

## ORIGINAL PAPER

# Numerical simulations of human tibia osteosynthesis using modular plates based on Nitinol staples

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### Abstract

The shape memory alloys exhibit a number of remarkable properties, which open new possibilities in engineering and more specifically in biomedical engineering. The most important alloy used in biomedical applications is NiTi. This alloy combines the characteristics of the shape memory effect and superelasticity with excellent corrosion resistance, wear characteristics, mechanical properties and a good biocompatibility. These properties make it an ideal biological engineering material, especially in orthopedic surgery and orthodontics. In this work, modular plates for the osteosynthesis of the long bones fractures are presented. The proposed modular plates are realized from identical modules, completely interchangeable, made of titanium or stainless steel having as connecting elements U-shaped staples made of Nitinol. Using computed tomography (CT) images to provide three-dimensional geometric details and SolidWorks software package, the three dimensional virtual models of the tibia bone and of the modular plates are obtained. The finite element models of the tibia bone and of the modular plate are generated. For numerical simulation, VisualNastran software is used. Finally, displacements diagram, von Misses strain diagram, for the modular plate and for the fractured tibia and modular plate ensemble are obtained.

**Keywords:** modular plates, Nitinol staples, numerical simulation, osteosynthesis.

### □ Introduction

Nitinol, an alloy containing an almost equal mixture of nickel and titanium, was invented in the late 1960s and belongs to a group of materials referred to as “smart materials” because of their unique physical properties that make nitinol so remarkable: shape-memory and superelasticity.

Of the SMAs available, NiTi is the only material with an appropriate level of biocompatibility and it became a key component of several revolutionary medical devices. Its properties enable new types of medical devices to be designed and produced in diverse fields of medicine. Applications of Shape Memory Alloys to the biomedical field have been successful because of their advantages over conventional implantable alloys, enhancing both the possibility and the execution of less invasive surgeries.

NiT has been approved for use in orthodontic dental archwires, endovascular stents, vena cava filters, diagnostic and therapeutic catheters, laparoscopic instruments, intracranial aneurisms clips, bone staples, and various orthopedic implants [1]. Several characteristics make NiTi extremely attractive for use in medical devices: the material has good biocompatibility [2], the devices can be pseudo-elastically or thermally deployed,

and the material can apply a constant transformation stress over a wide range of shapes [3]. Biocompatibility studies have shown NiTi to be a safe implant material, which is at least equally good as stainless steel or titanium alloys [4–6].

In orthopedic surgery, NiTi applications currently include compression bone staples used in osteotomy and fracture fixation [1, 7], rods for the correction of scoliosis, [8] shape memory expansion clamps used in cervical surgery [9], clamps in small bone surgery [10], and fixation systems for suturing tissue in minimal access surgery [11]. Other medical applications of NiTi in orthopedic surgery are presented in [12–15]. Typically, a fractured or cut bone is treated using a fixation device, which reinforces the bone and keeps it aligned during healing. Bone plates are surgical internal devices, which are used to assist in the healing of broken or fractured bones.

### □ The AO classification of the tibia/fibula diaphyseal fractures

The statistics show that ones of the most frequent fractures of human tibia bone are the diaphyseal fracture, type A (*AO Classification* [16]). The subgroups of the tibia/fibula diaphyseal fractures [16] are:

**A1 – Simple fracture, spiroid**

42-A1.1 Fibula intact;

42-A1.2 Fibula fractured at another level;

42-A1.3 Fibula fractured at the same level.

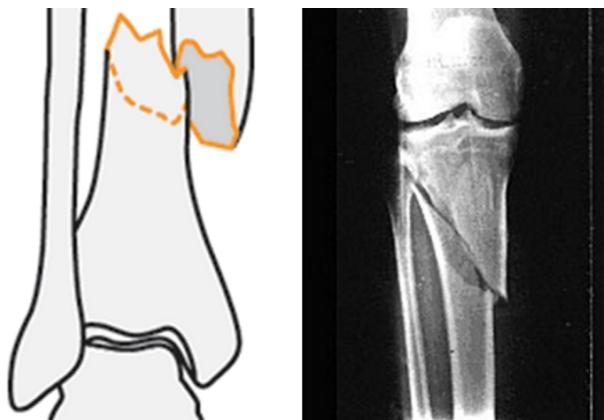
These are simple diaphyseal fractures of the tibia, with a spiroid line of fracture.

**A2 – Simple fracture, oblique ( $>30^\circ$ )**

42-A2.1 Fibula intact (Figure 1);

42-A2.2 Fibula fractured at another level (Figure 2);

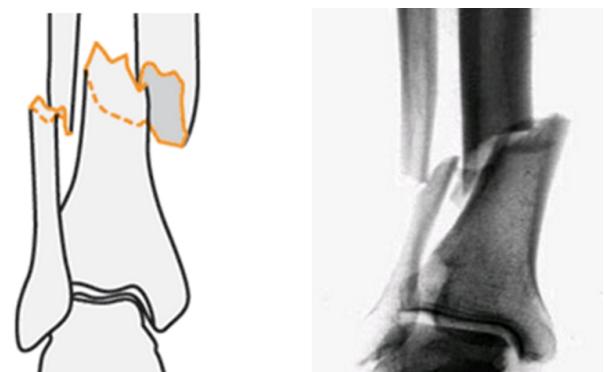
42-A2.3 Fibula fractured at the same level (Figure 3).



**Figure 1 – Fracture 42-A2.1 Fibula intact.**



**Figure 2 – Fracture 42-A2.2 Fibula fractured at another level.**



**Figure 3 – Fracture 42-A2.3 Fibula fractured at the same level.**

These are simple diaphyseal fractures of the tibia, with an oblique fracture line.

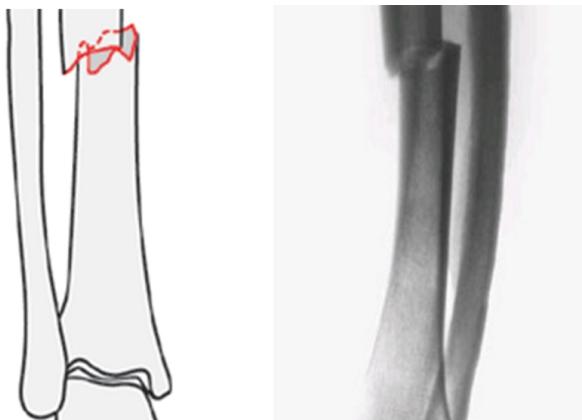
An oblique fracture line is defined by its inclination equal to or greater than  $30^\circ$  with respect to the perpendicular to the axis of the tibia.

**A2 – Simple fracture, transverse ( $<30^\circ$ )**

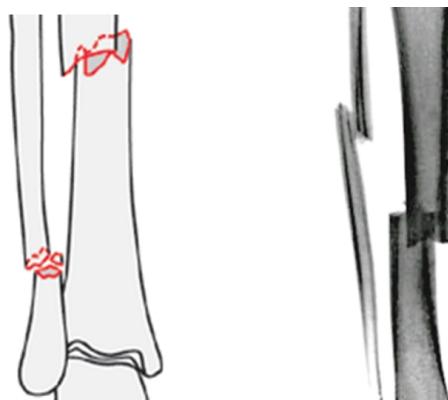
42-A3.1 Fibula intact (Figure 4);

42-A3.2 Fibula fractured at another level (Figure 5);

42-A3.3 Fibula fractured at the same level (Figure 6).



**Figure 4 – Fracture 42-A3.1 Fibula intact.**



**Figure 5 – Fracture 42-A3.2 Fibula fractured at another level.**



**Figure 6 – Fracture 42-A3.3 Fibula fractured at the same level.**

These are simple diaphyseal fractures of the tibia with a transverse fracture line ( $<30^\circ$ ), located at any level of the tibial diaphysis.

These fractures are considered more serious than the A2 group fractures because, once reduced, there is less contact surface at the fracture site.

For our study, the numerical simulations are made for the diaphyseal simple fracture of the human tibia bone.

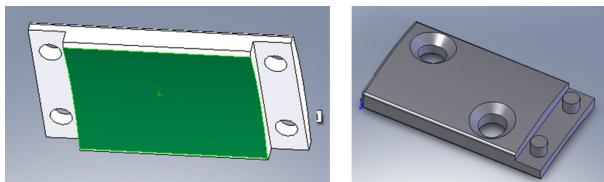
The figures which present the schema and the radiological view of the subgroups A2 and A3 (Figures 1–6) are taken from the site [www.aofoundation.org](http://www.aofoundation.org) and [www.wikipedia.com](http://www.wikipedia.com).

## ▫ Virtual modular plates

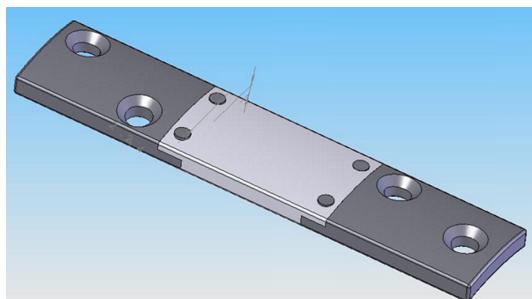
Our studies have been focused on identifying and analyzing modular implant structures. We have studied variants of modular plates based on shape memory alloys used for consolidating a diaphyseal fracture of long bones. The plates are implants in direct contact bones that had undergone physiological corrections or with traumatized bones.

The restrictions of the researched solutions had to do with biological and implantational compatibility based on minimally invasive techniques, which leads to a shortening of the recovering period and, also, lessens the risk of infection.

Osteosynthesis plates are attached to the bone on both sides of the fracture with bone screws. Healing proceeds faster if the fracture faces are under a uniform compressive stress. The proposed implants, which have been analyzed in this study, had a modular organization, using intelligent materials with shape memory as coupling structures between the support elements. The first alternative consists of making titanium or stainless steel plates and a Nitinol plate, which ensures the coupling of the two plates, fixed onto the fracture fragments (Figures 7 and 8).



**Figure 7 – Central module made of NiTi and extreme module made of titanium or stainless steel.**



**Figure 8 – Modular plate (first variant).**

When NiTi bone plates are used, the continuous compression is ensured by the return of the pre-strained plate to its original shape. This effect remains as long as the original shape is not reached. The major disadvantage of this solution is the high cost of the medial plate, which is entirely constructed of Nitinol, as well as the highly complex procedure of decoupling this central piece.

A second option focused the design on creating a modular adaptive plate for osteosynthesis, realized from identical modules, completely interchangeable, made of titanium or stainless steel and from connecting elements as U-shaped staples made of Nitinol. The staples carry out the role of a clamp in order to join damaged bones and to heal bone fractures. The Nitinol elements ensure the flexibility and the elasticity of the modular structure assembled from a number of modules of the right shape

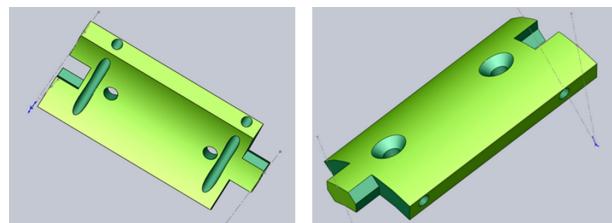
and dimensions. The identical structure of the modules ensures the attachment of the implant onto the bone fragments and with other elements. The attachment options differ according to the state of the fractured bone, the size of the fracture, the body size of the patient.

By cooling, in its martensitic stage, the staple is opened and driven into each side of the plate modules. As the staple warms (just upon heating to body temperature) the pins return to their original shape, pulling the fracture together. This means that the pseudoelastic properties of the clamp allow the force on the bone surfaces in contact. The fixation of the bone fracture is then achieved and a permanent axial compression is ensured. Upon cooling after fracture healing, the staples return to first shape, so that they can be easily extracted.

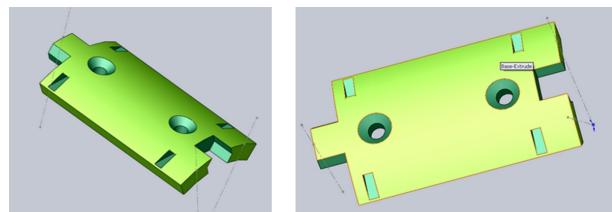
## ▫ Results

Using computed tomography (CT) images to provide three-dimensional geometric details and SolidWorks – a Computer Aided Design software package, we have obtained the three dimensional virtual models of the tibia bone and of the modular plates [17–19]. In Figures 9–13, different variants of modular plates are presented.

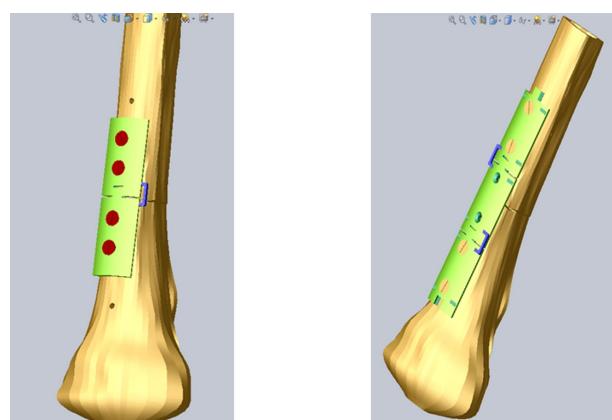
The finite element models of the tibia bone and of the modular plate are generated.



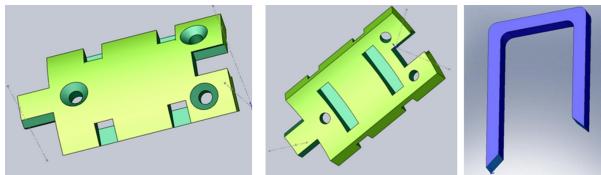
**Figure 9 – Module (second variant).**



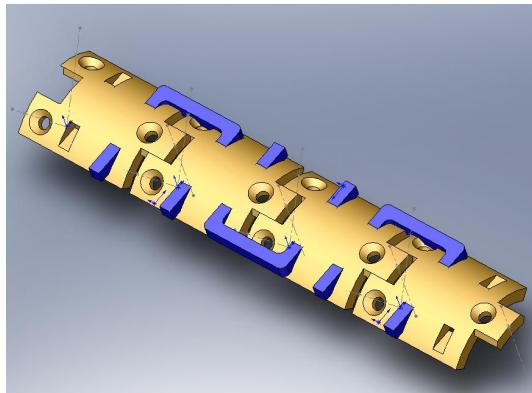
**Figure 10 – Module (third variant).**



**Figure 11 – The fractured tibia and modular plate made of two modules (second variant), and three modules (third variant), respectively.**

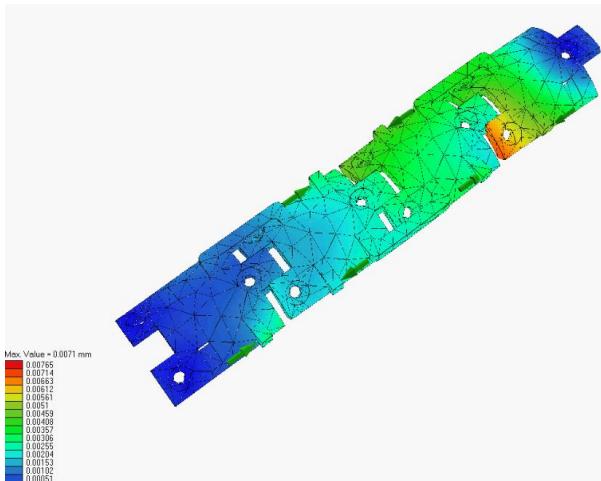


**Figure 12 – Module plate (fourth variant) and staple.**

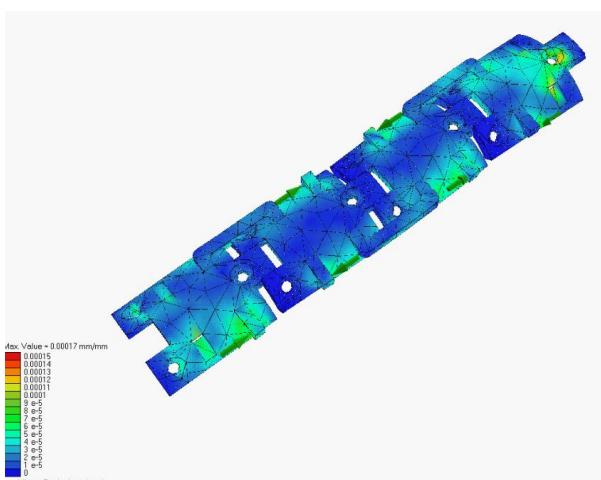


**Figure 13 – Modular plate.**

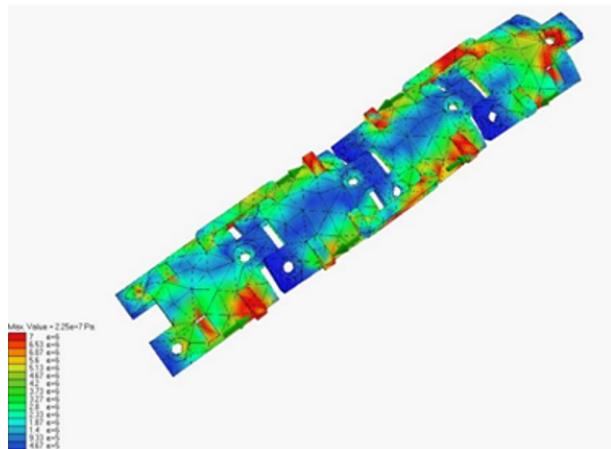
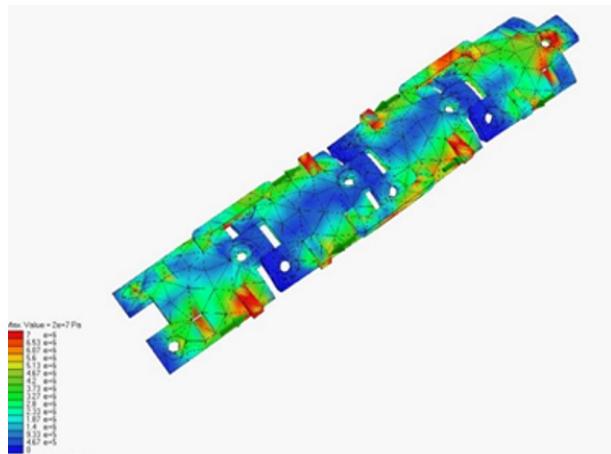
For numerical simulation, we used VisualNastran software. We have obtained displacements diagram, von Misses strain diagram, von Misses stress diagram for the modular plate and for the system made from fractured tibia and modular plate (Figures 14–21).



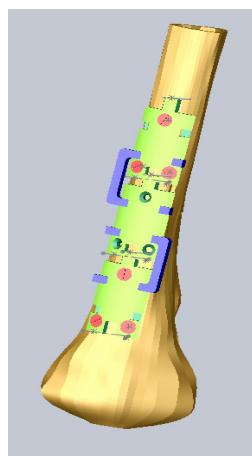
**Figure 14 – Displacements diagram in modular plate [mm].**



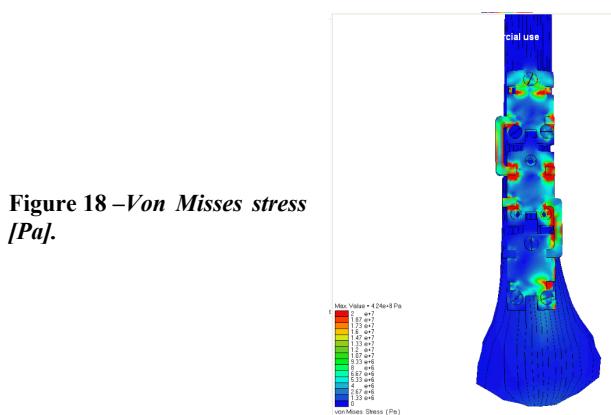
**Figure 15 – Von Misses strain diagram [mm/mm].**



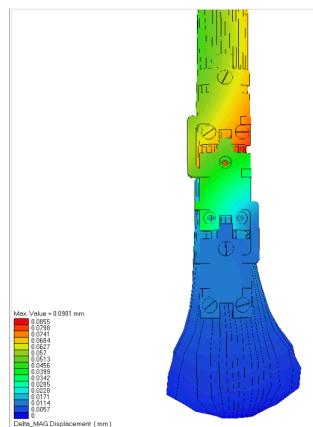
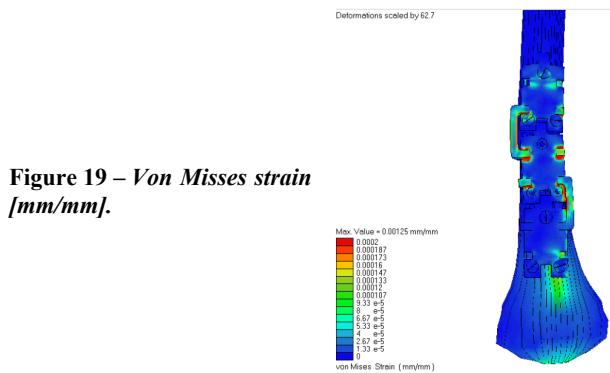
**Figure 16 – Von Misses stresses diagram [Pa] in two consecutive moments.**



**Figure 17 – The fractured tibia and modular plate.**



**Figure 19 – Von Misses strain [mm/mm].**



bone and of the modular plates. Using computed tomography (CT) images to provide three-dimensional geometric details and SolidWorks – a Computer Aided Design software package, we have obtained the three dimensional virtual models of the tibia bone and of the modular plates. Then, the finite element models of the tibia bone and of the modular plate are generated. For numerical simulation we used VisualNastran software. We have obtained displacements diagram, von Misses strain diagram, von Misses stress diagram for the modular plate and for the fractured tibia and modular plate ensemble.

Using the Rapid Prototyping 3D Zcorp 310 Printer system, we have obtained the prototype for the human tibia bone and for the plate modules, necessary for ulterior *in vitro* simulations.

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