Retrospective Analysis of Metal on Metal Lumbar Arthroplasties to Report on the Incidence of Metal Hyper-sensitivity in 217 Consecutive Patients

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Purpose of the study: Spinal disc arthroplasty implants are chiefly manufactured from metal and/or polymer materials. These materials include titanium, cobalt-chromium-molybdenum, stainless steels, ultra-high-molecular-weight-polyethylene, and PEEK. Biological reaction to wear debris ultimately requires clinical studies for assessment. Research into biological reaction of metal-on-polyethylene and metal-on-metal wear debris of knee and hip arthroplasties is well progressed, spinal arthroplasties are however not as well documented. The need therefore exists to evaluate the clinical outcome of metal-on-metal spinal disc arthroplasties.

Method: The Swedish Spine Register (SweSpine), in full use for 12 years, provides a resource for retrospective evaluation of adverse events and of clinical outcome. Adverse medical conditions are recorded within the register, which therefore serves as a closed loop of patient feedback for the period recorded. This database was used to select only lumbar arthroplasties featuring CCM-on-CCM wear couples (Kineflex, Maverick and Flexicore). These devices feature "mobile core" and "ball and socket" type of bearing surfaces.

Summary of the findings: In one clinic a total of 217 patients (103 male, 115 female), were treated with 337 "metal on metal" total lumbar disc replacement at one, two or three segments between 2003-10-08 and 2009-05-13. One-hundred and ninety seven cases were eligible for two year follow-up. TDRs were performed utilizing Kineflex in 69 cases and Maverick in 140 cases and FlexiCore in 11 cases. Average age and weight was 41.0 years and 76.6kg respectively. A total of 56 patients had previous spinal operations; 172 were active in sports, 27 were smokers. No reported cases of metal hypersensitivity or metallosis induced pseudo-tumours were recorded on the register or reported elsewhere.

Conclusion: Data from SweSpine provided record of the non-occurrence of symptoms from metal hypersensitivity or metallosis induced pseudo-tumours within this consecutively treated patient-group evaluated.