Medical Device Torsion Testing

Medical devices often experience multi-modal loading in vivo. In addition to axial loading, they can also experience torsion and bending. For some orthopedic devices such as bone screws, the torsional loading is imposed during the implantation, and the device needs to resist failure during the applied torsion. In some fixation devices, the head is designed to shear off at a predetermined torque so that it does not remain within the implantation site. For intravascular applications, the device often experiences torsional loading post implantation. For example, stent-grafts used in peripheral indications can experience torsion due to normal limb motion. Devices intended for aortic repair can sometimes experience torsional loading due to twisting of the torso. Over the years MDT has performed hundreds of torsional testing applications and has developed a toolbox of test fixtures and techniques for these applications.

MDT has many test systems that were designed to perform torsional testing. Most of our BOSE/TA ELF3300s, Instron ElectroPuls E3000s, and MTS systems are equipped with torsion stages to provide rotational motion to single or multiple specimens. This rotational motion can be used independently or in concert with the axial systems for multi-modal fatigue.

Test System	Axial Capacity (N)	Torque Capacity (N*M)
Bose/TA ELF3300-AT	1500N	27.7Nm
Instron ElectroPuls E3000	3000N	25Nm
MTS Hydraulic	10KN	100Nm

Table 1- Capacities of various MDT Torsion Test Systems.

Specifications for torsional tests typically include the rate of rotation (deg/s), rotational frequency (Hz), peak torque (N*m), or peak rotation (deg). This testing can be used for fatigue, validation and functional testing, destructive testing, and material characterization. Results typically take the form of cycles at fractures, max rotation at fracture, max torque at fracture, or a simple torque vs. angular displacement curve.

Here are a few examples of the medical devices MDT has developed torsion testing fixtures and tests for:

- Medical bone screw insertion/removal and fracture torque characterization
- Spinal disc implant fatigue testing
- Torsional modulus characterization of fine l wire
- Combined cantilevered and pure bend testing of peripheral stents
- Cantilevered and pure bending of instrument cables
- Rotational fracture testing of dental picks
- Validation of surgical tools
- SFA gait testing (tension/bending/torsion)

Bone Screw Testing

ASTM F543-13 is a test method used to measure the torsional yield strength, maximum torque and breaking angle of bone screws under standard conditions. MDT carried out ASTM F543-13 and ISO 6475:1989 compliant Fiducial Bone Screw insertion and removal torque testing using the rotational stage of a BOSE/TA ELF3300AT (Figure 1). A pair of linear bearings with an adjustable weight cylinder were used to apply smooth, constant axial pressure to the sample, while the rotation stage provided the requisite angular displacement (driving torque) to embed the screw in a block of simulated bone material. Data was collected in the form of angle of rotation vs. torque, and axial load. MDT also performed the accompanying ultimate torsional strength testing, holding the screw stationary and applying a measured angular displacement to the driving head until fracture occurred.

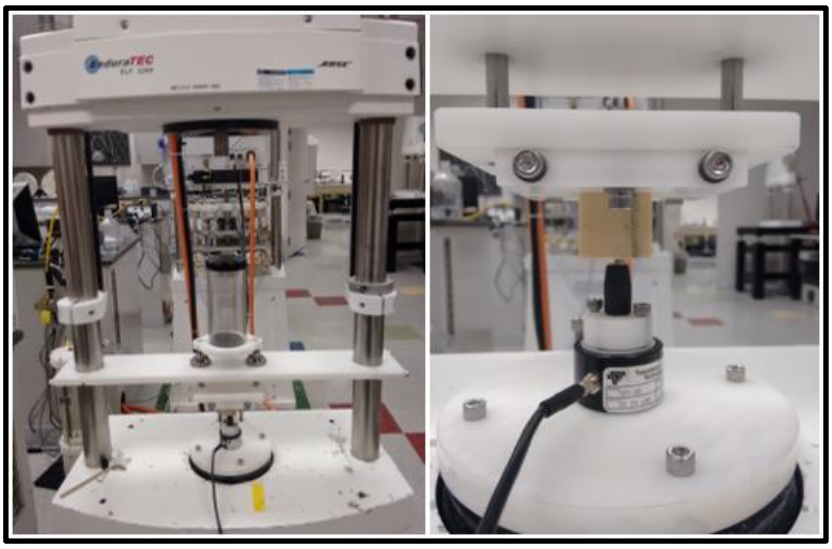

Figure 1-MDT Bone Screw Insertion & Removal Torque Testing.

Surgical Tool Testing

MDT has tested a wide variety of surgical tools and accessories in addition to the actual implants. Surgical tools need to be able to withstand rotational forces during use and are often tested to simulated forces they will experience during routine use in the operating room to observe any fracture, disassembly or damage during testing. The torque-to-fracture testing shown in Figure 2 was performed on an Instron ElectroPuls E3000 tester with a modular torsion stage and torque cell. Data was provided in the form of a continuous torque vs. angle plot and a maximum torque value. MDT also performed the accompanying axial force, multiple orientation 3-point bend, and suture pull tests for this device series. Tests were performed on the entire device as well as on device components.

Figure 2- MDT Torque-to-Fracture testing of an aortic leaflet repair device.

Peripheral Stent Testing

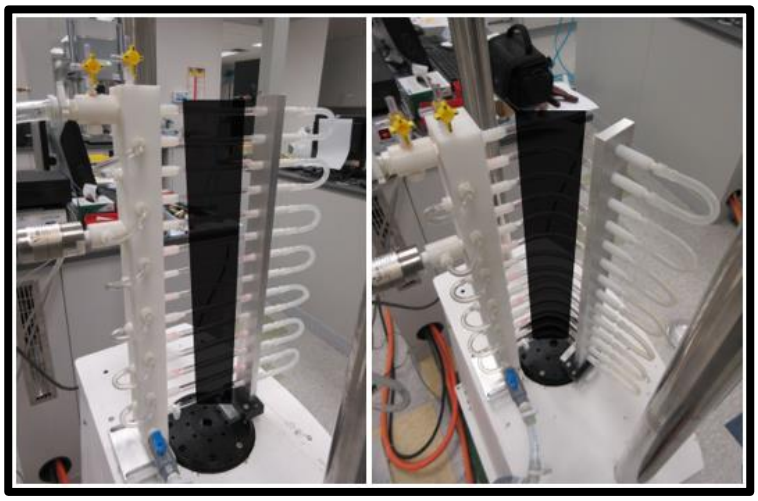

Figure 3- MDT Bend/Wag testing of peripheral stents.

Combined Cantilevered/Bend Testing (Wag Bend) testing is carried out using the rotational stage of a BOSE/TA ELF3300AT as shown in Figure 3. Constant physiological temperature and pressure in the samples are maintained by the recirculation of saline through a heated mean-pressure tank and the stationary manifold that provides the "base" for the bend. Bending radius and motion are verified through use of an overhead high-speed video camera and dimensional analysis software. A wide variety of sample diameters, lengths, and bending angles/radii can be accommodated in runs of up to n=12 samples.

SFA Testing

Figure 4- MDT SFA/Gait-Motion testing.

MDT has carried out many SFA gait motion tests on a variety of peripheral devices in compliance with ASTM 2942-13. The SFA tester mounted on a BOSE/TA ELF3300AT shown in Figure 4 uses both the axial and rotational actuators to apply cyclical tension, torsion, and local bending to the samples over test runs of many millions of cycles. Physiological pressure and temperature in the samples are maintained by a mean-pressure heated saline recirculation system.

In summary, the importance of torsion testing for many different types of medical devices is paramount. MDT's torsion test instruments coupled with several decades of torsion testing expertise have resulted in the design of a variety of torsion fixtures and test protocols for many challenging applications. Contact us today to discuss how torsion testing may complement your medical device mechanical testing and regulatory submission data.