

A training centre for intraocular pressure metrology

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ABSTRACT

The eye-tonometers are the important medical devices with measuring function which are necessary for the screenings of the intraocular hypertension (a serious risk factor for the glaucoma). However, it is not an easy task to ensure their correct metrological traceability. There is needed not only a wide range of various equipment but also the relevant know-how. Hence, a training centre for this quantity was established at the Czech Metrology Institute (CMI) within the framework of a smart specialisation concept for the intraocular pressure (IOP) metrology. The paper briefly outlines its history, scope, methodologies and future development plans.

Section: RESEARCH PAPER

Keywords: Training centre; metrological traceability; eye-tonometer; intraocular pressure

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1. INTRODUCTION

The IOP belongs to the basic diagnostic indicators in ophthalmology and optometry. Although this quantity is monitored also in the veterinary medicine, this paper deals exclusively with the human medicine. The screenings of the intraocular hypertension serve, first of all, for the prevention and early diagnosis of the glaucoma. Hence, there is a high societal interest in the correctness of these measurements which are performed by the eye-tonometers, [1]-[4].

Some European countries (Czechia, Germany and Lithuania) consider these instruments so crucial that they are a subject of the legal metrology. However, harmonization in this area is relatively low across Europe, [5].

The IOP is still measured and referenced in the millimetres of mercury (1 mmHg \approx 133.3 Pa) for the historical and practical reasons, [6]. There is a consensus that the normal values should be within the range from 10 mmHg to 20 mmHg. However, the task of the metrology is to ensure traceability in the complete physiological and pathophysiological range up to 80 mmHg.

2. PROJECT HISTORY

To overcome the obstacles in building the IOP metrology, the national metrology institutes (NMI) of Austria, Czechia, Germany, Poland, Slovakia and Turkey, together with Technical University in Bratislava and Palacký University in Olomouc formed a consortium within EMPIR programme, solving project inTENSE, which ran from June 2017 to May 2020, [5]-[9]. The scope was much broader, of course, but the main results from the point of view of the cooperation of the European NMIs in this field is the foundation of a Smart Specialisation Concept (SSC) for the IOP metrology, [10], and a training centre for IOP metrology in the premises of the CMI in the city of Most which was built with an essential help of the German colleagues. The advanced trainings of the CMI personnel were also accomplished and the needed technical expertise was successfully audited. An important part was a satisfying bilateral comparison in the IOP between the CMI and the Slovak Technical University (STU) in the beginning of 2020 during which two clinically tested non-contact tonometers NIDEK NT-2000 served as the laboratory standards and a set of the silicone eyes and an artificial eye served

as the transfer-standards. The centre is now able to provide the metrological traceability and the relevant trainings to the other European NMIs.

From the beginning it was envisaged that the SSC would be extended in future geographically beyond the Central Europe and thematically beyond the IOP metrology. Hence, the training centre also plays a crucial role in the follow-up EMPIR project CEFTON, which runs from September 2021 to February 2023, [11]-[12], which focuses on the IOP metrology know-how transfer to the NMIs of the selected Central Europe Free Trade Agreement (CEFTA) countries. CMI joined the forces with the NMIs of Bosnia and Hercegovina, Moldova, and North Macedonia that will serve as the pathfinders for the remaining CEFTA countries. The project has no research ambitions being entirely focused on the capacity building and engaging in the SSC. The scope and content of the offered trainings as well as the plans for future will be presented.

3. OUTLINE OF THE TRAINING CENTRE

3.1. Scope of the trainings

First, it must be highlighted that the centre does not provide training of use of the eye-tonometers on the patients. This is the task of the medical doctors and nurses. The centre aims to provide training for the metrologists, i.e., the ways how to establish a correct traceability (calibrations and verifications) of the eye-tonometers and of the respective instrumental standards. The training is based on the good practice guidelines developed during the project inTENSE, [7], which in turn reflect the relevant international standards and recommendations as well as the German and Czech regulations, [13]-[17]. In contemporary, the scope of the training centre covers the contact (impression and applanation) tonometers [18]-[22], the non-contact tonometers [23]-[25], the rebound tonometers [25], [26] and the contour tonometers [21], [27].

3.2. Impression tonometers

Impression (or indentation or Schiøtz) tonometer is the oldest (more than 120 years) eye-tonometry principle still in practical utilisation, see Figure 1.

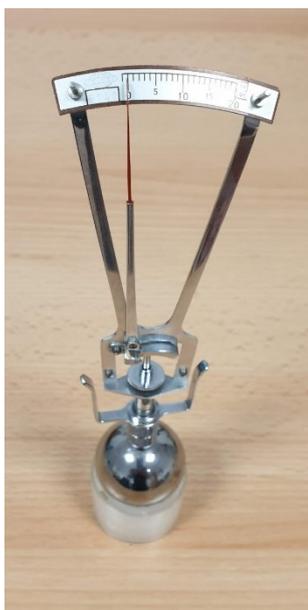


Figure 1. An impression tonometer placed on a precise calibration sphere.

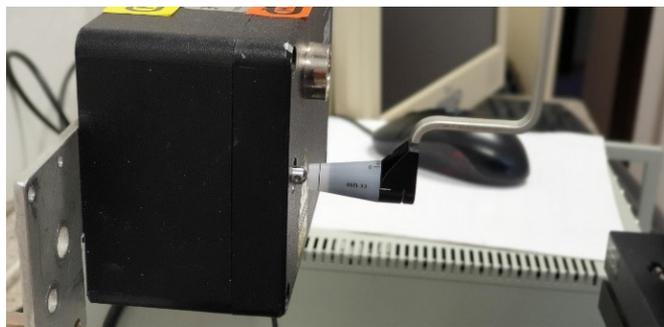


Figure 2. Calibration of an applanation tonometer (detail).

It determines the IOP by the depth of corneal indentation caused by a plunger with the exactly defined weight and dimensions. In order to measure the very high IOPs, extra weights can be loaded.

All these instruments are manufactured following the common standardized specifications. Hence, their traceability consists of the checks of all the prescribed geometrical (e.g., the curvatures of the contact areas) and mechanical (e.g., weights and friction) requirements and tolerance limits, see Figure 1. The weights can be checked by a mechanical or by an electronic balance in a special set-up. The laboratory is equipped with both.

3.3. Applanation tonometers

Applanation (or Goldmann) tonometer is also a long-time established principle but still considered to be a “golden standard.” It determines the IOP by measuring a force needed to reach an applanation (i.e., flattening) of a cornea caused by a transparent probe with a known contact area (a circle of 3.06 mm diameter).

The traceability of these instruments is again ensured in a classical way, by checking their geometrical specifications and optical quality and by calibrating their force sensor. Also in this case, the force can be defined by a mechanical balance or by an electronic sensor, see Figure 2. Again, the laboratory is equipped with both. The local acceleration due to gravity in the laboratory must be known with a sufficient precision.

3.4. Non-contact tonometers

The non-contact (or air-puff) tonometers are the most widely utilized tonometers in contemporary, because there is no mechanical contact with the eye during measurement resulting in no need of a topical eye anaesthesia. These instruments also aim at an applanation of a cornea, but they do not reach it by a direct mechanical contact (as Goldmann tonometers do), using instead a short and rapid pulse of air directed from a nozzle to the middle of a cornea. The moment of reaching the applanation is detected by a reflection of an infrared beam from the cornea. (In fact, we should speak about reaching a slightly concave shape instead of a real applanation.) The state-of-the-art devices are able to determine also other important ophthalmological measurands (e.g., central corneal thickness).

In contrast to the contact tonometers, there is no possibility of a direct classical traceability in this case. Their traceability must be ensured to another non-contact tonometer which is clinically tested (the training laboratory is equipped with one) via a suitable transfer standard. There are three possible types of transfer-standards available: a set of rubber (silicone) eyes, see Figure 3, an electronic eye and a flapper (PTB-jig), see Figure 4. The laboratory is equipped with all these devices, because none of these can be utilized universally with all the types of the non-

contact tonometers produced by the various manufacturers. The laboratory also took part in the mentioned above interlaboratory comparison in this quantity with the STU, [9].

A virtual digital model of the eye cornea was created at the STU during inTENSE Project. Then a real mechanical model (artificial eye) corresponding to the virtual model was constructed for the experimental verifications. The STU used this artificial eye as one of the transfer-standards in the mentioned above comparison. The target is to develop a „universal IOP transfer-standard“ with exchangeable artificial corneas of various thicknesses with a hydraulic or pneumatically regulated inner pressure, [8], [9], [24], [28]-[33], Figure 5 and Figure 6.

3.5. Rebound tonometers

The rebound tonometers emerged in the beginning of the 21st century and are becoming popular due to their ease of use (home diagnostic also possible). In this case, a very light and non-harming probe (plastic coated metal core with a spherical plastic tip) is ejected from the instrument against a cornea and is then reflected back into it. The probe movement can be monitored inductively, and the time response is used to calculate a value of the measured IOP.

The traceability of these instruments must be again ensured to a clinically tested rebound tonometer via a testing bench



Figure 5. The new transfer-standard during the comparison.



Figure 6. The new transfer-standard during the comparison.



Figure 3. A detail of a non-contact tonometer with a set of the rubber eyes.



Figure 4. A detail of a non-contact tonometer with a flapper.

consisting of a silicone membrane surrogating a cornea with an inner pressure regulated by a water column which enables to compare the readings of a clinically tested device and a calibrated device, see Figure 7 and Figure 8.



Figure 7. A rebound tonometer on its test bench.



Figure 8. A rebound tonometer on its test bench (detail).

3.6. Contour tonometers

The contour tonometer is another modern device. The head of this instrument has a concave shape corresponding to the typical shape and size of human cornea. The head is pressed to a cornea with a constant force (i.e., being in contact with the cornea but not applanating it). A miniature piezoresistive pressure sensor mounted in the head is then able to detect the IOP with such a sensitivity that it is even able to detect the minor IOP fluctuations caused by the cardiac cycle. The principle is less influenced by a corneal thickness or a corneal rigidity, but it is rather sensitive to a corneal curvature.

The traceability of this device can be relatively easily and straightforwardly ensured by a direct calibration of its internal pressure sensor, see Figure 9.

4. HISTORY OF THE TRAININGS

The first training for two experts of a German stakeholder took place during the project inTENSE in March 2020. Then these activities were interrupted due to the covid-19 pandemic. However, the trainings were resumed again in January 2022 within the project CEFTON when two colleagues from Bosnia and Herzegovina took part. It was followed by a training of six



Figure 9. A contour tonometer connected to a pressure standard.

people of the NMIs of Bosnia and Herzegovina, Moldova and North Macedonia in June 2022.

All the trainings took place at the training centre in Most and covered all the principles described above. It was found useful that both the instruments and the instrumental standards to which these are traceable are concentrated at one place. Hence, the attendees could more easily distinguish between “construction principles of the tonometers” and “traceability principles of the tonometers” which used to be a stumbling-block during theoretical lectures.

The only shortcoming found was the fact that the training does not cover Maklakoff tonometer. This predecessor and a very simplified variant of Goldmann tonometer has not been used in practice in the Central Europe for years but is still widely utilized in the area of the former Soviet Union.

5. TASKS FOR FUTURE

As it was mentioned in 3.4, some modern non-contact tonometers are able to determine more eye characteristics than the sole IOP value (e.g., corneal thickness, rigidity or hysteresis). However, it is still not solved how to ensure a traceability for these extra measurands. We remain in contact with the academic partners to solve these problems to. The artificial eye of the STU seems to be a good starting device for the studies of corneal thickness influence because it allows to utilize the artificial corneas of various thicknesses. Initial research in this direction has already started, [8]-[10] and Figure 10.

Also, we search for a possibility to obtain a sample of a Maklakoff tonometer and to establish a procedure for its traceability.

Moreover, as a greater emphasis is being given to the accuracy and reliability of the medical devices with a measuring function, [34]-[41], we consider the training centre a starting nucleus of further cooperation activities in the sector of medical metrology.

6. CONCLUSIONS

As a result of the fruitful cooperation of the European NMIs, the training centre for the IOP metrology at the CMI covers the most common eye tonometry principles, has the state-of-the-art equipment and remains in the intensive contacts with the NMI and academic partners to broaden its scope in the future.

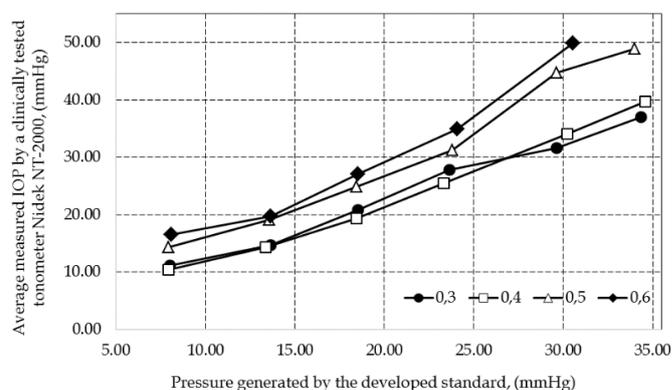


Figure 10. Experimentally found influence of the thickness of the artificial cornea on the non-contact tonometer response as found by the STU.

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