TEST REPORT MDT0xxxx

In Vitro Accelerated Fatigue Test: x Year Post-Implantation Pulsatile Fatigue and Durability Test of Sponsor x.xxmm Stents

Device Manufacturer:
Contact
Customer

Testing Facility
Medical Device Testing Services, Inc.
6121 Baker Rd Suite 101
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Test Engineer: Calvin Chao
Report: #
Date:

Scope

This benchtop test was intended to provide empirical evidence of the structural integrity of Sponsor devices (x.xxmm Lumen) when subjected to mechanical fatigue replicating *in vivo* conditions. The test was designed to simulate the device radial fatigue due to expansion and contraction of the vessel surrounding it. Physiological strain of a healthy vessel was modeled using latex arteries implanted with the device. The test was accelerated to obtain results in a shorter time period than physiological rates would allow. Testing was conducted under simulated physiological conditions: saline at 37°C +/- 2°. The testing objective is to meet the requirements for *in vitro* mechanical fatigue testing stated in ASTM F 2477 – 06 "Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents". This test demonstrated the integrity of Sponsor devices under mechanical fatigue failures for a minimum of x years post-implantation. A device failure was defined as any broken or cracked geometry (struts, crowns, links, etc.) visible at 30x magnification during or at the end of the test.

Summary

Test cycle parameters, resulting in x-x% physiological compliance, were determined in a physiologically simulating latex tube (x.xxmm=ID, x.xxmm=wall thickness). The stents were deployed in latex tubes (x.xxmm=ID, x.xxmm=wall thickness) according to Sponsor protocol and were subjected to x million cycles on an EnduraTEC stent fatigue tester in the Medical Device Testing Services lab (x/x/xx – x/x/xx). Each cycle applied pulsatile stresses within the tubes to simulate the circumferential strain at the *in vivo* application site. Test duration imitated x years of implantation life at 72 bpm. The %OD strain, count, temperature, pressure gradient, and migration were monitored daily. 30x endoscopic inspection indicated that x devices were intact at the end of the test.

Equipment

1.0 Model 91x0 EnduraTEC Stent/Graft Tester (MDT SGT 91x0-0xx) with Temperature Controller
2.0 EnduraTEC WinTest® Controls and Software
    a. PC 2543 Control Card
    b. DAS-1601/12 digital I/O card
3.0 Keyence LS-5000 series Laser Head and Controller
4.0 Computer ≥ 400MHz CPU
5.0 Sponsor' x.xx mm lumen stents (P/N xxxxxx) (CSP#)
6.0 Inflation device
7.0 Latex Arteries (n=) x.xxmm ID, x.xx mm wall thickness
8.0 Latex Arteries (n=) x.xx mm ID, x.xx mm wall thickness
9.0 Endoscope with 30X magnification (ISN#00217)
10.0 Isotonic Saline Solution (PBSS):
    a. Water
    b. Sodium Chloride 0.85% w/v
    c. Dihydrogen Potassium Phosphate - trace
    d. Sodium Dihydrogen Phosphate Monohydrate - trace
    e. Ethylene Glycol Monophenylether - trace

Procedures

The test followed test protocol agreed upon by MDT Services and Sponsor. Medical Device Testing Services abides by our documented Quality Process for all testing services

Machine Calibration and Validations:

The SGT 91x0 EnduraTEC Stent/Graft Tester (MDT SGT 91x0-xxx), Keyence LS-5000 series Laser Head and Controller, and the Temperature Controller were verified to be up to date with all calibration schedules. Tester functionality was verified by running the tester without samples.

Mock Artery Conditioning:

Twelve mock arteries (ID=x.xx mm, wall thickness=x.xx mm) were mounted on the SGT 9110 EnduraTEC Stent/Graft tester. The tester was filled with Isotonic Saline Solution (PBSS) and then purged of air. The tubes were conditioned for 2 hours: xx Hz, displacement levels -/+ .xx, 37°C. The conformity of the mock arteries was validated by measuring the empty tube diameter at each centimeter along the length of the tube under conditioning parameters. Each tube was numbered and marked with left and right reference points.

Physiological Compliance: Empty Artery

Physiological compliance was determined using a thin walled mock artery (ID=x.xxmm, wall thickness=x.xxmm) mounted on the EnduraTEC Stent/Graft tester (MDT SGT 91xx-xxx) in the position of the pressure transducer. The Keyence LS-5000 series Laser Head and Controller was used to measure compliance of the empty mock artery diameter at each centimeter along the length of the tube at static physiological conditions of 160 and 80 mmHg.

Physiological Compliance: Device Deployed Artery

One of Sponsor stents (stent #) was deployed according to Sponsor protocol (xxatm, for xxsec.) into the physiological tube. It was positioned at the center of the tube. 30x endoscopic inspection after deployment indicated that Stent # was intact and expanded. The Keyence LS-5000 series Laser Head and Controller was used to measure the tube diameter along the length of the deployed stent (stent #) at static physiological conditions of 160 and 80mmHg at 3 positions. Physiological test set-up is validated via comparison of the empty mock tube OD and stent deployed OD over a range of pressures. The target radial strain level for the accelerated fatigue testing was calculated using the physiological compliance data.

Accelerated Fatigue Test Set Up:

Sponsor x.xx mm stents were deployed according to the Sponsor protocol (xxatm for xxsec). The stent position and the center of the stents were marked on the mock artery as a reference. Mock arteries were deployed with x stents located at the left and right end of the artery. The EnduraTEC Stent/Graft tester (MDT SGT 91xx-xxx) was started at < 3% empty tube strain. The volumetric displacement levels, level 1(.xxml) and level 2 (-.xxml), and P-term (.xx) were adjusted until the target %OD strain for the mock arteries (ID=x.xxmm, wall thickness=x.xxmm) was achieved: .xx%.

Accelerated Fatigue Test Set Up Validation:

The Keyence LS-5000 series Laser Head and Controller was used to measure the tube diameter and radial strain at the center of each deployed stent as well as the empty tube located to the immediate left and right of the deployed stent under dynamic conditions. Accelerated test set-up is validated via comparison of the empty latex tube calculated max OD and stent deployed maximum OD under fatigue test conditions. The maximum outside diameter (OD) was calculated based on the measured radial strain at each point (Max OD = AvgOD*(1+(0.5*%OD Radial Strain)/100),

The WinTest software maintains the volumetric displacement using a closed feedback loop and linear variable differential transformers (LVDTs). The autolog function was enabled. The cycle count, saline temperature, pressure, %OD strain, and the average OD (mm) are monitored and recorded daily. Additionally, a hard copy scan at a single location is saved daily to the project file. Displacement levels were adjusted to maintain the target %OD throughout the duration of the test.

Disassembly:

At test completion the mock arteries were carefully removed from the tester and the structural integrity of the stents assessed via a 30x endoscope. The stents were not removed from the arteries prior to inspection.

Results

Physiological Compliance: Empty Artery

The physiological mock artery (ID=x.xxmm, wall thickness=x.xxmm) mean %ID Radial Strain Comp 160mmHg/80mmHg = **x.xx %** (Table 1), provided a physiological compliance within the 3-5% designated range.

Physiological Compliance: Device Deployed Artery

The mean strain across the deployed devices was converted to a %ID strain by multiplying it by the %IDstrain / %ODstrain ratio for the tube (x.xxmm=ID and x.xxmm wall thickness): %ID / %OD strain ratio = **x.xx** [Note:A %ID/%OD strain ratio was used to determine %ID strain from the measured %OD strain. Strain% = $\Delta OD/OD_{min}$x100.] The target %ID strain was converted again back to a target %OD strain this time for the thick walled fatigue mock arteries (x.xxmm=ID, x.xxmm=wall thickness), %ID / %OD strain ratio = **x.xx**. Mean %ID strain on the physiological tube was **x.xx%** (Table 2). The %OD target is then %ID (x.xx%)/%ID/%OD (x.xx) = **x.xx%OD** (Table 2). Test set-up was valid (Fig. 1).

Physiological Compliance Empty Mock Artery: Static Pressure (mm Hg) vs. OD (mm)

Positions (cm)	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*
Pressure (mm Hg)	OD(mm)							
80								
160								
OD% Comp								
ID% Comp								
Mean ID% Comp								

Table 1: Physiological compliance data for the empty mock artery (ID=x.xxmm, wall thickness=x.xxmm). *Measurement Position* – The position in cm of the laser micrometer along the length of the tube from left to right. *OD %Comp: T*he recorded diametral strain of the tube as measured by the laser per mmHg. Calculated by: ($\Delta OD/OD_{min}$ x 100)/dP x 100%) *ID %Comp* – Calculated from the product of the mean %OD Comp and the %ID/%OD strain ratio. Mean ID% Comp is within the x-x% physiological compliance range

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Physiological Compliance Stented Mock Artery: Static Pressure (mmHg) vs. OD (mm)

Positions(cm)	**6.6**	**7.8**	**9.1**	**10.4**
Pressure (mm Hg)	***OD(mm)***			
80				
160				
%OD Strain				
%ID Strain				
Mean %ID Strain				
Fatigue Test Target %OD Strain				

Table 2: Physiological compliance data for the stented mock artery (ID=x.xxmm, wall thickness=x.xxmm). *Measurement Position* – The position in cm of the laser micrometer along the length of the tube from left to right. *OD %Strain: T*he recorded diametral strain of the tube as measured by the laser per mmHg. Calculated by: ($\Delta OD/OD_{min}$ x 100) Strain was calculated for x positions along the deployed devices. *ID %Strain* – Calculated from the product of the mean %OD strain and the %ID/%OD strain ratio (x.xx) for the physiological simulating mock arteries *(*x.xxmm *ID,* x.xxmm *wall thickness). Fatigue Test Target %OD Strain* – Quotient of the Mean %ID Strain and the %ID/OD strain ratio (x.xx) for the fatigue testing mock arteries (x.xxmm ID, x.xxmm wall thickness).

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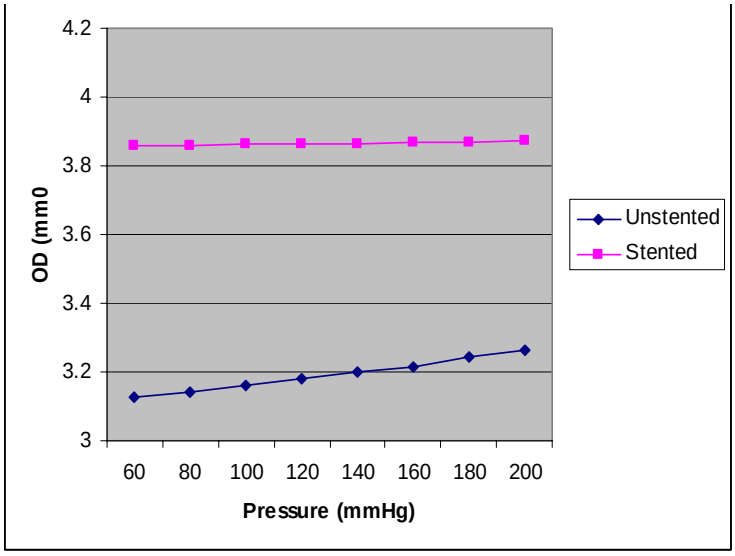

Figure 1: Results of the physiological test set-up validation, comparing the OD of an empty mock artery (x.xxmm=ID, x.xxmm=wall thickness) with OD of the same artery with a deployed stent. Test set-up is validated: the stent deployed area of the artery does not have a linear relationship with pressure. *Measurement Position* – The position in cm of the laser micrometer along the length of the tube from left to right.

Accelerated Fatigue Test:

Test conditions were maintained to meet protocol requirements (Table 3).

Accelerated Fatigue Test Set Up Validation

The maximum OD of the stent deployed area of the artery is always greater than the maximum OD of the unstented position directly to the left and right (Fig.2). This indicates that the stent is following the wall of the mock artery, and measurements of the stented position OD and Radial Strain (OD %) are accurate indicators of stent behavior under dynamic conditions. The accelerated fatigue test set up is valid.

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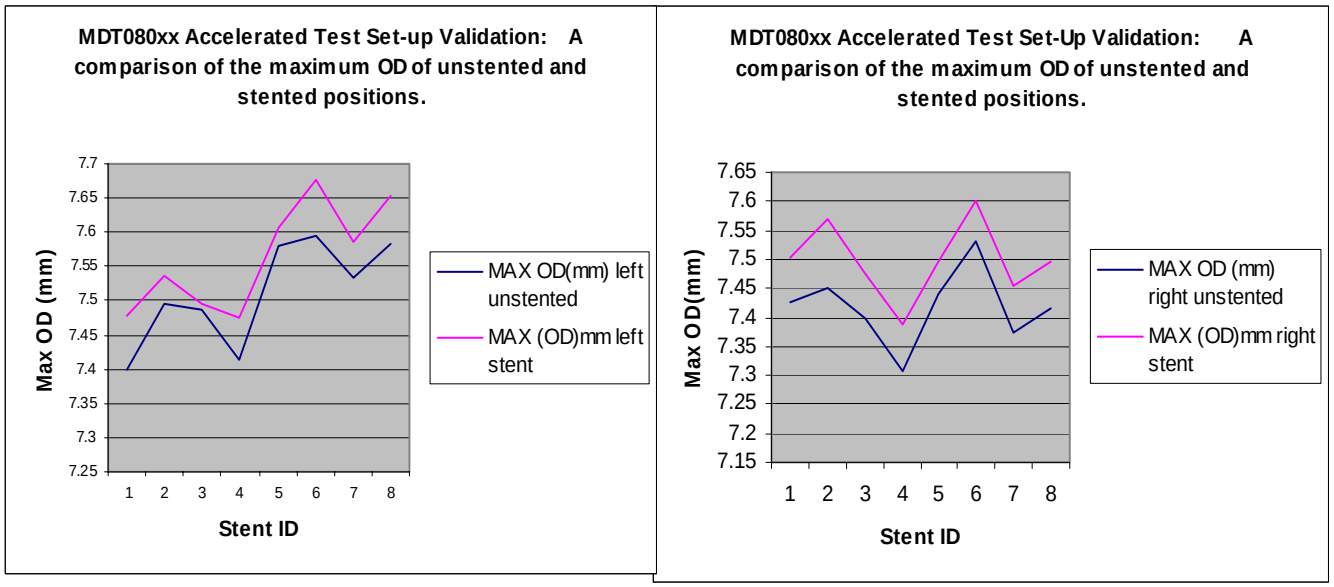

Figure 2: Results of the accelerated test set-up validation, comparing the maximum OD of unstented points along the empty mock artery (x.xxmm=ID, x.xxmm=wall thickness) on either side of a stented position. Test set-up is validated: the maximum OD of the stent deployed area of the artery is always greater then the maximum OD of the unstented position directly to the left and right. This indicates that the stent is following the wall of the mock artery, and measurements of the stented position OD and radial strain (OD %) are accurate indicators of stent behavior under dynamic conditions.

Volumetric displacement levels were adjusted throughout the test to maintain the calculated target %OD strain levels (Table 4). Mean %OD radial strain through out the duration of the 400x 10^6 cycle xHz accelerated fatigue test was **x.xx%** (Table 5). Mean OD (mm) was **x.xx mm** (Table 6).

Testing Conditions

	Mean	***Minimum***	***Maximum***
Temperature (C)			
Maximum Pressure (mmHg)			
Minimum Pressure (mmHg)			
ΔP			

Table 3: Summary of testing conditions, recorded daily.

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Test Parameter Alterations

Start	Finish	Level 1 (ml)	Level 2 (ml)	End #Cycles (million)	Frequency (Hz)

Table 4: Alterations to the volumetric displacement levels to maintain the calculated target %OD strain on the stents throughout the accelerated fatigue test.

%OD Radial Strain Test Data

Stent #	*Laser Position*	*%OD Mean*	*%OD Minimum*	*%OD Median*	*%OD Maximum*	*n=*
Test Duration		*Mean*	*Minimum*	*Median*	*Maximum*	*n*
Overall Stent Radial Strain						

Table 5: Summary of %OD Radial Strain Test Data. *Stent #* - Mock Artery number and stent position. *Laser position*-position in cm of the laser micrometer along the length of the tube from left to right. Data is representative of a single position on a single tube. *Test Duration*-Final data for Sponsor targeted fatigue positions; cumulative data for all positions on all tubes.

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OD (mm) Test Data

Stent #	*Laser Position*	*OD(mm) Mean*	*OD(mm) Minimum*	*OD(mm) Median*	*OD(mm) Maximum*	*n=*
Test Duration		*Mean*	*Minimum*	*Median*	*Maximum*	*n*
Overall Stent OD (mm)						

Table 6: Summary of OD (mm) Test Data. *Stent #* - Mock Artery number and stent position. *Laser position*- position in cm of the laser micrometer along the length of the tube from left to right. Data is representative of a single position on a single tube. *Test Duration*-Final data for Sponsor targeted fatigue positions; cumulative data for all positions on all tubes.

Disassembly:

30x endoscopic inspection at the conclusion of the test did not detect any signs of failure in the 10 Sponsor x.xxmm lumen stents. The devices were shipped to Sponsor for further inspection. The devices were not removed from the test arteries prior to shipping.

Revision	Description of revision	Date

MDT Medical Device Testing Services

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Medical Device Testing Services (MDT) tests are conducted in accordance with ANSI/ISO/IEC 17025-2005. In compliance with this standard, MDT test reports include complete and accurate documentation of the test protocol and results. Information including the specific test conditions, statements of compliance or non-compliance with test protocol, statements of the estimated measurement uncertainty, and opinions or interpretations may be provided. Any test method deviations, additions or exclusions are documented and reviewed with the customer prior to beginning the test. Opinions and interpretations will be clearly marked as such in the test report. Additional information required by customer specific, or customer group specific, methods will also be noted.

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