# Novel Tribological Test Capabilities for Medical Syringes

**Relevant for: Tribology, Syringes, Health Care, Medical Devices, Universal Micro Testing Machine MCR**

Medical syringes must meet high standards before they can be used on patients. Sensitive operation of them by the medical staff independent from material and environmental influences ensure safe use. Therefore, tribological properties play a decisive role in the development and quality control of these products. For this purpose, a novel test setup has been developed, which allows high sensitivity characterization of static and dynamic operating forces of prefilled/unfilled medical syringes.

## 1 Introduction

Prefilled syringes are omnipresent in modern health care systems and the number as primary packaging for biopharmaceuticals has increased constantly over the past years [1,2]. According to estimates, about 400,000 people die each year in the USA as a result of preventable medical errors [3]. Therefore, the ambition is that errors due to incorrect and careless operations should be reduced to a minimum. Gentle and controlled injection of the vaccine or drug is essential for safe and painless application in infusion therapy. In this case, knowledge of the force-displacement curve and thus the tribological performance of the overall system is a key value. Besides these parameters, the novel test setup can also be used to test and evaluate quality characteristics of the entire syringe system and the product quality close to the intended application.

This report aims to evaluate the most important tribological parameters, such as breakaway forces and sliding forces, on two commercially available syringes by using a novel developed test setup for the universal micro testing machine MCR. Furthermore, the influence of barrel material, ambient temperature, and injection media on operation parameters are investigated.

## 2 Experimental

### 2.1 Sample Mount and Test Setup

The core component of this test configuration is a novel designed sample mount displayed in Figure 1, showing the used sample mount (a) with an optional adapter sleeve (b) and the installed test setup at an universal micro testing machine MCR. The sample mount is attached to a linear drive for dynamic mechanical analysis (DMA) (e) which allows a vertical movement up to 9.4 mm. A measuring plate PP25 serves as a stamp (d), which is connected to the lift motor of the universal micro testing machine MCR, simulates a fixed counterpart and remains static during a test run. The solid shaft of the sample mount (a) is manufactured as hollow-body to provide volume for injection media. The syringe is placed in the upper section of the sample mount and fixed by a headless screw.

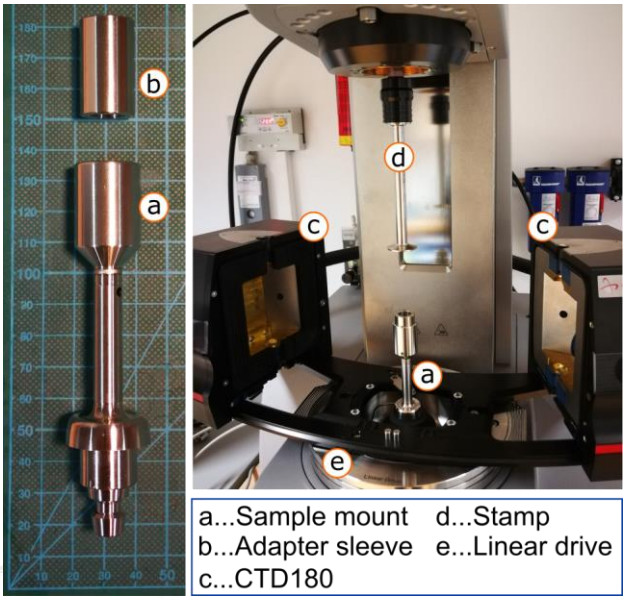


Figure 1: Sample mount with optional adapter sleeve (left) and implemented setup with stamp and a convection temperature device (CTD) (right).

Since drugs or vaccines should be stored and administered at specific temperatures (e.g. stored at 4°C in the fridge) a highly accurate temperature control chamber, either CTD180 or CTD600 (c), is used that can extend the testing temperature range from -160 °C up to 600 °C. Thus, testing conditions very close to the estimated application conditions can be realized.

## 2.2 Test Procedure

The developed test procedure can be divided into two main steps:

(i) *Preparation*, this includes pre-compression of the syringe and temperature conditioning if tests are carried out at higher or lower temperatures.
(ii) *Measurement*, in this step a force-displacement curve is recorded.

In step (i) the plunger rod and the plunger (elastomeric seal) are positioned at a defined starting-point before starting the measurement. This guarantees to cover the same section of the syringe for each test. After compressing a decompression step of 0.2 mm is set to avoid initial forces due to thermal expansion and give the elastomeric seal space for possible relaxation processes. After decompression, the temperature conditioning of the sample starts. Step (ii) covers the recording of a force-displacement curve for defined parameters. Figure 2 illustrates a schematic plot of a force-displacement curve. Important areas for further analysis and interpretation are marked with circles. After 200 µm of free travel, the piston encounters a static counterpart (stamp). The force increases until the static friction limit (breakaway force) is reached, where the plunger starts to move. Due to the motion of the plunger the force decreases and leads to the dynamic friction region (sliding force area).

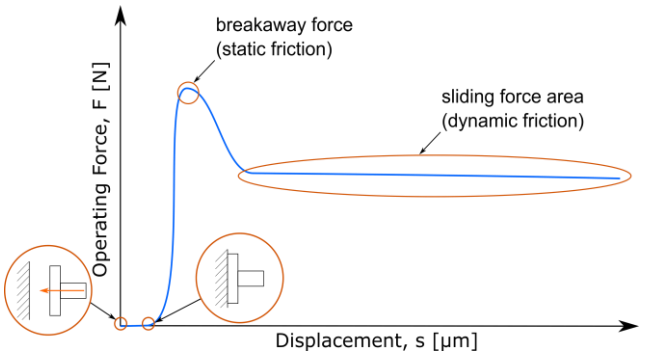


Figure 2: Schematic plot of force against displacement (F-s-diagram). Important areas for analysis are marked with orange circles.

## 2.3 Syringes and Test Parameters

### 2.3.1 Used Syringes

This report covers the evaluation of two different commercially available syringes. Both types were 3-piece single-use syringes equipped with an elastomeric plunger (seal-ring), a barrel, and a plunger rod (piston). The major difference can be found in the used material of the barrel. Syringe A (3 ml) consists of a glass barrel, and syringe B (10 ml) is made of a polymer (polypropylene). Due to the limited space of the temperature chamber, syringe B had to be prepared in the sense that the cylinder was halved in advance. Syringe A was used without further preparation.

### 2.3.2 Test Parameters

The investigations aimed to evaluate the tribological performance in different application related situations. Therefore, ambient temperature, sliding velocity and injection media was varied. Table 1 lists an overview of the used test parameters.

| Parameter | Value |
|---|---|
| Temperature range | -10 °C, 4 °C, 23 °C (RT) and 40 °C |
| Sliding velocity | 500 µm/s and 1,000 µm/s |
| Injection fluid | air (unfilled), dist. water and saline (0.9 % NaCl) |
| Max. stroke | 9 mm |

*Table 1: Overview of the used test parameters.*

The sliding velocity varies between 500 and 1,000 µm/s for all conducted experiments. The investigations of the influence of injection media were carried out exclusively at room temperature and 4 °C. The temperature dependence was realized by performing additional tests at lower (-10 °C) and higher temperatures (40 °C). However, these experiments were performed only with unfilled syringes (air). Three different media were used to investigate effects on operating forces and the tribological performance. Air (unfilled syringe) presents the default state, whereby distilled water and saline (0.9% NaCl solution) simulate commonly used injection media.

# 3 Results & Discussion

## 3.1 Reproducibility and Influence of Barrel Material

Figure 3 shows a force-displacement-diagram (F-s-diagram) for unfilled glass (syringe A) and polymer syringes (syringe B) with 3 repetitions (a, b, c). The samples were tested at room temperature and a sliding velocity of 500 µm/s.

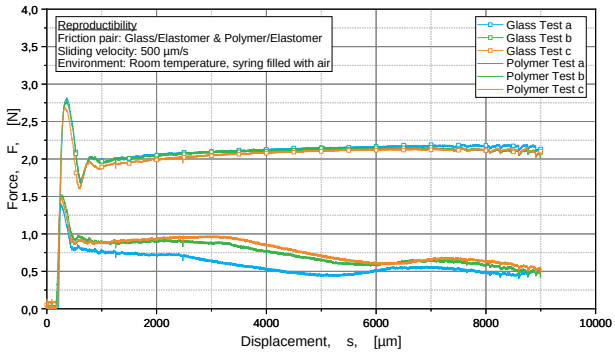


Figure 3: F-s-diagram for unfilled glass (marked line) and polymer (line) syringes, tested at a sliding velocity of 500 µm/s and at room temperature.

Both types offer a high reproducibility for the operating forces as well as for the level of the sliding force within the test series for specific parameters. Moreover, the influence of the barrel material on the operating forces can be well displayed. In this case a glass barrel made syringe offers significant higher operating forces compared to syringe provided with a polymer barrel. The maximum force (breakaway force) of syringe A was determined at 2.76 N (±0.07 N) and 1.47 N (±0.06 N) for the polymer syringes.

### 3.2 Influence Operating Temperature

Figure 4 gives an insight how breakaway forces and overall sliding force level depend on the ambient temperature for unfilled glass syringes at 1,000 µm/s.

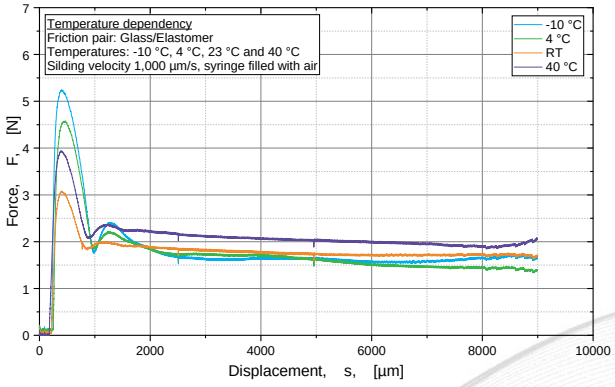


Figure 4: F-s-diagram for unfilled (air) glass syringes, tested at a sliding velocity of 1,000 µm/s. Variation of the temperature between -10 °C and 40 °C.

Tests at -10 °C show the highest breakaway force (5.25 N), followed by tests conducted at 4 °C (4.58 N) and 40 °C (3.94 N). Although the previous test series suggest a tendency, tests at room temperature (RT) show the lowest breakaway forces (3.08 N). The average sliding force level ranges from 2.01 N (40 °C) to 1.57 N (+4 °C) and is on a comparable level for all experiments. Figure 5 shows the F-s-diagram of unfilled (filled with air) syringes made of a polymeric barrel. Likewise, the tests were conducted in the same temperature range (-10 °C to +40 °C) and sliding velocity of the plunger was defined with 1,000 µm/s.

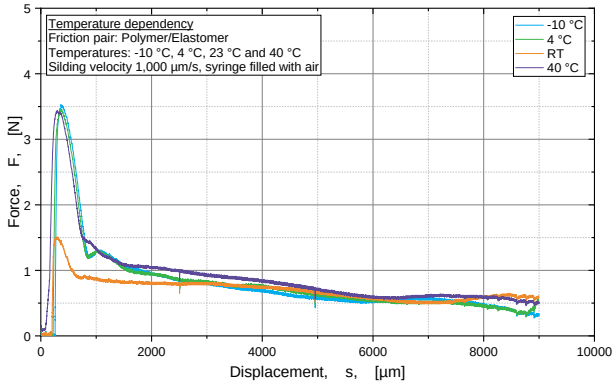


Figure 5: F-s-diagram for unfilled (air) polymer syringes tested at a sliding velocity of 1,000 µm/s. Variation of the temperature between -10 °C and 40 °C.

Since, the barrel material is for these syringes a polymer, the friction pair changes as well. This may lead to a change in the tribological behavior concerning operating forces. As stated in Figure 5 the breakaway forces for -10 °C (3.53 N), 4 °C (3.46 N) and 40 °C (3.44 N) are nearly identical. In contrast the maximum of the operating force at room temperature is considerably lower (1.51 N). Nevertheless, it can be observed that the level of the operating forces after the breakaway point differ from each other, due to material differences.

### 3.3 Influence Injection Media

Syringes are used with a wide range of liquids and chemicals and to show possible influences on the F-s behavior 3 different injection media (air, distilled water and saline) were compared. Figure 6 shows the dependency of the operating force on filling media at room temperature and a sliding velocity of the plunger of 1,000 µm/s.

It was observed that glass syringes offer higher breakaway forces for all tested conditions compared to polymer syringes. Additionally, both syringe types exhibit a dependency of the breakaway force and the sliding force on the injection media at room temperature. In particular, syringes filled with saline show the highest values for both types of syringes.

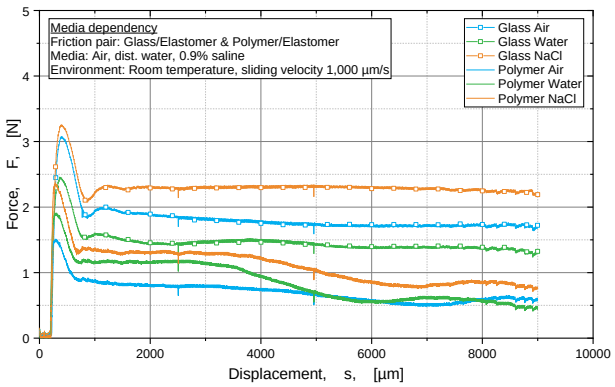


Figure 6: Dependency of the operating force on the injection media at ambient temperature for glass and polymer syringes.

The dependency of the operating forces at a temperature of 4 °C is shown in Figure 7. Generally speaking, the breakaway forces are considerably higher compared to values obtained from tests at room temperature (see Figure 6).

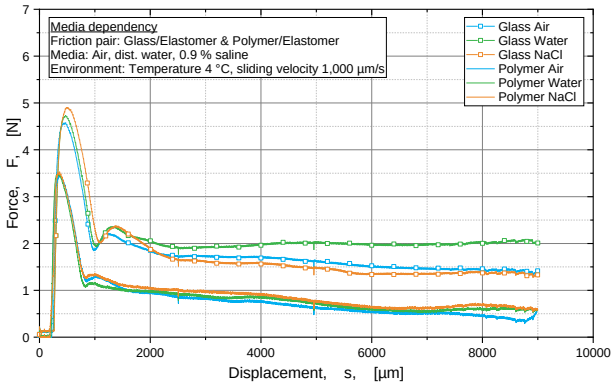


Figure 7: Dependency of the operating force on the injection media at 4 °C for glass and polymer syringes.

Glass syringes show a higher level of operating forces ($F_{Air}$ = 4.58 N; $F_{H2O}$ = 4.74 N; $F_{NaCl}$ = 4.91 N) compared to polymer ones ($F_{Air}$ = 3.64 N; $F_{H2O}$ = 3.50 N; $F_{NaCl}$ = 3.53 N). By the same token, this was also observed in previous observations (see section 3.1, Figure 3). The operating forces for polymer syringes show no evidence of dependency from the used injection media. This leads to a nearly identical performance in terms of tribological behavior. The same pattern was also observed for glass made syringes.

## 4 Conclusion

A novel designed test unit for the universal micro testing machine MCR was successfully implemented and tested for a broad range of various cases of applications. The conducted experiments show an excellent reproducibility for different operating temperatures, sliding velocities, injection media, and types of syringes.

Investigations of operating temperatures between -10 °C and +40 °C exhibit the lowest breakaway forces at room temperature. This effect was observed for both types of syringes, whereby syringe A showed a stronger characteristic of temperature dependence than syringe B.

Furthermore, the measurement setup is able to detect influences of different injection media on the operating forces for both syringe bodies. The impact of the injection media on the operating forces is more pronounced at room temperature than at 4 °C. At 4 °C a clear separation between syringe A and B was observed. However, in contrast to tests performed at room temperature no significant dependency of the used injection media was found.

## 5 References

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