

Metallosis is a complication of Titanium Growth Guidance Sliding Device LSZ-4D for early-on-set scoliosis treatment

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ICEOS

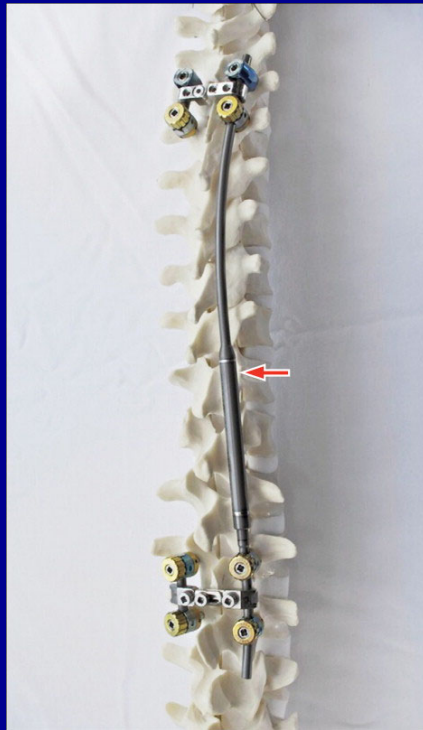
8TH INTERNATIONAL CONGRESS
ON EARLY ONSET SCOLIOSIS
AND GROWING SPINE

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Instrumentation for early-on-set Scoliosis treatment

Growing rods



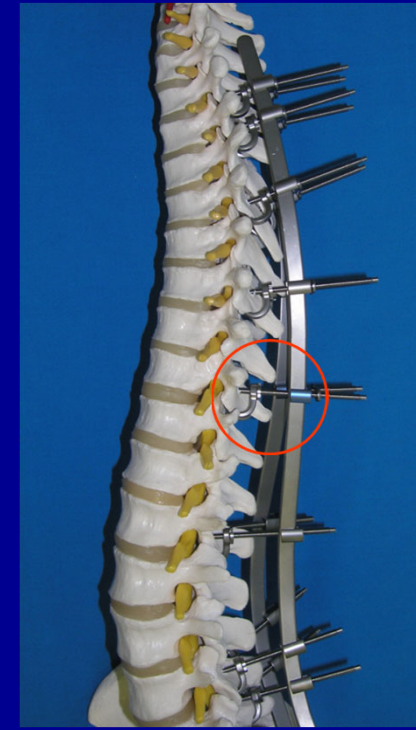
MAGEC (Ellipse, USA)

**Periodic extensions are required
(at least twice per year)**

Growth-guidance sliding devices



Shilla (Medtronic, USA)



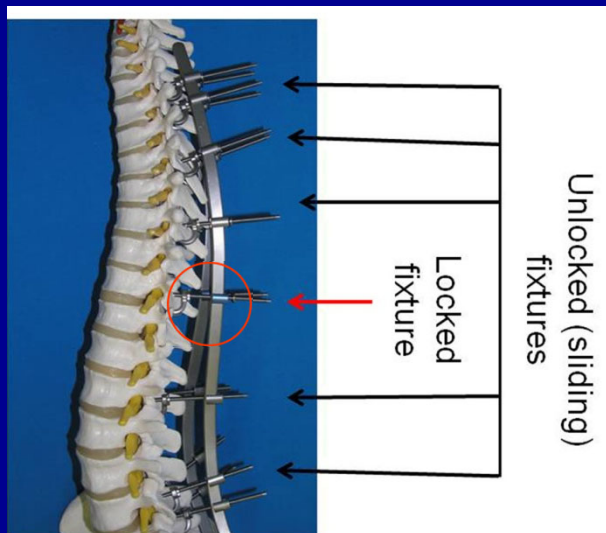
LSZ-4D (Conmet, Russia)

**Movement of rods against fixtures in
sliding devices might result in
excessive wear debris and metallosis**

The aim of our study was to evaluate the long-term complications and to reveal the content of metal ions in the blood and tissues after implantation of LSZ-4D sliding device made of titanium alloy (Ti6Al4V)

Study design: retrospective, Single clinical center study (Children's Hospital 38, Moscow, Russia)

LSZ-4D (Conmet, Russia)



Study group of patients:

25 patients (3m, 22 f) with LSZ-4D sliding devices

Age at primary surgery: 11.4 ± 1.2 years;

LSZ-4D included: 2 rods (6x4mm) and 40 fixture elements (20 ± 4 hooks and 20 ± 4 clips).

Material of device: Ti6Al4V;

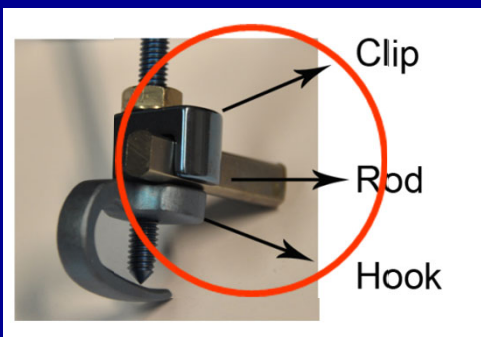
Number of operated levels: 10 ± 2

Implantation time: 6 ± 2 years

Control group of patients:

10 patients (1m, 9 f) without any implanted devices

Age : 11 ± 1.2 years



Methodology:

Content of Ti, Al and V ions in the whole blood and tissues was measured by ICP-MC on Nexion 300D (Perkin Elmer, USA)

Results of correction

Preoperative Cobb's angle, mean (range)	Number of patients	Postoperative Cobb's angle (3 year follow-up), mean (range) °	Correction rate
45 (30-50) °	8	9 (5-30) °	
85 (46-132) °	17	23 (17-50) °	

Long-term complications

5 patients had metallosis related complications:

2 seromas;

1 fistula without inflammation;

1 seroma accompanied by pyrexia?infection

1 fistula with inflammation

} Conservative treatment

} Revision surgery

4 patients had rods breakage

Content of metal ions in the whole blood

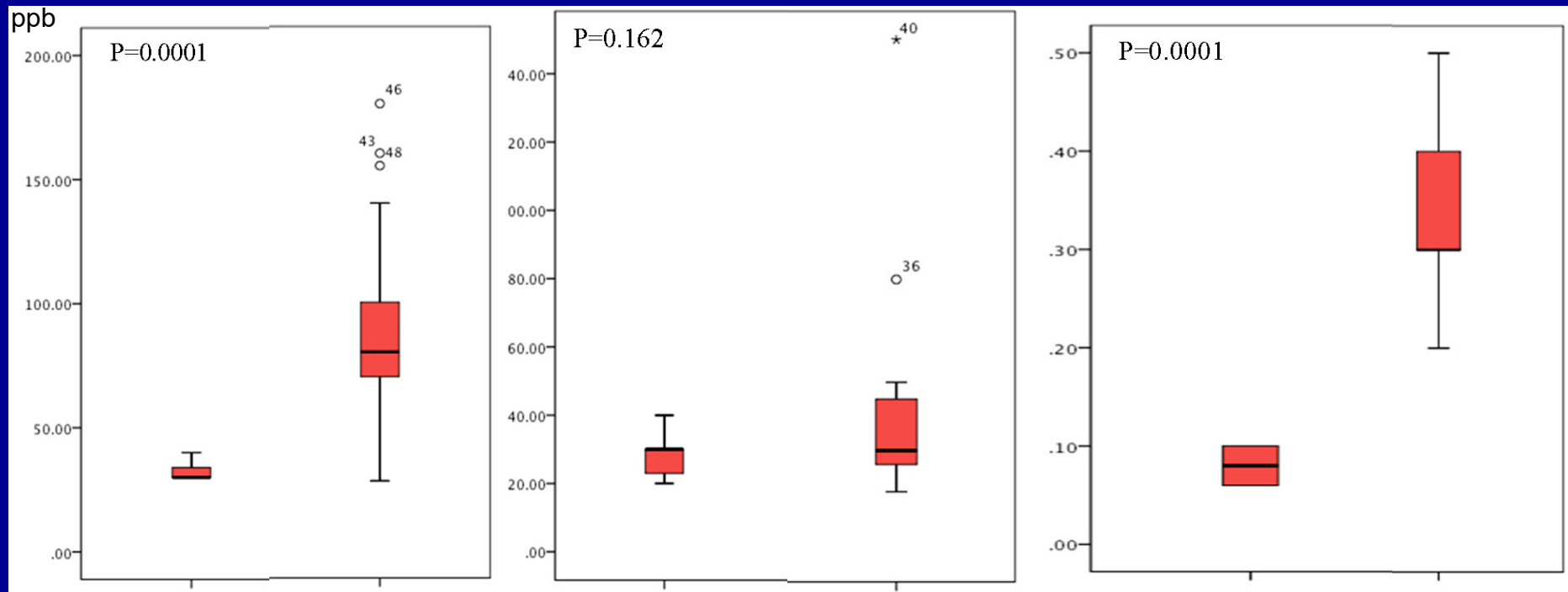
Titanium

2.8 fold increase

Aluminum

Vanadium

4 fold increase



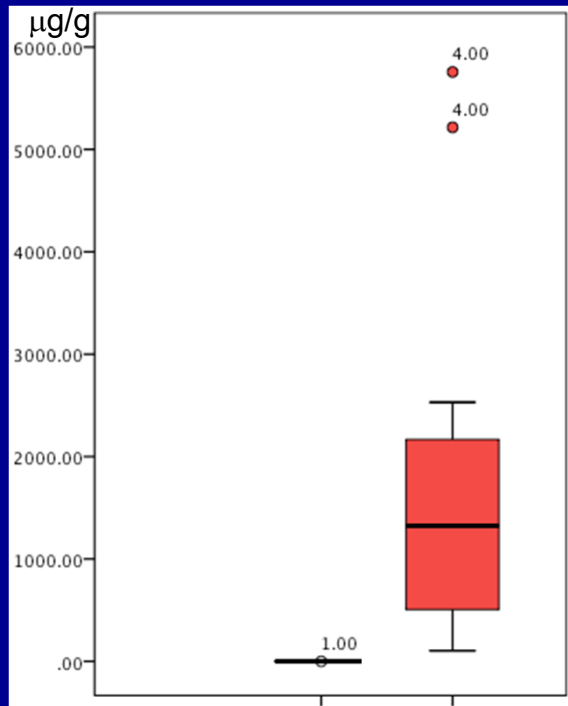
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- Patients who developed complications did not have any higher content of metal ions
- Similar increase of metal ions in patients' blood was reported by Kasai et al (Spine,2003), Richardson et al (Spine, 2008), Cundy et al (Spine,2013) after implantation of traditional fusion spinal instrumentation

Content of metal ions in tissues

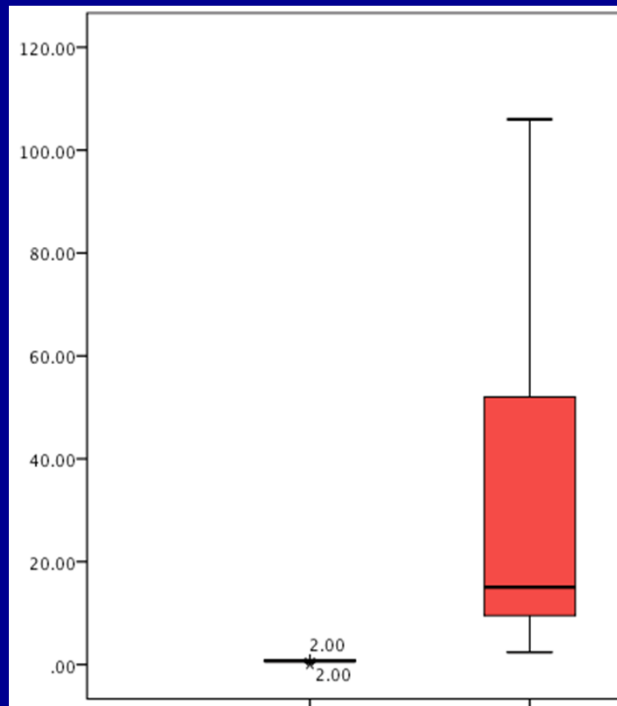
Titanium

> 1,500 fold increase



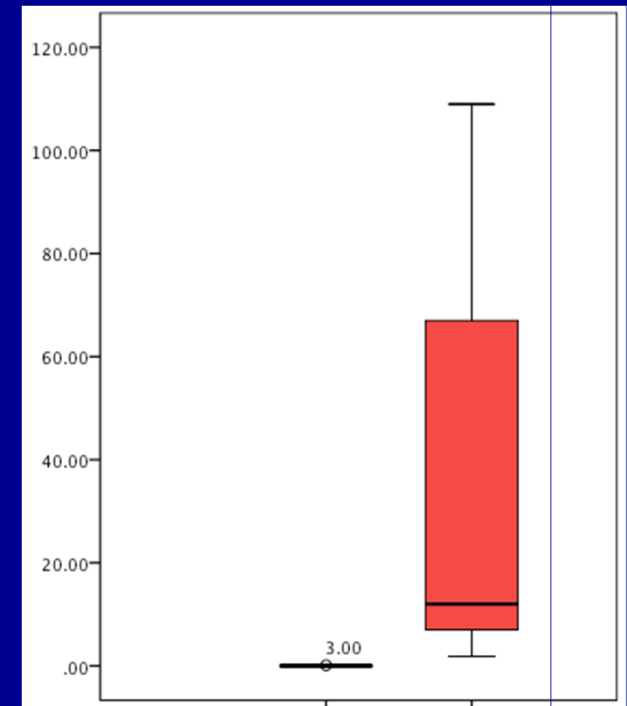
Aluminum

>30 fold increase



Vanadium

>100 fold increase



Control group Study group Control group Study group Control group Study group

- These values are much higher compared to those reported (30 fold for Titanium) previously (Wang et al, Spine, 1999) for spinal implants;
- It may be assumed that such high content of metal debris could be the reason of local clinical manifestations

Conclusions:

- 5 of 25 patients with implanted sliding LSZ-4D devices made of titanium alloy Ti6Al4V developed seromas or fistulas in the lumbar part of the spine. All patients had **significantly** increased levels of metal ions in the blood and tissues.

Limitations of the study:

- Only applicable to the described sliding device since the volume of wear debris depends on the **design** of sliding device, **wear resistance** of used material, **quantity** of fixture elements, **rod length**.

Recommendations:

- The level of metallosis needs to be characterised and understood. In order to completely exploit the benefits of sliding instrumentation application of biocompatible wear resistant ceramic coatings might be beneficial