SCIENTIFIC REPORT 4

"Using the Easyton tonometer to measure the intraocular pressure in patients with their contact lenses on"

I. Introduction

Contact vision correction is one of the most common forms of optical correction and has some indisputable advantages over wearing glasses. New technologies have allowed development of more comfortable and optically diversified lenses. This has, in turn, expanded the range of applications; they can be used by patients of nearly all ages and in those needing more complex corrections.

Those using contact lenses should be regularly monitored by an ophthalmologist or optometrist and the examinations must include intraocular pressure (IOP) measurement.

In practice, many wearers are reluctant to go through the admittedly small discomfiture of taking out and putting in their lenses again for the purposes of the test. There is a tendency to postpone the IOP measurement until a time when they can plan a visit without their lenses. This re-visit may be delayed indefinitely, all the while leaving the patient's IOP level unprotected by medical monitoring. It therefore seems opportune to introduce modern tonometry methods that avoid the problem by permitting IOP measurement in lens-wearing patients without sacrificing accuracy.

We conducted a controlled study of the Easyton intraocular pressure tonometer in patients wearing contact lenses to assess the possibility of determining IOP by transpalpebral scleral tonometry.

The study was carried out as part of scientific

cooperation activities incorporated in the research agreement, dated September 13, 2017, titled "Joint development and testing of intraocular pressure measuring instruments of the Scientific and Technical Center of the R&D Department of Elamed JSC". This was concluded between the Federal State Budgetary Institution "The Helmholtz National Medical Research Center of Eye Diseases" of the Ministry of Health of Russia and Scientific and Technical Center Yelatma Instrument Making Enterprise (R&D Dept. of Elamed, JSC).

Human subjects involved

The study included 30 patients (60 eyes) aged from 11 to 63 years with various refractive errors who wear soft contact lenses (conventional or multifocal) to correct eyesight, including:

- 5 patients (10 eyes) aged from 11 to 63 years (average age M±SD: 45.0±21.0 years) with hyperopia from +1.75 to +9.0 D (+4.4±2.6 D);
- 25 patients (50 years) aged from 12 to 57 years (average 26.4±13.50 years) with myopia from -0.5 to -11.25 D (-4.4±2.4 D).

Study Goals

1. To conduct transpalpebral tonometry using the Easyton tonometer and pneumotonometry using Reichert 7 Auto Tonometer in the examined patients when not wearing contact lenses.
2. To conduct transpalpebral tonometry using the Easyton tonometer in the same eyes of subjects both when wearing and not wearing their contact lenses.
3. To conduct a comparative analysis of the accuracy of IOP measurement between the Easyton tonometer and the pneumotonometer Reichert 7 Auto Tonometer.
4. Conduct a comparative analysis of the accuracy of IOP measurements using Easyton tonometer in the same eyes of the subjects when wearing and not

wearing their contact lenses.

5. To log all adverse events occurring during the testing phase of the Easyton tonometer operation, and to conduct a subsequent safety assessment

Study equipment

The Easyton intraocular pressure tonometer was manufactured by Yelatma Instrument Making Enterprise, JSC (registration certificate for medical device dated November 17, 2016, No. RZN 2015/2997) and was used to conduct transpalpebral tonometry.

The Reichert 7 Auto Tonometer manufactured by Reichert Inc., USA, was used as the reference product. It determined IOP values by pneumotonometry, the most common tonometry method.

IOP values measured by the two devices were compared.

The study duration was 7 weeks.

II. Brief introduction to the two medical devices used in the study

1. Brief information about the Easyton tonometer

Easyton tonometer is designed to measure intraocular pressure through the eyelid without the need for anaesthetics.

Contraindications for the use of Easyton tonometer are

- pathological conditions of the upper eyelid (inflammatory diseases, scars, eyelid deformation)
- severe scleral pathology in the measurement area.

The tonometer has two IOP measurement modes:

- Tonometric IOP measurement mode (Maklakov scale)
- True IOP measurement mode (Goldman scale)

The IOP is measured through the eyelid, which eliminates contact of the device with the sclera and cornea, and does not require anaesthesia.

The tonometer's operating principle of IOP measurement consists of recording the frequency of forced oscillations

of the eyeball under the impact of the tonometer's vibrator.

During the measurement, the rod is placed in the scleral area of the eyelid, pressing with a load of approximately 10 G. Thus, a unified bound rod-eye biomechanical system is created whose oscillation frequency is determined by the actual intraocular pressure.

The excitation of oscillations is carried out by a short electromagnetic pulse acting on the vibrator's rod. The movement of the rod is transmitted to the eye through the eyelid in the form of a short-term exposure, which stimulates the forced oscillations of the eye tissues.

The conversion of mechanical vibrations of the eye tissues into an electrical signal is carried out by the tonometer's electromagnetic system structurally connected with the rod.

The oscillation period is measured by the tonometer and is used to calculate the IOP displayed on the tonometer's screen.

2. Brief information on Reichert 7 Auto Tonometer (manufactured by Reichert Inc., USA)

The Reichert 7 Auto Tonometer is a non-contact pneumotonometer for checking IOP using the air-puff method

Technical specifications of Reichert 7 Auto Tonometer are shown in Table 1.

Height:	502 mm
Width:	267 mm
Depth:	356 mm
Weight:	10.43 kg
Power supply:	100/240 V, 50/60 Hz
Measuring range:	7 ~ 60 mm Hg (according to ISO 8612 standart for tonometres)

Contraindications:

- erosion, ulcers, corneal oedema;
- prior keratoplasty
- prior penetrating eye injury.

III. Methodology of the Study

Allocation of patients for the study applied the following exclusion criteria:

- pathology of the upper eyelid (inflammatory diseases, scars, eyelid deformation)
- severe scleral pathology in the projected measurement area
- erosion, ulcers, corneal oedema
- prior keratoplasty
- prior penetrating eye injury.

The patients included in the study signed informed voluntary consent to participate and were assigned individual ID numbers.

All patients underwent a standard ophthalmological examination: visual acuity measurement, autorefractometry and thorough examination of fundus. The data obtained were entered into the subject's individual patient record.

IOP was measured with the patient seated and was carried out on both eyes, first with the Easyton transpalpebral tonometer and then the Reichert 7 AutoTonometer pneumotonometer according to the techniques recommended by the manufacturers and specified in the respective operator manuals. When measuring IOP using the Easyton tonometer, the tonometer rod was located on the patient's upper eyelid in the sclera region corresponding to the corona ciliaris in the 12-o'clock meridian.

IOP was first measured without contact lenses. The patient then put in their lenses, and after 20 minutes a second measurement was carried out using each of the two tonometers. Each measurement (both the Easyton tonometer and the pneumotonometer, with lenses on and off, on the right and the left eye) was performed three times and the results were logged in the individual record file. For further analysis, the average value of three IOP measurements was calculated for each type of measurement.

The statistical processing of the obtained data included the determination of the mean value

and standard deviation (M±SD), as well as Student's criterion. The parameter values were considered different if $p<0.05$.

IV. Summary of results

The average IOP values for the right and the left eye over the whole group of examined patients are shown in Table 2

Table 2. Values of IOP (mm Hg) for the right (OD) and the left (OS) eye obtained using Easyton and the Reichert 7 AutoTonometer over the entire group of patients

IOP Measurement conditions	EASYTON		Reichert 7 AutoTonometer	
	OD	OS	OD	OS
Without contact lenses	16.3 ± 2.9	16.6 ± 3.2	16.6 ± 3.2	15.6 ± 3.3
With contact lenses	16.0 ± 3.9	16.7 ± 3.1	15.7 ± 2.9	15.5 ± 2.8

A comparative analysis of the data showed that IOP values measured for the same eyes of the same patients had no statistically significant difference irrespective of the method or whether the lenses were present or absent ($p>0.5$).

However, the IOP values determined by Easyton in patients with contact lenses were closer to the values without lenses than the respective values obtained by pneumotonometry.

In addition, while the interocular asymmetry of IOP (the difference between the right and the left eye) was practically absent for Easyton data, the respective values obtained by pneumotonometry showed slightly larger differences.

Since patients with significant anisometropia were not included in the study, the lack of IOP asymmetry with transpalpebral tonometry suggests a more satisfactory outcome than with pneumotonometry.

A separate analysis of the results of IOP determination in groups of patients with myopic and hyperopic refraction is interesting because contact lenses used to correct hyperopia and myopia differ not only in

curvature, but also in the central zone thickness, which could affect the results of pneumotonometry of patients with their contact lenses on.

According to the data shown in Table 3, the IOP obtained for hyperopic patients using Easyton, both with and without lenses, turned out to be higher than those measured using pneumotonometry ($p<0.05$).
Since the average age of the examined hyperopic patients was significantly higher than that of myopic patients, we would expect that the IOP in these patients should be higher on average (IOP is known to increase with age), and this was shown by the transpalpebral tonometry data.

Table 3. Values of IOP (mm Hg) for the right (OD) and the left (OS) eye obtained using Easyton and Reichert 7 AutoTonometer in the group of hyperopic patients

IOP Measurement conditions	EASYTON		Reichert 7 AutoTonometer	
	OD	OS	OD	OS
Without contact lenses	19.3 ± 2.8	19.6 ± 3.1	13.5 ± 2.7	13.2 ± 1.6
With contact lenses	19.5 ± 3.9	19.7 ± 3.3	14.0 ± 1.8	14.2 ± 1.7

In the group of patients with myopia, the difference between the results of TPT and pneumotonometry for patients with and without their contact lenses was not statistically significant, which indicates interchangeability of the measurement techniques in this category of patients (Table 4).

Table 4. Values of IOP (mm Hg) for the right (OD) and the left (OS) eye using EASYTON andReichert 7 AutoTonometer in the group of myopic patients

IOP Measurement conditions	EASYTON		Reichert 7 AutoTonometer	
	OD	OS	OD	OS
Without contact lenses	15.7 ± 2.6	15.9 ± 2.9	16.6 ± 3.8	16.1 ± 3.4
With contact lenses	15.2 ± 3.5	16.0 ± 2.7	16.1 ± 2.9	15.9 ± 2.9

The study also monitored the occurrence and frequency of adverse events. No adverse events, or adverse effects of either the Easyton tonometer or pneumotonometer were identified in any participants during the study.

We found neither design flaws nor difficulties in use when operating the Easyton tonometer.

Conclusion:

The study confirmed the feasibility of precise determination of IOP by the Easyton intraocular pressure tonometer in patients wearing contact lenses using the transpalpebral technique.

It was found that the difference in average values of IOP measured in the same study participants on the same eyes with and without contact lenses was less pronounced in Easyton tonometry than the respective difference obtained by pneumonometry.

No asymmetry of IOP (differences between the right and the left eye) was revealed by Easyton tonometry

The absence of any adverse events during the study confirms the safety of transpalpebral tonometry using the Easyton tonometer.

The use of transpalpebral tonometry may be preferable in a number of clinical situations, since, unlike corneal pneumotonometry, the factors related to the presence of a contact lens (its thickness, corneal fitting, presence of tear fluid, etc.) did not affect result reproducibility.

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