Post-operative monitoring of nickel ion level in scoliotic patients operated with novel nickel-titanium superelastic spinal implant

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Introduction: Nickel-titanium (NiTi) shape memory alloys have been used as surgical implants in orthopaedic procedures. However, nickel ion release remains a concern. Therefore, an advanced surface technology using plasma immersion ion implantation (PII) has been developed to address this issue. This paper describes serum nickel ion level monitoring of patients with scoliosis operated upon using nitrogen plasma implanted NiTi spinal rods compared with standard titanium alloy rods in a randomized human clinical trial.

Methodology: NiTi spinal rods with 50.8% Ni were treated by nitrogen PII at 40kV with 100Hz. Seventeen patients with spinal scoliosis were surgically treated by either Ti alloy rods or nitrogen plasma implanted NiTi rods. The mean age at operation was 16.6 years. The mean number of treated spinal segments was 9. Blood samples were collected as baseline before surgery and up to 1 year post-surgery. Nickel levels were assayed by inductively coupled plasma mass spectrometry.

Results and discussion: Twelve patients (7M and 5F, 6=NiTi and 6=Ti) were followed up for 6 months, and five patients (2M and 3F, 2=NiTi and 3=Ti) had completed 1-year follow-up. In all cases, at Day 1 after surgery, patients who had NiTi rods implanted had a 2.5 times increase in the Ni level compared with before surgery. However, all were within recommended safe limits. The Ni levels returned to baseline in all subjects between 7 days to 1 month post-surgery. No clinical signs and symptoms of Ni allergy or toxicity was observed. The elevated Ni level at early time points may attribute to the unprotected ends of NiTi rods. Due to surgical limitation, the full length (from T4-L5) of plasma treated rod has to be cut short during surgery so as to fit into the operated levels. The unprotected ends will be exposed to human body, thereby likely resulting to the raise of Ni levels at post-op Day 1. At later time points the passivation of unprotected ends may contribute to the subsequent reduction of Ni level.
Fig. 1 Intra-operative picture of scoliosis correction surgery. The patient implanted with dual NiTi alloy rods from T4-T12 with the use of posterior approach and the scoliotic curve had been then straightened right away.

Fig. 2 Serum nickel concentration of patients undertaking NiTi spinal implant and conventional Ti spinal implant after Day 1 to 6 months of operation. The Ni levels of the patients implanted with NiTi rods have increased at post-op Day 1 as compared with the patients with Ti alloy rods. However, the Ni levels have reduced to the amounts similar to the control group at post-op 24 weeks.

Fig. 3 Serum nickel concentration of patients undertaking NiTi spinal implant and conventional Ti spinal implant after Day 1 to 12 months of operation. The pattern of Ni levels of the patients with NiTi rods at post-op Day 1 to 24 weeks is similar to Fig. 2. Additionally, the serum Ni concentration in NiTi group remains at low level at post-op 1 year, which is comparable to the control group.

Conclusion: In summary, this study has demonstrated the safety and feasibility of nitrogen plasma treated NiTi spinal rods, which allow for a gradual change in spinal sagittal curvature, in scoliosis correction surgery. The increase of Ni level in serum has been found at initial time points. However, the level returns to the amount comparable to the control group at post-op 24 weeks.

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