Ti–Ni Rods with Variable Stiffness for Spine Stabilization: Manufacture and Biomechanical Evaluation

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Abstract A new concept of monolithic spinal rods with variable flexural stiffness is proposed to reduce the risk of adjacent segment degeneration and vertebral fracture, while providing adequate stability to the spine. The variability of mechanical properties is generated by locally annealing Ti–Ni shape memory alloy rods. Ten-minute Joule effect annealing allows the restoration of the superelasticity in the heated portion of the rod. Such processing also generates a mechanical property gradient between the heated and the unheated zones. A numerical model simulating the annealing temperature and the distributions of the mechanical properties was developed to optimize the Joule-heating strategy and to modulate the rod's overall flexural stiffness. Subsequently, the rod model was included in a finite element model of a porcine lumbar

spine to study the effect of the rod's stiffness profiles on the spinal biomechanics.

Keywords NiTi · Materials · Mechanical behaviour · SMA · Superelasticity

Introduction

Spinal disorders can be treated by several methods, including fusion surgery. Rigid posterior instrumentations are commonly used to relieve chronic back pain, fractures, instability, and neurological injury. These strong instrumentations are used to prevent motion in the instrumented segment and to avoid implant failure [1, 2]. However, this type of implant creates a significant stress concentration between the instrumented and the intact segments, which results from a difference in their mobility. Such a stress concentration leads to adjacent segment degeneration, proximal junctional kyphosis or even fractures [3, 4].

In order to relieve the stress observed on the adjacent segments, the so-called dynamic stabilization systems have been proposed. Such systems are designed to provide more motion at the instrumented level and to reduce the mobility at the adjacent level. However, these implants have yet to prove their efficiency as they are frequently associated with implant failure, inadequate stability or persistent adjacent segment degeneration [4–6].

An ideal configuration would combine strong stabilization in the fusion zone with a gradual mobility transition between the instrumented and intact segments. Such a transition could potentially be obtained by varying the stiffness along the rod. In this study, the use of Ti–Ni shape memory alloy (SMA) is proposed to manufacture monolithic rods with variable flexural stiffness.

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Nearly equiatomic Ti–Ni alloys can exhibit drastically different mechanical behaviours at a given temperature, depending on their thermomechanical processing. Ti–Ni parts are commonly produced using a specific sequence of plastic deformation and thermal treatments [7]. It has been shown that when the plastic deformation is performed at room temperature, a large number of defects induced in the material suppress the superelasticity, and a conventional elastoplastic mechanical behaviour is observed. Post-deformation annealing (PDA) is therefore needed to restore the superelasticity [8].

PDA is usually applied on complete parts, but can also be used to reduce the defect density in a confined zone of a monolithic SMA product. Local annealing can be carried out using several techniques, including Joule, laser or induction heating [9–11]. In particular, it has been shown that both elastoplastic and superelastic behaviours could be observed in a monolithic Ti–Ni Ø2-mm wire subjected to local Joule effect post-deformation annealing (J-PDA). A gradual transition between these mechanical behaviours is obtained due to a thermal gradient created by local annealing [12].

In this work, local Joule effect annealing is proposed to produce monolithic rods with variable flexural stiffness. Such rods could combine a strong stabilization capacity in the instrumented segment, while reducing the stress on the adjacent segment thanks to their softer superelastic extremities.

First, this paper describes the manufacture of the rod. Then, finite element models simulating the biomechanics of a porcine spine segment stabilized with variable-stiffness Ti–Ni rods are described and validated.

Methodology

Materials and Processing

Ti-55.94Ni (wt%) 5.5-mm diameter wire was supplied by Johnson Matthey Medical (San Jose, PA, USA) in two metallurgical conditions: as-drawn (hardened material, cold worked strain of about 30 %) and annealed (superelastic material).

Assessment of the Properties-Modification Capacity of J-PDA

Joule effect annealing was performed on a custom-made bench using an RE30-170 power supply capable of delivering 170 A at 30 V (Matsusada Precision, Japan). Temperature was measured using a type K thermocouple (TT-K-36-SLE, Omega Eng. Inc, USA.) and an E60 thermal

imager (FLIR Systems, USA). A photograph of the bench is presented in Fig. 1.

Hardened Ti–Ni rods subjected to Joule effect annealing at 260, 345, 430, 500 and 585 °C for 10 min were used to assess the property-modification capacity of J-PDA. Tensile testing was performed on 25 cm long rods using an MTS Alliance testing apparatus (MTS, MN, USA), with a crosshead speed of 0.1 mm/s. The rods were strained twice up to 6 %, and released before loading to failure. Such a sequence was used to characterize both the superelastic and the conventional elastoplastic behaviour.

Figure 2a shows the tensile stress–strain diagrams of specimens subjected to 10-min Joule-effect PDA at various temperatures. The stress–strain diagrams corresponding to annealing at 430 °C are used to explain how parameters of the finite element analysis superelastic material law were obtained (see “Numerical Modelling” section for details). Figure 2b, c illustrate evolution of the Young’s modulus under loading (E_{Aus}) and of the onset transformation stress ($\sigma_{\text{s,t}}^{\text{AS}}$) measured for the 2nd loading cycle as functions of the annealing temperature. It can be seen that starting from the 2nd loading cycle, the hardened material exhibits behaviour which can be called linear superelasticity. Ten-minute J-PDA at 430 °C restores plateau-like superelastic behaviour of the material with a Young’s modulus of 36 GPa and a critical stress of 350 MPa. On the contrary, 10-min J-PDA at 585 °C results in a stiff elastoplastic material with a Young’s modulus of 85 GPa.

Fig. 1 Photograph of the Joule-heating annealing setup

Fig. 2 **a** Stress–strain diagram of Ti-55.94 wt%Ni annealed at different temperatures and the corresponding idealized curves for FE analysis. Characteristic constants are illustrated on the 430 °C,

10-min diagram, **b** Young’s modulus, and **c** critical transformation stress, as functions of the annealing temperature

Numerical Modelling

Modelling of a Variable-Stiffness Rod

The numerical simulation of the variable properties was carried out in two steps: i) simulation of the temperature distribution during localized J-PDA, and ii) definition of the mechanical properties gradient using the calculated temperature distribution.

ANSYS 14 finite element analysis software (Ansys Inc., PA, USA) was used to predict the temperature distribution on the rod during J-PDA. The “Thermal-electric” and “Transient Thermal” ANSYS modules were used to simulate the temperature gradient during steady and transient states, respectively. Both models were validated using experimental data.

An ANSYS 14 “Static Structural” module was used to implement the mechanical model of the variable rod. The mechanical behaviour of the SMA was simulated using the

ANSYS SMA superelastic material law with the following input data: $\sigma_{s,t}^{AS}$, $\sigma_{f,t}^{AS}$, $\sigma_{s,t}^{SA}$, $\sigma_{f,t}^{SA}$, ϵ_L , E_{Aus} , and α . The constants stand for the starting and final stresses of the forward-phase transformation, the starting and final stresses of the reverse-phase transformation, the maximum superelastic plateau strain, and the Young’s modulus of austenite, respectively, in tension (see Fig. 2a for illustration). The last parameter, α , models the difference between the material responses in tension and compression; it is related to the values of the corresponding onset stresses for the forward-phase transformation (σ_t^{AS} for tension and σ_c^{AS} for compression) by the following expression:

$$\alpha = \frac{\sigma_c^{AS} - \sigma_t^{AS}}{\sigma_c^{AS} + \sigma_t^{AS}}$$

A value of $\alpha = 0.2$ [13] was considered in this work, which indicates that onset stresses of the forward-phase transformation are 50 % higher in compression than in

Fig. 4 Illustration of porcine lumbar model: **a** posterior view without instrumentation. **b** posterior view with pedicle screws and spinal rods

nucleus pulposus, a hyperelastic Mooney-Rivlin model was used. Nonlinear tension-only springs were employed to model the spinal ligaments. All material properties were drawn from the literature. Except for the anterior and posterior longitudinal ligaments and the intervertebral discs, porcine material property data were used for all tissues. Frictionless surface-to-surface contact elements were used to model the facet joints. Additionally, frictionless contacts were assumed between the screw circumference and the pilot holes in the vertebrae. Between the pedicle screw tip and the pilot hole bottom, fixed contacts were assumed. Bonded contacts were also employed to model the contact between the pedicle screw heads and the spinal rods during flexion. During the application of the compressive follower load, these contacts were replaced by frictionless contacts.

Brick and tetrahedral elements were used to mesh the lumbar spine and instrumentation components (see Table 2 in Appendix). A convergence study was carried out to balance between model accuracy and computation time. The meshed geometry was composed of 104,000 nodes and 129,500 elements. The meshed model is illustrated in Fig. 5c.

The caudal half of the L6 vertebra and the spinal rod extremity were rigidly fixed. Loading of the spine segment was done in two steps: a compressive follower load (400 N) was first applied between the centres of adjacent vertebral bodies (L1-L6). After applying the follower load, 18° forward flexion (pure moment) was applied on the cephalad endplate of L1 as shown in Fig. 5b, c. Rotation of 18° is slightly inferior to the range of motion measured by [16] under pure moment loading (7.5 Nm). This precaution was taken to decrease the risk of specimen damage during testing. The softer end of the variable-stiffness rod was

always positioned proximally on the spine segments according to our preliminary calculations [17].

The numerical model of the spine segment was validated by comparing its results with the experimentally obtained ranges of motion to establish its adequacy.

In vitro testing was performed on six porcine spine segments in uninstrumented and instrumented conditions. The specimens were loaded in forward flexion motion up to 18° rotation with a follower load of 400 N.

In the instrumented condition, the spine segments were stabilized using rods with variable properties (VAR) attached to the spine using pedicle screws (PS) (6.5 × 45 mm, Ti, Medtronic, MN, USA) at L5, L4 and L3. Both ends of the specimen were fixed in polyester resin (Bondo, MN, USA), while an aluminium block was used to solidly clamp the caudal ends of both rods (Fig. 5a).

VAR rods were manufactured by applying Joule effect annealing (585 °C, 10 min) to the annealed (SE) rods on half of their length. Such processing creates variable-stiffness rods with a Young's modulus of 86 GPa in the heated zone and a gradual transition towards the non-heated, compliant 36 GPa superelastic portion of the rod. During in vitro testing, the superelastic portion of the VAR rods was always placed proximally (Fig. 5b). Details and validation of the in vitro testing methodology can be found in [18, 19].

Results

Various Stiffness Rod Model Validation

Figure 6 shows results of cantilevered bending profiles for a hardened Ti–Ni rod subjected, on half of its length, to

Table 2 Material properties of spine tissues and posterior instrumentation

	Element type	Moduli: E (MPa) Stiffness: K (N/mm)	ν	Source
Vertebrae*	Solid185	E = 520,6 MPa	0.3	[22]
Annulus	Solid185	$c10 = 0.18$ $c01 = 0.045$	0.45	[23]
Nucleus	Soild186	$c10 = 0.12$ $c01 = 0.03$	0.49	
ALL	Combin39	K: Nonlinear force–deflection curves		[24]
PLL				
CL*	Combin39	K: Nonlinear force–deflection curves		[25]
SSL*				
ISL*				
LF*				
Collagen fibres	Combin39	K: Nonlinear force–deflection curves		[26]
Screws	Solid187	E = 100,000 MPa	0.3	

Asterisk superscripts indicate porcine material properties

Fig. 5 **a** Posterior view of an instrumented specimen; **b** Schematic illustration of the VAR rod model on porcine specimen; and **c** illustration of meshed instrumented lumbar spine model

J-PDA at a maximum temperature of 410 °C. Results from experiments (black bold lines) and from calculations (grey dotted lines) are presented. The temperature profile measured during J-PDA is also provided. In Fig. 6a, two bending profiles are presented: loading up to 91 N and then partial unloading to 47 N. A good correlation is observed between the experiment and the calculation cases. In order to further validate the model, the same rod was loaded in cantilever bending at 91 N, with its annealed part (Fig. 6b) and its hardened part (Fig. 6c)

fixed. Once again, good agreement is observed between the experimental measurements and the results from the calculations.

Porcine Spine Model Validation

Figure 7 shows the comparison between the experimental and predicted ranges of motion in instrumented and uninstrumented conditions. Pure moment bending (displacement

Fig. 6 **a** Temperature profile and bending profiles: (1) loading up to 91 N, (2) partial unloading at 47 N; bending profile for a similar rod with **b** the annealed end fixed, and **c** the hardened end fixed: experimental and numerically obtained data

controlled) forward flexion up to 18° was applied. In the uninstrumented condition, a good correlation is observed between the ranges of motion measured in vitro and those

obtained by calculation. In the instrumented configuration, the mobility gradient observed between the stabilized and adjacent segments is also well reproduced.

Fig. 7 Comparison between calculated and experimentally measured ranges of motion: **a** uninstrumented and **b** instrumented spine segments

Discussion

Posterior instrumentations are commonly used in spinal fusion surgery. Rigid and solid implants composed of metallic rods and pedicle screws are used to provide the stability needed for fusion and to avoid implant failure, but can lead to adjacent segment disease. An ideal implant should combine static and dynamic properties, with higher stiffness where stability is critical, and lower stiffness where dynamic properties and load-sharing capacity is important. Such complexity of properties can be obtained by applying local Joule effect annealing on Ti–Ni rods.

In a previous study, an original Joule effect annealing-based manufacturing technique for producing Ti–Ni rods with variable flexural stiffness was proposed and validated [12]. This technology provides an easy, reliable and fast process to manufacture Ti–Ni rods whose mechanical properties can be radically changed using annealing in as little as 10 min.

Ti–Ni Ø5.5-mm rods (Ti–55.94Ni wt%) subjected to the aforementioned process were characterized using tensile testing. The results obtained indicate that stress–strain behaviour can range from classic elastoplastic (30 % cold work) to rubber-like with 30 % elongation to failure (585 °C, 10 min). Specimens exposed to J-PDA at 430 °C for 10 min exhibit superelastic behaviour. These observations are explained by the higher-temperature range of the martensitic transformation and the lower defect density after high-temperature J-PDA. This is in line with what was described by [7, 20, 21]). Cantilevered bending tests show that applying J-PDA locally leads to variable mechanical properties along the monolithic rod. Furthermore, such local treatments do not weaken the sample during fatigue testing [12].

A finite element model to simulate the impact of local annealing on the bending stiffness of spinal rods was implemented. The model successfully predicts the bending profiles for the locally annealed Ti–Ni alloy; as well, it appears promising for optimizing the heating schedule and predicting the mechanical property profiles resulting from local J-PDA.

A porcine lumbar 3D finite element model was implemented and validated under both uninstrumented and instrumented conditions. The model will be used to optimize the stiffness profile of the rod; it will further serve to develop and optimize new implants that aim to reduce excessive stress on the adjacent, intact segment. Various anchor configurations combining pedicle screws and transverse process hooks will also be investigated.

Conclusion

The aim of this work was (i) to manufacture Ti–Ni rods with variable flexural stiffness, (ii) to develop a finite element model simulating a porcine spine segment, and (iii) to assess the stabilization capacity of such a rod experimentally and numerically.

Local Joule annealing can be used to manufacture variable-stiffness Ti–Ni rods. It is possible to model the local annealing process and its effect on mechanical behaviour. The 3D finite element model of the instrumented spine segment was validated using experimental data. The model will be used to design and optimize new implants and decrease stress on the adjacent segment.

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