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The mechanical properties of NiTi and biocompatibility implants in bone of albino rats

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Abstract

Study the mechanical properties of the shape memory alloy NiTi usability within the human body due to the importance of the cultivation of these substances inside the human body. To test the biocompatibility of designed NiTi alloy, a simple experiment was used. NiTi wire of specific diameter and length was inserted in the marrow of a fractured bone of rat. The implant site consists mainly of marrow tissue with a little of cortical layer of the bone. The fracture bone region shows good healing at 4 weeks of implantation and completed at 8 weeks of implantation.

Keywords: Shape memory alloy, NiTi, Biocompatibility, Femoral bone, Albino rat.

Introduction

NiTi alloys are important materials for biomedical and dental devices because of their unique properties and comparatively high corrosion resistance and good biocompatibility. Recently NiTi has been used in endovascular stents to provide a self-expanding mechanical superstructure that's collapsed into a catheter and transported in compact form for more precise and less invasive implantation (Lizhen *et al*., 2002).The growth of the use of NiTi in the medical industries has exploded over the past 10 years. Patients and care-providers have encouraged the transition from traditional open-surgical procedures that require long hospital stays to less-invasive techniques. Which are often performed in outpatient facilities (Pelton and Miyazaki, 2000).This demand for minimally invasive procedures has required novel instrumentation and implants to be designed by engineers and physicians (Stockel, 2000; Frank *et al*., 2000). NiTi wire has unique properties, thermal shape memory, super elasticity and good damping properties using its thermal shape memory property, a material sensing a change in external temperature are able to convert to a preprogrammed shape. This unique macroscopic behavior has attracted an increasing scientific and commercial interest since it can be exploited in innovative applications, ranging from orthodontic wires for correction of the tooth malposition (orthodontic appliances) to micro-structures used in the treatment of blood-vessel occlusions (stents) (Bogdanski *et al*., 2002; Huang and Liu, 2001). The biocompatibility is normally evaluated by experimental implantation the material coupons in the soft tissue (subcutaneously in the muscle) or in the bone (Fleming. and Feinberg, 1976).

There are two main factors that play a role in the biocompatibility of a material: the host reactions induced by the material and the degradation of the material in the body environment (Ryhanen, 1999). With the development of the new medical diagnostic and therapeutic devices, biomaterials with especial properties were needed. For example materials to be used as a catheter should have high elasticity to bend on applying stress on direction and at the time it should have high recoiling properties to return to straight shape on removing stress. Another example is the material that is used as an instrument for removal of stone from visceral organs; these substances should change their shape according to changing the temperatures. The unique properties of NiTi have promising applications in such medical field (Li *et al*., 2001; Lee and Lee, 2000). These applications have included everything from surgical tools to permanent implants, including implants within the blood stream. In this work we are investigating the biocompatibility of NiTi should be evaluated by using the wire as an implant.

Materials and Methods

We studied the application of shape memory alloy (SMA) on orthopedics and for the purpose of understanding the properties of NiTi alloy which is a type of SMA we studied its application as a splint in bone fracture. The tensile test used to determine the mechanical properties of engineering material. It is very useful and important for designing and forming of metal. Uniaxial tensile load is applied slowly by gripping the end of the specimen in tensile test machine where the specimen elongates in the same directions the applied load. The hydraulics pressure developed is directly proportional to the load, and registered through a bourdon–tube gage to a dial graduated to indicate the load in kilo newton.

Chart recorder plots the load as ordinate and the deformation as abscissa in the form of a graph. This graph can be changed into approximate stress-strain diagram.

Nominal stress is defined as the applied load divided by the original cross- sectional area (A°).

Nominal stress $\sigma = F / Ao$

Nominal strain is defined as total elongation divided by the original length (Lo).

Nominal strain $\varepsilon = (L\text{-}Lo)/L° = \text{-}\delta/\ Lo$

δ = total elongation.

L° = original gauge length.

Taking in commotion the biological reaction against its implantation. Four rats were included in this study the femoral bone was chosen because its diameter can adapt the width of the NiTi nail. All operation were done under general anesthesia using (Lignocaine) in a dose of (1mg/kg) and maintenance of anesthesia using inhaled ether. The operation was done under strict sterilized condition. After shaving and sterilizing the rat thigh using alcohol and iodine, we made (2.3 cm) longitudinal incision on the lateral surface of the thigh. The rat femoral bone was exposed by separating muscles at the area. Periosteal stripping was done using a periosteal elevator. Mid shaft osteotomy was done using bone cutter Retrograde introduction of NiTi nail through the osteotomy site and then reduction of the fracture was done and antigrade hammering of the nail to the distal segment. Closure of surgical wound was done in layers. X-rays were done for the nail in the shaft of femoral bone after the operation (Figure 1). Antibiotics (Keflin) were used in the drinking water of the animal for 3 days to prevent post-operative infection. 2 rats were examined after 4 weeks and the other 2 were examined after 8 weeks. The examination and the results rely on:

I- Clinical examination that include absent of movement at fracture site of the animal.

II-Histological examination of the bone reaction against the implants.

In histological examination, the animals were scarified by sinking, then the femur was exposed and biopsies from the bodies were taken, healing here assessed. Then histological sectioning of femur at site of osteotomy and the marrow were done.

Figure (1): X-ray for the nail of femoral bone.

Results and Discussion

One important characteristic of shape memory alloys (SMAs) is their superelastic property. NiTi polycrystalline with their unique biocompatibity and super elasticity has been successfully used to manufacture medical devices in recent years. Therefore, comprehensive biocompatibility studies are important before clinical use. A lot of research has been done previously to determine the Biocompatibility of NiTi in different tissues (Kapanen *et al*., 2002; Ryhanen *et al*., 1999; Assad *et al*., 1999). One of the most dramatically demonstrated examples is the utility of NiTi superplastic. High flexibility, large recoverable deformation, good fatigue life and outstanding superelastic behavior at or around the body temperature are qualities the superelastic NiTi alloy help to reduce and minimize the size of critical medical devices and to perform functions not possible with other materials. Polycrystalline Ni50Ti50 wire with diameters 0.7mm has been used in the present test. The experiment is conducted at room temperature 35 C^o in air.

Figure (2) Shows a typical measured nominal stress– strain curve of the NiTi wire under tension. At the beginning, the austenite exhibits linear elastic deformation. The maximum elastic strain is about 1 %. Once the stress reaches a critical value (at σ = 398.08 MPa) the martensite starts (Ms) to form in the middle portion of the wire. The elongation of the wire during the loading is realized by the growth of the nucleated martensite. The transformation strain inside the wire has been in uniform with the axial strain of 4.2% which is represents the martensite finish (Mf). After the whole length of the specimen transformation into martensitic, the stress starts to increase with the further elastic deformation of martensite.

During unloading the austenite phase propagated from the two ends of the wire towards the center as we see it starts (As) at stress σ= 790.1 MPa and finished (Af) at stress σ =79 MPa with a residual strain of ε =0.6%.

To test the biocompatibility of designed NiTi alloy a simple experiment was used. In this experiment, NiTi wire of specific diameter and length was inserted in the marrow of a fractured bone.

The operative procedure tries to simulate an internal fixation of a comminuted fracture. The implant site consists mainly of marrow tissue with a little of cortical layer of the bone. The fracture bone region shows good healing at 4 weeks of implantation and completed at 8 weeks of implantation.

At 4 weeks the bone was still immature with a large osteoblast lacunae (Figure 3) although the formation of osteoblast and lamellation of the bone trabeculae was observed. The trabeculae reach the implant surface were appear to follow the shape of the nail surface.

At this period the number of osteoblast cells at the implant surface was low. The repair of the marrow tissue was almost complete without a sign of inflammation or rejection, or major tissue reaction. At 8 weeks after implantation there was good remodeling of cortical bone with a formation of trabeculated bone alongside the fracture region.

This newly formed bone had a dense rather than tabular appearance (Figure 4). However it was still possible to distinguish between the original bone and the newly formed due to interrupted lamella (Figure 5). In the region of bone marrow, normal marrow with blood cells containing sinusoid fat cell and reticular connective tissue occupied great part of the thread. Most often a fibrous capsule had formed between normal marrow and implant surface, multinuclear giant cells were the most common cell type seen in the direct contact with the implant surface, also there are osteoclast, fibrous capsule present. Our results are agreement with (Sauli *et al*., 2004). who suggest NiTi suture material with good biocompatibility in tendon tissue and better strength properties than those of the conventional materials used in tendon surgery.

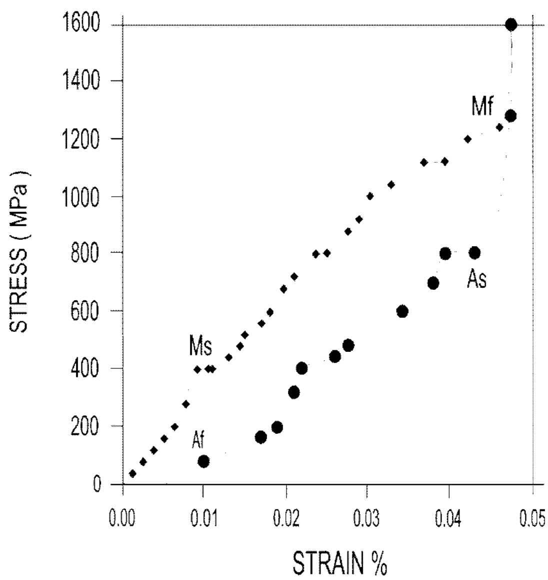


Figure (2): Stress –strain curve of Ni50Ti50 wire (loading /unloading)

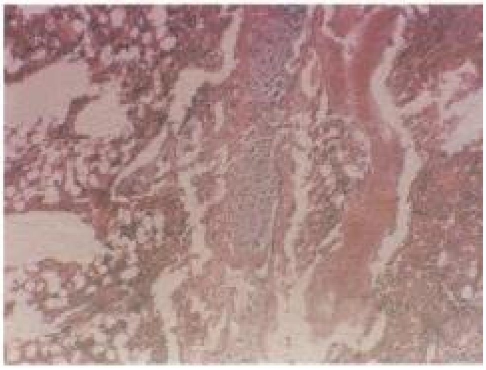
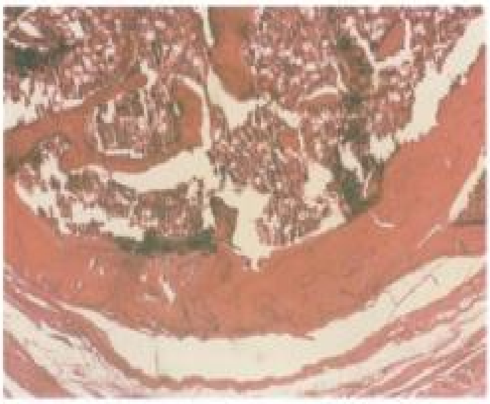


Figure (3): New bones formation (osteoid tissue), Bone trabecule and Adipos tissue (H&E,X100).



Figure(4) : Bone fibrous connective tissue and granulation tissue.(H&E,X200).

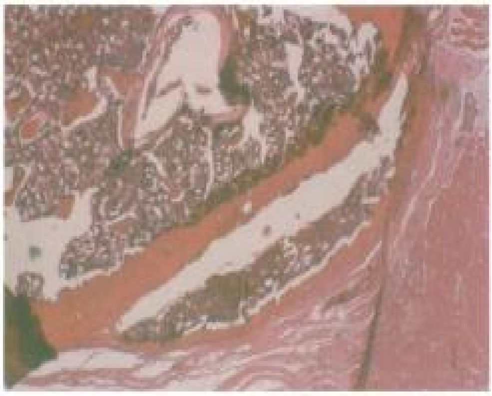


Figure (5): Bone fibrous connective tissue, granulation tissue.(H&E,X100).

Conclusion

From the data of the present work, it can be concluded that: The tension tests at constant temperature with a fixed length were carried out on NiTi wire. The stress vs. strain relation of the NiTi that we have tested in tension can be divided into three regimes. The first regime is mainly elastic deformation. The second regime involves a phase transformation. The third regime which corresponds mainly to the martensitic is re – orientation. By choosing the best ratio which is NiTi we found it successful in medical application by implantation in bone for 4 – 8 weeks without side effects.

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