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Metrological Comparison of Ocular Tonometers for Optometric Use

Stela Levická [1,*], Dominik Pražák [2], Václav Sedlák [2], Eliška Najmanová [1], František Pluháček [1]

[1] Department of Optics, Faculty of Science, Palacký University, 17. listopadu 12, 771 46 Olomouc, Czech Republic
[2] Unit of Primary Metrology of Pressure, Vacuum and Low Mass Flow, Czech Metrology Institute, Okružní 31, 638 00 Brno, Czech Republic

Abstract: This paper presents an international metrological comparison of non-contact tonometers used for measuring intraocular pressure (IOP), a critical parameter in glaucoma diagnosis. Since non-contact tonometry is affected by biological variability and lacks direct linkage to SI units, reliable calibration standards are essential. A newly developed universal model eye, independent of specific manufacturers and traceable to SI units, served as the primary metrological standard. The comparison involved tonometers tested at institution in the Czech Republic and Slovakia according to the ISO 8612:2009 standard under controlled laboratory conditions. Accuracy, repeatability, and deviations from reference values were evaluated. Results demonstrated stable performance with minimal deviations across the measured pressure range. The study confirms the suitability of the developed model eye as a universal calibration standard and highlights the importance of international comparisons for enhancing the reliability and standardization of IOP measurements in clinical practice.

Keywords: Intraocular pressure, Metrological comparison, Metrological traceability, Ocular tonometers

1. Introduction

At present, the metrological calibration of non-contact tonometers relies on several standard types, including silicone eyes, flappers, and electronic eyes. However, these standards are frequently constrained by their compatibility with specific manufacturers or device types, alongside other technical limitations. Such restrictions have underscored the necessity for a universal metrological tool capable of providing consistent and comparable calibration across a wide range of devices [1].

A new eye model has been developed within the framework of research projects [2], featuring innovations like independence from specific tonometer brands and types. This allows for a wider range of applications in ophthalmology and optometry. This paper presents the findings of an international metrological evaluation involving non-contact tonometers of the same brand (refer to Table 1 and Table 2) intended for optometric use. The newly developed eye model served as the metrological standard throughout this comparison. Carried out across institutions in both Slovakia and the Czech Republic, the measurements confirmed that every tested device complied with the clinical requirements of the ISO 8612:2009 standard [3]. Within this study, the comparison procedure and measurement methodology are detailed, alongside a data analysis essential for maintaining high precision and reliability in clinical intraocular pressure assessments.

Non-contact ocular tonometers measure intraocular pressure [4] using an air puff that flattens the cornea, with the time of this flattening being measured to calculate the pressure. Intraocular pressure is an important factor for the diagnosis of eye condi-

* **Corresponding author:** Stela Levická, ***E-mail address:*** *levicka.stela@gmail.com*

tions and the potential development of glaucoma [5]. Accurate measurement of intraocular pressure is crucial for the diagnosis and monitoring of glaucoma [6,7], therefore, it is crucial that tonometry devices provide accurate and reliable measurements.

A limitation of this measurement technique is that it is not physically linked to the SI base units [8] but relies on the biological variability of patients, which can affect the accuracy of the measured results. Therefore, various metrological standards are currently used to calibrate these devices to ensure reliable measurements within the field of medical metrology. Metrological comparisons are conducted across countries and different devices in order to evaluate measurement consistency and accuracy.

2. Experimental Section

The aim of the materials and methods used in the international metrological comparison of non-contact tonometers was to verify the reliability, accuracy, and comparability of intraocular pressure measurements across different devices and institutions while ensuring appropriate metrological traceability.

Selection of Standards and Devices

At present, the calibration and comparison of non-contact tonometers rely on several metrological standards, such as flapper systems, silicone eyes, and electronic eye models. However, these standards are frequently characterized by specific constraints and are often limited to certain manufacturers or device types. These restrictions necessitated the creation of a universal eye model featuring multiple innovations, including independence from specific device types and manufacturers, a broad measurement range, the inclusion of additional ophthalmological parameters, and metrological traceability to the SI base unit system [8].

The newly developed eye model was chosen as the primary metrological standard for this comparison due to its capacity for broader application within the fields of ophthalmology and optometry. Regarding the instruments under evaluation, these were selected based on their availability and their status as commonly utilized non-contact tonometers, ensuring that the study's findings remain relevant to a diverse range of devices.

Measurement Protocol

The measurement procedure was performed in accordance with the guidelines established by the metrological institute and in compliance with the requirements defined by the standard ISO 8612:2009 [3], which specifies procedures for the clinical testing of non-contact tonometers within medical metrology.

Non-contact tonometers determine intraocular pressure by generating a puff of air that temporarily applanates the cornea. The time required for this applanation is recorded by the device and subsequently used to calculate the intraocular pressure value. During the comparison, the capability of the tested tonometers to perform this measurement accurately and consistently was evaluated.

Use of the Tested Eye Model

The developed eye model served as the universal metrological standard for the calibration and testing of all evaluated tonometers. The model was designed to overcome the limitations of traditional calibration standards by providing a more flexible and consistent reference system for various types of non-contact tonometers. Its design ensures independence from specific manufacturers and device types, enabling its application in a wide range of clinical and research environments while maintaining direct physical (metrological) traceability [9].

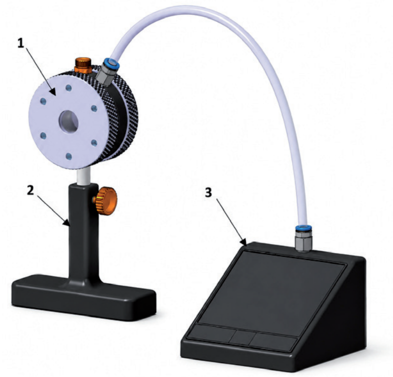

Figure 1: Set of model eye (1), base (2) and mini compressor (3) [2]

The eye model was used to simulate the conditions of the human eye during calibration and testing procedures to ensure that the measurements corresponded as closely as possible to real clinical conditions. Each non-contact tonometer was tested repeatedly using the eye model to verify the accuracy and repeatability of intraocular pressure measurements.

Data Collection and Analysis

Measurement data were collected from each non-contact tonometer according to the described measurement protocol. The obtained results were subsequently compared with the reference device used for metrological control at the Czech Metrology Institute. This comparison enabled the evaluation of the measurement performance of each tonometer and the identification of potential deviations or discrepancies.

The collected data were further analysed to identify potential sources of measurement error, including factors related to the biological variability of patients, which may influence the accuracy of non-contact tonometry. Measurement uncertainties for the model eye were analysed based on available literature [10] and quantified for the individual components of the developed standard. The overall uncertainty budget for the developed reference standard is based on a measurement model using the reference device with the model eye.

From the experiments conducted during the development of the reference device with the model eye, it follows that the reproducibility of the measurement (uA) contributes an uncertainty of 0.016 mmHg and was determined empirically. Systematic uncertainty components (uB) include the accuracy of time determination (0.001 mmHg, uniform distribution), pressure generation (0.200 mmHg, normal distribution), the distance between the eye and the nozzle (0.005 mmHg, uniform distribution), and the thickness of the artificial cornea (0.600 mmHg, uniform distribution). Further significant contributions to the measurement arise from the mechanical properties of the artificial cornea (0.800 mmHg, uniform distribution), environmental effects (0.100 mmHg, uniform distribution), and the position of the air jet (0.005 mmHg, uniform distribution). The analysis of these components allows quantification of the overall uncertainty of the calibration of the developed tonometer standard and provides essential information for the correct interpretation of measurement results and the optimization of the measurement process. Measurement uncertainty is an important parameter associated with the measurement result and should not be overlooked, even in clinical or optometric practice.

Such analysis is important for assessing the reliability of these devices in clinical practice and for ensuring the comparability of measurement results across different devices and institutions [9].

The results of the comparison are presented in the following section.

3. Results and Discussion

The used model eye was tested on the following types of ocular tonometers. Note: The measurements were carried out under laboratory conditions with constant temperature, pressure, and humidity, and all parameters for metrological comparison were met.

The Nidek NT2000 tonometer /CZ/ demonstrates overall very stable eye pressure measurements, with average deviations being relatively low, especially at lower pressure values. For a pressure of 10 mmHg, the average value is 11.0 mmHg with a deviation of only 0.4 mmHg, which is excellent. At higher values (e.g., 40 mmHg), the deviation increases to 1.0 mmHg, which may be influenced by the higher pressures, and ensuring accuracy at these values can be more challenging. Overall, this tonometer can be considered highly accurate, with minor deviations that may increase at higher pressures. In further studies, it is necessary to consider additional influencing measurement parameters, according to [8].

The Nidek NT2000 tonometer /SK/ shows similarly stable results, with the average deviation typically around 0.5 mmHg in most cases. Even at higher pressures, such as 40 mmHg, the deviations remain acceptably low (maximally 0.8 mmHg). Measurements at lower pressure values (10 and 15) mmHg demonstrate that the tonometer is reliable and has low variability, making this device suitable for a wide range of intraocular pressures. This tonometer is also well-calibrated and provides consistent results. In further studies, it is necessary to consider additional influencing measurement parameters, according to [11].

Discussion

The results of this metrological comparison involving Nidek NT2000 devices highlight the importance of standardization in ensuring accurate and reliable intraocular pressure measurements. The findings underscore the necessity for universal calibration models that maintain consistency across various pressure ranges and individual instruments. Although measurements can be influenced by biological variability, such as corneal thickness, it is essential to refine metrological tools and conduct regular international comparisons to maintain high-quality diagnosis for glaucoma and other ocular dis-

Table 1. Calibration using a model eye on the Nidek NT2000 ocular tonometer /CZ – Czech Metrological Institute, Regional Inspectorate Most/. Source: Own processing.

Ref. Pressure	Measured Intraocular Pressure Values (mmHg)									Evaluation (mmHg)	
Calibration Type: model eye		Tonometer type: Non-contact tonometer NIDEK NT2000/CZ/									
(mmHg)	1	2	3	4	5	6	7	8	9	10	Ø	SD
10.00	11	11	12	10	11	11	11	11	11	11	11.0	0.4
15.00	15	15	16	15	14	15	15	15	16	15	15.1	0.5
20.00	20	20	20	21	21	20	20	20	20	20	20.2	0.4
25.00	25	26	26	26	26	25	26	25	25	26	25.6	0.5
30.00	30	31	31	32	32	31	31	32	32	32	31.4	0.7
35.00	36	36	37	37	37	38	37	37	37	36	36.8	0.6
40.00	43	43	42	42	45	45	43	43	43	43	43.2	1.0

Table 2. Calibration using a model eye on the Nidek NT2000 ocular tonometer /SK – Glaucoma Clinic, Ružinov Hospital, Bratislava/. Source: Own processing.

Ref. Pressure	Measured Intraocular Pressure Values (mmHg)										Evaluation (mmHg)	
Calibration Type: model eye		Tonometer type: Non-contact tonometer NIDEK NT2000/CZ/										
(mmHg)	1	2	3	4	5	6	7	8	9	10	Ø	SD
10.00	12	12	11	11	12	11	11	11	12	11	11.4	0.5
15.00	15	16	16	16	15	16	15	15	15	16	15.5	0.5
20.00	20	21	21	21	21	21	21	21	20	21	20.8	0.4
25.00	25	26	26	27	27	26	27	26	26	26	26.2	0.6
30.00	32	32	32	32	32	31	32	32	31	31	31.7	0.5
35.00	37	37	36	36	37	38	37	38	36	37	36.9	0.7
40.00	42	42	42	42	44	44	43	43	43	42	42.7	0.8

eases.

Standardization remains a crucial factor in reducing measurement variations and improving diagnostic precision as tonometry technology continues to evolve. In this study, both Nidek NT2000 devices (from the Czech Republic and Slovakia) performed well under controlled laboratory conditions, demonstrating stable results with low average deviations even at higher pressure levels. However, further studies are required to evaluate their long-term reliability across more diverse conditions and patient populations. Continual international comparisons and technical improvements are key to maintaining consistent and high-quality eye pressure measurements for effective glaucoma diagnosis [12].

4. Conclusions

This paper presents the findings of the metrological comparison, offering a comprehensive overview of how several non-contact tonometers performed when evaluated against the developed eye model. Both the methodology and the results underscore the critical role of dependable metrological standards in ensuring consistent and precise intraocular pressure measurements, which are vital for managing and diagnosing ocular conditions like glaucoma. By evaluating instruments across different countries, this research seeks to support the creation of universal standards with global applicability in ophthalmology and optometry. Furthermore, this international evaluation highlights the necessity of ongoing innovation in metrological calibration tools to guarantee that non-contact tonometers deliver comparable and reliable data across various clinical environments.

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