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Is the PASCAL®-Tonometer suitable for measuring intraocular pressure in clinical routine? Long- and short-term reproducibility of dynamic contour tonometry

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PURPOSE. *Dynamic contour tonometry (DCT) is a new technique to measure intraocular pressure (IOP). In several studies no correlation between IOP values and corneal thickness was shown with DCT. This is in contrast to the gold standard, Goldmann applanation tonometry (GAT). The authors evaluated the reproducibility (RP) of DCT compared to GAT, a prerequisite for its introduction into clinical routine.*

METHODS. *IOP was measured with both DCT and GAT in 50 subjects with normal cornea. To evaluate the short-term RP, four DCT and four GAT measurements were performed at day 1 in a randomized order. Long-term RP was determined by one additional measurement per method at day 2, 5, and 8.*

RESULTS. *The short-term RP was defined as the mean value of all standard deviations (SD) of the individual measurements at day 1. Short-term RP was 1.1 mmHg for GAT and 1.2 mmHg for DCT. For long-term reproducibility, mean SD was 1.2 mmHg for GAT and 1.5 mmHg for DCT. Bland-Altman revealed a good agreement of the two methods. However, mean DCT values were on average 0.8±1.1 mmHg higher than GAT values. A significant correlation was observed between GAT and CCT (r^2=0.15, p=0.006), but not between DCT and CCT (r^2=0.032, p=0.21).*

CONCLUSIONS. *Short- and long-term reproducibility of DCT is comparable to that of GAT. GAT is more affected by CCT than DCT, measuring higher IOPs in eyes with higher central corneal thickness. (Eur J Ophthalmol 2008; 18: 39-43)*

KEY WORDS. *Dynamic contour tonometry, Glaucoma, Goldmann applanation tonometry, Reproducibility*

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INTRODUCTION

Goldmann applanation tonometry (GAT), the present gold standard for intraocular pressure (IOP) measurements, harbors various sources of error (1). Especially the influence of central corneal thickness (CCT) on GAT measurements is increasingly discussed. It has been suggested that GAT falsifies the IOP in humans with very thin or thick CCT (2, 3) and in patients who underwent laser-assisted in situ keratomileusis (LASIK) (4, 5). In the Ocular Hypertension Treatment Study, a thinner CCT was found to be a risk factor for the development of primary open-angle glaucoma (6). Several studies showed that patients with ocular hypertension have thicker corneas (7, 8). Therefore it was supposed that IOP might be overestimated in this patient group when using GAT. On the contrary, patients with normal-tension glaucoma (NTG) were found to have a lower CCT than the general population. Performing GAT measurements in these patients might result in an underestimation of IOP. Numerous algorithms for the correction of IOP have been developed, but each of these correction formulas harbors its difficulties (2).

Dynamic contour tonometry (DCT) is a novel method for measuring IOP that promises to be independent of

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corneal qualities. This raises hope that the real IOP can be determined noninvasively. Several studies, e.g. in eyes that underwent LASIK, have indeed shown that DCT appears to measure IOP independently of corneal biomechanical properties (9, 10).
However, before introducing a novel measurement device (DCT) into the clinical routine, which has the capability to replace the current gold standard for IOP measurements (i.e., GAT), it is necessary to ascertain its reproducibility. Therefore we determined the long- and short-term reproducibility of DCT. In addition, the according results were compared to the reproducibility of GAT defined within the same group of subjects.

METHODS

Fifty eyes of 50 subjects with normal corneas (21 men, 29 women; mean age 36±17, range 18–79 years) were included in this prospective study. The study was approved by the local ethics committee and was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki. All persons gave their informed consent prior to their inclusion in the study.
Exclusion criteria were corneal abnormalities (such as edema, scars, astigmatism >3 diopters), IOP >30 mmHg, and recent (<4 weeks) history of ocular surgery. All measurements were carried out by the same experienced ophthalmologist. All eyes were examined at the same time of the day to avoid changes due to diurnal fluctuation of IOP. Both methods for IOP measurement, DCT and GAT, have been described in detail elsewhere (11, 12).
Reproducibility was evaluated by calculating the arithmetic mean of all standard deviations (SDs) derived from the respective short- and long-term IOP measurement sequences.

Assessment of short-term reproducibility

At day 1 CCT was optically measured by means of the ORBSCAN II (Bausch & Lomb) first. Prior to the IOP measurement, the cornea was anesthetized with Thilorbin (oxybuprocaine hydrochloride 4 mg/mL, fluorescein-sodium 0.8 mg/mL; Alcon Pharma, Freiburg, Germany). All measurements were performed on right eyes only. During the measurement, subjects were asked to keep both eyes open, breathe normally, and to fixate a point in the distance behind the examiner. As recommended by the manufacturer only DCT measurements of quality (Q) 1 to 3 (Q1 = very good quality, Q3 = acceptable quality, Q5 = very bad quality of measurement) were included.
The IOP readings were not masked to the investigator. Therefore, IOP was determined by DCT (D; SMT Swiss Microtechnology, Port, Switzerland) and GAT (G; Haag-Streit, Koeniz, Switzerland) on day 1 in one of the four randomly selected orders: GGGGDDDD, DDDDGGGG, GGDDGGDD, or DDGGDDGG.
This randomly selected examination scheme was also chosen to avoid systematic errors like a change of IOP induced by applanation of the cornea.

Assessment of long-term reproducibility

For long-term reproducibility, IOP was assessed only one time with each technique in the same eye at day 2, 5, and 8. Thus, the order of the measurements was randomized again at day 2. The results of this randomization procedure were also used for subsequent visits: if the examination was started with DCT at day 2, GAT was performed first at day 5 and second at day 8.

Statistical analysis

Paired *t* test and correlation analysis were performed. A p value < 0.05 was considered to be statistically significant. Data are expressed as mean ± SD. The different measurement methods were compared for bias and agreement: for analysis of individual pairs of DCT and GAT measurements, the difference between the two methods (GAT–DCT) was plotted against the mean of the two methods (GAT+DCT) according to Bland and Altman (13). In the Bland and Altman plot the doubled lower and upper SD and the mean is given. The doubled lower and upper SD demonstrates the margin of deviation concerning the agreement of both methods. The mean shows the average deviation of the IOP values of one method in comparison to the other method.

RESULTS

Intraocular pressure

Mean IOP at day 1 was 14.7±1.9 mmHg for GAT and 15.5±2.3 mmHg for DCT. IOP values taken by DCT were on average 0.8 mmHg higher than GAT values. This result

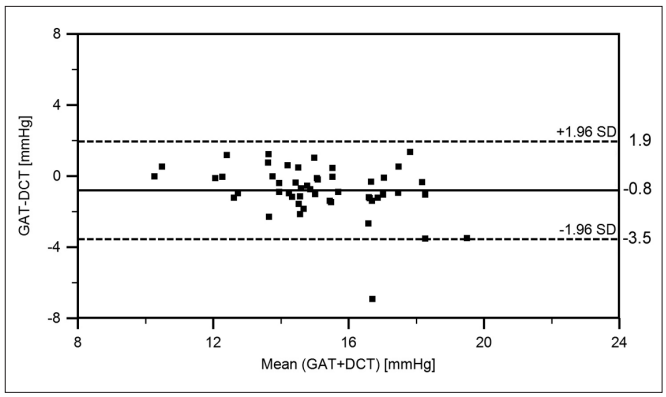

Fig. 1 - *Bland and Altman plot of the difference between Goldmann applanation tonometry (GAT) and dynamic contour tonometry (DCT) vs the mean of GAT and DCT and doubled lower and upper standard deviation (mean intraocular pressure values of day 1).*

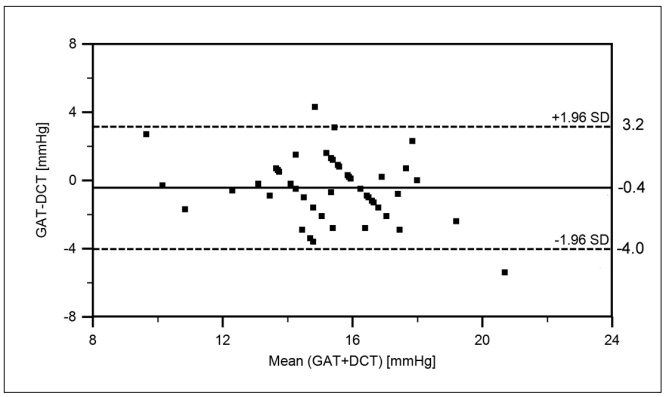

Fig. 2 - *Bland and Altman plot of the difference between Goldmann applanation tonometry (GAT) and dynamic contour tonometry (DCT) vs the mean of GAT and DCT and doubled lower and upper standard deviation (intraocular pressure values of day 2).*

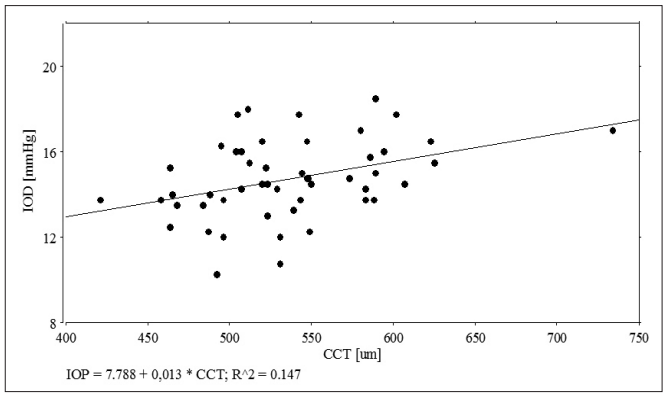

Fig. 3 - *Regression plot of Goldmann applanation tonometry vs central corneal thickness with regression equation and coefficient of correlation.*

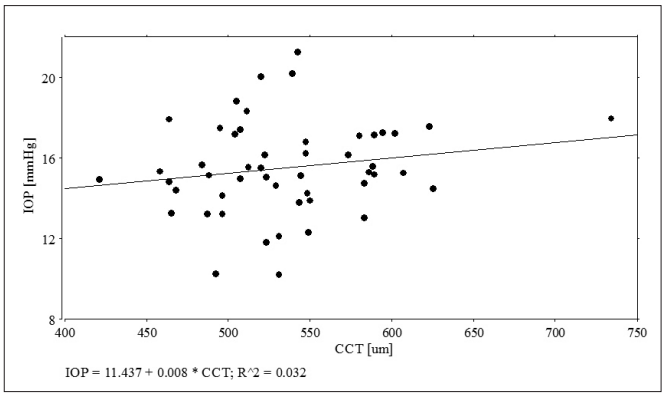

Fig. 4 - *Regression plot of dynamic contour tonometry vs central corneal thickness with regression equation and coefficient of correlation.*

corresponds to that of the long-term period: If IOP values of all days were taken into consideration, mean IOP was 14.8±1.8 mmHg for GAT and 15.6±2 mmHg for DCT.

A good agreement between GAT and DCT could be demonstrated by Bland and Altman analysis: 95% of the difference between GAT-DCT of day 1 was found within the interval (–3.5; +1.9 mmHg) (Fig.1). For days 2, 5, and 8, the 95% confidence interval was (–4.0; 3.2 [day 2 (Fig. 2)], –4.4; 3.0 [day 5], –4.9; 3.4 [day 8] mmHg), respectively. Comparing the mean IOP of the second (t2), third (t3), or fourth (t4) examination to baseline (t1; all measurements carried out on day 1), a significant decrease in IOP could be shown for DCT (16.1[t1]; 15.6[t2], p=0.026; 15.2[t3], p=0.007; 15.1[t4] mmHg, p=0.006), but not for GAT (14.8[t1]; 15.0[t2], p=0.28; 14.6[t3], p=0.21; 14.5[t4], p=0.1).

A significant correlation was observed between GAT and CCT (p=0.006, r^2=0.15, mean IOP values of day 1), but not between DCT and CCT (p=0.21, r^2=0.032, mean IOP values of day 1) (Figs. 3, 4).

Short-term reproducibility

The mean SD of the four measurements taken at day 1 was calculated across individual subjects to determine the short-term reproducibility, and was 1.2 mmHg for DCT and 1.1 mmHg for GAT. If measurements with quality 3 were excluded (n=37), the mean SD of DCT values decreased to 0.8 mmHg. When including only measurements with quality 1, mean SD was 1.0 mmHg (n=21).

Long-term reproducibility

Long-term fluctuation determined as the mean SD of the measurements assessed at days 1 (mean IOP of the four measurements), 2, 5, and 8 was 1.5 mmHg for DCT and 1.2 mmHg for GAT. When excluding quality 3 from the analysis (n=45), mean SD decreased to 1.3 mmHg. If only Q1 was taken into account, long-term fluctuation of IOP even decreased to 1.1 mmHg (n=24).

Neither for GAT nor for DCT was a correlation between short-term or long-term reproducibility and IOP observed (short-term: GAT: r^2=0.0075, DCT: r^2=0.0329; long-term: GAT: r^2=0.0022, DCT: r^2=0.0072).

DISCUSSION

The most important factors for the use of a medical instrument in clinical routine are its good agreement with the real value and its reproducibility. Our study demonstrates a good reproducibility of DCT both for short-term and long-term reproducibility. The results underline that DCT equals the current gold standard, GAT, in terms of reproducibility. Similar to previous studies, we could demonstrate a high level of agreement between DCT and GAT in healthy eyes.

In our study, DCT measurements (mean IOP of four IOP values of day 1) were on average 0.8 mmHg higher than those of GAT. This is in line with our previous study on 100 healthy eyes (14), where we found a mean difference of 1.0 mmHg. Other groups, however, found higher differences of up to 3.5 mmHg between DCT and GAT. In the Bland and Altman analysis, the 95% confidence interval was between +1.9 and –3.5 mmHg, whereas in a comparable study (15), the difference ranged from +7.3 mmHg to –2.3 mmHg. This difference might result from the fact that in our study, the mean of four IOP measurements was taken for the analysis.

There are a few studies addressing the short-term reproducibility of DCT, each of them in a different fashion. Our results are consistent with those of Viestenz and Langenbucher (16), who also demonstrated an excellent reproducibility of DCT. However, due to a nonrandomized order in their experimental setup a systematic bias could not be excluded experimentally. In their study, first DCT was repeated for three times, followed by an IOP measurement performed with Tono-Pen and GAT. Finally, a last examination with DCT was performed to investigate the tonography effect. Interestingly, the authors mentioned a significant decrease of IOP especially at the third but not at the last measurement. We observed a similar phenomenon after the first DCT measurement (and not after any of the GAT measurements). A tonography effect would have affected both methods, GAT and DCT. A more likely explanation for this decrease in IOP after the first DCT measurement might be that the first measurement performed with DCT induces a more disagreeable sensation to the patient than that with GAT, forcing the subject to close the eyes. Lid closure is prevented by the examiner. However, muscle contraction might induce an elevation of IOP. After the first measurement, subjects get used to the DCT method and the IOP values decrease (in the absence of the reflex reaction due to habituation). This adaptation might be responsible for a degradation of reproducibility. As a consequence, an IOP value measured with DCT might be more reliable after the second or even the third measurement, when the patient got used to this method. Kaufmann et al (17) reported a higher intraobserver variability for DCT compared to GAT (0.65 mmHg for DCT and 1.1 mmHg for GAT; p=0.008). However, in this study, only eight patients were examined three times with DCT and with GAT without randomization.

In contrast to previous studies, we also investigated the long-term reproducibility of DCT. This is another important factor for the use of a medical instrument in clinical routine, because various sources of error, such as decalibration, the amount of eyedrops, or the slit lamp model used have the potential to falsify the measurements. Here, we show that long-term reproducibility of DCT and GAT does not differ significantly.

Taken together, our data suggest an excellent short- and long-term reproducibility of DCT and therefore underlines its potential to become a first-line IOP measurement device.

The authors report no conflicts of interest.

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