Hydrophilic Coating Friction Test
A non-standard test to enhance in-vitro simulation

During the design process for interventional devices, many parameters and choices can affect the functional performance of the final product and in the end may provide a competitive edge against similar devices on the market. Several well known in-vitro test methods, such as Trackability, are used to assess the functional performance of interventional devices during simulated use. Trackability is a direct proximal measurement of the force required to advance a device in a tortuous anatomical path.

One design parameter that can influence trackability test results is the quality of the hydrophilic coating covering the outer surface of the device. Coating chemical formulation and surface finish vary greatly between manufacturers and lead to variable device performance characteristics. Even though trackability testing can be used to provide an overall assessment of the device performance in an in-vitro environment, it is difficult to determine which part of the device contributes the most to its performance.

To assess the impact of each individual component, and provide engineers with useful, actionable data, we have developed an in-house hydrophilic coating friction test to assess the performance of the hydrophilic coating on interventional devices. The results from a hydrophilic coating friction test provide guidance to engineers on addressing design issues including:

- Static friction = initial force required to start the test article moving
- Dynamic friction = drop off in force seen after movement begins
- Coefficient of friction (COF) = calculated by dividing the tracking force by the applied pinch load
- Durability = number of cycles to failure (failure can be set arbitrarily for example percentage increase in friction).

The key benefit of this study is to provide a comparison between groups of samples (for example to test several coatings or compare samples to a reference device). No standard exists for this test. It has been created based on a technical paper[1]. The results given by this study have no real physiological representation, because neither the pinch force/distance nor the material of friction are physiological.

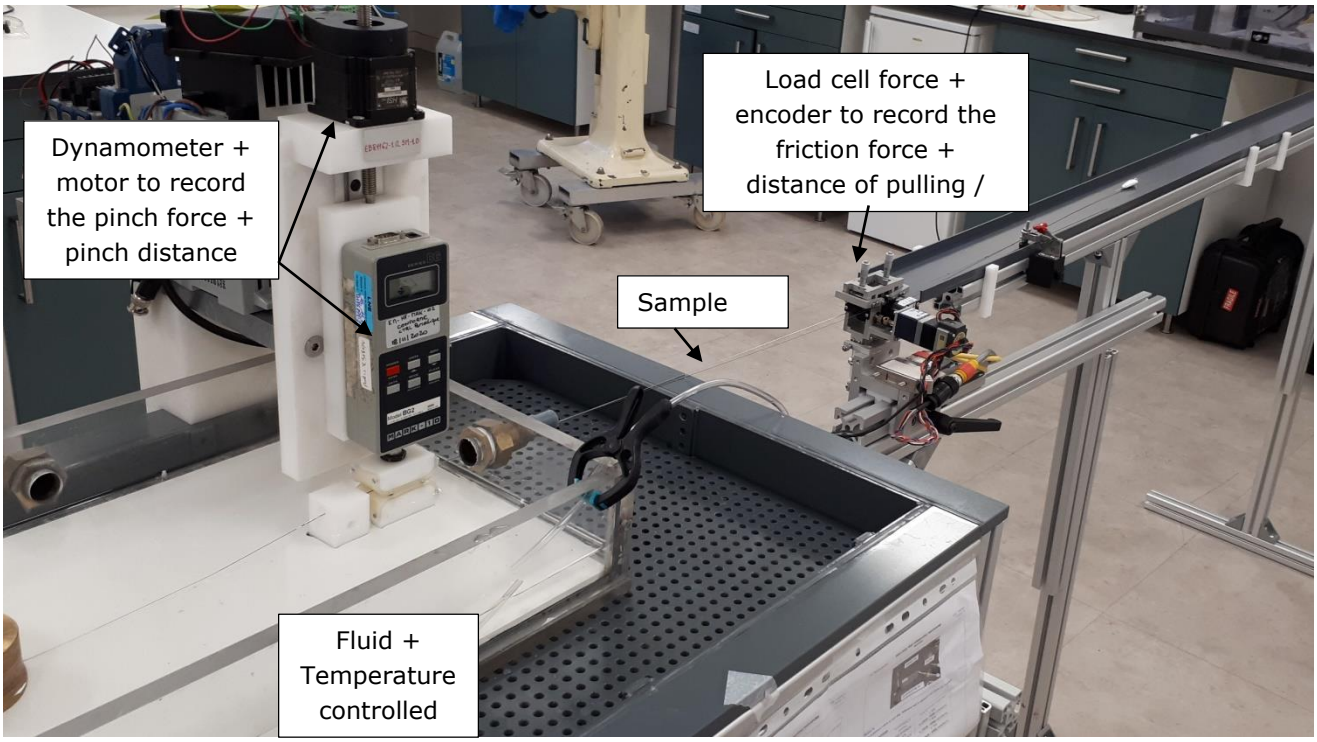
Our hydrophilic coating friction test shows how non-standardized test methods can address specific questions. In this example, our engineers have used their knowledge in equipment handling, instrumentation, setup, traceability, documentation, calibration and qualification to develop a non-standardized test method that assesses the performance of interventional medical devices in a simulated environment.

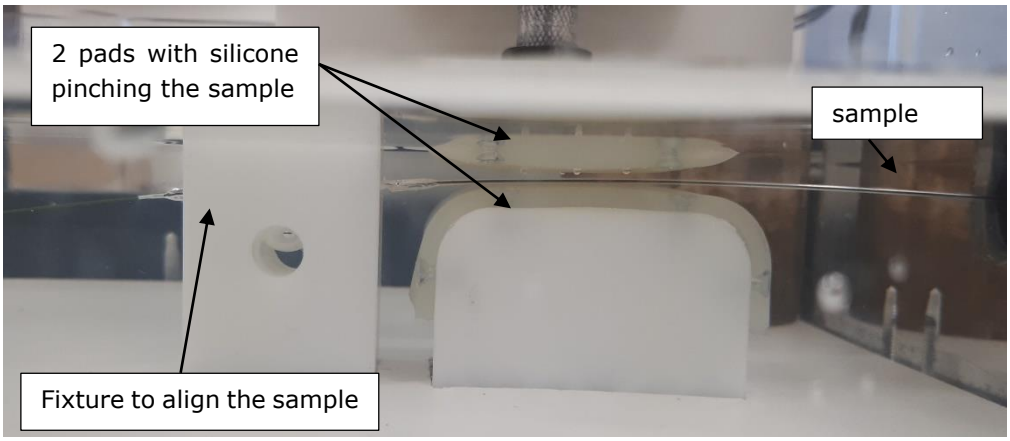
We have designed a customized tester which uses the capabilities of the IDTE system from Machine Solutions Inc and a published test method[1] for a hydrophilic coating friction test. The result is a unique test equipment solution that optimizes machine usage thereby increasing return on investment on an existing piece of equipment that optimizes setup time and expends our testing capabilities in relation to catheter testing. Our engineers have applied their test expertise, a known test method and a reliable development process to provide an efficient and cost effective solution to address a specific testing need that can be used by any R&D engineering group.

[1] Biocoat Technical White Paper: "Effect of Testing Parameters on Pinch Test Results for Hydrophilic Coatings" by J. Li, J. Simon, W. Work, 2012.

METHOD

This test involves pinching the sample between two plates (pads) with a known amount of force or a defined distance between the two plates, while using the IDTE roller system to pull and/or push the test sample through the plates. The force to pull and/or push the device through the plates is measured by the IDTE recording system. Passing the device through the pinch test fixture multiple times will eventually cause the coating to fail and friction readings will increase significantly.

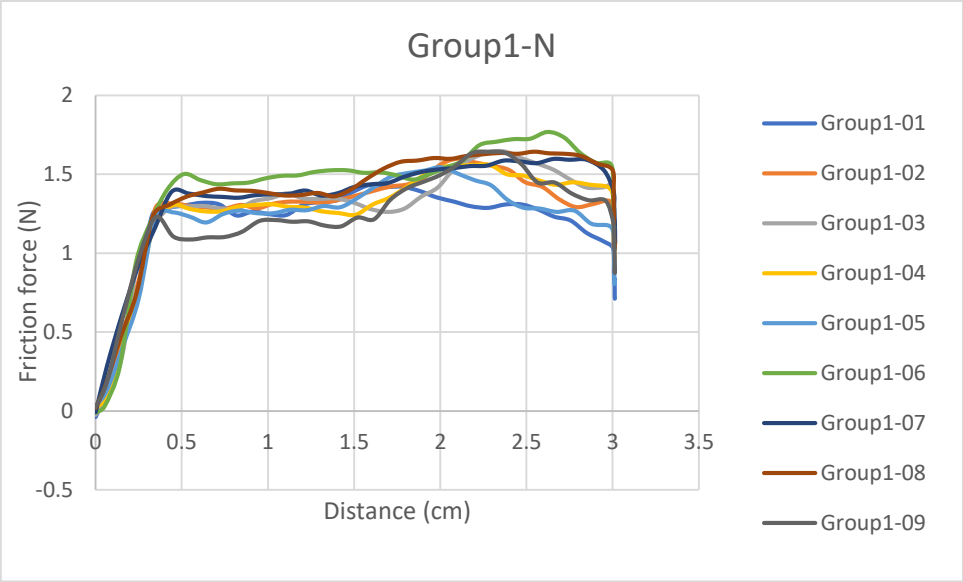


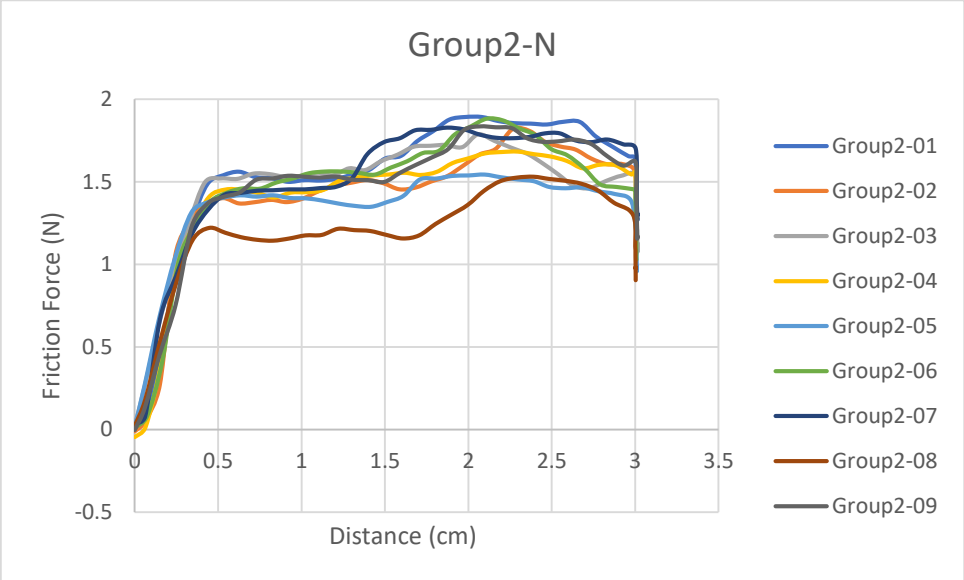


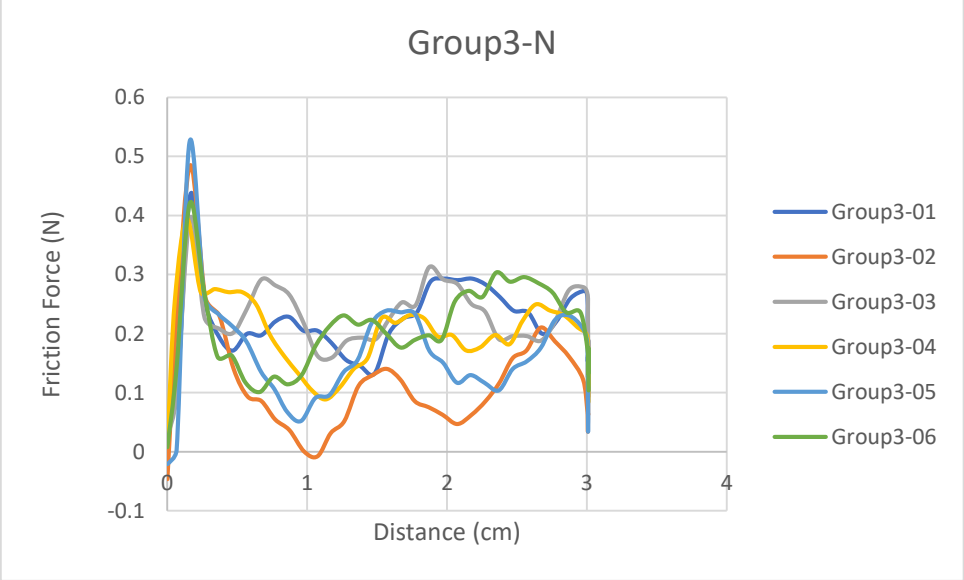
SIMPLIFIED OUTPUT

A comparative study was conducted on 2.50 x 40mm PTCA ETO sterilized catheters. The 24 samples were separated in 3 groups with various coating formulations, Group 1 with 9 samples, Group 2 with 9 samples, Group 3 with 6 samples. A total of 4 standard interventional 0.014'' guide wires (Cougar, Medtronic) were used to provide support for the catheters as required in standard interventional procedures. All samples were tested in randomized order combined with each of the 4 new guidewires.

The average friction force was statistically different between group 1 and 3 and between group 2 and 3. The difference was not statistically different between group 1 and 2. The maximum friction force had similar/same patterns. Group 1 and Group 2 exhibited the highest average force and maximum force. The friction force variation over the distance is represented for each sample of each group. The behavior of group 3 was significantly different than the rest of the groups.







The results of the hydrophilic coating friction test show significant differences between at least 2 groups. Group 1 and 2 were from the same manufacturer, but had different formulations, whereas group 3 was a reference device currently commercialized and used in current clinical applications. The study reveals the hydrophilic coating friction test is successful in determining differences in coating formulation and surface finish which vary between these two manufacturers.

CONCLUSION

The hydrophilic coating friction test shows how non-standardized test methods can be created to address specific questions and issues. In this example, our engineers use the knowledge required in equipment handling, instrumentation, setup, traceability, documentation, calibration and qualification to develop a non-standardized test method to assess the performance of interventional medical devices in a simulated environment. The results provide valuable input to R&D engineers during the development process.