Eur Spine J (2002) 11 : 100–106
DOI 10.1007/s005860100347

ORIGINAL ARTICLE

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Scoliosis correction with shape-memory metal: results of an experimental study

Received: 22 May 2000
Revised: 6 July 2001
Accepted: 13 August 2001
Published online: 14 November 2001

This work was supported by STW (Netherlands Technology Foundation).

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Abstract The biocompatibility and functionality of a new scoliosis correction device, based on the properties of the shape-memory metal nickel-titanium alloy, were studied. With this device, the shape recovery forces of a shape-memory metal rod are used to achieve a gradual three-dimensional scoliosis correction. In the experimental study the action of the new device was inverted: the device was used to induce a scoliotic curve instead of correcting one. Surgical procedures were performed in six pigs. An originally curved squared rod, in the cold condition, was straightened and fixed to the spine with pedicle screws. Peroperatively, the memory effect of the rod was activated by heating the rod to 50°C by a low-voltage, high-frequency current. After 3 and after 6 months the animals were sacrificed. The first radiographs, obtained immediately after surgery, showed in all animals an induced curve of about 40° Cobb angle – the original curve of the rod**.** This curve remained constant during the follow-up. The postoperative serum nickel measurements were around the detection limit, and were not significantly higher compared to the preoperative nickel concentration. Macroscopic inspection after 3 and 6 months showed that the device was almost overgrown with newly formed bone. Corrosion and fretting processes were not observed. Histologic examination of the sections of the surrounding tissues and sections of the lung, liver, spleen and kidney showed no evidence of a foreign body response. In view of the initiation of the scoliotic deformation, it is expected that the shape-memory metal based scoliosis correction device also has the capacity to correct a scoliotic curve. Moreover, it is expected that the new device will show good biocompatibility in clinical application. Extensive fatigue testing of the whole system should be performed before clinical trials are initiated.

Keywords Scoliosis · Surgery · Correction · Shape memory metal · NiTi

Introduction

Operations for scoliosis are designed to correct the deformity and to prevent its progression by achieving a solid fusion. In 1962, Harrington introduced the use of spinal instrumentation for the surgical treatment of scoliosis [16]. In the 1980s, the development of spinal instrumentation expanded considerably. New anterior and posterior systems were introduced [2, 6, 10, 12, 18, 32]. With these advanced segmental systems, better corrections are possible in the coronal and the sagittal plain in comparison with Harrington instrumentation. However, the literature is contradictory on the effect on axial rotation and rib cage deformity. In most literature it is suggested that axial plane correction is limited [13, 19, 21, 33].

Because of its special properties, the nearly equiatomic nickel-titanium alloy, could be very suitable for use in a scoliosis correction device. The alloy belongs to a group of metals that demonstrate the ability to return to some previously defined shape when subjected to a thermal treatment (shape-memory alloys). At present, the shape-memory nickel-titanium alloy is used clinically in wires for orthodontic tooth alignment, osteosynthesis staples, and vascular applications, for instance in a stent and a vena cava filter [1, 5, 11, 17, 22, 26, 31]. In the area of scoliosis correction, Schmerling and co-workers experimented with a shape-memory metal rod to replace a standard Harrington rod in a human cadaver in the early 1970s [30]. Preliminary investigations were also conducted with an anterior system: a shape-memory metal wire was used with Dwyer instrumentation [4]. In China, Lu reported on surgical procedures in patients with an idiopathic scoliosis using shape-memory metal rods instead of Luque rods [22].

Veldhuizen and colleagues have developed a shape-memory metal based scoliosis correction device for a posterior surgical approach that is unique, because it is engineered from the start with the aim of obtaining a gradual three-dimensional correction of the scoliotic deformity [29, 34]. This new device is expected to keep the spine force loaded postoperatively, and it is believed that this will take advantage of the viscous behavior of the spine in order to obtain extra correction. Just like the current operative scoliosis correction methods, the new system seeks to achieve a postoperative fusion. This fusion should prevent failure of the system in the long term. It is expected that the additional postoperative correction can be obtained before this vertebral fusion takes place.

Although the biomedical application of shape-memory metal in a scoliosis correction device is intriguing, the implantation of nickel-containing materials in the human body requires caution, especially when such devices are implanted into young patients [8]. Moreover, it is well known that spinal implants are prone to corrosion due to their construction. In particular, the junction between pedicle screw, hooks and sublaminar wires to the rod might lead to biocompatibility problems [3, 9, 35, 36]. Therefore, new spinal implants should be examined in vivo to ascertain whether corrosion and a reaction in adjacent tissue occur.

The aim of this study is to evaluate the shape-memory metal based scoliosis correction device in an animal model to determine its functionality by initiating a scoliotic deformation, and to evaluate possible local and systemic toxicity.

Materials and methods

Surgical procedure

Six immature pigs, approximately 6 months old, weighing between 70 and 90 kg were used in the study. The size and shape of the spine of these animals resembled the human spine. All pigs were identified with numbered ear tags. The operations took place under standard sterile conditions. Permission for the protocol followed was obtained from the regional ethical committee for experiments on animals.

The induction of anesthesia took place with 800 mg ketamine, 50 mg Valium, and 0.4 mg Robinal, administered intramuscularly. The animals were then transported to the operating room and placed in a prone position. Endotracheal intubation was performed. General anesthesia was maintained with isoflurane 2–3% in O_2. Intravenous antibiotics were administered (1000 mg ampicillin) and muscle relaxants (4 mg Pavulon i.v.). Continuous monitoring of vital parameters such as oxygen saturation and ECG was maintained during the entire operation.

Preoperatively, a blood sample was taken to determine the serum nickel concentration. The determination of the serum nickel concentration was achieved using atomic absorption spectrometry [38]. After being positioned, the animals were shaved, disinfected and covered with a sterile cloth. A longitudinal skin incision was made along the median line from T11 to L5. These vertebrae were identified prior to surgery using X-rays. The paravertebral muscles were stripped subperiosteally from the spinous process and laminae and shifted to lateral. Then the pedicle insertion points were

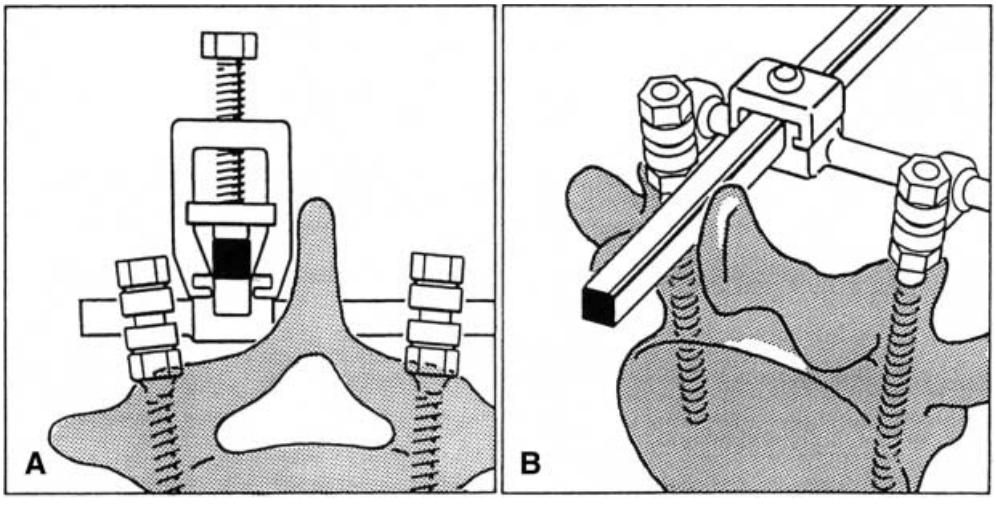

Fig. 1 **A** Transversal view of the approximator, which is used for positioning of the rod on the rod-bridge interface. **B** An oblique view of the definitive fixation of the rod on the bridge

identified on both sides of T12, L2 and L4. Access to the pedicle was obtained with the pedicle probe and, after tapping, the pedicle screws (4.75×40 mm) were placed. Care was taken to damage as little periosteum or bone as possible during this procedure. The pedicle screws were connected to a bridge at the three levels.

In order to initiate the scoliotic curve, a square shape-memory metal rod (6.35×6.35 mm) with rounded edges and an original curve of 40° Cobb angle was used. The transition temperature of the rod, i.e., the temperature at which low-temperature phase martensite changes to the high-temperature phase austenite, was 25°C. For the composition and surface treatment of the used shape-memory alloy, the reader is referred to the articles on corrosion and biocompatibility [37, 38]. The rod had been stored in sterile conditions at –18°C. The bent rod was easily straightened in this cold condition, using the "bender" prior to its application to the animal spine. Then it was positioned on the bridge with a specially designed approximator and fixed with a cap while the set screw was not yet tightened (Fig. 1). Next, the shape-memory effect of the rod was activated by heating the rod to a temperature of 50°C with a high-frequency, low-voltage electric current, using a specially developed heating apparatus (Fig. 2). To control the maximum temperature, two thermocouples continuously monitored the rod's temperature during this procedure. After being heated, the set screw was tightened. This bridge-rod connection was not a fixed connection. Small shifts under the set screw were possible for postoperative correction. The wound was then closed layer by layer.

Postoperative period

After closure of the wound, anteroposterior and lateral radiographs were obtained and a second intravenous nickel sample was taken. The test animals were then transported to their pens. Postoperative analgesia was given in the form of flunixin 200 mg i.m. Antibiotics continued to be administered until 3 days after surgery. As in clinical practice, follow-up took place after 1 week, after 6 weeks and after 3 months. Radiographs were obtained and a nickel sample was taken. Both were performed under brief anesthesia. After 3 months, three animals were sacrificed with an injection of T61 (euthanasia solution). After 6 months, the remaining three animals were sacrificed using the same procedure.

Immediately following sacrifice, routine gross necropsy was performed. Dissection and macroscopic inspection of the instrumented part of the spine took place. For histologic evaluation, samples were taken from the tissues in close contact with the device, especially tissue adjacent to the pedicle-bridge and bridge-rod connection, to look for potential wear debris effects. Additional samples were obtained from the periaortic lymph nodes, lung, spleen, liver and kidneys. The tissue samples were preserved in a 10% buffered formalin solution. For light microscopy, the fixed samples were embedded in paraffin, sectioned and stained with hematoxylin-eosin and toluidine blue.

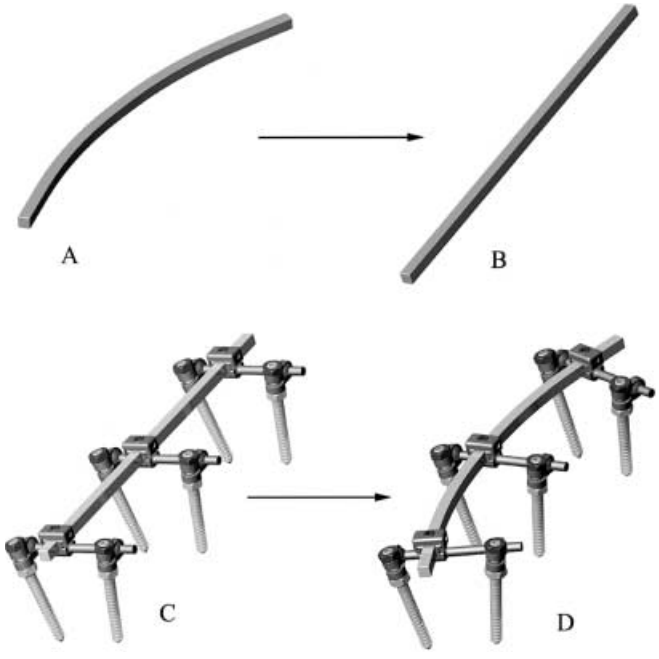

Fig. 2A-D Oblique view of the used instrumentation and successive steps in the animal experiments. **A** The original shape of the rod in the cold condition. **B** The straightened rod before implantation and heat treatment. **C** The implanted straightened rod with anchor system. **D** The recovered original curve of the rod with anchor system after heat treatment

Results

The implantation procedure proved to be relatively simple and caused no complications in any of the animals. In one procedure, the positioning of the rod took more time and the rod began to return to its original curve due to the body heat of the test animal. The rod was cooled down again and straightened. It was then possible for the rod to be placed in a satisfactory position.

A significant scoliosis was induced in all test animals by heating the rod during the procedure. Macroscopically, no signs were found of tissue damage when the rod was heated to 50°C. The first radiographs, made immediately after surgery, showed a curve of about 40° Cobb angle – the original curve of the shape-memory metal rod. There were no indications that the pedicle screws had broken loose, that the posterior complex was fractured, or of any other failure of the device. The induced Cobb angle of about 40° remained constant on the radiographs after 1 week, 6 weeks, and 3 months of follow-up.

Postoperatively there were no signs of neurologic dysfunction; the animals recovered quickly and often mobilized a few hours after surgery. Moreover, the animals did not exhibit any discomfort from the scoliosis induction. One of the animals developed a wound infection, caused by the shape-memory metal rod, which extended too far distally. In view of the nature of the complication (a complication of the implantation procedure), the animal was sacrificed prematurely and excluded from the study. Because of this exclusion, a new test animal was added to the study. The radiographs taken after 1 week showed a loosened connection between the rod and the bridge in one animal. This caused no further complications, and therefore this animal remained included in the 3 months evaluation.

The animals that were sacrificed after 3 months had reached a weight of about 120 kg. Macroscopic inspection of the scoliotic segment showed that the device was almost overgrown with newly formed bone. Corrosion, fret-

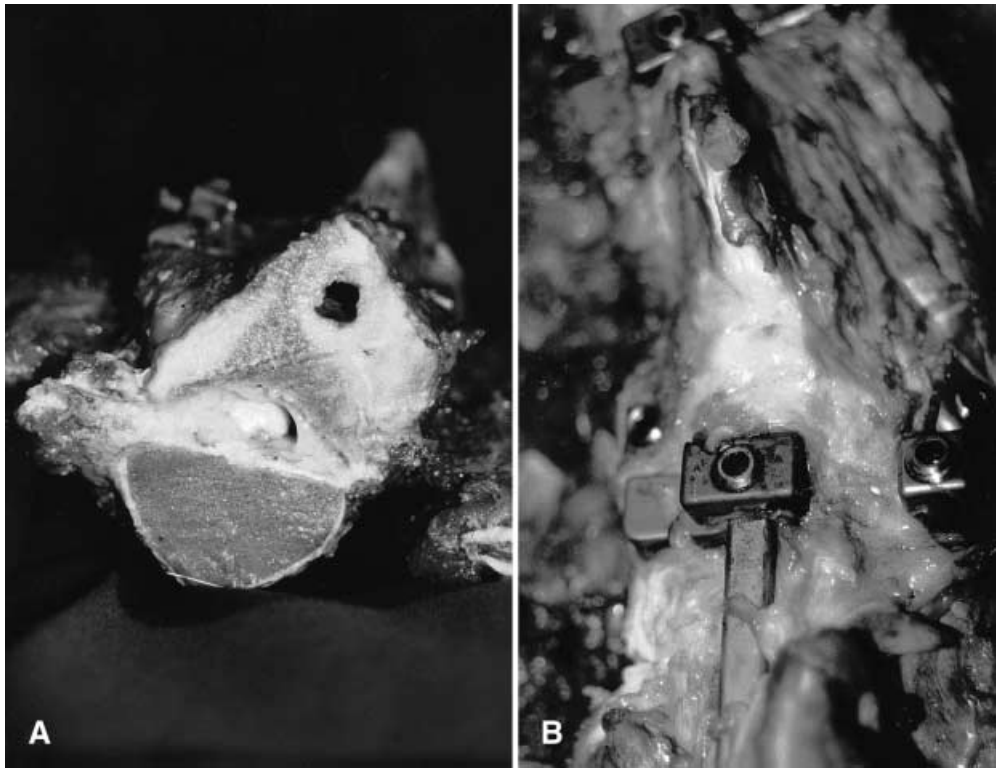

Fig. 3 **A** Transversal and **B** dorsal view of the shape-memory metal correction system, covered almost completely with newly formed bone after 6 months follow-up

ting, tissue discoloration, or accumulation of black granular material due to corrosion and wear processes around the rod or near the rod-bridge interface were not observed.

In two of the three animals that were sacrificed after 6 months (they weighed about 160 kg each), the radiograph showed a rod breakage. In both cases the breakage had occurred near the rod-bridge connection. The breakage had not been observed in the radiological follow-up after 3 months. Moreover, the induced scoliotic curve had remained unchanged. Macroscopic inspection of the instrumented spine segment of all cases showed a completely fused spine. The rod had been covered with newly formed bone, except for tips of the rod (Fig. 3). The two animals with the broken rod showed no indication of pseudoarthrosis. Moreover, the device and instrumented spine showed no signs of local stress or fretting corrosion on visual inspection.

Histologic examination of the sections of the surrounding tissues and sections of the lung, liver, spleen and kidney of the animals that were sacrificed after 3 and 6 months showed no evidence of an acute or chronic inflammation reaction.

The serum nickel measurements, immediately postoperatively, and 1 week, 6 weeks, 3 months and 6 months postoperatively, showed values hovering around the detection limit of 2.5 μg/l (max. 4.8 μg/l), and were not significantly higher than the preoperative nickel concentrations. Nor were higher nickel concentrations found in the case of the loosened rod-bridge connection or in the animals with rod breakage.

Discussion

In current surgical methods, more or less instantaneous correction of the scoliotic curve is achieved by a maneuver performed by the surgeon with the aid of the spinal instrumentation. With the shape-memory metal based scoliosis correction device, a new form of scoliosis correction is introduced: a force-driven correction, in which a shape-memory metal rod functions as the correcting element.

The so-called “one-way shape-memory effect” of the alloy is used for the scoliosis correction. The initial situation is a rod well below the transition temperature, in the lower temperature form (martensite phase). In this phase, the rod has a very low yield strength, and can be deformed quite easily into the shape of the scoliotic spine. In this shape, the rod can be fixed to the spine using a relatively easy procedure. When the rod is subsequently heated to its higher temperature form (austenite phase), it will regain its original shape and rigidity. If this shape recovery is prevented, the rod generates considerable shape recovery stresses. Using an adequate anchoring system, these stresses can be turned into forces that correct the scoliotic curve. The desired shape after the heat treatment can be programmed prior to the correction procedure by bending the rod beyond its reversible limit of about 6–8%. The rod can then be bent to the sagittal curve and, if desired, to the scoliotic rest-curve.

The device is designed in such a way that forces are generated that induce a bending moment to correct the lat-

eral and sagittal curves of the scoliotic spine, and a torque to correct the axial rotation. A good torque transfer is ensured by the square cross-section of the shape-memory metal rod. The size of the rod (6.35×6.35 mm) was chosen with respect to the selected magnitude of the load applied by the device: based on data from literature, a maximum bending moment of 7.5–10 Nm was chosen for the correction of the lateral deviation and a torque of 2–5 Nm for the correction of the axial rotation [29, 34]. From biomechanical tests of the shape-memory metal rod, it appears that the desired correction moments are achieved when the deformed rod is heated to a temperature of between 40°C and 50°C. In this situation, the rule applies that the higher the overshoot in temperature above the body temperature, the larger the correction forces: for example, 10°C increase in temperature realizes an extra bending moment of about 4 Nm. Resistive heating, using a low-voltage, high-frequency current, was chosen to heat the rod [29, 34].

Before the innovative device may be applied clinically, it should meet two important criteria: functionality and biological safety. Preliminary tests on human cadavers showed that the device can be implanted easily, and that it is capable of inducing a scoliotic curve with a Cobb angle of about 45° [29]. In the presented experimental study, the shape-memory metal rod induced a significant scoliotic deformation in all test animals. The initiation of the curve took place without the pedicle screws breaking out and without failure of the rod-anchor system. The original curve of the rod was regained in the first hour after implantation, and remained constant during the entire experiment.

It should be borne in mind that the animal study deals with a healthy lumbar spine of young animals, in which a scoliotic deformation was induced. The size and the speed with which the curve is induced will finally depend on the reaction forces that occur in the spine. If smaller forces had been applied during the experiment, it is likely that part of the scoliosis induction would have taken place postoperatively. The extrapolation of the results of scoliosis initiation in the animal study to the human situation is difficult. In clinical applications, the device will be used to correct a scoliotic curve – a situation in which not only elastic, but also structural, deformations have taken place in the spine. In the future, clinical trials will have to show whether the correction forces have been well chosen and whether the viscous properties of the spine may be utilized for a postoperative correction.

Extensive corrosion and biocompatibility experiments have already been performed with the nickel titanium alloy used in this study. In these biocompatibility experiments, conducted according to the regulations of the International Organization of Standardization (ISO), the shape-memory metal, nickel-titanium alloy provoked no cytotoxic, allergic or genotoxic responses [37]. An excellent implantation study was published by Ryhänen et al. [27]. In their study, the general soft tissue responses to nickel-titanium were compared with corresponding responses to stainless steel and Ti6Al4 V alloy in rats. The overall inflammatory response of the nickel-titanium alloy was comparable to both other alloys. The good biocompatibility and the associated good anti-corrosive properties of the shape-memory metal may be ascribed to the strong bonding between the nickel and titanium atoms, and the presence of a mainly passive, TiO_2-based, surface layer [25, 38]. This protective, chemically stable, oxidized passivation layer is also thought to be responsible for the good anti-corrosive properties and tissue compatibility of the titanium alloy, Ti6Al4 V [15, 20]. Moreover, studies have revealed that titanium-based alloys naturally form a calcium-phosphate layer on their passive oxide film after exposure to a bioenvironment. It is suggested that the formation and growth of this layer is governed by the existence of titanium oxide, and may serve as a further barrier against ion diffusion [14, 38]. However, biological safety is not only determined by the corrosive properties and the potential toxicity of the used metal, but also by the construction design of the device. The junction between the rod and the anchoring system in spinal devices may cause a local mechanical breakdown of the protective surface layer. Especially in the case of pseudoarthrosis, cyclic movements at the non-fused level may initiate corrosion and fretting processes, which may cause an increase in the passive ion release or a release of particulate wear debris [3, 9, 35, 36]. Local tattooing of the surrounding soft tissue by wear debris and the accumulation of gray, brown or black serosanguineous fluid are typical signs of these wear processes. The inflammatory response ultimately depends on the degree of wear, the particle size and toxicity, the rate at which the oxide surface film may be re-established, and environmental conditions [39]. The presence of a continued soft tissue inflammation caused by the corrosion and wear processes may have a deleterious influence on the spinal fusion mass, due to bone resorption.

J. O. Sanders and co-workers reported on experiments with goats in which a shape-memory metal bar was attached to the spine with transspinous process wires of stainless steel [28]. A good curve correction of the previously induced scoliotic curve was achieved, but the fixation of the rod to the spine with the stainless steel wire fixation caused sedimentation of black granular material and increased nickel and titanium levels in the surrounding tissues. A comparable study was conducted on monkeys, in which two L-shaped, shape-memory metal rods were attached to the spine with sublaminar wiring comparable to the Luque system [23]. It was concluded that the device could induce a gradual correction of the induced scoliotic correction, and that the correction rate could be controlled through the rod's temperature. Some doubts were vented about the biocompatibility, because, postoperatively, significantly higher nickel concentrations were found in blood and urine than the concentrations found in a control

group. Fretting between the sublaminar wire fixation and shape-memory metal bar was again considered the most probable cause of the increased nickel concentrations that were found.

The device used in the present study was fixed to the thoraco-lumbar spine with pedicle screws. The screws were connected to a bridge on which the shape-memory metal rod was fixed. Fixation of the rod was achieved with a set screw after the larger part of the scoliotic deformation had been induced. At the follow-up after 3 and after 6 months, no indications of corrosion or fretting near the rod-bridge or pedicle-bridge junction were found. In addition, the postoperative serum nickel measurements showed values hovering around the detection limit, and were not significantly higher than the preoperative nickel concentrations. Histological examination of the tissue adjacent to the device showed normal tissue reactions without evidence of an acute or chronic inflammation response. Moreover, the instrumented spine had been covered almost completely with newly formed bone, which is also a sign of a good tissue tolerance.

In spite of the solid spinal fusion, a rod breakage was found after 6 months follow-up in two of the three animals. It is known that a good fusion prevents metal fatigue and implant failure. It should be noted that the weight and length of the immature animals increased during the study: in the phase that the rod broke, the animals weighed between 140 and 160 kg. Moreover, extensive mechanical in vitro tests were performed on the rods in question prior to the animal experiments. Data on shape-memory metal fatigue are scarce. In terms of flexion fatigue, it is allegedly superior to stainless steel [28]. Nevertheless, shape-memory metal is known to be a notch-sensitive material [7, 8]. In this study both rod breakages occurred close to where the rod was connected to the bridge. Therefore, local damage of the rod caused by the anchoring system seems one of the most probable causes of the rod failure.

In summary, given the results in this study, it is expected that the shape-memory metal based scoliosis correction device has the capacity to correct a scoliotic curve. Moreover, it is expected that the new device will show good biocompatibility in clinical application. Modifications of the current design, the development of a thoracic fixation system and extensive fatigue testing of the whole system should be performed before the clinical trials can be initiated.

Acknowledgements We gratefully acknowledge B. van Leeuwen from the Division of Artificial Organs, Faculty of Medical Sciences, University of Groningen, for performing the histological procedures, D.R.A. Uges and J. Ijmker, from the Pharmacy Department of the University Hospital Groningen, for the nickel measurements, and G. Rakhorst, G. Nijenbanning and M.M. Sanders for useful discussion.

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