RETRIEVAL ANALYSIS OF METAL-ON-METAL LATERAL LUMBAR TOTAL DISC REPLACEMENTS

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Introduction

The XL-TDR (Nuvasive, San Diego, CA) was an investigational metal-on-metal (M-o-M) lumbar total disc replacement (LTDR) implanted between 2009 and 2012 through a lateral approach, with a unique, extra wide footprint compared to other LTDRs.[1] Three-to-five-year outcomes from clinical trials were highly promising, despite this, the XL-TDR was not brought to market.[2-4] Considering the efficacy of M-o-M bearings has been in question for some time, it is important to perform evaluations of investigational and post-market devices with M-o-M bearings in order to determine if their failure was due to the bearing surface or other design features.

Methods

Twenty XL-TDRs were received and inspected. Specimen were analyzed in two stages; visual inspection and physical examination including coordinate measuring machine (CMM) measurements and soft tissue histology. Semi-quantitative scoring was used to document organic deposits, scratches, and polishing. Maximum linear wear and clearance values between the concave and convex bearing surfaces, measured by CMM, were compared to a non-implanted XL-TDR. Additionally, soft tissue histology was performed to identify the presence and extent of inflammatory cells and wear debris. Radiographic assessments included sub-optimal surgical positioning, migration, subsidence, heterotrophic ossification (HO), or loosening. Sub-optimal surgical positioning was determined by Medical Metric Inc. (MMI). In addition to inspections for wear patterns, measurements were taken of an exemplar XL-TDR of size 45 x 10 mm in order to create a CAD model used to determine the range of motion in each plane prior to impingement. The impingement points seen in the CAD model were then correlated to observed signs of impingement damage on the endplates.

Results

Overall, median time to removal was 23 months (<1-55 months), and no devices were removed for metal hypersensitivity. Impingement (65%) and heterotopic ossification (60%) were the most common mechanical complications in this cohort of retrievals. Of the implants with impingement damage, 62% had damage located at the mid-anterior aspect, 48% exhibited damage at the left/right anterior aspect, and 8% had impingement signs at the left-lateral aspect. This was consistent with our CAD based analysis, which found a mean range of motion (ROM) of 10° in flexion, 11° in extension, 13° in lateral bending, and 9° with combined flexion and lateral bending. The closest correlated factor with impingement was loss of fixation (R^2=0.34, p=0.15). Loss of fixation, indicated by migration or loosening, was observed in 65% of the cohort (n=13). Sub-optimal surgical placement was identified in a majority of these revisions (n=15). During our physical examinations of wear patterns, only three specimens displayed CMM deviations greater than 25 µm (65 µm, 56 µm, and 37 µm). Overall, very little bony attachment was identified on either endplate's porous coating regardless of time in vivo. Few implants did have small, sparse patches of attached bone. More commonly, the titanium porous coating was covered in loosely attached fibrous tissue. Lastly, histological observations of tissue samples were consistent with degenerative diseases, surgical healing, and/or mild histiocytic response. Titanium particles from the porous coating were found in one tissue sample, but no CoCr debris were found.

Conclusion

Reliance on bony ongrowth for fixation and geometric constraint likely contributed to high rates of observed impingement, HO, and loss of fixation. CAD-based modeling further supported that limited flexion range and early anterior contact predisposed the device to impingement. These findings suggest that fixation strategy and implant geometry, rather than the bearing material, were likely the primary contributors to XL-TDR failure. These observations, combined with articular surface measurements, i.e. low spherical deviations and tissue analysis, indicated that metal-on-metal bearing wear did not play a prominent role in these failures. Impingement was highly prevalent in this cohort, but its low correlation with other factors like time in vivo implies a complicated root cause. Endplate impingement has been seen in other disc replacements including the ProDisc-L (metal-on-polyethylene) and Prestige cervical disc replacement (M-o-M) [5,6], so this phenomenon is not unique to the XL-TDR or M-o-M bearings; however, it may be exacerbated by the unique footprint or poor fixation of the implants. In our cohort, the high prevalence of fixation loss, and that the porous coatings were primarily integrated with loosely adhered fibrous tissue instead of bone, suggests that inadequate initial fixation may have contributed to device failure. It is most likely that these revisions were not caused by the XL-TDR's M-o-M bearing, and were the result of improper placement, poor fixation, or endplate impingement.

Significance

In this study, the absence of initial fixation due to lack of stabilizing features and geometric constraint in flexion, likely contributed to observations of impingement, HO, and loss of fixation. These findings underscore the need for large-scale retrieval analysis to better assess design-related failure mechanisms rather than attributing poor outcomes solely to a single factor.

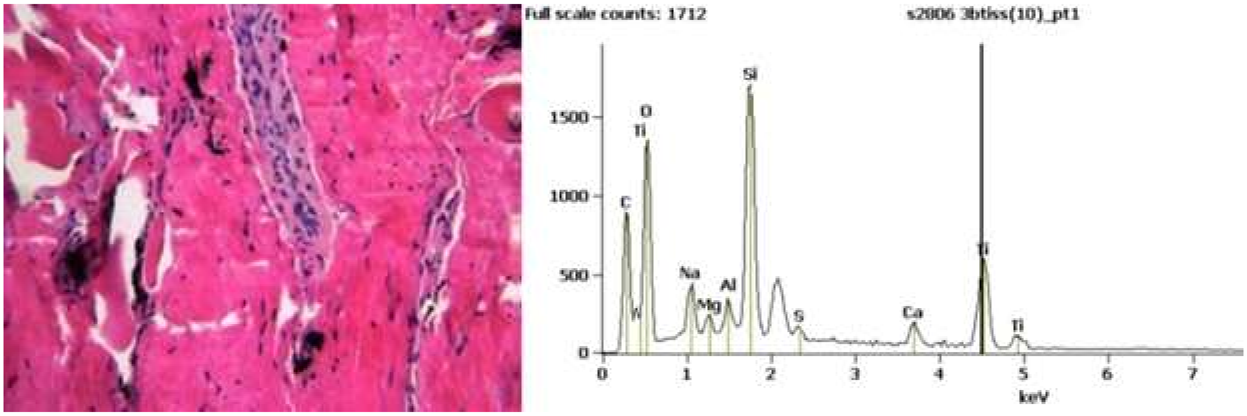

Figure 1: Tissue analysis of single specimen with Titanium nanoparticles present.

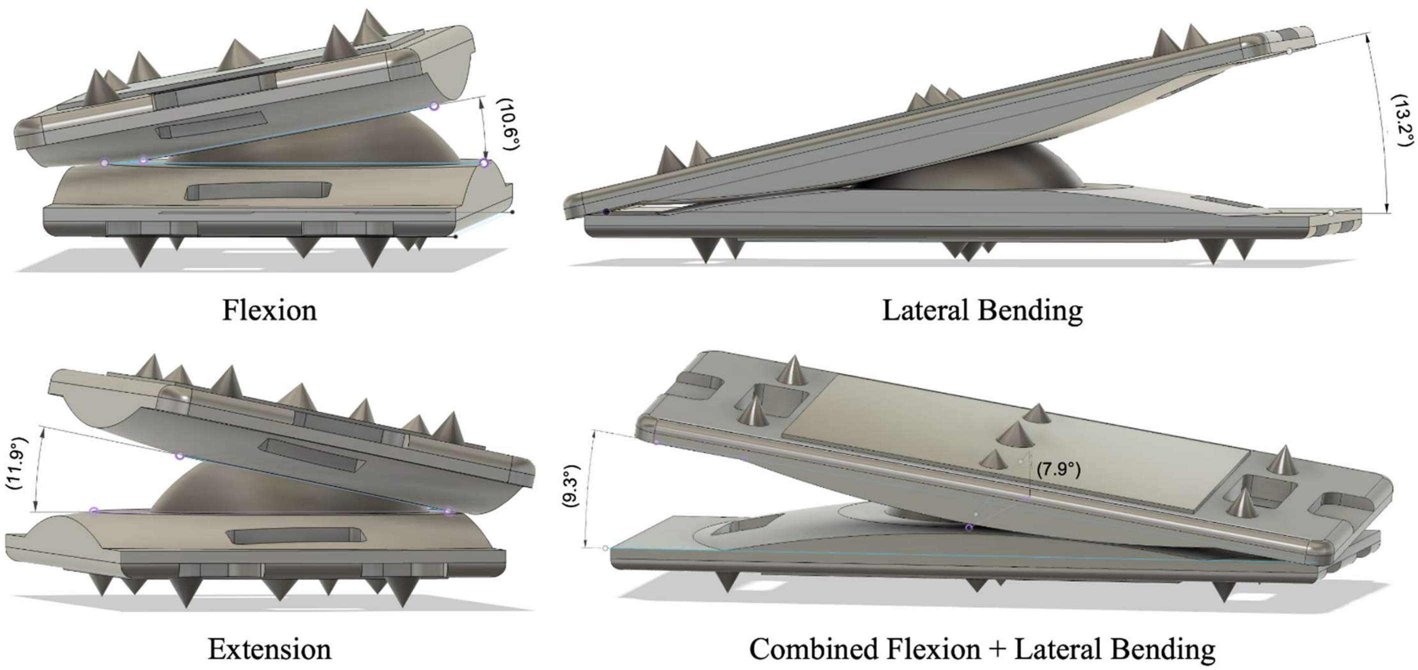

Figure 2: Outlined evidence of endplate impingement.

Observation	Instances
Improper Placement	15
Loss of Fixation	13
Impingement	13
Heterotrophic Ossification	12
Migration	10
Loosening	8
Subsidence	3
Trauma	3

Table 1: Observational Findings

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