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The evaluation of tonometry and self-tonometry with Ocuton tonometers

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Summary

Background: The purpose of the present study was to evaluate the clinical applicability of the Ocuton-A and Ocuton-S applanation tonometers, and to compare their use and accuracy parameters to those of Goldmann applanation tonometry (GAT).

Material/Methods: In the first study, intraocular pressure (IOP) was measured with an Ocuton-A tonometer, followed by another measurement using GAT in 15 subjects (30 eyes). Ocuton-tonometry was performed on three occasions separated by three-minute intervals. In Study 2 the impact of increased patient familiarity on measurement accuracy using the self-tonometer was investigated in 5 subjects (10 eyes) by comparing two consecutive series of five Ocuton-S measurements. In Study 3 nine trained volunteers measured their own IOP with an Ocuton-S self-tonometer after GAT and Ocuton-A measurements by an experienced investigator.

Results: Study 1 showed that the measured IOP value was significantly higher using the Ocuton-A tonometer, compared to values obtained using GAT. In Study 2 we found that increased practice in self-tonometry did not alter measurement accuracy. In Study 3 the difference between IOP readings obtained with the Ocuton-S and Ocuton-A instruments was not significant.

Conclusion: The portable Ocuton-A tonometer may become a useful instrument for IOP measurement by professional workers outside the clinic. Qualified patients are able to use the Ocuton-S self-tonometer reliably even after limited training, and its measurement accuracy is acceptable for IOP monitoring. Both the Ocuton A and S devices consistently overestimate the IOP by approximately 2 mm Hg compared to the corresponding Goldmann readings.

key words: **applanation tonometers • glaucoma • Ocuton-A • Ocuton-S**

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Remark: The Authors have no financial interest on Ocuton devices.

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BACKGROUND

Elevated intraocular pressure (IOP) is one of the most important risk factors for both the development and progression of glaucoma [1]. It is well known that diurnal variation in IOP is clinically significant in some cases, and frequently includes elevated values ('spikes') occurring outside of normal working hours [2]. Assessment of IOP curves is generally based on the use of the Goldmann tonometer, which represents the 'gold standard' for applanation tonometry. Unfortunately, however, this device cannot be used outside the clinic or between evening and early morning when the patients are at home. The Ocuton-A and Ocuton-S tonometers represent a new family of hand-held, portable applanation tonometers, which calculate IOP electronically [3]. While the Ocuton-A instrument is intended for use by the ophthalmologist, the Ocuton-S tonometer can be operated by the patient without any expert assistance. This creates a possibility for IOP monitoring in the patient's home and during normal activities, without hospitalization. Self-tonometry may be especially useful to detect IOP 'spikes', as well as to provide IOP measurements outside normal working hours. However, to obtain these advantages the readings must be reliable and accurate. To investigate whether self-tonometry by glaucoma patients is able to fulfil these criteria, we compared IOP measurements with Ocuton-S and Ocuton-A tonometers to those made with a Goldmann applanation tonometer, in three different studies.

MATERIAL AND METHODS

The clinical investigation protocol was approved by the Ethics Committee of the University. Written informed consent was obtained from all participants. Fifty-eight eyes of 29 patients (mean age 62.5 years, range 47 to 81 years) suffering from medically treated primary open angle glaucoma were included in three different studies. All participants had previously undergone IOP measurements using Goldmann tonometry, and were able to perform self-tonometry without technical problems. The patients' central visual field was preserved, and their technical skill was sufficient for self-tonometry. Different measurements were performed on the same population. Patients were considered well trained when the fitting of the tonometer to the eye was easy, and the patients did not produce eye-closing or Valsalva maneuvers during the measurement. The exclusion criteria were tremor, ocular inflammation, ocular surgery within the previous three months, corneal astigmatism higher than ± 2.0D, and use of contact lenses.

The reproducibility of self-tonometry was studied in nine patients. The Ocuton-A and Ocuton-S tonometers (EPSa Elektronik & Praezisionsbau, Saalfeld, Germany) are portable, hand-held applanation tonometers. The measurement principles and technique have been described elsewhere [3,4,5]. In brief, during measurement the tonometer emits a light beam towards the surface of the cornea via a small prism. The prism then moves forward to contact and slightly depress the corneal surface. The applanation of the measured portion of the cornea is detected automatically by a built-in detector, which senses the change in the reflected light. IOP is calculated from the corneal area applanated by the prism and the force necessary to achieve the applanation. The movements of the prism, the area, and the force of the measurements, as well as IOP calculation and storage of the read-out are all controlled automatically by a built-in microprocessor.

The measurement can be performed with the subject either in sitting or lying position. Before measurement the forehead rest of the instrument is adjusted by the operator to position the contact-prism at approximately 10 mm from the cornea. The measurement is then initiated by pushing a button. The prism moves slowly toward the central corneal surface, touches the anesthetized cornea, and then returns to the baseline-position. The Ocuton-A tonometer is intended for use by an operator who has a viewing window to assist in correct positioning. The Ocuton-S model projects an aiming light into the eye being tested, which enables the subject to position the prism correctly him- or herself before and during the measurement procedure. This is the only technical difference between the two models. After a few seconds the device displays the IOP reading, in mm Hg. Both Ocuton tonometers are portable and are supplied with a special carrying-case, which contains a battery-charger and provides automatic ultraviolet-light sterilization of the contact prism surface (following manual cleaning with an ethanol-soaked pad).

All measurements were performed with the subject in sitting position using topical anesthesia with oxibuprocainum 0.4 %. Different Ocuton A and S tonometers were used under the same conditions, in a quiet room with air temperature 21±2 C°. Before study 1 and study 3, the patients were carefully trained in the use of the Ocuton-A and Ocuton-S instruments respectively. Before study 2 the participants received more limited training (see below).

In Study 1 IOP measurements were performed by a professional operator on 30 eyes of 15 patients (8 men, 7 women, mean age 62.5 years). GAT was performed first, and ten minutes later the IOP was measured three times (at three minute intervals) using an Ocuton-A tonometer. To estimate any influence of the order of measurement techniques, the IOP was measured again in inverted sequence (three Ocuton-A measurement, followed by GAT) after a 30-minute interval.

In *Study 2*, the participants (3 men, 2 women, mean age 59.7 years) received only a single initial training session of 15 minutes, and the influence of increased practice in self-tonometry on the measured IOP values was investigated. Five patients performed Ocuton-S self-tonometry on both eyes on five consecutive occasions separated by three-minute intervals. After a 30-minute break the procedure was repeated.

In *Study 3*, the IOP of 18 eyes of nine patients (5 men, 4 women, mean age 65.3 years) was measured successively with GAT and Ocuton-A tonometry by the investigator,

and then by the participants themselves, using an Ocuton-S tonometer. GAT was performed first, followed by a ten-minute pause; then three consecutive Ocuton-A measurements were performed at three-minute intervals. Finally, after a ten-minute break, the volunteers measured their own IOP five times at three-minute intervals.

Intraocular pressure values from the different instruments were compared using the paired t-test. Regression analysis was used to investigate whether the correlation between the Ocuton and the Goldmann readings was dependent on the IOP value. P values less than 0.05 were considered significant.

Results

After the training all the patients were able to handle the Ocuton-S tonometer appropriately. No adverse effects were observed in connection with either Ocuton-A tonometry or self-tonometry.

In *Study 1*, comparing GAT with the Ocuton-A instrument, the IOP (mean ± SD) measured with GAT was 15.53(3.60 mm Hg, and varied between 10 mm Hg and 29 mm Hg (Table 1). The IOP measured using the Ocuton-A tonometer averaged 17.60±3.96 mm Hg. The mean difference between the GAT and the Ocuton-A readings was 2.07 mm Hg (p=0.005). When the order of the measurements was reversed, the IOP averaged 17.50±3.52 mm Hg with Ocuton-A tonometry and 15.90±3.29 mm Hg with GAT. The mean IOP difference between the measurement by the two types of instrument in this second case was 1.60 mm Hg (p=0.05). The difference between the GAT and the Ocuton-A readings in either measuring sequence was independent of the IOP value (p=0.58 and p=0.75, respectively).

In *Study* 2 no influence of a 'learning effect' by the subject was found (Table 2). Self-tonometric IOP was 23.52 (2.96 mm Hg in the first series of measurements and 23.04 (2.50 mm Hg in the second series (p=0.32).

In *Study 3*, comparing all three instruments, the average IOP was 15.70±2.16 mm Hg with GAT, 17.62±3.33 mm Hg with Ocuton-A tonometry, and 18.34±3.97 mm Hg with Ocuton-S self-tonometry (Table 3). The difference between the Ocuton-S and GAT values was 2.27±1.27 mm Hg (p<0.0001). However, comparing the Ocuton-A with the Ocuton-S readings the difference of 0.59±1.58 mm Hg (p=0.15) was non-significant. In this third study, the IOP value (measured with GAT) varied between 12 mm Hg and 22 mm Hg. The difference between the IOP readings measured with GAT and with Ocuton-S tonometry was not dependent on the IOP value (p=0.74).

Discussion

Tonometry performed outside the ophthalmology clinic may provide important information on the diurnal IOP curve. In principle self-tonometry represents an optimal approach for IOP measurement, since it does not require any medical assistance, does not disturb the usual daily routine of the glaucoma patient, and makes it possible to measure IOP during the night and early morning hours without hospitalizing the patient. However, the portable tonometer and especially the self-tonometer must be safe, reliable, and easy to use for the trained patient. In our study we were able to train selected glaucoma patients (free of ocular inflammation, pain, tremor and high astigmatism) to use the Ocuton-S self-tonometer instrument successfully. All the subjects involved had long experience being measured with Goldmann applanation tonometry, as well as sufficient skill and the requisite sufficient visual field to be able to use the Ocuton-S instrument.

The sample size of our pilot study was small, but it was sufficient to detect differences between intraocular pressure as measured with the Goldmann tonometry and Ocuton tonometry. IOP values measured with the Ocuton-A and Ocuton-S tonometers on the same eyes did not differ significantly from each other. Similarly, increased practice in self-tonometry after a single 15-minute training session did not significantly change the measured IOP value. These results of our pilot study on selected patients suggest that a single training session is sufficient for most glaucoma patients. The measurement accuracy of self-tonometry was found to be similar to

Table 1. IOP measured with Ocuton-A and GAT tonometry.

Measuring sequence	IOP (mm Hg, Mean±SD) GAT	IOP (mm Hg, Mean±SD) Ocuton-A	Mean difference (mm Hg)	p*
GAT→Ocuton-A	15.53±3.60	17.60±3.96	2.07	0.005
Ocuton-A→GAT	15.90±3.29	17.50±3.52	1.60	0.05

*(paired t-test)

Table 2. The influence of increased practice in self tonometry on measured values.

IOP (mm Hg, Mean±SD) Series 1	IOP (mm Hg, Mean±SD) Series 2	p*
23.52±2.96	23.04±2.50	0.32

*(paired t-test)

Table 3. IOP measured with Ocuton-S self-tonometry, Ocuton-A tonometry and GAT.

	IOP (mm Hg, Mean±SD)	Mean difference from Ocuton-S values (mmHg)	p*
GAT	15.70±2.16	2.27±1.27	<0.0001
Ocuton-S	18.34±3.97		
Ocuton-A	17.62±3.33	0.59±1.58	0.15

*(paired t-test)

that achieved by a professional investigator who had considerable experience in tonometry.

On the other hand, both models of the Ocuton tonometer overestimated the IOP compared to the values measured by the Goldmann tonometer. The mean difference between IOP readings obtained with the Ocuton-A tonometer and the Goldmann tonometer on the same eyes was 2.07 mm Hg when Goldmann tonometry was performed first, and 1.60 mm Hg when Ocuton-A tonometry was the first measurement. Ocuton-S self-tonometry resulted in a mean IOP 2.27 mm Hg higher than the corresponding Goldmann tonometric value. The minimal difference between the pressure values found in Study 2 and the other two studies represents the usual diurnal intraocular pressure fluctuation. In our studies, the value of IOP measured by the Ocuton tonometers was consistently about 2 mm Hg higher than the value measured by standard Goldmann tonometry. This value is in agreement with the results of other investigators [6], although another group has reported a substantially greater and less consistent mean difference from the 'standard' instrument [4]. The difference between the Goldmann applanation tonometric values and those achieved with Ocuton tonometers depended on the measuring technique and was not instrument-dependent, since the difference remained unchanged when different instruments of the same type were used. It is important to emphasize that for neither of the Ocuton instruments was the difference from the Goldmann values dependent on IOP; in the measured IOP ranges (10-29 mm Hg and 12-22 mm Hg, respectively) the difference remained constant. No eyes with higher IOP range were involved in our investigation, since self-tonometry in the range of intraocular pressure over 30 mm Hg is without clinical relevance; in any case of IOP higher than 30 mm Hg, medical or surgical intervention is urgently needed. Intraocular pressure values as measured with Ocuton tonometers, however, can be used to detect IOP 'spikes' in the diurnal curves. Nevertheless, in another study we found that the relation between the Ocuton-S and Goldmann tonometry readings was not constant during the 24 hours of the day: the self tonometry IOP readings were consistently higher while the subjects were active, but consistently lower compared to the corresponding Goldmann readings during the sleep period [7]. This means that the correlation between values obtained with these two measurement techniques may vary around the clock.

CONCLUSIONS

In summary, we think that the portable Ocuton-A and Ocuton-S tonometers may become useful instruments in clinical practice for detecting IOP spikes and measuring IOP variations outside normal working hours; however, ophthalmologists may have to correct the measured readings.

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