SMA-activated nail for the fixation of long bone fractures

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Summary

A common methodology in the surgical treatment of long bone fractures consists inserting metallic nails into the medullar channel naturally present in the bone core. This process is made difficult by the need to machine the channel in order to allow the placement of the nail. Furthermore, a certain interference between the nail and the surface of the bone inner channel is necessary, requiring, in turn, a considerable insertion force to drive the nail into its seat. The insertion stress is usually greater than the typical working load and, combined with the surgical preparation of the channel, can induce local necrosis of the bone tissue.

Using shape memory alloy wires as actuators to ensure the required nail-bone contact force only after the nail has been correctly positioned, led to the development of a new nail which does not require any implantation stress. The results obtained in the study of this nail are very promising from the viewpoint of ease of insertion as well as the possibility of subsequent extraction and substitution of the nail.

Introduction

The surgical nails usually adopted in the treatment of fractured long bones require a preliminary machining of the medullar channel, in order to obtain a cavity as straight and smooth as possible. This operation is detrimental to the future health of the bone, so that an implantation procedure which does not contemplate machining the channel could be very advantageous. Another issue regarding the surgical treatment of fractured bones concerns the method of constraining the nail to the two halves of the fractured bone to ensure the correct load carrying function of the device. The nail can be attached to the bone ends either by screws with their axes perpendicular to the long bone axis, or by friction forces developing at the contact between the outer surface of the nail and the inner surface of the bone channel. In the latter case, an appropriate contact pressure is essential to prevent the nail sliding into the channel and to generate the total friction stabilizing the treated bone and allowing the bypass action of the nail. In order to generate the contact pressure, the nail must be forced into its seat during implantation and this procedure is then responsible for overloading the bone, possibly damaging the tissue and initiating local necrosis.

In order to minimize the negative consequences of typical nail installation, the

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nail should meet one fundamental requirement: during insertion it should have a cross-section small enough to allow the placement using low insertion force and without bone machining; once positioned, the transverse dimensions of the nail should increase so that the correct amount of pressure is achieved at the bone-nail contact surface. This principle has been applied in some nails with an initial diameter, small enough to facilitate the insertion, which can then be increased by applying hydraulically-operated pressure, inducing the controlled plastic deformation of the nail. In this case, the removal or substitution of the nail is necessarily accompanied by significant damage to the bone.

Proposed solution

A way of overcoming the above problems was sought by developing a new type of intramedullary nail, as in the scheme of Figure 1. The transverse dimensions of the nail are varied by a Shape Memory Alloy actuator, activated by the heat generated by the human body, inducing only elastic deformation of the nail and, therefore, providing a reversible implantation. During insertion into the medullar channel, the nail diameter is small enough to allow it to slide into the correct position without any frictional resistance. The SMA wires are then released to allow their contraction, forcing two conical mandrels to move toward the nail center section, so expanding the appropriately machined nail ends.

The SMA wire, pre-strained at 5% or more when in the martensitic phase at temperatures below value T_M, contracts returning to its original length when heated above a temperature T_A (T_M, and T_A are typical of each alloy). Using this feature, it is possible to produce the system of Figure 1. The SMA wire, coupled with the spring, acts as an actuator to move the conical mandrels back and forth, depending on the temperature. The axial motion of the two mandrels induces variations in the diameter of the outer tube constituting the nail.

The shape memory alloy used is Nitinol, a Ni-Ti alloy whose stress-strain curves, shown in Figure 2, were derived experimentally by pulling 100 mm long wires at temperatures below T_M and above T_A, for martensite and austenite respectively. Pulling tests performed at constant load and variable temperature indicated that the material was able to undergo a maximum recoverable strain of 5% in the martensitic phase before yielding occurred, this constituting the upper limit for the stroke of actuators of any given length.

Temperature was controlled differently for the high and low temperature; the Joule effect was induced by feeding a direct current into the wire, while the cooling system consisted of two Peltier cells and a small fan unit (Figure 3). During experimental tests, the wire temperature was monitored using an infrared camera with a resolution of 0.1 °C.

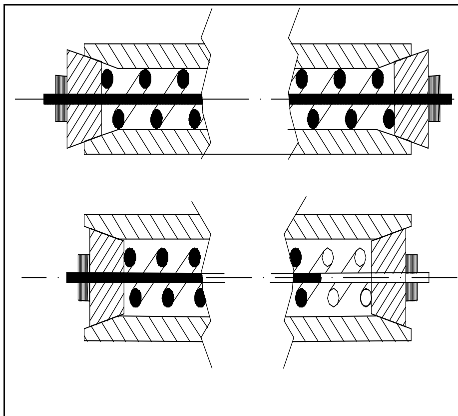

Figure 1: SMA-activated nail

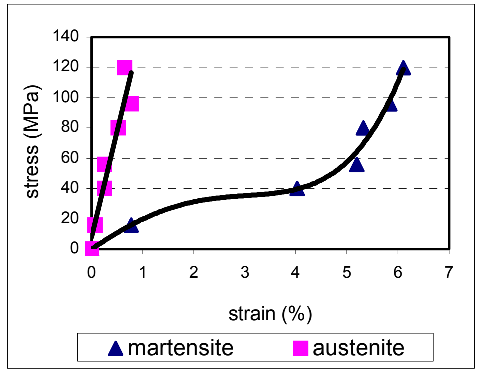

Figure 2: stress-strain curves for NiTi

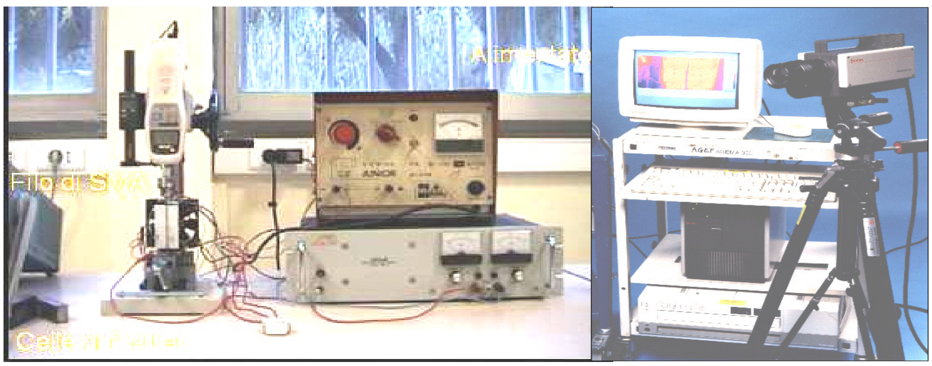

Figure 3: Experimental setup: tensile test machine and temperature acquisition system

In our case, the length of wire and actuator was 280 mm, so the maximum available contraction was close to 15 mm. Each mandrel must be pulled by the wire or pushed by the spring so that it is displaced by a distance equal to half the wire contraction, thereby inducing the desired variation in tube diameter (Figure 4).

Two tubes (280 mm long and 1 mm thick) were produced in PMMA and aluminum; the first one was realized only to verify the expansion system but, due to the low stiffness, it is not applicable to long bone fractures. Four longitudinal notches (30x2 mm) were cut at each end of the tube to allow the deformation, with a circular hole at the base of each notch to reduce the stress concentration effect. The four wings were coated internally with a thin layer of Teflon to reduce wear and were knurled externally (at the bone contact) to increase adhesion to the bone.

The Nitinol wire was positioned along the longitudinal axis and constrained by suitable clamping screws. Two internal steel springs were calibrated (26 mm free length, 15 mm mean diameter, 2 mm wire diameter, 3.3 N/mm axial stiffness) to ensure wedges were released when the wires were cooled and elongated by the action of the springs. On heating, the truncated conical steel wedges (9 mm long, 18 mm maximum diameter and 16.5% inclination) enter the tube in their entirety, opening the wings. Figures 4 and 5 show the different configurations and the final prototype.

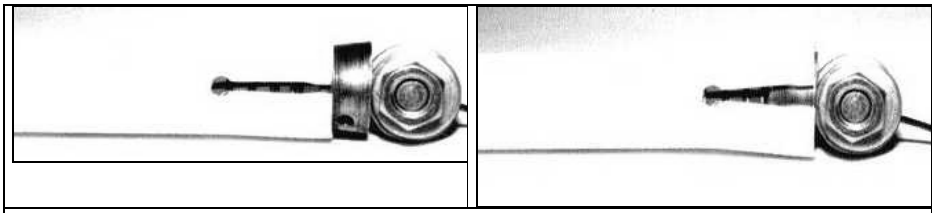

Figure 4: Cold and warm configurations of the nail showing the wire shortening and the wedge insertion and, consequently, the radial deformation

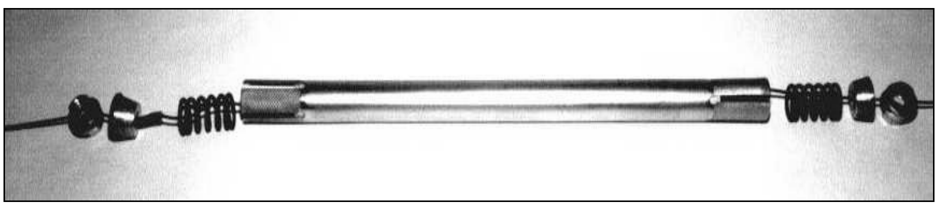

Figure 5: Prototype of the nail in aluminum

Experimental trials were performed, inserting the nail into the channel of a wooden tube simulating the long bone (Young's modulus of orange wood is very close to that of cortical bone), to quantify the wedge displacement in constrained conditions and the axial force required by the shortening SMA wire. In order to generate sufficient adhesion, two SMA wires were coupled. The displacement of the wedge was, clearly, much less (about 0.5 mm), given that the external diameter of the tube was almost the same as the internal diameter of the channel. This resulted in an increase of 0.165 mm in the diameter of the tube. Figure 6 shows one moment during the test.

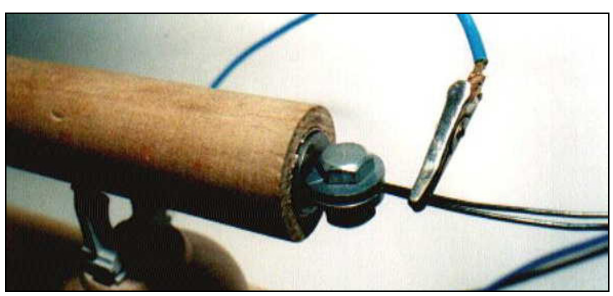

Figure 6: Shortening of SMA wires inside the wooden channel

Numerical Analysis

A numerical simulation was performed using MARC/MENTAT software. The model consisted of three parts (Figure 7), the diaphysal zone of the bone (considered simply cylindrical), the aluminum tube and the wedge. Since the structure is symmetrical, only one half was considered. The 3D-mesh consisted of 5496 eight-node brick elements. The lower elements of the bone were associated with a material “callus” with variable stiffness, in order to verify the changing behavior of the nail during the different phases of callus formation, varying the E modulus of the material, as detailed in Table 1.

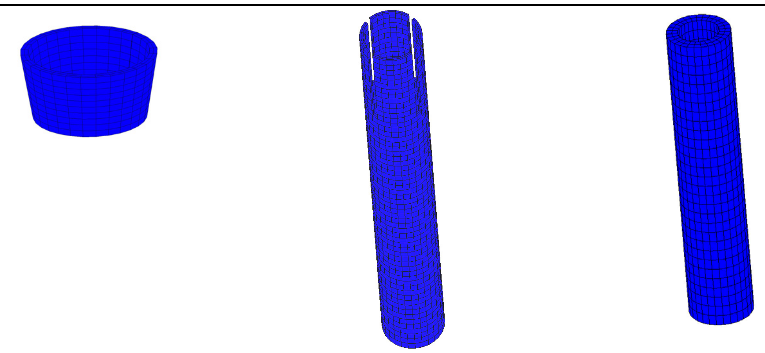

Figure 7: the three part of the FEA model (from the left wedge, tube, bone)

Configuration	E modulus (MPa)	Clinical condition
A	10	First week after surgical treatment
B	30	Second week of callous growth
C	90	Second to seventh week of callous growth
D	520	Seventh to twelfth week of callous growth
E	4400	Twelfth to fifteenth week of callous growth

Table 1

A 3200 N physiological load (four times the mean body weight, taking into consideration muscle and inertia forces) and a 0.5 mm wedge displacement into the tube were considered. The wedge-tube and tube-bone contacts were considered “touching”, with a finite “separation force”. The spring was also inserted between the internal diameter of the tube and the wedge.

The Von Mises stresses and axial displacements shown in Table 2 were obtained on the bone (Figure 8). In all of the configurations, however, the stress was well below that admissible for cortical bone (100 MPa). The compression effect necessary for the adhesion of the nail, is therefore easily supported by the bone tissue.

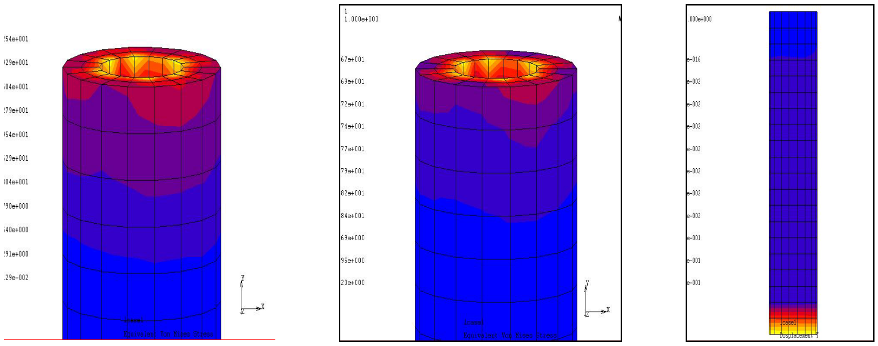

Figure 8: Ideal Von Mises Stresses in configurations A and E and total displacements in configuration A

Configuration	Stress on the bone (MPa)	Axial displacement (mm)
A	32,5	0.138
B	33	0.134
C	34,2	0.123
D	38,46	0.089
E	41,67	0.06

Table 2

Conclusions

A new internal device for the reduction of long bone fractures is proposed. The SMA actuator ensures adhesion to the internal channel of cortical bone and allows easy insertion of the nail with minimum force. A prototype was constructed and successfully tested. Numerical simulation verified that the values of the contact stress on the bone were limited.

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