An innovative NiTi based stent as an emergency treatment for acute urinary retention in case of benign prostatic hyperplasia

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1. Introduction

As life expectancy is increasing, population is getting older. Ageing diseases are thus becoming more and more numerous. Benign Prostatic Hyperplasia (BPH) is a pathology mostly striking elder men : 40% of men over 50 years old show evidences of BPH [1]. BPH consists in an anarchic proliferation of prostatic stromal and epithelial tissues [2], resulting in an increase of the prostate volume. Since the prostatic urethra is surrounded by the prostate, BPH may eventually obstruct it, leading to Acute Urinary Retention (AUR). AUR is one of the most problematic complications of BPH, and requires an emergency treatment. Today, the first line treatment of AUR consists in catheterization. However, this procedure comes with various drawbacks :

- it is uncomfortable, and often painful,
- it reduces the patient autonomy and social life (due to the catheter and drainage bag),
- it may lead to Nosocomial Urinary Tract Infection (NUTI).

Urinary infection is a key issue, since catheterization is responsible for 80% of NUTI [3]. It is worth noting that infection risk increases by 3% to 10% each passing day [4]. Patients presenting AUR due to BPH are often old, polypathologic, and thus more likely to develop complications due to NUTI. Beyond the medical concern, NUTI is also responsible for a dramatic increase of the treatment costs.

To circumference these issues, an innovative NiTi based stent has been developped as an alternative to catheterization.

2. Urethral stenting and shape memory alloys

First intra urethral stentings began around 1985, notably with the *Prostakath*® prosthesis [5]. Various urethral stents have been developped ever since. Urethral stenting enables to treat AUR, with a minimized infection risk and discomfort. However, due to their complex and time-consuming implantation mechanism (for instance *Memokath*® stent requires sterile hot/cold water for its expansion/removal), existing conventional stents are inconvenient as an emergency treatment, and thus remain scarcely used.

The aim of the work introduced is this paper is to provide a suitable solution for the emergency treatment of AUR. In order to fulfil the clinical needs, this stent presents different innovative features :

- at least two distinct shape memories triggered successively by increasing its temperature : (1) an extension phase to release the urethra, and (2) a contraction phase to easily remove the stent,
- a bio-compatible silicone coating. This coating prevents the stent, heated using Joule effect, from damaging surrounding tissues,
- a global implantation procedure suitable for emergency treatment.

Double shape memory effect is achieved using NiTi shape memory alloy (SMA). SMA show interesting properties, as a rough description [6] :

- Through thermal treatments, SMA is given a transition temperature (T_{trans}), associated to the "set shape" of the alloy.

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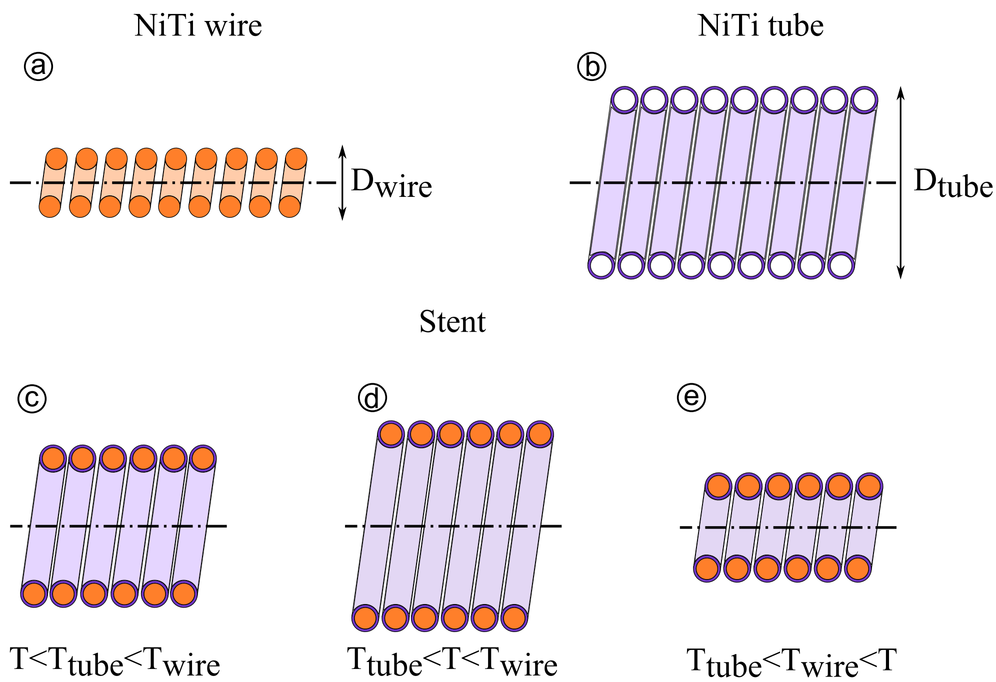

Figure 1: The double shape memory stent : an helical wire (a) inserted into an helical tube (b) ; and its various configurations (c,d,e)

- For $T < T_{trans}$, SMA is in martensitic state, and can be easily pseudo plastically deformed (SAM shows pseudo-plasticity around 1% strain).
- For $T > T_{trans}$, SMA austenitic state is triggered and presents super elasticity (up to 12%).
- When heated above T_{trans}, an initially deformed sample almost instantly recovers its set shape, if its shape is unconstrained : this is the shape memory effect.

3. Stent design

To achieve a two shape memory stent, a specific design was developed. (1) A NiTi wire, diameter 0.5mm, was given for shape memory an helical shape at diameter D_{wire}, and a $T_{trans} = T_{wire}$ (Fig 1,a). (2) A NiTi tube, inner diameter=0.5mm and wall thickness=0.05mm, was given for shape memory an helical shape at diameter $D_{tube} > D_{wire}$, and a $T_{trans} = T_{tube} < T_{wire}$ (Fig 1,b). The wire was then inserted inside the tube.

The stent obtained this way shows three different behaviours and shapes, according to its temperature T :

- For $T < T_{tube} < T_{wire}$, both wire (1) and tube (2) are in martensitic state. The stent can be easily deformed (Fig 1,c). Notably, the stent can easily be rolled around a specific insertion catheter.
- For $T_{tube} < T < T_{wire}$, the tube (2) shape memory is triggered while the wire (1) remains in martensitic state. The stent is thus expanded, and releases the urethra (Fig 1,d). The patient is then able to return home during HBP treatment, without discomfort or NUTI risk.
- For $T_{tube} < T_{wire} < T$, the wire (1) shape memory is triggered. The stent collapses, allowing an easy removal (Fig 1,e).

An alternative solution to obtain a double shape memory is to use a single wire, with two distinct set shapes associated to two distinct T_{trans}. This can be achieved using local thermal treatment, such as laser treatment for example.

To ensure that the stent is suitable for emergency use, the activation ($T > T_{tube}$) will be made using Joule effect, a custom made insertion catheter enabling electrical contact between the stent and the power supply. In fact, currently available urethral stents are mostly activated using hot water. Consequently, the clinical staff has to heat sterilized water and then to inject it inside the stent to expand it. It is understandable that this type of activation prevents the stent from being used in emergency. Using Joule effect allows to activate the stent fastly (less than 10s), without any specific procedure. To ensure that the urethral tissues are not burnt during activation, the stent is coated with a biocompatible silicone layer. A preliminary axis-symmetric thermal simulation provided the duration of the release operation $t_{activation} = 8s$, and the maximum temperature of the urethra $T^{max}_{urethra} = 57^{\circ}C$. This temperature can easily be reduced by increasing the thickness of the silicone coating, knowing that for the simulation the coating thickness was $0.25mm$.

4. Conclusion

A innovative NiTi based stent has been developped. This stent is meant to be used as an emergency treatment for AUR due to BPH as an alternative to catheterization. Thanks to its double shape memory effect, the stent can be easily expanded, and removed, without hurting surrounding tissues. As a consequence, this stent will reduce the risk of NUTI and associated morbidity.

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6. References

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