

Accelerated Pulsatile Fatigue Testing of Ni-Ti Coronary Stents

By Richard Glenn
and Jeff Lee
IsoStent, Inc.

Abstract

Ni-Ti coronary stents were fatigue tested in a 37 degrees Celsius saline solution using an accelerated circumferential pulsatile method to simulate the compliance of coronary arteries. Stents were inspected using a Scanning Electron Microscope both before and after fatigue testing to compare any changes in surface characteristics. Load versus deflection testing was also performed before and after fatigue testing to compare any changes in stiffness of the stents. The thirty Ni-Ti stents outperformed the ten stainless steel control stents in fatigue testing to 100 million cycles, and performed as well as the thirty Ni-Ti controls used for mechanical evaluation.

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Introduction

Stents are a minimal surgically invasive technique used to combat coronary artery disease. Stents themselves are small wire mesh tubes that fit along the inner diameter of arteries, acting as scaffolding to keep open a diseased or injured section. Stents are delivered to the specific arterial site by means of a catheter. The stent's diameter is reduced, then placed in the catheter for delivery to the site in the artery where they remain permanently implanted in the patient.

Because of Ni-Ti's unique super-elastic and shape memory properties, a stent of this alloy may be a viable alternative to the present standard of stainless steel available in the U.S. market. By taking advantage of Ni-Ti's shape memory, the thermally activated stent becomes self-expanding and there is no need for a balloon to deploy the stent, as with stainless steel designs. The Ni-Ti stent is deployed using a mechanical pullback catheter and self-expands to a known diameter within the artery. The nature of the pumping heart causes the arteries to constrict and expand with the systolic and diastolic pressures, respectively, resulting in circumferential forces on the stent. The human adult has average arterial pressures of 120 mm hg systolic and 80 mm hg diastolic, creating a "pressure-pulse" of 40 mm hg. In order to accurately test the fatigue life of the stent it needs to be tested under similar physical conditions along with an increased cycling rate to reduce overall testing time. Thus, the fatigued cycled stents were subjected to an accelerated circumferential pulsatile fatigue test at 45 Hz in 37 degrees Celsius saline solution to simulate the physiological conditions within the arteries.

To evaluate any differences in mechanical stiffness after fatigue cycling, the stents were flat plate and radial hoop tested. The

results of both tests were compared to a control group of the same stent type with zero-cycles.

One of the most notable effects of fatigue is a change in the affected material's surface, such as crack propagation. For this reason, the fatigue tested stents were inspected using a scanning electron microscope (SEM).² The results were compared to the surface of a zero-cycled control group. Also SEM may aid in determining a failure due to fatigue by magnifying the fracture surface to allow study of any patterns indicative of fatigue type failures.

Test Methods

Thirty of IsoStent's Ni-Ti 15mm long stents and ten balloon expandable stainless steel stents (the control group) were fatigue tested. The ten stainless steel stents were PalmazShatz™ 15 mm long stents from Johnson and Johnson Corporation, approved by the FDA and available for human use in the United States.

The fatigue test equipment used was an Intra-Vascular Stent and Graft Tester manufactured by EnduraTEC Systems Corporation. Natural rubber latex tubing was used to simulate human arteries. Two electro-dynamic pump assemblies on either side of saline filled latex tubing, re-create the systolic and diastolic pressure within the simulated arteries. The pumps move axially towards and away from each other (180 degrees out of phase) to displace the fluid. Because it is a closed system and fluid is incompressible, the latex tubing expands or constricts to keep the volume constant. It is this constriction and expansion which mimics the action of the human artery and applies the circumferential forces to the stent. A laser measurement system monitors and records the tubing's compliance (diameter as a function of pressure).

Before loading the stents into the tubes, the machine was "pre-tested" at a cycle rate of 45 Hz with systolic and diastolic average pressures of 250 and -100 mm hg, respectively. The empty tubes measured 4.5%-5.5%. The "pressure pulse", the difference between the systolic and diastolic pressures, averaged 350 mm hg, more than 8.5 times that seen in a human.

The Ni-Ti stents were deployed in 0.125" I.D. x 0.063" wall thickness latex tube using a mechanical pullback prototype delivery system. The Palmaz-ShatzTM stents were deployed in the same size tubing using the standard J&J 3.0 mm balloon delivery system. Each stents location was externally marked on the tube to monitor any migration. After deploying the stents, the same settings as the "pre-test" were maintained, resulting in compliance between 1.0%-1.5%.

After cycle testing each tubing was carefully cut away from the stents. Each stent was visually inspected under a microscope at 50X for obvious damage. The stents were then inspected using a SEM at magnification levels from 200X to 2000X, emphasizing the stents structural intersections and junctions.

Fifteen "zero cycled" Ni-Ti stents were flat plate tested and fifteen radial hoop force tested to use as controls for determining a base value to compare the fatigued samples to. The flat plate test is used as an evaluating tool to determine the force required to reduce the diameter of a stent 50 % under a uni-axial load without supporting the circumference. The radial hoop test consists of a rigid external support around 70% of the circumference, while applying a point force along the longitudinal axis. Both tests yield a curve whose slope is a relative measure of the stents stiffness for each respective test method, and also give a maximum force applied.

Results and Discussion

Table 1 shows the stainless and Ni-Ti stents survivability from fatigue testing. A stent with at least one broken strut is classified as a failure. Only 30% of the stainless steel stents survived the same testing that 97% of the Ni-Ti stents survived. All stents passed the one million cycle point, equivalent to approximately 12 days of the heart pumping in an average human adult.

Table 1: Stent Fatigue Test Survival Summary

Stent Type	Fatigue Cycles	"Human Time"	Quantity Tested	Quantity Passed
Ni-Ti	1 million	12 days	6	6
Stainless	1 million	12 days	2	2
Ni-Ti	10 million	4 mths.	6	6
Stainless	10 million	4 mths.	2	0
Ni-Ti	40 million	16 mths.	6	6
Stainless	40 million	16 mths.	2	1
Ni-Ti	100 million	2.5 years	12	11
Stainless	100 million	2.5 years	4	0

The testing was broken down into stages to monitor any failure rates and help determine an estimated life cycle under these accelerated pulsatile test conditions.

After studying the location of the stents which failed, there appears to be no correlation between the location of the stent's placement in the tube and it's failure. It was observed through the latex tubing the control stents (stainless steel) would first structurally fail, then because of their weakened mechanical integrity, migrate axially in the tube. However, migration of the stent may contribute to failures not directly related to the circumferential cyclic fatigue. The only Ni-Ti failure occurred on a stent which migrated, after approximately 60 million cycles, and was physically stopped by the brass port where the latex tube is fixed. The failure occurred at an intersection on the end of the stent which came into direct contact with the port. SEM inspection photos at 500X indicate a general starting point of the failure probably originated at a corner. In a cross-sectional view this would be the outer most fiber at the intersection's radius. A possible cause for failure, other than the circumferential cyclic stresses alone, is from the stents impact against the port.

However, this theory has very little physical evidence to support it. The SEM photos do not show a distinct contact area. Damage to the surface of the stent would be expected if failure was immediate upon contact. Also, both the port and stent have round ends and initial contact would be between the two flush surfaces, making it difficult to sever any portion of the stent.

The most obvious possible failure mode is from cyclic stresses alone. From the SEM photos the appearance of "peaks" or "waves" parallel to each other on the fracture surface present evidence the failure may be due to classic fatigue.³ This leads one to believe failure of the stent occurred before migration (at approximately 60 million cycles) as with the stainless steel type. However, the presence of "waves" usually occurs in brittle materials, which of course Ni-Ti is not. Based on the super-elastic properties of Ni-Ti, unless there was a defect at that point of failure or damage done to the stent at the time of deployment (which isn't apparent in the SEM photos), the stent probably did not fail under cyclic stress testing alone.

A third possibility for failure is the combination of cyclic fatigue for the first 60 million cycles and then contact with the port for the final 40 million. With the stent's position against the port, the tubing is not necessarily in direct contact around the end of the stent butted against the port. The tubing I.D. enlarges slightly to fit over the brass port, leaving a gap between the latex tube and the stent. Also, where the tubing is fixed to the ports, there is a 0.25" to 0.5" section where the compliance is severely reduced. Without the circumferential force to hold the stent in place, it may have moved longitudinally and hit against the port's surface continuously over the remaining 40 million cycles, enough to cause a fatigue failure. However, without witnessing when the fracture occurred,

the exact reason for failure remains inconclusive.

Other issues noticed upon SEM inspection was the inconsistent finish from the several processing steps a Ni-Ti stent goes through for manufacturing. Numerous surface cracks were discovered in the 0.002" radii at the materials intersections and junctions in the Ni-Ti control group during the SEM inspections. The average length appears to be between 10um and 25m and a depth of 1um to 5um. SEM inspection of the fatigued stents at the same magnification showed no visible difference in the cracking patterns or dimensions, leading to the conclusion that under these accelerated pulsatile conditions, the integrity of the stent was not jeopardized by the small cracks created before being subjected to fatigue testing.

The mechanical testing shows no degradation in the collapse strength under the failure modes tested for the Ni-Ti stent. Since only three of ten stainless designs passed the fatigue testing a significant number could not be mechanically tested. The summary of the flat plate and radial hoop test results are listed in Tables 3 and 4 for the Ni-Ti stents. The tables indicate the maximum force in pounds required to collapse the stent 50% of its outside diameter. The max force occurred before reaching the full displacement in all cases for both tests.

Table 2: Ni-Ti Flat Plate Test Summary

CYCLES	SAMPLES "n"	AVERAGE (lbs.)	STD. DEV (lbs.)
Zero	15	0.819	0.131
1 million	3	0.884	0.128
10 million	3	0.974	0.042
40 million	3	1.085	0.073
100 million	6	1.056	0.116

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Although it initially appears the Ni-Ti stents may actually increase in "strength" due to the repeated cycling of stresses, a statistical analysis shows otherwise. Using a students t-test, and assuming equivalence of variance, the fatigue tested samples were compared to the control group (zero-cycles). Table 4 shows whether or not there is a significant statistical difference at a 95% confidence level.

Table 4: "t-test" Summary Table

CYCLES	FLAT PLATE Significant difference At 95% confidence?	RADIAL HOOP Significant difference At 95% confidence?
1 million	No	No
10 million	Yes	No
40 million	Yes	Yes
100 million	Yes	Yes

Although the average force for each test was greater than the zero-cycled control group, the only indication that both the flat plate and radial hoop test's data coincided is for stents tested to 40 million and 100 million cycles. Because of the small sample size, there is some uncertainty in the results, even though a trend is evident. The most important information gathered from the mechanical testing is there appears to be no loss of mechanical integrity evident from the post-fatigue testing performed.

Conclusion

Ni-Ti stents may prove to be a viable alternative to the current material being used, stainless steel. By utilizing and taking advantage of Ni-Ti's super elastic and shape memory properties, this material could be used in coronary arteries. One of the first steps in proving the safety of this application is a fatigue test simulating physiological conditions. Due to obvious time constraints, the pulsatile testing is accelerated. Under these conditions and compared to the stainless steel control group, the Ni-Ti stents outperformed the controls in both fatigue test survivability and the post-fatigue mechanical testing. Based on the promising results from this testing, the next step is to test the Ni-Ti stents to 400 million cycles, equivalent to 10 years "human time". Also for future evaluations, another approach to quantify the integrity of fatigue tested Ni-Ti stents is to implement Thermal Mechanical Analysis to check for a change in the Af Temperature, which may be a better indication of unseen changes due to cyclic fatigue within the alloy.

References

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