# Results from the Largest Retrieval Cohort of Cervical Disc Replacements

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INTRODUCTION: Inspection of explanted patient-retrieved total disc replacements (TDR) is necessary to determine if the preclinical testing adequately predicted the clinical performance. However, relatively few retrieval studies have been published to date on this topic, and none for large cohorts of TDRs. Therefore, the purpose of the present study was to evaluate a cohort of retrieved cervical disc replacements inspected by an independent lab. The goals were to identify and report the most commonly observed types of damage, and to identify any patient-related, surgery-related, and implant-related variables that are associated with the observed causes for revision.

METHODS: A total of 216 M6-C devices from 187 patients were received by the retrieval center between 2016 and 2023. Devices with no clinical, radiographic, or surgical information, or devices that were first-generation device design were excluded. De-identified demographic information was collected, and each device was analyzed through visual examination, photographic documentation, and analytical measurements. The surgeon-stated reason for revision was recorded. The cervical level and the number of levels treated with a disc replacement (single, 2-level, 3-level) and/or a hybrid procedure (TDR + 1 or more fusion(s)) was recorded. Visual and photographic documentation for all components focused on the mechanical condition, specifically distinguishing extraction damage from in vivo damage, and assessment of fixation status at the time of removal. Gravimetric assessment was performed in intact and/or individual device components, provided no destruction was necessary to separate components. A semi-quantitative scale was used to assess polyethylene fiber damage. Radiographs were analyzed, and for specimens with tissue samples provided, histopathology was conducted. Confirmed mechanical failure was defined as radiographic evidence of device collapse, core mass loss of >20%, or endplates in contact. Provided information, such as reported reason for revision and time in vivo, were compared with the outcome variables from the inspection, such as confirmed mechanical failure or radiographic evidence of osteolysis.

RESULTS: Of the 216 devices received, 23 failed to meet the inclusion criteria. The final cohort included 193 devices from 171 patients implanted between 2009 and 2021 and removed between 2011 and 2023, primarily from Europe and Australia. The mean age at index procedure was 41.9 years (21-71), and the mean time to removal was 56.1 months (0.1-144). Most devices were from single-level total disc replacement (TDR) procedures, followed by 2-level TDR only, followed by hybrid procedures. The presence of an adjacent level device or fusion was not correlated with time to revision ($P>0.10$, Figure 1). Bony ongrowth and other indications of fixation were observed in 94.7% of devices. Osteolysis and infection were the most common surgeon-reported reasons for removal. Devices that were revised due to a confirmed infection were removed at a median time of 56 months in vivo. Time in vivo was not significantly different for devices with a confirmed infection and without a confirmed infection. However, patients with confirmed osteolysis had the device removed significantly later than patients without osteolysis, specifically $60.8 \pm 24.6$ compared to $55.5 \pm 32.7$ months ($P=0.05$). Confirmed mechanical failure occurred in 38% of devices (Table 1). Devices that mechanically failed were removed significantly later than devices that had not failed mechanically, specifically $70.1 \pm 28.6$ months compared to $41.4 \pm 33.9$ months ($P<0.001$). Confirmed osteolysis was correlated with wear debris ($P=0.10$) and suspected infection ($P=0.19$), though not statistically significant. Additionally, surgical factors, including suboptimal sizing and positioning, which represented 14% of the explants, were at increased risk of mechanical failure than other devices ($P=0.03$). Interestingly, 105 of these devices was found to have evidence of bony ongrowth and were assessed to have been well-fixed at the time of removal. Only one device of 156 migrated, due to reported early post-operative trauma (Table 1). All other devices remained in place at the time of removal and many had heavy extraction damage, or required significant destruction of the polymeric components, to avoid damage to the bony endplates during revision surgery.

DISCUSSION: The present study is the first large-scale cervical disc replacement retrieval analysis. In this cohort, osteolysis was one of the most common surgical reasons for revision. It is important to note that total number of devices inspected represent <0.5% of the total devices implanted over the last two decades (>70,000 worldwide), so the overall success rate is unknown. This device has been approved and in use overseas since 2006, and approved domestically, for single-level use, since 2019. Overall, it was interesting to note that early migration was observed in only one case, yet loosening and migration have been common observations in the MAUDE database for other disc replacements. In the present study, infection was suspected in nearly half of the cases, though only reported as definitively confirmed in a fraction of those cases. Several previous studies have reported the presence of P. Acnes and S. Aureus at the time of removal; however, in many cases, it is unclear if this finding is incidental, or the cause of patient-reported pain or observed osteolysis. Further retrieval studies with careful collection of clinical, surgical, and radiographic data are essential to understand the relationship between infection, osteolysis, and long-term device performance. The present study is limited by the lack of available data on the devices that are in clinical use. As this study focused solely on devices that were removed and returned to the manufacturer, it is unclear what the clinical performance of the majority of the devices that have not been returned, or reported to have been removed, has been. Nevertheless, findings from these devices provides valuable insight for future studies.

SIGNIFICANCE/CLINICAL RELEVANCE: Cervical disc arthroplasty is gaining popularity, yet few retrieval analyses have been conducted and none have contained an extensive number of retrieved devices. This is the largest study to date to present the findings from all explanted devices of a single design, inspected by an independent academic lab.

TABLES AND FIGURES:

**Table 1. Radiographic Analysis**

| | Number of Devices |
|---|---|
| **Total with sufficient early post-op imaging** | 94 |
| *Radiographic Factors (Reported by Medical Advisor)* | |
| **Incorrect Size** | 15 |
| **Mal-positioned** | 21 |
| **Patient contraindicated** | 6 |
| *Radiographic outcome* | |
| **Bone changes of any kind** | |
| **Hypertropic Bone Formation** | 21 |
| **Osteolysis (Inflammatory)** | 80 |
| **Bone Loss (Non-Inflammatory)** | 60 |
| **Migration** | 1 |
| **Mechanical device failure** | 61 |

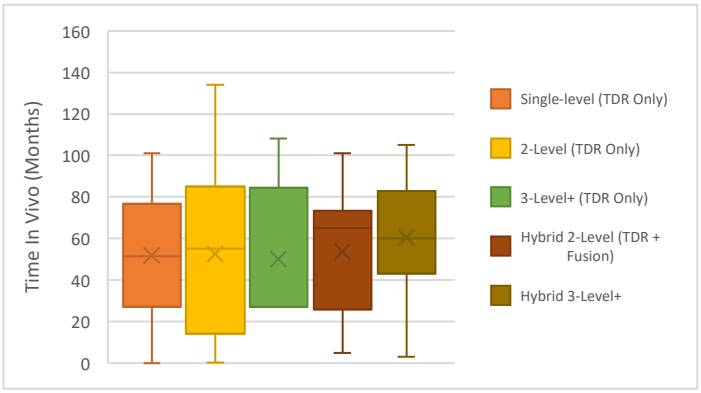


Figure 1 Boxplots representing time to revision based on number of levels treated by TDR and/or fusion. Each box represents the 25th, 50th (median), and 75th percentile. The whiskers depict the minimum and maximum values, while the "x" in each box represents the average.