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Simulated Testing in Medical Device Design

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Bench-top testing of a typical catheter is described here to show how early prototype evaluation can decrease product development time. Trackability and pushability are assessed and compared using some novel laboratory tests, which can be applied to a variety of medical devices.

Image: Eyewire Images

The test sequence

Developers of new medical devices are keen to perform animal testing early in the product-development process. Yet, a properly constructed laboratory-based test sequence will produce convenient, reproducible and cost-effective results. This approach facilitates a better understanding of how devices will perform in vivo and permits product designers to appraise early prototype designs in the laboratory. Additional benefits include an accelerated product-development timescale and lower overall development costs.

Medical devices are tested against a range of requirements at various stages in their life cycle. Numerous groups need to be satisfied by this device testing at different phases throughout the design process, for example:

- Feasibility testing following completion of the initial design phase; extensive testing is performed on the prototype to ensure the required product performance can be met.
- Statistically valid testing is required for regulatory approval.
- Performance and comparative testing for marketing groups to illustrate ease of use, performance enhancements and superiority over competitive products, data that are essential for creating a sales message in the field.

The objective of the testing will determine the approach that is taken. Unsophisticated test setups are adequate early in the design cycle to confirm that the device will perform its basic functions. At a later stage in the process, the design can be tested against relevant standards or the product specifications. The evaluation of new designs usually follows a general sequence such as

- Phase 1: Bench testing
- Phase 2: Preclinical animal studies
- Phase 3: Clinical evaluation (restricted availability)
- Phase 4: Clinical application (unlimited availability and further trials).

Industry usually performs Phases 1 and 2 without clinical input, hence the accuracy of the results from these Phases is essential. These Phases encompass testing of all materials and prototypical devices prior to testing or use in humans. Guidance in designing test plans for prototypical medical devices may be obtained from a number of sources. However, most guidance documents are relatively nonspecific in nature and require the application of sound scientific method to the specific device in question.

Table I: Established tests used in the evaluation of new designs.

Balloons	Stents	Catheters/Delivery systems
Bond ($\sigma_{TS}/\sigma_C/\sigma_P$) strength	Bend/σ_F strength	Bond ($\sigma_{TS}/\sigma_C/\sigma_P$) strength
Diameter and profile	Radial strength	Bend/ σ_F strength
Pressure testing	Diameter and profile	Diameter and profile
Inflation and deflation time	Stent crimping	Contrast media flow rate
	Fatigue testing	Crossing profile
		Tip pulling and torquing
		Trackability and pushability
		Kink resistance
		Deployment force

σ_{TS} = Tensile strength, σ_C = Compressive strength, σ_P = Peel strength, σ_F = Flexural strength.

Devices should be tested in animals to evaluate performance characteristics only after changes in material and design have been completed during product development. Hence, Phase 1 testing must involve a large number of mechanical and chemical tests. Some of the most established mechanical test methods are listed in Table I.

Moving to Phase 2 testing

Many medical device manufacturers are keen to conduct initial animal testing prior to the completion of a full range of bench testing. Although animal models offer an in vivo environment, their anatomy and physiology can differ significantly from that of a human. As well as differences in structural anatomy, the size of, and accessibility to the site requiring intervention must also be compatible with clinical device function and use in man. For example, the size of the access (femoral) artery for percutaneous vascular devices must be similar to that of man, which is approximately 8–10 mm outer diameter (o.d.). Few common laboratory animals have a femoral artery this large.[1] Hence, selection of an animal model for preclinical medical device testing is a complex and often difficult task. It can also be costly, time consuming and require dedicated facilities. Furthermore, it is difficult to compare many characteristic qualities because the measurement conditions are not standardised.[2,3] Consequently, the use of bench-top equipment that can replicate the anatomy and in vivo environment in question, facilitates quick, cost-effective, repeatable and comparable results.

Simulated 2D Phase 1 testing

Two-dimensional (2D) tortuous vessel pathways have been used in the past to great effect during the development phase of a large number of devices. For the purposes of illustration in this discussion, bench-top testing will focus on the testing of a typical catheter; however, similar testing can be applied to practically any medical device. The application of known failure modes (risk assessment) is employed by most engineers to identify the sequence in which tests will be performed. Device models chosen for testing should encompass the range of ideal characteristics to be achieved and consider, for example, the most tortuous vessel pathways and environmental factors.

Trackability test

Measurement of a stent delivery system's trackability allows the designer to obtain measured force values for prominent points in the 2D model via the charted curves. The forces obtained allow an assessment of typical tracking qualities and enable comparison of competitive systems. The higher the trackability force, the more force the physician will have to exert to track the device to the location requiring treatment. This would result in a higher probability of a perforation in the vessel. Figure 1 (a) is an illustration of a typical 2D model. This model is used in the trackability testing of stent delivery systems. The route chosen can be changed to suit the desired tortuous path being replicated. The test was performed using custom-made equipment as shown in Figure 1 (b). The water bath lies in a horizontal position and the crosshead has mobility along it. After the guidewire is fed into the model, the catheter is threaded up the guidewire and advanced through the chosen pathway. Silicone tubing is normally used inside the 2D model to reproduce as closely as possible the dimensions and texture of the vessel. The red line marked in Figure 1 (a) follows the path taken during a particular trackability test. The black arrow indicates the point at which the test commenced. The parts underwent 60° and 90° bends during the trackability test.

Test results

Various samples were tested using this path. Comparisons of some sample results are presented in Figure 2. The test is sensitive enough to recognise a 7% reduction in o.d. between Sample A →

Figure 1: (a) One of the peripheral models used, which can be adapted to the anatomical relationships of different vascular regions. The red line represents the path taken during the test. (b) Custom-made trackability testing equipment.

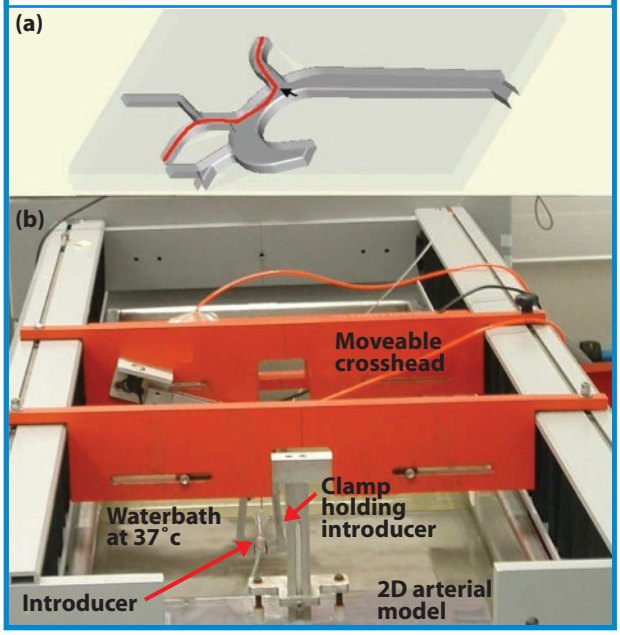


Figure 2: (a) Trackability graphs; (b) pushability values obtained for sample A and sample B.

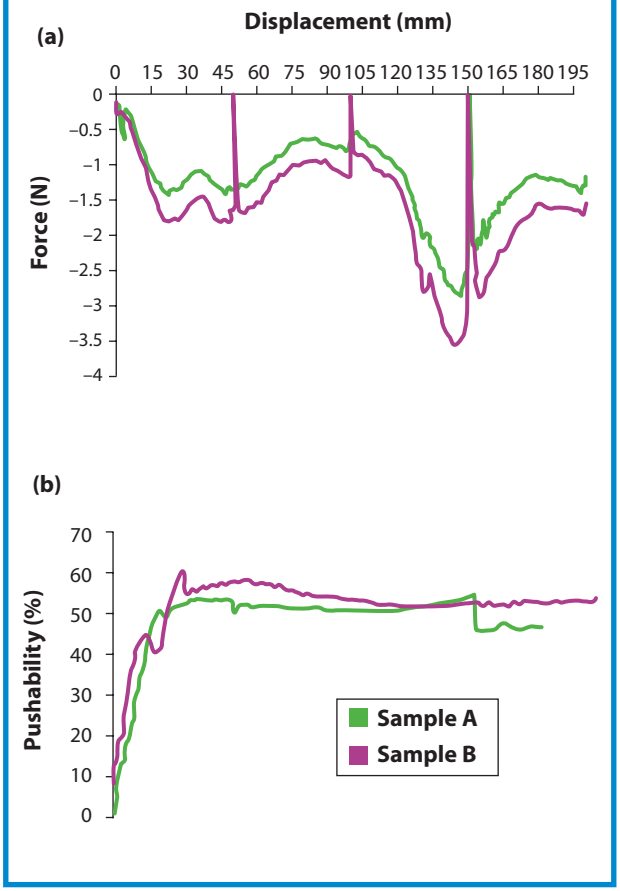


Figure 3: (a) Trackability and (b) pushability results obtained during benchmark testing of stent delivery system A and stent delivery system B.

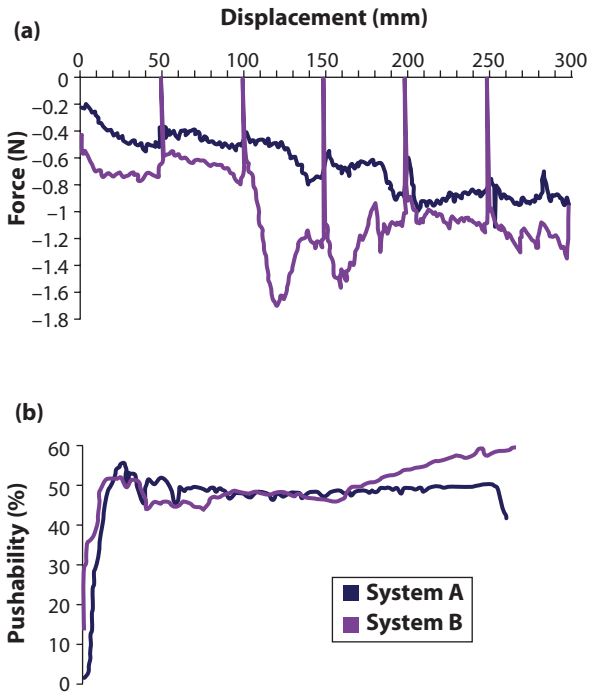
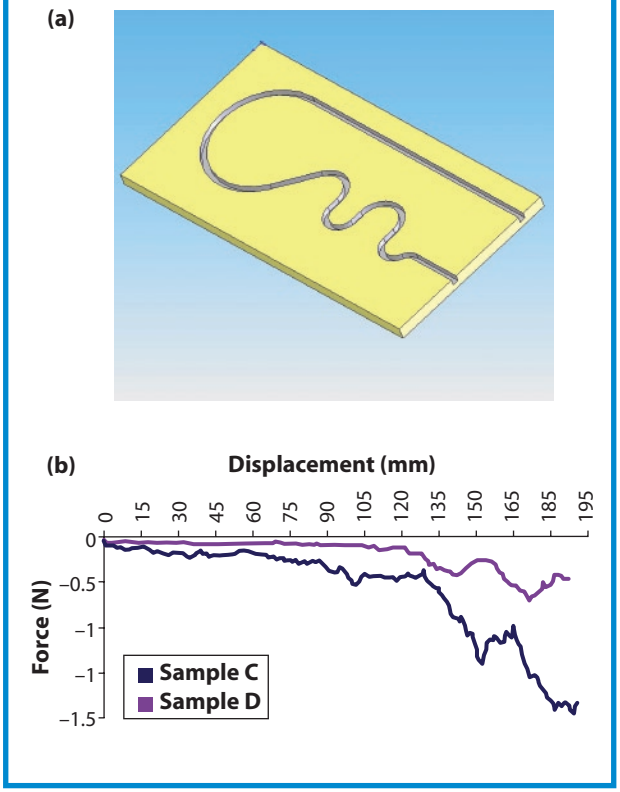


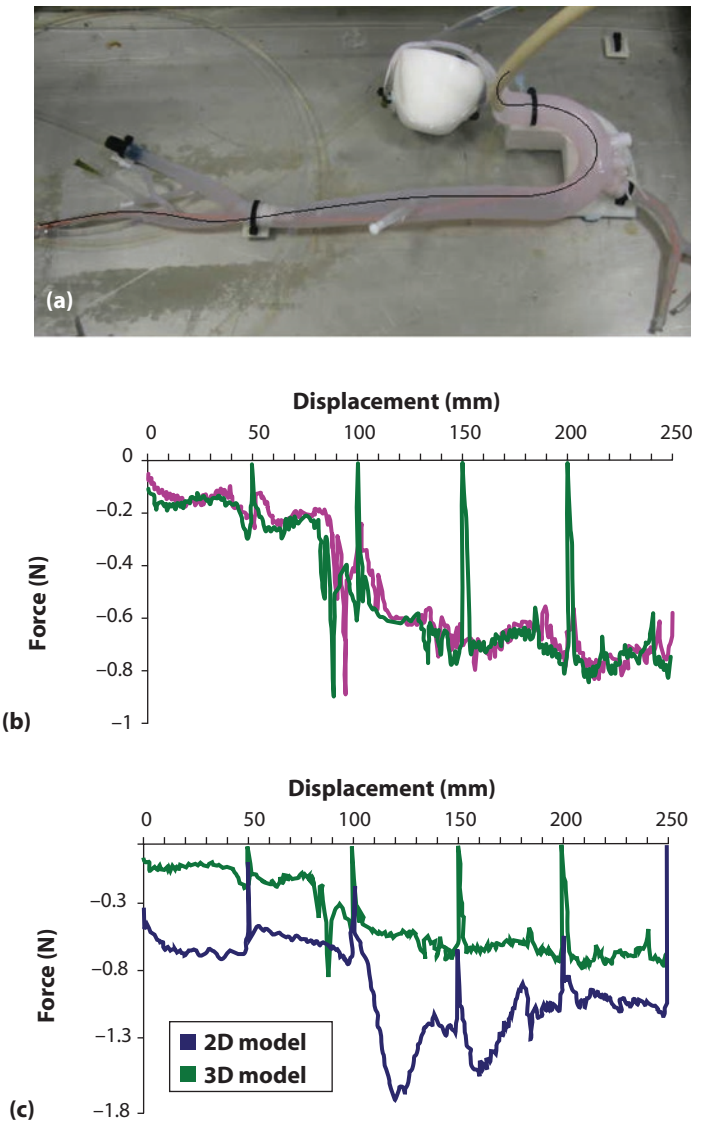
Figure 4: (a) Coronary block model; (b) trackability test conducted on sample C and sample D.



and Sample B. It is clear from Figure 2 (a) that the trackability force has decreased with a reduction in o.d. of the sample. The results of pushability tests conducted on the same samples along the same path are shown in Figure 2 (b). A 6% reduction in pushability was recorded when the o.d. was reduced by 7%.

Benchmarking a new or existing product against an accepted market leader is a common practice in the medical device industry. Trackability and pushability are frequently used when considering the pros and cons of a device with a physician. The trackability and pushability results for two competitive stent delivery systems are shown in Figure 3, where the model in Figure 1 (a) was used. The systems were pushed and released every 50 mm for 300 mm during the trackability test to imitate the physician's insertion of the system during a procedure, hence the vertical lines present in Figure 3 (a). When comparing the results, it is clear that although delivery system A and delivery

Figure 5: (a) Overview of the 3D vascular track model in which the black line indicates the path taken during trackability testing; (b) trackability curves obtained for stent delivery system B using 3D model show repeatability of test; (c) comparison of trackability curves obtained for delivery system B using the 2D and 3D models.



system B have similar pushability characteristics, system A requires less force to track through the same pathway.

Similar investigations were performed to measure the effect that surface treatments had on the trackability of a stent delivery system. Figure 4 (a) illustrates the 2D coronary model used in this test. The outer surface of Samples C and D, which were made of the same base catheter, were treated with similar coatings. Sample C was coated with a lubricious, hydrophilic coating and Sample D had a slightly different, covalently crosslinked, hydrophilic polymer coating. As can be seen in Figure 4 (b), Sample C experienced greater frictional force during the tracking process compared with the results obtained with Sample D.

Simulated 3D Phase 1 Testing

The next generation of testing has evolved with a three-dimensional (3D) model of the vascular system. A glycerine–H_2O composition with equivalent viscosity to blood[4] is circulated through the model using a pulsating pump (Figure 5). A pulse rate of 70 beats/min is employed during use. The guidewire is tracked to the intended location, followed by a guide catheter. The force required to track the stent delivery system under investigation along the guidewire is subsequently recorded.

Delivery system B employed in Figure 3 was tracked through the 3D model using the path indicated in Figure 5 (a). Trackability curves presented in Figure 5 (b) indicate that the test generates repeatable results. The 3D model is a replica of the 2D model used to test delivery system B in Figure 3. Both results are compared in Figure 5 (c). It is clear that the force required to track delivery system B through the 2D model is greater than that recorded using the 3D model. From past experience, this dissimilarity reflects the variation in results when comparing 2D model results with those obtained from animal trials.

The 3D model was further evaluated to ascertain whether or not it could distinguish minor variations in stent delivery systems. Two stent delivery systems with different tips were tracked through the model and the forces were recorded. The path taken during the execution of this investigation is shown in Figure 6 (a). At approximately 195 mm, the device emerges from the guide catheter, which results in an increase in track force. The system with Tip A experiences greater track forces (1.42 N) when it emerges from the guide catheter, as shown in Figure 6 (c), compared with the system with Tip B (1.10 N). These results suggest that the model set-up is sensitive enough to differentiate between minor differences in stent delivery systems.

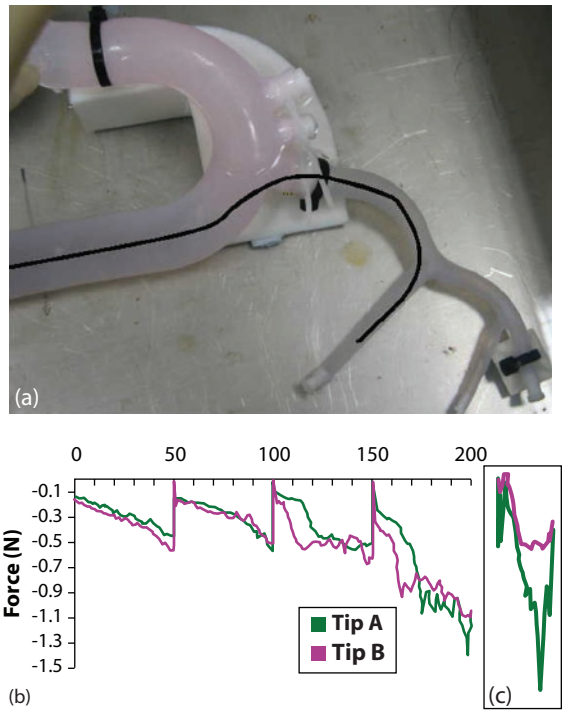
Conclusion

Although trackability testing is not a requirement by the United States Food and Drug Administration or International Organisation for Standardisation standards, it is becoming an increasingly important performance measure. Most medical device organisations evaluate this feature and use it as an input to development. This is so common that the medical establishment has listed it as a parameter it needs to know.[5–6] Most consultant cardiologists judge the performance of the devices they use on their ability to track to the site location:

"It provides excellent trackability … is suited for both proximal and distal lesions … This is among the most popularly used stents in Europe, because of its remarkable trackability."[6]

Therefore, by allowing designers to evaluate early prototype designs realistically in the laboratory, trackability testing can help decrease product development time, while providing functional comparative data.

Figure 6: (a) The black line indicates the path taken during testing of Tip A and Tip B; (b) trackability curves obtained for Tip A and Tip B; (c) a close-up of the maximum tip force recorded.



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