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Design, Analysis, and Simulated Testing of a Surrogate Nitinol Fatigue Specimen

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Endurance limit analysis and testing require an accurate determination of the strain environment a device experiences in its life cycle (crimp strains, mean strain, and strain amplitudes) as well as the strain capability of the processed device. Surrogate fatigue specimens that represent a critical portion of a device can be designed through finite element analysis to experience the requisite strain life cycle, and in addition, can be efficiently tested to failure in a controlled strain environment. The surrogate should be processed in a similar manner as the parent device to ensure accurate material micro-structural properties as well as surface finish characteristics. In this article, we present the design, analysis, and simulated testing of a fatigue test specimen to determine a fatigue endurance limit to be used in the design assessment of a medical device. The Neyer D-Optimal sensitivity test method was used in a simulation to construct a design envelope.

Keywords fatigue, finite element analysis, medical device, Neyer D-Optimal test, nitinol

1. Introduction

The evolution in the application of nitinol to a myriad of medical devices requires careful consideration of durability. While the superelastic capability of NiTi allows novel device designs to address a wide range of therapies, fatigue performance is required to be demonstrated for each unique application since analogous testing results cannot typically be applied. The raw material, whether wire or tubing, is exposed to various amounts of cold-work and annealing steps which creates unique micro-structures, influencing durability. The devices are post-processed uniquely through shape setting operations of varied temperatures and times resulting in additional micro-structural differences. Surface finish is another critical fatigue design parameter that varies from process to process and design to design.

While complete device fatigue testing is commonly performed, it is prudent to conduct sub-component testing to reduce patient risk and provide confidence in the final device design and processes. The typical sub-component test concept that arises is to section the complete device into fatigue coupons. A challenge with this approach is that the applied loads or displacements to the sub-component can produce strain concentrating artifacts.

Several researchers have conducted tests on ''stent like'' fatigue coupons (Ref 1-3), producing common trends but often large ranges in quantified results. A large scatter in the range in cycles to failure also lower the confidence of the results, often two orders of magnitude exist in the failure range of some results. In some cases, the fatigue coupons were flattened from tubing, possibly compromising the microstructure of the samples. These results provide further motivation to perform sub-component device specific tests to verify endurance limits.

The life cycle of the nitinol medical devices often includes an important aspect often overlooked by prior efforts (Ref 1-3); this is the catheter loading operation or device compression. Device design goals often include limits on the peak strain resulting from compression loading (commonly 8-10%). The location of these peak strains should be taken into consideration when evaluating peak alternating fatigue strains. As strains exceed 6%, permanent set is often produced, indicating flow and possible local damage to the material (Ref 4, 5). The influence of this local damage on fatigue performance should be assessed.

The endurance limit of nitinol has been shown to be a strong function of strain amplitude and a weaker function of mean strain. Surface finish variations, distributed inclusions, and material micro-structural differences will cause varied levels of strain amplitude endurance for a nitinol structure. In assessing the endurance limit of a typical nitinol medical structure, with multiple crowns or hinge points, it can be postulated that the structure has multiple values of strain amplitude endurance due to these process and material variations even without considering mean strain effects.

The goal of this study is to develop a process of design, analysis, and testing that builds on earlier fatigue studies with a test method developed in the aerospace arena. The study presents a surrogate nitinol fatigue specimen that replicates all the critical design and loading environments that are inherent to the parent device using finite element analysis (FEA). The FEA will ensure the fatigue surrogate produces a similar strain life cycle as the parent, including compression loading and fatigue strains. The Neyer D-Optimal sensitivity test method (Ref 6)

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will be shown to determine the endurance limit of the surrogate in terms of strain amplitude in a statistical manner. The test method has been used in a wide variety of applications to determine various parameters in explosive sensitivity, dose toxicity, and fracture toughness.

2. Design, Finite Element Analysis, and Fatigue

A generic vascular NiTi parent structure, a section of which is shown in Fig. 1, provides the basis for the design of the surrogate fatigue specimen. The parent structure is cylindrically symmetric and made up of a number of "free" crowns (circled in Fig. 1) with adjacent interconnected crowns. The parent structure represents a device that is laser-cut and expanded in several shape set operations, followed by cleaning and electropolishing. The device would be compressed to fit within a delivery catheter, and then deployed into the vasculature where it is primarily exposed to a radial fatigue dilation condition, among other loadings.

The analysis of the parent structure entailed simulating the life cycle of the device through FEA to quantify the strain environment experienced during catheter loading, deployment, and dilatation fatigue. The non-linear, finite element program LS-DYNA (Ref 7) was used in implicit MPP mode to conduct the analyses. A NiTi material model (available in LS-DYNA) (Ref 8) allows the non-linear material behavior to be represented. The parent structure was first analytically expanded from a 3-D laser-cut form to create the proper initial geometry. No symmetry was assumed for the model.

The structure was next compressed to reproduce the loading strains of the delivery catheter. This process was simulated using a constricting cylinder to reduce the diameter of the structure to the minimum ID of the catheter. The results of this portion of the simulation are shown in Fig. 2. The peak tensile strains produced during the compression loading stage were 7.8%, and were located at the transitions of the struts to crowns. This strain level is typical of most efficient designs.

The structure is then deployed into a compliant elastic cylinder used to simulate the target vessel. The structure was oversized to be compressed diametrically 15% by a 4% elastic compliant vessel with a nominal internal pressure of 80 mmHg. The cylinder used to compress the structure was expanded allowing the structure to make contact with the compliant vessel. This result of deployment is shown in Fig. 3, and peak strains have reduced to near 2%.

Following deployment, the internal pressure is ramped to 180 mmHg and reduced back to 80 mmHg to represent the fatigue loading of the structure. The pressure cycle is repeated to ensure the strain path is converged. The strain tensors from the analysis are extracted at the extremes of the loading pressure and processed to obtain the mean principal strains and principal strain amplitudes. These results are plotted in Fig. 4. The peak strain amplitude of 0.13% at a mean strain of 2.4% is identified in the plot and occurs near the peak compression loading strain location. The stress-strain history of the critical element is shown in Fig. 5.

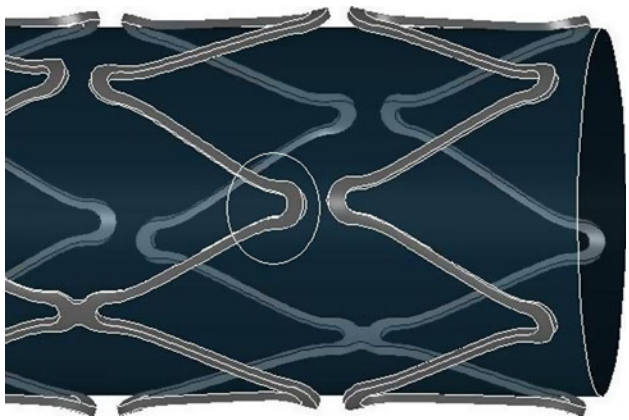

Fig. 1 Rendering of the parent NiTi structure considered in this study. The circled area was identified as a critical fatigue region

Fig. 2 The compression response of the parent device; fringe plot showing maximum principal strains on the left

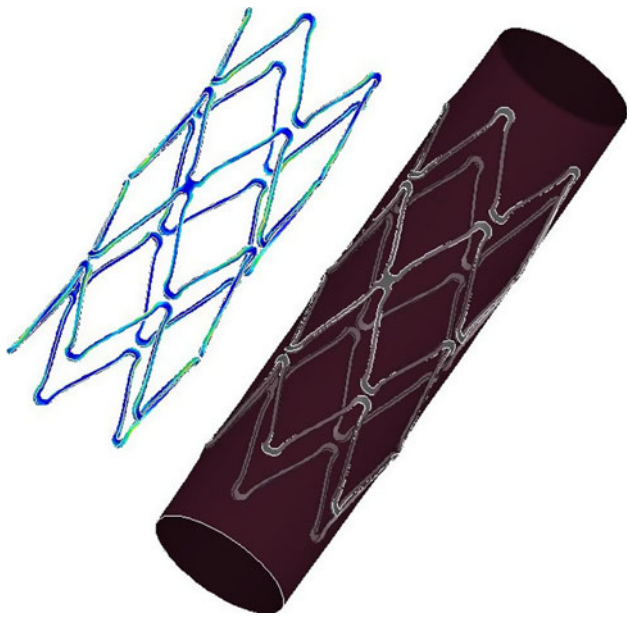

Fig. 3 The parent device is deployed on right into a compliant vessel for fatigue evaluation; a fringe plot showing maximum principal strains is on the left

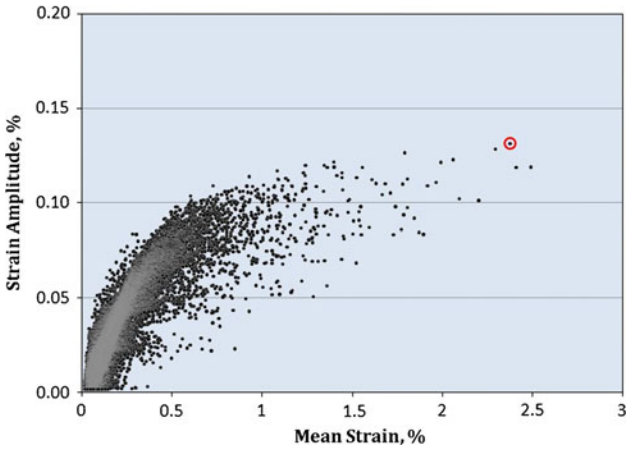

Fig. 4 The mean and alternating strains produced in the parent device with a 100 mmHg pressure delta applied to the compliant vessel. A critical element from the parent is identified by the circle (highest strain amplitude)

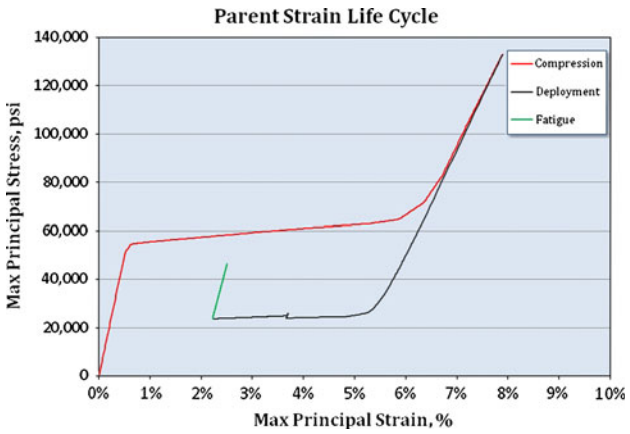

Fig. 5 The peak stress-strain history of critical element in the parent device, showing compression, deployment, and fatigue stress-strain history

The analysis of the parent structure showed that the crowns were a critical fatigue region and the surrogate design focused on this portion of the structure. The basic dimensions of the parent structure crowns (crown width, radii, and strut width) were used to iteratively design through FEA the fatigue specimen to produce the desired strain responses. The design was driven primarily by the compression loading strain environment near the crown shoulders when the crown is compressed. The surrogate was expanded in a sequence of shape set operations to open the structure, as well to mimic the parent processing. The surrogate, like the parent, is a laser cut base form, which was modeled in 3-D. An FEA rendering of the expanded surrogate is shown in Fig. 6. The amount of opening was governed by the desire to create ~8% peak tensile strains when the specimen is compressed fully closed.

The requisite strain environments are produced in the surrogate by displacements applied at the upper central edge of the test coupon, as shown in Fig. 7. The central edges of the test coupon are not allowed to rotate, and the displacement is purely vertical. Typical test platforms for this type of test are units such as Bose ELF or Instron Electropuls. Force-displacement tests can be conducted and compared with FEA results for model

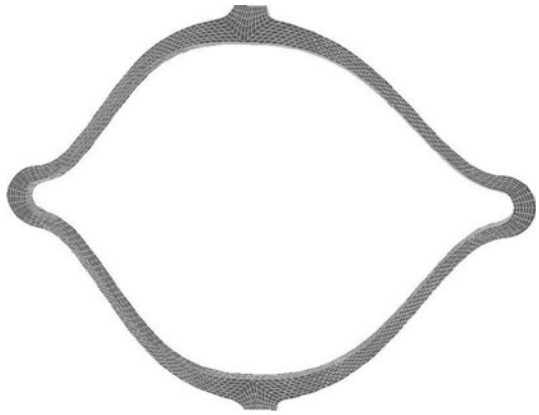

Fig. 6 FEA rendering of the surrogate fatigue specimen. The critical dimensions of the parent device are incorporated into the design

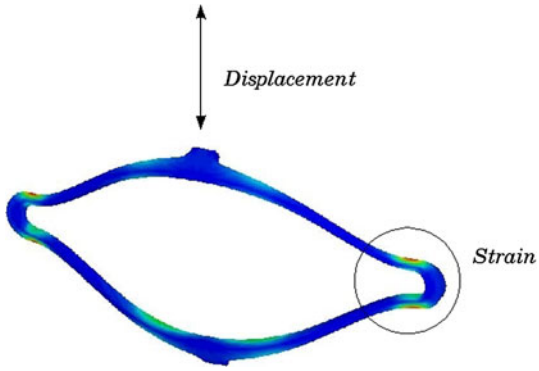

Fig. 7 Strain contours show the maximum principal strain response to central displacement of the fatigue coupon. The coupon can be tested in a typical displacement controlled test platform (mounting features not shown)

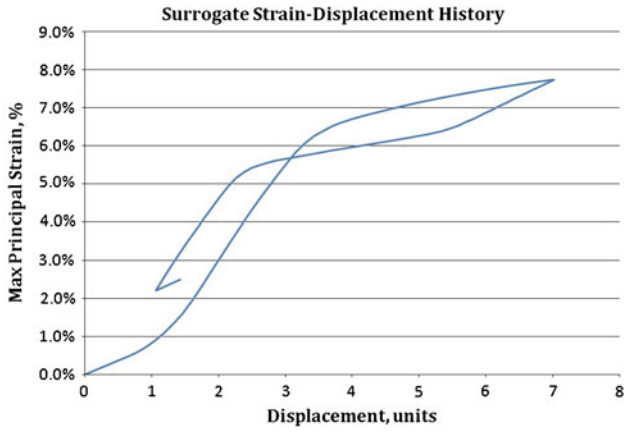

Fig. 8 The strain-displacement response of the surrogate coupon was found iteratively with the goal of matching the parent device strain history

validation purposes. In this case, the analysis compressed the surrogate to nearly closed, simulating the catheter loading environment, followed by opening to a displacement to match the strain history of the parent structure. The strain-displacement history, shown in Fig. 8, was found iteratively with the goal of

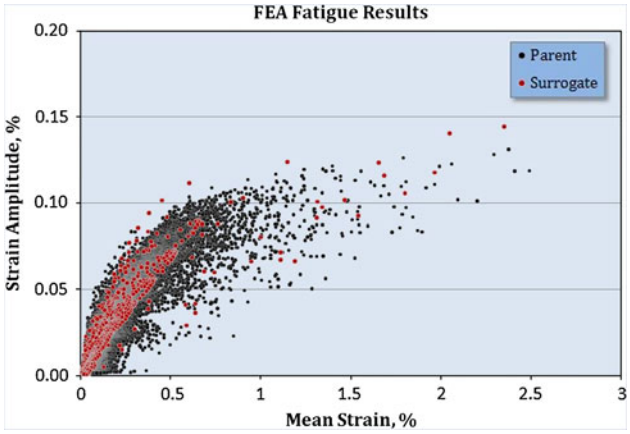

Fig. 9 The fatigue response of the surrogate is overlaid on the parent device response. The surrogate response correlates well with the parent device

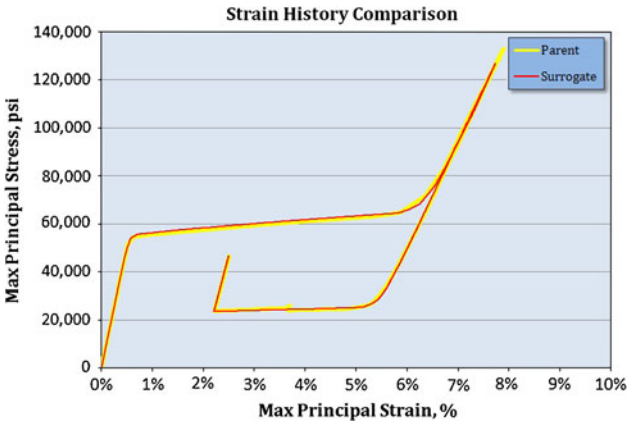

Fig. 10 The stress-strain history of a critical element in the surrogate closely matched the parent device

matching the parent strain history. The fatigue environment is produced by a cyclic displacement applied to the surrogate, with the intent to also match the fatigue strain environment of the parent. A scatter plot of the resulting mean strain and strain amplitude for the surrogate is shown in Fig. 9 with the parent structure results included for comparison. The stress-strain history of the critical element in the surrogate compared with the parent critical element is shown in Fig. 10. Note that the test coupon has not been flattened (it retains the net tubing curvature) and produces the appropriate strain behavior with a linear displacement, compared to the circumferential displacement of the parent. The overall strain response of the surrogate is nearly identical to the parent and shows that the surrogate can be confidently used to assess fatigue performance.

Typical fatigue test methods used by earlier investigators would involve testing multiple specimens at a given strain amplitude and mean strain to a given number of cycles (e.g., constant life diagram). A grid of varied mean strain and strain amplitude would be tested sequentially to "map" the fatigue response. A hypothetical example of the "grid" method results is shown in Fig. 11, along with the results of the fatigue scatter plot results from the parent and surrogate analyses. The closed squares indicate that all units failed in the test, while the open squares indicate that all units achieved run-out. There is a

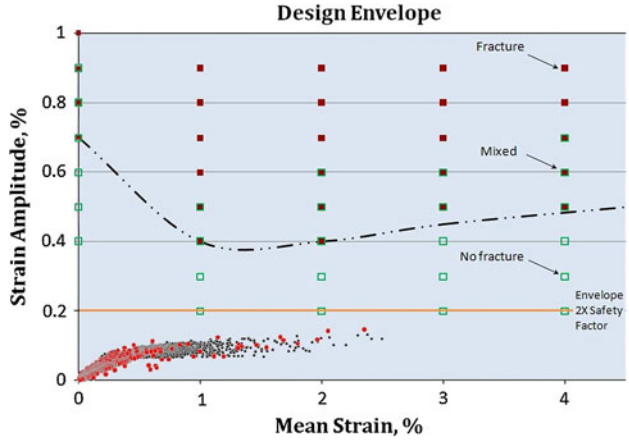

Fig. 11 The typical fatigue evaluation would consider test data created in a "grid" fashion and place a limit curve below the levels where some mixed responses occurred. A safety factor exceeding 2 would be computed

region of mixed results, with the solid square bounded by the line, indicating at least one failure or at least one non-failure. Superposed on the data is a curve that passes through the lowest extreme of the mixed results. Since the number of specimens tested at each point may be on the order of 10, the results are not statistically significant to a high reliability. Testing ten samples at fixed strain amplitude and observing no failures ensures at a 90% confidence that the true failure rate may be no higher than 25.9% for this stimulus level (Ref 9). Due to this uncertainty, an endurance limit is suggested using the lowest strain amplitude with the mixed results, such as 0.4% and reducing it by a factor of two. The lower horizontal line at 0.2% can be used to evaluate designs and provide an envelope in which to design within. This method of analysis does provide a level of confidence in the fatigue capability of the device, but does not quantify the reliability of the device or predict how many failures a population of devices may experience.

3. Sensitivity Test Methods

The aerospace industry uses explosive or pyrotechnic devices for a wide range of applications. These devices need to be qualified to a high level of reliability not only due to the energy released by these compact devices but also due to the assurance of the performance of critical operations. The qualification testing of so called "single-shot" devices includes the characterization of the sensitivity of the devices to an input stimulus. Typically an electric current is provided to a pyrotechnic system to initiate an ordnance function, such as rocket motor ignition, stage separation, or payload initiation. Sample testing is conducted to characterize the "sensitivity" of the initiation device to the input stimulus. Bruceton (Ref 8), Langlie (Ref 10), and the Neyer D-Optimal are sensitivity test methods that were developed to quantify critical functional levels for single-shot devices and have been used for decades (Ref 11).

Testing of a single-shot device is constrained by the issue that the device can be exposed only once to a stimulus level. For example, the test exposes the device to a single current level (and duration) and the device either functions or not. The

response is recorded, and another device from the sample is tested at an altered stimulus level. Since the first device was exposed to a stimulus, the performance of the device was possibly altered if it did not function. The stimulus can also not be ramped, since this may also alter the response of the device. The methods typically require from 20 to 30 units to generate an estimate of the mean and standard deviation for the population. The methods use each response (fire/no fire) to generate a successive stimulus input. The methods use a statistical algorithm for the successive test level and the algorithms were designed to produce an efficient method for determining the device sensitivity statistics as evidenced by the small sample size required to achieve over 1 in 1000 (0.1%) sample stimulus reliabilities (Ref 6, 9, 12, 13). Testing a sample of 30 units at a fixed stimulus level for a binary response, as with the grid method, would only ensure an 11.6% stimulus upper bound (at 95% confidence), which is two orders of magnitude higher than can be achieved with the Neyer method. The critical values identified for the pyrotechnic devices are the "no-fire" and "all-fire" current levels, and they are statistically determined with these test methods typically to a minimum of 95% confidence and 99.9% reliability.

An analogy to nitinol fatigue testing can be made by considering testing the component at a constant mean strain and the stimulus level is the strain amplitude. After fatigue testing a sample for $N \times 10^6$ cycles (run out) at a specific strain amplitude, the unit has either fractured or not fractured (fire/no fire), and the response is recorded. In addition, the sample has been exposed to a "damaging" or modifying stimulus and would not be considered for further testing. The tested sample, if not fractured, would not be exposed to some type of ramping stimulus to initiate a fracture. Based on the binary response (fracture/no fracture), the next sample would be exposed to a new input stimulus (strain amplitude) dictated by the sensitivity test algorithm, and so on. The testing can be used to generate the "no fracture" strain amplitude (no fire) and the "all fracture" strain amplitude (all fire) to a specific reliability and confidence level. The "no fracture" strain amplitude would be analogous to the endurance limit for the component.

4. Sensitivity Test Simulations

The Neyer D-Optimal sensitivity test method will be demonstrated through a simulation of the response of a hypothetical population of surrogate test coupons. The coupons will have a normally distributed response to the strain amplitude stimulus input, and also include a function of mean strain. (It can be assumed that material inclusions and grain boundaries are distributed randomly through the raw material, providing initiation sites for fracture in the sample, and that the mean number of initiation sites at the critical location of the crowns follows a normal distribution). The coupon population will have the distributions as defined in Table 1. The mean endurance amplitude values were chosen to be similar to the earlier "grid" test example, and note that the standard deviations are also varied with mean strain.

The test simulation will use a normally distributed random sample of 30 coupons for each mean strain (0-4%) and use the SENTEST software (Ref 14) to conduct the hypothetical tests. The method requires an initial estimate for the mean and standard deviation, and for the test simulation, the estimated

Table 1 Hypothetical statistical endurance limit description for the surrogate test coupons

	Endurance amplitude, %	
Mean strain, %	Mean	SD
0	0.70	0.035
1	0.40	0.025
2	0.40	0.045
3	0.45	0.025
4	0.50	0.040

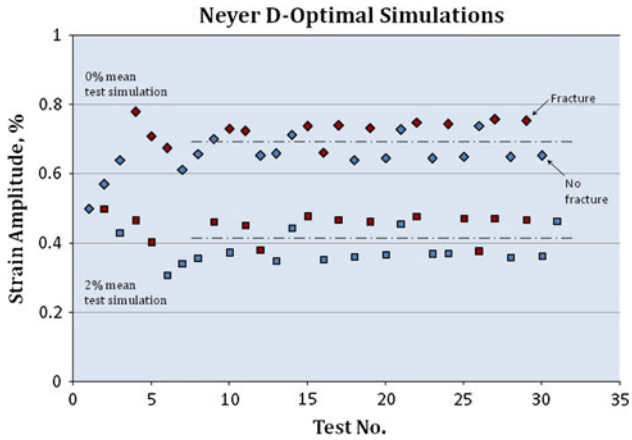

Fig. 12 The sequential responses in the simulated Neyer D-Optimal test method of the 0% mean strain coupons and the 2% mean strain test coupons. The algorithm quickly finds the mean, and stimulus levels tend to surround the mean

mean endurance amplitude for all mean strains was 0.5% with an estimated variance of 0.035%.

The sequential test results from the 0 and 2% mean strain simulations are shown in Fig. 12. The light and dark diamonds are from the 0% mean strain test simulation, where the light diamonds indicate no fracture occurring (run-out to $N \times 10^6$ cycles) and the dark diamonds indicating fracture prior to run-out. The squares are from the 2% mean strain test simulation, with the same no-fracture/fracture indication. For the 0% mean strain test, the initial stimulus level of 0.5% produced no failure and the algorithm increased the test level, which was another no fracture result. At the fourth test a fracture was produced and the test level ratchets down. As can be seen, the method eventually centers its stimulus levels on the mean of the population. The 2% mean strain test example exhibits similar behavior, and note that the same initial guesses for mean and standard deviation were used for both tests. The simulated test was conducted 100 times for each mean strain and the averaged statistics from the tests are shown in Table 2. The mean endurance amplitude values are estimated very well, while the standard deviations appear to be slightly under predicted for each case.

The results of the final test simulation at each mean strain were used to generate two design envelopes: (1) a 99.9% reliability level, and (2) a 95% confidence level at 99.9% reliability. The design envelopes were created using the statistics produced by the SENTEST software, which uses the likelihood ratio method (Ref 14) to compute estimates of

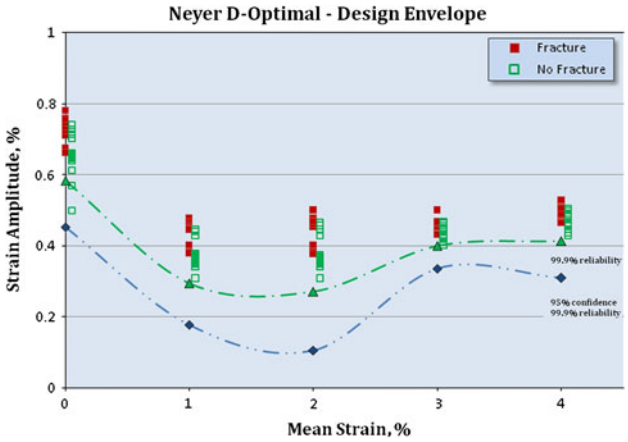

Fig. 13 The statistics produced by the method allow for reliability envelope curves to be generated. This allows for a quantitative reliability assessment to be made

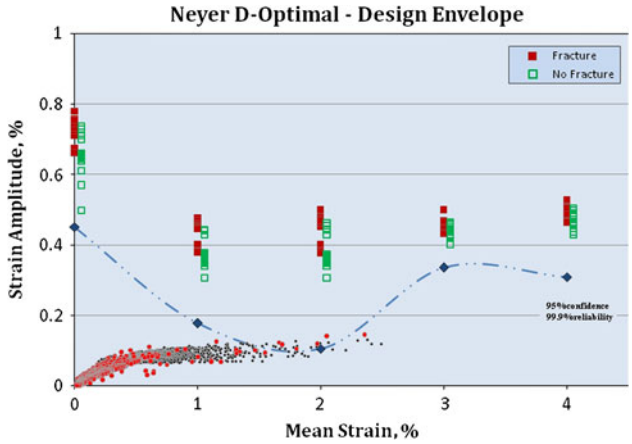

Fig. 14 In this hypothetical test, some of the fatigue response lies above the 95/99.9% confidence-reliability curve

Table 2 A comparison of the test sample statistics with the Neyer D-Optimal test method show an accurate prediction of the mean endurance strain amplitude (average of 100 runs)

	Endurance amplitude, %			
	Sample statistics		Neyer D-Optimal test results	
Mean strain, %	Mean	SD	Mean	SD
0	0.70	0.034	0.70	0.032
1	0.40	0.025	0.40	0.021
2	0.40	0.044	0.40	0.039
3	0.45	0.025	0.45	0.020
4	0.50	0.039	0.50	0.036

the statistical parameters. A smooth curve was placed through the results for each mean strain. The design envelopes are shown in Fig. 13, and the figure also includes the simulated test results at each mean strain. The open symbols are no fracture results, while the filled are fracture results. The no fracture results are slightly offset for visualization. The total number of tests shown to develop the envelope is 150. Of interest is the influence of the larger standard deviation at 2% mean strain which pushes the envelope downward to account for the larger statistical variation at this mean strain. This is hypothetical, but shows the capability of the method to sense and predict this possible variation.

The fatigue predictions from the parent and surrogate FEA are shown plotted against the sensitivity test results in Fig. 14. In this hypothetical case, the fatigue estimates are seen to exceed the 95% confidence/99.9% reliability endurance in a region from 1.5 to 2% mean strain. The higher standard deviation in the surrogate response at 2% mean strain has pushed the envelope downward to strain amplitude of 0.105%. It may be expected for the variance in the fatigue response of nitinol to vary with mean strain, much as the endurance amplitude levels have been shown to vary with means strains. The power of the Neyer D-Optimal method to quantify this type of response is intriguing.

5. Conclusions

A surrogate fatigue specimen was designed and analyzed with FEA to produce the same strain life cycle and fatigue response as a critical region of a parent device. The specimen was able to reproduce the compression loading strains of the parent (without clearance issues) allowing the specimen to be fatigue tested following a simulated compression cycle. This would address concerns about the influence of the catheter loading environment on the endurance performance. The fatigue analysis results from the surrogate also matched well with the parent device as evidenced by the close agreement in the scatter plots of mean strain-strain amplitude. The surrogate was found to reproduce all critical strain aspects of the parent device, and provides confidence that the surrogate could be used to perform an endurance assessment.

A simulation of the Neyer D-Optimal test method provided a novel demonstration to determine the fatigue endurance limit of a theoretical surrogate coupon population. The statistical representation of the endurance performance was determined from simulated tests of 30 samples at each mean strain. The method, developed primarily in the aerospace ordnance industry, was shown through the simulation to provide a quantitative reliability assessment of the endurance strain amplitude. The ability of the method to produce a quantifiable reliability assessment is seen as a marked improvement over earlier fatigue assessments.

Acknowledgments

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References

1. W.J. Harrison and Z.C. Lin, *SMST-2000: Proceedings of the International Conference on Shape Memory and Superelastic Technologies*, S.M. Russel and A.R. Pelton, Ed., p 391–396
2. C. Kugler, D. Matson, and K. Perry, *SMST-2000: Proceedings of the International Conference on Shape Memory and Superelastic Technologies*, S.M. Russel and A.R. Pelton, Ed., p 409–417

3. A.R., Pelton, X.Y. Gong, and T. Duerig, *SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies*, S.M. Russel and A.R. Pelton, Ed., p 293–302
4. T.L. Lopes, X.Y. Gong, and C. Trepanier, *SMST-2003: Proceedings of the International Conference on Shape Memory and Superelastic Technologies*, S.M. Russel and A.R. Pelton, Ed., p 311–320
5. A.R. Pelton, J. DiCello, and S. Miyazaki, *SMST-2000: Proceedings of the International Conference on Shape Memory and Superelastic Technologies*, S.M. Russel and A.R. Pelton, Ed., p 361–374
6. B.T. Neyer, A D-Optimality Based Sensitivity Test, *Technometrics*, 1994, **36**, p 61–70
7. "LS-DYNA Keyword User's Manual", Vol. 1, Version 971, Livermore Software Technology Company, May 2007
8. F. Auricchio, R.L. Taylor, and J. Lubliner, Shape-Memory Alloys: Macromodeling and Numerical Simulations of the Superelastic Behavior, *Comput. Methods Appl. Mech. Eng.*, 1997, **146**, p 281–312
9. T.R. Nichols, Assessing Pass/Fail Testing When There Are No Failures to Assess, *MDDI Magazine*, http://www.mddionline.com, 1997
10. J.W. Dixon and A.M. Mood, A Method for Obtaining and Analyzing Sensitivity Data, *J. Am. Stat. Assoc.*, 1948, **43**, p 109–126
11. H.J. Langlie, *A Reliability test method for "One Shot" Items, Technical Report U-1792.*, 3rd ed., Aeronutronic Division of Ford Motor Company, Newport Beach, CA, 1965
12. B.T. Neyer, Sensitivity Testing and Analysis, *16th International Pyrotechnics Seminar*, Jonkoping, Sweden, 1991
13. K.S. Banerjee, *On the Efficiency of Sensitivity Experiments Analyzed by the Maximum Likelihood Estimation Procedure Under the Cumulative Normal Response*, Technical Report ARBRL-TR-02269, U.S. Army Armament Research and Development Command, Aberdeen Proving Ground, MD, 1980
14. Neyer Software, "Sentest", Version 3.0c