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

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 O2. 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...