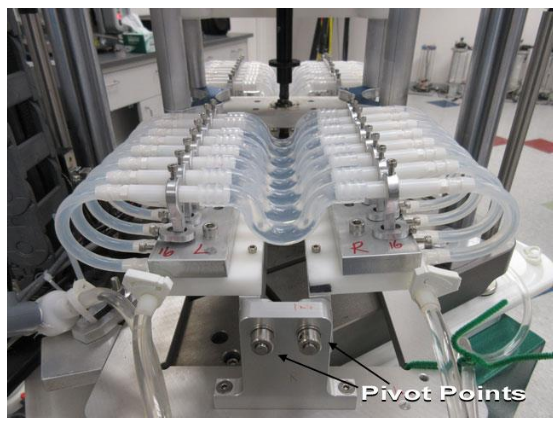
## Cardiovascular Device Bend Testing

Stents and other cardiovascular medical devices are often subjected to bending moments during use. FDA's "Guidance for Industry and FDA Staff – Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" issued on April 18, 2010 provides guidelines on the types of mechanical tests manufacturers should consider for their devices.

Ormiston et al[1] contracted Medical Device Testing Services (MDT) to perform accelerated cyclic bend testing of 6 different stent designs from multiple manufacturers (Abbott Vascular, Biosensors International, Medtronic, and Boston Scientific) for 10 million cycles and observed that fracture sites seen with their study were similar to those clinically observed. Therefore, bend testing can provide device manufacturers critical design information.

There are many ways to test bend properties and obtain the information you need for your regulatory submissions. Your device design, intended use, and required bending radii will largely determine the most appropriate test configuration. All of MDT's fixtures are suitable for use in a phosphate buffered saline (PBS) bath with or without circulation and maintained at 37°C.

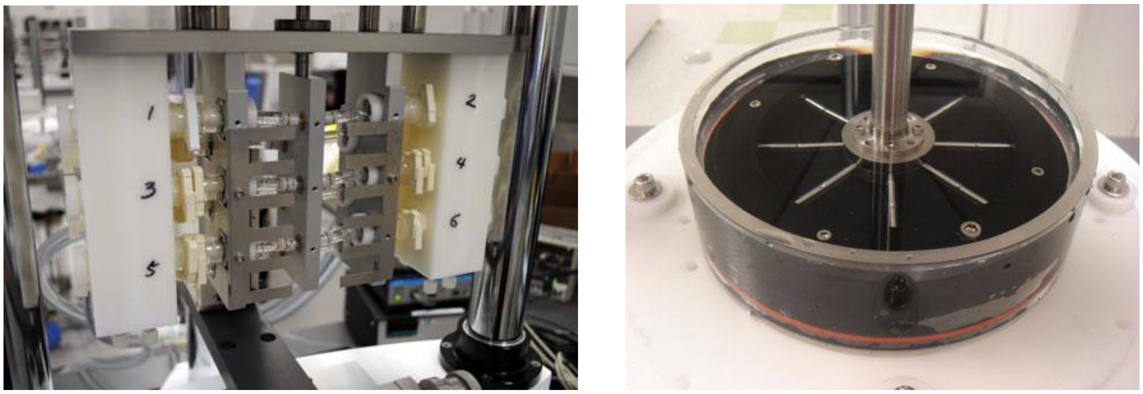
- With **pure bending**, a bend moment is applied to the proximal and distal ends of the device so that the center of the device is in a pure bending configuration. MDT's fixture (right) can be modified to accommodate short and long devices and is suitable for stimulator lead attachment coils and peripheral stents. The fixture is compatible with a PBS bath and can be used as a 10- or 16-station for statistically-significant sample size testing.




**Pure Bending Fixture for Peripheral Stents**

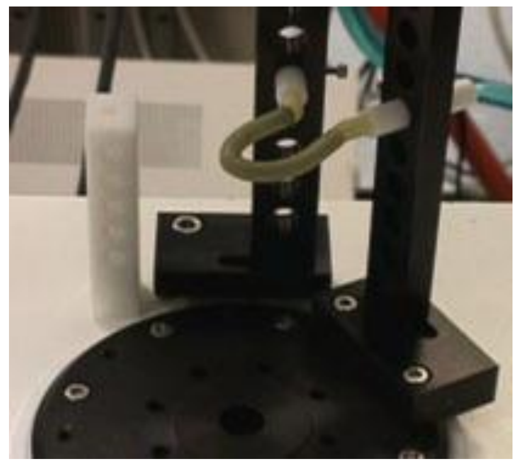
- In **cantilevered bending**, the proximal end of the specimen is fixed while an orthogonal displacement is applied to the distal end. Thus, with a **single cantilevered** bend fixture, the portion of the device near the fixed end moves in a bending motion. In some instances, both ends of the device are fixed while their centerlines are displaced. This **double cantilevered** approach imparts bending near both ends of the specimen. The fixtures are designed to apply cantilevered bending across multiple samples at a customizable radius of curvature, angle or displacement. The fixture is particularly well suited for renal stent testing or device indications that require simulation of the breathing cycle. The cantilevered bend fixtures are designed to be used in a PBS bath at 37°C or with a flow loop and recirculating pump. The relative displacement of the orthogonally-moving end can be measured using either the test instrument displacement transducer or a laser micrometer. The laser micrometer can be configured to measure the bend displacement of each stent at predetermined positions along its length.

[1]Ormiston JA, Webber B, Ubod B, White J, Webster MW. Coronary stent durability and fracture: an independent bench comparison of six contemporary designs using a repetitive bend test. EuroIntervention 2015; 10(12):1449-55



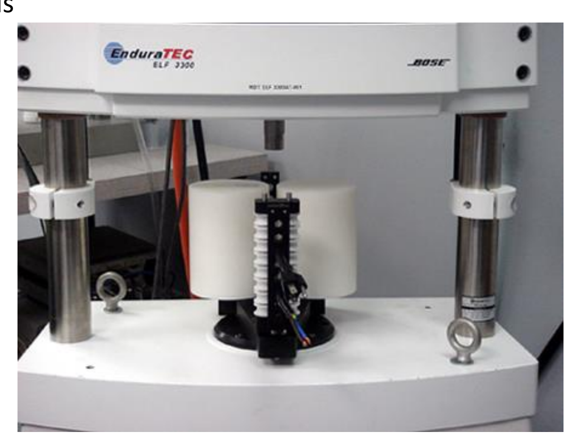
Single (left) and Double (right) Cantilevered Bend Fixtures

- With **combined cantilevered and pure bending**, the proximal end of the specimen is fixed while the distal end is moved through an arc with a fixed radius. This is sometimes referred to as the “wag” test as it resembles the wagging of a tail. The specimen either “finds” its own radius of curvature, or it is wrapped around a mandrel of known radius. MDT fixtures are ideal for devices that require large bending radii. To facilitate pure bending, the rotary actuator of the test frame is used to swing the distal end of the device through a fixed angle.



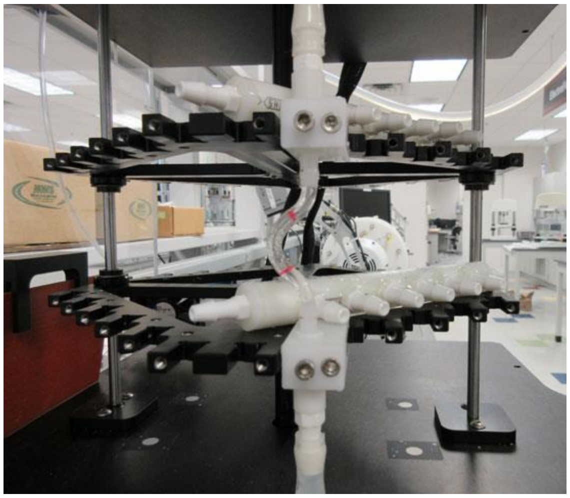
Combined Cantilevered and Pure Bending Fixture

- In **constant radius bending**, a bending moment is applied at a fixed radius. This type of testing is sometimes referred to as “bending on a mandrel”. With this approach, the proximal end of the specimen is fixed while the distal end is moved through an arc. To ensure that the specimen bend achieves a fixed radius, it is bent over a mandrel of known radius. This test is useful for achieving predictable positive and compressive stresses. To facilitate bending, a rotary actuator may be used or a linear motion is converted to rotary motion.

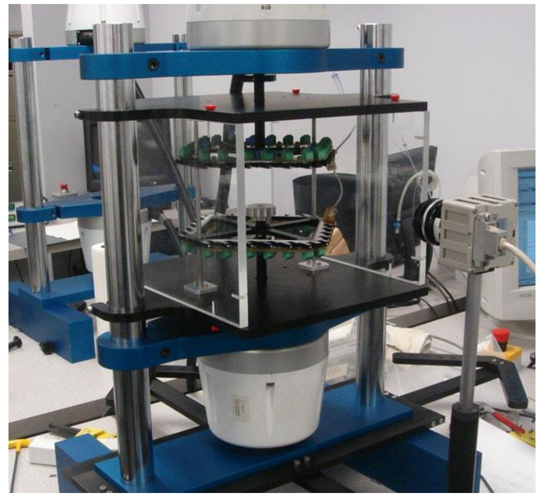



Constant Bend Radius Fixture with Power Cable

- With **compression bending**, axial motions are applied to the distal and proximal ends of a device that is pre-formed into an omega (or “inch-worm”) shape. As the ends are brought together, the radius of the specimen bend decreases. Unlike pure bending where only one bend is created, compression bending creates three bend radii (distal, center and proximal). Since the bend angle at the center radius is most extreme, this is where the specimen fails first. This approach can be used to evaluate the bending fatigue resistance of peripheral stents and pacemaker/defibrillator lead wires. MDT fixtures are ideal for devices that require smaller bending radii, and up to 20 devices can be mounted in each fixture. To facilitate compression bending, one or more axial actuators are used to bring the specimen ends together at a fixed displacement.

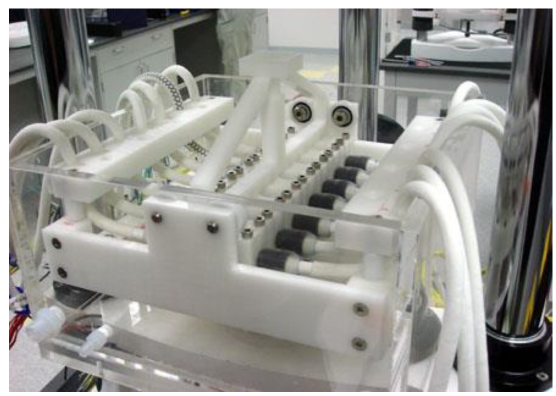


**Peripheral Stent Compression Bend Testing**



**Defibrillator Lead Compression Testing**

- In **shear-induced bending**, a shear motion is applied to one or both ends of the specimen to induce both bending and shearing into the device. The specimen is generally left to find its own radius of curvature based on the applied motions. The induced bending is generally a "rolling bending" where the center of the bend radius moves along the length of the cable. MDT's fixture can accommodate up to 14 samples and be immersed in a PBS bath at 37°C.



**Shear-induced Bending on a Left Ventricular Assist Device (LVAD) Cable**

The breadth of test applications reflects the types of available medical devices and their unique design characteristics. While MDT has developed a plethora of test fixtures over the years, we continue to iterate designs to meet even the most challenging test needs. Contact us to discuss your medical device test application and how we can help you assess the bend properties of your device.



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