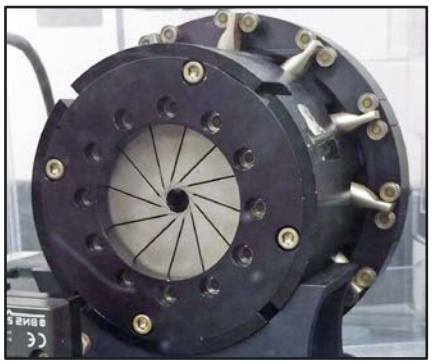
Radial Force Testing



Radial force testing is well known in cardiovascular stent characterization. However, this test is applicable for many types of cylindrical medical devices as it can provide useful data about radial stiffness and strength.

While there are no specific standards for radial force testing, you can find relevant information in ISO 25539-1:2017 and ISO 25539-2:2012 for cardiovascular implants. FDA Guidance document 1545, Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, section IV.B.7 recommends measuring the radial force exerted by self-expanding stents against the vessel wall after deployment and specifying both minimum and maximum values for the radial outward force.

High radial force and complete stent apposition are important criteria for optimized stent implantation to overcome lesion resistance and elastic recoil (Rieu et al, Catheter Cardiovasc Interv 1999, Kalmár et al, J Vasc Interv Radiol 2002, Watson et al, Open Heart, 2017). Another study in a juvenile porcine model (Freeman et al, Connect Tissue Res 2010) found a link between stent radial forces and vascular wall remodeling and suggested an optimal stent radial force for minimal vessel restenosis. Radial stent strength is largely determined by three factors: the metal alloy (or polymer), strut thickness and stent architecture. The method below describes how Element performs medical device radial force testing.

Test Method

ISO 25539-1:2017, section 8.5.2.5, specifies patency-related tests, including radial force to determine the outward force as a function of the diameter of the endovascular prosthesis. The test is applicable to self-expanding but not balloon-expandable prostheses, since self-expanding endovascular prostheses exert an outward force against the vessel wall. ISO 25539-2:2012 sections 8.6.2.6 and 8.6.5.6 discuss determining the force exerted by a self-expanding stent as a function of the stent diameter to assess fixation effectiveness and patency. This test may be used to assess excessive or inadequate radial force.

Annex D (Test Methods) found in both ISO 25539-1 and -2 describes in more detail the conditioning, test method, expression of results and test report recommendations. Briefly, the stent is deployed within the fixture such that initial diameter is less than or equal to the minimum vessel diameter indicated in the instructions for use, the stent is then compressed to the minimum indicated vessel diameter and the radial force is measured as function of stent diameter. Radial pressure is subsequently calculated based on the measured force and the cylindrical area under test.

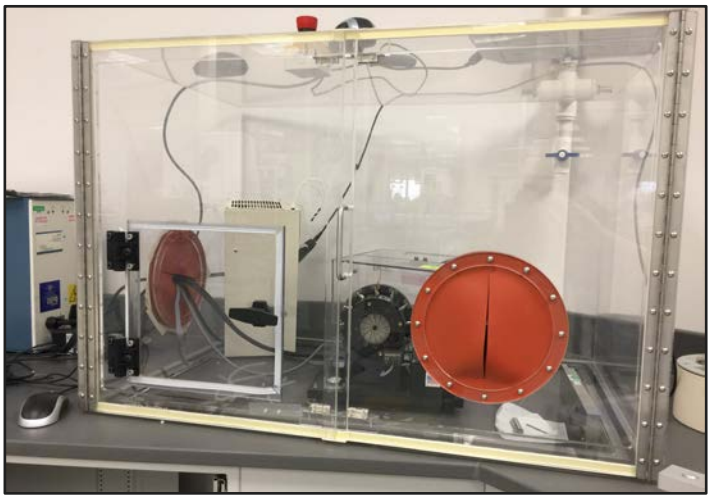
Radial Force and Hoop Force

As a quick primer, radial force (RF) is the average pressure over the surface of the compressed object multiplied by the surface area, while hoop force (HF) is the total compressive force in one wall of a tubular object (Blockwise Engineering LLC, Hoop Force – Radial Force – Pressure Derivation). The relation between RF and HF can be derived by a free-body diagram force balance on half of a tube: $HF = \frac{RF}{2\pi}$

Radial Force Tester

Element uses a Machine Solutions Inc. RX500 radial force tester equipped with a temperature sensor and environmental air chamber for conducting tests at physiological temperatures. The equipment uses an optical encoder to measure the angular rotation of the force collector, and the software employs experimentally-determined polynomial curve fits to calculate the opening diameter from the angular rotation. The opening iris is a stainless steel 12-segment design, and the equipment measures the force applied by the specimen to the 12 sides of the iris sub components.

Static (ramp) and cyclic (square wave) testing can be performed using the RX500 radial tester. Its key specifications are listed below:



- 1-14 mm diameter range
- 60 mm head length
- up to 50 lbs. radial force
- up to 1.0 mm/sec rate of expansion/closure
- ±0.4% of max opening diameter calibrated accuracy
- ±0.15% of full scale, standard deviation, repeatability
- 0.01 mm resolution

Data is reported as either hoop force, radial force or pressure; diameter and time are also recorded. For a ramp test, start/end diameter values and ramp rate are programmed into the software. Upon diametrical reduction, the device stays compressed while radial force is constantly monitored until it stabilizes. Specimen diameter and length dimensional verification inspection is performed pre- and post-testing.

It should be noted that as the wall of the specimen expands or contracts, it rubs against the 12 rigid surfaces of the iris head. The head-to-specimen friction varies depending on the materials and construction of the specimen. This friction has a systematic and somewhat repeatable effect and does not typically mask differences measured among specimens.

Consultation

If you would like assistance with your device's radial force testing and characterization, please fill out our test questionnaire or call us at 952-933-1152 to discuss how we can help.

Element Materials Technology offers the broadest scope of medical device testing, so if you are looking for services such as package testing, microbiological testing, accelerated shelf life testing or EMC/EMI testing, contact us to connect with the right lab.