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FACTORS AFFECTING MEASUREMENTS OF IOP USING NON-CONTACT EYE TONOMETER

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Abstract: The objective measurement of intraocular pressure (IOP) represents the identification of the symptoms of some diseases, e.g. glaucoma. This objective measurement can only be achieved by correct calibration of tonometers. Today, there is no uniform methodology for this calibration. Therefore, we introduce potential sources of error and try to quantify their contributions in this paper. Subsequently, a calibration standard containing an artificial cornea with similar properties to the human one should be designed.

KEYWORDS: measurement, intraocular pressure, non-contact eye tonometer, uncertainties and factors

1 Introduction

Correct metrological assurance in ocular tonometry is very important in the prevention of such insidious diseases as glaucoma. Specifically, to ensure accurate measurement of intraocular pressure with eye tonometer is the goal of our efforts. The most commonly used type of ophthalmological tonometers in ophthalmic practice are those that measure eye pressure using contactless methods. Popularity of non-contact tonometers is growing and they are the most used devices in practice. It is important that these devices from different manufacturers are independently controlled with regular frequency and under the same conditions regardless of manufacturer, ie ensuring metrological traceability. In this context, we have started to deal with standard equipment meeting the above requirements.

2 Uncertainty of non-contact eye tonometers

Uncertainty determination is one of the most crucial indicators of the limitations of the measurement methods and capabilities by means of quantifying each individual factor affecting the generated value. The overall uncertainty budget that lists the most significant factors affecting the non-contact determination of intraocular pressure (IOP) is based on the used measurement method principles, procedures and conditions under which it should be routinely used. For our specific case we have considered a scenario by which a non-contact tonometer is used by an experienced physician in a medical praxis environment. The detailed values based on uncertainty evaluation Type-A can be seen in Table I., the influential factors based on Type-B uncertainty evaluation can be seen in Table II. [1, 2, 3]

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All of the provided results have been obtained by using non-contact eye tonometers, more specifically Nidek NT 2000. The number of tested devices was two.

The standard uncertainty evaluated by type-A method was determined by a total of 120 measurements with two types of references that simulated a human eye with specific static values of IOP (indicated in Table I. as a Nominal value reproduced by the standard). The results within Table I. show average values of Type-A uncertainty for a specific type of standard and pressure point. The results from two types of references represented by commercially available silicone eyes and an independently developed artificial cornea eye model, have shown that the levels of repeatability in all pressure ranges is comparable. This is an indication of the performance of a specific non-contact eye tonometer type in terms of Type-A uncertainty evaluation. [1]

Table I. Detailed values based on uncertainty evaluation Type-A

Evaluation of uncertainties by Type-A method for silicone eyes	
Nominal value reproduced by the standard	U_A values
16.0 mmHg	0.33 mmHg
22.8 mmHg	0.48 mmHg
42.5 mmHg	0.88 mmHg
Evaluation of uncertainties by Type-A method for the artificial cornea eye model	
Nominal value reproduced by the standard	U_A values
14.5 mmHg	0.32 mmHg
22.9 mmHg	0.59 mmHg
42.8 mmHg	0.82 mmHg

The standard uncertainty evaluated by Type-B method includes effects affecting a given measurement outside the statistical effects of the measured intraocular pressure values.

The overall measurement accuracy associated with measurements of non-contact eye tonometers depends on their basic principles and function. These tonometer types make use of applanation of the eye cornea (human eye, silicone eye, artificial cornea eye model). The pressure caused by the stream of air originating from the nozzle is chosen by the device itself. The measurement takes place without direct contact between the tonometer and the cornea (human and artificial). For each cornea there are always 3 measurements, from which the arithmetic mean is calculated by the device from various inputs (during patient examination); during the calibration process measurements are performed at least 10 times. The device increases the pressure until the cornea reaches the required applanation. The duration of pressure application is recorded by optical means; more specifically by an infrared light source that is reflected into the detector upon reflection from the flattened cornea, during the application the detector detects higher power from the pressure source than when reflected from the cornea of an unexposed air stream which is normally convex. The IOP calculation is done by the device, by using the time of the application at the pressure value generated by the air flow [1, 8].

Based on the study of scientific literature, drawing upon the experience of the Czech Metrology Institute, measurements at the Ružinov Hospital, measurements performed at the Slovak Institute of Metrology, Slovak University of Technology and Palacký University in Olomouc, we considered these sources of uncertainty evaluated by Type-B method as presented in Table II.

Table II. Detailed values of the listed influential factors (Uncertainty Type-B components) [8]

Uncertainty component	Value		Distribution
Time measurement*	u_{B1}	0.001 mmHg	Uniform
Pressure generation	u_{B2}	0.200 mmHg	Gaussian
Distance between the device nozzle and the eye surface*	u_{B3}	0.005 mmHg	Uniform
Mechanical properties of the artificial cornea (including its thickness)**	u_{B4}	0.700 mmHg	Uniform
Environmental conditions (temperature and humidity)*	u_{B5}	0.100 mmHg	Uniform
Centering of the nozzle*	u_{B6}	0.005 mmHg	Uniform
	$\boldsymbol{u_B}$	**0.735 mmHg**	

*Values derived from experimental measurements,
**Estimated value based on literature.

The evaluation of the intraocular pressure is based on variables recorded by a tonometer which is afterwards used to calculate the intraocular pressure. These calculations are done by devices internal algorithms that are unique for every manufacturer. The tonometer uses parameters such as applied pressure, time, elastic modulus of the eye tissue, especially the cornea. These elastic modulus values and the process of calculation is neither independently tested nor independently validated. This gives considerable room for possible errors in the calculation of the "true" intraocular pressure value. [1, 4]

The most influential factors of the non-contact measurements of IOP are:

- the ideal distance between the eye and the air source (nozzle),
- measurement conditions (accurate time measurement, including the regulation of air pressure, more precisely the consistency of the generated pressure at repeated air pulses),
- environment (air temperature and humidity, illumination),
- measuring range set on the instrument,
- automatic or manual measuring mode
- experience with operation of contactless eye tonometer.

As multiple of the influential factors of the measurement can affect each other it would be certainly appropriate to consider defining the covariations between each factor. By defining their interaction we can increase the resulting uncertainty, but also significantly reduce it. It all depends on the nature of whether the uncertainty components act in agreement or disagreement on the two uncertainty estimates under consideration; in particular, the values generated from the non-contact eye tonometer will be correlated with each other [1, 8].

3 Effect of cornea thickness

Some of the influential factors that have a potential to affect the measured IOP value are the mechanical properties of the eye cornea. As the biological material properties in a real human

eye have small variations (in a healthy patient), the thickness of the cornea, which significantly affects the measurement of IOP, determines the exact effect of high interest.

Due to ethical and technical complications that arise regarding taking measurements on biological tissues, the results presented in this section demonstrate the effect of thickness on the measured IOP by means of artificial cornea of same geometry and of identical and homogenous material.

A series of measurements were conducted on artificial corneas with variations in thicknesses. Specifically the thicknesses of the silicone based corneas, investigated were 0.3 mm, 0.4 mm, 0.5 mm and 0.6 mm thick. The results of these measurements are presented in Fig. 1. Each point on the graph represents an average of 12 measurements done for each respected pressure.

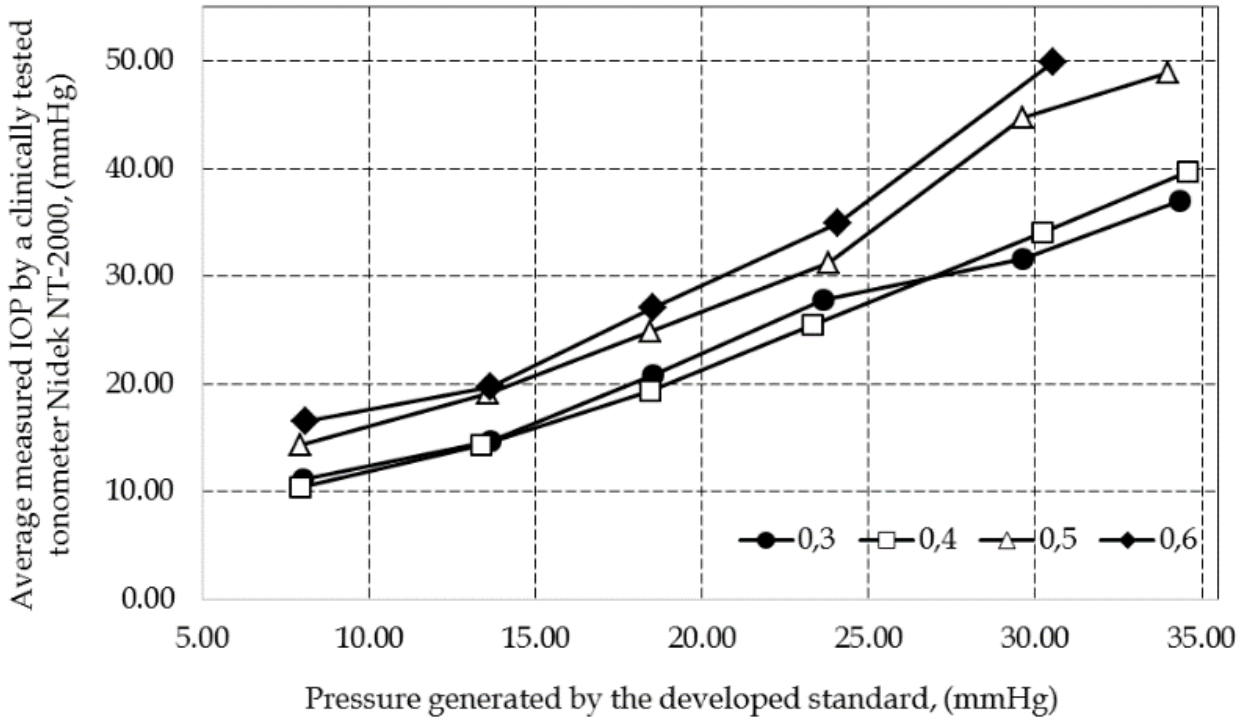


Fig. 1 Comparison of difference artificial cornea thicknesses and their effect on the IOP measurement by a clinically tested non-contact tonometer NidekNT2000. [8]

The Fig. 1 shows how the set pressure by the developed standard corresponds with the indicated IOP pressure by a clinically tested non-contact tonometer Nidek NT 2000. This clinical test was done in accordance with the ISO 8612 standard. As it can be seen, the smallest differences throughout the whole measurement range between the tonometer device and the developed reference was achieved with a 0.4 mm thick artificial cornea. The use of higher thicknesses had caused a more significant deviation and the decreasing the thickness to 0.3 mm had shown no benefit but has caused instability at higher pressures. It should be noted that the 0.7 mm thick cornea has caused the absence of an applanation and therefore no data could be measured [1, 8].

4 Remarks on the cornea stiffness as the influencing factor and uncertainty of intraocular pressure measurement

Measuring method of IOP: contact and non-contact are based on the measurement of cornea deflection [5, 6]. There is a correlation between the cornea deflection and IOP. Therefore the mentioned methods are very sensitive on the accuracy of deflection measuring. From the

mechanics point of view, the deflection depends on the stiffness of the cornea as an accumulated factor. The stiffness contains information about the geometry and mechanical properties of the cornea. For example in beam theory (we can simplify the cornea as a curved beam) the deflection is a function of the beam stiffness $= \frac{cL^n}{EI}$, where c is the constant, n is the integer exponent depending on the type of loading, E is Young´s modulus (mechanical parameter), L je the beam length and I is the quadratic moment of cross-sectional area (geometrical parameters). If stiffness is increased, the deflection will decrease. To reach the same value of deflection the applied load must be higher (air puff or the applied force of intender). The measured deflection of cornea is limited to the applanation of cornea. If the defection reaches the applanation, then the applied pressure is in an equilibrium with IOP – the Flick law.

The cornea itself represents the prestressed structure. The prestressed state arises due to IOP. Subsequently the load is applied to the prestressed cornea. The stiffness of prestressed cornea is naturally higher. Therefore we can conclude that the influencing factors of cornea stiffness are:

- geometrical parameters – for example the central corneal thickness (CCT), etc.;
- mechanical parameters - Young´s modulus, Poisson´s ratio, etc.;
- prestressed state – as the initial state.

We have made numerical and preliminary experimental observations on the corneal stiffness. The applied loading during meaning IOP is always the compressive one. Therefore the mentioned stiffness can be called as the compressive one too. The rheological model for the compressive corneal stiffness can be represented by the simple and well-known spring model. In this case

$$F = kx \tag{1}$$

Where F is the applied force, k is the spring stiffness and x is the deformation of the free spring end. Thus the spring stiffness can be calculated

$$k = \frac{F}{x} \tag{2}$$

The experimental measurements have been done on the human sample of cornea placed into to testing device, schematically presented in Fig 2.

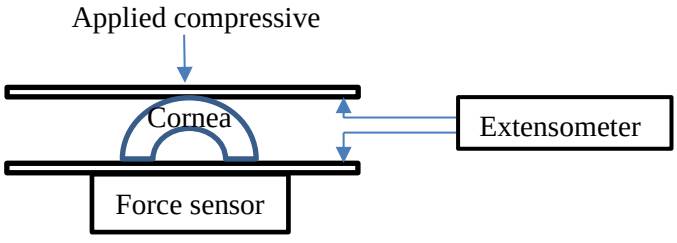
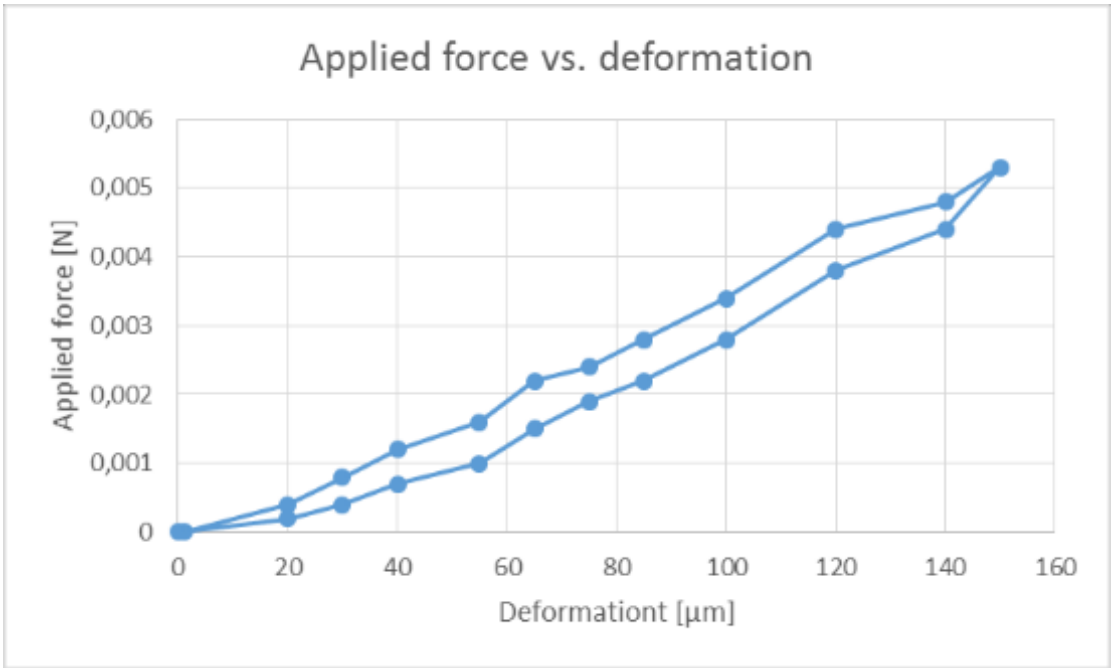
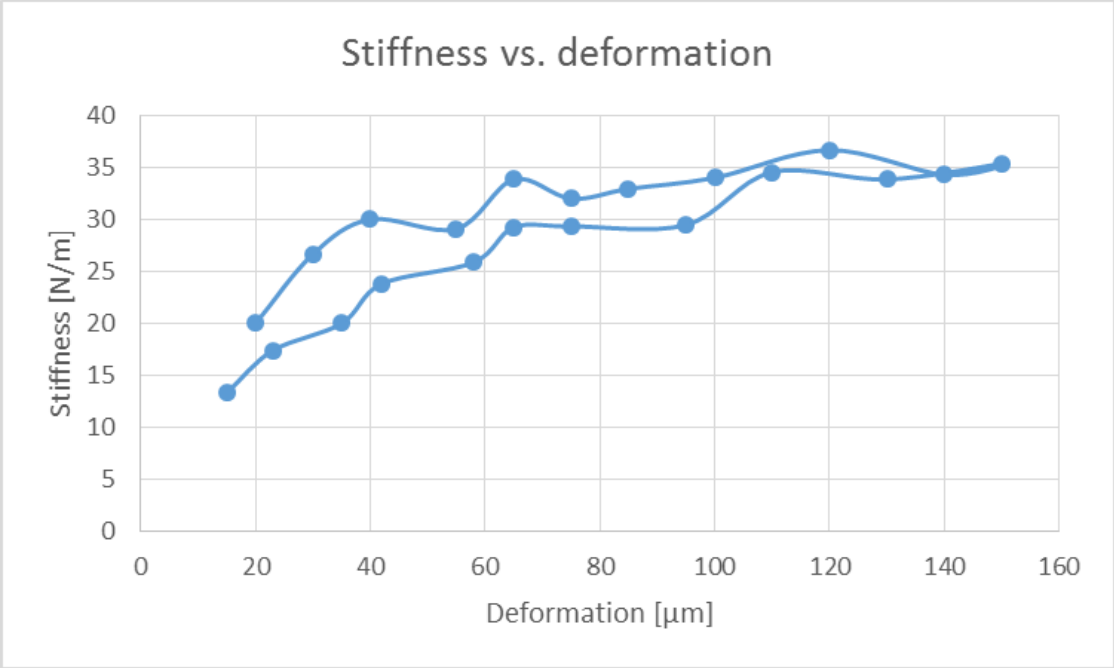


Fig. 2 Scheme of measuring setup

We measured the applied compressive force and the vertical deformation of corneal tip. We obtained the graph of the applied force and displacement with the hysteresis, see Fig. 3 a. The compressive stiffness of cornea showed variations due to the deformation, see Fig 3 b.



(a)



(b)

Fig. 3 Results of experimental observations

Similar hysteresis has been also observed in ORA diagrams as the difference between the primary and secondary applanation [5, 6]. Results of the corresponding deformation of cornea are identical to those presented in [6].

To evaluate numerically the effect of prestressed state contribution to the corneal stiffness we applied the modal analysis of numerical models. We compared the first eigenvalues for prestressed state and the state without prestressing. We built two different FEM models [7]: plane and shell ones. Then ratios of the first eigenvalues for both models [7] are following

$$r_{plane} = 1.07 \quad r_{shell} = 1.04 \tag{3}$$

These results mean that the influence of prestressed state can be from 4% to 7%.

CONCLUSION

The aim of this paper is to point out the importance of metrological assurance of ocular tonometry. An important task is to analyze the factors affecting accurate measurement of eye pressure with respect to the developed device model eye as an independent standard measure for metrological provision of contactless eye tonometers. With this device, we want to reliably generate pressure and ensure its reproducibility. From the analysis of influencing factors, the artificial cornea, especially its mechanical properties, appears to us as the biggest source of uncertainty. Further experiments will be needed to gradually reduce the uncertainties of these components. These experiments are the subject of further research. From the discussion, it is clear that the properties of the artificial cornea need to be closer to the properties of the human cornea. In this way, we want to provide a reliable basis for the metrological traceability of non-contact ophthalmic tonometers.

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