Experimental Analysis of Orthopedic Staple Pin made by Nickel Titanium Alloy

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Abstract - *A Shape Memory alloy can be deform when cold but return to its deform when cold but return to its preformed shape when heated. Shape memory alloy is one of the most preferred suitable materials for manufacturing orthopedic staple, medical devices and tools because of its unique super elasticity properties. The existing materials used in orthopedic staples would not completely satisfy the biomedical requirement like light weight, anticorrosion properties ability to not harmful to human tissue etc. Hence this work attempts to develop an orthopedic staple pin made by nickel titanium shape memory alloy for addressing the existing drawback of conventional orthopedic staple pin. The selection nickel titanium shape memory alloy (Nitinol) has elastic modulus properties which are very close to the human close to the human bone than any other materials. It has a superior property is great elasticity and returns back to its original shape. For ensuring the human safety, a static potentio corrosion test was performed on the chosen nitinol. The result revealed that the selected material is suitable for making the orthopedic staple pin.*

Key Words: Shape Memory Alloy, Orthopedic staple pin, Nickel titanium, Corrosion test.

1. Introduction

Shape memory alloy can be deformed when cold but returns to its pre deformed shape when it is heated. It may also be called memory metal, memory alloy, Smart metal, smart alloy or muscle wire. Material that is capable of regaining and with standing large strain tracking inflexible plastic deformation and remember the last configuration to retain the principle shape with varying temperature a class of shape alloy or muscle wire. Material that is capable of regaining and with standing large strain lacking inflexible plastics deformation and remember the last configuration to reclaim the principle shape with varying temperature are a class of smart material specified shape memory alloy. Nickel-titanium has been approved as a metal biomaterial used in medical implants and devices. Shape memory alloy are widespread is such application as an orthodontic wire staple for osteosynthesis stents endodontic and mechanical properties high corrosion resistance and biocompatibility.

1.1. Orthopedic staples

Orthopedic bone staples are similar in shape to the staple in the staple that sits on a disk, bone staples are made of surgical grade stainless steel or titanium and they are thickness, stronger and larger. After a bone is surgically cut, one or more staples may be applied to the bone to keep the bone segment in the corrected position. Bone staples can also be used to attract tendons or ligaments to the bone for reconstruction surgery. A bone staple called the Blount staple can be inserted so that it straddles a growth plate placing a staples so that it straddles only one side of the growth plate can correct the alignment of a bone called guided growth or hemiopia physiodesis placing staples so that they straddle both side of the growth plates can stop a bone from growing longer called growth plate fusion or epiphysiodesis.

2. Nickel titanium rod

Nitinol alloys exhibit two closely related and unique properties the shape memory effect super elasticity (also called pseudo elasticity) shape memory is the ability of nitinol to undergo deformation at one temperature, stay in its deformed shape when the external force is removed, and its original temperature. Super elasticity is the ability for the metal to undergo large deformation and immediately return to its undeformed shape upon and removal of the external load. Nitinal can deform 10-30 times as much as ordinary metal and return to its original shape. Whether nitinol behaves with the shape memory effect or elasticity depends on whether it is above the transformation temperature of the specific alloy. Below the transformation temperature of the specific alloy. Below the transformation temperature it exhibits the shape memory effect and above that temperature it behaves super elastically.

3. Room temperature super elastics (Se).

In this form of Nitinol bone staple, the austenite finish (Af) transformation temperature is near or less then room temperature and the staple must be held open by some type of device prior to deployment. This type of staple will attempt to spring closed at any temperature is near or less than room temperature as soon as the constraint is removed.

4. Body temperature activated (Bt).

This types of nitinol staple has an Af temperature. Shape recovery is triggered by the thermal shape memory effect as the staple reaches body temperature. It is important to maintain the temperature during insertion to prevent premature deployment. This can be accomplished through a combination of external cooling and sufficiently rapid insertion.

5. Heat activated (Ha)

This category of Nitinol Staple has an austenite start (As) temperature near or slight above body temperature but with an (Af) temperature near or slight above body temperature but with an Af temperature near low enough to allow deployment 60°C is generally recognized as the temperature at which tissue damage can occur so the activation temperature for the staple must ideally be kept below this temperature. This type of staple can be activation in one of two way by simple application of a heating element such as a cautery device or by using a specially designed external heat source the allows the amount and duration of the applied heat to be precisely controlled depending upon the degree of shape recovery desired. The better type of staple will be referred to in subsequent discussion as controlled heat activated. Staple of all three type are commercially available. A list of some of the commercially available nitinol bone staple, along with their type of deployment mechanism.

6. Types of nitinol bone staple

With a typical Nitinol bone staple, holes are predrilled, an open nitinol staple is inserted into the holes, and the staple recovers either super elastically or via shape memory to pull the fractured bone together and apply a compressive force to the fracture surface. Different staple designers and manufacturer have executed this basic approach in a number of different ways.

6.1 Blount Staples

The Blount staples are available in 1.5mm to 5mm diameter and width ranging from 15mm to 25mm, these staples are useful for the temporary arrest of growth in order to correct a deformity or equality of length. The implant combines the technical advantages of the traditionally used rigid Blount staples, which may be a biomechanical advantages in temporary epiphysiodesis and has an easy and guided implantation technique like the eight plate. As in eight plates supposedly only two rigid tacks are sufficient for temporary epiphysiodesis compared to six Blount – staples in traditional treatment.

6.2 Conventry Staples

The Coventry staples are available in 5mm to 15mm steps (increments of 5mm). They are utilized in tibia osteotomies to correct varus or valgus deformities resulting from conditions like rheumatoid arthritis, trauma or osteoarthritis. Coventry Staple is used for correcting angular deformity at the knee. Two or more Coventry Staple should be used on each side of the epiphysis. Our Coventry Staples are made from the finest quality medical grade material to ensure the highest quality.

6.3 Thorny Staples

The thorny staples are utilized for fixation of soft tissue to bone-like in bony avulsions or tibia fixation in bone reconstruction. They have serrations for the hold of soft tissue. The thorny staple is used for fastening small bones, epiphyseal metaphysical area of the long bones, and fixation in collateral ligaments of knee/elbow.

7. Nitinol staples fit in the traditional fracture

Minimax fracture fixation was popularized by the influential Bernhard. SMA staple constructs are an extrapolation of his minimax fracture fixation concept. Small problem focused implants used to do specific job that are then supported by a more robust fracture neutralization construct such as plate metrology based implant or external fixation frame.

Shape memory alloy staple are most useful in appendicular skeleton fracture pattern that are not reality amenable to conventional interfragmentary compression technique such as leg screw compression plate osteosynthesis or the usage of an articulates tensioning device or some variation there of comparison plate osteosynthesis can be challenging and time consuming to execute correctly and is dependent on a perfect plate contour and on adequate bone stock to generate sufficient friction between the plate and bone.

8. Fabrication of orthopedic staple pin shape memory alloy

The ratio of titanium to nickel in the Ni–Ti alloy has a significant influence on transformation temperature. The change in transformation temperature according to nickel composition.1 a 0.1% change in nickel composition results in a 10° C change in the transformation temperature. In commercial production, analysis for chemical composition is often done in situ or on a button sample. However, in the case of Ti–Ni alloys, it is difficult to evaluate whether the composition is correct or not by analyzing chemical composition, because melting and casting of Ni–Ti alloy is performed under vacuum, and also because a small change in nickel and titanium content causes a large change in transformation temperature. For these reasons, Ti–Ni alloy composition is commonly evaluated using differential scanning calorimetric (DSC). To measure the nickel and titanium content using DSC, it is important that the sample has been annealed in a vacuum or inactive gas (specified by the heat treatment method defined by ASTM, JIS, etc.), and has been protected from processing distortion or oxidization. A typical DSC curve for a shape memory alloy. DSC measures endothermic and exothermic reactions at phase changes.

In order to control the transformation temperature and mechanical properties of a Ti–Ni alloy, it is common to add a third element. The element added most commonly is copper, because it can be in a solid solution with Ti-Ni alloy at a Cu content of 30% or more. Ni-Ti–Cu alloy is used as an actuator, which utilizes the shape memory characteristic. Other elements such as Fe, Cr, Co, and Pd, can also be added to Ti-Ni alloys and almost all the additions lower the transformation temperature or improve formability.3 However, additional elements are not permitted in Ti-Ni alloys used for medical devices, under specification ASTM F2063-05.

The cutting method is based on similar principles to those in the hole-drilling method. Once more, stress is relaxed by the removal of material. This time a notch is removed from a specimen, resulting in the creation of a free edge. Nickel-titanium rod of 210mm length is cut with help of hand cutting machine. Use safety gloves while machining the rod.

A bench grinder is a similar or larger version of grinder that is mounted on a pedestal, which may be bolted to the floor or may sit on rubber feet. These types of grinders are commonly used to hand grind various cutting tools and perform other rough grinding. After cutting of nickel titanium rod, the rod is grinded with the help bench grinding machine.

While the exact mechanics vary depending on the type of machine press, most machine presses work by pressing a plate or die onto or against a work piece. Using hydraulic pressure, the machine press pushes the plate or die against the surface of the work piece, which causes the work piece's shape to deform. After grinding the rod the bend with the help of bending machine the rod bended as Blount staples.

The fig 8 is the prototype of Blount type orthopedic staple pin which can be used for medical implantation and fracture fixation for human injuries.

Fig 8. Fabricated orthopedic staple pin.

9. Experimental analysis

Corrosion testing refers to the processes conducted by laboratories in order to solve, prevent or mitigate problems related to corrosion. These processes can be applied in industrial materials and infrastructure products, and are often used in failure analysis.

All corrosion laboratories are composed of expert failure analysts, chemists and engineers that are all certified in corrosion testing. Such tests can provide useful information in order to make sound decisions regarding the selection of materials, processing, and treatment

10. Static corrosion test

Corrosion testing is a laboratory simulation of a corrosive saline environment. It is used as an accelerated means of testing the ability of surface coatings to withstand atmospheric corrosion. Also known as salt fog testing, it is one of the oldest testing methods used in the HVAC-R coatings industry, and for this reason, is often referred to when selecting HVAC-R coatings.

First, small panels (typically 3×5 inches or 4×6 inches) are prepared with the coating to be tested. The edges and the backs of the panels are protected, typically with tape. Then the front of the panel is "scribed" with a sharp tool to produce a scratch through the coating to the metal substrate. After the panel is prepared, it is placed inside the test cabinet. The cabinet contains racks to hold the panels in position as specified by ASTM B-117 – tilted back 15 to 30 degrees from the vertical.

The cabinet is then closed, and a 5% salt solution is delivered at a constant rate and temperature into the cabinet through an atomizer. Salt fog is sprayed upwards so that droplets will descend and settle on the panels

After this point, there will be periodic checks of the test panels, as well as monitoring of the salt spray cabinet to ensure that it functions properly throughout the duration of the test. During these brief evaluations of the panels, it is determined whether the test is progressing as expected or if the coating on the test panels is failing prematurely

Although each laboratory has a slightly different set up, the basics of the test are as described above. Weiss Umwelttechnik is fortunate to have a cabinet with a digital readout displaying the total hours of test cabinet operation, as well as alarms that will 19 notify us about a variety of important things, such as if the salt solution level becomes low. These features are important because some salt spray tests run for extremely long times. For example, Weiss Umwelttechnik P-413 was tested against ASTM B-117 for 6,000+ hours. That's 250 straight days (or a little over 8 months) of continuous salt spray.

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11. Results and discussion

The machined nickel-titanium rod subject to corrosion test analysis. The extent of corrosion on the nickel-titanium rod is below that there is no corrosion formation in nickel-titanium rod. The intended purpose of subjecting the panels to corrosion analysis is to check the corrosion resistance property. The nickel-titanium rod was analyzed for its corrosion resistance after 24 hrs. There is no sign of corrosion observation in the sample.

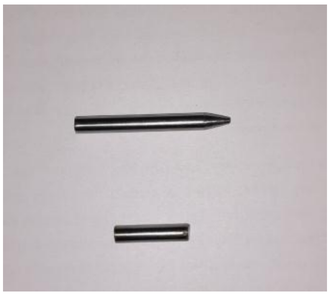

Fig 11. After corrosion test

11.1 Test report

Table 11.1 corrosion test report for samples

CORROSION TEST REPORT FOR SAMPLE – I	
Type of test	Corrosion test
Type of salt / water	Nacl (lr grade) / dm water (type - iv)
Chamber temperature	35.0° ± 2.0°c
Salt solution (concentration / specific gravitatiy)	5% Nacl method / 1.02 – 1.04 g/cm³
Ph VALUE / COLLECTION DEVICE	6.5 to 7.2
Air pressure	0.7 to 1.4 bar
Position of specimen	15° to 30° Angle
Rate of collection of solution	1 to 2 ml/hr
Method of cleaning	Tap water
Method of handling	Plastic tray
Interval of inspection time	Once in 24 hours
Requirement of test duration	24 hours
Sample receipt condition	Good
Temperature & humidity	30 ± 5°c, < 75% RH
CORROSION TEST REPORT FOR SAMPLE - II	
Type of test	Corrosion test
Type of salt / water	Nacl (lr grade) / dm water (type - iv)
Chamber temperature	35.0° ± 2.0°c
Salt solution (concentration / specific gravitatiy)	5% Nacl method / 1.02 – 1.04 g/cm³
Ph. VALUE / COLLECTION DEVICE	6.5 to 7.2
Air pressure	0.7 to 1.4 bar
Position of specimen	15° to 30° Angle
Rate of collection of solution	1 to 2 ml/hr.
Method of cleaning	Tap water
Method of handling	Plastic tray
Interval of inspection time	Once in 24 hours
Requirement of test duration	24 hours
Sample receipt condition	Good
Temperature & humidity	30 ± 5°c, < 75% RH

11.2. Observation

Table 11.2. Corrosion observation report for samples

Time	Observation I
At 0 hrs.	Component placed in the chamber. Test started
At 24 hrs.	No sign of corrosion observed over the sample
Time	**Observation II**
At 0 hrs.	Component placed in the chamber. Test started
At 24 hrs.	No sign of corrosion observed over the sample

12. Conclusion

The result indicates that the nickel-titanium rod was excellent, indicated by the observation that it could have corrosion resistance and wear resistance. There is no corrosion formation in the nickel-titanium rod after the corrosion test. The corrosion test confirms the capability of the nickel-titanium rod is suitable for making the orthopedic staple pin.

Based on the pin on disc wear test results of nickel titanium rod, it can be used for the application of orthopedic implantation process that Nickel titanium rod is have highly wear resistance. The implantation process increase the hardness shape memory alloy. There is no practical undesirable effect was perceived on the instruments in nickel titanium rod.

In addition that it is planned to conduct a cytotoxicity test for getting more assurance of human safety without causing any internal injuries.

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