Accelerated Fatigue Testing Done Right

The requirement for 10-year fatigue evaluation of intravascular devices has generated the need for high frequency accelerated fatigue testing. The performance of a high frequency test is dependent on several factors: the desired applied stress/strain or inputs applied to the specimen, the response of the specimen to the applied test inputs, and the test system/fixture dynamics. Over the years, Element has been a leader in accelerated frequency testing and has worked with test equipment developers to create the first linear motor driven test systems capable of running high frequencies over billions of cycles. With decades of experience testing hundreds of medical devices, Element engineers have learned to adapt these linear motor driven test systems to virtually any high frequency test application.

Physiological Loading Determination

The first step in the process is determining physiological loading parameters. These parameters can be obtained through computer modeling and/or experimental methods. For example, finite element analysis is often used to create meshes of complex geometries and gather data about target strains and worst-case device loading parameters. Some of this data might also be available through previous studies and can be retrieved through literature searches. In some cases, these parameters can be assessed experimentally. An example of the latter scenario is described below.

For stent pulsatile fatigue testing, a mock vessel with target physiological compliance is selected for the tests. Target compliance is determined based on the device's application site. The physiological vessel is then used to determine the physiological loading on the device, based on the device's outer diameter (OD) and the vessel OD/ID (inner diameter) relationship. Using a stent graft tester with a laser micrometer, tests are run at target physiological frequencies, typically 1.2 Hz, and pressure waveforms, e.g., 80 mmHg to 160 mmHg. A laser micrometer is used to measure radial OD strain of the mock vessel at specific locations across its length to determine the physiological % OD strain.

Accelerated Frequency Stability Evaluation

Test instruments such as the stent graft tester, ElectroForce 9100 series, for pulsatile fatigue and the ElectroForce 3200 and 3300 test instruments for axial fatigue testing can be used to perform frequency sweeps to determine stable accelerated frequencies based on fixture mass and system/fixture/device compliance. These stable frequencies can be determined by replicating the exact system setup that you will use for testing, which is why you will typically hear a range of potential accelerated frequencies instead of a specific value, until actual samples are run.

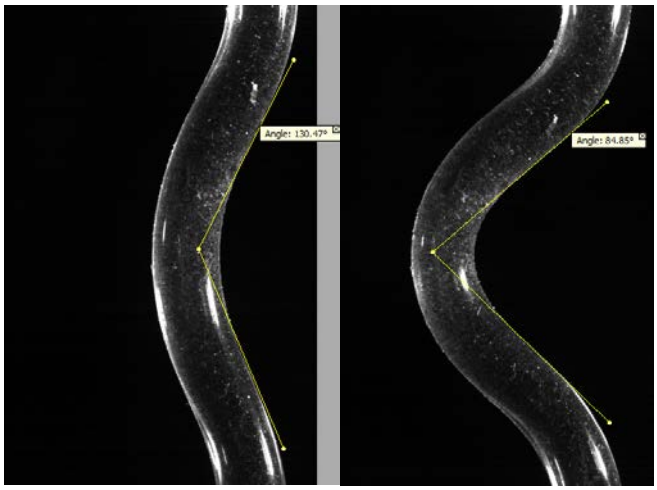
Accelerated Frequency Validation

Once a stable accelerated test frequency has been determined, the final step is validation of the target %OD at that accelerated frequency. This step is very important as you may accelerate your test and complete it faster but subject your device to conditions very different than the physiological targets, which could jeopardize the validity of your data and regulatory submission outcomes. The accelerated fatigue test target %OD is calculated as follows:

$$Accelerated\ Fatigue\ Test\ Target\ \%OD = \frac{Mean\ \%ID (for\ deployed\ devices\ in\ the\ physiological\ artery)}{\frac{\%ID}{\%OD} strain\ ratio\ for\ the\ testing\ vessels}$$

If there are deviations between actual and target values, the system pressure head may need to be adjusted and/or additional accessories utilized to maintain the target values.

One of the most common issues with accelerated pulsatile fatigue testing of stents is lack of wall apposition within the mock vessel. A strobe light and high speed video are often used to verify that the motion of the device follows the motion of the silicone mock vessel. The images below show the movement profile of empty mock vessels at 30 Hz using a high-speed video camera with a 2000 frames per second rate. These images were used to verify the min and max angles and compare them to target values.



Monitoring and periodic inspections throughout testing are highly recommended to ensure that target loading parameters are maintained over the test duration.

Consultation

If you would like assistance with your device's accelerated frequency testing, 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.