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Research paper

On the experimental testing of fine Nitinol wires for medical devices

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ABSTRACT

Nitinol, a nickel titanium alloy, is widely used as a biocompatible metal with applications in high strain medical devices. The alloy exhibits both superelasticity and thermal shape memory behaviour. Basic mechanical properties can be established and are provided by suppliers; however the true stress–strain response under repeated load is not fully understood. It is essential to know this behaviour in order to design devices where failure by fatigue may be possible.

The present work develops an approach for characterising the time varying mechanical properties of fine Nitinol wire and investigates processing factors, asymmetric stress–strain behaviour, temperature dependency, strain rate dependency and the material response to thermal and repeated mechanical loading.

Physically realistic and accurately determined mechanical properties are provided in a format suitable for use in finite element analysis for the design of medical devices. Guidance is also given as to the most appropriate experimental set up procedures for gripping and testing thin Nitinol wire.

1. Introduction

The move towards increasingly minimally invasive surgical techniques, which can be performed on a higher percentage of the population, has resulted in a need for more technologically advanced interventions. As more complex solutions are developed, the materials considered for use within these devices also become more sophisticated. One material that has found particular favour within the biomedical industry is the shape memory alloy Nitinol. This, near equi-atomic Nickel–Titanium alloy, exhibits both superelasticity and shape or thermal memory capabilities. Coupled with its biocompatibility, it is now being utilised in a variety of applications from orthodontic archwires to surgical guide wires.

Nitinol is used in a variety of different geometrical configurations within the medical devices industry, but is often found as laser cut tubing or fine wire. There are several applications that utilise the material as fine wire, including several stent graft type devices such as the Anaconda endovascular device produced by Terumo Vascutek which is used as the industrial case study in the present work.

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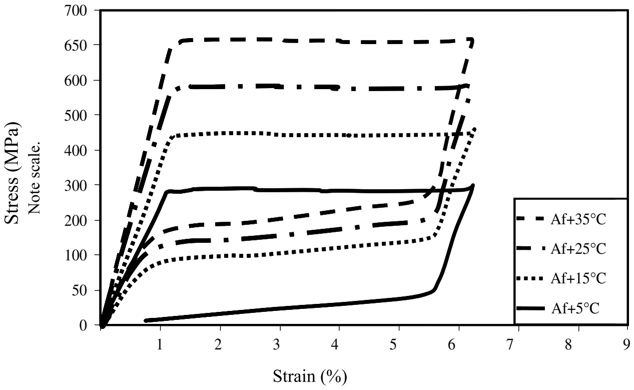

Fig. 1 – The stress–strain response of Nitinol with increasing temperature.

These devices, and others, exploit the superelastic material properties of the wire in its austenitic phase, to allow the large deformation compaction of a device into a small diameter catheter for minimally invasive deployment *in vivo*. As many of these devices are manufactured from straight drawn wire, coiled into rings and not subsequently heat treated, the primary loading mechanism is seen to be bending (McCummiskey, 2008).

Sophisticated 'design-by-analysis' techniques, underpinned by numerical methods are often employed to allow the engineering simulation of potential components, without the need to build expensive and time consuming prototypes, and to allow optimisation of product design. These methods require accurate physical representation of the material properties in order to achieve a realistic behaviour of the component under load. This is particularly important with Nitinol, which has highly individual material properties, as a result of 'prior thermo-mechanical processing.

The work herein presents an experimental programme undertaken on fine Nitinol wire for the determination of the mechanical properties for use in finite element simulations. Consideration is given to key factors such as temperature dependence, gripping methods, asymmetry in tension and compression and cyclic response of the wire within the superelastic phase of the material. The paper emphasises the complications of obtaining accurate material characteristics for the Nitinol wire using testing regimes commonly available and therefore the generation of uncertainties experienced in any finite element modelling exercise.

2. Basic Nitinol characteristics

Superelastic Nitinol usually consists of 55.6 wt% Nickel with the balance Titanium and only a trace of other elements. The process dependency of Nitinol can render it with a range of different properties; however it is often the superelastic range which is sought by designers of medical devices, although an increasing number of uses are being found for its thermal shape memory properties. The superelastic region of the material allows for designs to be realised which were previously impossible due to the plastic deformation of most alloys, such as steel, at less than 1% strain. In several different medical devices, where devices are implanted and must be inserted through narrow arteries with complex pathways to the site of repair, Nitinol is being turned to for its largely recoverable strains of up to 8%–10%. Meanwhile, thermal memory is also becoming more sought after in the medical device industry as more in depth understanding allows manipulation of the material with temperature to take on a secondary shape once implanted *in vivo*.

The superelastic phase of the material occurs when it is stable in its austenitic crystallographic structure, and recoverable strains in the region of 8% are achievable (Otsuka and Wayman, 1999). The material, under strain of above $\sim$1%, will undergo stress induced phase change into a martensite crystal structure, and a superelastic plateau will form, as shown in Fig. 1 for several samples of virgin (first cycle) material. Completion of the phase transformation from austenite to fully stress induced martensite occurs at the end of the plateau.

The temperature dependence of the material can also be seen in Fig. 1, which shows first cycle data with increasing temperature beyond the austenite finish temperature (A_f). The material is seen to be stable in its superelastic phase at temperatures above the A_f temperature. However, as the material increases in temperature above this A_f temperature, the plateau shrinks in width and become less pronounced (ie has a higher gradient). This is not seen with huge effect within the demonstrated temperature regime. The material, at temperatures far beyond the A_f temperature, will have linear elastic material properties. It is reported in the literature that this breadth of superelasticity exists for approximately 50 °C above the A_f, however the breadth is often a result of material composition (Otsuka and Wayman, 1999). The temperature window for superelasticity is a function of alloy composition and of microstructure, which can be modified by prior thermo-mechanical treatment.

3. Experimental characterisation of Nitinol wire

In order to achieve the most realistic results from a finite element analysis, it is necessary to input accurate physically