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NiTi based stent for the treatment of acute urinary retention due to benign prostatic hyperplasia: a preliminary study on NiTi wires and tubes under pure bending

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1. Introduction

Benign prostatic hyperplasia (BPH) remains an incompletely understood disease, mostly striking old men. In fact, 40% of men over 50 show evidence of BPH [1]. The main consequence of BPH is an uncontrolled growth of prostate epithelial and stromal tissues. Eventually, this may lead to an acute urinary retention (AUR) [2], calling for an emergency treatment. Today, the first line treatment consists in emergency catheterization. However, catheterization is responsible for 80% of nosocomial urinary tract infections (NUTIs); with NUTI risk increasing by 3%-10% a day [3]. As an alternative to catheterization, an innovative NiTi shape memory alloy (SMA) based stent, made of a helical wire inserted into a helical tube was developed. In particular, this stent presents at least two distinct successive shape memories during heating, allowing an extension phase to release the urethra, and a contraction phase for an easy removal. This paper presents the stent mechanism, and the first mechanical characterization of the NiTi wires and tubes, under pure bending.

2. Methods

SMAs show very different mechanical behaviours according to their temperature. These behaviours have been widely studied and reviewed in the literature [4]. Essentially, every SMA sample is given a transition temperature T_{trans} , and a set shape, which can be adjusted through appropriate thermal treatments. Under this temperature T_{trans} , SMA is in a martensitic state, its elastic modulus is lowered, and it shows pseudo-plasticity around 8% strain. In particular, SMAs are able to recover their set shape when heated above T_{trans} .

A NiTi wire, diameter 0.5mm, was given a helical shape at diameter D_1 , and a $T_{trans} = T_1$ (Fig.1.a). A NiTi tube, inner diameter=0.5mm and wall thickness=0.05mm, was given a helical shape at diameter $D_2 > D_1$, and a $T_{trans} = T_2 < T_1$ (Fig.1.b). To achieve a complex one-way shape memory stent, the wire was then inserted inside the tube. The stent

obtained this way shows three different behaviours and shapes, according to its temperature T_{stent} :

- $T_{stent} < T_2 < T_1$: both elements are in martensitic state, the stent can be easily reshaped at different diameters (Fig.1.c).
- $T_2 < T_{stent} < T_1$: The wire remains in martensitic state whereas the tube is activated and tries to recover its set shape, expanding the stent (Fig.1.d).
- $T_2 < T_1 < T_{stent}$: both elements are activated, but strength applied by the wire is superior to the one applied by the tube, thus the stent is contracting (Fig.1.e).

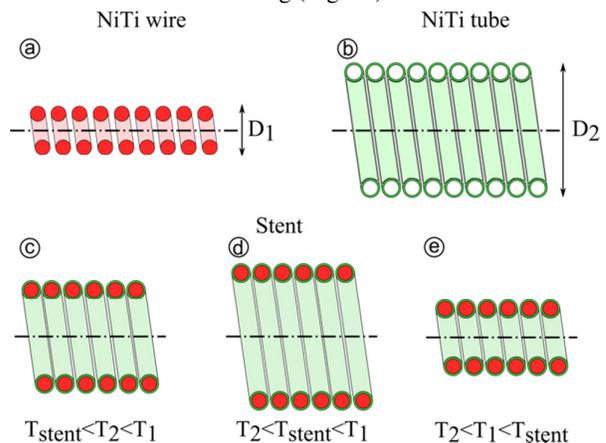


Figure 1: The stent and its various configurations

The stent is given a helical shape. However, unlike a typical compressed helical spring, where wire is mostly loaded in torsion, the stent diameter is changing during expansion (or contraction). For this reason, both the wire and the tube are mostly loaded under bending when the stent is expanding or contracting. In order to design a stent that will interact with the prostate tissues with proper extended and contracted diameters, the behaviour of NiTi wire and tube was investigating under pure bending. NiTi materials present tension-compression asymmetry [5,6], which makes bending behaviour difficult to predict. A specific

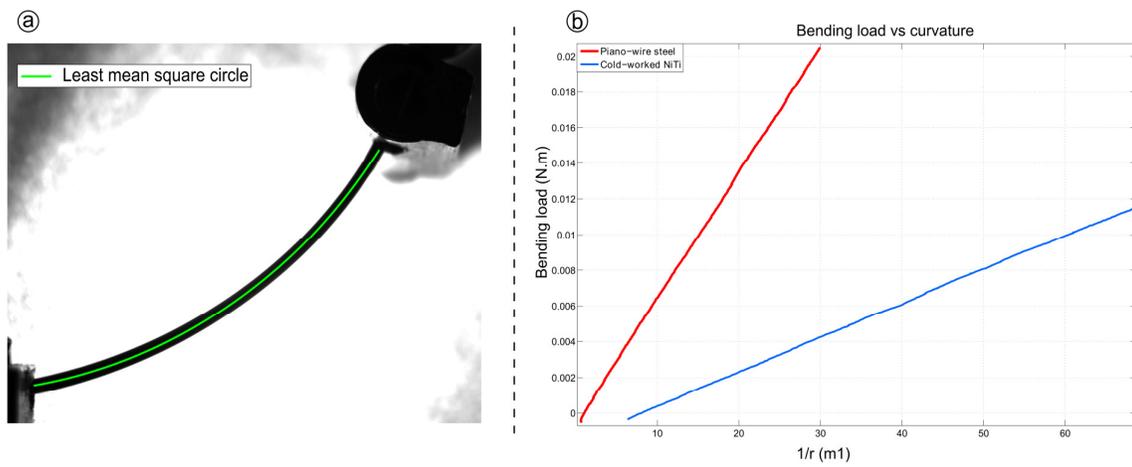


Figure 2: a-Photograph of the bending test with its least mean square circle ; b-Results for cold-worked NiTi wire and steel wire

apparatus has been designed. It enables pure bending testing with a wide range of radii of curvature (from a linear geometry to 1cm radius of curvature) on small samples (less than 1mm diameter).

Steel wires diameter 0.5mm, NiTi wires and tubes described before, length 2.5cm, were tested under bending load, for a radius of curvature reaching about 1.5cm. Various thermal treatments and testing temperature were used, providing results for different crystallographic states: cold-worked, martensitic and austenitic. Testing was carried out on a Gabo Eplexor 500N equipped with a 25N load cell at $\dot{\epsilon}_{max} = 0.01\% \cdot s^{-1}$. Maximum strain reached was $\epsilon_{max} = 1.75\%$ for NiTi samples and $\epsilon_{max} = 0.75\%$ for steel samples. Pictures of the loaded sample were taken during the testing (Fig.2,a). Radius of curvature was then determined through these pictures, using an in-house program to fit a least mean square circle on each picture (Fig.2,a).

3. Results and Discussion

Experiments on steel wires were used to validate the bending apparatus. Since steel samples were tested in their elastic field, bending load is supposed to increase linearly with curvature. Results obtained for steel wires (Fig.2,b, red) show a good linearity, as predicted by the theory. The Young modulus was determined as $E=220\text{GPa}$, which is a common value for piano-wire steel. First results obtained for cold-worked NiTi wire (Fig.2,b, blue), show a good linearity too, and provides a first measurement of Young modulus, $E=62\text{GPa}$, which is consistent with the literature (Fig.2,b) [4]. These results confirm the ability of the bending apparatus to provide tested material mechanical behaviour under pure bending.

Further experiments on NiTi should be carried out, to investigate specific phenomena that have recently been mentioned in the literature, such as localization[7].

4. Conclusions

Bending tests at low radius of curvature were performed on NiTi, using an innovative bending apparatus. This gave first characterization of NiTi behaviour under pure bending, and provided useful information on NiTi behaviour under compression.

Acknowledgments

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