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Blood Metal Ion LevelsFollowing Implantation of the All-metal FlexiCore® Lumbar Intervertebral Disc Replacement, 24-36 Month Follow-up

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Introduction: Metal-on-metal bearing surfaces have been employed in disc arthroplasty design in efforts to maximize durability, minimize wear debris, provide overall strength, and prolong the life expectancy of the device. The preferred bearings incorporate alloys of cobalt and chromium due to their hardness and resistance to corrosion. Metal wear and corrosion, however, generate insoluble metal particles and soluble metal ions, with the latter passing into systemic circulation. The systemic effect of mechanically-released metal ions warrants examination. The purpose of this investigation was to measure the levels of metal ions in the blood following implantation of the all-metal FlexiCore® artificial lumbar intervertebral disc replacement (Stryker Spine, Allendale, NJ).

Methods: A total of 40 patients enrolled in the Continued Access FlexiCore® Intervertebral Disc study were recruited into a prospective study. All patients underwent single level surgery. Patients were required to have met the standard inclusion criteria of the study and to agree to the collection of blood at each of the study time points: pre-operatively, 6, 12, 24, and 36 months.

At each time point, whole blood specimens were obtained for each patient. Analysis of chromium ions was conducted using Graphite Furnace Atomic Absorption Spectroscopy with a Lower Limit of Quantitation (LLOQ) of 2.0 ppb (mcg/L) for blood. Both cobalt and molybdenum ions were measured using Inductively Coupled Plasma with Mass Spectrometry. The LLOQ for cobalt and molybdenum are 2.0 ppb and 1.0 ppb, respectively.

Results: Of the 40 patients initially enrolled in the study, 24-month data was available for 35 patients and 36-month data was available for 21 patients. To summarize the data, univariate statistics were generated as well as change from baseline values. There was no change in the mean cobalt ion concentration from preoperative sampling LLOQ at either 24 or 36 months. For chromium ion analysis, samples were divided between values below the LLOQ and values above the LLOQ. A McNemar’s test was performed to examine the shift from baseline for the two groups. At 24 months, no significant difference was found (p = 0.5367). At 36-months, the mean chromium ion level actually decreased from baseline and was below the LLOQ. For molybdenum, a signed rank test was used for analysis. The mean molybdenum ion concentration was increased from baseline (1.4 ppb) at both 24 months (1.9 ppb) and 36 months (2.2 ppb) (p = 0.0168 and 0.0047, respectively).

Discussion: Many other blood studies analyzing metal ion production from orthopaedic implants have been performed on serum. Chromium tends to accumulate in red blood cells, thus an analysis excluding cells may adversely affect the true reading. Wide variations of chromium have been noted between plasma and serum. Whole blood analysis provides a better estimation of systemic metal ion exposure than an analysis of plasma or serum alone. In this study, there was no measured elevation at either 24 or 36 months in the mean whole blood cobalt or chromium metal ion levels following implantation of the FlexiCore® Intervertebral Disc. Mean molybdenum ion levels were increased from baseline at both 24 and 36 months. Long term follow-up should be completed.