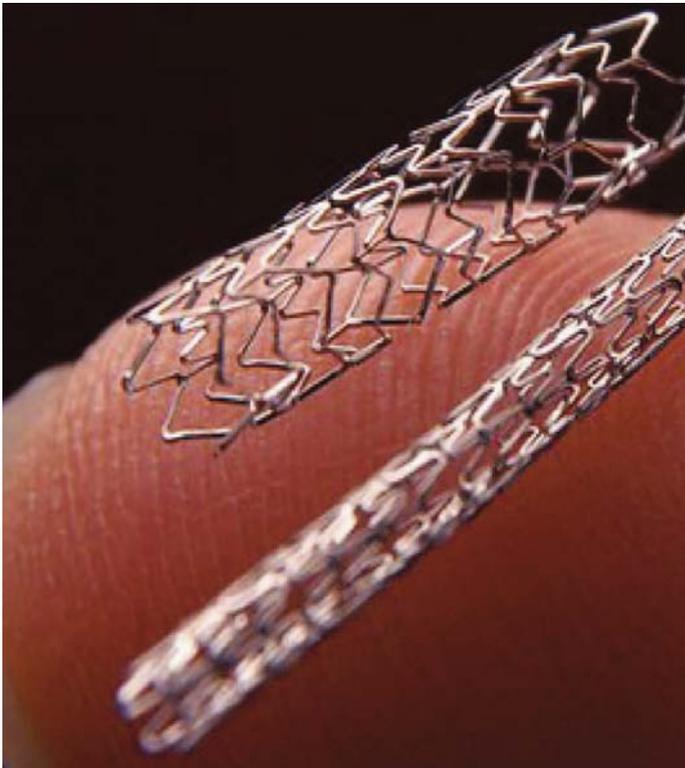


Testing of Stents and Stent Materials

**Toby Kemp and James Ritchey,
Medical Device & Biomaterials Markets**

Stents are a wonderful creation of modern medical engineering that aid physicians and surgeons in the treatment of heart disease. Conditions such as smoking, diabetes and high cholesterol help promote atherosclerosis, the build up of fatty plaque within arteries, which can ultimately lead to heart attack and stroke.



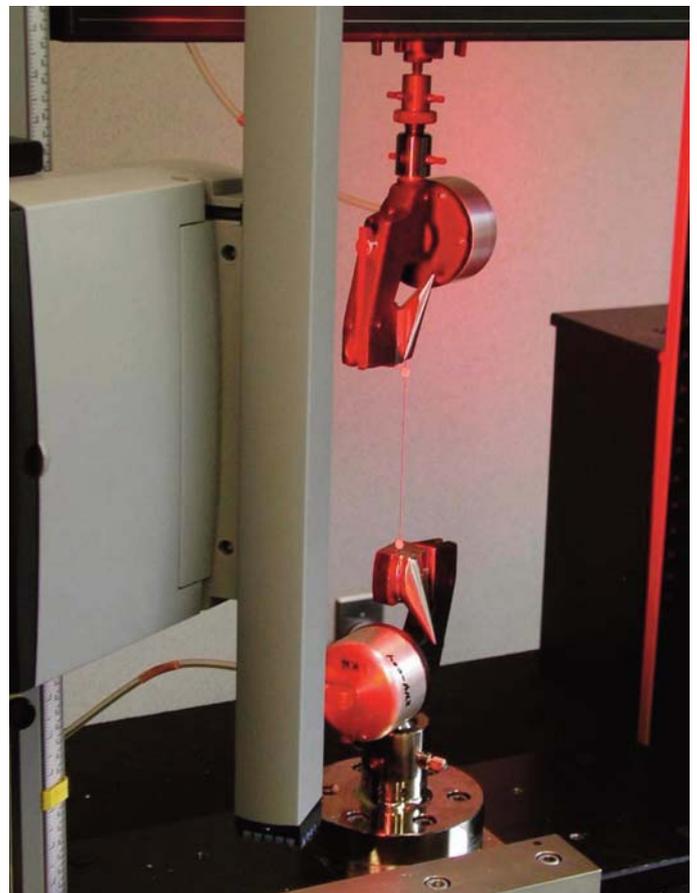
Stents are small tube-like medical devices, usually constructed of a biocompatible stainless steel or metal alloy, which are used by surgeons to widen or unblock clogged arteries to help restore normal blood flow and reduce risk of heart attack. Today, stenting is a common practice, making up over 70 per cent of total coronary angioplasty procedures.

More recently, smart materials such as Nitinol (Nickel Titanium Alloy) have been used by stent manufacturers in the production of stents. Nitinol exhibits both shape memory and superelastic properties, which makes it perform particularly well when used for self-expanding stents. Nitinol stents are slightly larger than the size of the intended artery, and after deployment exhibit a chronic radial force to maintain position.

Mechanical Testing

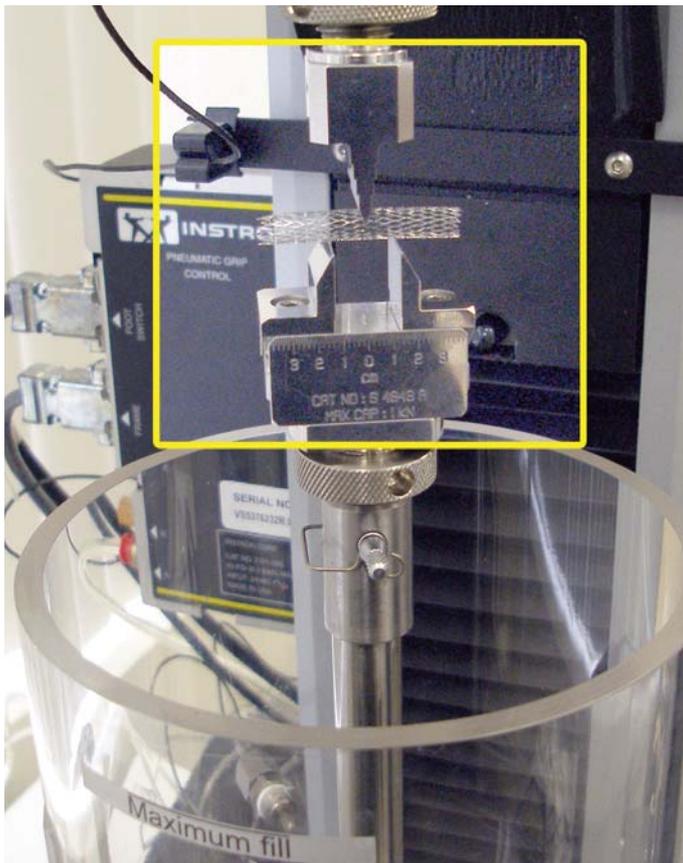
With stringent requirements from regulations, manufacturers must demonstrate that they have considered risks of device failure and satisfactorily mitigated against them. Mechanical testing of stent and stent materials is performed in vitro to aide designers and researchers gather performance data ahead of device approval and clinical use. Although mechanical testing does not begin to simulate the complete in vivo conditions that devices undergo, it does allow experimental validation and provides more accurate data for Finite Element Analysis (FEA) and computer modelling of cardiovascular devices to be undertaken.

Mechanical testing takes many forms, from testing of the constituent metals and alloys, compression and flexural testing of complete devices, through to dynamic simulation of pressure pulsation.



Tensile Testing of Stent Materials

Tensile properties of Nitinol can be evaluated using ASTM F2516 "Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials", which specifies a method to understand the upper and lower plateau strengths, tensile strength and elongation of this superelastic material. This test method presents a number of practical challenges to mechanical testing. Nitinol materials are relatively hard and are difficult to clamp using conventional jaws. Also, the ability to accurately measure elongation becomes difficult as standard clip-on extensometers can cause premature failure of the material.



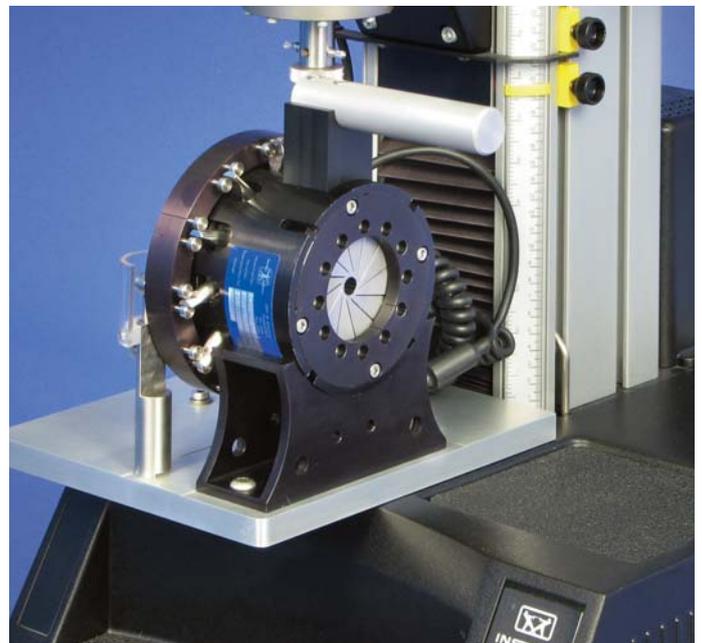
Techniques for gripping have often revolved around using jaws with adjustable clamping forces, such as pneumatic or hydraulic grips, or specialist strain measurement is carried out using a non-contacting video based extensometer.

Flexural Testing of Stents

ASTM F2606 "Standard Guide for Three-Point Bending of Balloon Vascular Stents and Stent Systems" provides a method to characterize the bending flexibility of stents and the guide catheter to help understand how the behaviour as they pass through the vascular track. The test involves subjecting either a deployed stent or a stent system to a three-point bend to generate a force-displacement curve for both loading and unloading.

Radial Force Testing of Stents

One of the most critical parameters for successful procedures using stents, stent grafts or embolic filters is the radial force that they impart onto the arterial wall. Insufficient forces can result in a poor fit of device and ultimately in costly and risky revision procedures.



Using a specialist fixture incorporating a segmental compression mechanism, it is possible to determine radial stiffness, chronic outward forces during expansion and compression, as well as the radial reactive force during compression of different devices. This approach provides uniform application of radial forces for easy comparison

to FEA generated data. Although several other testing techniques exist including the sling apparatus and the pneumatic/hydraulic apparatus, the segmented approach has gained growing acceptance within the testing community.

Stent Securement Testing

ASTM F2394 "Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System" provides guidance in the evaluation of the securement characteristics associated with endovascular stents to the delivery balloon catheter. This guide is intended for use by researchers and manufacturers for the development and selection of pre-test treatments, tests and test endpoints to measure stent securement (displacement distances and dislodgment forces). This "testing guide" should be used with discretion in choosing securement tests due to the vast array of clinical uses and potential failure modes. At the highest level, the guidelines will assist developers in the design, in vitro characterization of pre-mounted, unsheathed, balloon-expandable stent delivery systems by determining the shear forces to displace or dislodge a secured stent.

The guide can be utilized for other test standards as well. Parts 2 and 3 of the requirements of EN 14299, Section 7.3.4.4 on Trackability can be addressed with this guide. Additionally, it may be of use for developing a test to meet section VII-C-8 of CDRH Guidance document.

Fatigue Testing of Stents and Stent Materials

Traditional fatigue testing of complete stent devices is addressed by ASTM F2477 "Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents", which specifies methods for fatigue of complete devices through hydrodynamic pulsation. The method involves placing complete devices into mock arteries and subjecting them to 400 million cycles of internal pressure pulsation (10 years of human heartbeats), forcing them to radially expand and contract in each cycle. The test can either be performed between pressure limits, simulating diastolic and systolic pressures; or displacement controlled, reproducing the minimum and maximum diameters that a stent would see in vivo under worse case conditions. Tests are typi-

cally performed at frequencies of up to 50 cycles per second, resulting in typical test durations in the three to six month range..

The acceptance criterion of devices is a simple pass/fail one, in that no fracture of the stent can occur during these in vitro tests for success. Many devices from varying manufacturers have undergone Pre-Market Approval (PMA) by Food Drug Administration (FDA) and have gone into clinical use. Although this traditional "Test to Success" approach of fatigue testing has not resulted in failures, the reality is that many of these devices are fracturing in vivo.

In early 2006, the FDA and ASTM started looking at ways that could eventually improve the current durability assessment of cardiovascular devices. Initially, two working groups under the ASTM F04.30.06 Endovascular



Devices Task Group were established; the first group concentrates on better understanding of the physiological conditions devices undergo in vivo and transferring this knowledge into boundary conditions for use in testing, evaluation and modelling, whereas the second group, entitled "Fatigue to Fracture" (FtF) group, was charged with developing alternative and improved test methods for fatigue testing of cardiovascular devices.

An alternative method that is being rapidly adopted is a "Fatigue to Fracture" approach. A rudimentary technique that is more akin to aerospace testing, this methodology involves a combination of FEA modelling and in vitro testing to assess the durability of stents through established fracture mechanics techniques. These testing guidelines and standards are still under development.

Several testing techniques have been developed recently that provide testing results that provide support as manufacturers submit products for regulatory approval. To enable a representative sample of specimens to be evaluated and to reduce overall test time, multiple samples must be tested. The multi-specimen fixtures are available to assist cardiovascular implant manufacturers to assess these long-term fatigue characteristics of nickel-titanium (Nitinol), CoCr, stainless-steel and other stent materials and structures. It is important that each specimen station feature a fatigue-rated load cell, precision alignment adjustment and applicable grips for the material or structure undergoing test. The specimens should be tested in vitro at body temperatures. Results should include trend monitoring of forces to determine each specimen fracture.

Summary

Although stents have proven to be effective and important devices for the medical device community and the general patient population, they continue to evolve. Larger and smaller stents designed for peripheral arterial networks in distal extremities like the superficial arteries, carotid arteries and neural arteries test the limits of the existing materials and testing technology. Continued material evaluation, and development, and the delivery of new testing methods will be important for the evolution and success of these devices. Close monitoring of new requirements will be required by manufacturers as these products mature.

For more information: Go.instron.com/stenttesting

Instron Deutschland GmbH
Werner-von-Siemens-Straße 2
64319 Pfungstadt / Germany
Phone +49 (0) 6157 4029 600
Fax +49 (0) 6157 4029 700
vertrieb.de@instron.com