CLINICAL STUDY

In vitro tensometric measurements of the tensions caused by NiTi alloy springs with memory in metal tubes and human femurs

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Abstract

The aim of this paper is to quantify tangential and axial tensions that develop within metal tube and human femur after insertion of a NiTi alloy spring following the activation of memory shape effect. We can see that resulting tensions inside the bone caused by the mentioned NiTi alloy springs are safe as far as the bone solidity is concerned. Intramedular fixation strength is satisfactory enough to bring about osteosynthesis. Therefore we recommend to use NiTi alloy springs with memory shape effect for intramedular osteosynthesis of long bones. ***(Fig. 20, Ref. 10.)***

Key words: NiTi alloy, memory shape effect, tensometry.

The term “intelligent alloys” has been increasingly used in the last two decades of the 20th century in technical as well as medical community. One of the unique characteristics of these alloys is up to now unknown thermodynamic quality of the so called “memory shape effect” (MSE) (Warlimont, 1974, in Musialek, 1997). Under this group fall metal alloys that have the capacity to recover after deformation of their original shape or their size. They regain their original form after being heated to “working temperature”. If we freeze e.g. a spring from this alloy we can reach it’s plastic deformation. It’s form will change in accordance with the direction and size of the deforming power. Any MSE piece will stay in this deformed shape but nevertheless it “remembers” it’s original shape. If we heat afterwards that piece to a defined temperature it will restore it’s original size and shape. Theoretically it can be shaped any way (Fig. 1). Out of many materials with the mentioned quality the medical science uses in practice above all the equiatomary alloy of Nickel and Titanium (NiTi alloy).

Intramedullary tensometric measurement and MSE: History and present

The principle of MSE resides in thermodynamic transformation of a soft, plastic martensit to a hard and stiff austenite after it received energy by heating. Discovery of MSE offers possibilities to apply this phenomenon in practical medicine. As a prerequisite, this material must fulfil necessary biological criteria.

NiTi alloy with MSE was first used in traumatology and orthopaedic practice by Johnson a Alicandri (1969, in Musialek 1997) for rigid fixation of bone fragments. Since that time many authors introduced NiTi material for internal fixation of skeleton (Vitiugov, 1986; Yang, 1987; Zhang, 1989; Kuo, 1989; Dai, 1993; Schmerling, 1976 – all in Musialek, 1997; Bensmann, 1983; Baumgart, 1978; Saglis-Soglio, 1992; Sanders, 1993). Matsumoto (1993) applied it to treat scoliosis. The memory phenomenon of NiTi alloy was used by Takami (1992, in Musialek 1997) for rehabilitation purposes. At present is NiTi material used in traumatology and orthopaedic practice for the fixation of small leg bones. Musialek (1997) fixes the bone fragments by compression using the phenomenon of fixation element (NiTi clamp) being shortened after the activation of MSE. This technique was applied following osteotomy of the Ith metatarsus. Winkel et al (1999) successfully fixes by compression the bone fragments of navicular bone after fracture by NiTi clamps. The firm Johnson & Johnson markets Mitek’s “anchors”, that are used for reinsertion of the tendon origins and joint capsules (during operation sec. Bankart, reinsertion of *muscullus supraspinatus*, *ligamenta collateralia genus*…). It seems that application of NiTi alloy with MSE is more widespread in general, vascular and uro-

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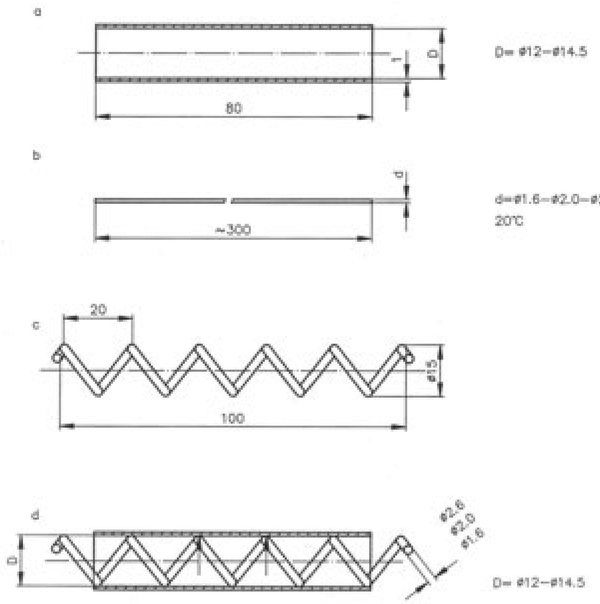


Fig. 1. Diagram of the position of the NiTi wire in metal tube.

genital surgery, than in orthopaedics and traumatology in spite of the fact that alloy with MSE is so far the only known material that makes it possible to compress bone fragments without any mechanical devices.

NiTi material can substantially widen the choice of conventional metal materials used in osteosynthesis. Characteristics of this material enable it's application in intramedulary osteosynthesis of long bones. The work of Haasters et al (1984), who was considering the possibilities of intramedulary osteosynthesis by nails from NiTi alloy with MSE did not provide any information on real tensions inside the bone after the activation of MSE by heating. Given the characteristics of NiTi material with MSE (of all metal materials it has the best flexibility modul) it is appropriate to consider it's intramedulary application (osteosynthesis, fixation of endoprothesis, etc.). Except of the work of Haasters (1984), there was no mention in the available literature concerning this application. Given the lack of basic facts in literature about tensions developed by NiTi implants with MSE in intramedulary application, we concentrated on this issue using tensometry method (VÚZ Bratislava, doc. Ing. P. Ondrejček. CSc.) in vitro in metal tubes and in human femurs.

Material and methods

Principle of the tensometric measurement

In an effort to get basic information on physical characteristics of NiTi wires made in Research Welding Institute in Bratislava a set of tensometric measurements of tangential and axial tensions in metal tubes and human bones was prepared. Disposal samples of NiTi wires with diameters of 1.6, 2.0 and 2.6 mm were used. Working temperature of these samples was 45 °C. The wires have been shaped in such a way that after being heated to working temperature they took the shape of a spring with diameters of 15.0 and 17.0 mm (Fig. 1).

Tests were performed on the premises of Research Welding Institute with the help of doc. Ing. P. Ondrejček and Ing. M. Jesenský. The simulation was performed in accordance with the diagram given in Figs 2 and 3. Metal tubes with inner diameters of 12.0 to 14.5 mm were chosen because the inner diameter of human femur is typically within this range. The length of metal tubes was 80.0 mm. Six tensometres HBM type 1.5/120 LY 11, Banks, USA, were fixed on these tubes.

After insertion of frozen (-18 °C) wires in straight form into the tubes these tubes were puted into the furnace heated to 45 °C. After heating the wires took a shape of spring and caused in points of contact with the tube wall local tension that was measured in a tensometric way. The diagram of tensometers installation is in Figure 2.

The principle of measurement of tension (tangential or axial) resides in measuring the changes of electric resistance of the tensometer after every, even a very small, deformation either in length (axial tension) or in width (tangential tension).

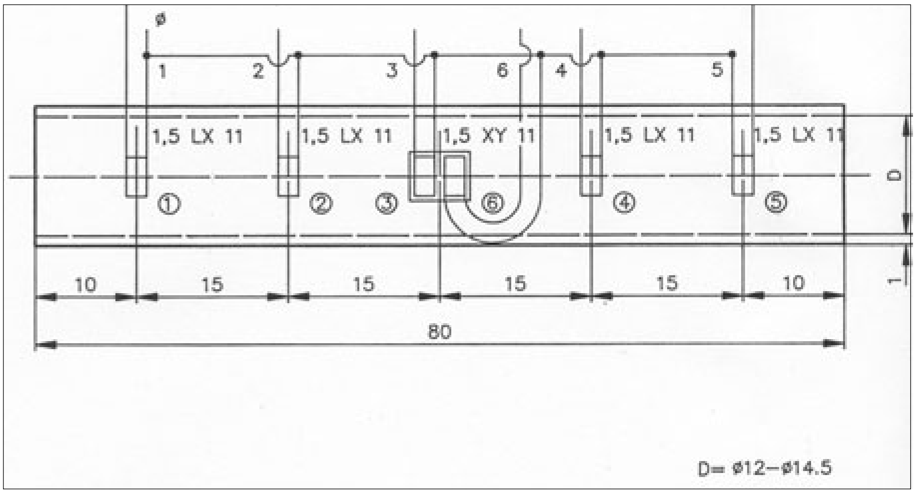


Fig. 2. Diagram of tensometers installation.

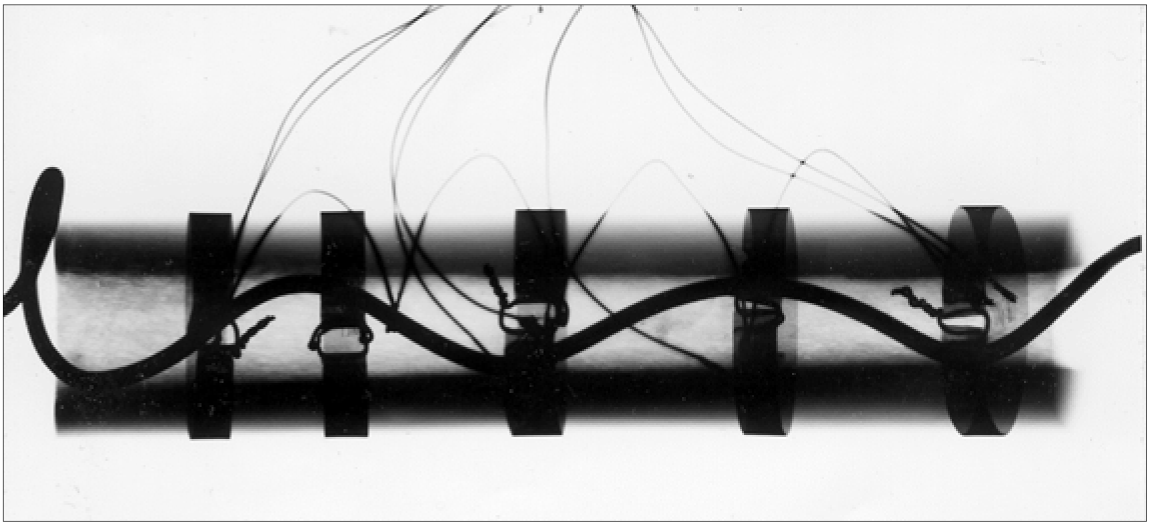


Fig. 3. X-ray of human femur with tensometres and NiTi spring

After measuring the values ε_t and ε_o the values of tension $б_t$ and $б_o$ can be calculated in accordance with the formula:

$$б = - \frac{E}{1-w^2} (\varepsilon_o + w.\varepsilon_t), \text{ or } (\varepsilon_t + w.\varepsilon_o), \text{ where}$$

б – is tension in tangential or axial direction (t or o),
E – is flexibility modul of material (metal tube or bone),
ε – is relative deformation in tangential or axial direction (t or o),
W – is tensometric diameter of deformation

The reason for this measurement is to find out the maximal values of tension in points of contact between the NiTi wires spring and inner surface of metal tube.

The tests were made in a similar way with human bones. We measured the tensions in medial part of the femur where it is most narrow. It could be expected that the tensions there will be the biggest. The risk of bone lesion because of tension from inside would be most probable here. The method of measurement of tangential and axial tensions was the same with the only difference that during the bone tests the tensometres were fixed to a thin copper tape, 0,08 mm thick, belted around the bone. We used 2.2 mm and 2.6 mm NiTi wires shaped after heating to spring form with 17.0 mm diameter. We measured the tensions in diaphyses of four different femurs with inner diameter ranging from 11.5 to 17.0 mm. We measured the tensions twice:

a) after activating the wire in the femur by heating it in the furnace to 45 °C,

b) after subsequent cooling to 25 °C (Figs 4 and 5). For the calculations bone flexibility modul by Beznoska (1986) - E = 15.2 GPa, was used.

Results of the tensometric measurements in metal tubes

Figs 4–16 show the results of tension measurements with 1.6 mm, 2.0 mm and 2.6 mm wire diameters. All of the three wires were tested in several metal tubes with 12.0 to 14.5 mm diameters. The measured values are visible in diagrams. The diagrams prove that maximal values shift in relation to the respective positions of both NiTi springs and the tensometres placed on the external surface of the tube. These measurements helped to find out maximal values of tension caused by thermal activation in points of contact of the spring with the inner surface of the tube. 6 tenzometres placed on the total length of 80.0 mm are sufficient to yield valuable data. The smaller the inner diameters of tube, the higher were the maximal values measured for one wire diameter.

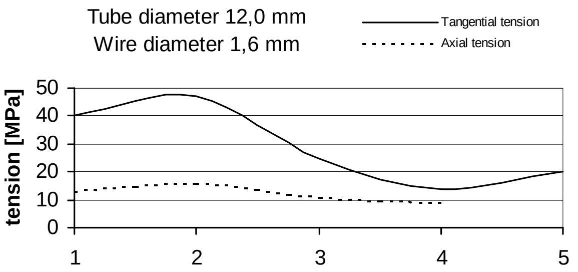
Results of the tensometric measurements in human femurs

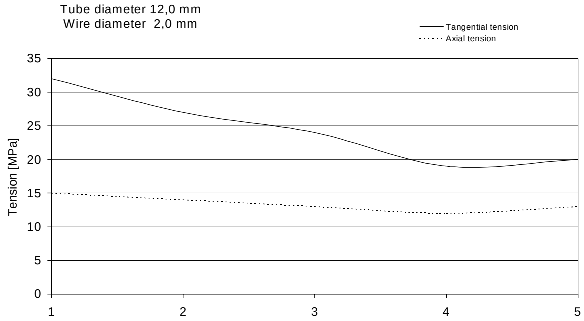
The measured results can be found in Figs 17–18. They show the diagrams of dynamic tangential át and axial tensions áo on bone surface where the tensometres were placed. The maximal tangential tensions ranged between 5.2 MPa and 10.0 MPa with 2.2 mm wire diameter. When using the 2.6 mm wire diameter the maximal measured value of tangential tension was 13.0 MPa. Position of the TiNi wire in the bone is shown on Figure 3.

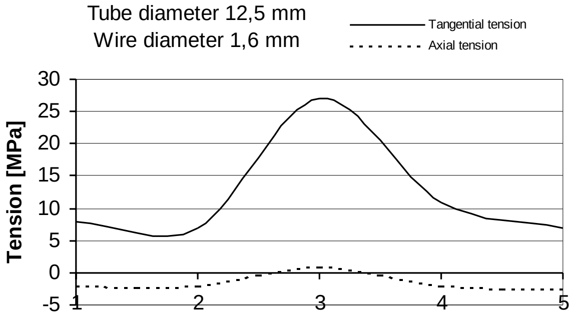
If we suppose that the tension caused by the spring inside the bone is being transferred onto the copper tape uniformly, it is possible to explain the dynamic changes of the tension by local changes of the inner diameter of the bone, whereas the spring has a constant diameter of 17.0 mm. The smaller the bone's inner diameter, the higher the local tangential tension and vice versa.

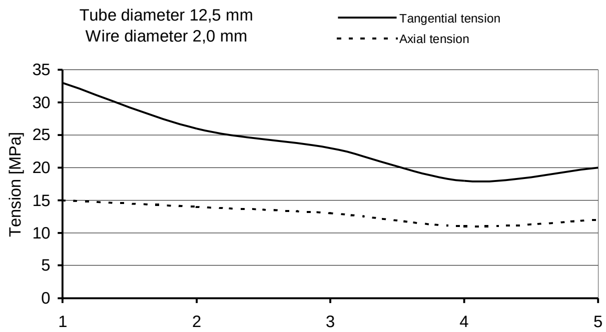
The above mentioned tensions were taken after cooling to 25 °C as well. These results are shown in the lower diagrams on Figs 19–20. These values of tension are practically the same as tensions taken by working temperature of 45 °C.

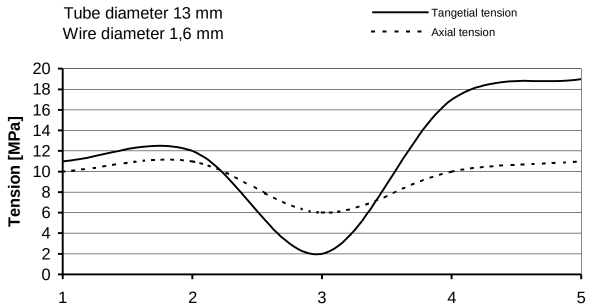
According to the work of Beznoska, 1986 the limit of the bone strength is 90 MPa. The maximal tension caused by the spring with a wire diameter of 2.2 mm is 11 % and in the case of

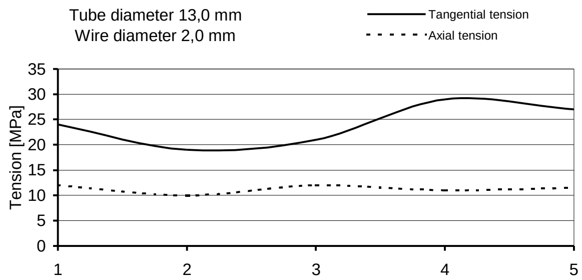

Tube diameter 12,0 mm
Wire diameter 1,6 mm
Tangential tension
Axial tension
tension [MPa]

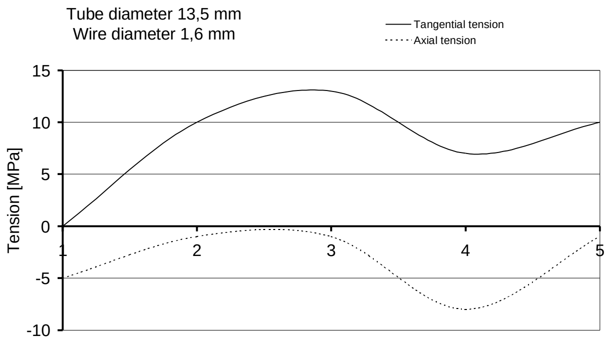

Tube diameter 12,0 mm
Wire diameter 2,0 mm
Tangential tension
Axial tension
Tension [MPa]

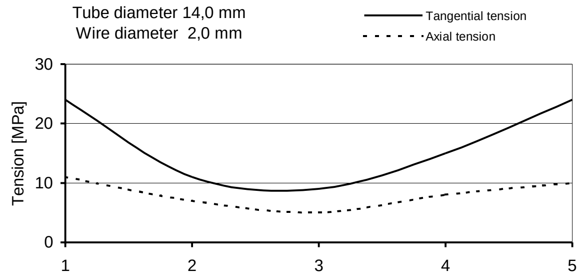

Tube diameter 12,5 mm
Wire diameter 1,6 mm
Tangential tension
Axial tension
Tension [MPa]

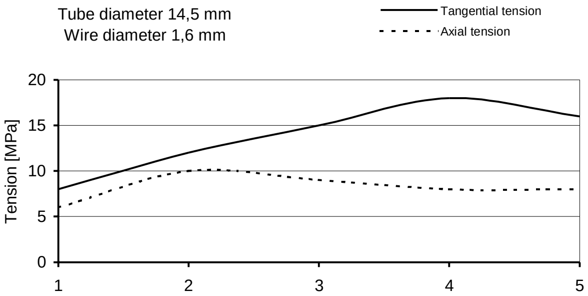

Tube diameter 12,5 mm
Wire diameter 2,0 mm
Tangential tension
Axial tension
Tension [MPa]

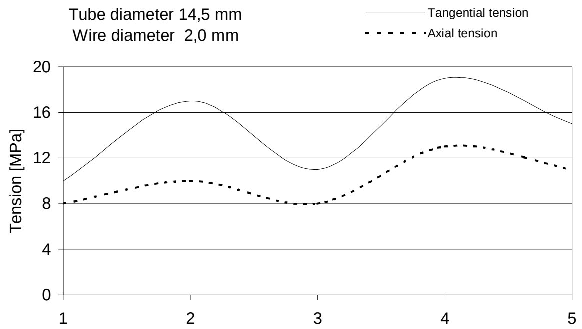

Tube diameter 13 mm
Wire diameter 1,6 mm
Tangetial tension
Axial tension
Tension [MPa]


Tube diameter 13,0 mm
Wire diameter 2,0 mm
Tangential tension
Axial tension
Tension [MPa]


Tube diameter 13,5 mm
Wire diameter 1,6 mm
Tangential tension
Axial tension
Tension [MPa]


Tube diameter 14,0 mm
Wire diameter 2,0 mm
Tangential tension
Axial tension
Tension [MPa]


Tube diameter 14,5 mm
Wire diameter 1,6 mm
Tangential tension
Axial tension
Tension [MPa]


Tube diameter 14,5 mm
Wire diameter 2,0 mm
Tangential tension
Axial tension
Tension [MPa]

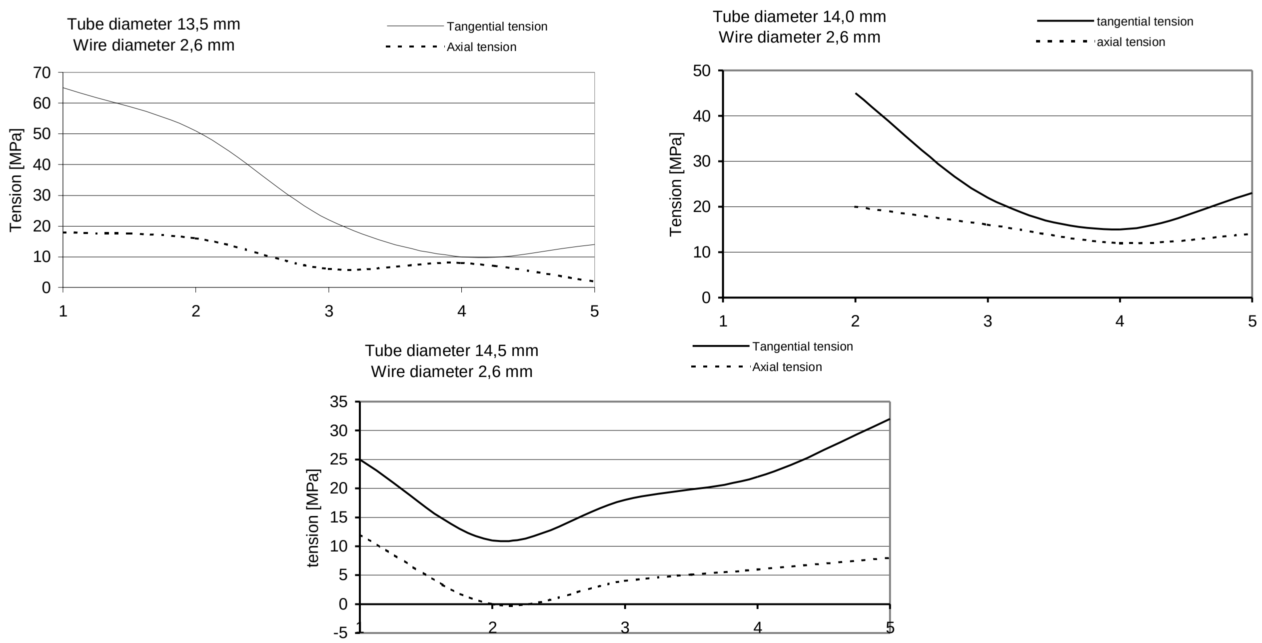


Fig. 4–16. Diagrams of dynamic tangential and axial tensions in 12.0–14.5 mm diameter tubes with heat activated 15.0 mm diameter spring; wire thickness ranging from 1.6–2.6 mm.

wire diameter of 2.6 mm, 14.5 % of this limit. It was necessary to apply the force of 1000 N in order to extract the activated spring from the bone.

Discussion

The unique characteristics of NiTi alloy, especially the MSE, superelasticity, as well as the best flexibility module (Musialek, 1997) suggest it's suitability for intramedullar application in osteosynthesis, fixation of prosthetic components, etc. First reformance of this application is from Haasters (1984), who suggested to construct the Küntscher nail from NiTi alloy with MSE. But he didn't finish and his work lacks any information concerning the possible tensions caused by this material inside the bone. Our results are first of this kind and make it possible to quantify and assess the tensions that come up during this process on the inner surface of metal tube or human bone. Although the measured values of tangential tensions in metal tubes might seem too high, the measurements in human femurs showed that tangential tensions in this environment with a different flexibility module are but a fraction compared to previous values. These tangential tensions caused by the spring in intramedullary space can be considered safe in view of the possible lesion of the bone. Moreover the „anchoring" of the spring in the bone is tight enough to fix it. To extract it was necessary to apply the force of approx. 1000 N. Another important fact that we have found out is that these tensions measured at working temperature do not differ from the tensions measured after cooling the whole set to 25 °C.

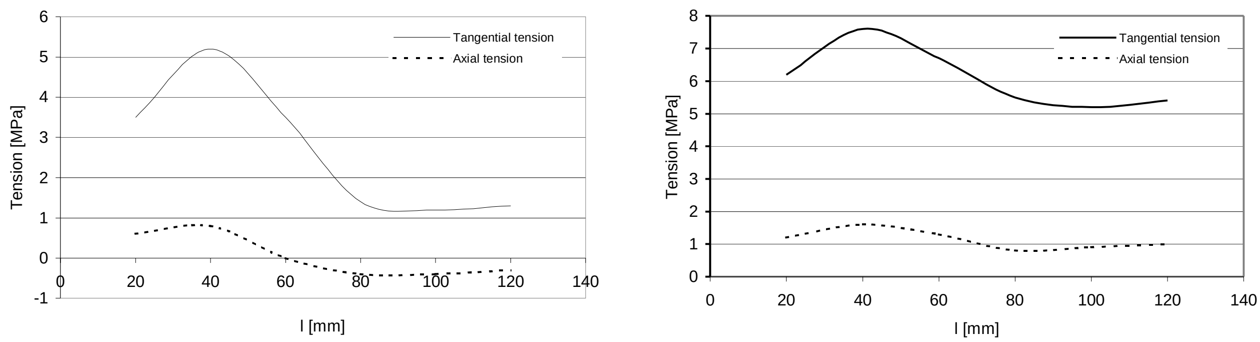


Fig. 17–18. Dynamic changes of tangential and axial tension in the bones Nr. 1 a 2 caused by the pressure of heat activated NiTi alloy spring with a diameter of 17.0 mm. The spring wire diameter is 2.2 mm. The inner diameter of the bone varied from 11.0 to 17.0 mm.

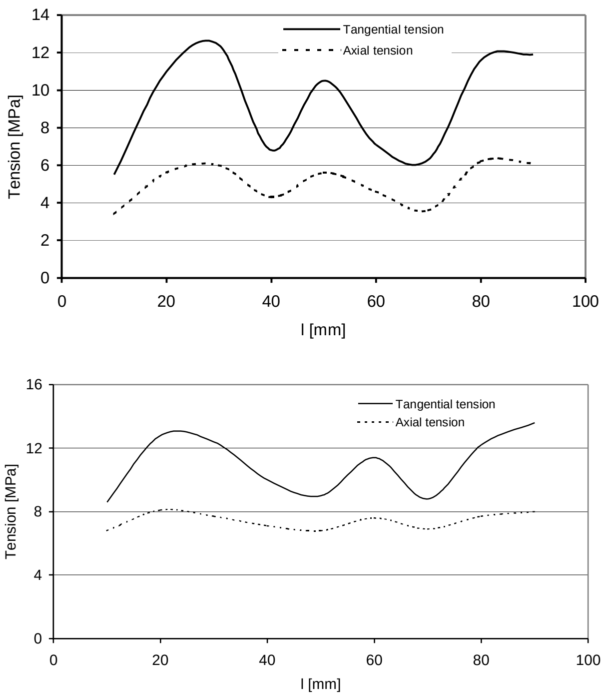


Fig. 19. Dynamic changes of the tangential and axial tension in the bone Nr. 3 after activation of NiTi alloy spring with diameter 17.0 mm. Diameter of spring wire is 2.6 mm. The inner diameter of the bone varied from 13.0 to 16.0 mm. The lower diagram shows the tensions in the bone after cooling to 25 °C.

It is important especially in view of the function of the implant which does not lose its functionality even after cooling (possible cooling-down of the body). Another surprising fact is that the spring once activated inside the bone does not create the pre-programmed number of coils because of the resistance of the smaller inner diameter of the bone. This is documented on Figure 5, that shows the X ray picture of the simulation of the tension measurement in the human femur. The number of coils after heating is approximately 100 % less than pre-programmed. Obviously, it diminishes the potential possibilities of tensions in radial direction in the bone.

Our results from these tensometric measurements are only the start. Before the real applications into the human organism it will be necessary to realize a number of further experiments (the relation of length between the applied and the pre-formed spring, the securing of the fixation point, to which the spring shortens during activation, the critical tangential tension, etc.).

The values of the tangential and axial tension obtained during tenzometric measurements was are the first of this kind and show that the intramedullary tensions can be considered safe in view of possible lesion of the bone.

The tangential and axial tensions after activation of NiTi alloy implants and after cooling are not different.

Anchoring of the NiTi springs after activation is tight enough to fix fragments of the bone in intramedullary osteosynthesis.

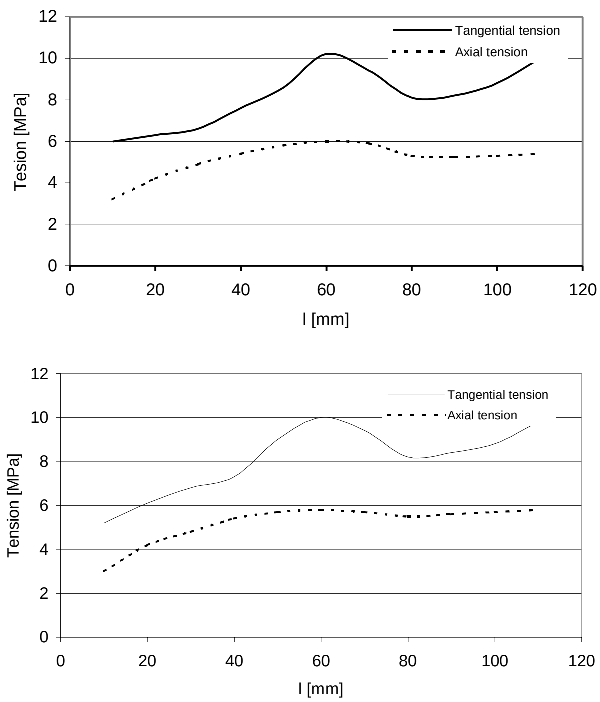


Fig. 20. Dynamic changes of the tangential and axial tensions in the bone nr 4. after activation NiTi alloy spring with diameter 17.0 mm. The diameter of spring wire is 2.6 mm. The inner diameter of the bone varied from 14.0 to 17.0 mm. The low diagram shows the tensions in the bone after cooling on 25 °C.

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