Superelastic NiTi springs for corrective skull operations in children with craniosynostosis

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Abstract This paper concerns the formation and characterization of superelastic springs and rings of NiTi alloys for long-term skull correction. Superelastic properties of the rings were induced in the process of ageing of the already formed rings which cause hardening of parent phase by the precipitation of coherent Ni_4Ti_3 particles. The efficacy of the worked out springs and rings were successfully proved in several clinical applications.

Introduction

Distraction osteogenesis is a biological process of new bone formation between two incised or decorticated bone segments subjected to tension.

Presently, the generally used clinical technique of bone lengthening is based on mechanical distractors activated by a screw mechanism which moves apart the two ends of the sliced or decorticated bone.

Mechanical distraction devices have very limited application in craniofacial surgery. For this reason the long-term distraction was applied in craniofacial surgery as

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Clinic of Maxillofacial Surgery, Silesian Academy of Medicine, Francuska 20/24, Katowice 40-027, Poland a new technique. Two successful cases of craniofacial reshaping using the long-term distraction were described by Lauritzen et al. [1]. The distraction was achieved by using steel springs implanted into the craniofacial skeleton. The springs that were used were made of stainless steel wire in the form of a safety pin. After three months the boys showed normal appearance and the cephalogram was within normal limits.

The possibility of replacing the gradual distraction achieved by screw mechanism through a long term distraction was proved by Sasaki et al. [2] using superelastic NiTi springs. The studies were carried out on rats using W-shaped springs located in the holes drilled in maxillary and temporal bones. The initial force was approximately 0.2 N. The purpose of this research was to evaluate the effect of mechanical separation of sutures on the craniofacial growth without osteotomy. On the basis of histologic and radiographic findings, the induction of new bone formation via sutural distraction was shown. No apparent differences were found in histologic changes in comparison to the control groups. The efficacy and safety of the dynamic spring-mediated cranioplasty carried out on rabbits was confirmed by David et al. [3]. The studies were done using stainless steel and shape memory alloy springs and no significant differences in the obtained results for both groups of rabbits were observed.

High efficacy of the spring-mediated cranioplasty was confirmed by Guimares-Ferreira et al. [4]. This method was compared with the "pi-plasty" method in the management of sagittal synostosis. The expander elements were made of stainless steel wire of 1.2 mm diameter with an initial force of 15 N. The mean absolute change of skull height for spring-mediated cranioplasty group was significantly greater than in the pi-plasty group.

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As it is well known, steel springs during their expansion lose their force. For this reason, the application of superelastic NiTi springs with their force plateau for the long term mandibular distraction has been proved [5].

The basic assumption for bone elongation was to achieve a continuous and constant force in a wide range of deformations using superelastic springs and rings. The very plateau stress-strain curves exhibited by superelastic NiTi alloys can be used advantageously to sustain constant forces or minimise their variations over a large range of deformations. It concerns the loading and unloading plateau connected with stress hysteresis.

This study presents the process of forming out the superelastic springs and rings of NiTi wire that have been used for experimental elongation in clinical research of modelling the cranial vault in children with craniostosis.

The idea of this work was to use rings-instead of springs for cranioplasty, which by flattening to an ellipse would be connected to the skull and during long-term expanding would result in the elongation of cranial bones perpendicularly to sagittal direction and their contraction in frontal plane would cause the craniofacial reshaping. The problem was to achieve superelastic behaviour of the rings, which means presence of broad force plateau on the forcedeformation curve during force releasing. The rings welded from straight superelastic wires did not show the presence of a force plateau.

Materials and methods

The studies were carried out on two commercially available NiTi alloys in the form of straight wire. The chemical composition and their characterization are given in Table 1. The chemical analysis was carried out using the energy dispersive spectroscopy (EDS) method in scanning electron microscope (SEM) JSM-6480. For the first stage of the studies superelastic wires of 0.8, 1.0 and 1.2 mm diameter provided by SMATEC were used. The U-and Ω shaped expansion springs as well as rings of different diameters (60-90 mm) were formed from straight superelastic wires. The length of the wire which corresponds to the perimeter of the Ω -shape spring was between 40 and 60 mm. The same length of the wire was used to form the U-shape springs. The U- and Ω -shaped expansion springs were formed by compression from a straight superelastic wire as shown on the sketch inside Fig. 4. On both ends of the wire piece loops of 2 mm diameter were formed. They were screwed onto the margins of both sides of the cranial bone. The rings were formed by bending straight wire to a round form and then located in the holder which allows the laser beam welding. To ensure a safe connection both ends of the wire overlapping welds were made. The welding was carried out in a pure argon atmosphere using a Nd-YAG Dental Laser Welder type 2002 S with 1064 nm wavelength, pulse frequency 10 Hz and power of 30 W. The characteristic temperatures and the course of the martensitic transformation were studied using differential scanning calorimetry (DSC) method using the Perkin-Elmer DSC-7 instrument. The courses were registered by cooling and heating speed of 10 degree per minute. The measurements of forces and deformations of springs taken during bending and unloading were recorded at a computerised measuring point and presented in the form of a graph showing the relation between force and displacement. For the second stage of the studies the annealed NiTi wire of 1.0 mm diameter delivered by AMT (Belgium) was used. The aim of the second stage studies was to achieve a superelastic behaviour of rings during their deformation by flattening to an ellipse. This alloy (no 2) marked by NT-10 is destined to form complex shapes and induce the superelasticity by ageing. To obtain the best superelastic behaviour the optimisation of ageing parameters was necessary. The ageing was carried out in the temperature range between 300 and 500 °C for different time holding. Before implantation the springs and rings had undergone the passivity in an autoclave in steam at 134 °C for 30 min. The structure of the obtained TiO₂ layer, about 4 nm thick, was amorphous, which was confirmed by high resolution electron microscopy (HREM) examination.

Alloy Ni at % Ti at % Si at % M_s °C $A_f \,^\circ C$ State of the wires Shape of Delivering Al at % the springs company SMATEC 1 50.8 ± 0.27 49.0 ± 0.40 n.m. n.m. As received after U-shape quenching 800°C/1 h Ω -shaperings -15 +112 51.02 ± 0.36 48.71 ± 0.36 0.12 0.14 -80-30 As received after Rings AMT quenching 800 °C/1 h -65 -35 (NT-10) after ageing 500 °C/15 min -30+15

Table 1 Chemical composition and characteristics of the springs and rings

n.m.-no measurable

The precipitation process was also controlled by transmission electron microscopy (TEM) method in a JEM 200B. The thin foils were prepared by jet polishing in a solution containing 20% HClO₄ in CH₃COOH.

The tensile tests of these wires were done on the Instron machine. The 3-point bending tests in loading-unloading experiments were carried out on a specially computerised device equipped with a Hottinger force converter, Peltron linear displacement indicator and digital temperature indicator.

Results and discussion

Superelastic springs for distraction

The first step before forming the springs was the characterization of the supplied wire. Usually, the manufacturer's data of the superelastic wires are given for the tensile loading-unloading curve but not for the bending test. For this reason both of these tests were carried out in order to compare the superelastic behaviour at tensile and bending test. In Fig. 1 the tensile stress-strain curve is shown and Fig. 2 presents the bending test of superelastic wires of alloys 1. As it can be observed, the bending curves also show a force plateau necessary for springs deformed by bending.

The concept of bone distraction using the Ω or U-shaped springs is shown as a sketch of the U-shaped superelastic springs in Fig. 3.

In order to characterize the relation between the force and spring displacement for both U and Ω -shaped springs, a special computerised device was build. The characteristic of the elastic behaviour during loading and unloading of

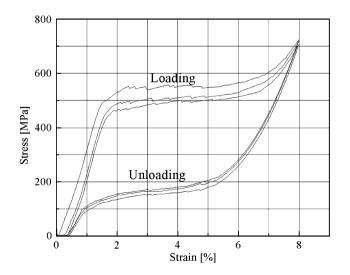


Fig. 1 Tensile test stress-strain curves for three cycles of loadingunloading of the superelastic wire

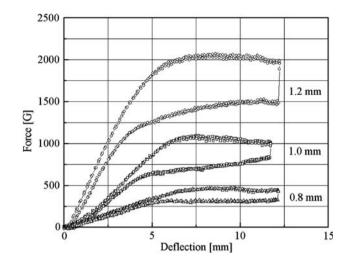


Fig. 2 Force-deflection, loading-unloading curves for 3-point bending test of superelastic wires of different diameters (alloy no 1)

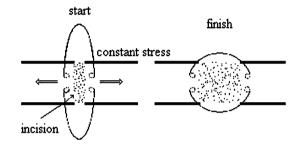


Fig. 3 Sketch of distraction by the U-shaped superelastic springs

the Ω -shaped springs prepared from alloy no 1 is shown in Fig. 4.

Depending on the diameter of the wire and the length of span average forces measured during the expansion of

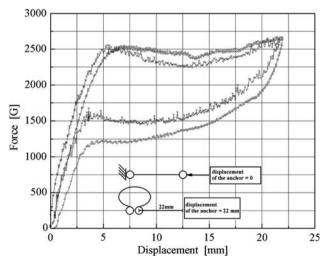


Fig. 4 Effect of temperature on the elastic behaviour of Ω -shaped springs during loading and unloading. (o) Room temperature, (x) at 37 °C

double springs on superelastic slide distractors were between 10 and about 40 N.

The preliminary experimental lengthening of bones was carried out on the mandible of three pigs. The details of those results are described in [5]. Whereas the clinical results of skull correction by using such springs are shown in Fig. 13.

Superelastic rings

A simplification of the surgical treatment for skull correction in the long-term distraction may be achieved using a spring in the form of ring. A flattened ring in the form of an ellipse is implanted on the skull and the forces exerted on it are schematically shown in Fig. 5.

The rings formed from the straight superelastic wire were welded with the use of a laser beam. Their elastic characteristic during loading-unloading which was obtained when the ring was flattened to an ellipse, does not show the presence of a typical force plateau but rather a linear relationship between force and deflection with a slope to the deflection axis as shown in Fig. 6.

In order to obtain typical superelastic properties of the ring \Leftrightarrow ellipse deflection, another method of superelastic induction for the rings was worked out. Based on the idea that superelasticity in more complex shaped springs may be induced by the precipitation process, an alloy with higher nickel contents (alloy 2) was chosen.

Received wire have been the parent phase structure at room temperature. Tensile test (Fig. 7) and 3-point bending test (Fig. 8) show a considerable recovery of elastic strain but simultaneously large permanent plastic strain, which for both kinds of deformation is nearly the same and equals about 4%.

The course of the martensitic transformation for alloy no 2 is shown on the DSC cooling and heating curves in

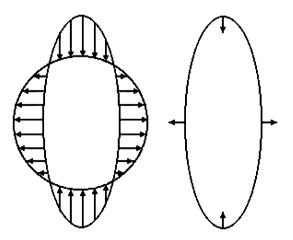


Fig. 5 Sketch of forces exerted on the skull in a flattened ring

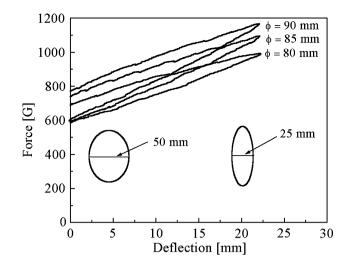


Fig. 6 Force versus displacement for flattened rings formed of straight superelastic wire (alloy no 1)

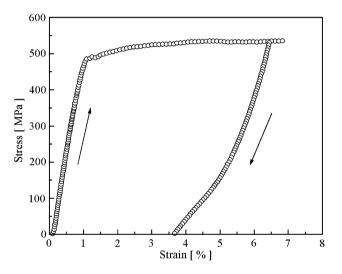


Fig. 7 Stress-strain tensile curve of the wire in the delivery state (alloy no 2)

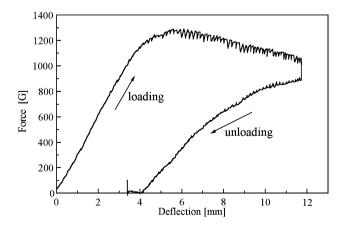


Fig. 8 The force-deflection loading-unloading curve for the 3-point bending test (alloy no 2)

Fig. 9. Figure 9a shows the only one peak on both curves at low temperatures related to the reversible martensite transformation. The effect of predeformation and ageing at 500 °C for 15 min is shown in Fig. 9b. The cooling curve shows two peaks related to the $B2 \Rightarrow R \Rightarrow B19'$ transformation sequences. The peak of the martensitic transformation shows an overlapping of two peaks characteristic for the aged alloys. The same sequences of a reverse transformation are seen on the heating curve. As it can be seen at room temperature the aged alloy is in a fully parent phase state.

Ageing of a straight wire has shown the possibility of improving the elastic behaviour of this wire but still the amount of permanent strain was 2.5%. Considerable improvement of superelastic behaviour has been achieved by ageing of the wires preliminary deformed by tension. The 3-point bending test for such a state after ageing at 500 °C for 15 min shown in Fig. 10 exhibits a typical superelastic curve with very low (about 0.1%) permanent strain.

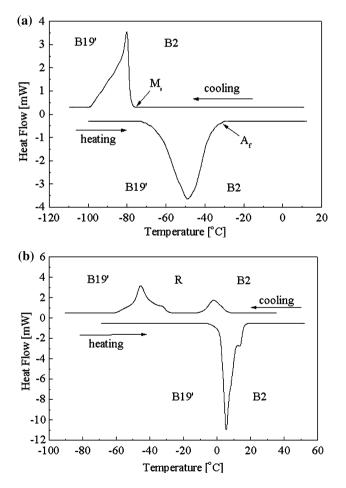


Fig. 9 DSC cooling and heating curves for alloy no 1 (a) for the delivery state, (b) after the preliminary deformation and ageing for $500 \text{ }^{\circ}\text{C}/15'$

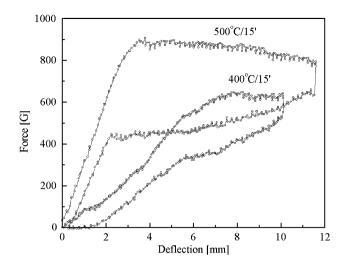


Fig. 10 Comparison of the 3-point bending test for prestrained wires aged at 400 $^{\circ}\mathrm{C}$ and 500 $^{\circ}\mathrm{C}$

Large differences of superelastic behaviour shown in Fig. 10 for the samples aged at 400 and 500 $^{\circ}$ C can be explained by the fact that ageing at 400 $^{\circ}$ C induces the R-phase transformation. As a result, the wire contains both the parent and R phases. The elastic modulus of the R-phase is three times lower than for B2 parent phase which causes the worsening of the elastic characteristic of this wire.

The favourable affect of small deformation on induced superelasticity is also shown in Fig. 11 which shows the deformation by flattening the rings.

The formed rings were welded and aged at the optimal temperature and time (500 °C/15′). The ageing of rings results in hardening the parent phase by the precipitation of the coherent Ni_4Ti_3 phase. As a consequence, during

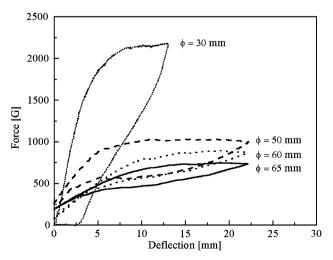


Fig. 11 Superelastic behaviour of the rings of different diameters while deflecting to an elliptic shape and their reversion to the previous ring shape

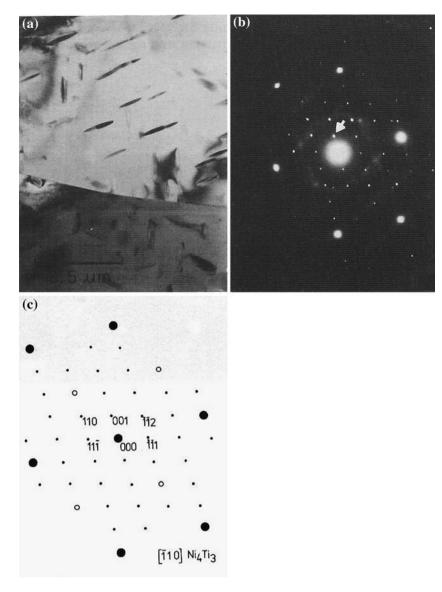


Fig. 12 Particles of Ni_4Ti_3 phase in the alloy aged at 500 °C for 1 h (a) bright-field image (b) diffraction pattern from the area (a), (c) indexed electron diffraction pattern

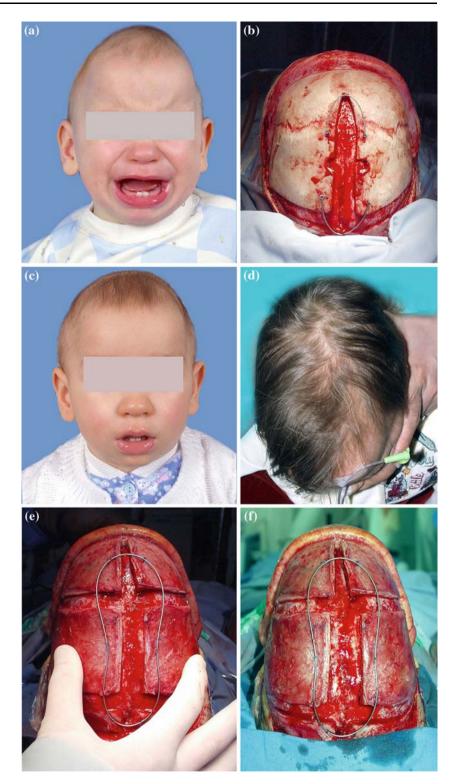
deformation the parent phase exhibits superelastic behaviour with a clear force plateau shown in Fig. 11 for rings of different diameters. As it can be seen, the level of force plateau lowers when the ring diameter increases.

The rings with the smallest diameter (D = 30 mm) show the highest force of the plateau but simultaneously a large residual strain. This residual strain is caused by the dislocations which appear at the interface between the parent phase and martensite due to the stress induced martensite.

The smaller is the diameter of the ring the larger is the pre deformation during it forming and the higher is the induced stress. Does mean that a relatively low deformation before the ageing is favorable for the precipitation process. The precipitation of particles and their identification was done using the TEM method. Figure 12 shows the disc shape of the coherent precipitation and their diffraction pattern.

This particles cause the matrix lattice distortion which achieve the maximum values perpendicular to the axis of the particles. In case of coherent Ni₄Ti₃ particles this maximum appears in the < 111 > direction of the matrix and is equal to the lattice misfit of both phases $\delta = (d_{111p}-d_{111B2})/d_{111B2} = 2.9\%$ and acts as tensile tension in this direction. Perpendicular to the < 111 > direction: [110] and [112] the lattice misfit is equal 1.4% and acts as compression stress. As a result the stress distribution around the particle is inhomogeneous but exhibits symmetry in respect to < 111 > direction [6, 7].

In accordance with the results obtained by Chumlyakov et al. [8] the superelastic effect is induced only **Fig. 13** Application of superelastic springs and rings in cranioplasty



under the following conditions: Ni_4Ti_3 particles are coherent to matrix and they do not undergo martensitic transformation and have the size of 50–100 nm. Coherent particles of Ni_4Ti_3 are the source of internal stress, sites of preferable nucleation of martensite and assist lowering of the stress plateau. On the other hand particles do not undergo martensitic transformation and when induced into the martensite plates become the source of reverse stress fields and assist the storage of elastic energy [9]. As shown by Pelton et al. [10], the ageing parameters should be optimized to achieve maximum precipitation rates. Clinical craniofacial reshaping by long-term distraction with the use of superelastic springs and rings was carried out in the Hospital and Clinic of Plastic Surgery in Polanica. The positive results of the operations carried out with the use of the superelastic springs and rings can be seen in Fig. 13.

Conclusions

- The method of forming superelastic rings was worked out using precipitation hardening of the rings previously formed out from wires of the NiTi alloy containing 51 at% Ni.
- Superelastic springs and rings deformed by bending act with constant force in the desired displacement range.
- Clinical research confirmed the possibility of applying superelastic rings and springs in cranioplasty.

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