FEATURE *Biomechanics Series: Part 1*
by K.E. Perry and C. Kugler

NEW SERIES

NON-ZERO MEAN FATIGUE TESTING OF NiTi

This paper describes a fatigue test protocol that was used to determine the factor of safety for a superelastic NiTi implantable medical device. Devices of this type experience both an oscillating strain condition related to pulsatile arterial blood flow and a mean strain condition resulting from an oversizing of the device with regard to the host vessel.

For typical implantable stent structures, it is customary to demonstrate a lifetime of 10 years at 75 cycles/min, or roughly 400M cycles of service. A rotating cam test apparatus was designed to collect the necessary life-cycle data. Fatigue test specimens were designed as scaled-up versions of the implantable device and processed in accord with the established manufacturing specifications for the actual device. This insured that the local strain conditions as well as material processing effects would be accounted for in the characterization of the material's fatigue limit.

Data were generated for three levels of mean strain: ε_m = 2.0, 3.4 and 4.8%. The results of over 100 specimens tested to 700M cycles demonstrate that the mid- to high-cycle fatigue life of NiTi increases with increasing mean strain in the range of ε_m = 2–4%.

SPECIMEN DESIGN

Diamond shaped test specimens were laser cut from drawn NiTi tube to resemble a scaled-up version of the repeating design element in the implantable device. A schematic of the specimen is shown in Figure 1. Dimensions in the areas of high strain (near the eyelets and shoulders) were selected based on the actual dimensions of the implantable device. In this way, the local strain conditions in the test specimen and the implantable device were, by design, identical.

After laser cutting, the specimens were electro-polished to remove laser slag and surface flaws according to the same process as the implantable device. The specimens were then expanded in four steps with shape setting heat treatments applied between each step.

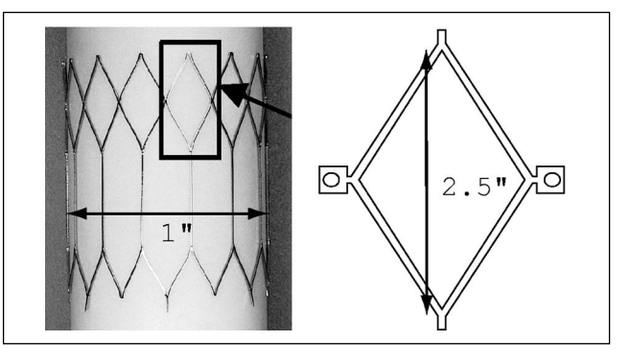

Fig. 1: Photograph of device and schematic of the scaled-up test specimen

Finite element analysis was used to model the steps affecting the strain levels in the specimen throughout the manufacturing process. This included shape setting, heat treatments and cyclic deflection. The predicted strains prior to each annealing were verified to match those experienced by the actual device during manufacture. A typical contour plot in a high strain region of the specimen is shown in Figure 2. Analyses included shape setting, heat treatment and cyclic deformation.

The finite element simulations provided a correlation between the mean and alternating deflections (δ_m and δ_z) imposed by the fatigue test apparatus and the mean and alternating strains (ε_m and ε_a) experienced in the specimen.

FATIGUE TEST APPARATUS

A custom fatigue test apparatus was designed specifically for this work. It was based on a simple rotating cam with an adjustable fixed displacement cycle. Both the (nominal) mean and alternating strain displacement could be easily adjusted. A microswitch monitoring lever would automatically stop the tester when a specimen failed. A photograph of the test apparatus is shown in Figure 3.

A total of 20 testers were built, calibrated and used to generate the fatigue data. Each tester cycled a total of three cells in a distilled water bath at 37°C. Testing was done at 60 Hz. The number of cycles along with the mean distance, oscillating distance, and strut dimensions were recorded for each specimen. Testing was stopped at 700M cycles for those specimens that did not fail.

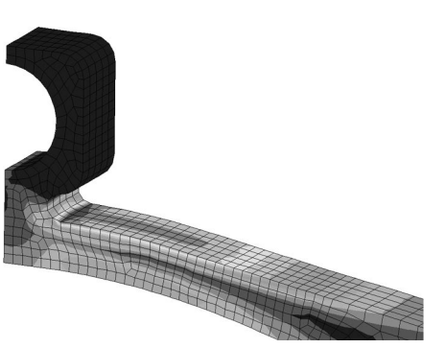

Fig. 2: Strain concentration predicted by FEA

Editor's Note: The new Biomechanics Feature Series will provide a forum for novel experimental techniques in the areas of biological and biologically inspired materials. This series will showcase developments in advanced materials systems with an emphasis on biological, biomedical and biomimicry applications.

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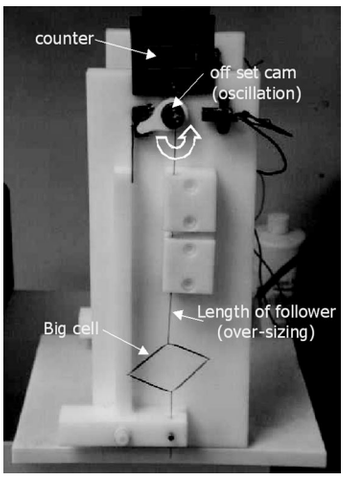

Fig. 3: A photograph of the test apparatus

After failure or run-out, the mean and oscillating deflections were converted to mean and oscillating strains based on a look-up table derived from the finite element analysis of the fatigue test specimen. These corrections on the nominal strain values improved the accuracy of the data and also served as a sensitivity study for deviations in manufacturing process.

RESULTS

The mean and alternating strain parameters for the fatigue study were chosen based on a 3D finite element analysis of the optimized implant design. The *in-vivo* worst case strain conditions were derived from boundary conditions supported by physician testimonials and published data. A factor of safety for the device was determined by comparing the worst case strains to the test results.

Results from seven combinations of mean and alternating strain conditions are presented in this paper. Fifteen samples were tested for each pair of conditions. The mean and alternating strain values with the percent of failed specimens for each condition are summarized in the table below. Note that the alternating strain, ε_a, represents the full strain range.

	$\varepsilon_a = 0.2$	$\varepsilon_a = 0.6$	$\varepsilon_a > 0.8$
$\varepsilon_m = 2.0$	0%	73%	—
$\varepsilon_m = 3.4$	0%	7%	40%
$\varepsilon_m = 4.8$	0%	13%	—

No failures occurred in the specimens tested up to 700 million cycles (18 years of implant life) for $\varepsilon_a = 0.2$. At an alternating strain range of 0.6%, only 7% of the specimens failed when ε_m was 3.4%, compared to a 73% failure rate for samples tested at the same alternating strain and $\varepsilon_m = 2.0$. A strain-life plot is shown in Figure 4.

CONCLUSIONS

The mid- to high-cycle fatigue life of the material tested in our laboratory appears to increase with increasing mean strain in the range of 2–4%. Additional testing is underway to further refine the data and understand the mechanisms involved in the fatigue of NiTi.

Our experience also confirms that processing variations affect fatigue performance. It is emphasized that the data presented in this paper are specific to the design and processing parameters developed for this device and should not be used to determine a factor of safety for other devices that undergo different processing. ■

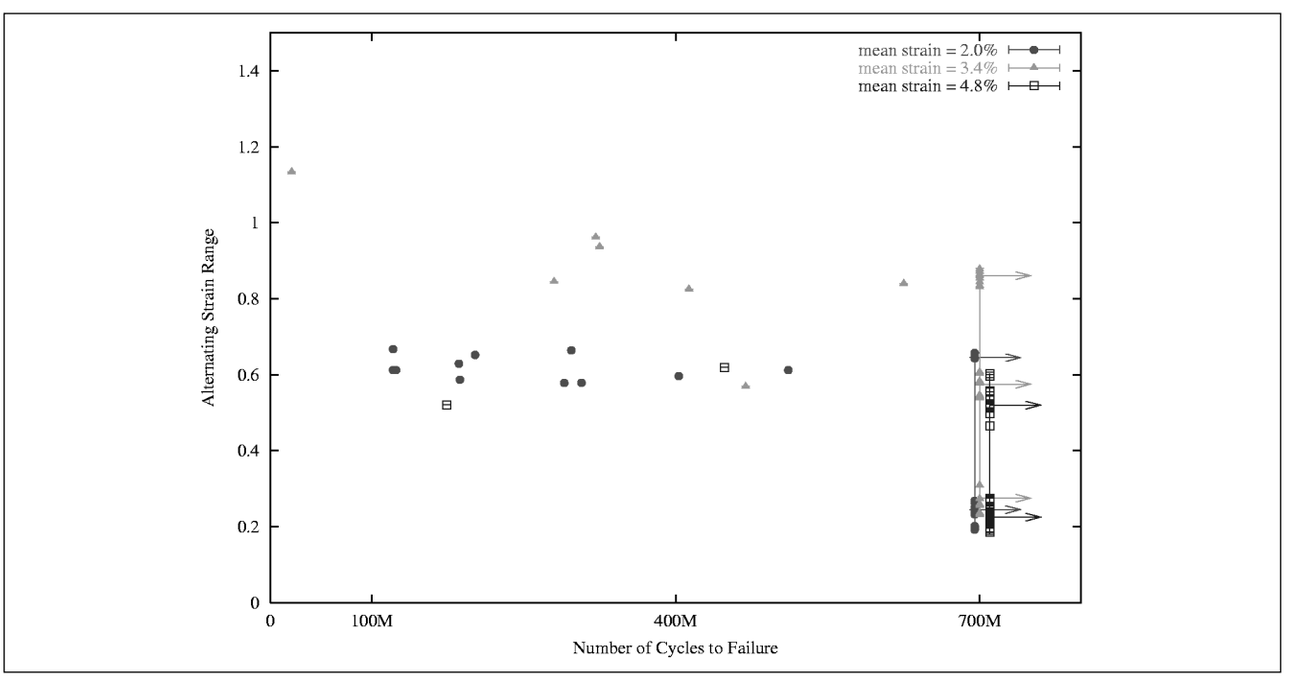

Fig. 4: Alternating strain versus cycles to failure for three mean strain conditions