Journal of the Mechanical Behavior of Biomedical Materials 75 (2017) 558–566

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

Design considerations for a novel shape-memory-plate osteosynthesis allowing for non-invasive alteration of bending stiffness

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ARTICLE INFO

Keywords:
Shape memory alloy
Fracture healing
Nickel-titanium (NiTi)
Inverse-dynamisation, osteosynthesis plate
Stiffness alteration

ABSTRACT

Biomechanical stimuli play a major role in fracture healing. Changing the fixation stiffness through the course of healing might accelerate bone healing and prevent healing complications. Shape memory alloy (SMA) based implants were developed to allow for non-invasive stiffness alteration during the fracture healing process. To gain a deeper understanding of the implant functionality based on the alloy characteristics and geometric design, the mechanical properties of different shape memory alloys where mechanically characterized.

SMA bone plates were manufactured and the structural bending stiffness of the implants was determined at different temperatures and configurations.

The temperature required for complete recovery of shape after deformation increased continuously with increasing pseudo-plastic deformation in SMA probes. Full recovery was observed at temperatures ranging from 38 °C to 52 °C after pseudo-plastic deformations ranging from 0.2% to 1.0% outer fibre strain, respectively.

The small fragment inverse-dynamisation implants revealed bending stiffnesses ranging from 0.09 N m^2 to 0.34 N m^2 in the initial state and from 0.16 N m^2 to 0.46 N m^2 after shape alteration. Dependent on the design, a relative gain of the implant stiffness ranging from 18.8% to 115.0% could be observed.

The large inverse-dynamisation implants revealed bending stiffnesses from 3.7 N m^2 to 7.1 N m^2 before and 4.1 N m^2 to 12.6 N m^2 after triggering the shape memory effect. Dependent on the design a gain in stiffness from 11.8% to 117.2% was observed.

Warming the SMA implant to 40 °C for a short period of time, leads to a moderate increase in implant stiffness of up to 64.5%, while triggering the implant with 50 °C leads to a maximum increase in stiffness of up to 127.3%.

The Nitinol shape memory bone plates have a huge potential for improving the treatment of long shaft fractures by allowing for the increase, decrease or incremental change of implant stiffness in fracture stabilization. However, the interaction between design, material properties, and manufacturing processes need to be carefully considered for each specific application to achieve optimum function of SMA-based, stiffness altering, fracture-fixation implants.

1. Introduction

Biomechanical stimuli play a major role in fracture healing (Augat et al., 2005; Hente et al., 2004; Lienau et al., 2005). While articular fractures require anatomic reduction and consolidate *via* direct (primary) bone healing without callus formation, this concept of absolute stability has occasionally led to non-unions, delayed healing or implant failure in shaft fractures. More mechanically flexible devices for fixation of shaft fractures, such as bridging plates, intramedullary nails or external fixators have therefore been introduced, which allow for indirect fracture healing *via* callus formation (Perren, 2002).

Indirect fracture healing consists of several phases: haematoma

Abbreviation: IFM, inter fragmentary motion; NiTi, nickel-titanium; SMA, shape memory alloy; SME, shape memory effect; DYN, dynamisation; IDYN, inverse dynamisation; M_s, martensite start temperature; M_f, martensite finish temperature; A_s, austenite start temperature; A_f, austenite finish temperature; T, temperature; E, elastic modulus; K, bending stiffness; I, moment of inertia

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http://dx.doi.org/10.1016/j.jmbbm.2017.08.024
Received 1 March 2017; Received in revised form 10 July 2017; Accepted 21 August 2017
Available online 23 August 2017
1751-6161/

formation and inflammation, progression into fibrous tissue, enchondral ossification and formation of hard callus, and remodelling of the bone (Einhorn, 1998). It seems likely that as fracture healing progresses through these phases, the amount of interfragmentary motion (IFM) changes during healing and consequently the need for stability as well (Thompson et al., 2002; Klein et al., 2003; Schell et al., 2005; Epari et al., 2007; Claes et al., 2009). The ideal fracture fixation stiffness might therefore differ for the various stages of the healing process. Besides external fixation, all available options for adapting the stability or stiffness of fracture fixation *in situ* are invasive. External fixation relies on transcutaneous pins, and other approaches require invasive procedures such as the removal or adding of bolts or screws in nail or plate osteosynthesis (Durall et al., 2004; Tigani et al., 2005).

The goal of this study was to develop a Nickel-Titanium alloy (NiTi) based shape memory implant, which allows for non-invasive alteration of the internal fixation stiffness towards lower (dynamisation) or higher (inverse-dynamisation) stiffness during the course of fracture healing. To implement the dynamisation or inverse-dynamisation of fracture fixation, *i.e.* in order to achieve an *in situ* increase or decrease of the IFM, a concept was developed which allows for bending stiffness of the plate fixation to be altered by triggering the one-way shape memory effect *in situ* (Pfeifer et al., 2013). Depending on alloy composition and thermo-mechanical treatment, the transition temperatures, martensite-start-temperature (M_s), martensite-finish-temperature (M_f), austenite-start-temperature (A_s) and austenite-finishing-temperature (A_f), can be determined to be between −150 and 200 °C (commercially available alloys have a range of about −20–120 °C), allowing custom designed shape memory effects (SME) (Van Humbeeck and Stalmans, 2002). Alteration of the implant's bending stiffness $K = I * E$ is achieved based on the implant's modification of the area moment of inertia I (geometric shape change) and the elastic modulus E (microstructure).

Depending on whether the implant is constructed for dynamisation or inverse-dynamisation, the outer lamellae of the functional portion of the implant were deformed either into "wing" or "dogbone" configuration respectively.

Inductive warming triggers the one-way SME of the implant after implantation (Fig. 1). When warmed, A_s is reached and the outer lamellae begin to return to their original (straight) configuration, resulting in a significant alteration of I_y and therefore K. Since we are employing a one-way effect, this shape is retained after the implant has cooled back to the body temperature (Fig. 1). A_s and A_f are set to be significantly above the normal body temperature, but low enough to avoid tissue damage. Implant conversion can be triggered at the desired point in time with the aim of optimized fracture healing (Pfeifer et al., 2013).

In an initial experimental and numerical proof-of-concept study, we investigated the change in stiffness that could be achieved with a set of prototype fixation plates of differing design (Olender et al., 2011). In further studies, the induction warming process was investigated both *in vitro* and in an animal model to define suitable warming parameters and the possible negative effects of warming on the surrounding tissue *in situ* (Pfeifer et al., 2013; Mueller et al., 2010; Müller et al., 2014, 2010). The concept was subsequently further investigated *in situ* in a leporine tibia-osteotomy model (Müller et al., 2015). More recently, an upscaled large-animal implant was further investigated in an ovine tibia-osteotomy model (Decker et al., 2015). By means of these studies, we have demonstrated the function and successful implementation of a concept for the *in situ* non-invasive alteration of fracture fixation stiffness. Nonetheless, several issues regarding the behaviour of the SME alloy and the application of the SME as well as implant design remained open.

Several factors influence the change of the elastic modulus when the one-way-SME effect is triggered and thus contribute to the change in the implant's stiffness. For example, the hysteresis pattern of SMA influences the change in elastic modulus. We therefore posed the question of how the hysteresis pattern of a NiTi alloy could be tailored to meet the requirement of a maximized change in implant stiffness. As we observed differences in the material behaviour with degree of deformation, we also wondered to what extent the degree of deformation influences the SMAs' shape recovery. Finally we were particularly interested to what extent the stiffness of an individual implant could be guided to allow for patient-specific treatment.

In summary, this study aims to answer the following research questions:

(1) How do the hysteresis-patterns and associated changes in elastic modulus of the shape memory alloy need to be tailored to maximize functionality of the implants?
(2) To what extent is the shape recovery of the SME influenced by mechanical deformation?
(3) What is the maximum attainable stiffness alteration in small and large animal plates?
(4) Does the novel implant concept allow for an incremental alteration of stiffness?
(5) To what extent is the stiffness alteration of the implants induced by the change of the elastic modulus?

2. Materials and methods

2.1. Shape memory alloys

For both implant concepts dynamisation (DYN), and inverse dynamisation (IDYN), one nickel-titanium alloy was selected in a preliminary material characterization series of different commercial and tailor-made alloys. Selective criteria were an A_f in the range of 45 and 65 °C as well as a short transiting band between A_s and A_f. In addition, depending on whether the alloy was selected for the dynamisation or inverse-dynamisation concept, the material was selected to exhibit a narrow or broad phase transformation hysteresis respectively.

Overall three different nickel-titanium SMAs with a nominal composition of 45.0–50.0% Ni (rest: Ti) were used for this study (Table 1). One commercially available shape memory alloy with only a marginal

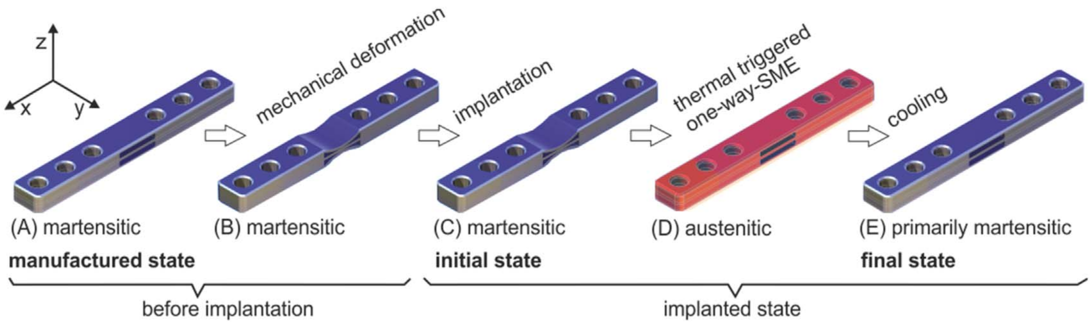

Fig. 1. General concept of an implant with alterable stiffness (here an inverse dynamisation resulting in an increase in bending stiffness). By triggering the one-way SME after implantation, bending stiffness is altered due to both a change in the implant's geometry (area moment of inertia) as well as a change in its elastic modulus.