

# Metal Release from Spinal Instrumentation Implants - Synchrotron-Based Multi-Element Detection in Human Peri-Implant Tissues

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INTRODUCTION:

Safety concerns about the release of metal particles from orthopaedic implants have been raised over decades, recently calling into question the use of metal-on-metal hip implants and the practice of off-label mixing of arthroplasty components of different composition. Metallic spinal implants also carry risks of wear and corrosion, and the use of mixed-alloy combinations and metal-metal junctions involving different metal alloys is not uncommon in spine surgery. Yet, the effects of metal particles released from spinal instrumentation into peri-implant bone and soft-tissues have not been studied in-depth.

We aimed to investigate the accumulation and distribution of metals relevant in spinal surgery by spatially micron-resolved synchrotron-based X-ray fluorescence (XRF) imaging of tissue(s) adjacent to metallic spinal instrumentation.

**METHODS:** Ethics approval was obtained from the institutional review board. Peri-implant tissue specimens from n=7 patients were collected during revision surgery of various types of lumbar spinal instrumentation. Excised tissue specimens were fixed in PFA and either embedded in paraffin (soft tissue) or PMMA (soft tissue with bone mineral content). In total, 10 µm tissue sections were analyzed by synchrotron-XRF at the MicroXAS Beamline of the Paul-Scherrer-Institute (Swiss Light Source). The beamline was set to 9.8 keV to excite implant-relevant metals such as titanium, cobalt, chromium, and iron.

## RESULTS:

The spatially-resolved multi-element detection in peri-implant tissue sections revealed exposure to titanium, steel (FeCrNi), and CoCr (Figure 1). Titanium exposure was particularly found in soft tissue samples from around pedicle screw heads, loosened screws, broken screws, and from within the screw channel. Steel particles were detected in soft tissue specimens excised from loosened screws, a broken rod, and in one case from interspinous soft tissue. CoCr exposure was found in one soft tissue specimen excised from the intervertebral disc space.

Figure caption:

**Figure 1** | Synchrotron-based XRF analyses revealed multi-metal exposure in tissues adjacent to spinal implants. (a) Substantial titanium exposure in S1 left-sided, "peri-screw-head" tissue. (b) Co-localized iron-, chromium-, nickel-containing particles (steel) in soft tissue from around a loosened screw. (c) Co-localized cobalt and chromium within tissue from intervertebral disc space L5/S1.

**DISCUSSION AND CONCLUSION:** This is the first study showing significant local accumulation of metal wear particles from spinal instrumentation in adjacent soft and bony tissues analyzed by synchrotron-XRF at the MicroXAS Beamline. Considering potential adverse local tissue reactions including osteolysis and instrumentation loosening and the close anatomical proximity to complex neural networks and articular facet joints, further research is necessary to evaluate the safety of currently used spinal instrumentation components and the practice of mixing components of different metal alloys.

