Advanced Capabilities for Testing Medical Needles on a Universal Micro Testing Machine MCR

Relevant for: Medical Needles, Tribology, Universal Micro Testing Machine MCR

Beside standard tribological setups the universal micro testing machine MCR is capable to cover a wide range of required applications. With the help of a newly designed measuring setup for medical needles, it is possible to realize quality control as well as improvements regarding geometry and needle materials. In this report medical needles were tested by varying environmental conditions and test parameters. In addition, the method was tested with different needles and septa to evaluate the versatility of the test setup.

1 Introduction

Medical equipment and devices must meet high safety standards. To ensure that the equipment can be used sensitively and, above all, safely by medical employees, the quality of the products must be checked sufficiently. Medical needles have to meet special requirements in this respect, as they come into direct contact with the human body. The standard DIN ISO 11040 part 4 defines the standards for testing medical needles (1). Even today, new materials are being researched and existing ones further developed that may find applications in medical syringes in the future. To get an overall impression of the performance of the material/geometry, tests in real environmental conditions are helpful. The universal micro testing machine MCR manages the balancing act by offering a highly sensitive sensor system and the ability to simulate a wide range of environmental conditions. A previous application report "*Novel Tribological Test Capabilities for Medical Syringes*" already demonstrated the application possibilities of the universal micro testing machine MCR with regard to the test possibilities of medical syringes.

In this report, needles with three different diameters are tested on two commercially available septa. The influence of the ambient temperature and the insertion speed on the force-displacement curve (F-s-curve) is determined.

2 Experimental

2.1 Test Setup

The test setup which is used in this report is a modified standard holder. The used sample was a septum which is usually part of plastic sealing caps. The cap was screwed on a glass vial with a volume of 4 ml. The sample was then fixed in a specifically designed sample mount (vial holder). To carry out a movement of the sample, the vial holder was attached to the linear drive. The upper drive of the universal micro testing machine MCR carried the needle. To allow a convenient and easy change of the needles a Luer-Lock adapter system was implemented on a standard MCR shaft. Figure 1 shows a schematic illustration of the used test setup. To ensure reproducible test results the septum, as well as the needle, was replaced for every single test run. Every parameter set was conducted three times to receive a satisfying statistical certainty.

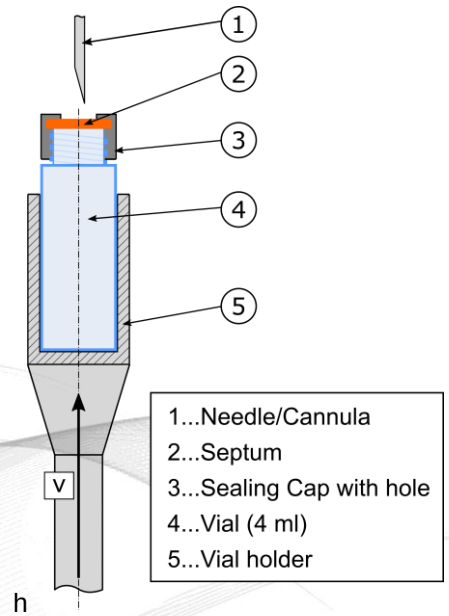

Figure 1: Schematic illustration of the used test setup.

2.2 Test Procedure & Parameters

2.2.1 Procedure

Figure 2 shows the penetration and cutting process during the experiment as well as a schematic presentation of the resulting force-displacement-diagram (F-s-curve) according to DIN ISO 11040 [1]. Figure 2 (i to iv) illustrates schematically the different states of the needle during the cutting/penetration process. In the beginning (i) the tip of the needle gets in contact with the septum. As the test proceeds, the force rises and the septum undergoes a deformation (i to ii). If the force exceeds a critical level the cutting process starts (ii). Within this process, the tip of the needle cuts the surface and penetrates the septum. At the end of the cutting process, the force reaches a maximum (iii). Subsequently, the cut septum gets widened to the diameter of the needle. This process leads to an additional maximum force (iv) at the end of the expansion.

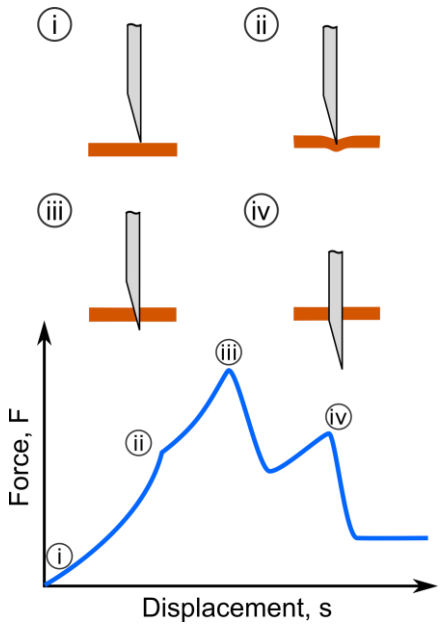

Figure 2: Force-displacement curve for the cutting and penetration process, according to DIN ISO 11040.

The recorded force-displacement data also includes the pull-out process of the needle (not displayed in Figure 2). In “Results and Discussion” these data are also illustrated.

2.2.2 Parameters

The selected test parameters are based on recommendations of the DIN ISO 11040 standard, which suggests a velocity of 50 mm/min. Due to manifold applications, the DIN ISO 11040 standard allows defining specific velocities to cover requirements for desired applications. Therefore, three different velocities were used within this study to check the capability of the test setup. Furthermore, the temperature was varied to simulate different ambient conditions. In Table 1 the used materials and test parameters are listed. Both septa consist of two different polymer layers. The top layer was either silicone or natural rubber and the bottom layer was PTFE.

Parameter	Value
Material septum 1 (SEP1)	Silicone/PTFE
Material septum 2 (SEP2)	Natural rubber/PTFE
Diameter needle	0.6, 0.9 and 1.2 mm
Sliding velocities	500, 1 000 and 2 000 µm/s
Ambient temperature	4 °C, 23 °C (RT) and 40 °C

Table 1: Used materials and test parameters.

3 Results and Discussion

3.1 Influence of Velocity

In Figure 3 the resulting F-s-diagram for SEP1 in combination with a needle of a diameter of 1.2 mm is displayed. At a sliding velocity of 500 µm/s the max. operating force was 4.02 ± 0.10 N, at 1 000 µm/s the maximum force reached 4.17 ± 0.06 N and at 2 000 µm/s the max. force was observed to be 4.09 ± 0.08 N. The results show no clear influence of the applied velocity on the resulting maximum operating force. The horizontal shift of the peak maximum is caused by the change of the septum after each test. The touch point of the needle tip varies within a few micrometers, because of small deformations during compression and fixture with the sealing cap. This leads to small deviations in course of the cutting process.

The pull-out process provides similar results. The minimum force, in this case, is between -0.75 N and -0.83 N and shows no correlations between the velocity level and the force level.

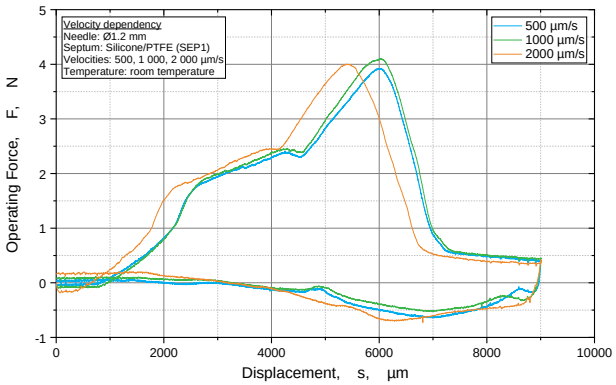

Figure 3: Resulting F-s-curve for a needle with a diameter (Ø) of 1.2 mm and SEP1. Tested at 500, 1 000 and 2 000 µm/s and at ambient conditions.

3.2 Influence of Temperature

Since a universal micro testing machine MCR can be equipped with a convection temperature device (CTD) the testing temperatures can be freely selected in the range of -160 °C to +600 °C. Figure 4 reveals a significant influence of the ambient conditions on the F-s-diagram. The average values of the maximum forces show similar trends for the measurements at 5 °C (4.12 ± 0.16 N) and at 23 °C – room temperature (4.24 ± 0.14 N). At 40 °C the required operating force decreases to an average maximum force of 3.35 ± 0.11 N. Due to higher temperatures, the polymer becomes softer and facilitates the indentation process. As a consequence, the max. operating force decreases, whereby the characteristics of the curves are comparable to those of lower temperatures (RT).

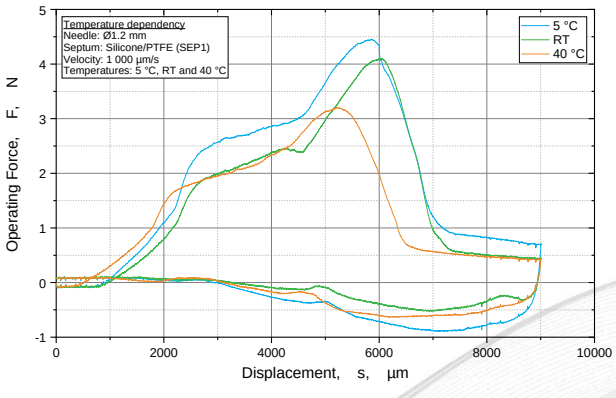

Figure 4: Resulting F-s-curve for a needle with Ø = 1.2 mm and SEP1. Tested at 5 °C, 23 °C (RT) and 40 °C and 1 000 µm/s.

3.3 Influence of the Septum

Figure 5 exhibits an exemplary presentation of the F-s-curves of two different septum types. The septum equipped with a natural rubber top layer (SEP2-green line) provides a significantly lower operating force level. The average max. operating force for SEP1 (silicone/PTFE) is 4.18 ± 0.08 N and for SEP2 (natural rubber/PTFE) it is 1.62 ± 0.90 N. It can be seen that for SEP2 the maximum force level decreases. This results in a flatter development of the F-s-curve and enhances the control of the force during application. However, the pull-out process shows relatively small differences between the two material combinations. The average minimal force for SEP1 is -0.45 ± 0.17 N and for SEP2 it is -0.55 ± 0.08 N.

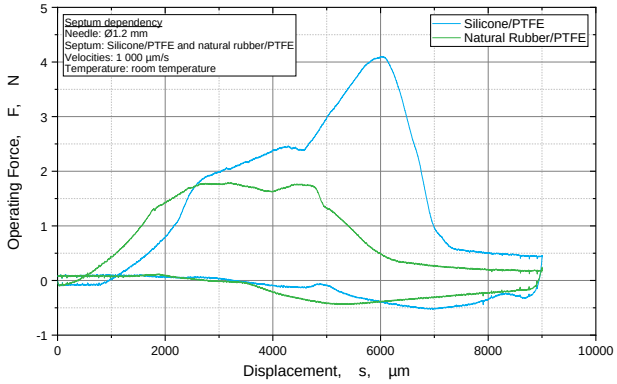

Figure 5: Resulting F-s-curve for a needle with Ø = 1.2 mm, at 23 °C and at 1 000 µm/s. Tested with a silicone/PTFE and a natural rubber/PTFE septum.

3.4 Influence of the Diameter of the Needle

The last section of this report deals with the influence of different needle diameters on the F-s-curve.

In Figure 6 results of the experiments are displayed using needles with a diameter of either 0.6 mm, 0.9 mm or 1.2 mm. Larger diameters result in increasing maximum forces. Due to the larger diameter of the needle, it takes more effort to widen the material after the cutting process. In general, this leads to a higher force level and the maximum load is rising strongly. The average max. force for a diameter of 0.6 mm is 1.17 ± 0.19 N, for 0.9 mm it is 1.85 ± 0.15 N and for 1.2 mm the max. force reaches 4.17 ± 0.06 N. The pull-out forces show the same trend. If needles with a larger diameter are used, the pull-out process needs to overcome higher resistance. The average min. forces are -0.49 ± 0.03 N (Ø = 0.6 mm), -0.61 ± 0.09 N (Ø = 0.9 mm) and -0.75 ± 0.17 N (Ø = 1.2 mm).

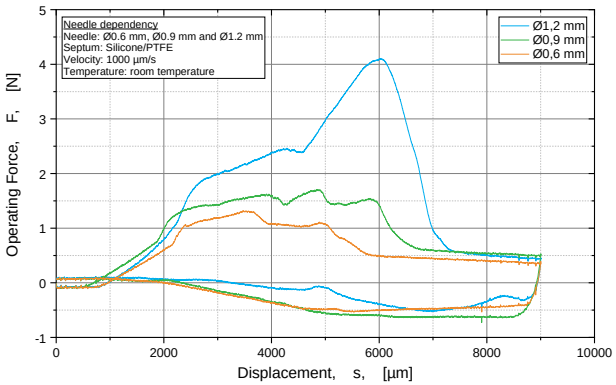

Figure 6: Resulting F-s-curve for three different needles with diameters of Ø = 0.6 mm, Ø = 0.9 mm and Ø = 1.2 mm and SEP1. Tested at 23 °C and with a velocity of 1 000 µm/s.

4 Conclusion

The newly developed test setup was implemented successfully on a universal micro testing machine MCR. The obtained results show clear trends for temperature, the material composition of the septum, and the used needle diameter. The used velocity showed no detectable influence on the required operating forces. It was observed that higher temperatures reduce the required operating force. Especially temperatures above room temperature have a significant impact on the needed forces. Within this study, it was also examined that the diameter of the needle has a notable influence on the maximum operating force. A larger diameter leads to higher forces. Comparative observations between two different setups showed a clear difference and form of the actuation force that must be applied.

Through this setup, it is possible to test a wide base of medical needles. Besides basic quality control, this setup can also be used for further developments of the geometry or materials of these products. Due to the high-resolution sensor technology a detailed analysis of the required operating force is feasible. Completed with comprehensive equipment for the control of the environmental conditions (CTD), almost all fields of applications can be tested and simulated.

5 References

1) DIN ISO 11040-4:2017-07, Vorgefüllte Spritzen - Teil 4: Spritzenzylinder aus Glas für Injektionspräparate und sterilisierte und vormontierte Spritzen zur Abfüllung (ISO_11040-4:2015)

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