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ABSTRACT

Bending is the predominant deformation mode in Nitinol medical devices and components. Many of these applications also impose cyclic bending loading conditions. The present study of rotary bend fatigue provides insight into the behaviour of Nitinol under zero mean-strain conditions. This investigation also gives a better understanding about the influence of the surface condition, transformation temperature and test temperature on the bending fatigue characteristics of Nitinol.

These rotary bend results are also supplemented with non-zero-mean strain results that were obtained using a 4-point bending fixture attached to a dynamic electro force testing system. These results can be used as the basis of a constant life diagram for fatigue-resistant design of medical devices.

INTRODUCTION

Bending is the predominant mode of deformation in medical application use [1-2]. Furthermore, deformation is often cyclic in nature leading to potential bending fatigue failures. For example, endodontic dental files are subjected to rotary-bend fatigue conditions. In this case, the outer fibers are under alternating compressive and tensile strains with an approximate net zero-mean strain. These *in vivo* conditions can be adequately simulated with rotary bend fatigue tests.

Other Nitinol medical devices are subjected to dynamic bending loads with an applied mean strain. For example, the predominant fatigue loading mode for a stent strut is bending with a mean strain present due to oversizing of the stent relative to the artery wall. The bending characteristics under non-zero-mean strain conditions can be studied using a 4-point bending fixture.

For this study superelastic and shape memory wires were tested in the rotary bending mode. The superelastic wires had different A_f temperatures and surface conditions. These wires were tested at a range of temperatures in order to obtain a better understanding of the influence of the test temperature on the fatigue behavior of Nitinol.

The purpose of this paper, therefore, is to report on a recent investigation of the bending fatigue characteristics of shape memory and superelastic Nitinol. The goal of the study is to establish the relationships between mean and alternating strain on fatigue behavior.

MATERIALS AND METHODS

The following material was tested in rotary bending or 4-point bending mode:

- Ø0.8mm SE-wire, electropolished surface, A_f = 13°C
- Ø0.6mm SE-wire, bright surface, A_f = 1°C
- Ø0.6mm, SM-wire, dark-oxide surface, A_f = 70°C

Rotary Bending

Rotary bending tests were performed using a guided rotary bend tester, which was used for previous studies [3,4]. The specimens were guided around a fixed diameter mandrel. Different mandrel diameters were used in order to produce a range of outer-fibre strains. Strain was estimated with $\varepsilon = r/\rho$ where ε is the strain, r is the radius of the wire and ρ is the radius of curvature of the mandrels used. Test temperatures from –30°C to +60°C were realized with a Haake K15 temperature-control liquid bath. Tests were run until failure was detected or until 10^7 cycles.

4-Point Bending

Non-zero-mean-strain bending tests conditions were obtained with a 4-point bending fixture with a span of 25.4mm. Equidistance loading was used for the four points in the test setup. This fixture was installed onto an Electro Force Tester (Enduratec-ELF 3200 Series), which allows testing at selected mean and alternating displacements. The test frequency was 40Hz and tests were stopped using electrical break detectors. If the samples did not break after reaching 10^6 cycles, the test was stopped and the samples were considered a run out.

RESULTS AND DISCUSSION

Rotary Bending

Fig. 1 shows half–amplitude strain versus cycles to failure data for different superelastic wires as well as for a shape memory wire. Comparable rotary bend test data are also included from Reinoehl, *et al*. [5], which were obtained on two different lots of superelastic Nitinol wires (Ø 0.27mm, A_f = 9°C and 13°C). These tests were conducted in a room-temperature water bath.

In general it can be seen that the shape memory (SM) material has a significantly higher fatigue resistance than the superelastic (SE) material both in the low-cycle and in the high-cycle regions. These data demonstrate that the fatigue resistance of non-transforming martensite is higher than that of transforming austenite, consistent with the results from Dauskardt, *et al*. [6] and Miyazaki, *et al.* [7].

The three sets of SE data all show similar trends with respect to the effects of strain on fatigue life. At the highest strains (≥ 2.75%), the fatigue life is approximately constant (~10^3 cycles) and independent of strain. This was observed by Miyazaki, *et al.* [7,8] and Sheriff, *et al.* [4] and is likely due to the effect of stress-induced martensitic transformations. At intermediate strains in the 10^3 – 10^4 range, there is an increase in fatigue life with decreasing strain. Strains less than ~ 1% strain correspond to high-cycle fatigue with > 10^4 cycles. Each of these three regions indicates that Nitinol fatigue is dominated by different mechanisms.

Two separate factors can account for the differences in the low-cycle fatigue resistance of the three sets of SE wires. First, comparisons can be made between the A_f = 13°C data and the Reinoehl study [5]. These sample sets have similar transformation temperatures and were tested in water baths at approximately 20°C. However, the samples from the current study were electropolished prior to testing in order to minimize effects from any surface defects, whereas the other study used dark oxide wire. As expected, higher fatigue life was obtained with the electropolished wires. Comparison can also be made between the A_f = 1°C wire with the chemically etched surface (bright) and the other two SE wires. The lower-A_f wire has a lower fatigue life compared to the electropolished wire, which indicates that A_f is a strong factor in fatigue behaviour as shown by Miyazaki, *et al.* [7]. Surprisingly, however, there are only minor differences between the Reinoehl data and the lower A_f data. This may be due to the offsetting effects of surface finish (dark oxide *vs.* bright) and transformation temperature (~10°C *vs.* 1°C).

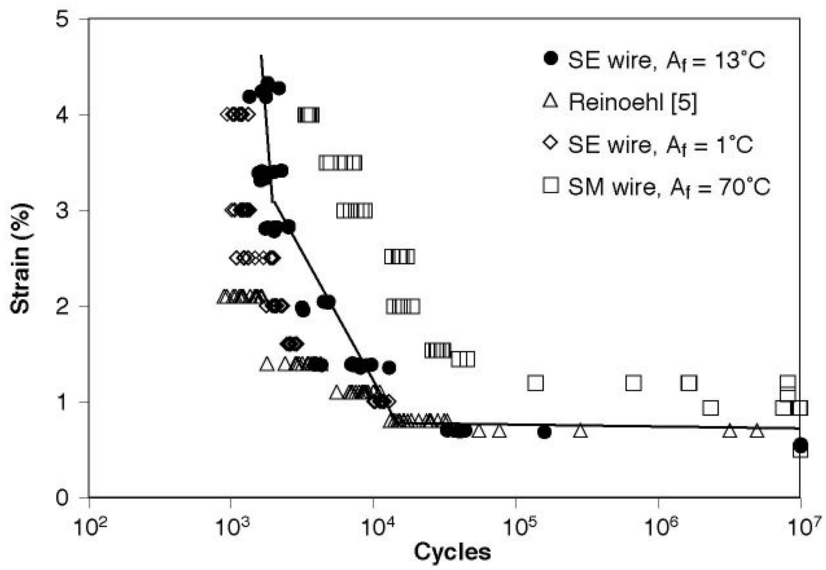

Fig. 1: S-N curves for different Nitinol wires tested at room temperature.

To get a better understanding about the influence of the test temperature on the low-cycle fatigue behaviour, the A_f = 1°C wires were tested at –30°C, 20°C and 60°C. These comparative data are plotted in Fig. 2.

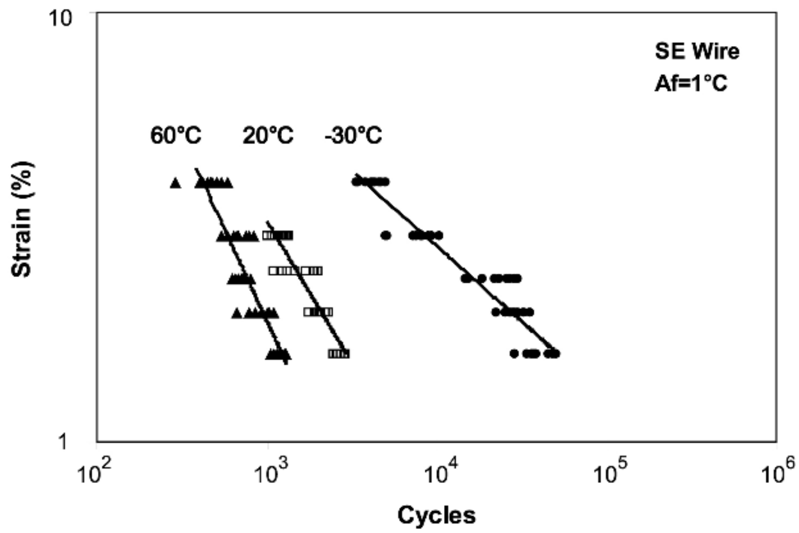

Fig. 2: Rotary bend data for superelastic wire (bright surface) tested at different temperatures

4-Point Bending

Since there is no predefined radius of curvature for a 4-point bending experiment, the radius of curvature has to be determined in order to calculate the strain on the outer fibre of the test specimen. The contour along the sample for different deflections was measured using a laser micrometer.

The measured profiles can be fit very accurately using second order polynomials. The curvature in the middle of the sample can be then obtained as the second derivative of these polynomials. Using these curvatures to calculate the maximum strain at the outer fibre, a linear relationship of sample deflection and strain can be found. In this case it was found that strain ε in percent is equal to 0.77 times the deflection in mm (see also [9]).

The strain-deflection relationship was used to generate the alternating strain vs. mean strain diagram shown in Fig. 3 for SE wire with A_f = 13°C. Each data point represents at least four samples subjected to the same testing conditions.

The preliminary interpretation of the data indicates that the10^6-cycle fatigue limit for a non-zero-mean strain conditions are lower than for zero-mean strain. The results also show that the oscillating strain has a greater effect on the fatigue life of Nitinol than the mean strain. This principal trend is in good agreement with the findings of other authors [10-12] on the effect of mean and alternating strain on the fatigue characteristics of Nitinol. The limit for the alternating strain found in the study of Tablani, *et al.* [10] on uniaxial tensile tests is about 0.2%. Results for "Big Cell" pull-pull fatigue tests from Nitinol stent-like devices conducted by Perry, *et al.* [11] show that there is no break prior to 100 Million cycles for alternating strains smaller than 0.5% for mean-strain between 2-4%. A similar fatigue limit of 0.4% was found on Nitinol diamond samples in more physiologically appropriate push-pull fatigue tests [12].

A comparison of the data obtained in air and saline solution indicate that saline solution decreases the fatigue life slightly for smaller mean strains. However, the data collected so far is not sufficient to draw any final conclusions.

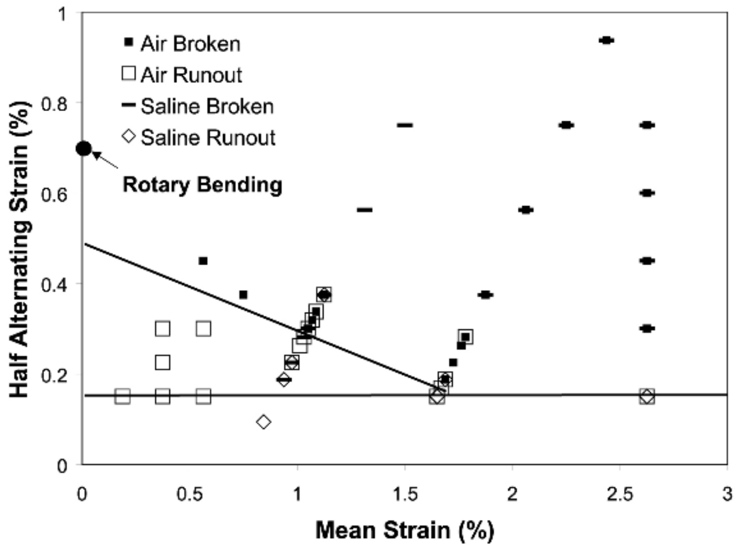

Fig. 3: Alternating strain vs. mean strain data for the 4-point bending test conducted in air and Saline solution. Rotary bending limit for zero-mean strain from Fig. 2 is added for reference.

The data collected for this study indicate that for this 4-point bending mode no breaks prior to 10^6 cycles occurred for alternating strains smaller than 0.2%, for mean strains up to 4%. A comparison of the limits where no break appears independent of the mean strain shows that this limit varies significantly with the test conditions. The mode of deformation is known to have a strong influence on the fatigue limit in general. From a fundamental point of view Macherauch [13] reports a strong dependency of the fatigue limit and the deformation mode that is valid for most conventional materials. According to Melton and Mercier [14] the fatigue limit found in rotary bend is higher than that in bending, which is higher than the fatigue limit for tension-compression mode.

CONCLUSION

This study investigated the bending fatigue characteristics of Nitinol. Rotary bending tests were used to establish zero-mean strain data on different Nitinol materials. In addition to this, 4-point bending tests were performed to understand the influence of a non-zero-mean strain the fatigue behaviour. The following trends were observed from the collected data:

- Shape memory (SM) material seems to have a superior fatigue resistance compared to superelastic (SE) material. The surface finish as well as the A_f temperature of Nitinol has an effect on the fatigue resistance: increased fatigue life was observed for electropolished wire and for higher A_f Nitinol wire.
- Three distinct regions were observed in the SE fatigue data, consistent with proposed mechanisms of cyclic strain accommodation. In the low-cycle region, fatigue life appears to be independent of strain, consistent with a mechanism of transforming austenite to

stressed induced martensite. In the intermediate strain range, fatigue life increases with decreasing alternating strain. This strain range is a transition region between linear elastic and transforming austenite and mechanistically is likely to be the most complicated. The high-cycle region corresponds most closely to a traditional linear-elastic fatigue.

- An initial constant-life diagram was developed using the 4-point bending data. These preliminary data indicate that cyclic strain is more influential than mean strain for fatigue life. Changing the test environment from air to saline solution decreases the fatigue life for smaller mean strains.

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