**Simulated Testing in Medical Device Design**

While the developers of new medical devices are keen to perform animal testing early in the product development process, 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 permitting product designers to appraise early prototype designs in the laboratory, accelerating the product development timescale and lowering overall development costs.

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**Introduction**

In 1929, a German surgical trainee, Werner Forssmann, experimented on a human cadaver and realized how easy it was to guide a urological catheter from an arm vein into the right atrium. He went so far as to dissect the veins of his own forearm and guide a urological catheter into his right atrium. With the catheter in place, he walked to the x-ray room with no ill effects to have his chest x-rayed, see Figure 1. This made Forssmann the first to document right heart catheterization in humans using radiographic techniques. In return, he was fired from his position at the hospital, however won the Nobel Prize in 1956.

One suspects that it would be quite difficult to find a doctor/design engineer prepared to test a new device on themselves! 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:

- Feasibility Testing - following completion of the initial design phase, extensive testing is performed on the prototype to ensure it achieves the required specifications.
- Regulatory Approval – this testing is generally conducted to provide confidence of device safety prior to use in humans in a clinical trial.
- Performance and Comparative Testing for Marketing Groups – testing to illustrate ease of use, performance enhancements and superiority over competitive products are keystones to creating a sales message in the field.

**The Test Sequence**

The objective of the testing will determine the approach. Unsophisticated test setups are adequate early in the design cycle in order to confirm 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 & further trials).

Industry is responsible for phase 1 and 2. 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 non-specific in nature and require the application of sound scientific method to the specific device in question.

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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 include:

**Table 1 List of established tests used in the evaluation of new designs.**

<table>
<thead>
<tr>
<th>Balloons</th>
<th>Stents</th>
<th>Catheters/Delivery Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bond $(\sigma_{TS}/\sigma_C/\sigma_{peel})$ strength</td>
<td>Bond/$\sigma_i$ Strength</td>
<td>Bond $(\sigma_{TS}/\sigma_C/\sigma_{peel})$ strength</td>
</tr>
<tr>
<td>Diameter &amp; profile</td>
<td>Radial Strength</td>
<td>Bend/$\sigma_i$ Strength</td>
</tr>
<tr>
<td>Pressure testing</td>
<td>Diameter &amp; profile</td>
<td>Diameter &amp; profile</td>
</tr>
<tr>
<td>Inflation &amp; Deflation time</td>
<td>Stent Crimping</td>
<td>Contrast media flow rate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Crossing profile</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tip pulling &amp; torqueing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trackability/Pathability</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kink resistance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Deployment force</td>
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</table>

**Moving to Phase 2 Testing**

Many medical device manufacturers are keen to conduct animal testing prior to the completion of a full battery of bench testing. While animal models do offer an *in vivo* environment, their anatomy and physiology may differ significantly from that of a human. In addition to structural anatomy, the size and accessibility to the structure 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 (~8-10 mm $\phi$). 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 since 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, would allow quick, cost-effective, repeatable and comparable results.

**Table 2 Explanation of the terminology used to describe various examination techniques.**

<table>
<thead>
<tr>
<th>Test</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trackability</td>
<td>The ability of the system to advance distally along the path of the vessel, including in narrow tortuous vessels.</td>
</tr>
<tr>
<td>Pushability</td>
<td>The ability of the system to transmit sufficient, even force proximally, allowing equal &amp; smooth movement distally.</td>
</tr>
<tr>
<td>Flexibility</td>
<td>The ability of the stent/delivery system to bend in order to accommodate a turn or angle it is required to negotiate, &amp; the flexibility of the stent to conform with the vessel after the stent is deployed.</td>
</tr>
<tr>
<td>Torque strength</td>
<td>The ability of the joints/tip to resist fracture on the application of torque.</td>
</tr>
<tr>
<td>Torqueability</td>
<td>The efficiency with which the device can transfer torque between the proximal and distal sections (i.e) the number of rotations required to get the device to turn once.</td>
</tr>
</tbody>
</table>

**Simulated 2D Phase 1 Testing**

Two-dimensional tortuous vessel pathways have been used in the past to great effect during the development phase of a large number of devices. For the purpose of illustration in this discussion, the examination of bench top testing will focus on the testing of a typical catheter, however, similar testing can be applied to practically any
medical device. Table 2 provides an explanation of some of the terminology used for mechanical testing of parts. The application of known failure modes (risk assessment) is employed by most engineers to identify test selection. Device models chosen for testing should encompass the range of ideal characteristics to be achieved and consider the most challenging circumstances to which they could be exposed (e.g.) tortuous vessel pathways, environmental factors etc.

### Test Design - Trackability
Measurement of a systems’ trackability allows one to obtain measured force values for prominent points in the two-dimensional 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 energy the physician will have to input to track the device to the location requiring treatment. This would result in a higher probability of producing a perforation in the vessel. Figure 3 (a) is an illustration of a typical two-dimensional model. This model is used in the trackability testing of Stent Delivery Systems (SDS). The route chosen can be changed to suit the desired tortuous path being replicated. The test was carried out in custom-made equipment as shown in Figure 3 (b). The water-bath lies in a horizontal position, while 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 pathway chosen. Silicone tubing is normally used inside the 2-D model in order to reproduce the vessel dimensions and texture as closely as possible. The red line marked in Figure 3 (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

![Figure 3](image)

**Figure 3 (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 equipment.

![Figure 4](image)

**Figure 4 (a)** Trackability graphs and **(b)** Pushability values obtained for Sample A (■) & Sample B (□).

Various test samples were tested using this path. Comparisons of some sample results
are presented in Figure 4. The test is sensitive enough to recognise a 7% reduction in OD between Sample A and Sample B. It is clear from Figure 4 (a) that the trackability force has decreased with a reduction in sample OD. The results of pushability tests that were carried out on the same samples along the same path are shown in Figure 4 (b). A 6% reduction in pushability was recorded when the OD was reduced by 7%. As mentioned previously, benchmarking a new/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 2 competitive devices are shown in Figure 5, where the model in Figure 3 (a) was used. The devices were pushed every 50 mm for 300 mm for the trackability test, hence the vertical lines present in Figure 5 (a). Comparing the results, it is clear that although device A and B have very similar pushability characteristics, device A requires less force to track through the same pathway.

![Figure 5](image)

**Figure 5 (a) Trackability & (b) Pushability results obtained during benchmark testing of Device A (■) & Device B (▲) SDS products.**

Similar investigations were carried out in order to measure the effect that surface treatments had on the trackability of a SDS. Figure 6 (a) illustrates the two dimensional coronary model used in this test. The outer surface of samples C and D, which were made of the same base catheter, were both treated with similar coatings. Sample C was coated with a lubricious, hydrophilic coating, while the coating used for Sample D was a slightly different, covalently crosslinked, hydrophilic polymer coating. As can be seen from Figure 6 (b), Sample C experienced greater frictional force during the tracking process when compared to the results obtained with Sample D.

### Simulated 3D Phase 1 Testing

![Figure 6](image)

**Figure 6 (a) Coronary block model (b) trackability tests carried out on Sample C (■) & Sample D (▲).**

The next generation of testing has evolved with a 3-dimensional model of the vascular system. A glycerine/H$_2$O composition, with equivalent viscosity to blood[^4], is circulated through the model as shown in Figure 7, using a pulsating pump. A pulse rate of 70 beats per minute is employed during use.
The guidewire is tracked to the intended location, followed by a guide catheter. The force required to track the device under investigation along the guidewire is subsequently recorded. Device B employed in Figure 5 was tracked through the 3-D model using the path indicated in Figure 7(a). Trackability curves presented in Figure 7(b) indicate that the test generates repeatable results. The 3-D model is a replica of the 2-D model used to test Device B in Figure 5. Hence, both results were compared in Figure 7(c). It is clear that the force required to track Device B through the 2-D model is greater than that recorded using the 3-D model. These results would suggest that current trackability indicators are not as close, as purported, to forces experienced in-vivo.

The 3-D model was further evaluated to ascertain whether or not it could distinguish minor variations in SDS devices. Hence, two devices 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 8(a). At approximately 195 mm, the device emerges from the guide catheter, which results in an increase in track force. The device with Tip A experiences greater track forces (1.42 N) when it emerges from the guide catheter, as shown in Figure 8(c) compared to the device with Tip B (1.10 N). These results suggest that the model set-up is sensitive enough to differentiate between minor differences in devices.
Conclusion

Although trackability testing is not a requirement per FDA and ISO standards, it is becoming an increasingly important performance measure. Almost all of the multinational medical device organisations measure this parameter and use it for marketing purposes. So much so that the medical establishment have listed it as a parameter they need to know\cite{5-6}. Senior 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"\cite{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.

References