Laser Cut Nitinol Tubing Fatigue Coupon: FEA's Role in Design, Testing, and Endurance Limit Determination

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Abstract: Nitinol medical device implants made from laser cut tubing (i.e. stents, valve structures, etc...) often require a fatigue assessment, which makes determining the material fatigue properties necessary. Towards the goal of determining the strain based endurance limit of medical grade super-elastic Nitinol tubing, a coupon was designed and evaluated via FEA using Abaqus software, produced via laser cutting, shape setting, and electro-polishing processes, and then fatigue tested to 10 million cycles. Extensive use of FEA was made to both design the coupon, but also to determine the strain versus alternating displacement amplitude for the coupon. Error due to dimensional tolerances was also quantified with FEA. The coupons where then fatigue tested in a 37C temperature water bath at alternating strain levels ranging from 0.75% to 4.0% at zero mean strain. Sample replication was greater than 90%, and the median alternating strain fatigue limit was determined via two methods. Confidence and reliability with maximum likelihood statistics are used to present a strain based endurance limit for the material.

Keywords*: Nitinol, Fatigue, Fatigue Life, Fatigue Strain Limit, Endurance Limit,Medical, Stent, Laser Cut, Abaqus/Standard, Coupon, and Fatigue Test.*

1. Introduction

It should be noted that much of this work was presented at the 2013 ASM International SMST Conference in May of 2013. This version of the presentation of the work is intended to be more towards the FEA component of the work.

The medical device industry frequently depends upon international and domestic standards for testing the safety of a device. One such standard ANSI/AAMI/ISO 5840:2005/(R)2010 (AAMI, 2010) for Cardiovascular Implants and Cardiac Valve Prostheses. Annex O of this standard states a requirement that a "fatigue assessment" be performed on a given device. This fatigue assessment involves verifying the device's lifetime via some combination of stress/strain analysis, material fatigue property determination, and complete device testing. The most important fatigue property of any material is of course the endurance limit of the material. This value is a function of the raw material and processing thereof, and is independent of device design. To determine this value an experimental fatigue test method must be implemented. Rather than testing an entire finished device to failure, it is more effective to use a coupon specifically designed to capture the fatigue characteristics of the finished device. This coupon can then be tested at various load conditions and with higher repetition to acquire data which can form an endurance life diagram for

the material, typically using stress or strain versus cycles to failure (i.e., an S-N diagram or ε-N diagram). Also, in the future this type of coupon test may be implemented as a qualification for new lots of incoming material to be used to manufacture existing approved devices. Such test data can also drive updates to material processing to enhance device fatigue performance.

2. Fatigue Coupon

The general role of FEA in this context is to aid in the evaluation of various designs, track the strain of the coupon during its forming process, determine the strain in the fatigue sample, and to evaluate sources for possible error (tolerances).

2.1 Coupon Design Requirements

Two basic tenants drive the design of the fatigue coupon: applicability to the finished device, and practicality for testing. For applicability to the finished device, the basic requirements for the fatigue coupon are that it should:

- be made from same material as the finished device
- be made from the same process as the finished device (i.e. laser cut, shape set, and electro polished Nitinol tubing)
- be stressed in the same relative direction as the device's critical areas during the worst case in vivo loading
- have dimensions very similar in scale to the finished device
- be tested in similar conditions (i.e. for a medical implant – at body temperature)

For practicality of performing the testing, ideally the fatigue coupon should:

- be able to have desired predetermined alternating load levels in sample
- be compatible with the fatigue test machine (i.e. accurate stroke length of machine corresponding to desired increments of load levels in the device)
- have an electrical conductive path through sample for break detection (or alternatively force sensing)
- be easily mounted and and removed from the test fixture
- be easy to measure/inspect to ensure consistency
- have an alternating strain range of 0.1% to 4.0%
- be an efficient use of tubing material
- have no moving surfaces that rub/wear (unless finished device would have these conditions)
- not require sliding/pivoting action if submerged in body temperature test medium (i.e. saline).

2.2 Design Development of Coupon

Many different designs were evaluated via FEA. Simple cantilevers were the first choice, although this inevitably requires the fixture that is deflecting the tip of the cantilever to rub the test sample unless a complex mechanism is employed. Eventually, the simple concept of "v", or half

diamond, sample was determined to be the best at meeting the requirements outlined above. This design is shown in figure 1. The fatigue coupon features pairs of mounting holes on the top and bottom and is flexed up and down from this initial configuration (with the mounting hole pairs each remaining perfectly horizontal). Its overall dimensions are 9.5mm x 7.5mm, with the centers of the pairs of mounting holes 6.5mm apart. It is fabricated from laser cut Nitinol tubing in the same way that a Nitinol stent or similar could be made. Figure 2 shows the two dimensional layout of the design fit to a 0.199 inch (5.05mm) outer diameter tube. Ten coupons can be fit around the circumference, an efficient use of material. The coupons were manufactured by LaserAge Technology Corporation using the same process for a stent, prosthetic valve frame, or similar implantable medical device.

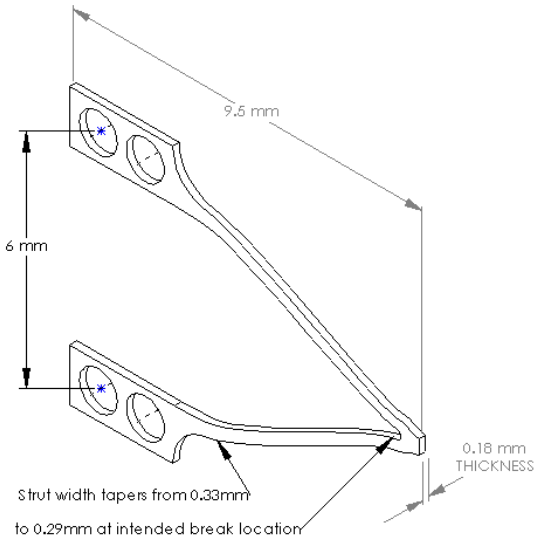


Figure 1. Fatigue coupon design.

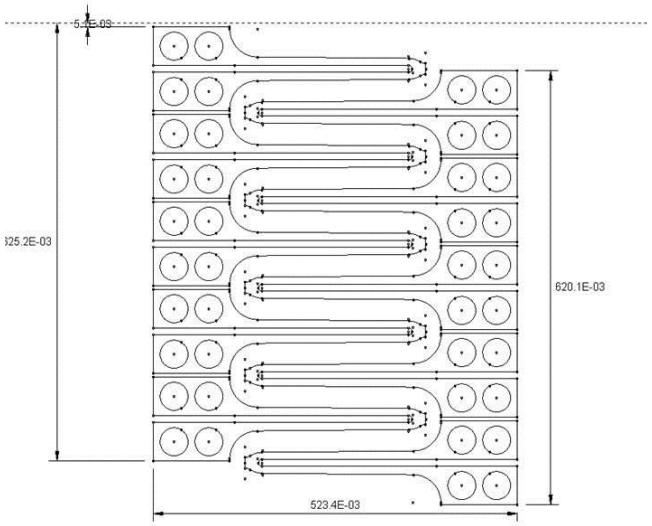


Figure 2. Fatigue coupons, laid out and nested in 2 dimensions – the vertical dimension on the left is the circumference of the tubing (in inches).

In the same way a stent would be cut from a tube and expanded and shape set, the coupon is also stretched out and shape set. Abaqus/Standard version 6.12-1 was used extensively to evaluate the coupon design concept, and to hone in on final dimensions. FEA modeling was used to simulate the forming and fatigue of the coupon. Figure 3 shows an FEA (finite element analysis) model, in the as laser cut configuration. Figure 3 also shows the same coupon, stretched out and flattened to its final shape. This forming analysis is not the focus of this paper, but for completeness the steps in the analysis included stretching out the to a "v" shape and flattening between two rigid surface plates. Figure 4 shows an FEA model of the forming process. The coupon experiences a maximum of 10% strain before being annealed to the final shape.

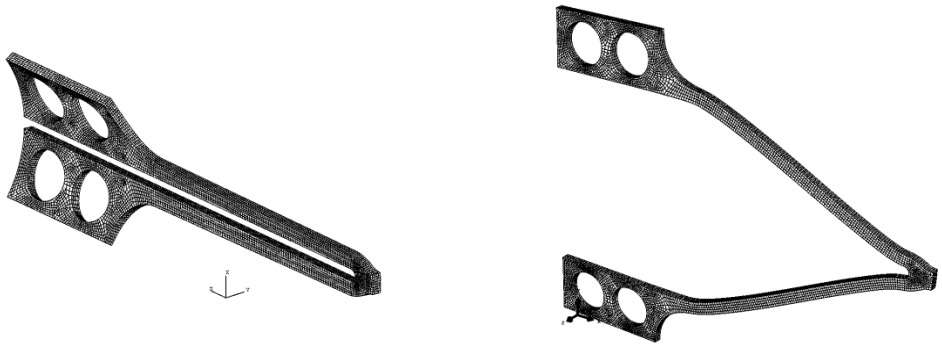


Figure 3. Abaqus/Standard FEA model of the fatigue coupon, as laser cut (left) and after shape setting to final configuration (right).

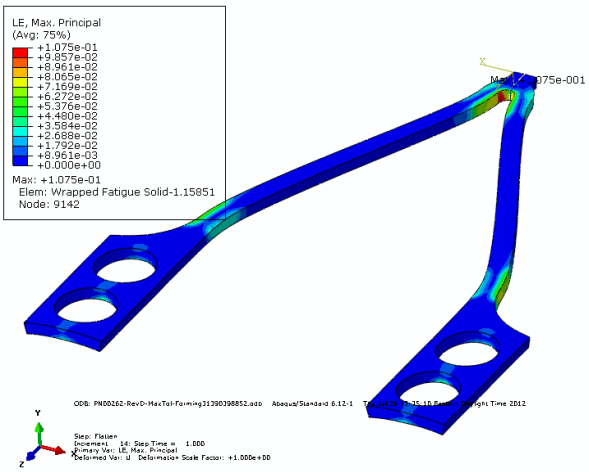


Figure 4. Abaqus/Standard FEA model of the fatigue coupon forming process, stretched out and flattened, before annealing.

2.3 Coupon Design Verification and FEA Model Verification

Before continuing the FEA model of the coupon in fatigue, the constitutive material model must be verified so there will be confidence that for a given coupon cyclic deflection, the actual test strain in the coupon will be known accurately.

2.3.1 Coupon Material Model Input Check

The input material model can also validated by comparing the input values to the results of a simple tensile test FEA model. Towards this end, a single element model, using a single C3D8R hexagonal element covered with a skin of membrane elements was created. These elements are the same ones used in the larger analysis of the fatigue coupon. This single element was then displaced to +/- 8% strain, and the results recorded. The results are plotted along with the data points input to the Abaqus/Standard built in Nitinol user material. This is shown in figure 5. They correspond exactly. Thus there is confidence that the material model was input to the FEA program as intended.

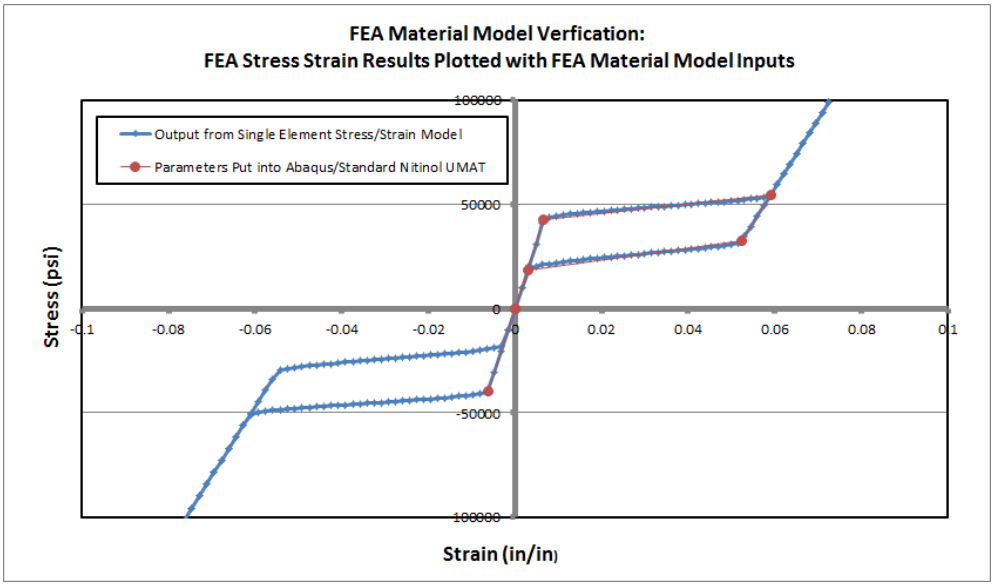


Figure 5. Output from a simple FEA stress/strain analysis plotted alongside the data points used for the Nitinol UMAT input.

2.3.2 Coupon FEA Model Force Response Verification

The elements used in the model of the coupon (C3D8R with skin of 1 millionth of an inch thick M3D4 elements) are easily verified for basic structural response by the analysis featured in section 2.3.1 above, and also by comparing to small displacement tension and cantilever closed form solution models. This is relatively simple and can also be found in the Abaqus/Standard documentation as well, so it will not be reproduced here.

However, ensuring the accuracy of the coupon model's response over a larger displacement requires additional work. Towards this end, six coupons were taken from the manufactured lot, each having as close to nominal dimensions as possible, and these coupons were mounted on a Lloyd tensile test machine appropriately sized load cell, and subjected to a deflection of 0.50 inches (1.27mm) and return to zero.

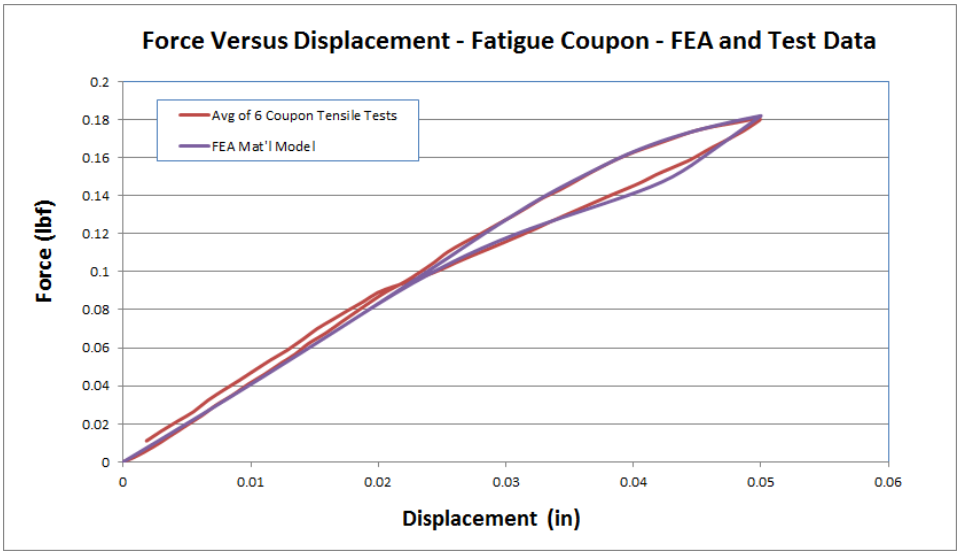


Figure 6. Average of 6 Coupons Tensile tested plotted along with FEA Model simulation result of same displacement.

The force versus deflection curves for these six coupons were similar and were averaged together. An FEA model of a nominally dimensioned coupon was then subjected to the same deflections. The material model inputs in the Abaqus FEA software were then calibrated slightly so that the results accurately matched the test data. Figure 6 shows both the test data and data from the FEA model of a nominally dimensioned coupon plotted together, the results are very close.

2.3.3 Additional FEA Model Details

The coupon was modeled with reduced integration 8 node hexagonal bricks (C3D8R), with enhanced hour glass control, and a skin of very thin (1 millionth of an inch) membrane elements (M3D4) which were not reduced integration. These membrane elements served to act as a "strain gage" and results for stress and strain were used from these elements.

The model was also attempted with 8 node hexagonal incompatible model elements, which are slightly more expensive computationally, and no difference in the response or strain results from the model were observed. Mesh density used was seven elements through the cross section where the fatigue bending occurred, and 5 elements through the thickness dimension where bending did not occur. Mesh convergence studies were also performed. No appreciable difference was observed going to a denser mesh than what is presented here. The model contained 27,978 nodes, 20,650 solid elements, and 13,620 membrane skin elements.

3. Coupon Fatigue Cycle FEA Results and Tolerance Analysis

Figures 7 and 8 show the coupon FEA results from its maximum intended stroke, which is +/- 0.048 inches (1.22mm). Figure 7 shows upward (spreading apart) and Figure 8 shows downward (compressing). As these figures indicate this will result in an alternating strain of +/- 4.0% at the

intended break location, however the mean strain is non zero and is 0.3%. This is because the loading through the section of the coupon experiencing the most strain is not perfectly symmetric. However, it can be shown that at lower strain levels the mean strain is near zero. Figure 9 is a plot of strain at the coupon's intended break location versus the sine wave deflection amplitude of the test fixture. As shown in figure 9, mean strain will be near zero at the critical strain test strain levels where the endurance strain limit may likely occur based upon similar work by Pelton et al (Pelton, Gong, & Duerig, 2003).

Additional considerations in implementing a fatigue test coupon include tolerance considerations. Not every coupon will be exactly the same and the inspection tolerances' influence on desired test strain levels should be considered. Figure 10 shows a second graph of coupon strain versus displacement, but includes tolerance model results for the maximum and minimum tolerances allowed for the coupon to pass an incoming inspection. Clearly the permitted tolerances do not have a great effect on the strain levels in this critical area of the graph. It should be noted that it would also be relatively rare for all dimensions to be at the extreme of all high or all low tolerances.

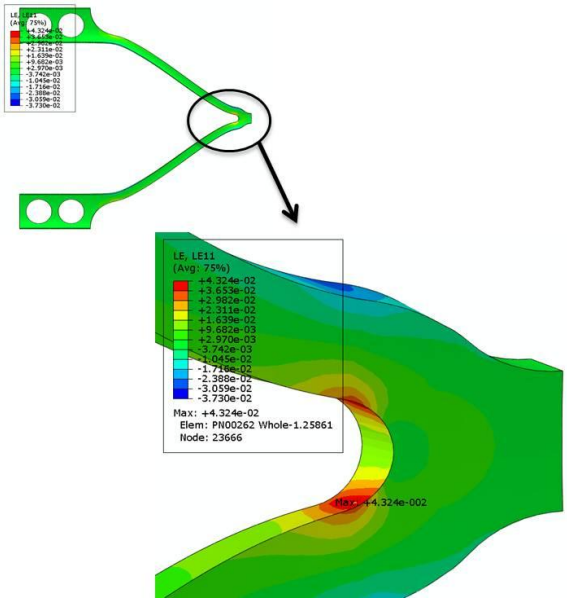


Figure 7. FEA results from the tension half of the maximum intended coupon fatigue stroke, which is +/- 0.048 inches (1.22mm) at the mounting points.

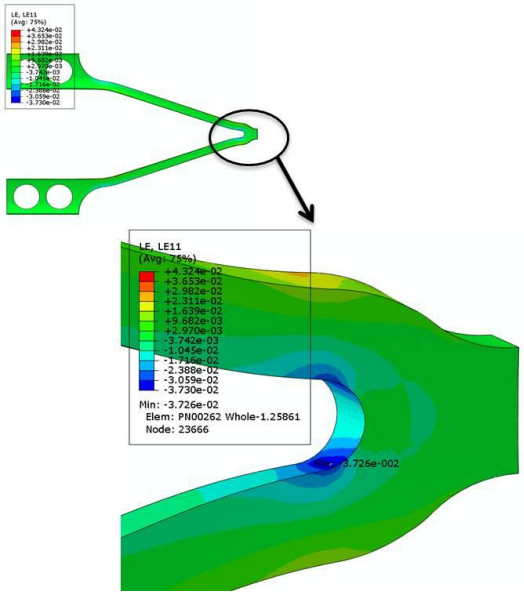


Figure 8. FEA results from the opposing compression half of the maximum intended coupon fatigue stroke, which is +/- 0.048 inches (1.22mm) at the mounting points.

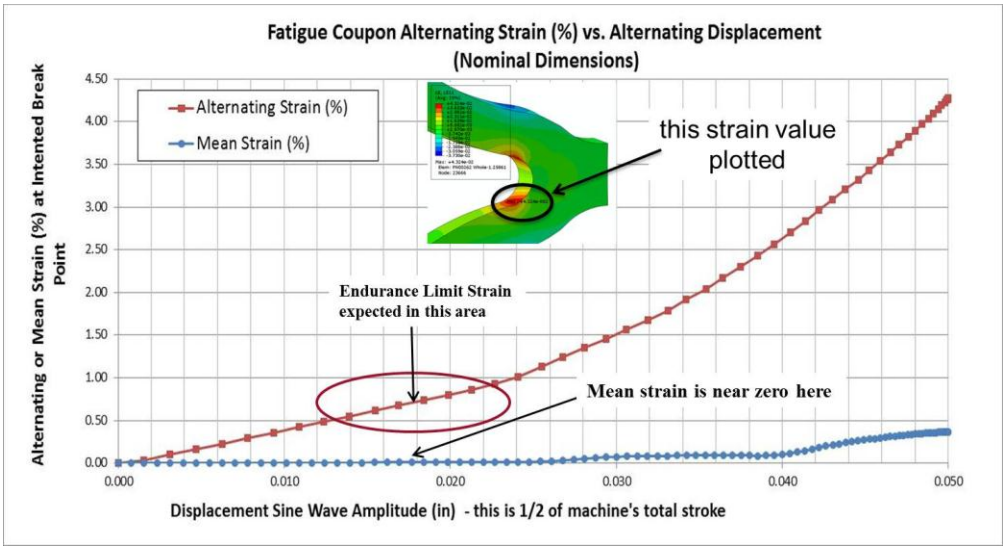


Figure 9. Strain at the coupon's intended break location versus the sine wave deflection amplitude of the test fixture.

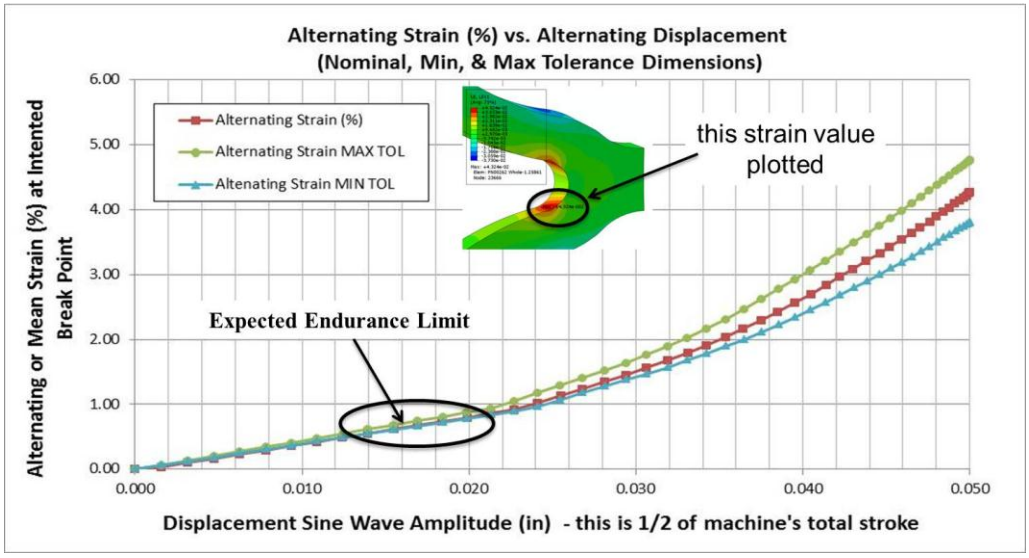


Figure 10. Coupon strain at intended break location versus displacement, including tolerance model results for the maximum and minimum tolerances allowed.

4. Fatigue Test Results

In order to execute the actual fatigue test, a standard ASTM guideline was consulted: ***ASTM STP588: Manual on Statistical Planning and Analysis for Fatigue Experiments*** (ASTM, 1975). This guideline states that to generate reliability data, replication of 75% to 88% minimum is recommended. Replication, R, as a percentage is:

$$R = 100\left(1 - \frac{[no.\ of\ strain\ levels\ tested]}{[total\ no.\ of\ test\ specimens]}\right)$$

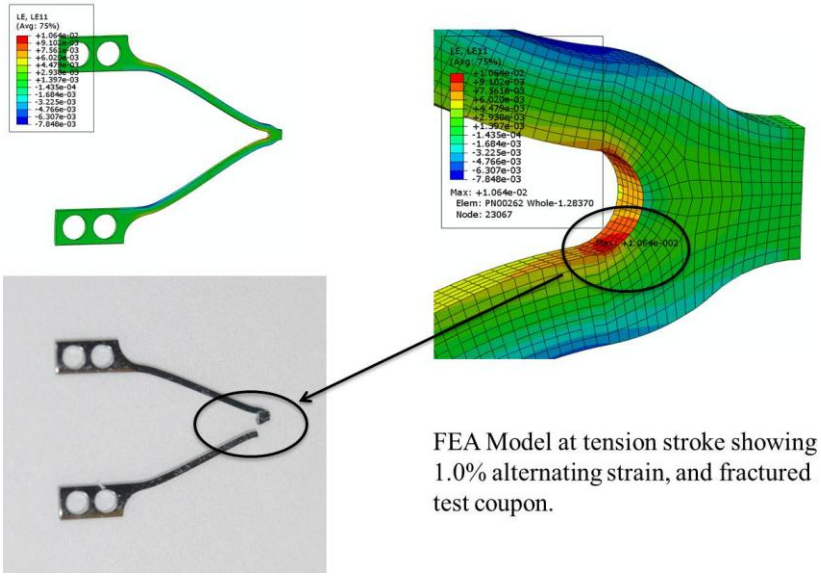
A total of 114 coupons were tested. The test machine was from BDC Labs, and was the model LDT-1500, which in the configuration used, held 8 coupons in a heated water bath and with continuity break detection monitored separately for each sample. These coupons were made from material meeting the ASTM F2063-05 Nitinol material standard with austenite finish temperature of 25 +/-5C. The coupons were tested in a body temperature 37C bath. Tests included ten different alternating strain levels ranging from +/- 0.75% to +/- 4.0%. This resulted in a replication of 91.2%, good enough to generate reliability data (ASTM, 1975). The test was censored at 10 million cycles, similar to previous work by Pelton (Pelton, Gong, & Duerig, 2003) and accepted as reasonable practice when defining an endurance limit (Suresh, 1998). Intended mean strain was zero for all tests.

All samples failed at 4.0%, 3.0%, and 2.0% alternating strain. The highest alternating strain at which a coupon passed 10 million cycles was 1.4%, and the lowest alternating strain at which a coupon experienced a break was 0.9%. Table 1 shows all strain levels and failures in an

event/trial format. Figure 11 shows a typical coupon fatigue failure, closely matching the FEA model's predicted break location.

Alternating Strain (%)	Number Of Failures	Number Of Tests
4.00	8	8
3.00	5	5
2.00	5	5
1.45	14	16
1.24	12	16
1.13	4	16
1.00	1	16
0.90	1	16
0.81	0	8
0.75	0	8

Table 1. Event/Trail format for test results.



FEA Model at tension stroke showing 1.0% alternating strain, and fractured test coupon.

Figure 11.

All coupons broke at this location (or its mirror location on the other coupon leg). Of the 50 samples that fractured, SEM (scanning electron microscopy) was performed on 5 samples' fracture surfaces and typical fatigue with overload at finish was observed. Grain size for the

material was not evaluated post forming of the coupon, but the raw tubing certification listed a grain size of 7.

Using Minitab statistical software, two methods were used to determine the fatigue strain limit. The data was evaluated for best model fit and both Lognormal and Loglogistic were found to be the best fits and had similar results. Both the 2 Point Method and the Probit Method (ASTM, 1975) resulted in a mean and median alternating strain fatigue limit of +/-1.2%. The 2 Point Method only uses two strain levels and did not have enough replication to determine reliability statistics. The Probit Method uses all of the strain levels tested, and hence had enough replication to determine reliability for the fatigue strain limit, resulting in a 95/95 confidence/reliability lower limit of +/-0.81% and a 95/99 lower limit of +/-0.65%. Figure 12 shows a probability plot for the failure event, as created by a Probit analysis, and this figure includes the median, 95/95, and 95/99 lower limit fatigue endurance strain limit values, which are 0.81% and 0.65% alternating strain, respectively. Figure 13 shows a typical ε-N diagram of alternating strain versus cycles to failure, with the above statistical results included.

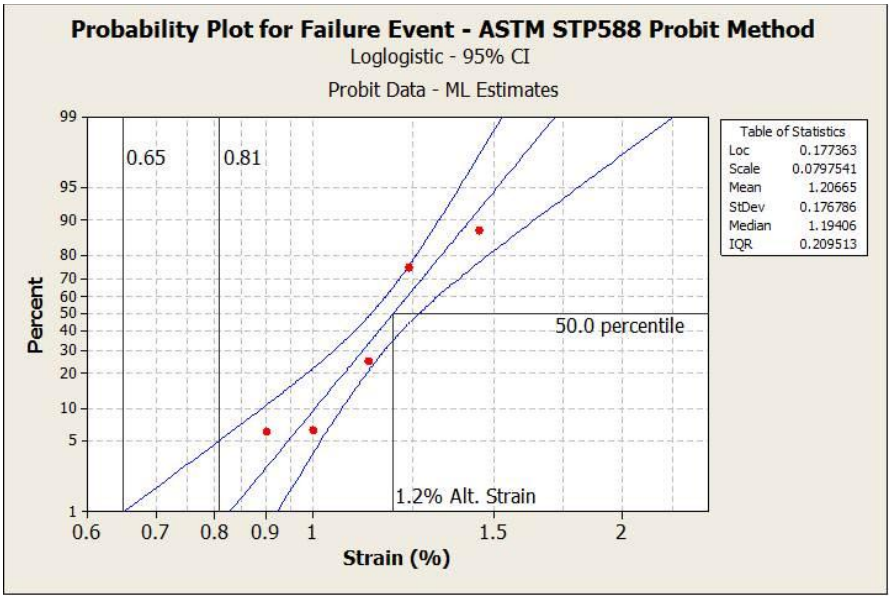


Figure 12. Probability plot for the failure event, as created by a Probit analysis.

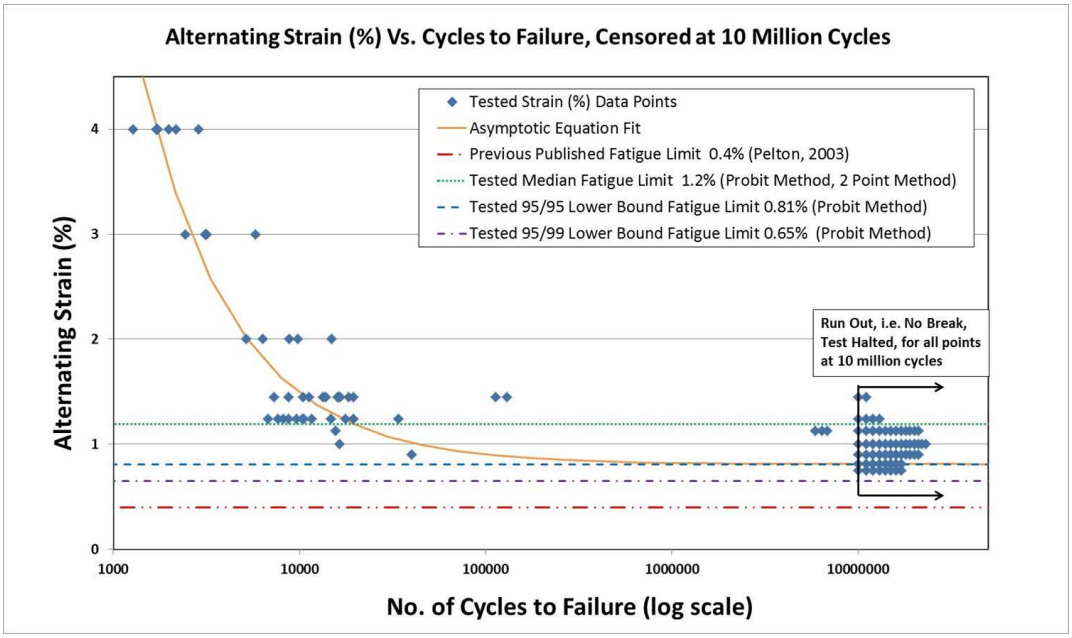


Figure 13. Strain-Life (ε-N) diagram of alternating strain versus cycles to failure, with the statistical results included.

5. Discussion

5.1 Use of FEA

It has been shown that Abaqus/Standard FEA software is valuable in the work presented here. Many models were evaluated during the coupon design phase, which are not presented here. The software was used to evaluate the feasibility of making the coupon (layout on tube, forming strain, etc…) before it was ordered. Then after the coupons were procured, the software was used to determine the strain in the test specimen for a given cyclic displacement. Finally, the software was instrumental in determining the influence of dimensional tolerances of the coupon.

5.2 Material Test Results

At first inspection, the results presented here seem similar to the 0.2% to 0.8% strain limits published from a variety of test configurations by various authors: Pelton et al (Pelton, Gong, & Duerig, 2003), Robertson et al (Robertson, Stankiesicz, Gong, & Ritchie, 2004), Siekmeyer et al (Siekmeyer, Hientzsch, Bayer, & Schuessler, 2007) and Wick et al (Wick, Gong, Fino, Sheriff, & Pelton, 2004).

However, each of these works did not include confidence interval statistics, and the lowest load value at which a failure occurred was then presented as the endurance limit. Using this method the work here would conclude a value of 0.9%. When designing a medical device it would be

more prudent to use the 95/95 or 95/99 lower limit, and to then use a safety factor calculated from these values.

As a further check on the material behavior, a Coffin-Manson analysis can be done on the coupons that failed in low cycle fatigue, i.e. less than 10,000 cycles. This method is from ASTM E739-10 Standard Practice for Statistical Analysis of Linearized Stress Life and Strain Life Fatigue Data (ASTM, 2010).

The Coffin-Manson equation is:

$$\frac{\Delta\varepsilon}{2} = \varepsilon_f'\left(2N_f\right)^c$$

The exponent c = -0.62 for test data presented here. The value of c is usually -0.5 to -0.7 for most metals according to Suresh (Suresh, 1998). Pelton et al. (Pelton, Gong, & Duerig, 2003) found it to be -0.42.

6. Conclusions

The fatigue strain endurance limit for this specific material and process are determined. Finite Element Analysis software with the ability to accurately model the super-elastic material Nitinol has proven to be a valuable tool in determining the fatigue life of the material when used in concert with careful design and testing. Abaqus/Standard has enabled the author to design a medical device subject to fatigue and have some confidence of the fatigue safety to be expected.

7. Suggestion for Best Practices

Several suggestions arise regarding determining the fatigue properties of laser cut Nitinol tubing material using this method:

- Design the coupon with finished device in mind (i.e., max fatigue strain location, direction, etc…)
- Consider fatigue test machine specifications (position accuracy, fixture, break detection, air or liquid)
- Use same process, scale, and applicable load directions for coupons as with finished device worst case critical fatigue areas
- Validate FEA model as much as possible (element, load, boundary conditions, material, etc…)
- Verify/inspect coupon dimensions
- Consider sources of error (dimensions, break location, strain determination, material model, etc…) – and minimize and quantify all if possible
- Use ASTM STP588 or similar as guideline
- Use statistical analysis (Probit) to determine endurance limit
- Design the device around 95/95 or 95/99 lower bound for endurance strain limit, and use safety factor from there

8. References

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9. Acknowledgements

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