Promev strategy

Introduction to SMART SUTURE
SELFKNOTTING WIRE

www.pro-mev.com

Tuttlingen April 10, 2015

A new design of shape memory alloy NiTi ring for suturing in deep surgical field

Villiam Dallolio
Neurosurgeon - Italy

www.pro-mev.com

villiam.dallolio@gmail.com

When the surgical field is particularly restricted, suturing can become difficult and the time of intervention may drastically increase.

In addition, in case of non-absorbable suture, the surface quality of some of these suture materials may cause adhesions with the surrounding tissues.

To solve

Possible inconveniences related to the modern suturing :

A new simple interrupted stich made of NiTi shape memory alloy (SMA) wires, able to regain a predetermined ring shape when heated.

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 so-called pseudoelastic property.

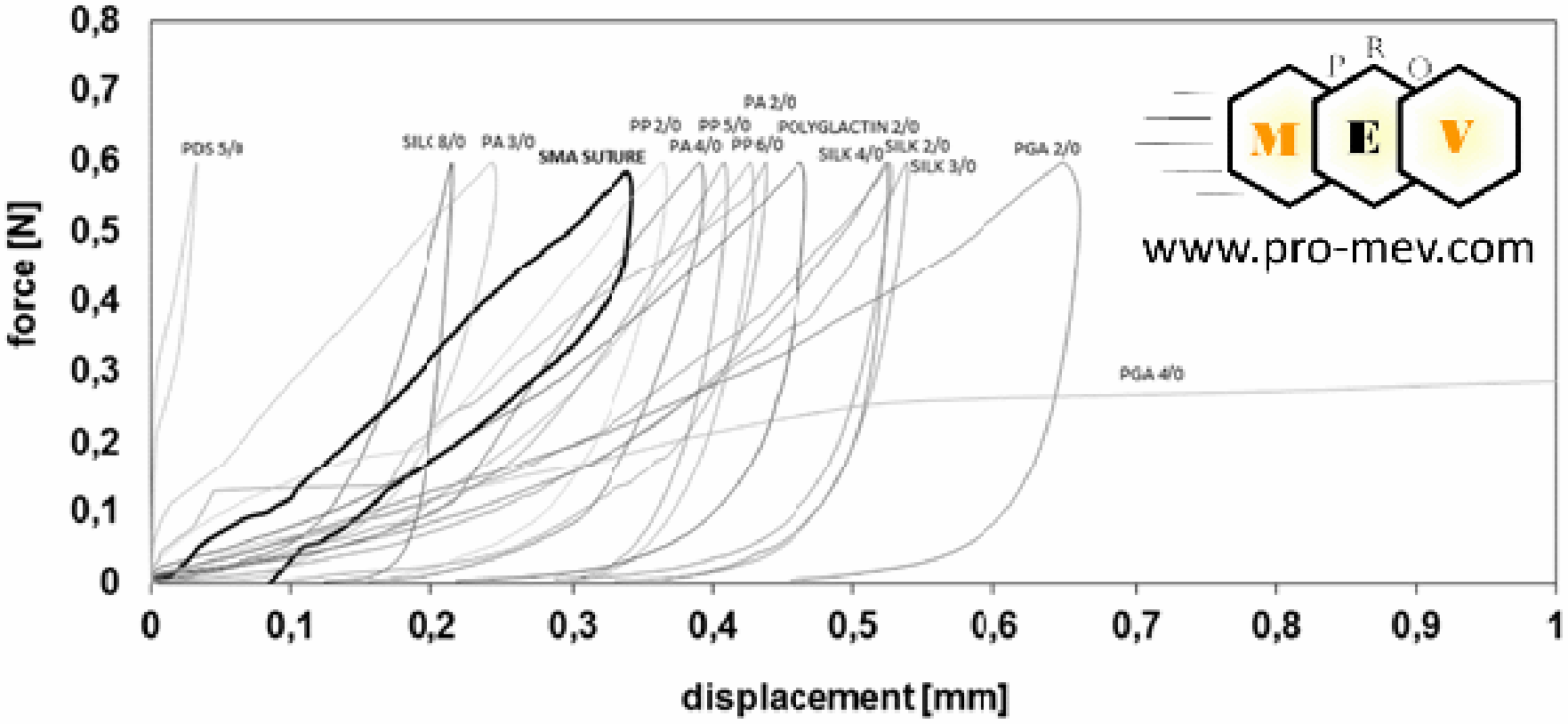

Fig 6. Tightneing force vs. deformation of NiTi and commercial sutures registered at 38°C.

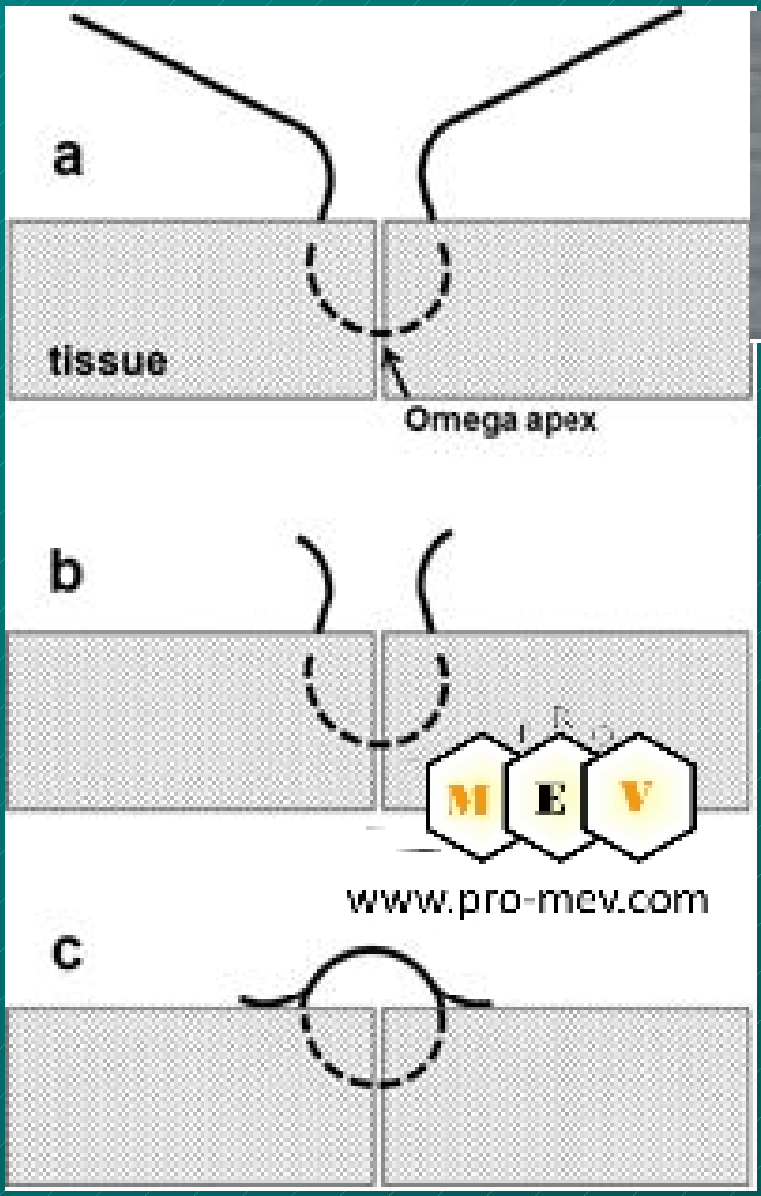

Fig 10. Photograph of the omega shaped part of the NiTi suture wire before (on the left) and after (on the right) heating above

Fig. 9. Schematization of the positioning procedure of the NiTi suture.

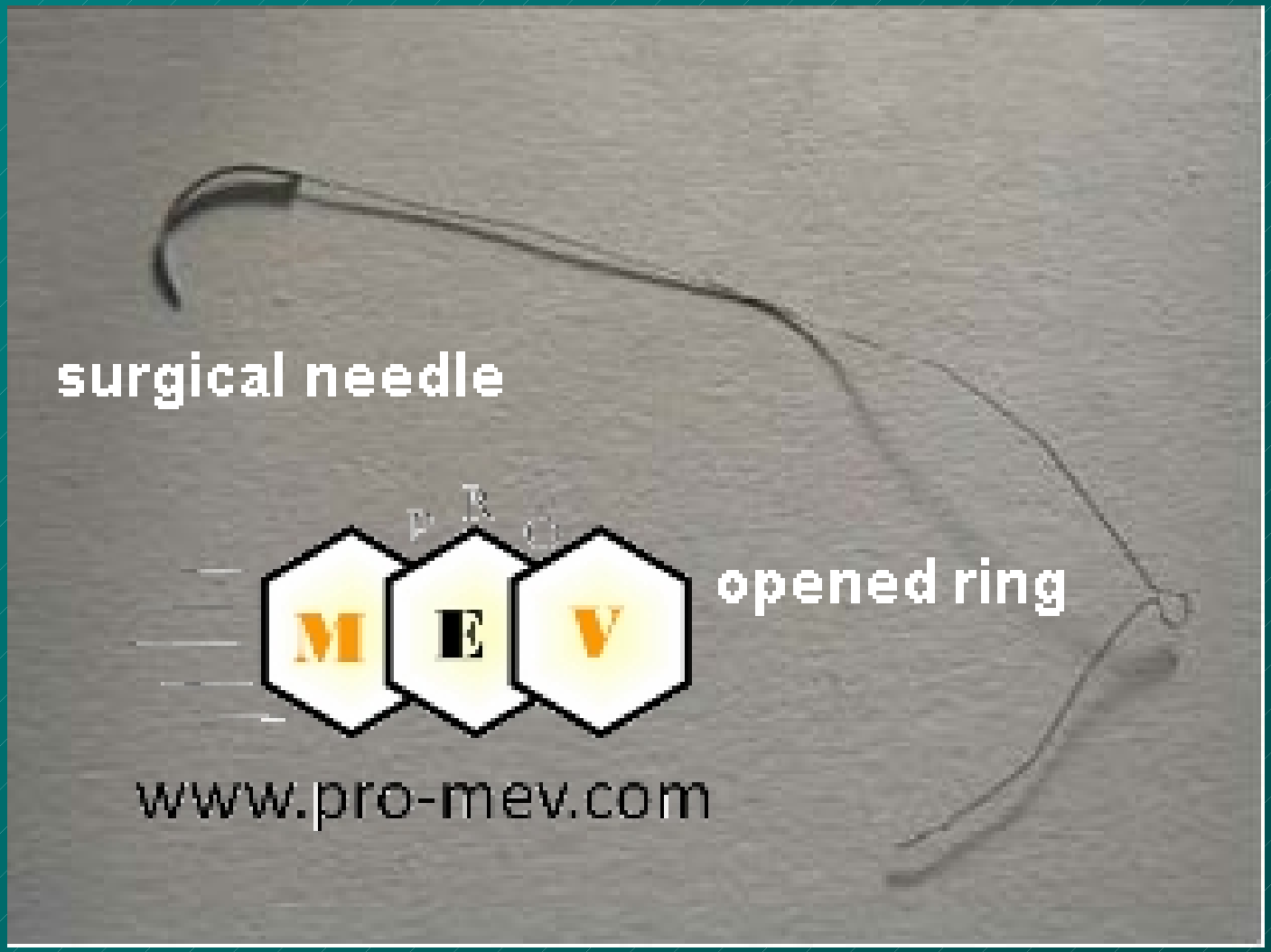

Figure 8. NiTi simple stitch equipped with a 3/0 surgical needle

Several tests have been accomplished to evaluate the handiness of the NiTi suture positioning; these kinds of test have been accomplished on animal anatomical samples (commercially available). In particular, Figure 11 depicts four main steps of the positioning procedure: first, the NiTi suture is placed to have the omega apex inside the wound and the two ends outside the body skin (Figure 11-a, b). The two NiTi suture ends are then cut near the omega curved parts (Figure 11-c); finally, the NiTi suture is heated up to Af temperature to recover the original ring shape (Figure 11-d).

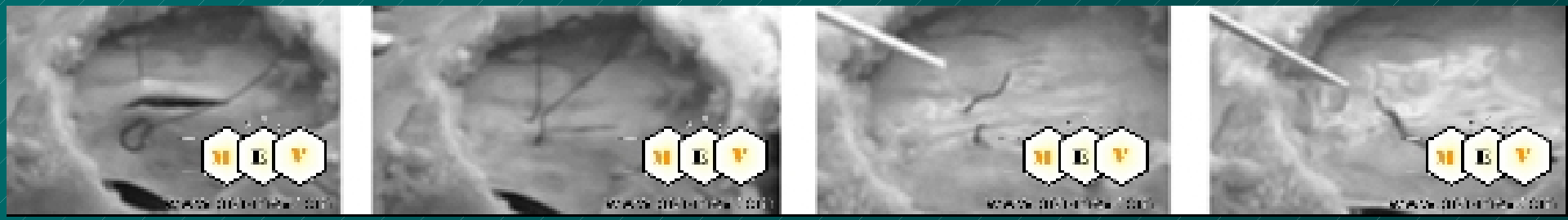

Fig 11. Positioning of the NiTi suture on animal anatomical sample.

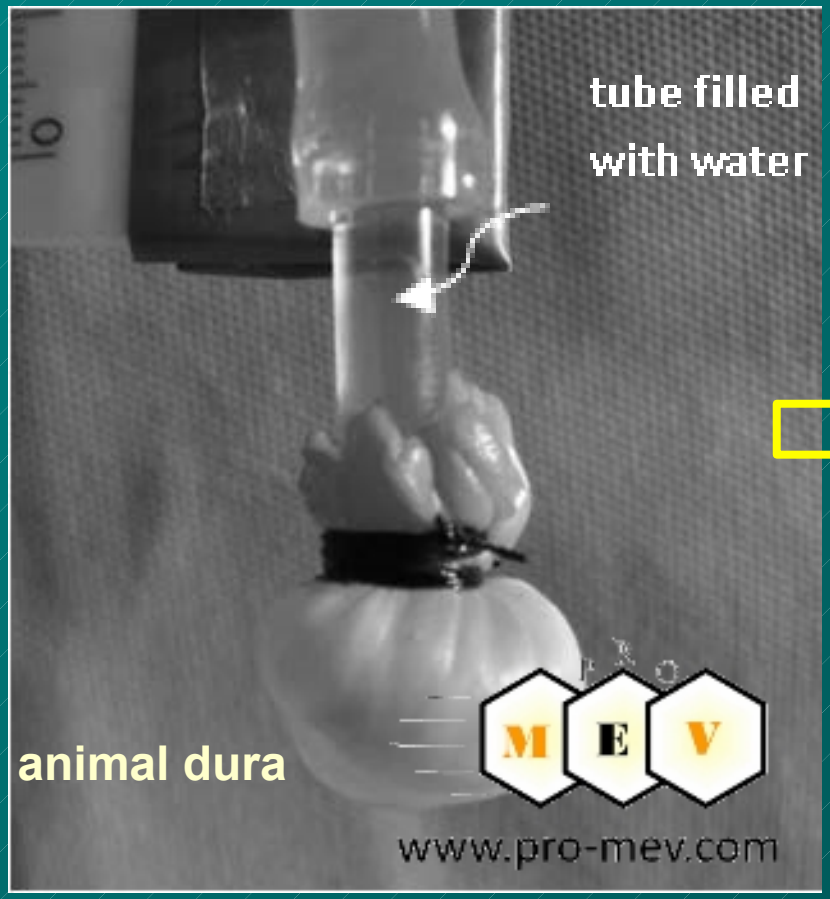

Figure 4. Experimental setup used to test the NiTi knots under 30 mmH2O pressure.

Figure 12. Pressured commercial animal tissue (about 30 cmH2O), sutured with three NiTi suture knots.

Discussions

In this paper, a new shape memory alloy suture has been presented.

The device is made by a NiTi wire hot shaped in a single-loop ring.

The NiTi suture has **several advantages** that are related to the peculiar characteristics of shape memory alloys:

Advantages:

1-the tightening force does not depend to the surgeon skill as the anchorage is only assured by the self-accommodation of the material during the parent transition while heating. **(selknotting)**

2-mechanical tests show that traditional manual-knotting sutures may presents high deformation under low forces, due to the intrinsic high deformability of polymeric materials. **(superelastic)**

3-moreover, besides, optical microscopy observations reveal that the **NiTi** surface shows a near-smooth surface with 10 μm pores; this is positive, as this surface quality reduces the possibility to generate adhesion with the surrounding tissues **(no adhesion)**

4-low thermal fluctuations around the typical internal human-body temperature [21] do not affect the mechanical performance of the suture. In fact, according to DSC results, the **NiTi** suture is permanently in the austenite state inside the human body. Subsequently, any increasing or decreasing of temperature (locally or outside the body) does not affect the correct functioning of the **NiTi** suture as the mechanical properties of the material are solely related to the austenite microstructure**.(no modification)**

5-the **NiTi** suture biocompatibility is guaranteed by the thin TiO_2 thin layer that origins naturally in the material during the hot forming process of the medical grade material. In this condition, a negligible release of Ni ions, with concentrations below the normal human daily intake, is guaranteed.**(biocompatible)**

6-practical experiments on animal tissues show that suturing with the **NiTi** device results simple, fast and safe. Besides, preliminary investigations about the tightening of the **NiTi** suture in particular conditions of pressurized tissues were also accomplished. **(suture is simple, fast, safe)**

During these tests pressure has been set and kept to 30 cmH2O (near 22 mmHg), that is quite similar to the cerebral spinal fluid. At present, new suture designs are under consideration in order to validate the **NiTi** suture performance at higher pressures.

Conclusions

In the current work, a preliminary investigation on the use of shape memory alloy for suturing is presented. The new device is suitable for deep surgeon field where the manual knotting may become challenging. The self-knotting together with the temperature stability, high tightening forces, good surface quality make the presented **NiTi** suture a good option for suturing in critical areas.