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A new design of a Nitinol ring-like wire for suturing in deep surgical field

Adelaide Nespoli [a,*], Villiam Dallolio [b], Elena Villa [a], Francesca Passaretti [a]

[a] Consiglio Nazionale delle Ricerche, Istituto per l'Energetica e le Interfasi (CNR-IENI), Corso Promessi Sposi 29, 23900 Lecco, Italy
[b] ProMev, via Cavour, 41-23900 Lecco, Italy

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ABSTRACT

The present work proposes a new suturing procedure based on self-accommodating suture points. Each suture point is made of a commercial NiTi wire hot-shaped in a single loop ring; a standard suture needle is then fixed at one end of the NiTi suture. According to this simple geometry, several NiTi suture stitches have been prepared and tested by tensile test to verify the closing force in comparison to that of commercial sutures. Further experimental tests have also been performed on anatomic samples from animals to verify the handiness of the NiTi suture. Moreover, surface quality of sutures has been carefully investigated via microscopy. Results show that the NiTi suture expresses high stiffness and a good surface quality. In addition, the absence of manual knotting allows for a simple, fast and safe procedure.

1. Introduction

In the current surgical procedure, suturing of biological tissues occurs using either absorbable or non-absorbable threads made of polymeric material, or silk. These sutures can be run continuously or can be accomplished with simple interrupted stitches. When the surgical field is narrow, suturing can become difficult and the time of medical intervention may drastically increase. This inconvenience could happen in critical human body areas like the spinal Dura Mater, basicranium, heart valves, arteries and veins. In addition, in case of non-absorbable suture, the surface quality of some of these suture materials may cause adhesions with surrounding tissues. Therefore, to solve possible inconveniences related to the modern suturing, we present a new simple interrupted stitch based on NiTi shape memory alloy (SMA) wires.

Near equiatomic NiTi alloys are a well-known class of SMA that are currently used in the cardiovascular, orthopedic and orthodontic branches because of their capability to recover a pre-defined shape at a temperature similar to the one of the human body, even after high deformations. Their biocompatibility, their smart properties and their peculiarity to cause less and minor artifacts during magnetic resonance imaging are the main reasons for the existence of a large number of SMA biomedical applications [1–4].

The SMA shape recovery is related to the existence of two solid states that stay stable in two critical temperature ranges: a simple thermal loop across these two limits causes a reversible thermoelastic martensitic transformation (TMT) from one phase to the other one. At high temperature, the NiTi alloy shows a body centered cubic lattice (B2, austenite) meanwhile, at lower temperature the alloy transforms into a monocline lattice (B19′, martensite) [5–8].

For this alloy, the inconvenience of Ni ion release is naturally hindered by the passivation through TiO_2 thin layer. It can also be controlled and avoided by specific surface post-processing. In fact, surface

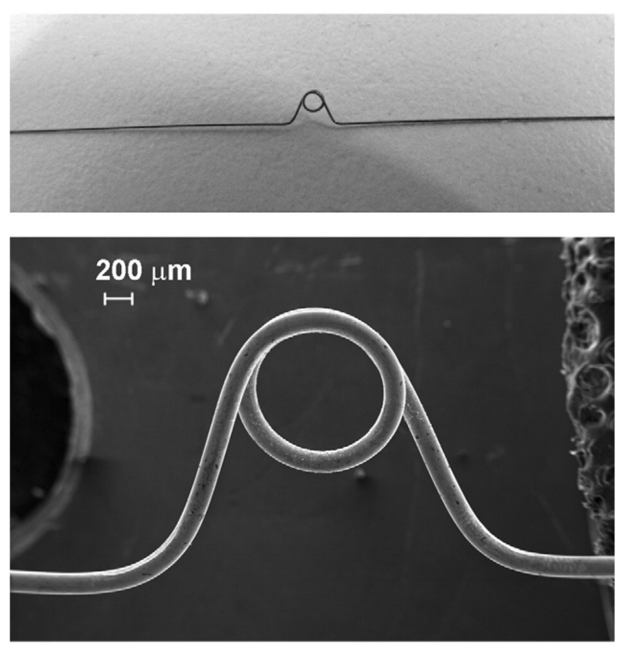

Fig. 1. Photograph and SEM image of the ring-like NiTi wire.

* Corresponding author.
E-mail address: a.nespoli@ieni.cnr.it (A. Nespoli).

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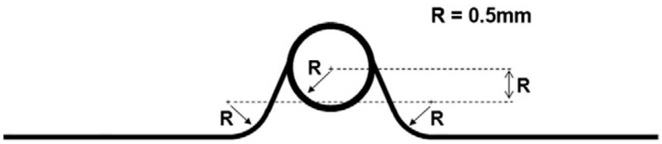

Fig. 2. Dimensions of the suturing SMA ring (R = 0.5 mm).

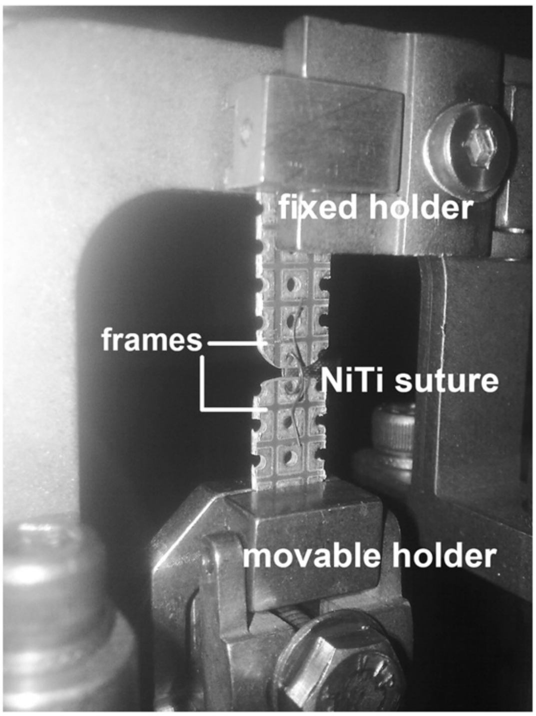

Fig. 3. Arrangement of the NiTi suture ring during mechanical tests.

modifications, such as coating, oxidation treatment, biochemistry method and ion implantation, cause the lowering of the amount of Ni ion release below the critical values that induce allergy and below the daily dietary intake level [9–14].

In most of medical applications, the temperature at which the NiTi specimen is completely transformed into the austenite phase, Af, is always lower than the internal human body temperature. In this situation, when the NiTi device regains its shape at the human body temperature, it shows the well-known pseudoelastic property. In the stress–strain diagram, pseudoelasticity appears as a flag-shaped curve, and in particular stress conditions a recoverable maximum strain of 8% can be associated to the unloading stress–strain plateau [15,16]. This unloading stress can be used to produce very slow movements at a constant force level of some biological tissues, as it occurs for pseudoelastic NiTi orthodontic archwires and cardiovascular stents.

In some medical uses, we can find one more great class of SMAs, commercially known as body temperature (B) alloys, which have Af very close to the human body temperature and that need an extra heating to complete the transformation into the austenite phase [17–22]. After the implantation in a human being, the B-type SMA remains in the austenite state and performs according to the flag-shaped pseudoelastic behavior.

In this work, several SMA suture stitches have been designed and realized starting from a B-type SMA commercial wire. The idea behind this study was to achieve a device easy to use and with a low cost of production.

To date, some new chirurgical approaches based on SMA suture have already been presented. The most representative is the self-closing NiTinol U-clip (Medtronic Inc., Minneapolis, MN, USA) that is an anastomotic device designed to eliminate knot tying during an interrupted stitches procedure. It is composed by a needle/suture delivery system that contains a superelastic NiTi wire. Once the device is placed, the NiTi wire is squeezed out and returns to a predetermined closed-loop configuration [23,24]. It is worth noting that the U-clip is composed of a set of components: a suturing needle, a delivery system, a NiTi element and a miniature spring used to cover the NiTi element.

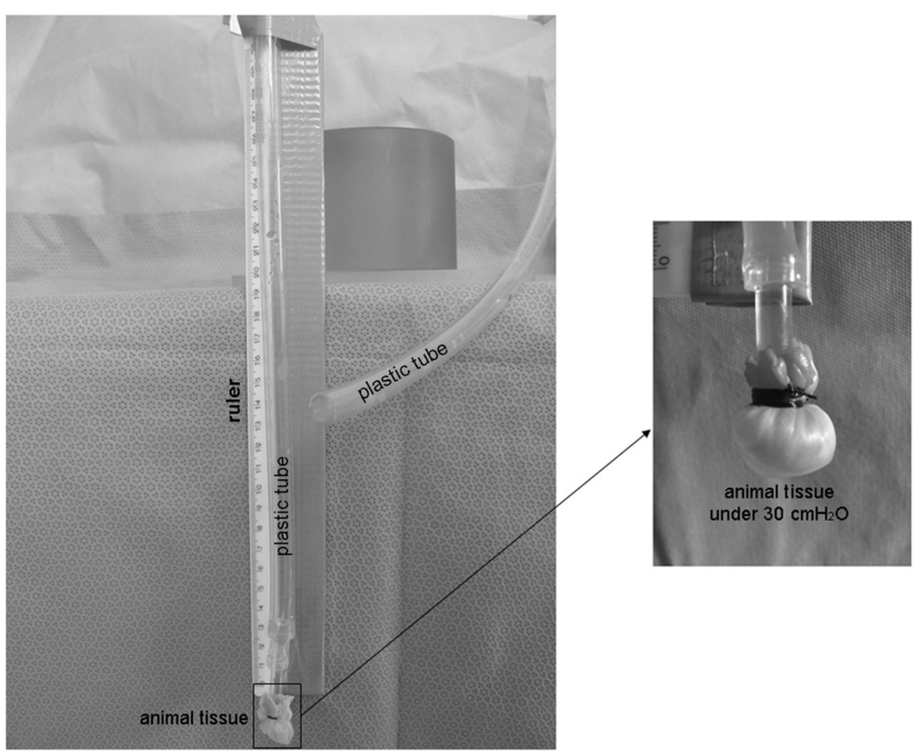

Fig. 4. Experimental setup used to test the NiTi knots under 30 cm H_2O pressure.