16RPT03 – InTENSE – Deliverable 3

International metrological comparison of the silicone eyes versus a model eye

Jan Rybář[1], *Vítězslav Suchý*[2], *Peter Pavlásek*[1,3], *Dominik Pražák*[2]

[1]Slovak University of Technology in Bratislava

[2]Czech Metrology Institute

[3]Slovak Institute of Metrology

Content

1. Introduction

Several types of (transfer) standards are currently used for the metrological controls of non-contact eye tonometers: silicone eyes, flapper and electronic eye, see [1]. Within the framework of research activities of inTENSE project and a dissertation thesis [2], newly developed standard device – a model eye has been developed.

Fig. 1: Measurement using silicone eyes in the Ružinov Hospital

Fig. 2: Measurement using standard device - eye model - at the Czech Metrology Institute

This report deals with preparation, realization and results of an international comparison of silicone eyes (belonging to the Czech Metrology Institute - CMI) and a model eye (belonging to the Faculty of Mechanical Engineering of the Slovak University of Technology and co-developed by the Slovak Institute of Metrology - SMU) on two non-contact eye tonometers of the NIDEK brand, type NT-2000, series I and III. The measurements were carried out at the Czech Metrology Institute, Regional Inspectorate in Most and at the Ophthalmology Clinic in the Ružinov Hospital in Bratislava in January 2020. In Czech language, the comparison and its results were described in [3].

2. Preparatory phase

Non-contact eye tonometers are instruments working on the principle, when the pressure of the air that briefly blows out of the tonometer is fenced off by eye cornea. The value of intraocular pressure is then calculated using the time required to flatten the cornea with this air flow. During this measurement, the time of applanation is recorded, so the device is equipped with a very precise timekeeping, which measures exactly up to a thousandth of a second (from blowing the air flow through the applanation of the cornea, which has been flattened, including recording the air pressure flattening caused). This measurement procedure is the same for both the patient examinations and the metrological controls, i.e. for standards – silicone eyes and eye model.
In the field of the non-contact eye tonometers, the initial evaluation of a laboratory standard consists in conducting a clinical test of the eye tonometer according to EN ISO 8612:2009. Clinical investigation is an important prerequisite for the traceability of ophthalmological instruments – tonometers, based on ISO 15004-1 and IEC 60601-1:2005, where the minimum requirements and conformity procedures for the design and use of tonometers are specified, see [2, 4].
Both assessed non-contact eye tonometers met the clinical trial requirements according to EN ISO 8612:2009. The clinical trials took place under the medical supervision and after approval by the ethics committees at Most Hospital, Czech Republic and Ružinov Hospital, Slovakia. The instruments evaluated in such a way were subsequently subjected to a bilateral comparison using the silicone eyes and the model eye.

Fig. 3: Silicone eyes

The silicone eyes are the most commonly used way of calibrating or verifying the non-contact eye tonometers in ophthalmological practice due to their simple use, lower time demands and no-need to enter a service mode of a tonometer. Each silicone eye realizes a pre-set nominal value point of intraocular pressure. Each manufacturer of such device must define these reference values and their tolerances. Their main drawback is that for each type or for each manufacturer it is necessary to use a specific type of silicone eyes for the metrological checks. In order to pass the inspection, the tonometer shall not exceed a certain maximum deviation from the nominal value of the pressure represented by the silicon eye in each pressure range.

Procedure of metrological control of a non-contact eye tonometer using silicone eyes:

- Place a silicone-eye holder on a headrest on the non-contact eye tonometer while the artificial eye corneas face a nozzle of the tonometer.
- Turn on the non-contact eye tonometer, center a chosen silicone eye for a specific pressure and start the measurements. The artificial eye cornea can be centered by using a screen and a joystick.
- Perform ten measurements for each silicone eye with a relevant measurement range properly set; always wait a few seconds between the individual measurements.
- Calculate the averages and compare them with the declared values.

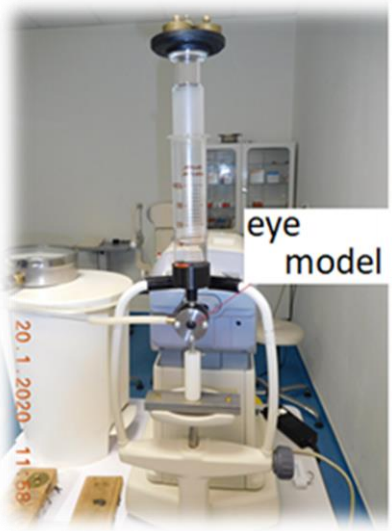

Fig. 4: Eye model during metrological inspection (Glaucoma Ambulance I., Ružinov Hospital) on non-contact eye tonometer NIDEK NT-2000 (series III)

The standard device developed within this project – model eye – simulates the intraocular pressure and properties of the ideal human cornea by setting a variable range of pressures in eye model in the monitored interval, [1, 2]. The advantage of the model eye is that we can replace the pressure gauge with other types of manometers (analogue, digital), we can change the type of material and thickness of the artificial eye cornea, and it would be also possible to change the fluid inside the closed system. Another advantage is the possibility to measure continuously the entire scale of the pressures assessed. The disadvantage is, above all, impractical manipulation in ophthalmological outpatient clinic and work with fluid.

Procedure of metrological control of a non-contact eye tonometers using a model eye:

- Fix the stainless steel base on the head-rest of the non-contact eye tonometer, using two nut screws.
- Prepare an artificial eye cornea according to the requirements for its parameters (thickness) and place it under the cover (under the covers) of the artificial eye corneas, attach the cover (covers) with the screws, pay attention to tightness.
- Attach the eye model to its nylon stand; it can be further adjusted vertically.
- Connect the flange of the eye model to the pressure balance by a connecting hose.
- Fill the connecting hose with the distilled water as soon as the air is released from the system, which is then sealed by connecting it to a calibrated pressure gauge.
- Ensure the same height level of the eye model and the pressure gauge using a water level. It is important to fix the entire system so that it is stable and sealed.
- The standard device is now ready for measurement, we can attach weights to the piston, thus generating the necessary pressure inside the eye model.
- Turn on the non-contact eye tonometer, center the model eye and start the measurements. The pressure in the closed system can be continuously changed by means of the pressure balance.
- Repeat measurements at least ten times. This gives ten average values (each from three readings on a tonometer). Compare them with the values from the manometer.

- It is possible to repeat the same procedure for different loads, different thicknesses of artificial corneas and ranges.

3. Implementation phase

The first comparison round took place in the Ružinov Hospital, Slovakia. The second comparison round took place at the Czech Metrology Institute, the Regional Inspectorate in Most, Czech Republic (details are in Table 1). The transfer standards were the silicone eyes (C.NO. 3148, belonging to CMI Most) and the model eye with an artificial cornea of 0,5 mm thickness.

Tab. 1: Conditions during international comparison at individual workplaces

workplace	CMI Most		Ružinov Hospital	
device	NIDEK NT-2000 (series I)		NIDEK NT-2000 (series III)	
year of clinical testing	2013		2019	
room	laboratory		ambulance	
air conditioning	yes		yes	
transfer standard	silicone eyes	eye model	silicone eyes	eye model
ambient temperature	21,2 °C	20,8 °C	22,5 °C	21,5 °C
atmospheric pressure	1001,5 hPa	1003,8 hPa	1014 hPa	1014 hPa
relative humidity of environment	41 % Rh	35 % Rh	30 % Rh	32 % Rh
number of measurement points	3	5	3	5

4. Results of the comparison

The intraocular pressure (IOP) calculation is done by the device, by using the time of the applanation at the pressure value generated by the air flow. For each cornea there are always 3 measurements, from which an arithmetic mean is calculated by the device (during patient examination). During the calibration, these measurements were performed 14 times for each pressure point.

The results from the realized metrological comparison using the silicone eyes and the model eye are processed from the measured values for each nominal pressure, subsequently the average is calculated against the given nominal value. Then the corrections of the average values in respect to the calibration curves resulting from the clinical trials were applied. And finally, the differences between the averages with and without correction according to the used verification methodology at CMI Most were determined.

The results are presented in Table 2 to Table 5 (the corrected value or corrected average expresses the measured IOP by the specific device that was adjusted by taking into account the results obtained from the clinical measurements according to ISO 8612:2009 [4]). These values are then compared with Table 6, which indicates the highest permissible measurement errors for the electronic non-contact eye tonometers, reported according to [5].
If we are to assess the highest permitted measurement error for the silicone eyes and for the eye model, then after the conversion and correction of the measured values, the errors are for both cases of standards in accordance with [5], except in one case (see table 5 is highlighted in red, for 11,25 mmHg nominal pressure point).

Tab. 2: Average results of measurements at CMI Most and Ružinov Hospital for silicone eyes

	CMI Most			Ružinov Hospital		
nominal value of pressure point	average	corrected average	Difference (average – corrected average)*	average	corrected average	Difference (average – corrected average)*
[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]
16	15,13	15,43	–0,31	16,50	16,17	0,33
22,8	23,28	23,54	–0,27	23,88	24,22	–0,35
42,5	44,02	44,17	–0,15	43,23	45,48	–2,24

*rounded

Tab. 3: Differences between CMI Most and Ružinov Hospital for silicone eyes

difference between CMI Most and Ružinov Hospital	corrected difference value
[mmHg]	[mmHg]
–1,38	–0,73
–0,60	–0,68
0,79	–1,31

Tab. 4: Average results of measurements at CMI Most and Ružinov Hospital for eye model

	CMI Most			Ružinov Hospital		
nominal value^{P} of pressure point	average	corrected average	Difference (average – corrected average)*	average	corrected average	Difference (average – corrected average)*
[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]	[mmHg]
Base**	14,02	14,33	–0,32	15,13	14,62	0,51
11,25	19,31	19,60	–0,29	22,54	22,76	–0,22
22,87	26,79	27,03	–0,25	29,35	29,95	–0,61
34,87	34,52	34,72	–0,20	34,87	36,29	–1,42
42,75	38,36	38,54	–0,18	40,11	42,03	–1,94

P – in eye model; pressure gauge error, including measurement uncertainty cca 0,33 %
* rounded
** without pressure load, represents the mechanical properties of the artificial cornea

Tab. 5: Differences between CMI Most and Ružinov Hospital for eye model

difference between CMI Most and Ružinov Hospital	corrected difference value
[mmHg]	[mmHg]
–1,12	–0,29
–3,23	–3,16
–2,56	–2,92
–0,35	–1,57
–1,75	–3,51

Tab. 6: Highest permissible measurement errors for non-contact eye tonometers

measuring range	maximum permissible error
[mmHg]	[mmHg]
0 to 19	±2
over 19 to 35	±3
over 35	±4

5. Uncertainty evaluation

The analysis and evaluation of the measured values on silicone eyes and a standard device eye model is summarized below. All of the provided results have been obtained for three nominal pressure points P_{nom} by measurements using two non-contact eye tonometers of the same type (Nidek NT-2000), series I in Most and series III in Bratislava.

Tab. 7: The values for Type-A uncertainty evaluation of the silicone eyes

P_{nom} [mmHg]	16,0	22,8	42,5
u_{AMost} [mmHg]	0,20	0,29	0,27
$u_{AMost\text{-}tot}$ [mmHg]	0,43		
u_{ABrat} [mmHg]	0,13	0,20	0,16
$u_{ABrat\text{-}tot}$ [mmHg]	0,28		
u_{Ase} [mmHg]	**0,52**		

Tab. 8: The values for Type-A uncertainty evaluation of the model eye

P_{nom} [mmHg]	base	22,87	42,75
u_{AMost} [mmHg]	0,14	0,11	0,14
$u_{AMost\text{-}tot}$ [mmHg]	0,22		
u_{ABrat} [mmHg]	0,14	0,15	0,20
$u_{ABrat\text{-}tot}$ [mmHg]	0,28		
u_{Ame} [mmHg]	**0,36**		

The standard uncertainty evaluated by method A (u_A) was obtained using statistical evaluation of 14 measurements for each nominal pressure value, each NIDEK NT-2000 piece; always in AUTO60 mode (this mode is automatic with a measuring range of 0 mmHg to 60 mmHg) on both NIDEK NT-2000 tonometers. The measured values were processed for each measuring range according to [5]. The results from two types of references, represented by the commercially available silicone eyes and an independently developed artificial cornea eye model, see Table 7 and Table 8, indicate that the levels of repeatability at each pressure range are comparable (u_{AMost} and u_{ABrat} referring to the measurements performed in Most and in Bratislava respectively) and the representative values ($u_{AMost\text{-}tot}$ and $u_{ABrat\text{-}tot}$ again referring to the measurements performed in Most and in Bratislava respectively and $\boldsymbol{u_{Ase}}$ and $\boldsymbol{u_{Ame}}$ meaning the grand total representative values for silicone exes and model eye rerspectively) were obtained via geometrical mean.
The standard uncertainty evaluated by method B (u_B) includes all other effects influencing the measurements, except statistical effects from the measured intraocular pressure values. The estimations of these influential factors are in Table 9.
Evaluation of an intraocular pressure is based on variables recorded by a tonometer which are afterwards used to calculate the intraocular pressure. These calculations are done by an internal algorithm that is unique for each manufacturer. The tonometer uses parameters such as applied pressure, time, elastic modulus of the eye tissue, especially the cornea. These values and the process of calculation is not available to the users or testing bodies.
Based on the study of literature, the experience of the Czech Metrology Institute, the measurements performed at the Ruzinov Hospital, at the Slovak Institute of Metrology, at the Slovak University Of Technology and at the Palacky University, we concluded the sources of uncertainty evaluated by Type-B method as presented in Table 9 for both the silicone eyes and the eye model.

Tab. 9: Estimated sources of uncertainty determined by the Type B method for the NIDEK NT-2000 non-contact eye tonometer

Uncertainty component		Uncertainty value / mmHg	Distribution
time measurement*	u_{B1}	0,001	uniform
uncertainty of generated pressure	u_{B2}	0,2	normal
distance between nozzle and cornea *	u_{B3}	0,005	uniform
corneal mechanical properties**	u_{B4}	0,7	uniform
microclimate*	u_{B5}	0,1	uniform
centering of jet nozzle*	u_{B6}	0,005	uniform
	u_B	0,73	

** Estimated value,*
*** Including corneal thickness. Estimated value based on experimental measurements.*

For the uncertainty evaluation, we took the representative uncertainties determined by the A method and combined them with all the uncertainty sources determined by the B method. The combined uncertainty u_C was then expanded by $k = 2$, which corresponds to a probability of covering the true value of 95 %. All the values are summarized in Table 10.

Tab. 10: Uncertainty Chart for Silicone Eyes and Eye Model Standard Device

Uncertainty component (impact assessed)		Standard uncertainty u_i [mmHg]	Distribution	Sensitivity coefficient c_i	Contribution to uncertainty [mmHg]	
					$c_i \cdot u_i$	$(c_i \cdot u_i)^2$
u_A	$u_{A\ \text{silicone eyes}}$	0,52	uniform	1	0,52	0,27
	$u_{A\ \text{eye model}}$	0,36	uniform	1	0,36	0,13
u_{B1}		0,001	uniform	1	0,001	$1 \cdot 10^{-6}$
u_{B2}		0,2	normal	1	0,2	0,04
u_{B3}		0,005	uniform	1	0,005	$2{,}5 \cdot 10^{-5}$
u_{B4}		0,7	uniform	1	0,7	0,49
u_{B5}		0,1	uniform	1	0,1	0,01
u_{B6}		0,005	uniform	1	0,005	$2{,}5 \cdot 10^{-5}$
$u_{C\ \text{silicone eyes}}$		0,90 mmHg				
$u_{C\ \text{eye model}}$		0,82 mmHg				
$U\ (k = 2)_{\ \text{silicone eyes}}$		1,80 mmHg				
$U\ (k = 2)_{\ \text{eye model}}$		1,64 mmHg				

6. Conclusion

The comparison showed that the both laboratory standards easily conform to the legal metrology requirements as stated in [5]. It also showed that both the transfer standards, silicone eyes and model eye can reach comparable results and uncertainties. The use of the long-time established silicone eyes was without any discrepancy. The model eye, although appears to be more promising in the upper range, still has some limitations that need to be solved in the lower range, where one discrepant results appeared. This remains the task for future investigations together with the long term stability determination, which will be part of cooperation between Slovak Technical University, SMU and CMI. These will first of all focus on the mechanical properties of the artificial cornea.

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