MEDICAL ENGINEERING TECHNOLOGIES

TECHNICAL AND SCIENTIFIC SOLUTIONS

Force Testing in Medical Devices

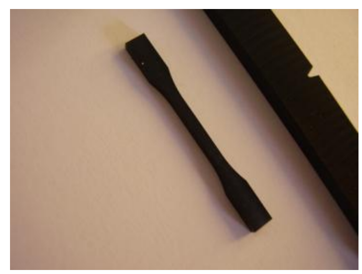
Introduction

Force testing machines are sometimes termed universal testers as they have a wide variety of applications. Many of the testing modes available on these machines are relevant to medical device manufacture and development. But, the forces in question are much smaller than a ‘classic’ universal tester would be set up to do. Relevant testing modes include: torque, compression, flexing, peel, repetitive strain, impact and tensile tests. This article examines the variables in a testing process and their application in medical device testing.

The variables in the testing process include: sample dimensions and orientation, gauge resolution, sample rate, speed of movement and repeat testing frequency.

Sample Dimensions and Orientation

When a new material is being selected for use in a product it is often the well known ‘dumbbell’ shaped sample that is used for testing. The sample shape and dimensions for these tests are defined in ISO 527 1997 *Plastics -- Determination of tensile properties*. It is important for the testing of these samples that the gripping jaws and the sample are all in a straight line. Misalignment could cause inconsistent results.



Typical tensile and IZOD impact test samples.

In other tests such as the 90^{O} peel test an alternative orientation is expressly chosen. Peel testing sample dimensions for medical device package testing are described in ASTM F88 / F88M - 09 Standard Test Method for Seal Strength of Flexible Barrier Materials. In peel tests the average force measured is often important as well as the peak force. This gives information on the uniformity of the bond. Yet more detail can be obtained using graphing software.

For other products or prototypes the details of fixation will depend upon design and intended use. For example button actuation pressures may be measured by pressing perpendicular to the button or at some other anticipated angle of use.

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When testing designs and production, sample alignment may be dictated by foreseeable use or misuse. When testing the strength of a joint in tubing or the insertion force of a needle through a septum, it is tempting to ensure that the samples are aligned perpendicularly. But, when a tubing set snags as a patient moves would it be subject to a straight forward in-line tug or would it be pulled at an angle? Similarly is a needle always pushed straight into a vial or does the user approach from an angle and rotate the need to perpendicular once it has started to penetrate the septum. These angles of approach can make a difference to the performance of products and should be considered at least in the design phase.

The method of sample production can influence tensile strength. Moulded and extruded samples will behave differently to each other and to machined samples. In addition some plastics are known to be ‘notch sensitive’, that is the tendency to a sudden failure at an inhomogeneity is a feature of brittle materials.

Gauge Resolution

Modern force measurement gauges provide a wide range of measurement with good resolution. But, the full scale deflection is still an important consideration when specifying a test. A valve opening force may be set at 0.4N within a tubing set which shears at 50N. The gauge of choice for the tubing set is likely to read up to 100N with a resolution of 0.1N. Whilst this gauge could measure the valve opening force it is not ideal. Greater accuracy would be achieved using a second gauge measuring up to 1N with a resolution of 0.2mN.

Typical Force Gauge

The choice of gauge therefore depends on the accuracy required. In most tests extreme accuracy is not required. Let’s say that the minimum load specified for the tubing set joints is 1.5kg. If the QA test is set to accept anything over 1.6 kg a gauge offering 5% accuracy would be easily sufficient. However if we are measuring the retention forces (or rather removal force) for a stent on a balloon there may be a finer balance between crimping tightly enough for the stent to stay in place whilst it is being delivered yet readily expanding on balloon inflation. That is the stent should not distort when being delivered through a tortuous vasculature, but must still be readily expanded on deployment and have the hoop strength to resist collapse after balloon deflation.

Speed of Movement

Motor driven test stands typically offer a range of movement distance and of speed of movement. Plastics (and metals) can behave quite differently depending on how rapidly a tensile or compressive force is applied. They rapidly pass their elastic limits and the flow properties of molecules (or atoms for metals) within the samples become important. Typically, for a final product test such a tubing set, a shock loading is the worst case example. For orthopaedic products a very wide range of standards specify loading rates and speed of movement in many fatigue and stand alone tests.

Sample Rate

When measuring small forces it can be necessary to ensure a high frequency of sample rate to ensure that peak and minimum forces are not missed. An example of this is the packaging 'seal peel test'. Testing is usually carried out under the guidance found in ASTM F88. 15 or 25mm wide samples cut from across the pack seals are pulled apart at a rate of 200-300mm per minute. At 300mm per minute a standard 8mm wide peel seal will be fully separated in 1.6 seconds. If data was only being sampled twice per second there would be very few data points across the seal. A sample rate of at least 5,000 Hz is appropriate for this test.

Repeat Testing

Repeat or fatigue testing is typically used for devices to be used in a dynamic environment. These include vascular products such as stents or heart valves. The also include orthopaedic products especially load bearing items. In many cases 5 or 10 million cycles are required.

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Application to Medical Devices

Peel Tests

Packaging opening forces are the obvious example of peel tests. In addition to the ASTM test they are described in EN 868-5:2009 *Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.* Pull rates are specified in the standard and force sampling frequency should be recorded.

Another application of peel testing is skin adhesion tests for dressings, ECG electrodes and other peel off items. Welds on fluid pouches may be tested as a peel test, but, a 180^o peel could be considered a tensile test. In both cases a slow pull rate is probably closer to a real life situation, High sampling frequency can be a good idea as elastic materials can stretch suddenly. Also repeat testing is often relevant when considering visitors or hospital staff brushing past a tubing set or collection bags being drained and refilled. The strength of fluid containers could alternatively be tested using pressure test techniques.

Tensile Force

This test is typically applied as a QA test to bonded and welded components. Tubing joints to hubs, chambers and valves are typical. When used as design verification the effects of sterilisation on the joint under test should be considered. Some devices will have associated consensus standards which specify tensile strengths. Others will not, in which case risk analysis is used to ascertain the test force and required safety factor. Generally a slow strain will allow time for tubing to 'neck' down and produce a more severe test.

Other tensile applications are: suture pull out forces, ligament strengths, catheter removal forces, hanger strengths and many more.

Compression Tests

Compression force is measured in actuation tests such as switches and syringes. It is also used in orthopaedics often as a repetitive dynamic test. There are specific cardiovascular applications such as compressive resistance, hoop strength, insertion / removal forces, fatigue testing. Most of these areas have specific standards detailing parameters and set up.

Compressive force is also used a measure for the robustness of a piece of material as determined by piercing it with a known object, and observing the required force.

Torque Measurement
Typically rotational forces are important for products like orthopaedic screws, rotation products like centrifuges or apheresis devices and twist off caps or rotating valves.

For example when a cap on a closure is loosened the maximum torque value is measured. Insufficient or excessive opening torque may present a problem. Capping machines used by pharmaceutical packaging plants should be set to tighten the caps sufficiently to prevent accidental loosening, such as through movements during transportation. However, the cap should still be easy enough to loosen by the user.

Impact Tests
Impact tests for medical devices most frequently occur in transit testing, as prescribed in standards such as ISTA 2A. It is also used in materials selection when a material is known to be under stress in use. A typical protocol is the Izod impact test described in ISO 180:2000
Plastics -- Determination of Izod impact strength.

Impact testing can be combined with tensile testing to confirm quality of materials at the time of supply and as a QA check on any materials processed in house. Alteration of polymer chain lengths in processing and losses or degradation of additives can show up in strength tests.

Flexural Tests
Common flexural tests are the ‘classic’ 3 point bend and cantilever tests. These are used for orthopaedic implants and surgical instruments.

Conclusion

Strength testing is a powerful tool for quality assurance and product development in the medical devices realm. Many product tests are described in ISO and ASTM standards. Risk analysis should always be used to ensure that all aspects of a devices application and foreseeable misuse have been addressed.

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References

ISO 527
Plastics -- Determination of tensile properties

ASTM F88 / F88M - 09
Standard Test Method for Seal Strength of Flexible Barrier Materials

EN 868-5:2009
Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods.

International Safe Transit Association -
Test Schedule 2A

ISO 180:2000
Plastics -- Determination of Izod impact strength.