eyes and underestimated corneal diameter in 10% of eyes. U-tool measurement was possible in the awake or sleeping state without the use of sedatives in 82% of the cases. This shows that U-tool can be practically used in about 80% of infants without difficulty or need of sedatives.

While obtaining U-tool reading with the smartphone using an image editor, a rectangle drawn across two arms of the

U-tool minimized parallax error. Furthermore, the U-tool is lightweight, easily constructed, and disposable; thus, it can be used in intensive care units to avoid the possible spread of hospital-acquired infections in the child. In addition to the corneal diameter, the photograph also gives an idea about corneal clarity and record for future follow-up and which could be used in Telemedicine services.[17]

Limitations of this technique include the following. Measurement error could occur if the U-tool or phone is not placed parallel to the eye while taking photographs. Placement of U-tool far away from the eye could cause a measurement error. Sedatives might be required in a noncooperative child. In our study, 18% of the infants required sedatives. Stretched limbus in congenital glaucoma could also cause variation in the measurement of corneal diameter by different observers. This study was done in Asian eyes and the correction factor might differ according to different population groups.

Conclusion

U-tool can be used for screening congenital glaucoma by first-contact physicians and optometrists. It can also be used by ophthalmologists when EUA is delayed due to the unstable medical condition of the patient. However, evaluation of other parameters such as intraocular pressure, axial length, and optic nerve head is imperative for establishing the diagnosis of congenital glaucoma which are best assessed under sedation or anesthesia, where Castroviejo calipers would be preferred over U-tool to measure the corneal diameter.

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Conflicts of interest

There are no conflicts of interest.

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