ORIGINAL PAPER

Modular adaptive bone plate for humerus bone osteosynthesis

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Abstract

The present paper describes a bionics application of shape memory alloy in construction of orthopedic implant. The main idea of this paper is related to design modular adaptive implants for fractured bones. In order to target the efficiency of medical treatment, the implant has to protect the fractured bone, for the healing period, undertaking much as is possible from the daily usual load of the healthy bones. The adaptability of this design is related to medical possibility of the doctor to made the implant to correspond to patient specifically anatomy. Using a CT-realistic numerical humerus bone model, the mechanical simulation of the osteosyntesis process for humerus bone using staples made out of Nitinol. The stress and displacements diagrams for bone, for plate modules and for staples, are presented.

Keywords: osteosyntesis, modularity, implants, numerical simulation.

Introduction

Applications of Shape Memory Alloys (SMA) 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 [1–4].

Different applications exploit remarkable properties of Nitinol like: biocompatibility, superelasticity, force hysteresis, the shape memory effect (one-way or two-way), the steerability, torquability, less sensitivity to magnetic resonance imaging, excellent corrosion resistance [5–8].

The shape memory alloys possess the ability to undergo shape change at low temperature and retain this deformation until they are heated, at which point they return to their original shape.

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 sturdy internal devices, usually made of metal, that mount directly to the bone adjacent the fracture.

To use a bone plate to repair a discontinuity of a bone, a surgeon typically:

(1) selects an appropriate plate,

(2) reduces the discontinuity (e.g., sets the fracture),

(3) fastens the plate to bone portions disposed on opposite sides of the discontinuity using suitable fasteners, such as screws and/or wires, so that the bone portions are fixed in position.

Modular adaptive implant

Studies and experiments done during this step have been focused on identifying and functionally analyzing modular implant structures. The hypotheses that were formulated at the end of the studies revolved around the theme of implants in direct contact with traumatized bones or bones that had undergone physiological corrections.

The restrictions of the researched solutions had to do with biological and implantational compatibility based on minimally invasive techniques. Along these lines, the following central restrictive elements were identified:

The human organism cannot accept foreign bodies, even if they are biocompatible, for a period longer than two months. This period can be extended, but the risks elevate the longer the period. The time necessary for the affected bone to realign and reform is minimum two months.

Minimally invasive surgery leads to a shortening of the period necessary to recover and also lessens the risk of infection. Surgery to introduce classic implants is realized, in the case of minimally invasive interventions, by using portable X-ray devices, which pose a high risk of radiation for the medical staff and for the patient.

Compared to stainless steel, Nitinol has the great advantage that it is compatible with very modern radiological techniques such as MRI, which do not pose radiation risks [7, 8].

The implants that were exposed to the traumatized bony structures, which have been analyzed in this study, had a modular organization, using intelligent materials with shape memory as coupling structures between the support elements [9]. The proposed implant 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.

In this paper, we present a variant of an internal implant, in the case where the implant is used for consolidating a transversal fracture of the humerus [10].

This option underwent experiments with specialized software (SolidWorks, ANSYS, Catia) to determine the way in which these structures react under normal or extreme tensions [10]. The results of the simulation are extremely promising, but physical experiments need to be conducted on bone structures to determine the effects of these implants. For the simulation of the Nitinol elements behavior and for the study of their effects, we have considered only the surface placed in the proximity of the humeral head. The small plates were placed both ways of the longitudinal axis of the bone, proximate under its head, following the curve and dip of the bone surface geometry. The virtual model of the ensemble bone–implant for humerus is presented in Figure 1.

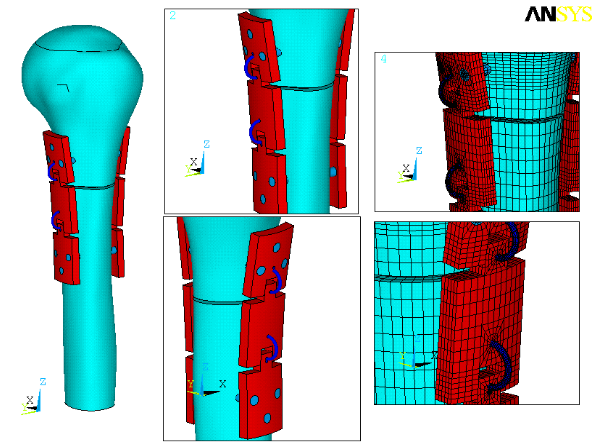

Figure 1 – ***The virtual model of the ensemble bone–implant for humerus.***

There were simulated the screws for fixing the small plates and the bone. The contact between the screw and the plates was simulated with common nodes. On a bone area situated on the intermediate plates' region, the bone was interrupted (on a distance of 1–2 mm), obtaining two bone segments that are about to be joined using the small plates and the Nitinol holding elements.

Between the guiding area of the small plates, there were introduced surface on surface type contact elements. Between the internal areas of the intermediate plates and the bone area that is possible to take contact with the plates contact elements were introduced.

The plates have the dimensions 15×20×3 mm, the whole diameter for the screws being equal with the diameter of the screw, and having 3 mm. The plates are not fixed in a position initially, they can move 2 mm.

The holding elements are having the wire diameter of 1 mm and a "U" form with a 7 mm distance between the two sides.

Used materials

▪ Cortical bone: isotropic, homogenous, E=17000 MPa, Poisson's coefficient = 0.3;

▪ Spongious bone: isotropic, homogenous E=1800 MPa, Poisson's coefficient = 0.2;

▪ Plates: isotropic, homogenous (Titanium);

▪ Fixing screws: isotropic, homogenous (Titanium);

▪ The holding elements: Nitinol – simulated material in ANSYS using the material model "shape memory alloy" especially realized for the NiTi alloy simulation of Nitinol-type.

The presence of the contact elements and of the superelastic material (Nitinol) are transforming the structure equation system into a non-linear system, being necessary a resolution using the Newton–Raphson iterative method for reaching the system convergence.

To highlight the use of Nitinol material for the holding elements it is necessary to fallow three steps. To review all the steps, the two bone segments have been embedded in the extreme end.

Step 1

In this step, the upper and lower plates are fixed with screws on the bone. It simulates the mounting of head off for holding elements on the fixed plates on the bone, the holding elements having the other head already mounted in the middle plates (common nodes). In this step, the temperature of all the elements and of the holding elements is 23^{0}C – the room temperature. Because of these movements imposed, the middle plates are moving because of tensions created by the holding elements (Nitinol), representing the simulation of a pretension for Nitinol elements. We are obtained the map of resultant displacements in plate modules (Figure 2), in Nitinol staples (Figure 3), in humerus (Figure 4) and the map of von Mises stress in Nitinol staples (Figure 5) and in plate modules (Figure 6).

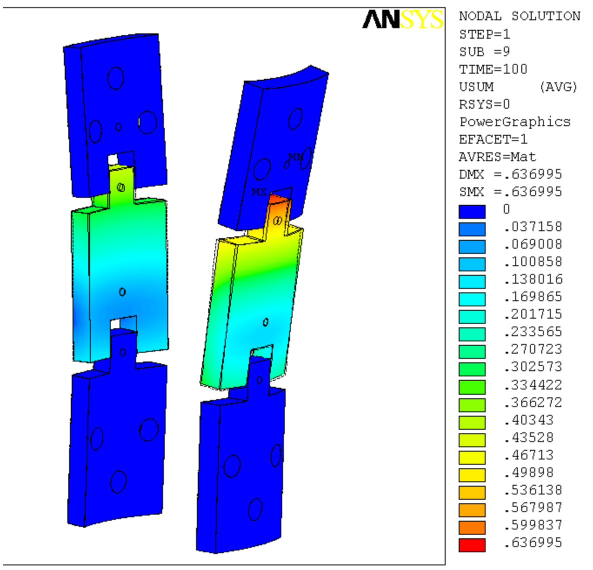

Figure 2 – ***Resultant displacements in plate modules [mm].***

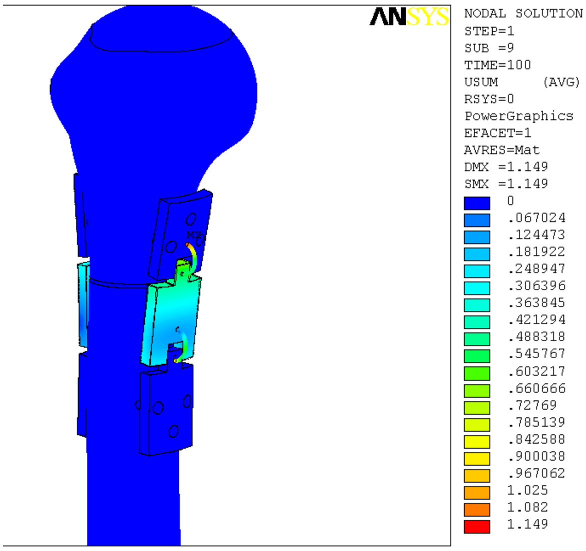

Figure 3 – ***Resultant displacements [mm] in Nitinol staples.***

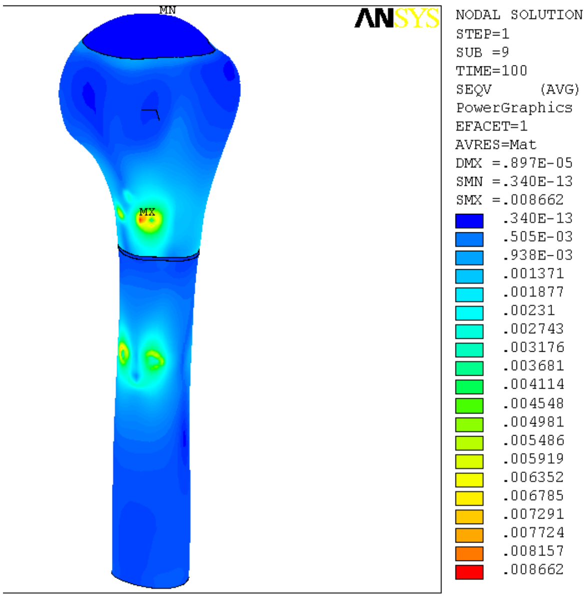

Figure 4 – ***Resultant displacements [mm] in humerus.***

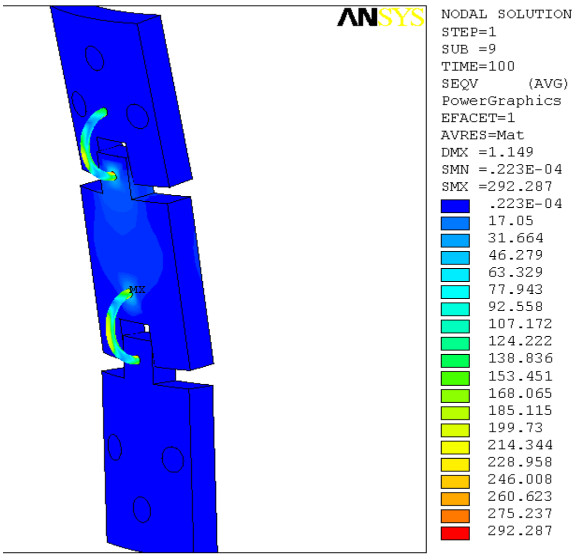

Figure 5 – ***Von Mises stress [MPa] in Nitinol staples.***

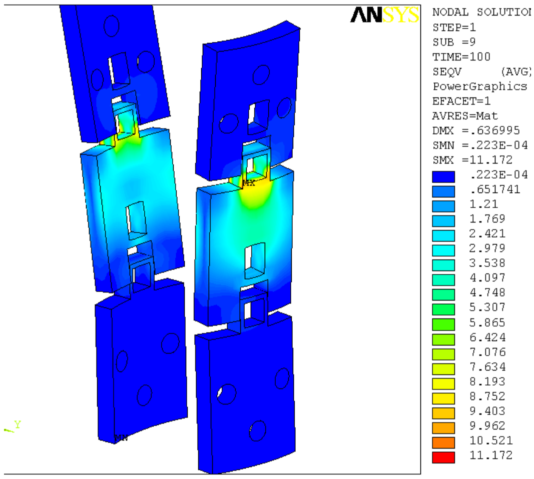

Figure 6 – ***Von Mises stress [MPa] in plates.***

Step 2

In this step, the ends of the Nitinol elements are considered mounted in plates, considering the pretension of Step 1, eliminating imposed movements, realizing the state of tension for mounting the prosthesis. The temperature in this case is considered 23^{0}C – the room temperature. For this step are important the reaction forces that are acting in the rigid fixing area of the bone.

The map of von Mises stress in Nitinol staples (Figure 7) and in plate modules (Figure 8) are presented.

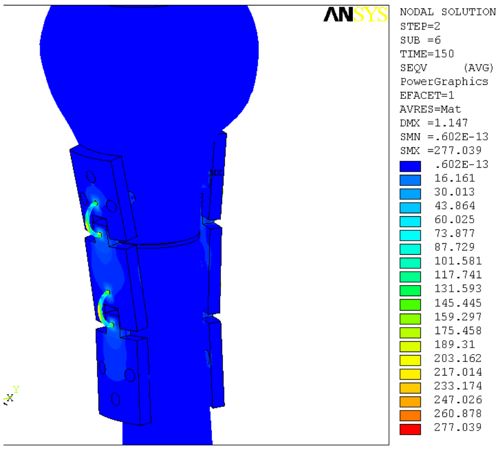

Figure 7 – ***Von Mises stress [MPa] in Nitinol staples.***

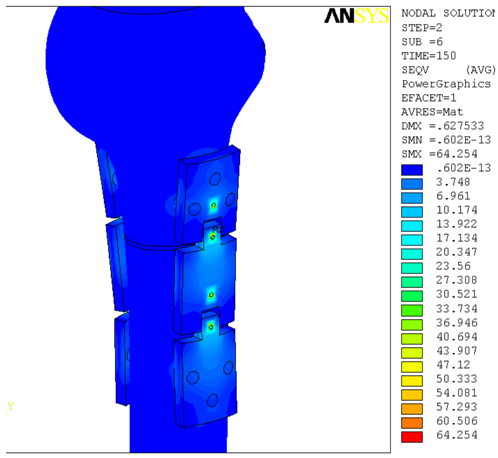

Figure 8 – ***Von Mises stress [MPa] in plate modules.***

Step 3

Starting from the final state of tension obtained in step 2 we are simulating the increase of temperature for holding elements from room temperature to body temperature 36.5^{0}C. In this step, we are showing the state of tension in bone-implant ensemble (Figure 9), resultant displacements in plate modules (Figure 10), resultant displacements in humerus (Figure 11), Von Mises stress in Nitinol staples (Figure 12), in plate modules (Figure 13), and in humerus (Figure 14).

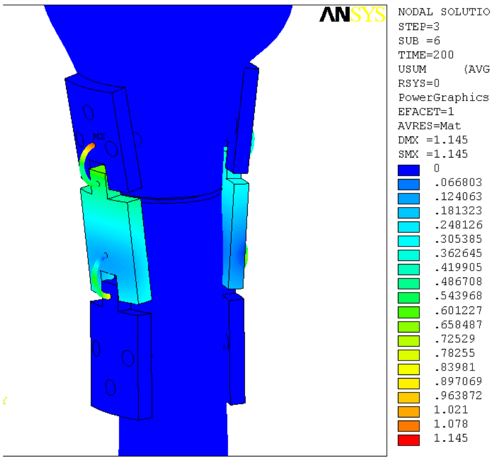

Figure 9 – ***Von Mises stress [MPa] in bone-implant ensemble.***

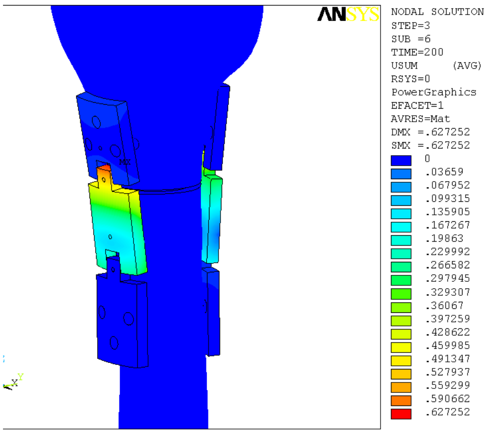

Figure 10 – ***Resultant displacements [mm] in plate modules.***

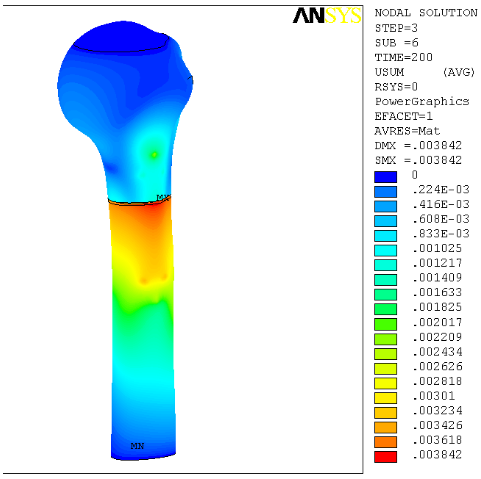

Figure 11 – ***Resultant displacements [mm] in humerus.***

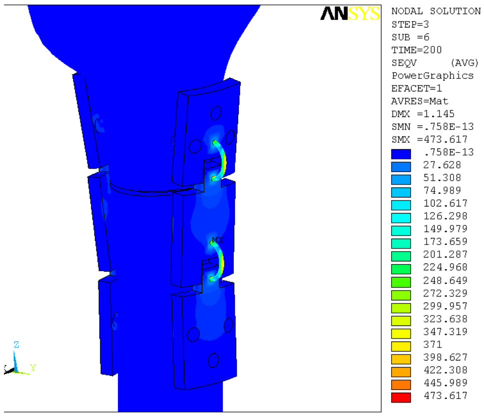

Figure 12 – ***Von Mises stress [MPa] in Nitinol staples.***

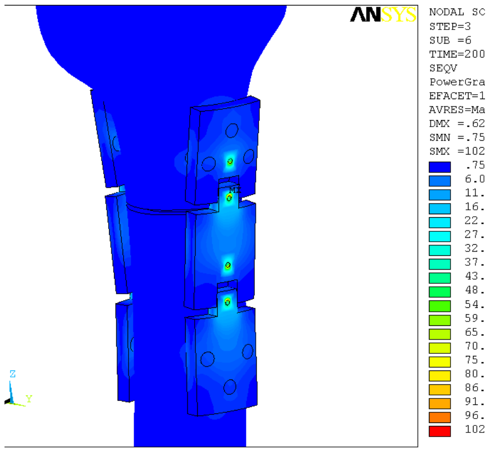

Figure 13 – ***Von Mises stress [MPa] in plate modules.***

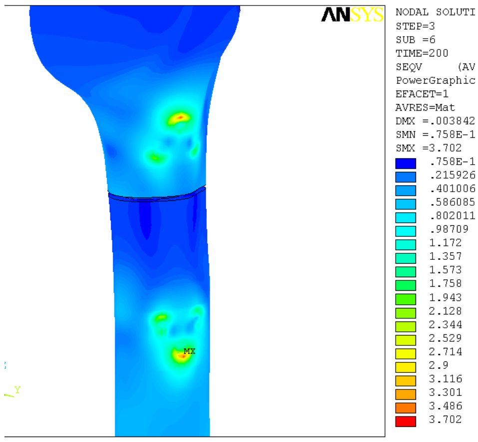

Figure 14 – ***Von Mises stress [MPa] in humerus.***

The use of modern structures involves a chain of special characteristics that has to be considered in projected systems case.

Intelligent coupling and catching system in internal implants for the proposed internal implant was conceived as having coupling elements the type of Nitinol clamps. Extracting them will realize easily by heating them. Channels on the modular plates have a little slope, which favors clamp slipping when heating for rapid extraction.

Tests carried out on Nitinol were aimed at identifying its compatibility with the required heat regime imposed by the sterilization process, along with energizing/modular decoupling issues.

The force developed by a sheet, a wire or a spring depends linear in respect with shear modulus. **S**hape **M**emory **A**lloys depend very much of temperature. The shear modulus increases at high temperature. Therefore, the variation of the shear modulus leads to the variation of the force developed by the device made out of SMA or by the device, which has in its structure elements made out of SMA.

The martensitic temperature and the austenitic temperature are very important in the designing of the intelligent structures because their variation determines the increasing or the decreasing of the shear modulus and the reaction of the devices based on SMA. For a correct implementation of the modular structure based on SMA, elements made out of SMA, type sheet, wire and spring, were studied. The used method was **T**hermal **A**nalysis **M**ethods. The used techniques were **T**hermo **G**ravimetric **A**nalysis, **D**ifferential **T**hermal **A**nalysis and **D**ifferential **S**canning **C**alorimetry [11, 12].

The transformations of SMA sheet

The first experiment was a simulation of the sterilization of shape memory alloys, and it was identified a few of changes which could improve or not the biocompatible properties [11, 12]. We can observe the TG graphic is almost constant (Figure 15).

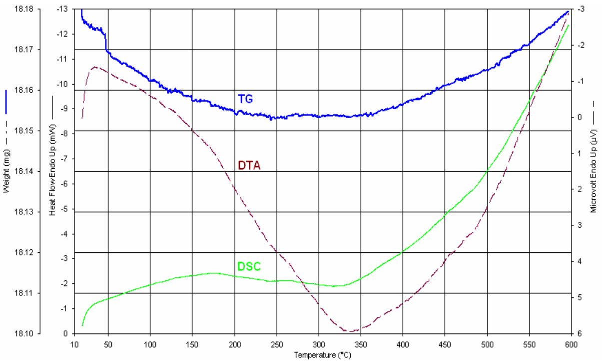

Figure 15 – ***The experimental graphics obtained for the heating of SMA at maximum temperature of 600^{0}C.***

The second experiment (Figure 16) had the following evolution: the increasing of temperature from 30^{0}C to 160^{0}C with the speed 5^{0}C/min.; the keeping of this temperature for 10 minutes; the decreasing of the temperature from 160^{0}C to 20^{0}C with 5^{0}C/min.

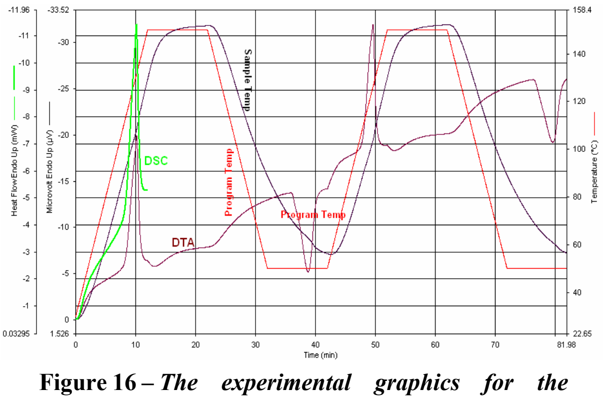

Figure 16 – ***The experimental graphics for the second experiment.***

To identify optimal constructive solutions, energy/ decoupling solutions were analyzed for each proposed implants. Minimal invasive technique allowed by these types of implant, include the use of incisions that give the space necessary to incorporate/extracting all the plates. If, in most cases, the introduction of these plates is relatively easy, most of the fractures being open, their extraction issue after the bone healing process, requires, in a classic case, a new small incision, the size of implant and plate extraction. Major problem of this type of intervention is the need of incisions at both ends of the plate to remove the grip screws. Use of Nitinol clamps for plate coupling is not the best solution because the extraction of these clamps must be performed, however, an incision. A first solution was to use some of Nitinol clamps to grip the extremities of the plates.

Conclusions

The holding force created by the Nitinol elements is less if the area where the plates are mounted has an irregular geometry. The use of Nitinol elements makes contact pressure between the two bone segments to grow by 58%.

The maximum tensions from the screws' area are less than 4 MPa, which does not affect changes in bone structure, the bone in this area managing much higher tensions (50 MPa).

The maximum tensions in Nitinol elements are 473 MPa to humerus, values that are in the area of elastic material (between 400 and 500 MPa).

The maximum tensions on the small plates are 100 MPa, values below the limit of proportionality.

The maximum tensions on the fixing screws are 23 MPa, values below the limit of proportionality.

If the bone has a more complex geometry, the holding elements generate the offsetting forces of the two bone segments, because of the impossibility of fixing the two symmetrical rows of small plates. To remove the offsetting forces of the two bone segments there have to be investigated other forms or types of small plates.

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