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Multi-sensor measurement of an insulin injection needle

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Abstract
Insulin injection needles are microparts which are produced in a very high number. Their outer diameter is slightly conical with a mean diameter of approx. 235 µm and the inner diameter is approximately 150 µm. Precise measurements of the geometry of the needles are urgently needed to support their quality assurance which to date is based on flow rate measurements.
This contribution describes multi-sensor measurements of the geometry of such a needle. The reference measurement of the part was carried out using a tactile-optical microprobe (3D fibre probe). Due to the high aspect ratio of the inner hole, the use of a custom dual sphere probe was necessary. The uncertainties of the reference measurement are 2.5 µm (outer diameter) and 1 µm (inner diameter). Additionally, the needle was measured using two industrial CT systems (voxel size approximately 3 µm) and a high-resolution CT scan using the synchrotron radiation source at Bessy II in Berlin, Germany (voxel size approximately 0.5 µm).
The results of the reference measurement were compared with the results achieved by the three CT systems. In this comparison, the different structural resolutions of the measurements must be taken into account.
The investigations were carried out within the European joint research project (EMRP) "Microparts". The needle is one of the workpiece-like reference standards used in the project.

Microparts, injection needle, fibre probe, multi-sensor measurement, computed tomography

1. Introduction

In the joint research project "Multi-sensor metrology for microparts in innovative industrial products (Microparts)" [1] of the European Metrology Research Programme (EMRP), a consortium of 16 partners, including national metrology institutes, designated institutes, universities, research facilities and representatives from industry, supplemented by 13 collaborators from industrial and research facilities, are working on the improvement of multi-sensor measurements of microparts using tactile probes, optical sensors, and computed tomography.

An important role in this project is played by workpiece-like reference standards, i.e. standards representing important industrial measurement tasks. One of the selected standards of this kind is a commercial needle for insulin injection from the health care company Novo Nordisk, Denmark.

This needle is produced in a very high number and its measurement is challenging due to its high aspect ratios, small diameters and low stiffness.

This paper compares measurement results on an injection needle achieved with different measurement techniques.

2. Measurement tasks

The measurement object (see Fig. 1 left) is an insulin injection needle made of steel. The outer diameter has a slightly conical shape with an outer diameter of approximately 240 µm. This shape is achieved by an electro-polishing process. The diameter of the inner hole is approximately 150 µm. Due to the manufacturing process, the form deviations are very large at the inner diameter (approx. 15 µm).

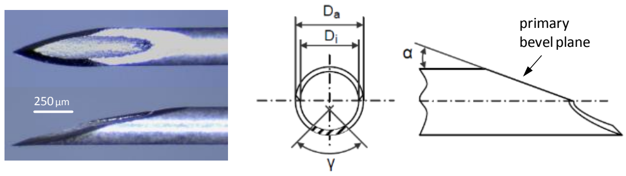

Figure 1. Injection needle and measurement tasks.

In order to reduce the pain when applying the needle, the tip of the needle is produced in a two-step grinding process. First, the primary bevel plane (see Fig. 1 right) is ground. After that, two secondary bevel planes are ground (lower half of tip shown in Fig. 1 right).

Before specifying the measurement tasks, a workpiece coordinate system was defined. The orientation of the z-axis is given by the orientation of the axis of the outer cone, positive to the needle's tip. The yz-plane is oriented perpendicular to the primary bevel plane. The intersection of the cone axis with the primary bevel plane defines the coordinate origin.

The measurement tasks are as follows (see also Fig. 1):

- Inner diameter D_i and outer diameter D_a at $z = -0.7$ mm (this ensures that there is no influence of the primary bevel plane)
- Outer cone $D_{a,Cone}$ at $-0.7 \text{ mm} \geq z \geq -4$ mm (5 equidistant circles)
- Diameter $D_{i,Cylinder}$ of the inner cylinder at $-0.7 \text{ mm} \geq z \geq -2.35$ mm (5 equidistant circles)
- Outer cone angle φ_{cone}
- Primary bevel angle α.

3. Measurements

3.1. Tactile reference measurement

The reference measurement of the needle was carried out by Werth Messtechnik, Gießen, Germany, with tactile-optical 3D (fibre) probes [2].

For the reference measurement of the outer diameter and the primary bevel angle, a standard 3D fibre probe with a tip diameter of 250 µm was used. The reference measurement of the inner diameter required the use of a special dual sphere probe to eliminate shadowing effects and shaft probing (see Fig. 2). With this kind of probe, the deflection of the probing sphere (tip diameter 100 µm) is derived from the measured deflection angle of a second sphere fixed to the probing shaft approximately 5 mm above the probing sphere. At every circle, 16 measurement points were determined by single-point probing. Due to shaft probing, the inner diameter could only be measured to a depth of 2.35 mm. The estimated expanded uncertainties (k = 2) of the reference measurement are 2.5 µm (outer cone diameter) and 1 µm (inner cylinder diameter).

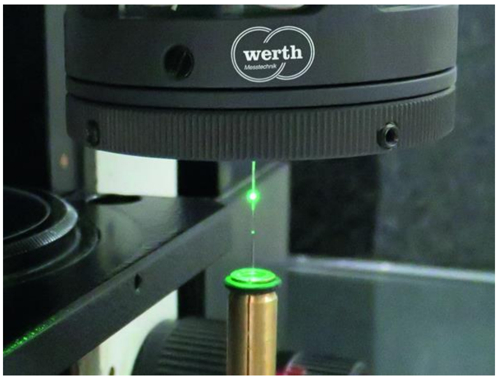

Figure 2. Measurement setup to measure the inner diameter with a dual sphere 3D fibre probe. The illuminated second sphere on the probing shaft is clearly visible.

3.2. Measurements with industrial CT

Measurements with industrial CT were carried out by PTB using a Nikon MCT225 and by Werth Messtechnik using a Werth TomoScope. The voxel size was approximately 5.3 µm (PTB) and 3 µm (Werth Messtechnik). During the evaluations, all measured points at the five equidistant circles given in section 2 were used. Under consideration of the workpiece-characteristics and the applied corrections the estimated expanded uncertainties (k = 2) of the diameter measurements with both CTs are in the order of 2.5 µm.

3.3. High-resolution synchrotron CT measurement at Bessy II

The needle was measured at BAMline [3] using the microscope device with the 10x objective, the pco.4000 camera, and a 25 µm thick CWO scintillator. The projected pixel size (0.4359 µm) was determined by shifting a reference object by 1 mm with the linear stage parallel to the scintillator and measuring the shift in detector pixels. Due to the very small measurement volume, only the circles at z = -0.7 mm could be determined. The estimated uncertainty of the diameter determination is 0.5 µm.

4. Results

The evaluation of the measured data was carried out with WinWerth Software (tactile reference measurement, CT measurement by Werth) and GOMInspect software (CT measurements by PTB and BAM).

The results are summarized in Table 1. Additionally, the results are shown graphically in Fig. 3.

Table 1. Measurement results (all diameters are in µm).

Measurement task	Tactile Reference	Industrial CT 1	Industrial CT 2	Synchrotron CT
D_a at z = -0.7 mm	238.1	234.8	235.3	232.3
D_i at z = -0.7 mm	155.5	158.1	152.5	159.4
$D_{a,Cone}$ at z = -0.7 mm	238.1	235.5	235.8	
$D_{i,Cylinder}$	155.3	158.2	151.4	
φ_{cone}	0.36°	0.35°	0.40°	
Bevel Angle α	10.82°	10.97°	10.81°	10.59°

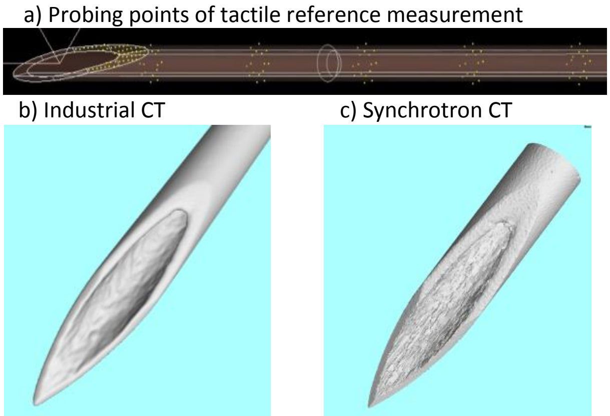

Figure 3. Graphical representation of the measurement results.
a) Location of tactile measurement points, b) result achieved with industrial CT 1 (tip region only), c) result achieved with synchrotron CT.

5. Conclusions and outlook

This article compares measurement results achieved on an insulin injection needle with a tactile microprobe and two types of CT systems with different resolutions.

There were large deviations measured at the outer diameter, which need to be analysed in more detail. The inner diameters, measured with industrial CT 1 and synchrotron CT, are larger than the inner diameters measured with the fibre probe. This is probably caused by the large form deviations in combination with the comparably large probing sphere. The tactile probe cannot measure grooves smaller than the tip diameter. Additionally, the surface determined by CT differs from the tactile surface, because it represents the average of the surface texture. The smaller inner diameters measured with CT 2 need to be analysed. A reason for different results achieved by industrial and synchrotron CT are probably caused by different artefact correction requirements and methods.

In future investigations, additional CT measurements will be performed and the CT results will be filtered and thinned out to achieve a better comparability to the tactile measurement. In addition, an optical measurement of the outer geometry is planned.

Acknowledgement

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