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Design Considerations for Nitinol Bone Staples

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The use of Nitinol in orthopedic staples has a long, successful history beginning with their first commercial introduction in the early 1980s. Nitinol bone staples are generally inserted through a process of being chilled, opened, and inserted into predrilled holes. Upon insertion, they recover their preprogrammed shape either through springing back after removal of a constraint (using superelasticity) or thermal triggering (using thermal shape memory). In general, Nitinol bone staples fall into one of three categories: (1) those which are superelastic at room temperature, (2) those which recover their shape upon heating to body temperature, or (3) those which recover their shape upon heating above body temperature with the application of an external heat source. These three different design approaches—room temperature superelastic, body temperature activated, and heat activated—each have different performance characteristics. A version of the heat activated staple that uses a controlled heat source appears to have the best combination of clinical forces and procedural control.

Keywords biomaterials, medical devices, Nitinol, orthopedic

1. Introduction

Devices for fracture fixation, including bone plates and staples, were one of the very first applications of Nitinol in medicine. One of the first recorded patents for a Nitinol medical device was for a bone plate in 1974 (Ref 1). Bone staples soon followed, with the first commercial Nitinol staples released to the Chinese market in 1981, to the European market in 1990, and to the U.S. market in the mid-1990s (Ref 2).

Nitinol staples are part of a broader category of metallic compression staples used today for fracture fixation, arthrodesis and osteotomies. Bone staples are especially useful for treatment of bones in the hand, foot and ankle, and metallic bone staples of one form or another have been used in the U.S. since 1906 (Ref 3). The advantages of using staples for these procedures include good approximation of the bone fragments, dynamic compression of the fracture surfaces, avoidance of infection issues associated with external fixation, and reduced operating time as compared to bone screws (Ref 4). Application of bone staples is a four-step process: (1) temporarily fixate the two pieces of bone to maintain proper alignment prior to fixation, (2) predrill holes to accept the bone staple, (3) insert and seat the staple, and (4) trigger recovery of the staple's preprogrammed shape either by removal of a constraint or by application of heat (Ref 4).

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1.1 Types of Nitinol Bone Staples

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

1.1.1 Room Temperature Superelastic (SE). In this form of Nitinol bone staple, the austenite finish (A_f) transformation temperature is near or less than 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 at or above room temperature as soon as the constraint is removed.

1.1.2 Body Temperature Activated (BT). This type of Nitinol staple has an A_f temperature below body temperature but above room temperature. Shape recovery is triggered by the thermal shape memory effect as the staple reaches body temperature. It is important to maintain the temperature of the staple sufficiently below body temperature during insertion to prevent premature deployment. This can be accomplished through a combination of external cooling and sufficiently rapid insertion.

1.1.3 Heat Activated (HA). This category of Nitinol staple has an austenite start (A_s) temperature near or slightly above body temperature but with an A_f temperature low enough to allow deployment without the application of excessive heat. Approximately 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 (Ref 5). This type of staple can be activated in one of two ways: by simple application of a heating element such as a cautery device (Ref 6) or by using a specially designed external heat source that allows the amount and duration of the applied heat to be precisely controlled depending upon the degree of shape recovery desired (Ref 7). This latter type of staple (a subset of the HA category) will be referred to in subsequent discussion as "controlled heat activated."

Fig. 1 Examples of commercially available Nitinol bone staples: (left to right) the heat activated OSStaple™ from BioMedical Enterprises, Inc., the room temperature superelastic EasyClip™ staple from Memometal, Inc., and the body temperature BioPro® Memory Staple

Table 1 Examples of commercially available Nitinol bone staples

Trade name	Company	Deployment	Indications
Memory™ Staple	Depuy	BT activated	Foot, ankle
Stimulink™	Intellifuse	Heat activated (Intellifuser™)	Head and face, soft tissue, hand and foot, bone fragments, lower limbs
Memoclip®	Memometal	Heat activated	Hand and foot
EasyClip®	Memometal	RT superelastic	Hand and foot
MEMODYN™	Telos Medical/ BioResearch Innovations	Heat activated (cautery)	Foot, ankle, hand, wrist
OSStaple™, BOSS™, OSSArc™, OSSpine™, OSSAnchor™ Grip	BioMedical Enterprises	Controlled heat activated (OSSforce™)	Head, face, sternum, pelvis, cervical spine, hand and foot, upper and lower extremities
BioPro® Memory Staple	BioPro	BT activated	Foot, ankle, hand, wrist

Staples of all three types are commercially available. An example of each type of staple is shown in Fig. 1. A list of some of the commercially available Nitinol bone staples, along with their type of deployment mechanism, is shown in Table 1.

2. Clinical Experience

The two most important factors that govern bone healing are blood supply and the biomechanical conditions, especially the stability of the fracture (Ref 8). A strong staple that reduces relative motion of the two parts of the fracture is important for stability. A key advantage of Nitinol staples over conventional metallic staples is the ability to apply a continuous compressive force to the fracture surfaces. Not only does this ensure stability of the fracture site, but such compressive forces are also known to speed healing (Ref 9). Optimization of such forces is important, however, as excessive forces can cause pressure necrosis and prevent healing while insufficient forces can slow healing and may even allow the fracture to reoccur (Ref 9).

A review of the literature (Ref 4, 8, 10-15) indicates a generally favorable opinion among physicians regarding Nitinol bone staples. A typical physician comment on Nitinol bone staples is, ''The shape memory designed into the Nitinol staples studied shows the ability to produce an actively dynamic compressive force … The benefits of this type of device can provide unlimited options for repair of osteotomies, arthrodesis and fractures (Ref 14).''

3. Benchtop Measurement of Compression Forces

While Nitinol shape memory staples appear to be well-received in the marketplace, the different staple types have different procedural characteristics and compressive forces. To examine the compressive forces exerted by the different types of staples, an experimental study was conducted on the three different types of Nitinol bone staples: room temperature superelastic (SE), body temperature activated (BT), and heat activated (HA). In each case, the staples were subjected to a simulated deployment and the final forces were measured at body temperature. Similar staple designs and sizes were used in each case to eliminate differences in design as a factor in the results. In addition, all of the Nitinol materials were thermo-mechanically processed in a similar manner, with only the final aging heat treatment adjusted to create the different final transformation temperature characteristics. Interestingly, unlike most other medical device made from Nitinol, many commercial Nitinol bone staples are made from heavily annealed and aged Nitinol with very little residual cold work. This results in a lower strength material in general, but the lower strength is compensated for by thicker material cross-sections to achieve the desired compressive forces.

3.1 Experimental Protocol

Two different geometries of rectangular wire-based Nitinol staples were studied for the SE, BT, and HA staples: (1) 20 mm back, 20 mm legs, and a 2×3 mm wire cross-section (2020)

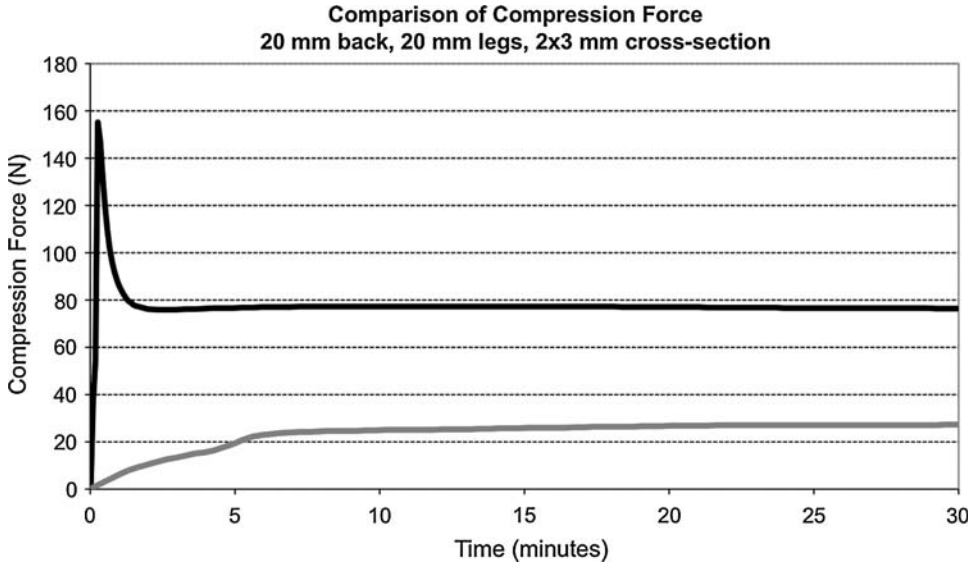

Fig. 2 Examples of compression forces as a function of time for 2020 BT (bottom, gray line) and HA (top, black line) staples. The SE staples showed similar recovery curves to the BT staple shown here

Table 2 Experimental procedures for measuring compressive forces exerted by three different types of Nitinol bone staples

SE	BT	HA
1. Pry open the staple mechanically at room temperature. 2. Insert the staple into the force-measuring jig. 3. Insert the jig into a temperature chamber at 37 °C and close the chamber door. 4. Record the compression force for 30 min.	1. Place the force-measuring jig in the 37 °C temperature chamber for 1 h to allow it to equilibrate. 2. Quickly insert the staple into the force-measuring jig using chilled forceps and close the chamber door. 3. Record the compression force for 30 min.	1. Place the force-measuring jig in the 37 °C temperature chamber for 1 h to allow it to equilibrate. 2. Insert the staple into the force-measuring jig. 3. Begin force data collection. 4. Heat the test staple to 55 °C using an electrical heating unit. 5. Close the temperature chamber door and record the compression force for 30 min.

and (2) 15 mm back, 12 mm legs, and a 2 × 2 mm wire cross-section (1512). The same staple design was used for all three staple types to enable direct comparison of the recovery mechanism independent of other possible differences in staple design. A staple design with an S-shaped back was chosen for the experiments as this is a common shape for commercial BT and HA staples; however, no SE staple is currently sold with an S-shaped back.

The starting material for all three staple types was a typical commercial-grade Nitinol alloy with 50.8 at.% Ni (balance Ti). The material was cold drawn to the appropriate rectangular shapes with approximately 30 to 40% final cold work. The staples were then heat treated by a commercial staple manufacturer (BME, Inc., San Antonio, TX) using their proprietary in-house process to set the staple shape, followed by aging between 450 and 550 °C to achieve the final desired transformation temperature characteristics. The final transformation temperatures of the staples were measured via bend and free recovery per ASTM F2082-06 (Ref 16). The measured transformation temperatures for the three different staple types were as follows: SE (A_s = 15 °C, A_f = 25 °C), BT (A_s = 30 °C, A_f = 37 °C), and HA (A_s = 38 °C, A_f = 43 °C). Each type of staple was tested per a specific experimental protocol as shown in Table 2.

Table 3 Force exerted by the three different staple types—SE, BT, and HA

Staple	Steady-state force, N, at 37 °C after deployment	Force magnitude scaled to BT staple
2020-2 × 3 SE	61.6	2.24×
2020-2 × 3 BT	27.5	1×
2020-2 × 3 HA	75.7	2.75×
1512-2 × 2 SE	50.3	2.14×
1512-2 × 2 BT	23.4	1×
1512-2 × 2 HA	30.5	1.30×

3.2 Experimental Results

The measured steady-state forces exerted by the three different staple types are shown in Table 3. Figure 2 shows an example of compression forces as a function of time measured for

the same size BT and HA 2020 staples. The spike in forces for the HA staple corresponds to the application of the heat source. Since the BT staple did not have a separate external heat source applied, it does not show a similar spike, but instead shows a gradual recovery to its final steady-state force as it reaches its final temperature of 37 °C. The shape of the SE recovery curves was similar to that of the BT curve as shown here.

The recovery forces were very sensitive to the precision of the span of the force-measuring jig. This was especially pronounced in the SE staples where the staple was seen to lose as much as 85% of its force if the jig was improperly set up with a span only 0.5 mm smaller than intended. In real-world clinical practice, this emphasizes the need for precision in the location of the predrilled holes to achieve predictable compressive forces.

4. Discussion

The well-known Clausius-Clapeyron equation determines the temperature-stress relationship of the Nitinol martensitic transformation:

$$\frac{d\sigma}{dT} = \frac{-\Delta H}{\varepsilon_0 T}$$

where σ is the stress, T is the temperature, H is the enthalpy of transformation, and ε_0 is the transformation strain.

Note that change in stress is inversely proportional to the change in temperature. In practice, one can use this relationship to estimate the relative differences between Nitinol recovery forces for devices with different transformation temperatures. For example, for superelastic devices, the larger the difference between ambient temperature and the A_f temperature, the higher the superelastic recovery force. Therefore, for devices recovering at body temperature, one would expect the recovery force of a ''colder'' staple (i.e., the SE staple) to be higher than that of a ''warmer'' staple (i.e., the BT staple) since the difference between the ambient temperature (37 °C) and the transformation temperature is greater for the superelastic staple. Indeed, this is shown to be the case for the SE and BT staples. However, it is more difficult to estimate the steady state recovery force for the HA staples as they involve the application of external heat to drive the temperature to a higher point (and conceivably drive the transformation to greater completion), followed by a reduction in temperature to the steady state 37 °C. Surprisingly, we see that after this activation process, these high-temperature HA staples can exhibit reasonably high steady-state compressive forces, sometimes exceeding even those of the SE staples. In spite of the fact that they are at a temperature below their A_s temperature when they cool back down to body temperature after being triggered at the initial high temperatures, the HA staples maintain a reasonably high holding force that is sustainable over time.

As expected, the lowest forces are consistently seen in the BT staples. Their forces take about 5 min to achieve their maximum level, and the final force level is low partly due to the stress-temperature relationship described above and partly due to the fact that a Nitinol material with its A_f temperature close to its use temperature will have difficulty reaching its total force potential based on the fact that as it transforms, it encounters greater resistance, which in turn effectively raises its A_f temperature. This continues until a force-transformation temperature equilibrium is reached at 37 °C. HA staples overcome this limitation by driving the staple beyond their inherent temperature limitations and, as a result, they are able to achieve their true compressive force potential to a greater degree.

One commercially available HA staple, the OSStaple™, has an additional benefit of using a special controller (the OSSforce™), which allows the amount of heat input and duration applied to the staple to be precisely controlled. This type of staple is referred to as ''controlled heat activated.'' As a result of this additional control, the shape recovery (and resultant forces) of the staple can be more precisely controlled. This allows the physician to tune the implant for a particular application. For example, if the procedure calls for multiple staples to improve rotational or bending angle stability, each staple can be individually tuned at an appropriate force level to optimize the final force balance and fixation characteristics. This could also allow the physician to adjust for any imprecision in the location of the predrilled holes.

4.1 Procedural Factors

Other factors that influence staple choice include activation control, force control, ability to stabilize the fracture, and ease-of-use. A qualitative comparison of various characteristics of the different types of staples is given in Table 4. Overall, the HA staples achieve the best balance of high fixation forces and procedural control. The controlled heat activated subset of this larger category staples has all the benefits of HA staples with increased control of the recovery process and subsequent compressive forces.

5. Future Directions

Most staples today are rather simple in design, being made from rectangular Nitinol wire with a mostly constant cross-section. Recent advances in manufacturing techniques have resulted in more finely engineered designs, incorporating

Table 4 Qualitative comparison of different staple types

Characteristic	SE	BT	HA	Controlled heat activated
A_f range, °C	0-25	25-35	45-55	45-55
Activation control	++++	++	++++	++++
Force control	++	++	++	++++
Ease-of-use	+++	++	+++	+++
Fracture stability	++++	++	++++	++++
Compression force	High	Low	Medium/High	Optimizable

Fig. 3 The Barbed OSStaple™ (BOSS) from BioMedical Enterprises, Inc., is an example of a next generation staple, incorporating recent advances in manufacturing technology and staple design

design elements such as barbs and three-dimensional features to enhance staple security, prevent rotation of the fixation site, and allow tailoring of the compression forces at different parts of the staple. An example of such advanced staples is the Barbed OSStaple™ (BOSS) shown in Fig. 3. More manufacturers are likely to adopt similar sophisticated designs in the future.

References

1. A. Johnson and F. Alicandri, Thermoconstrictive Surgical Appliance, U.S. Patent 3,786,806, 2 Jan 1974
2. J. Ryhänen, "Biocompatibility Evaluation of Nickel-Titanium Shape Memory Metal Alloy," Dissertation, Department of Surgery, University of Oulu, Oulu, Finland, 1999
3. W.L. Bargar, N.A. Sharkey, and H.A. Paul, et al., Efficacy of Bone Staples for Fixation, *J. Orthop. Trauma*, 1987, **1**(4), p 326–330
4. T.M. Mereau, and T.C. Ford, Nitinol Compression Staples for Bone Fixation in Foot Surgery, *J. Am. Podiatr. Med. Assoc.*, 2006, **96**(2), p 102–106
5. J.D. Bronzino, *The Biomedical Engineering Handbook*, 3rd ed., CRC Press, Boca Raton, FL, 2006
6. Telos Medical Memodyn™ Compression Staple Product Information Available at http://www.telosmedical.com/memodyn.htm
7. BioMedical Enterprises, Inc. OSSforce™ Implant Controller Product Information Available at http://www.bme-tx.com/Product/OSSforce.html
8. N. Shibuya, et al., A Compression Force Comparison Study Among Three Staple Fixation Systems, *J. Foot Ankle Surg.*, 2007, **46**(1), p 7–15
9. A.K. Forsythe and C.J. Green, Bone Fracture Compression Device and Method of Usage, U.S. Patent 3,866,607, 18 Feb 1975
10. R.K. Choudhary, et al., First Metatarsophalangeal Joint Arthrodesis: A New Technique of Internal Fixation by Using Memory Compression Staples, *J. Foot Ankle Surg.*, 2004, **43**(5), p 312–317
11. J.T. Braun, et al., The Efficacy and Integrity of Shape Memory Alloy Staples and Bone Anchors with Ligament Tethers in the Fusionless Treatment of Experimental Scoliosis, *J. Bone Joint Surg.*, 2005, **87A**(9), p 2038–2051
12. J.J.G. Malal, G. Hegde, and R.D. Ferdinand, Tarsal Joint Fusion Using Memory Compression Staples—A Study of 10 Cases, *J. Foot Ankle Surg.*, 2006, **45**(2), p 113–117
13. P.J. Ronchetti and S.M. Topper, Lunocapitate Fusion Using the OSStaple Compression Staple, *Tech. Hand Up. Extrem. Surg.*, 2006, **10**(4), p 231–234
14. T.J. Chang and B.D. Overley, "An In Vitro Comparative Study of Screw and Nitinol Staple Compression: A Model Showing Active 'Dynamic' Compression," *Presented at the American College of Foot & Ankle Surgeons 65th Annual Scientific Conference*, Orlando, FL, March 2007
15. P. Fernández-de-Retana, D. Poggio, and J.P. Ortega, Technical Tip: First Metatarsophalangeal Arthrodesis with 20-mm Memory Compression Staples, *Foot Ankle Int.*, 2008, **29**(6), p 613–615
16. "Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery," ASTM F2082-06, ASTM International, West Conshohocken, PA, 2006